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ABSTRACT

RTI International conducted a comprehensive evaluation of five laboratories funded under the National Institute of Justice's (NIJ's) 2009 DNA Unit Efficiency Improvement Program (EIP). The evaluation team documented the implementation of each laboratory's grant activities and conducted five process and outcome evaluations to determine the impact of the EIP. Data used in the evaluation were collected through site visits, routinely scheduled meetings via the telephone and Web, performance metrics and data collection tools, and surveys of key laboratory personnel. This evaluation occurred in conjunction with the laboratories' DNA Unit EIPs for the first 28 months (October 2009 to January 2012); during this time, one laboratory completed its EIP, one laboratory implemented its EIP in April 2011, and three laboratories were still actively progressing to an EIP implementation. At the end of the project, the evaluation team documented the evaluation results based on the various stages of the laboratory EIPs; complete outcome evaluations were not possible for all laboratories. Staff identified strategies to assist other DNA laboratories in future EIPs. The five DNA EIP laboratories evaluated under this 2009 DNA Unit EIP are the Denver Police Department Crime Laboratory Bureau (DPD), Denver, CO; University of North Texas Health Science Center Department of Forensic and Investigative Genetics (UNTHSC), Ft. Worth, TX; Orange County Crime Laboratory (OCCL), Orange/Santa Clara, CA; Oklahoma State Bureau of Investigation Forensic Science Services (OSBI), Edmond, OK; and Palm Beach County Sheriff's Office Crime Laboratory (PBSO), West Palm Beach, FL.

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List of Acronyms

ASCLD/LAB	American Society of Crime Laboratory Directors Laboratory Accreditation Board
BPL	Biology Processing Laboratory
BPM	Business project management
BRPSD	Boca Raton Police Services Department
CODIS	COmbined DNA Index System
COTR	Contracting Officer's Technical Representative
CRL	Continuous Read Length
DNA	deoxyribonucleic acid
DPD	Denver Police Department Crime Laboratory Bureau
ECU	Evidence Control Unit
EIP	Efficiency Improvement Program
FBU	Forensic Biology Unit
FDLE	Florida Department of Law Enforcement
FSDAL	Full-Service DNA Analytical Laboratory
FTA	Flinders Technical Associates
GAN	Grant Adjustment Notification
GPRA	Government Performance and Results Act
IRB	Institutional Review Board
IT	Information Technology
LDIS	Local DNA Index System
LEPC	Law Enforcement Planning Council

LIMS	Laboratory Information Management Systems
LPT	Legal property technician
MOU	Memorandums of Understanding
mtDNA	Mitochondrial DNA
NCE	No-cost Extension
NFSIA	National Forensic Science Improvement Act
NIJ	National Institute of Justice
OCDA	Orange County District Attorney’s Office
OCCL	Orange County Crime Laboratory
OHRP	Office for Human Research Protections
OSBI	Oklahoma State Bureau of Investigation Forensic Science Services
PBSO	Palm Beach County Sheriff’s Office Crime Laboratory
PCR	Polymerase Chain Reaction
PI	Principal Investigator
PM	process mapping
QA	quality assurance
QC	quality control
RDL	Research and Development Laboratory
RFLP	Restriction Fragment Length Polymorphism
RFQ	Request for Quotation
RFU	Relative Fluorescent Unit
RTI	RTI International
SDIS	State DNA Index System

STR	Short Tandem Repeats
SOP	standard operating procedure
STATIS	Sample Trace Assessment Tool and Integrated Summary
SWGDM	Scientific Working Group on DNA Analysis
SWIM	Scientific Work Improvement Model
TS	Traces Sequences
TT	Technology Transfer
UNT CHI	University of North Texas Center for Human Identification
UNTHSC	University of North Texas Health Science Center Department of Forensic and Investigative Genetics

EXECUTIVE SUMMARY

Overview—Forensic DNA Unit Efficiency Improvement Program

DNA evidence has taken an increasingly central role in the investigation, prosecution, and defense of criminal cases. As a result, more DNA evidence is collected and submitted than is analyzed, resulting in substantial laboratory backlogs. These backlogs can have serious consequences by impairing defense and prosecution actions, creating feelings of distrust among crime victims, and potentially allowing perpetrators to commit more crimes (AFSCME, 2006).

The National Institute of Justice (NIJ) recognized the need for innovative ideas to address laboratory efficiency and capacity, so the Agency created the Forensic DNA Unit Efficiency Improvement Program (EIP) to support the development and adoption of improved laboratory processes. Priority was given to novel and innovative methodologies that have the potential to affect the entire DNA forensic community. NIJ awarded nearly \$6.5 million to laboratories between 2008 and 2010; however, funds will no longer be awarded under this EIP program (NIJ, 2011). To date, 15 laboratories were selected during a 3-year funding period to receive funding to address these fundamental processing changes through NIJ's DNA Unit EIP. Of these 15 laboratories, only 12 accepted the award and completed or are in the process of completing an EIP. Five laboratories receiving funds in 2009 participated in this evaluation.

This Evaluation of Forensic DNA Unit EIP final report seeks to document the implementation of each laboratory's grant activities and to conduct a process and outcome evaluation of each laboratory to determine the impact of its Unit EIP. RTI International (RTI) completed the evaluation for five laboratories over a 28-month period of performance, ending January 14, 2012. At this time, only one of the five laboratories has completed its DNA Unit EIP; the other four EIPs are still in progress. As part of this evaluation, RTI staff collected

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evaluation results, which involved documenting activities and performance metrics and identifying strategies that show promise to help improve efficiency in DNA laboratories and to describe processes that could be replicated in other laboratories nationwide.

Strategies Laboratories Selected to Improve Efficiency

RTI evaluated five DNA forensic laboratories under the 2009 DNA Unit EIP:

- Denver Police Department Crime Laboratory Bureau (DPD), Denver, CO
- University of North Texas Health Science Center, Department of Forensic and Investigative Genetics (UNTHSC), Ft. Worth, TX
- Orange County Crime Laboratory (OCCL), Orange/Santa Clara, CA
- Oklahoma State Bureau of Investigation Forensic Science Services (OSBI), Edmond, OK
- Palm Beach County Sheriff’s Office Crime Laboratory (PBSO), West Palm Beach, FL.

The purposes for and objectives of these laboratories are summarized in **Table ES-1**

Table ES-1. 2009 DNA Unit EIP Summaries

EIP Laboratory	Description
DPD	The objectives of the DPD is to modify and use off-the-shelf management efficiency software called SIMUL8 (available at http://www.simul8.com) to explore options for revising laboratory processes to best maximize the laboratory resources. SIMUL8 has been used internationally for a range of industries, including manufacturing, healthcare, government, business, and energy. SIMUL8 assists in visually identifying and eliminating bottlenecks, increasing quality and efficiency, improving resource utilization, and helping to plan for future growth and capacity.
UNTHSC	The objective of the UNTHSC is to develop and validate a novel expert system that will automate the routine and repetitive tasks in interpretation of mitochondrial DNA (mtDNA) sequence analysis, thereby improving laboratory efficiency and the speed of data analysis. Expert systems such as this one exist for nuclear DNA analysis, but not mtDNA. This expert system, eFAST and MExpert software, will fully automate the analysis of high-quality mtDNA data. The expert system will also redirect “challenged data” to the analyst for review of the specific DNA region and will aid in a decision to report a result, or to direct the analyst for re-analysis.

(continued)

Table ES-1. 2009 DNA Unit EIP Summaries (continued)

EIP Laboratory	Description
OCCL	The objectives of the OCCL are to implement an efficient, laboratory-wide, Web-based case triage procedure and to establish two teams of DNA analysts that will be dedicated to property crime analysis, property crime sample batching, and a high-throughput analysis line, all of which increases the overall use of laboratory automation.
OSBI	The objective of the OSBI is to validate a commercially available AmpF ϕ STR Identifier Direct Polymerase Chain Reaction (PCR) Amplification Kit on buccal swabs, which are commonly used for the collection of known reference samples in most forensic and paternity laboratories worldwide. The goal of the OSBI EIP includes method validation of a DNA collection kit that is simple to use, cost effective, eliminates the need for a DNA extraction process, and provides reliable results.
PBSO	The objective of PBSO is to create a central Biology Processing Laboratory (BPL) in an existing space within the Boca Raton Police Services Department (BRPSD) to pre-screen crime scene evidence for southern Palm Beach County law enforcement agencies (Delray, Boynton Beach, and Boca Raton). The BRPSD BPL will process evidence for the confirmation of blood and semen, perform microscopic analysis of hair to complement DNA analysis, swab items for touch DNA evidence, and submit all informative evidence to PBSO for DNA analysis. Evidence prescreened at the BPL will be prioritized within assignments for confirmational DNA testing at PBSO.

The DNA Unit EIP laboratories used established approaches to efficiency Summarized in **Table ES-2**. These approaches included developing case acceptance policies, conducting process mapping, and strengthening technology development and transfer. Approaches can represent managerial strategies or analytical or laboratory solutions that are used to streamline a laboratory's operation

Table ES-2. 2009 DNA Unit EIP—Approaches to Efficiency

Approach	Description	Type	Lab
Case acceptance policy	Development of policy and procedures to limit number of cases received, prioritize sample acceptance (e.g., criminal case, known or unknown subject), return or deny samples if unacceptable turnaround times are probable, and impose a limitation on the number of samples per case	Managerial strategy	DPD, OCCL, PBSO
Process mapping (PM)	Development of flowcharts of laboratory processes (can be electronic or hardcopy PM) to help visualize information, identify solutions to maximize efficiency, and develop a strategic management plan for implementation	Managerial strategy	DPD
Business project management (BPM)	Use of a computerized tool that supports change and innovation to streamline administrative and analytical processes (e.g., SIMUL8, eFAST, MTexpert) as part of BPM	Managerial strategy	DPD, UNTHSC
Laboratory automation	Use of analytical advancements such as robotics, equipment integrations, expert systems software, and computerization that simplify and increase the speed of laboratory processes	Solution	OCCL, PBSO, UNTHSC

(continued)

Table ES-2. 2009 DNA Unit EIP—Approaches to Efficiency (continued)

Approach	Description	Type	Lab
Laboratory process improvement	Design laboratory process adaptations to automate sample processing and analysis (e.g., high-throughput DNA analysis line for property crime, screening laboratory within law enforcement agency, method development and validation)	Solution	OCCL. OSBI. PBSO
Technology transfer (TT)	TT is the process of conveying an adopted technology from one party to another; TT also shares technical information by means of education and training and installation of new analytical procedures or equipment	Solution	OCCL OSBI
Technology development	Development of technology, such as expert systems and other software, that can streamline and improve laboratory procedures and/or analytical methods or equipment	Solution	UNTHSC

Evaluation Methods

RTI collected data through site visits; Web meetings; laboratory performance metric tables staff interviews; monthly conference meetings via phone; and other correspondences of key laboratory personnel to address the project’s objectives and progress. RTI used findings from the process and outcome evaluations to recommend guidelines and preliminary models for future replication of EIPs for DNA laboratories.

The process evaluation collects information on the challenges and barriers to implementation faced by the laboratories and the solutions developed in response. These activities were conducted as part of the effort to identify lessons learned that may inform NIJ and other laboratories undertaking similar EIP strategies.

Process Evaluation

Identifies and examines the EIP approaches and elements by which the NIJ-funded EIPs are initiated and carried out in the laboratories.

During the evaluation, RTI collected monthly or quarterly data from the laboratories to assist with the outcome evaluation. DNA analysis

Outcome Evaluation

Documents the impact of the EIP on DNA analysis capacity, outcomes and other performance measures identified by the laboratories.

capacity may include turnaround, throughput, and case backlog, while laboratory outcomes include entries into COmbined DNA Index System (CODIS) databases and investigations aided. Other performance measures identified and provided by the laboratories included staff training

time, staff courtroom time, staff EIP labor hours, number of items of forensic evidence processed per case, software revision outcomes, and financial costs associated with the EIP. The purpose of the outcome evaluation is to determine whether the expected outcomes or performance measures were achieved. For example, the EIP is expected to (1) reduce the average number of days between the submission of DNA samples to a laboratory and the delivery of the test results to the requesting agency, (2) increase DNA analysis throughput, and (3) reduce laboratory DNA casework. Similar to the process evaluation, we collected performance measurement data from laboratories throughout the evaluation period, and the data were evaluated based on documented time periods within each laboratory's EIP (e.g., baseline or pre-EIP implementation, EIP implementation, post-implementation). The evaluation process was halted on September 30, 2011, to allow preparation time for the draft final report submission on November 15, 2011 to NIJ for review prior to the EIP evaluation project completion date of January 14, 2012. At this time, only one EIP had been completed (i.e., OSBI); however, it was not implemented into the casework laboratory. One laboratory (i.e., OCCL), implemented its EIP in April 2011, but only limited data (approximately 5 months) were collected post-implementation for an initial and limited outcome evaluation. Three laboratories (i.e., DPD, PBSO, and UNTHSC) had not completed implementation at the time of this report; therefore, only one complete outcome evaluation can be made, but it does not include implementation of this EIP in the current laboratory's casework process (i.e. validation on non-casework samples performed).

Evaluations included both qualitative and quantitative data. Data sources include the following:

- Review of laboratory documents (e.g., proposal, grant progress reports, relevant standard operating procedures [SOPs], management plans, accreditation and audit documents, training documents)
- Laboratory on-site visits
- Interviews and routine correspondence with key laboratory personnel
- Data collection and performance metrics (e.g., pre-assessment and scheduled monthly or quarterly data collection).

These data were collected prior to and throughout the performance period of the evaluation (i.e., baseline data, pre-implementation, and EIP implementation periods).

Administrative data were manually collected by laboratory personnel and by supporting agencies (e.g., law enforcement agencies, district attorney's offices) or extracted from Laboratory Information Management Systems (LIMS) (e.g., backlog, turnaround time, CODIS hits). Although an effort was made to collect a consistent and standard set of data from each laboratory, this practice was not always feasible for a number of reasons. As previously mentioned, the performance periods for each laboratory varied, and only one laboratory completed its EIP prior to the writing of this report. Furthermore, each laboratory implemented a unique approach to improving efficiency such that some information was relevant to one laboratory, but not to others. In almost all cases, traditional laboratory performance metrics such as backlog, turnaround time, and analyst caseload were either not impacted or minimally impacted at the time of this report due to ongoing progress of the EIPs. In the *Main Findings* section, below, the various data collection methods and instruments are described in greater

detail, along with the task order management and timeline, implications, and recommendations for future EIPs.

Main Findings

Task Order Management and Timeline

The collective experience of the evaluation team reflects expertise in forensic science and evaluation methodology, ensuring that the evaluation was methodologically rigorous and comprehensive. This evaluation project collected and analyzed detailed information on the participating laboratories based on the proposed and updated evaluation plans, linking the evaluation objectives identified in the Request for Quotation (RFQ) to explicit tasks and deliverables. In addition, a Task Activity Summary was completed and summarizes the project's goals, objectives, accompanying tasks, and deliverables. Following the project kick-off meeting with the NIJ Contracting Officer's Technical Representative (COTR), the evaluation plan was updated and finalized according to details of each EIP. **Table ES-3** shows the 2009 DNA Unit EIP evaluation plan developed by RTI.

Table ES-3. 2009 DNA Unit EIP Evaluation Plan

Objective	Task	Deliverables
1. Plan and execute project startup	<ul style="list-style-type: none"> ▪ Project startup activities <ul style="list-style-type: none"> – Hold kickoff meeting with COTR and NIJ Grant Managers (for evaluation project and for each EIP laboratory) – Make initial contact with laboratories – Develop a pre-assessment checklist of items to request from EIP laboratories – Complete the Institutional Review Board (IRB) process 	<ul style="list-style-type: none"> ▪ Completion of Project Staff and Consultants Nondisclosure Agreements (Oct-Nov, 2009) ▪ EIP evaluation letter to grantee laboratories (Dec-Jan 2010) ▪ IRB exemption (Feb 2010) ▪ Pre-assessment checklist (Mar 2010)

(continued)

Table ES-3. 2009 DNA Unit EIP Evaluation Plan (continued)

Objective	Task	Deliverables
2. Document the implementation of the Forensic DNA Unit EIP grants	<ul style="list-style-type: none"> ▪ Review grantee proposals; extract information on <ul style="list-style-type: none"> – Laboratory configuration and characteristics of EIPs ▪ Conduct semi-structured telephone interview(s) with key laboratory personnel <ul style="list-style-type: none"> – Verify and document laboratory operations – Verify or update planned efficiency improvements ▪ Prepare laboratory “profiles” documented in the laboratory completed “Baseline Data Collection Instrument” 	<ul style="list-style-type: none"> ▪ Preliminary laboratory profiles (e.g., type and number of cases, number of clients, process maps, current performance indicators) ▪ Final planned approaches to efficiency improvements, including solutions, timeline, and performance measures ▪ Reviewer’s checklist for site visits; personnel interviews ▪ Electronic files containing profiles(Baseline Data Collection Instrument), improvements, and performance measures for EIP laboratories
3. Conduct a process and outcome evaluation of each grantee’s EIP	<ul style="list-style-type: none"> ▪ Conduct a Web meeting with laboratories to describe planned evaluation activities ▪ Conduct site visits <ul style="list-style-type: none"> – Tour the laboratory – Collect baseline data defining laboratory characteristics or “inputs” – Conduct semi-structured interviews with key staff ▪ Collect monthly/quarterly performance metrics or other metric studies as appropriate for each laboratory ▪ Conduct semi-structured monthly telephone meetings to document progress, discuss metrics, and determine if evaluation is going as planned, including the timeline 	<ul style="list-style-type: none"> ▪ Meeting minutes ▪ Site visit agenda; preliminary list of performance measures ▪ Site Visit Interview Tool ▪ Minutes of pre-site-visit meeting ▪ Documentation of laboratory operations, EIP plans and progress, activities that may impact the outcome of the EIP, and ability to report proposed performance measures ▪ Monthly progress reports describing implementation issues, performance measures, current project activities, and planned activities for next month ▪ Documentation of changes in laboratory operations, EIP progress, activities that impacted EIP outcomes and ability to report performance measures ▪ Approved Grant Adjustment Notifications
4. Produce a report that documents the results of the evaluation and provides recommendations of models to be considered by other forensic science laboratories	<ul style="list-style-type: none"> ▪ Draft and revise the final report <ul style="list-style-type: none"> – Analyze process data – Analyze outcome data – Identify lessons learned and recommendations – Propose preliminary models and guidelines 	<ul style="list-style-type: none"> ▪ Final report (Draft Nov. 15, 2011; Final Jan. 14, 2012)

All project start-up activities (Objective 1) were completed within the first 6 months of the project (October 2009–March 2010). Activities and deliverables for Objective 2, which involved the documentation of the EIP implementation for the 2009 Forensic DNA Unit EIP

grants, occurred during the entire 28-month evaluation process (October 2009–January 2012). The process and outcome evaluation activities and deliverables (Objective 3) began 4 months after start of the project and continued until September 2011 to allow for final report preparation.

Implications and Recommendations

Developing a successful efficiency model for forensic laboratories can have a direct impact on criminal justice practice and policy. If laboratories become more efficient in processing and analyzing DNA samples, direct benefits can be realized in criminal investigations and prosecutions, as well as in the exoneration of innocent people convicted of serious crimes. As previously mentioned, forensic laboratories have experimented with a variety of methods for improving laboratory capacity. This project offers a unique opportunity to identify innovative ideas that serve as the most promising approaches for improving laboratory functioning and reducing DNA case backlogs. To better understand the selected 2009 DNA Unit EIPs, NIJ included an external process and outcome evaluation of each to occur simultaneously during the EIP stages. One EIP was followed to completion, whereas other four evaluations occurred during pre-implementation and implementation of the planned EIP activities. Successful approaches, including management of these approaches, will benefit other forensic laboratories that are seeking new solutions for handling the problems associated with bottlenecks in the system. A summarized list of laboratory guidelines and recommendations for making a laboratory EIPs more successful includes the following:

- **Optimization of communication:** Whether it is between management and laboratory personnel, team members, partners, and stakeholders of the EIP, the success of all of the EIPs is heavily determined by the communication before, during, and after the EIP implementation.

- **Management acceptance and promotion:** If the Criminal Justice System leaders and laboratory management are actively involved with the EIP during planning and execution, their ability to promote and route it through the system is much greater.
- **Laboratory personnel acceptance and promotion:** If laboratory personnel are aware of the EIP, are actively involved, and give input during EIP planning and execution, the laboratory dynamics are much more favorable.
- **Full understanding of the project scope and timeline at onset of EIP:** Research and planning of an EIP prior to its beginning minimizes or eliminates project delays, team member frustration, under budgeting, and incomplete or abandoned EIPs.
- **Planning of an EIP evaluation:** There are many reasons why an EIP should be evaluated, and the timing of the evaluation is a key component. The laboratory can include an internal evaluation that helps it document the process and its outcomes to management and key stakeholders, as well provide insight into how to improve an EIP in the future. Similarly, an external evaluation performed independently of an EIP allows a laboratory to focus on the EIP's purpose and goals and can minimize laboratory biases. Prospective evaluations that occur simultaneously with the EIP can have a greater impact, questions can be answered much earlier in the EIP, and evaluation findings can allow for interventions and streamlining of the EIP process.

A summarized list of Evaluator/Funding Agency guidelines and recommendations for making an *evaluation* of a laboratory's EIP more successful include the following:

- **Agreement of project extension requirements for EIP grants and the external evaluator project:** The deliverables of this contract were significantly impacted because

the outcome evaluations could not be completed in the time allowed by NIJ. Although RTI was granted one 6-month no-cost extension (NCE) to January 14, 2012, all five laboratories were allowed NCEs up to the month before RTI's evaluation project completion date (one laboratory) or 3 to 9 months beyond (four laboratories). As such, the deliverables of the RFP and proposal could not be met. **Table ES-4** highlights the current status of the EIPs in relation to evaluation type that RTI can complete, the EIP implementation dates, and the laboratory NCE dates.

Table ES-4. 2009 DNA Unit EIP Status and Planned Evaluation Type

Laboratory	EIP Implementation Date	NIJ Approved NCE Date	Evaluation Type
Denver Police Department (DPD)	9/1/2011 (estimated)	5/31/2012	Process only. Software will be validated, but not fully implemented into the laboratory casework.
University of North Texas (UNTHSC)	3/1/2012 (estimated)	9/30/2012	Partial process only (software design will not be completed or validated in 2011).
Orange County Crime Lab (OCCL)	4/1/2011	6/30/2012	Process and short-term outcomes.
Oklahoma State Bureau of Investigation (OSBI)	3/1/2011	12/31/2011	Process and outcome specific to EIP, but not implemented in laboratory (ongoing research project).
Palm Beach County Sheriff's Office (PBSO)	1/15/2012 (estimated)	9/30/2012	Partial process only (BPL will not be built before final report is due).

- EIP timing:** First, to assess the impact of an EIP on various outcomes, the evaluation performance period must be longer than that of the laboratory to collect data post-implementation, conduct analyses, and report the results. This evaluation was limited in this regard because the laboratories were funded as grants and were allowed NCEs to complete EIPs; however, the evaluation was funded as a contract with a maximum extension of 6 months. This limited this evaluation project to primarily focusing on the

process component of the evaluation. Although the process is certainly important, the results would have been more useful had outcomes also been assessed.

- **Challenging to generalize findings from an evaluation:** It is also challenging to generalize findings from an evaluation of a small number of unique EIPs. As described in **Section 5** of this report, the five EIPs evaluated herein cannot be compared to each other in totality because each is distinctly different. Given the composition of EIPs here (and the lack of post-implementation outcomes for most laboratories), RTI could not determine whether a specific type of EIP has the potential for success at the point of this evaluation report because too little time has passed since implementation of the one laboratory that has completed its EIP. In these types of situations, conducting a series of case studies for each laboratory is more appropriate. However, if EIPs are similar and a large number are awarded, then a multi-site evaluation that includes comparison sites should be conducted. This would allow for more generalizable findings about the impact of a particular efficiency strategy.
- **Optimization of communication:** Regular communication between the evaluation team and the key laboratory staff participating in an EIP is critical to documenting and performing a process and outcome evaluation. RTI chose to have, at a minimum, one monthly scheduled call with each laboratory once laboratories moved well into their pre-implementation activities and continued until 1 month before the draft final report was due to NIJ. These scheduled meetings could have begun sooner in the process. After our kick-off meetings with laboratories, we did not talk to them on a regular schedule for 6 months after these meetings, so updates and communications were limited and the EIP in some cases appeared to be slow to progress. Perhaps, scheduled meetings could have

improved the process of the pre-implementation period. During these scheduled conference calls, the evaluation team undoubtedly received much information that may have gone undocumented otherwise.

- **Adequate time for outputs and outcomes:** Once an EIP is implemented, it takes some time to adequately measure impacts of the EIP to the laboratory (sometimes years). Premature expectations of these measurements can limit the use of the measures and sometimes even penalize the laboratory if the EIP is considered unsuccessful by management and policy makers. During the outcome evaluation, the goal should be to clearly identify and collect both short- and long-term outcomes.

RTI used findings from the process and outcome evaluations to construct a preliminary model of effectiveness for future replication of EIPs for DNA laboratories (**Figure ES-1**).

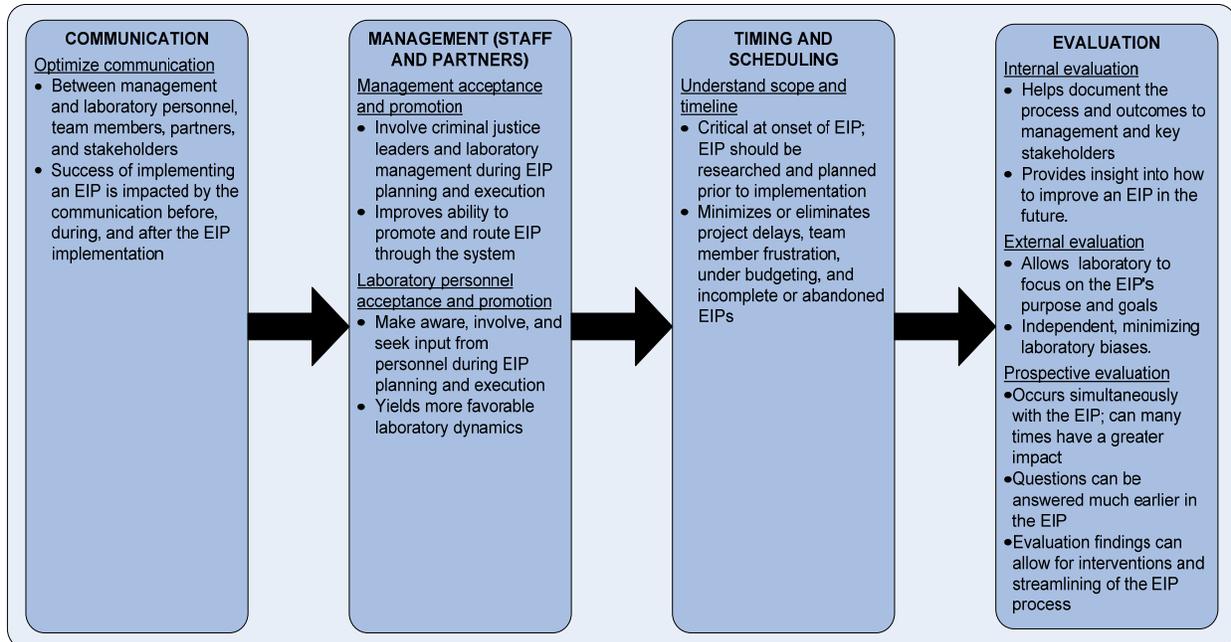


Figure ES-1. Model of effective DNA Unit EIP.

This process and outcome evaluation identified and examined the EIP's approaches and elements by which 2009 DNA Unit EIP were initiated and carried out in the laboratories. The process evaluation collected information on the EIP progress challenges and barriers to EIP implementation and developed solutions to identify lessons learned. Providing models for DNA Unit EIPs for the future is premature at this time since the EIPs evaluated are not complete and impacts cannot be fully realized. As these laboratory EIPs continue, further impacts to the laboratory, its community, and the criminal justice system can be realized. Ultimately, these guidelines and recommendations are direct results of a better understanding of how a forensic laboratory can successfully plan and carry out an improvement that provides efficiency in both time and cost. Consequently, more samples and cases can be analyzed, and the criminal justice system can be more expedient.

1. NATURE AND EXTENT OF PROBLEM

1.1 *Need for Enhanced DNA Laboratory Capacity*

DNA evidence has taken an increasingly central role in the investigation, prosecution, and defense of criminal cases. This change has led to an increase in DNA submissions by law enforcement agencies to crime laboratories and an increase in the collection of DNA from felons and arrestees, which, in turn, has fueled case backlogs within crime laboratories. In other words, more DNA evidence is collected and submitted than is analyzed, resulting in substantial laboratory backlogs (Durose, 2008; Peterson & Hickman, 2005; Steadman, 2000, 2002). These backlogs can have serious consequences by impairing defense and prosecution actions, creating feelings of distrust among crime victims, and potentially allowing perpetrators to commit more crimes (AFSCME, 2006; Estes, 2007; Perkel, 2007; *New York Times*, 2002; Willing, 2007).

1.2 *Other Programs Addressing DNA Capacity*

The National Institute of Justice (NIJ) provides funding to address DNA backlog issues through several programs. Local and state crime laboratories can apply for funding to address their DNA case backlogs under the Forensic DNA Backlog Reduction Program, which is NIJ's largest funding program. These funds are used to hire additional staff, contract with private laboratories, and purchase equipment (e.g., automated DNA extraction robots, high-throughput genetic analyzers, expert systems, Laboratory Information Management System [LIMS] to make in-roads in backlogs) (Nelson, 2011). Between 2004 and 2010, NIJ awarded nearly \$400 million to laboratories under this program (for more information on this program, see <http://www.nij.gov/topics/forensics/lab-operations/capacity/backlog-reduction-funding.htm>). NIJ also offers two programs that focus specifically on reducing the backlog of convicted offender

and arrestee DNA samples (i.e., the Convicted Offender/Arrestee DNA Backlog Reduction Program and the Convicted Offender/Arrestee DNA Backlog Reduction Outsourcing Program). Funds from these programs were used to help test approximately 1.8 million convicted offender and arrestee samples, resulting in more than 18,000 COmbined DNA Index System (CODIS) hits (Nelson, 2011).

A 2009 NIJ report shows that forensic laboratories have become more efficient in processing and analyzing DNA cases (Lothridge, 2009). However, despite increased productivity, most laboratories are not making significant reductions in their existing DNA backlogs. This failure is due, in part, to increasing numbers of DNA sample submissions by law enforcement. In addition, state laws have expanded their requirements for DNA sample collection from only violent offenders to anyone arrested on a felony charge (Pinchin, 2007; Ritter, 2008). Forensic laboratory personnel are increasingly required to testify in court as expert witnesses, resulting in less time spent in the laboratory to perform analyses (NIJ, 2003). Moving forward, it is critical that measures to address case backlogs go beyond adding more staff or contracting with private laboratories and that more focus is placed on how laboratories manage and process their caseloads (Frappier et al., 2008; Safir, 2007).

NIJ recognized the need for innovative ideas to address laboratory efficiency and capacity. Thus, the Forensic DNA Unit Efficiency Improvement Program (EIP) was developed by NIJ to support the development and adoption of improved laboratory processes. Priority was given to novel and innovative methodologies that have the potential to affect the entire DNA forensic community. NIJ awarded nearly \$6.5 million to laboratories between 2008 and 2010; however, funds will no longer be awarded under this EIP program (NIJ, 2011). To date, 15 laboratories were selected during a 3-year funding period to receive funding to address these

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fundamental processing changes through NIJ's DNA Unit EIP. Of these 15 laboratories, only 12 accepted the award and completed or are in the process of completing an EIP. Five laboratories receiving funds in 2009 participated in this evaluation.

This Evaluation of Forensic DNA Unit EIP final report seeks to document the implementation of each laboratory's grant activities and to conduct a process and outcome evaluation of each laboratory to determine the impact of its Unit EIP. RTI International (RTI) completed the evaluation for five laboratories over a 28-month period of performance, ending January 14, 2012. As part of this evaluation, RTI staff collected evaluation results, which involved documenting activities and performance metrics and identifying strategies that show promise to help improve efficiency in DNA laboratories and to describe processes that could be replicated in other laboratories. This final report begins with an Introductory section, *Nature and Extent of Problem*, and includes six additional sections documenting the process and outcome evaluations, implications and recommendations, project management, and timeline:

- **Section 2, *Conducting the Evaluation***
- **Section 3, *Process Evaluation***
- **Section 4, *Outcome to Evaluation***
- **Section 5, *Comparison of Findings Across EIP Sites***
- **Section 6, *Implications and Recommendations***
- **Section 7, *Task Order Management and Timeline*.**

2. CONDUCTING THE EVALUATION

The ultimate goal of this evaluation was to help NIJ assist the forensic laboratory community in addressing growing capacity needs by identifying strategies that have quantifiable impacts in terms of improvements in laboratory efficiency. The project's key objectives were to

1. Accurately document the implementation—including efficiencies, problems, resolutions, modifications, and other information—of the Forensic DNA Unit EIP Grants in each of the participating forensic laboratory sites.
2. Conduct a rigorous process and outcome evaluation in each of the laboratory sites. The process evaluation examines and defines the processes by which the NIJ-funded EIP was initiated and carried out, and the outcome evaluation quantifies changes in key outcomes associated with turnaround time, analyst productivity, and DNA case backlogs.
3. Document and discuss the evaluation results, and identify strategies for using certain methodologies to improve a laboratory's processing and analysis of DNA cases.

RTI's ability to meet these objectives was hindered by the extension of laboratory performance periods without a corresponding extension to the evaluation performance period. All five laboratories for which RTI began conducting a process and outcome evaluation requested and received an NIJ approval for no-cost extensions (NCEs), ranging from December 31, 2011, to September 30, 2012; however, the evaluation final report for each EIP was due in November 2011 (the evaluation performance period terminates in January 2012). The difference in the extensions granted for laboratories and RTI significantly limits the findings of this evaluation.

At the time of writing this report, four out of five laboratories evaluated were still in the process of implementing their EIPs and will not have full implementation before the end of the evaluation. Thus, this final report contains incomplete information for these laboratories; only one laboratory (i.e., the Oklahoma State Bureau of Investigation) was far enough along in its EIP to make a full process and outcome evaluation feasible. For the other four EIPs, the process evaluations document the implementation to date and the outcome evaluations list short-term outcomes, where feasible. It is important to note that the impact of the EIPs on performance measures, including backlog and turnaround time reduction, cannot be fully assessed until implementation is complete.

2.1 Description of DNA Laboratory Process and the 2009 EIPs

We evaluated five DNA forensic laboratories under this 2009 DNA Unit EIP:

- Denver Police Department Crime Laboratory Bureau (DPD), Denver, CO
- University of North Texas Health Science Center Department of Forensic and Investigative Genetics (UNTHSC), Ft. Worth, TX
- Orange County Crime Laboratory (OCCL), Orange/Santa Clara, CA
- Oklahoma State Bureau of Investigation Forensic Science Services (OSBI), Edmond, OK
- Palm Beach County Sheriff's Office Crime Laboratory (PBSO), West Palm Beach, FL.

A brief description of each EIP's purpose, goals, and objectives are summarized in **Table 2-1**.

Table 2-1. 2009 DNA Unit EIP Summaries

EIP Laboratory	Description
DPD	The objectives of the DPD is to modify and use off-the-shelf management efficiency software called SIMUL8 (available at http://www.simul8.com) to explore options for revising laboratory processes to best maximize the laboratory resources. SIMUL8 has been used internationally for a range of industries, including manufacturing, healthcare, government, business, and energy. SIMUL8 assists in visually identifying and eliminating bottlenecks, increasing quality and efficiency, improving resource utilization, and helping to plan for future growth and capacity.
UNTHSC	The objective of UNTHSC is to develop and validate a novel expert system that will automate the routine and repetitive tasks in interpretation of mitochondrial DNA (mtDNA) sequence analysis, thereby improving laboratory efficiency and the speed of data analysis. Expert systems such as this one exist for nuclear DNA analysis, but not mtDNA. This expert system, eFAST and MTexpert software, will fully automate the analysis of high-quality mtDNA data. The expert system will also redirect “challenged data,” to the analyst for review of the specific DNA region and will aid in a decision to report a result, or to direct the analyst for re-analysis.
OCCL	The objectives of OCCL are to implement an efficient laboratory-wide Web-based case triage procedure and to establish three teams of DNA analysts that will be dedicated to property crime analysis, property crime sample batching, and a high-throughput DNA analysis line, all of which increases the overall use of laboratory automation.
OSBI	The objective of OSBI is to validate a commercially available AmpF ϕ STR Identifier Direct Polymerase Chain Reaction (PCR) Amplification Kit on buccal swabs, which are commonly used for the collection of known reference samples in most forensic and paternity laboratories worldwide. The goal of this EIP includes method validation of a DNA collection kit that is simple to use, cost effective, eliminates the need for a DNA extraction process, and provides reliable results.
PBSO	The objective of PBSO is to create a central Biology Processing Laboratory (BPL) in an existing space within the Boca Raton Police Services Department (BRPSD) to pre-screen crime scene evidence for southern Palm Beach County law enforcement agencies (Delray, Boynton Beach, and Boca Raton). The BRPSD BPL will process evidence for the confirmation of blood and semen, perform microscopic analysis of hair to complement DNA analysis, swab items for touch DNA evidence, and submit all informative evidence to PBSO for DNA analysis. Evidence prescreened at the BPL will be prioritized within assignments for confirmational DNA testing at PBSO.

There are many variables that determine criteria for how a DNA laboratory process is performed. The number of samples and types of samples, analysis, and DNA all vary with the purpose of the DNA testing. The basic steps of DNA analysis are shown in **Figure 2-1**.

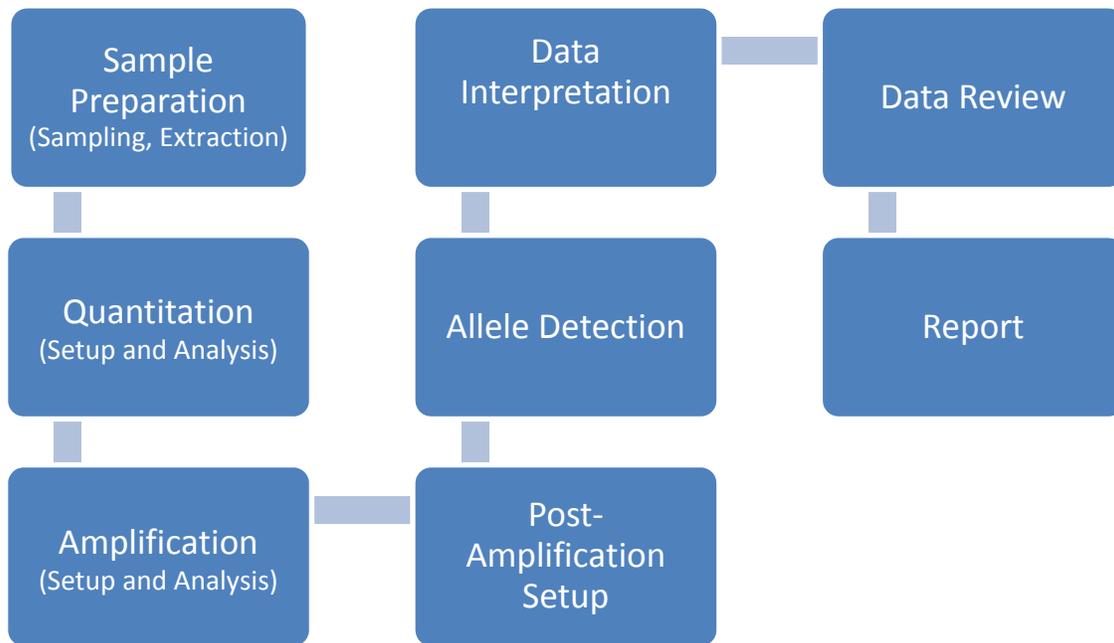


Figure 2-1. The DNA analysis process.

Sampling of the evidence will differ depending on the type of evidence and the sample collection device. Physical evidence, such as clothing or “surface wipes,” requires cuttings of the evidence itself or the sample collection device, which can include swabs, FTA cards¹, or Vacutainer blood tubes (a tube containing ethylenediaminetetraacetic acid that has a lavender stopper). For the evaluated EIPs, sample types and sample collection devices were typical for the testing being performed, but each laboratory was not exclusive or inclusive as to all types. After the “screening” or “sample” preparation phase, the analysis scheme is primarily the same.

Next, samples are prepared by lysing the cells and purifying the DNA through an extraction process, which may include adding reagents, heating, shaking, centrifuging, decanting, and collecting samples for the next steps. Samples can then be quantified to determine if enough DNA is present to continue on to amplification and DNA analysis. Once samples are amplified, they require post-amplification processing, including allelic detection, before data interpretation

¹ Specialized paper containing specialized, embedded chemicals which break open cellular contents for collection of DNA; FTA stands for “Flinders Technical Associates”, the Australian company of invention

and review can proceed. Finally, DNA results are reported by the testing laboratory, and profiles can be uploaded into appropriate DNA databases. Although there are many steps to consider for DNA analysis, the time saved would primarily be in the initial screening and sample preparation phases and may depend upon how automated each laboratory makes its EIP. Because reagents are required at most steps in the process (e.g., extraction, quantitation, amplification, post-amplification), these stages are where the use of the robotics is most effective.

Four of the EIPs involve casework testing, and one laboratory (i.e., UNTHSC) is a research and development laboratory that does not analyze forensic DNA cases on a contractual basis as a “core facility.” The four EIP laboratories performing casework did so using nuclear DNA. The UNTHSC analyzes mtDNA, autosomal Short Tandem Repeats (STRs), and/or Y-STRs. When conducting DNA analysis, a buccal swab is submitted as a family reference specimen to be compared to missing person cases for upload into various CODIS applications: Local DNA Index System (LDIS), and possibly the State DNA Index System (SDIS); and the National DNA Index System (NDIS), which is operated by the FBI. The type of casework performed included violent crime and property crime cases. One laboratory’s EIP (OCCL) was specific to property crime. Another laboratory’s EIP (OSBI) was specific to offender sample analysis, although this EIP was a method validation that was not ultimately implemented or tested on actual casework. Two EIP laboratories (PBSO and DPD) performed both violent and property crime case work.

The complexity of the DNA testing varies as to the type of case work. The analysis of evidence for property crimes is limited in scope. Property found in the place of interest (e.g., crime scenes)—for example, a pry bar, hammer, or screwdriver used in a burglary—could be swabbed for DNA. Similarly, entry points within a residence or business, such as window

frames, sills, or glass panes, could also hold a suspect's DNA. Violent crime evidence can be composed of known blood or saliva samples; items of interest, including weapons (e.g., guns, knives, bats, pipes), clothing, and property submitted to the DNA laboratory for testing; and swabs from large or immovable items that cannot be submitted to the laboratory. In general, there are far fewer items of physical evidence analyzed per case for property crimes than violent crimes. Reference samples, whether offender/arrestee samples or family reference samples, are fewer still.

Some U.S. laboratories have begun addressing fundamental case management and processing issues, and several strategies have been implemented (Kemp, 2007; NIJ, 2008; Selavka, 2006; Sikellis, 2007). Established approaches to efficiency, whether in a laboratory or otherwise, exist and have been successfully used and results and impacts have been published. **Table 2-2** summarizes approaches used by the 2009 DNA Unit EIP laboratories, which include establishing case acceptance policies, conducting process mapping, and strengthening technology development and transfer. Approaches can represent managerial strategies or analytical or laboratory solutions that are used to streamline a laboratory's operation (Zint & Montgomery, 2007). For example, case acceptance policies establish decision rules to limit the number of cases that are received, under the assumption that not all cases are created equal with respect to the evidence presented (NIJ, 2008). The results of implementing these strategies can be striking, but it does take time to fully realize the impact of the EIP. Once an efficiency improvement has been adopted by a laboratory, it can easily take a few years for measurable results. For example, in 2000, the Florida Department of Law Enforcement (FDLE) undertook a process mapping approach to address its existing case backlog. By 2002, FDLE's backlog had been eliminated, despite a 31% increase in sample submissions (NIJ, 2008).

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Table 2-2. 2009 DNA Unit EIP—Approaches to Efficiency

Approach	Description	Type	Lab
Case acceptance policy	Development of policy and procedures to limit number of cases received, prioritize sample acceptance (e.g., criminal case, known or unknown subject), return or deny samples if unacceptable turnaround times are probable, and impose a limitation on the number of samples per case	Managerial strategy	DPD, OCCL, PBSO
Process mapping (PM)	Development of flowcharts of laboratory processes (can be electronic or hardcopy PM) to help visualize information, identify solutions to maximize efficiency, and develop a strategic management plan for implementation	Managerial strategy	DPD
Business project management (BPM)	Use of a computerized tool that supports change and innovation to streamline administrative and analytical processes (e.g., SIMUL8, eFAST, MTextpert) as part of BPM	Managerial strategy	DPD, UNTHSC
Laboratory automation	Use of analytical advancements such as robotics, equipment integrations, expert systems software, and computerization that simplify and increase the speed of laboratory processes	Solution	OCCL, PBSO, UNTHSC
Laboratory process improvement	Design laboratory process adaptations to automate sample processing and analysis (e.g., high-throughput DNA analysis line for property crime, screening laboratory within law enforcement agency, method development and validation)	Solution	OCCL, OSBI, PBSO
Technology transfer (TT)	TT is the process of conveying an adopted technology from one party to another; TT also shares technical information by means of education and training and installation of new analytical procedures or equipment	Solution	OCCL, OSBI
Technology development	Development of technology, such as expert systems and other software, that can streamline and improve laboratory procedures and/or analytical methods or equipment	Solution	UNTHSC

2.2 Evaluation Questions

The evaluation sought to answer a number of questions for each of the laboratories. The process evaluation identified and examined the EIP approaches and elements by which the NIJ-funded EIPs were initiated and carried out in the laboratories. In addition, the process evaluation included collecting information on the challenges and barriers to implementation faced by the laboratories, as well as the solutions developed in response to these challenges and barriers. Some of these questions were asked of laboratory personnel at various points throughout the EIP evaluation to document when or if a key question had a “turning point” in the laboratory’s perspective. The outcome evaluation documented the impact of the EIP on DNA analysis capacity (e.g., turnaround, throughput, case backlog) and outcomes (e.g., entries into CODIS

databases, investigations aided), as well as other performance measures identified by the laboratories. **Figure 2-2** summarizes the inputs, throughputs, outputs, and outcomes that were proposed for the process and outcome evaluation model. This proposed plan was designed without the knowledge of the EIPs to be evaluated and later required modifications to better achieve the goals of the evaluations. **Table 2-3** identifies the primary questions to be addressed by the process and outcome evaluation model.

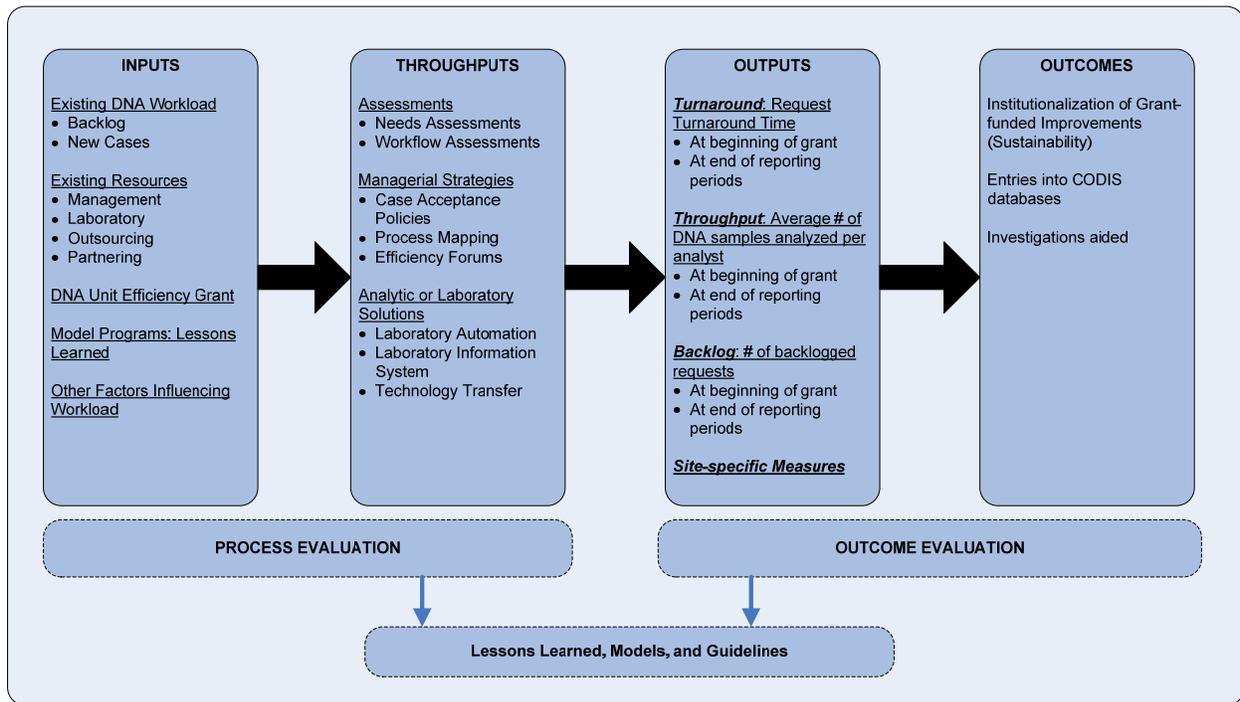


Figure 2-2. Proposed process and outcome evaluation model.

Table 2-3. Evaluation Questions

Research Questions	
Process Evaluation	<ul style="list-style-type: none"> ▪ Were there required modifications to the original implementation plan? ▪ Is the laboratory's proposed EIP adequate to realize results? ▪ Are laboratory staff and management content with project's progress? ▪ Do staff members have the necessary level of training and competence? ▪ What were noticeable impacts of EIP to the laboratory operations? ▪ Was the implementation within budget, or did it exceed projections? ▪ Was the implementation within projected timeline, or did it exceed projections? ▪ What issues or problems were encountered during each stage of the EIP, including implementation?
Outcome Evaluation	<ul style="list-style-type: none"> ▪ Were performance metrics and other outcome measurements easily extracted from a LIMS, or was a manual collection required? ▪ What is the effect of the EIP on average monthly turnaround time? ▪ What is the effect of the EIP on DNA cases/samples analyzed per analyst? ▪ What is the effect of the EIP on DNA case backlog? ▪ Did the EIP provide specific impacts in improved capacity or provide other benefits to the laboratory? ▪ Did this EIP specifically affect the entries to CODIS databases each month? ▪ If so, how many CODIS database entries occurred each month? ▪ How many CODIS hits each month?

2.3 Methods of Data Collection

Both qualitative and quantitative data were collected as part of the evaluation. Data sources included document review (e.g., laboratory documents, grant applications); site visits with and interviews of key laboratory personnel; and the collection of administrative data, either manually by laboratory personnel or extracted from LIMS (e.g., backlog, turnaround time, CODIS hits). These data were collected throughout the performance period of the evaluation. Although an effort was made to collect a consistent and standard set of data from each laboratory, this was not always feasible for a number of reasons. As previously mentioned, the performance periods for each laboratory varied, and only one laboratory completed its EIP prior to the writing of this report. Furthermore, each laboratory implemented a unique approach to improving efficiency such that some information was relevant to one laboratory, but not to others. The remainder of this section will describe the various data collection methods and instruments in greater detail.

2.3.1 Pre-assessment Data Collection

Early in the evaluation process, each laboratory was contacted and requested to provide some background information about its laboratory and EIP project and supporting documentation. This information was requested via a questionnaire that included both closed- and open-ended questions (see **Appendix A**). The questionnaire covered the following areas:

- Definitions of potential outputs and outcomes used by the laboratory (e.g., backlog reduction, cold hit, turnaround time)
- Staffing and jurisdiction
- Case load
- Impacts and influences of EIP on the laboratory
- Grant information
- Request for documents and other materials (i.e., organizational chart and staffing plan; local/state policies that influenced EIP submission; laboratory mission statement; quality manuals and statements of policy as relevant to the EIP; CODIS system policies and procedures; recent laboratory inspection findings; and a list of jurisdictions and/or clients served).

Each laboratory completed and returned its pre-assessment questionnaire. The results from this questionnaire were used to help understand each laboratory's EIP and the context in which it would be developed and implemented. The results also informed the development of both an interview guide to be used during site visits and a standard set of performance metrics to evaluate EIP outcomes (both described in greater detail below).

2.3.2 Site Visits

After reviewing the pre-assessment data and laboratory documents, a single semi-structured interview guide was developed to use during site visits with each laboratory (see **Appendix B**). Although the same guide was used during visits with each laboratory, the number and role of laboratory staff involved varied based on the EIP. Between 3 and 15 laboratory staff participated in the site visits. Approximately 1 week prior to each site visit, the laboratory staff were e-mailed a copy of the interview guide so they would have a better understanding of the purpose of the evaluation and the information that would be discussed, and to assist them in preparing materials beforehand.

Each site visit began with a general overview of the goals and objectives of the evaluation and the evaluation research team. Laboratory staff were then presented the opportunity to ask any questions of the evaluation team or to share information. Because of the semi-structured format of the site visit, the order in which questions were asked varied.

However, each site visit consisted of the following:

- Laboratory tour
- Assessment of how the project had progressed to date
- Review of pre-assessment materials
- Review of EIP objectives and how they are being implemented, including
 - EIP data collection
 - Timeline
 - Planned activities and any necessary modifications
 - Staffing
 - Expenditures
 - Partners

- Barriers and solutions
- Lessons learned.

2.3.3 Quantitative Performance Metrics

The RTI research team developed a standard set of performance metrics and shared this with the laboratories for their review and input. Review of the pre-assessment data suggested that laboratories did not consistently define key EIP performance metrics, such as turnaround time and backlog. However, to make comparisons between the impacts of each EIP, consistent definitions were preferred. To address this issue, the evaluation research team constructed a list of performance metrics by which to evaluate each EIP. These metrics were explicitly defined so that each laboratory would provide requested information in a consistent format. **Appendix C** includes each metric requested and the formula for calculating additional metrics derived from the raw data.

Each laboratory was requested to provide monthly statistics for a number of measures on the following topics:

- Staffing and hours
- Turnaround time
- Cases
- CODIS hits
- Samples
- Financials.

For the most part, laboratories were able to provide requested statistics; however, in some cases, exceptions were made. The actual metrics collected from each laboratory are described in detail in the outcome evaluation sections.

For example, OSBI's EIP focused on validating the use of Applied Biosystem's Identifiler® Direct amplification kit for use on buccal swabs. Because the validation did not involve actual casework, all metrics related to casework (e.g., cases assigned, cases not assigned, cases being worked) were not relevant to OSBI's EIP and thus were not collected. Because PSBO's EIP involved the development of a Biological Processing Laboratory (BPL) that would serve three cities in PBSO's jurisdiction, it was important to collect metrics that reflected changes to those specific cases rather than to the larger laboratory, which serves a number of other jurisdictions. To address this issue, each metric was altered to accurately reflect the impact an EIP was intended to have. Because it would take PBSO additional time to identify the BPL sample, metrics were provided quarterly rather than monthly.

2.4 Methods of Analysis

For the process evaluation, the primary methods of analysis included describing the nature and functioning of a program during and after implementation, and then comparing these findings to an EIP's theory, or how it was intended to achieve its goals. The primary source of data was the site visits. During each site visit, each research team member took notes on the EIP interview guide. Upon return from the visit, the Project Director drafted the first set of site visit notes. These notes were then distributed to the research team for further refinement and clarification. In most cases, additional questions or points of clarification were needed from the laboratory. Once each member of the research team was satisfied that the current draft of the site visit notes for a laboratory was as complete and accurate as possible, these notes were shared

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with the laboratory. This allowed the laboratories to provide clarification and address additional questions that arose during the refinement of the site visit notes. Laboratory staff were also asked to review the content of the notes for accuracy and to provide any additional information. Furthermore, monthly meetings were scheduled with each laboratory after the site visit so that progress in implementation could be monitored and any changes could be documented. Similar to the analysis of the site visit notes, an initial draft of notes from each meeting was developed and then shared with the research team for further detail, clarification, and revision.

Because the laboratories EIPs were not fully implemented, the outcome evaluation was limited. The intended design was to assess differences in the performance metrics for each laboratory pre- and post-implementation. This includes developing graphs of each metric to illustrate the trajectory over time and allow for the visual inspection of changes that may have occurred over the implementation period. The rate of change for each metric would be calculated for the pre- and post-implementation periods and compared to determine whether the rate of change was affected by the EIP. If a change was observed, rival explanations for change (e.g., other laboratory or law enforcement changes that were not part of the EIP) would be investigated to assess whether it was plausible that these led to the change in performance rather than the EIP. Finally, the results between each of the EIPs would be compared to assess which type of EIP was most associated with success. However, as previously mentioned, only one laboratory was fully implemented at the conclusion of the EIP, although it was not implemented and tested on actual casework samples. Available metrics pre-implementation are provided for each laboratory; short-term post-implementation outcomes are described where available. Because the laboratories are not fully implemented, the ability to detect change, assess rival explanations for change, and compare results between EIPs is significantly limited.

2.5 Summary of Forensic DNA Unit EIP

Recognizing the need for innovative ideas to address laboratory efficiency and capacity, NIJ created the Forensic DNA Unit Efficiency Improvement Program (EIP) to support the development and adoption of improved laboratory processes. Priority was given to novel and innovative methodologies that have the potential to affect the entire DNA forensic community. NIJ awarded nearly \$6.5 million to laboratories between 2008 and 2010; however, funds will no longer be awarded under this program. Five laboratories receiving funds in 2009 participated in this evaluation.

3. PROCESS EVALUATION

3.1 Orange County Crime Laboratory (OCCL)

OCCL proposed a two-prong approach to improve laboratory efficiency and capacity to process crime scene samples from property offenses. The proposal consisted of (1) implementing a property crime DNA case submission triage system and (2) creating a Property Crime DNA Program in which dedicated teams of analysts assigned to the program would be devoted exclusively to the processing of property crime DNA samples using a customized scheduling system and a highly automated DNA processing platform. Funds were requested (\$1,499,930) to cover a number of costs associated with the triage system and Property Crime DNA Program, including personnel (four full-time Analysts, one Forensic Technician, one Legal Property Technician, and one Clerical Aide); equipment (Applied Biosystems 3500 Genetic Analyzer; four thermomixers; centrifuge; Qiagen Universal BioRobot; QIAgility post-PCR liquid handling robot; Tecan/Prepfiler HID EVOLUTION Extraction System; Eppendorf Speed Vac [Vacuum centrifuge]; Biotek ELx900 absorbance microplate reader; and Applied Biosystems genetic analyzer); supplies; the installation of electrical lines for the new extraction robots; and software (GeneMapper IDX).

3.1.1 Context

3.1.1.1 Setting

OCCL serves citizens in Orange County, CA. While OCCL accepts evidence from over 40 law enforcement agencies, the bulk of its submissions are made by two agencies: Garden Grove and Santa Ana. OCCL also does outsourcing for other law enforcement agencies on a contract basis.

The American Community Survey estimated Orange County's population to be about 3 million in 2009. More than 60% of the population identified themselves as white and 2% identified themselves as black. More than one in three Orange County residents indicated they were of Hispanic or Latino ethnicity. In 2009, the combined crime rate of the cities in Orange County was less than the national average, with 7,184 violent crimes (248 per 100,000 residents) and 58,490 property crimes (2,020 per 100,000 residents) (UCR, 2010) (**Figure 3-1**).

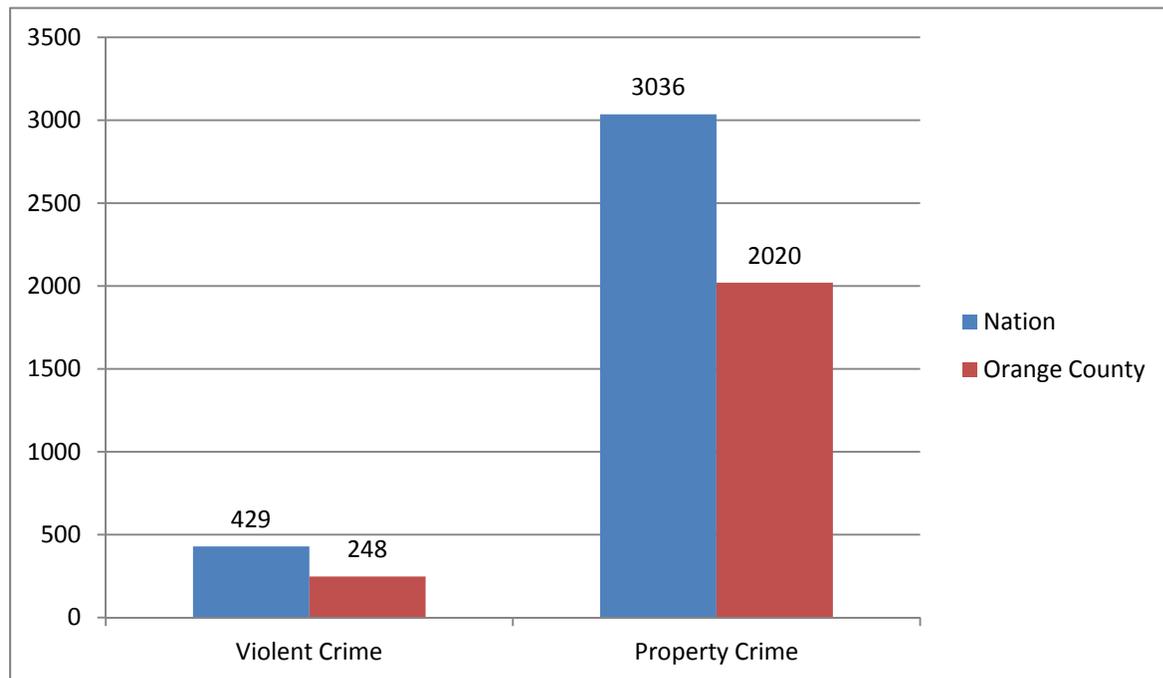


Figure 3-1. Crime rate per 100,000 residents.

NOTE: Based on summed UCR statistics and population estimates for the following cities: Aliso Viejo, Anaheim, Brea, Buena Park, Costa Mesa, Cypress, Dana Point, Fountain Valley, Fullerton, Garden Grove, Huntington Beach, Irvine, Laguna Beach, Laguna Hills, Laguna Niguel, Laguna Woods, La Habra, Lake Forest, La Palma, Los Alamitos, Mission Viejo, Newport Beach, Orange, Placentia, Rancho Santa Margarita, San Clemente, San Juan Capistrano, Santa Ana, Seal Beach, Stanton, Tustin, Villa Park, Westminster, Yorba Linda.

3.1.1.2 History of Program

OCCL has been at the forefront of DNA evidence processing since its DNA program began in 1988. OCCL was one of the first public crime laboratories to invest in a DNA program with restriction fragment length polymorphism (RFLP) analysis, the predecessor of current

polymerase chain reaction (PCR)–based testing . From the beginning, OCCL DNA staff members were involved in training investigators and district attorneys in the use of forensic DNA analysis through participation in panel discussions at professional seminars and training sessions offered through the National District Attorney’s Association. In addition, OCCL had a representative on The Technical or Scientific Working Group on DNA Analysis Methods (originally TWGDAM, now Scientific Working Group on DNA Analysis [SWGDM]) and also on the Federal Bureau of Investigation’s (FBI’s) DNA Advisory Board. In 1992, OCCL relocated to a new larger facility, which included a dedicated PCR laboratory. Casework was initiated using the D1S80 and DQ alpha PCR typing systems in 1994. In 1995, OCCL began reviewing cold cases for DNA evidence and obtained their first database hit on a serial murder case from the early 1980s. OCCL’s numerous identifications in cold cases using CODIS have lead to successful prosecutions since that time.

OCCL has continually improved its technology and laboratory efficiency. As new technology became available, the laboratory validated and implemented the following STR profiling methods: CTTA (Promega), Profiler Plus (Applied Biosystems), COfiler (Applied Biosystems), Power Plex Y (Promega), Identifiler® (Applied Biosystems), Identifiler Plus® (Applied Biosystems), and Y-filer (Applied Biosystems). In 2006, OCCL incorporated a batch processing system that is managed by the LIMS created by in-house staff. This led to an easy transition of implementing robotic liquid handling instruments. Additional robotics and multi-channel capillary electrophoresis instruments, such as the Applied Biosystems 3130 and 3500 Genetic Analyzers, have been incorporated into the DNA analysis flow as they became available.

The DNA Section of OCCL currently consists of 1 DNA laboratory director, 3 supervising senior forensic scientists, 26 full-time DNA analysts, and 2 half-time DNA analysts.

Since 2004, OCCL has also received funding from grants under the NIJ DNA Backlog Reduction and Capacity Enhancement Program. Prior to this DNA Unit EIP, OCCL received funding in 2005 through an NIJ Property Crime Expansion Grant. The grant involved the coordinated review of cases and evidence by forensic scientists at OCCL, a deputy district attorney at the Orange County District Attorney’s Office (OCDA), and a police sergeant at Orange County Sheriff’s Department. The OCDA initiated a subsequent property crime project aimed at improving the triage process for reviewing property crime cases prior to DNA analysis. These two projects provided the foundation for developing the current EIP.

3.1.1.3 Laboratory

The current OCCL facility is 18 years old, and the laboratory covers about 7000 to 8000 square feet. The equipment purchased with 2009 DNA Unit Efficiency Improvement Grant and matching county funds is summarized in **Table 3-1**.

Table 3-1. OCCL Equipment, 2009 DNA Unit EIP

Equipment	Quantity	Use
Thermomixer	4	Initial extraction steps of the DNA isolation procedure
Centrifuge with plate rotor	1	Initial extraction steps of the DNA isolation procedure
Tecan/Prepfiler HID EVOLution Extraction System	1	Separation and purification of DNA from other cellular components
Eppendorf Speed Vac (Vacuum centrifuge)	1	Dry-down plates at the end of the Tecan/Prepfiler extraction process so they can be reconstituted with standard volumes
Qiagen Universal BioRobot	1	Liquid-handling robot used to set up quantitation and amplification plates
QIAgility post-PCR liquid handling robot	1	Set up of Genetic Analyzer plates
Biotek ELx900 absorbance microplate reader	1	Calibration of the syringes of the liquid handling robots in the post-PCR area
Applied Biosystems 3500 (8 capillary) Genetic Analyzer	1	DNA sequencing by capillary electrophoresis to separate DNA fragments based on size and genetic analysis software to determine DNA loci pattern (specific DNA genotype) of the sample

One of the primary challenges faced by OCCL is a tight budget. However, one of the laboratory’s primary strengths is its ability to work well with other stakeholders; the partnership

with the OCDA is working well, and the laboratory's cross-functional teams are cohesive. OCCL's history of being a leader in DNA evidence processing pushes the laboratory to stay in the forefront. Examples of commitment to DNA analysis include participating in evaluation opportunities; examining high-throughput potentials; use of custom information technology (IT) processes; exploring innovation; fundraising for DNA equipment through the Orange County Sheriff's Office; its commitment to quality; and its American Society of Crime Laboratory Directors Laboratory Accreditation Board (ASCLD/LAB) the International Organization for Standardization (ISO) accreditation.

3.1.1.4 Decision to Develop the EIP

In 2008, the OCDA developed a projection of Orange County's needs for DNA analysis. The results indicated that county law enforcement agencies are adopting more policies and procedures aimed at increasing the use of DNA analysis to solve crimes, and that the collection of DNA evidence from the scenes of property crimes would increase significantly in the next few years. These trends suggested that OCCL would see an increase in demand for DNA analysis, which would likely result in an increase in the backlog of cases awaiting analysis. OCCL realized that a novel approach was needed to address this increasing demand. Prior to this EIP, DNA analysis of property crime cases was given lower priority than violent crimes. Two factors led OCCL to focus this EIP on property crimes: (1) the laboratory had already begun work to improve the property crime triage process through NIJ's Property Crime Expansion Project and an additional project initiated by the OCDA, and (2) increasing the number of property crime samples to DNA databases can increase the number of CODIS hits, which can solve both property and violent crimes.

3.1.2 Goals and Objectives

OCCL's goals of its EIP grant were to create and implement a property crime case submission triage system and a Property Crime DNA Program. OCCL anticipated that this approach would result in a reduction in median turnaround time from the submission of DNA analysis to a completed report from 125 days to 25 days for property crime. Although the EIP focused exclusively on property crime cases, OCCL also expected a minimum of 15% reduction in turnaround time for violent crimes and major cases due to the laboratory's ability to focus exclusively on those cases. OCCL also expected the EIP to substantially reduce, or even entirely eliminate, its DNA backlog.

3.1.3 Staffing

At the onset of the EIP, the DNA section of OCCL was staffed by 1 manager; 3 supervisors; 23 full-time and 4 half-time casework analysts; and 1 technician. The OCCL management planned to use grant funds to hire additional staff (4 DNA analysts, 1 legal property technician, 1 forensic technician, and 1 clerical aide).

3.1.4 Proposed Activities

OCCL proposed to develop and implement a property crime case submission triage system and a Property Crime DNA Program. The triage process was proposed to include training, triaging of cases submitted to OCCL, and notification of agencies about case status and follow-up requests. Together, OCCL and the OCDA would train each police agency on current submission guidelines (including special requirements for the submission of property crime cases); best forensic opportunities; and the requirement for elimination samples. Case triage would be conducted by deputy district attorneys and OCCL Forensic Scientists on at least a bi-

weekly basis. Each request for DNA analysis for property crimes would be reviewed by the team to verify the presence of DNA and determine whether the case would provide an investigative lead, and prioritize the evidence for processing. Agency communication and notification would be handled by the Clerical Aide, who would assist the High Volume DNA Supervisor with reviewing work requests and promoting work requests, requesting evidence from the agencies, and facilitating case assignment.

The second component of the OCCL EIP, the Property Crime DNA Program, would involve creating teams of dedicated property crime DNA Analysts, who would use an automated DNA instrumentation platform and work on a rotational schedule. OCCL proposed dedicating two property crime teams, each consisting of four full-time analysts. Two half-time analysts would be available to both teams on an as-needed basis. Each team would follow a fixed 5-day schedule, with each team starting the schedule on a different day to avoid overlap. OCCL proposed hiring the following additional staff for the program: 4 DNA analysts, 1 legal property technician, 1 forensic technician, and 1 clerical aide. Instrumentation needed for the automated platform was purchased for use as described above in Table 3-1.

3.1.5 Implementation

3.1.5.1 Actual Activities

OCCL's activities fall into three general areas: the property crime case submission triage system, teams of DNA analysts dedicated to the analysis of property crimes, and the property crime high-throughput DNA analysis line.

Property Crime Case Submission Triage System

OCCL forensic scientists and the deputy district attorneys provided training to all Orange County law enforcement agencies between June and August 2009. The law enforcement agencies were instructed to complete a work request form in which they described and prioritized evidence to be analyzed for property crimes. OCCL began triaging property crime cases on September 1, 2009. The triage team included a senior forensic scientist, a deputy district attorney, and a paralegal. The triage review included checking the OCDA's case management system to determine whether a suspect had already been identified, was already processed, or had pled guilty to the crime. The work request forms submitted by law enforcement were reviewed, and the priority order for DNA analysis was established as follows:

1. Blood and saliva evidence from a potential perpetrator, or a potential suspect identified.
2. Tools or personal property left by suspect.
3. Victim property that had been handled by the suspect.

Requests were returned to law enforcement if they did not include complete case information, adequately describe the evidence, collect victim elimination standards, or present a good opportunity for forensic analysis.

In November 2010, OCCL developed and mandated the use of a new Web-based system for submitting work requests and conducting triage. At this point, the triage team ceased having bi-weekly review meetings and began reviewing and prioritizing property crime case requests online. Additional modifications were made to the Web-based work request system to improve its usability, and additional training on the process was provided when requested by law enforcement agencies.

Property Crime DNA Program

In late 2009, five OCCL DNA analysts (four full-time and one half-time) were selected as members of the Property Crime DNA Team and began working exclusively on property crime cases and on validating some of the equipment (Tecan robot/Prepfilers extraction system). In late 2009 and early 2010, OCCL also began recruiting to hire additional staff for the Property Crime Team (4 forensic scientists, 1 forensic technician, 1 legal property technician, and 1 clerical aide). These positions were filled by August 2010. The clerical aide was hired in March to assist DNA supervisors with various aspects of the triage process (e.g., searching databases, entering work requests, logging evidence), and the legal property technician was hired in May to work in the Evidence Control Unit. In June, existing OCCL employees were promoted to fill two of the forensic scientist positions, and in August, three laboratory interns were hired to fill the remaining two forensic scientist and one forensic technician positions.

The hiring permitted OCCL to have two teams dedicated exclusively to property crime DNA analysis. The teams were developed so that all of the existing staff members were on “Team 1” and the new hires were on “Team 2.” While Team 2 completed its training modules, Team 1 was able to focus on validating the Tecan/Prepfilers extraction system, training Team 2 on operating the system, and reviewing work completed by Team 2 while analyzing incoming and backlogged property cases.

Property Crime High-Throughput DNA Analysis Line

OCCL recognized the need to reorganize their existing DNA extraction area and effectively create two separate high-throughput DNA analysis lines. This required installing additional electrical lines and purchasing laboratory benches and cabinets for installation in the

examination room that houses the instruments dedicated to the property crime high-throughput DNA analysis line. This was completed in June 2010.

Validation of the new Tecan/Prepfiler extraction robot began in May 2010 and was completed in December 2010.

3.1.5.2 Considerations for EIP Implementation

There were four major categories of considerations/issues encountered during the EIP process: Partnering, Personnel, Construction, and Instrumental. These issues are summarized in **Table 3-2**.

Table 3-2. OCCL Considerations Encountered during the EIP

Category	Consideration/Issue	Comments
Partnering	Orange County District Attorney's Office (OCDA) originally wanted to develop its own DNA Unit	Agreed to partner with OCCL
	Organization and role responsibilities among OCCL, the OCDA, and law enforcement agencies had to be addressed	
	Web-based work request and case submission (WRCS) system required a learning curve by stakeholders and met with some initial resistance from law enforcement.	OCCL now has mechanism to request information and document dialog
	Required a culture shift in law enforcement to ensure more timely evidence submission	
Construction	Construction of the robot extraction room took longer than expected, resulting in delays in the validation of the Tecan/Prepfiler robotic extraction system.	

(continued)

Table 3-2. OCCL Considerations Encountered during the EIP (continued)

Category	Consideration/Issue	Comments
Instrumental	Universal BioRobot liquid handling robot had major problems. The repairs, software modifications, field calls, and repeated quality checks took more than 1 year.	
	The BSD swab cutter was no longer manufactured. This required OCCL to evaluate push off and break off swabs.	Law enforcement has not been using these swabs extensively due to costs. Swabs are still being manually cut with scalpel blades, impeding efficiency.

3.1.5.3 Modifications to Original Implementation Plan

There were three major modifications to the original implementation plan and EIP design. First, an Orange County hiring freeze resulted in a modification of the timeline due to a delay in building two teams to work on the high-throughput DNA analysis line. The first high-throughput DNA analysis line team was formed in November 2009; however, personnel for the second team were not hired or brought into the laboratory until June 2010 (two forensic scientists) and August 2010 (two forensic scientists and one forensic technician). The first team of analysts was not only processing property crime cases, but also selecting, validating, and creating methods and procedures for the new Tecan/Prepfilr robotic extraction system.

A second modification was that the vendor for the laser swab cutter (BSD, Inc.) was acquired by a larger company that discontinued manufacturing the laser swab cutter. OCCL performed an evaluation of cotton-and-polyester tipped swabs, recommending the push-off Fitzco CEP™ swab for collecting potential DNA from property crime evidence. These swabs were introduced in the First Responders training course offered to local law enforcement agencies in June 2011 and October 2011 and were included in the evidence collection kits provided to the attendees at the end of the training. To date, very few of the agencies have converted from regular cotton-tip swabs to the new Fitzco CEP™ swabs, primarily due to the cost.

Third, there were unanticipated changes in staffing. The resignation of the grant-funded office specialist in December 2010 resulted in the DNA supervisor who oversaw the high-throughput DNA analysis line spending a large amount of time accepting and printing work requests, requesting evidence from the agencies, and assigning cases. A new grant-funded office specialist was hired in August 2011 and has been able to take over these duties.

The legal property technician (LPT) hired for the Evidence Control Unit (ECU) went out on an unexpected family leave from May 2011 to July 2011. A sheriff's deputy who was on restricted work duty was hired to assist us in the ECU until the LPT returned. No background investigation and very little training were required. However, the sheriff's salary was more than twice that of the LPT's salary and had to be paid using grant funds.

The forensic technician who was hired for this project was promoted to a forensic scientist in July 2011 and transferred to the Forensic Alcohol Section for the promotion. She had been trained in DNA procedures and was scheduled to be promoted to a forensic scientist in the DNA Section when 2011 DNA Backlog Reduction and Capacity Enhancement Grant funds were awarded in October 2011. However, another limited-term, grant-funded position was unacceptable, so she transferred to the Forensic Alcohol Section. This resulted in the loss of time and money spent on the DNA training.

3.1.5.4 Staff and Management Perceptions of Project Progress

During the site visit, several DNA analysts commented on issues they struggle with in doing their job and on their DNA processes. The analysts felt that the triage process of reviewing casework submission every 2 weeks is helpful; prior to case triage, they had no mechanism to decline processing a case. They also felt that separating high-volume crime from other crime is a good idea.

Current Opinions

At the time of this report, OCCL staff reported that they were satisfied with the progress of the EIP because it provides a well-planned, streamlined process that they can follow on a weekly schedule. With the new implementation of the sample triage and electronic tracking systems, the staff can track at any time (e.g., daily) where a sample is anywhere in the process and what analyses needs to be done on the high-throughput DNA analysis line for property crime. Furthermore, the implemented high-throughput DNA analysis line has shared analysts' duties; a rotation through evidence examination, operation of the robotics, analysis of DNA data, and preparation of final reports is required of all analysts. This process ensures that no one is burdened with any one particular task, and team members can easily fill in for one another if there is court, training, or time off.

The DNA analysts and management appreciate the triage process that begins upon receipt of the work request. The triage process identifies cases that are not prosecutable, do not have necessary elimination standards, or do not contain enough case information and details. Triageing property crime work requests has helped to reduce the number of samples analyzed for DNA, but not uploaded to CODIS (e.g., no elimination standards collected, not enough case information submitted on the work request to know the DNA relevance to case). The analysts are satisfied that the work they now do has relevance and that the generated DNA profiles are regularly entered into CODIS, resulting in cold hits.

3.1.5.5 Budget and Timeline

The EIP implementation stayed within the budget. The cost of the personnel hired with grant and match funds now has to be paid by the county. The county has elected to pay the salaries and benefits for some of the personnel hired with grant funds (the trained DNA analysts),

but not all. They will not pick up the cost of the office specialist, the legal property technician, and the forensic technician. The other cost that has been added to the laboratory's budget is the additional cost of consumables, reagents, and other supplies required to process and analyze the increased volume of property crime samples being submitted to the laboratory for DNA analysis.

There were three no-cost extensions (NCEs) submitted for the grant: the first Grant Adjustment Notification (GAN) (008) was submitted on December 2010 and was approved in the same month. With the first NCE, the project end date was extended from March 2011 to October 2011. The reasons given for the extension were that additional time was needed to train both of the high-throughput DNA analysis line teams on how to use the Tecan/PrepFiler extraction system and to complete the DNA typing training of the four DNA analysts hired using grant funds. A second and subsequent GAN (009) was submitted on May 2011 and was approved in the same month. The project end date was further extended from October 2011 to March 31, 2012. The reason given was to continue funding the salary and benefits of the DNA analysts who were hired in August 2010. Their positions are to be funded up to the end of February 2012. A third GAN (012) was approved in January 2012 and extended the grant to June 30, 2012. This NCE allowed OCCL to continue funding the salary and benefits of the DNA analysts hired in August 2010 and use up the grant funds.

Given delays in staff hiring and equipment acquisition and validation, OCCL requested and received an NCE through March 2012. No additional funds were requested.

3.1.6 Impact of EIP on Laboratory Operations

Impacts of this DNA Unit EIP were realized early on in the process of implementation for OCCL and continue today. Similar to considerations for the EIP process, there were four major categories of impacts on laboratory operations encountered during the EIP process:

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Partnering, Personnel, Construction, and Instrumental. These issues are summarized in **Table 3-3**.

Table 3-3. OCCL Impacts of EIP Process

Category	EIP Impacts	Comments
Partnering	New Property Crime high-throughput DNA analysis line of EIP has required increased communications and commitment within the jurisdictional agencies, including OCCL and OCDA.	The OCDA has been working with the county agencies to help them follow-up on cases with CODIS hits (e.g., cold cases).
		The OCDA continues to help law enforcement agencies collect reference standards in cold cases.
		The increase in CODIS hits from property crime cases has led to an increase in the submission of confirmation standards for DNA testing. Once an individual is identified and arrested as a result of a CODIS hit, a confirmation swab is collected for testing by OCCL. Collection of the confirmation swab must be completed prior to the preliminary hearing, which is typically held 10 days after the charges are filed.
		The increase in the number of CODIS hits has resulted in an increased number of confirmation standards needing to be analyzed, which has resulted in increased analyst time spent processing the confirmation swabs, issuing a new report comparing the reference standard to the original evidence in the case, and testifying in court during the preliminary hearing and later the trial.
Personnel Hiring, training, reassigning, retention	Four new forensic scientists were hired.	The scientists needed to be trained in laboratory techniques ranging from evidence handling to DNA profiling and report writing.
	Four existing forensic scientists were reassigned as “Team 1” for the OCCL high-throughput DNA analysis line.	This reassignment has an impact on major crime casework since the scientists were taken from that casework and assigned to the High Volume Line to work on property crimes.

(continued)

Table 3-3. OCCL Impacts of EIP Process (continued)

Category	EIP Impacts	Comments
Personnel (continued) Hiring, training, reassigning, retention	Basic DNA training was planned for the new-hire scientists.	The training was planned to be external to the OCCL and conducted at Marshall University; however, the university cancelled this training. Internal training by DNA Section Staff was used, and staff served as mentors to demonstrate internal laboratory processes and policies. This ultimately helped to foster relationships and to allow the new scientists to fully learn the OCCL process first-hand. Internal training took away from the analysts' time to perform casework for a short duration. These hours were logged as part of the Performance metrics collected (629 hours of training, approximately equal to one-third time equivalent position).
	The county has agreed to continue the salaries of the DNA scientists hired with 2009 EIP funds. Support staff positions currently remain unfunded.	This agreement supports staff retention and added commitment of Orange County to the value of the EIP for the DNA Unit. Retention of four almost fully-trained DNA analysts (14 to 16 months training investment) at the time of this report. With the completion of the 2009 DNA Unit EIP Grant in June 2012, the county will not budget for grant-funded positions of an office specialist, a forensic technician, and a legal property technician. These tasks may become the responsibility of the scientists, which will reduce time for casework and analysis of property crime cases.
Construction	Construction of the robot extraction room	A separate room for DNA extraction and amplification is necessary as separate housing from initial sample accessioning helps prevent contamination of samples.
Instrumental	During the EIP implementation, the time and labor impacted the efficiency of laboratory operations. The impact of new instrumentation in the DNA Unit to specifically process high-volume property crimes with a greater focus and efficiency has only begun to be realized through laboratory outputs.	Tecan/Prepfil robotic extraction system – This system required validation prior to casework analyses, revisions to the Quality System manual, and staff training (e.g., review all training procedures and qualifying sample results).
		Liquid handling and extraction robots – The robots required completion of performance checks and manual updates.
		Collection device and processing – OCCL was unable to implement automated proposed laser swab cutter (BSD, Inc.) because it was no longer manufactured and supported. There was an alternative of using push-off and break-off swabs to reduce laboratory handling, yet still yield good DNA recovery. OCCL evaluated this alternative and introduced it to county law enforcement agencies via training. Law enforcement is slow to adopt the use of these swabs, primarily due to the cost. Laboratory analysts are still excising hundreds of property crime evidence swabs by manually using scalpel blades.
		Supplies and reagents – The costs increased from original proposal. Often times, supply contracts must be re-negotiated. This takes time and often results in an additional laboratory delay.
A Biomatrix dry storage system was implemented to store remaining DNA extracts in 96-well plates from property crime cases. The system works well for long-term storage for property crime cases, and OCCL plans to implement to major crime extracts in the near future.		

3.2 Denver Police Department Crime Laboratory Bureau (DPD)

The DPD proposed using an integrated and innovative approach to improving their DNA laboratory efficiency by applying process mapping and simulation, primarily through the use of SIMUL8 software. Requested funds (\$138,005) would be used to both hire an DNA EIP manager (proposed as an IT project manager, but later changed to this title with expanded role) and purchase the SIMUL8 software and other related supplies. The new employee would be responsible for using the software to model the DNA analytical process. The process mapping and simulation were expected to yield a true measure of the laboratory's capacity, an improvement over the existing subjective view of these processes. Simulating the workflow was expected to identify areas for improvement so that solutions could be tested and the process could be altered to achieve optimal performance with minimal risk.

3.2.1 Context

3.2.1.1 Setting

The DPD serves the citizens in both the City and County of Denver. The American Community Survey estimated Denver's population to be 610,345 in 2009. Over three-quarters (76%) of the population identified themselves as white, and 10% identified themselves as black. About one-third of Denver residents indicated they were of Hispanic or Latino ethnicity. In 2009, the crime rate in the city of Denver was slightly higher than the national average, with 3,493 violent crimes (578 per 100,000 residents) and 20,879 property crimes (3452 per 100,000 residents) (UCR, 2010) (**Figure 3-2**).

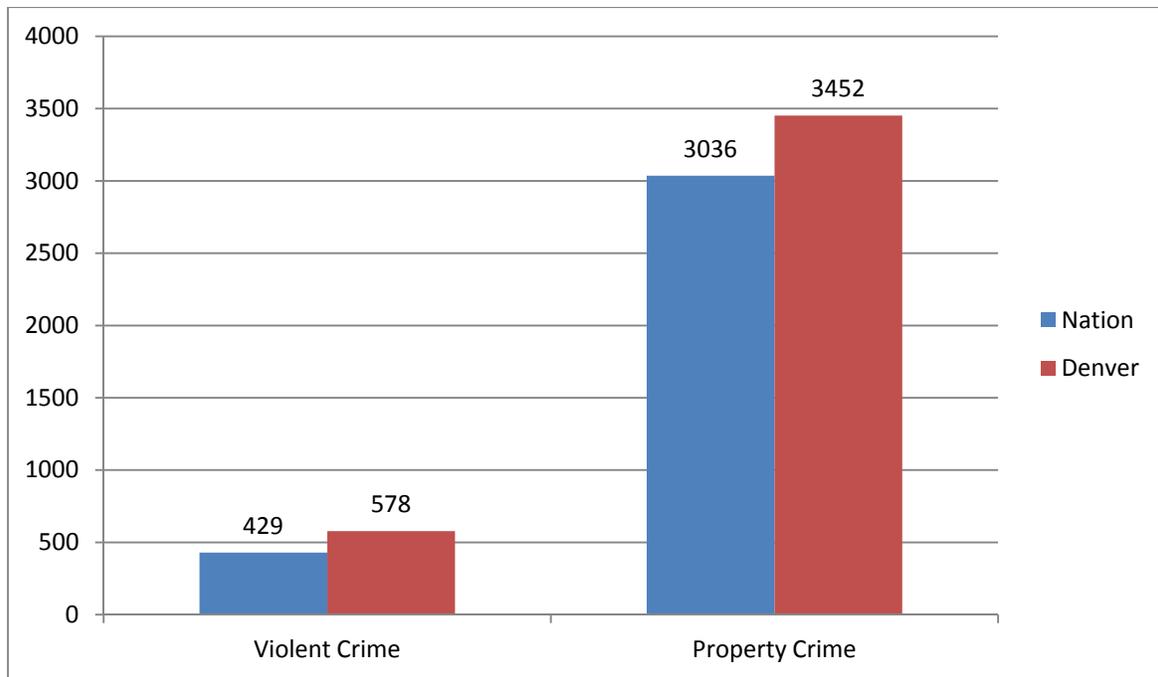


Figure 3-2. Crime rate per 100,000 residents (http://www2.fbi.gov/ucr/cius2009/data/table_08.html).

The DPD laboratory primarily operates on funds provided by the City and County of Denver. Excluding personnel, the Bureau's annual budget is approximately \$550,000. The DPD laboratory has seen a rapid increase in the number of cases submitted for DNA testing; the annual caseload nearly tripled between 2001 and 2007. Over the past 5 years, the vast majority of the forensic biology and DNA analysis requests came from the laboratory's primary clients: the DPD (1503 and 1303, respectively); the Denver District Attorney's Office (17 for both types of requests); and the Denver Fire Department (9 and 4, respectively). However, under special circumstances during the past 5 years, the laboratory also conducted DNA analysis on a few cases for the Aurora Police Department and the Golden Police Department.

History of Program

The DPD laboratory was established in the late 1940s with a firearms unit. Examinations of serological evidence began in 1978, when the laboratory was moved to its current location.

The laboratory is staffed by 50 personnel, 14 of which work in the laboratory's DNA Unit.

Prior to the 2009 DNA Unit EIP, the DPD laboratory had received federal funding since 2003 for other laboratory projects, including analyzing DNA evidence in property crimes (2005) and DNA backlog reduction. The DPD laboratory received funds in 2003 for solving cold cases (federal funding was received in 2007 to continue the program) and received two cold case grants from NIJ in 2009 and 2010. In 2006 and 2007, the laboratory participated in NIJ's DNA Expansion Demonstration Program, examining the efficiency and effectiveness of performing DNA testing on property crimes. During the course of this project, the DPD laboratory developed an electronic workbook that reduced the amount of time DNA analysts spent using hand-written worksheets, and it purchased two ABI 3130 Genetic Analyzers that reduced processing time. These changes more than doubled the number of DNA cases completed by the laboratory, and reduced the turnaround time by 15% in 1 year.

3.2.1.2 Laboratory

The DPD laboratory covers approximately 18,000 square feet (of which, 14,000 is usable space). The current laboratory is centralized in one building, but space is becoming limited. To address space issues, new laboratory space has been planned, with construction anticipated to be completed in June or July 2012. Part of the opportunity of the SIMUL8 software will be to map out process and staffing for the new laboratory space. While the current space has an efficient flow, it is at capacity. The increased space will provide room for growth. Currently, the DPD laboratory has three AB 3130 Genetic Analyzers, four AB 9700 Thermocyclers, two Qiagen

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BioRobot EZ1s, one Qiagen QIA Symphony, one CAS-1200, one AB Real-Time 7500, and two Thermalcycler temperature verification instruments. The laboratory does not outsource except to the FBI for mitochondrial DNA (mtDNA) testing.

3.2.1.3 Decision to Develop the EIP

The idea for the DPD laboratory EIP began in 2006 when the DPD Crime Laboratory Director, DPD Criminal Investigations Division Chief, and the Denver District Attorney travelled to the United Kingdom Home Office and learned of the Scientific Work Improvement Model (SWIM). One of the key lessons learned from this visit was that improving efficiency is about understanding and optimizing the entire process. Acquiring a novel piece of equipment or software will not dramatically improve efficiency in the same way that process mapping allows. The DPD Crime Laboratory Bureau took these lessons home and identified the need for implementing more robotics within the DNA laboratory, for example. Additionally, the Denver District Attorney utilized the SIMUL8 product to model the Denver County court system to better identify bottlenecks. It was decided that using both of these tools, as well as hiring a person dedicated to examining the process map and software, would help to identify low- or no-cost improvements for the laboratory's DNA Unit.

3.2.2 Goals and Objectives

The DPD laboratory identified two primary objectives of the EIP: (1) identify all bottlenecks in the DNA process, and (2) implement solutions to reduce DNA turnaround times, increase the number of DNA samples analyzed per analyst, and decrease the number of backlogged DNA cases. More specifically, staff wanted to reduce turnaround time on rush cases (i.e., those that pose a threat to public safety) to 1 week and reduce turnaround time on high-

priority cases (i.e., those with court dates) to 30 days. To meet the first objective, the DPD laboratory proposed to create a static flowchart of the DNA process, and then enter at least 6 months of DNA workflow data into SIMUL8. To meet the second objective, the laboratory proposed using a teamwork approach to evaluating SIMUL8 data to identify bottlenecks, develop and test ideas for improvement in SIMUL8, and implement the best ideas.

3.2.3 Staffing

In September 2010, the DNA laboratory was staffed by 12 employees: 5 forensic biologists, 5 DNA analysts, 1 forensic biologist technical lead (who can also do DNA work), and 1 DNA technical lead. One of the forensic biologists and one of the DNA analysts worked on property crime cases, while two forensic biologists and one DNA analyst were dedicated to cold cases. Current casework was handled by one forensic biologist and two DNA analysts, and backlog reduction casework was handled by one forensic biologist and one DNA analyst. Seven of these staff members are full-time employees of the City of Denver, while five are grant-funded. The laboratory staff has a wide range of experience, from less than 2 years to 38 years.

One of the challenges the laboratory faces is staff turnover; the average tenure at the laboratory is about 2.5 years. This has been particularly problematic for grant-funded employees. In the past 5 years, six grant employees left the laboratory for full-time jobs elsewhere. During this period, there was a turnover rate of 0% among permanent city employees and 75% among grant employees. Further, the laboratory is dependent on these grant positions, and should the grants not be extended, the laboratory would not be able to handle the DNA analysis needs.

3.2.4 Proposed Activities

The DPD Crime Laboratory Bureau proposed carrying about the project activities in five phases. Plans for Phase 1 involved getting the project started and accepting the funds, selecting the IT project manager, coordinating with NIJ to finalize the study design, and preparing for the next phase. Phase 1 was expected to be completed by Day 60 of the grant period.

The Bureau proposed purchasing the necessary computer hardware and software in Phase 2. Additionally, the DNA EIP manager and DNA technical lead would receive 3 days of onsite software training with representatives from SIMUL8. The DNA EIP manager would also begin to collect performance measurement data, including turnaround time from submission of sample to laboratory and delivery of test results; the number of DNA samples analyzed per analyst; the number of backlogged DNA cases; the number of profiles uploaded to CODIS; and the number of CODIS matches. The DNA EIP manager would also develop a static process map flowchart, capturing each step in DNA analysis and collecting data on the skills of each employee and the amount of time it takes to train an analyst in additional techniques. This could also include surveying laboratory staff about the amount of time each step takes. The flowchart would be reviewed and evaluated by all team members and DNA Unit staff to ensure that it is accurate and to suggest potential improvements to the process. Phase 2 was expected to be completed between Days 61 and 150 of the grant period.

Ideas for improvement based on the static flowchart were planned for implementation in Phase 3. Further, in Phase 3, the DNA EIP manager would collect a total of 6 months of DNA casework data—3 months retrospective and 3 months prospective—from the LIMS system, DPD's Records Management System, CODIS, and information in laboratory case files. These data would be entered into SIMUL8 to convert the static flowchart into a dynamic simulation.

Next, the software would be validated by running simulations for about 50 cases and comparing the results to actual casework. Phase 3 was expected to run from Day 151 to Day 210 of the performance period.

Plans for Phase 4 involved evaluating the data from SIMUL8 to identify bottlenecks that were not apparent with the static flowchart. The team would develop ideas for overcoming bottlenecks and the ideas would be tested in SIMUL8 for their ability to reduce turnaround time, increase the number of DNA samples analyzed per analyst, and decrease the backlog. The best ideas would be selected for implementation in the next phase. Phase 4 was expected to be completed between Day 211 and Day 300 of the grant period.

During Phase 5, the best ideas identified in Phase 4 would be implemented and ongoing performance measurement data would be collected. SIMUL8 would also be used to develop target turnaround times for different cases types based on priority. Additionally, the DNA EIP manager would work with the rest of the team to create a standardized method for prioritizing incoming cases. This final phase would run from Day 301 to Day 540 of the grant period.

3.2.5 Implementation

3.2.5.1 Actual Activities

The project began by hiring one new staff member and purchasing a laptop and software. While DPD proposed hiring an IT project manager, the title was changed to DNA EIP Manager for funding purposes. Then, both the DNA and Forensic Biology units' technical leads and the project manager received on-site SIMUL8 training over 3 days (in August 2010). The first 2 days consisted of hands-on training. Then, the SIMUL8 representative spent a day helping the group create a preliminary model of the forensic biology workflow. This preliminary model was based on a basic process map that had already been developed.

Before entering data into SIMUL8, a static process map flowchart was created for the Forensic Biology process by a three-person team. Then, the flow chart was presented to the full group for their comment and input. Each member of the Forensic Biology Unit attended this meeting to help create an accurate model of the process. This model was finalized in October 2010. In November, the project manager and the DNA technical lead began modeling the DNA workflow, and they presented a version to the DNA Unit in December. Similar to the process used in developing the Forensic Biology process map, the static DNA flow chart was presented to the DNA Unit during a 2-day meeting to solicit feedback from the entire team. This model was finalized in January 2011.

The flow chart was entered into the software system for validation. Originally, the DPD laboratory planned to enter 6 months of DNA casework data into the SIMUL8 process map. However, the SIMUL8 trainer recommended expanding this to 12 months of casework data to create the model system, and the DPD laboratory followed this recommendation. Casework data from August 1, 2009, and August 10, 2010, were extracted, yielding a total 2,088 reports. Data to be entered into the software included the number of days between each step in the process, the number of samples submitted on each case type, which analyst completed the work at a particular stage, and others. Data collection was completed in May 2011. After data collection and entry, the model developed in SIMUL8 needed to be validated with actual data to ensure that it was accurately simulating the laboratory workflow. However, software difficulties delayed the DPD laboratory's ability to begin this process. In October 2011, the laboratory was still waiting for the software manufacturer to resolve these problems and had not begun validation.

In preparing for inputting the process flow into the software, program members met to discuss challenges faced by the laboratory. By creating an environment of questioning

“processes,” some laboratory bottlenecks and inefficiencies were addressed, and proposed solutions were outlined. The EIP actually is generating several innovations that are being identified and addressed. It was decided that identifying opportunities for improvement based on the static model did not need to stop at the conclusion of Phase 2, but would be an ongoing process. This resulted in 21 issues being identified, a number of which were identified separately from the SIMUL8 program. These problems included the tracking of cases files, proficiency test ordering and assignment, and electronic workbooks used by laboratory staff for a variety of purposes. Solutions for 12 of these issues were implemented by October 2011. A summary of each efficiency issue solution is presented in **Table 3-4**.

Table 3-4. Summary of Efficiency Issue Solutions

Description	Status	Directly from SIMUL8	How Identified	Start Date	End Date
File Storage - finding case files	C	No	Employee interviews/questionnaire	Jul-10	Aug-10
Property Management Bureau Time	NS	Yes	Employee interviews/questionnaire	Jul-10	
DNA Differential Extraction Workbook	C	No	Employee interviews/questionnaire	Jul-10	Jul-10
FBIO Assignment Workbook	C	No	DNA technical lead/employee interviews	Jul-10	9/2/2010
FBIO Worksheets	C	No	DNA technical lead employee interviews	Jul-10	12/1/2010
FBIO Best Practices SOP	NS	No	DNA technical lead	Jul-10	N/A
Proficiency Tests	C	No	DNA technical lead	Jul-10	9/17/2010
Consumptive Testing	P	Yes	Employee interviews/questionnaire	Jul-10	10/4/2011
CODIS Report Templates	C	No	Customer request/CODIS admin	9/1/2010	10/7/2010
Adjudicated Cases check between laboratory and DA's office	C	Yes	Employee interviews/questionnaire	Jul-10	6/1/2011
Identifiler Validation	C	Yes	Wanted a single amp kit; AAFS meeting	Feb-09	5/19/2011
QiaSymphony Instrumentation	P	Yes	Needed a higher throughput extraction robot	Jul-08	N/A

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Description	Status	Directly from SIMUL8	How Identified	Start Date	End Date
Retention of Grant Employees	P	Yes	Employee interviews/ questionnaire	Nov-10	Aug-11
STR Statistical Workbook	C	No	Employee feedback	Jul-09	1/24/2011
Y-STR Mixture Workbook	I	Yes	Other existing tools did not meet needs	Nov-10	N/A
SA Kit Male Quant Screen	P	Yes	DNA technical lead	Oct-10	3/24/2011
Laboratory technician	IP		Employee interviews/ questionnaire	Jul-10	N/A

(continued)

Table 3-4. Summary of Efficiency Issue Solutions (continued)

Description	Status	Directly from SIMUL8	How Identified	Start Date	End Date
"Cut and Run" sample testing in FBI/O	P	Yes	DNA technical lead	Feb-11	N/A
Extraction Workbook - Preparing Plates	NS	Yes	Simulation model	Jul-11	N/A
GeneMapper ID-X Software	NS	No	Investigated due to move to new building and possible need of new computers	Jul-11	N/A
FBI/O Printer	P	Yes	Employee interviews/questionnaire	Jul-10	N/A

Note: C=Complete, NS=Not started, P=Pending, I=Implementation phase, IP=In progress

3.2.5.2 Considerations for EIP Implementation

There is a learning curve in understanding the full potential of utilizing the SIMUL8 software. While there is a visual logic to the software, it still requires time, practice, and repeated efforts to facilitate ease of use. Another challenge of the EIP is that multiple “innovations” are being worked on simultaneously. The value of defining challenges and proposing solutions supports an organizational culture of continuous improvement and of openness to change. By adding narrative issues with problem identification and proposed solutions that are not generated through SIMUL8, the scope of the EIP is expanded and tracking each innovation is challenging.

Table 3-5. DPD Considerations Encountered during the EIP

Category	Consideration/Issue	Comments
Personnel- Hiring, training, reassigning, retention	Learning curve for staff in understanding the full potential of utilizing the Simul8 software.	Besides the EIP project manager and laboratory manager, other staff are just now beginning to understand the potential of the SIMUL8 software. Their feedback will also advance the EIP with input from many analysts.
	High staff turnover: the average tenure at the laboratory is about 2.5 years.	This has been particularly problematic for grant-funded employees. Yet, the laboratory is dependent on these grant positions, and should the grants not be extended, the laboratory would not be able to handle the DNA analysis needs.

(continued)

Table 3-5. DPD Considerations Encountered during the EIP (continued)

Category	Consideration/Issue	Comments
Mini-EIPs	DPD was identifying many issues within their laboratory operations that needed attention in addition to the planned EIP. To help track these considerations, DPD developed “mini-EIPs” in which the issue, investigation, and resolution were documented (Table 3-1).	By adding narrative issues with problem identification and proposed solutions that are not generated through SIMUL8, the scope of the EIP is expanded, and tracking each innovation is challenging.
Instrumental	Completing the SIMUL8 validation took longer than laboratory staff originally anticipated.	Software difficulties delayed the ability to begin validating process map.

3.2.5.3 Modifications to Original Implementation Plan

Early in the project, a decision was made to shift from hiring an IT staff member to someone with more management analyst skills who could help to evaluate improvements and statistics and assist the group with work to provide suggestions for improvement. This new project manager was hired on June 20, 2010, and immediately began working on various tasks. Additionally, a laptop and the SIMUL8 software were purchased.

3.2.5.4 Staff and Management Perceptions of Project Progress

Completing the SIMUL8 validation took longer than laboratory staff originally anticipated; however, staff realized a number of benefits from implementing the mini-EIPs. Improvements made to the laboratory, including the validation of instrumentation and new software, were well received by both management and laboratory staff.

3.2.5.5 Budget and Timeline

While the original end date was July 2011, the DPD laboratory requested and received an NCE through May 31, 2012. The grant was extended for a couple reasons. First, the grant was not accepted until February 2010, due to a cash-match issue. Moreover, additional funds were available due to hiring an internal project manager instead of an IT specialist (described above).

While the project has remained within budget to date, it was modified to reflect an increase in the price of the software and an in-kind match requirement.

3.2.6 Impact of EIP on Laboratory Operations

The laboratory implemented 13 improvements to date and have 7 others in progress. The vast range of improvement types (Table 3-1) have impacted the laboratory in a number of ways, including reducing laboratory instrument time and reducing the need to reprocess samples. Additionally, the DPD laboratory conducted a cost-effectiveness study of funding, which resulted in changing the status of grant funded employees from “limited” (i.e., their employment had an end date) to “unlimited.” Finally, the DPD DNA EIP manager noted that, “In the short term, the staff of the laboratory has had to deal with an examination of their processes, which takes time away from casework. However, the benefits are well documented and thus each staff member is more than willing to work towards any efficiency improvement.” **Table 3-6** summarizes the EIP impacts to the DNA laboratory.

Table 3-6. DPD Impacts of EIP Process

Category	EIP Impacts	Comments
Personnel- Hiring, training, reassigning, retention	Grant supported one project manager for duration of EIP.	
	Staff examined laboratory processes, which takes time away from casework initially, but yielded efficiency improvements in the end.	
	Improvements made to the laboratory, including the validation of instrumentation and new software, were well received by both management and laboratory staff.	
	DPD conducted a cost-effectiveness study of funding, which resulted in changing the status of grant-funded employees from “limited” (i.e., their employment had an end date) to “unlimited.”	
Mini-EIPs	Implementation of multiple innovations has reduced laboratory instrument time and reduced the need to reprocess samples.	Will be implementing a similar study in Latent Prints through a Coverdell grant towards the end of 2012.

(continued)

Table 3-6. DPD Impacts of EIP Process (continued)

Category	EIP Impacts	Comments
Instrumental	SIMUL8 software	The laboratory can continue to use SIMUL8 as a prospective cost-effective way to determine where efficiency can be improved and when additional changes within the laboratory will affect the workflow.

3.3 Oklahoma State Bureau of Investigation (OSBI)

The OSBI laboratory proposed to validate the use of Applied Biosystem’s Identifiler® Direct amplification kit for use on buccal swabs. This procedure was expected to increase the speed and efficiency with which buccal swabs are processed by eliminating the need for DNA extraction. If successful, this would both cut the overall cost of DNA analysis while simultaneously increasing the laboratory’s capacity to process more samples. Funds were requested in the amount of \$23,783 to cover overtime pay to complete the validation testing and to document and report the results.

3.3.1 Context

3.3.1.1 Setting

OSBI serves the citizens of Oklahoma. The American Community Survey estimated Oklahoma’s population to be 3,687,050 in 2009. About three-quarters of the population identified themselves as white (75%) and 7% identified themselves as black. Less than 1 in 10 (8%) Oklahoma residents indicated they were of Hispanic or Latino ethnicity. In 2009, the crime rate in Oklahoma was higher than the national average, with 18,474 violent crimes (501 per 100,000 residents) and 131,769 property crimes (3574 per 100,000 residents) (UCR, 2010) (Figure 3-3).

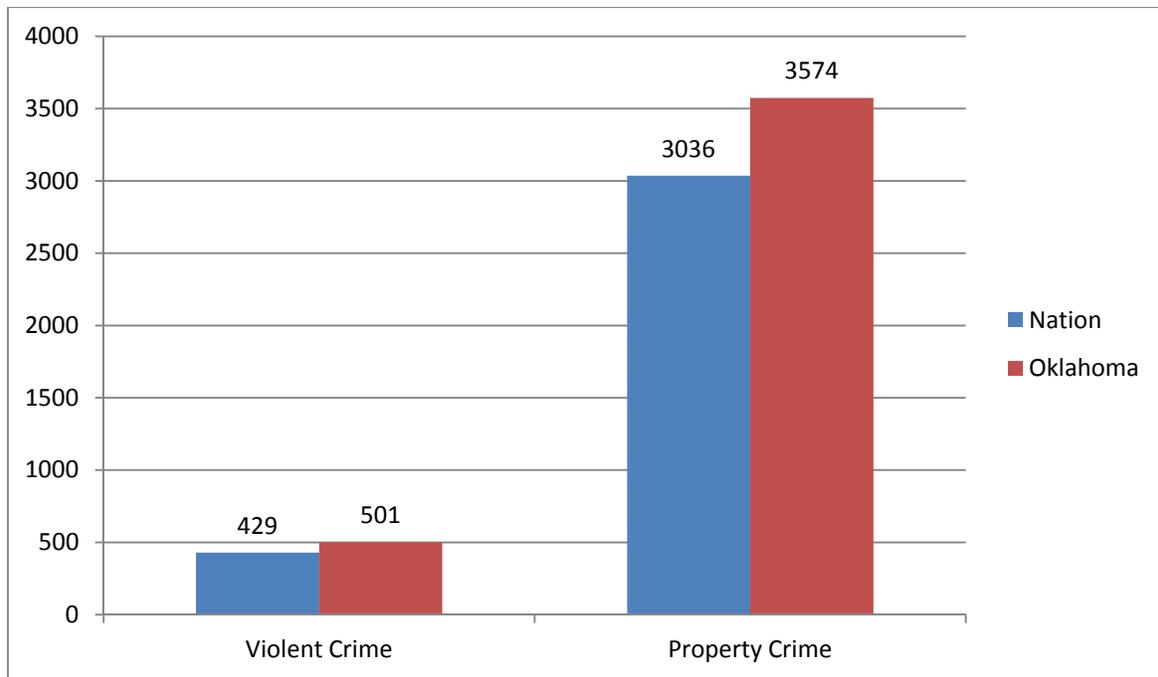


Figure 3-3. Crime rate per 100,000 residents (http://www2.fbi.gov/ucr/cius2009/data/table_05.html).

OSBI primarily operates on funding from the state legislation, revolving funds (e.g., fee-based collections specified in statute), federal grants, and state appropriations. In May 2009, legislation expanded the CODIS database to include 18 misdemeanor crimes. OSBI anticipated workload increases for DNA testing due to this legislative expansion, but at the time of the proposal, had not seen its full impact. OSBI provides forensic science services to all law enforcement agencies across the state and to the Oklahoma Department of Corrections when they submit evidence for criminal cases involving inmates or staff. Outsourcing has been used for prior NIJ backlog grants; however, all of the backlogs were completed by 2006.

3.3.1.2 History of Program

OSBI was established in 1925 and is the general investigative agency of the State of Oklahoma. OSBI includes five separate divisions: Investigative Services, Criminalistics Services, Informational Services, Administrative Services, and Information Technology

Services. In 2008, OSBI moved into their current facility, the OSBI Forensic Science Center, in Edmond, Oklahoma, which is a full-service forensic laboratory. In addition the Science Center, OSBI has four regional forensic laboratories that provide specific services, including the Tahlequah laboratory in which a significant portion of this EIP was conducted. Each of these five facilities is accredited under the ASCLD/LAB Program, following the requirements of the FBI's Quality Assurance Standards for both forensic and database testing laboratories.

OSBI had significant experience with grants prior to this EIP, having received funding from DNA Backlog Reduction Grants, CODIS Backlog Reduction Grants, Coverdell National Forensic Science Improvement Act (NFSIA) Grants, and Oklahoma Highway Safety Office Grants. Funding was used for a variety of activities, such as providing training for staff, purchasing reagents and consumables to perform DNA testing, purchasing equipment to increase capacity, providing overtime pay for staff working on backlog reduction, and outsourcing some casework to help eliminate past backlog of offender samples. OSBI also used Cold Case Grants to develop a Cold Case Unit that allowed them to review hundreds of unsolved crimes to identify any evidence that may be suitable for DNA testing, to locate/collect evidence and case records for these cold cases, and to perform DNA analysis on appropriate cases. Finally, Byrne and JAG grants were used to purchase equipment and supplies necessary to establish in-house capacity for processing CODIS samples.

3.3.1.3 Laboratory

The Edmond laboratory opened in 2008 as the OSBI Forensic Science Center. The current facility is 88,000 square feet and houses all forensic disciplines offered by OSBI. The CODIS Section within Forensic Biology Unit consists of 4,500 square feet of this facility. The facility is state-of-the-art in design and provides OSBI the ability to implement new forensic

technologies and explore more efficient ways of performing DNA analysis. The design allows a smooth flow with room to expand. Its current annual capacity is 500,000 samples. The Oklahoma CODIS database contains approximately 105,000 DNA profiles, and in its 15-year history, it has produced more than 940 hits involving homicides, rapes, and other violent and non-violent crimes. However, much of the method development was performed by the project manager at the Tahlequah laboratory. **Table 3-7** presents the age and location of OSBI's equipment.

Table 3-7. OSBI Laboratory Equipment, 2009–2011

Equipment	Quantity	Age	Housed
ABI 3730 Genetic Analyzer / DNA Sequencer (48 capillary)	2	less than 2 yrs	Edmond CODIS Unit
ABI 3130 Genetic Analyzer / DNA Sequencer (4 capillary)	1	~3 yrs	Tahlequah
ABI 310 Genetic Analyzer / DNA Sequencer (single capillary)	1	> 5 yrs	Tahlequah
ABI 7500 Real Time PCR System	2	~4 yrs	Tahlequah
ABI 9700 Dual Block Thermal Cycler	6	< 2 yrs	Edmond CODIS Unit
ABI 9700 Single Block Thermal Cycler	2	< 2 yrs	Tahlequah
Biomek 3000 (Smaller Capacity — Laboratory Automation Workstation for Liquid Handling)	1	~5 yrs	Edmond CODIS Unit
Biomek FX (Larger Capacity —Laboratory Automation Workstation for Liquid Handling)	1	< 2 yrs	Edmond CODIS Unit

One of the primary challenges faced by OSBI is cost and a tight budget. However, the laboratory benefits from the large capacity and lack of a backlog; for CODIS, there is only a short delay for batch analysis. Further, the laboratory analysts are receptive to change, which is important to the success of adopting new policies and practices.

3.3.1.4 Decision to Develop the EIP

On May 19, 2009, Oklahoma Governor Brad Henry signed into law SB1102, which expanded the number of offenses that require a DNA sample to be submitted to OSBI for entry

into CODIS. In addition to felons, who were already required to submit DNA for CODIS under the initial Oklahoma database law, the new law required individuals convicted of 18 misdemeanor offenses² and aliens arrested for being unlawfully present under federal immigration law to submit DNA for CODIS. It was anticipated that this law could increase the number of DNA samples received by OSBI by as many as 60,000 per year. This potential increase, combined with inadequate funding, led OSBI to consider ways to reduce costs in processing samples and increase the efficiency in which offender samples were collected and processed. Oklahoma's experiences indicated that after burglary was legislatively added to CODIS-allowable entries as a qualifying offense, the number of hits doubled and then doubled again with the expansion to all felony convictions. Like many national laboratories, OSBI recognized that many entries of the "less violent" offenders, as their crimes escalate, will often hit to unsolved violent crimes. Roughly a third of all hits obtained from an offender collected following a burglary conviction in Oklahoma have been linked to more violent offenses, such as homicide, rape, and robbery.

In order to meet the mission of OSBI, the goal of the CODIS Unit is to ensure that offender DNA profiles are entered into the database within 30 days of receiving the sample. The CODIS Unit faces and continually responds to increases in sample submission with little or no increase in instrumentation, staff, and funding. Consequently, the CODIS Unit has re-evaluated nearly every step in the analysis process while searching for the most cost-efficient methods that

² Assault and battery; domestic abuse; stalking; possession of a controlled substance prohibited under Schedule IV of the Uniform Controlled Dangerous Substances Act; outraging public decency; resisting arrest; escape or attempting to escape; eluding a police officer; peeping tom; pointing a firearm; unlawful carrying of a firearm; illegal transport of a firearm; discharging of a firearm; threatening an act of violence; breaking and entering a dwelling place; destruction of property; negligent homicide; and causing a personal injury while driving under the influence of any intoxicating substance.

can be implemented. One identified efficiency was submitted to NIJ for funding under the 2009 DNA Unit EIP and was subsequently awarded to OSBI.

Sample collection using cotton swabs may result in both reduced costs and increased efficiency. Further, it may be easier than other techniques. While Oklahoma law mandates collecting DNA from individuals convicted of felonies, less than half of the law enforcement agencies are collecting convicted offender samples. If sample collection using cotton swabs is both easier and cheaper than traditional techniques, it is plausible that a larger number of law enforcement agencies may collect and submit convicted offender samples.

3.3.2 Goals and Objectives

The goal of the OSBI EIP was to make swab processing easier, faster, and cheaper. This was to be done through two improvements: implement a new DNA collection process and subsequently eliminate the extraction step of the DNA process. Most states rely on blood and buccal samples to collect offender DNA. The collection of blood samples, while successful and cost effective for DNA analysis, requires trained medical staff, which is not feasible in all sites. The collection of buccal samples can be done by all agencies, but often does not produce good DNA results, primarily because transferring DNA from a swab to FTA paper is not always successful. Applied Biosystems developed a DNA amplification kit that would allow the amplification of DNA directly from the swab, eliminating the need to transfer and extract DNA. The purpose of the OSBI EIP was to validate and subsequently implement into laboratory practice the use of an Applied Biosystems Identifiler® Direct amplification kit for use on buccal swabs.

3.3.3 Staffing

At the beginning of the EIP, the CODIS Unit was fully staffed; however, 1 CODIS analyst and 1 CODIS technician resigned after the EIP started and will not be replaced. The validation team included 1 quality manager, 1 technical manager, 1 CODIS supervisor/manager, 1 laboratory supervisor, 2 CODIS analysts, and 1 CODIS technician. The quality manager helped review results and provided direction for additional studies. There was turnover in the technical manager position during the EIP; both individuals helped identify the research plan and review results from each study and also provided direction for additional studies. Since the proposal submission date, the CODIS supervisor/manager (also the EIP project manager) relocated from the Edmond laboratory to the Tahlequah laboratory. While he was replaced as the supervisor/manager, he continued to function as the EIP project manager. The original supervisor/manager developed the research plan and conducted the majority of the research testing, including analyzing data and reporting research results. The replacement supervisor/manager helped coordinate the samples being run for some studies and the monthly laboratory collection of performance metrics for the EIP. Of the three CODIS analysts, two were involved in the EIP; they helped identify a research plan and performed some laboratory analysis. One of the CODIS technicians provided statistical data for the EIP team and for NIJ reports, while the other did not. During the EIP, 1 CODIS analyst and 1 CODIS technician left OSBI, but neither of these individuals performed work on the EIP.

3.3.4 Proposed Activities

OSBI proposed to validate Applied Biosystems new DNA amplification kit, Identifiler® Direct, for use on buccal swabs. At the time of the proposal, Applied Biosystems had already validated the amplification kit for use on FTA. The validation would include a side-by-side

comparison of several hundred buccal samples analyzed using the current OSBI procedures and with Identifiler® Direct. The two techniques would be compared on a number of metrics, including the percent of samples successfully analyzed on the first attempt, the overall quality of data, concordance of DNA profiles from each set of samples, time spent on analysis, and cost. The new amplification kit would be considered successful if the results between the two techniques were comparable and the new technique yielded a significant increase in productivity per analyst and decrease in cost.

3.3.5 Implementation

3.3.5.1 Actual Activities

Buccal samples were collected from laboratory staff and their families for use in the validation study. The EIP was completed by comparing the ability of various combinations of lysing reagents, temperatures, reagent volumes, amounts of amplification aliquots, and swab sizes (small, medium, and large) in order to validate the use of Identifiler® Direct on buccal swabs. Combinations included the following:

1. Type of Lysing Reagent (DNA IQ Lysis Buffer, Stain Extraction Buffer, Stain Extraction Buffer + ProK, Stain Extraction Buffer with no DTT, Stain Extraction Buffer with water)
2. Volume of Lysing Reagent (200µl to 400µl)
3. Lysing temperature (70 to 95° C)
4. Amplification Aliquots (µl of sample lysate to µl of amplification reagent)
5. Lysing Times (15 to 60 minutes)
6. Swab Head Size (regular, half, quarter).

Early in the project, the lysing variables showed that naturally occurring inhibitors and the amount of DNA present would not promote amplification. However, ABI, the manufacturer of the amplification and quantitation kits, suggested continuing with amplification of a few to see if it was possible. The quantitation kit may not be sensitive enough to determine the true capabilities of the amplification kit. Further studies showed that this was true.

Through an iterative process, OSBI eliminated certain combinations and identified three combinations that produced full profiles, but which varied in peak heights, peak height ratios, artifacts, and amount of preferential amplification. After identifying the promising combinations, additional tests varied swab sizes and the amount of DNA template used during amplification. A total of 43 combinations were tested. It was determined that the optimal combination included “Method 16.” This combination was considered ideal because quantitation results showed an acceptable DNA yield ranging (buccal swab: ~0.020 to ~1.77ng/μl [average of ~0.456]), smaller lysate volume (at 2.5μl lysate, 1/10 of amplification reagent), an overall pass rate of DNA profiles at 63% (15 of 24 samples; unacceptable samples included dropout and/or no data peaks), and a low percentage of samples with artifact (17%). At the completion of the optimization studies, it was determined that all samples did have DNA peaks present, but the majority of them were below the peak detection threshold. Results indicate that increasing the amount of template DNA that is amplified did increase the peak heights of most samples without causing artifacts and preferential amplification effects. A larger volume of lysate is most likely required during the amplification (e.g., 5.0ul, 7.5ul, 10ul) to improve current results.

As a final study, OSBI completed a parallel study of the selected optimized method (Method 16) using the laboratory’s current sample collection device (FTA card) and the

proposed EIP sample collection devise (buccal swabs). Results are summarized in the outcome evaluation for OSBI.

Consideration for EIP Implementation

Another activity performed by OSBI was a simple cost analysis. The cost analysis was based on a cost savings potential of cheaper kits to be utilized with buccal swabs and reduction of an extraction step. Initial calculations show that the current method using FTA cards costs the laboratory \$22.69/sample. Removing the extraction step with use of a buccal swab would reduce the laboratory cost by \$2.00/sample just in laboratory supplies.

3.3.5.2 Modifications to Original Implementation Plan

No major changes were made in the scope of the EIP. However, the proposal was based on legislative proposals to expand the CODIS database that did not pass due to both cost and potential civil liberty violations. It was anticipated that, if this law was enacted, the number of annual DNA samples received by the laboratory could reach 60,000 samples. Although the CODIS expansion did not occur, the EIP proceeded as planned, and results from the validation study can still be used to identify ways to reduce costs in processing samples and increase the efficiency in which offender samples are collected and processed.

Additionally, the work was not completed entirely at the Edmond laboratory as proposed. Due to the project manager's relocation, the EIP work was performed at both laboratories, such that method optimization and early validation was conducted at Tahlequah and final validation and processing of staff samples was conducted at Edmond. Parallel studies were also conducted at the Edmond facility.

3.3.5.3 Staff and Management Perceptions of Project Progress

The OSBI project manager reported that while the EIP did not reach full implementation during the EIP timeline, much information was collected and has left OSBI with the ability to use buccal swabs in the future when currently purchased FTA card consumables are exhausted and with subsequent method optimization and validation.

OSBI successfully researched the advantages and disadvantages of several types of DNA collection kits to select a new buccal collection kit that combines the best qualities of several different collection kits into one. As stated in OSBI's draft final report:

“This ‘All-In-One™’ DNA collection kit is simple to use, provides reliable results, all at an affordable cost. The simplicity of the kit design allows for any law enforcement agency to properly collect known reference DNA samples without any transfer steps or drying steps required. This direct DNA collection method helps to ensure that sufficient DNA is present, allowing the laboratory to obtain a full DNA profile on the first analysis attempt, thus reducing the time and cost of unnecessary re-testing. In addition, the cost of the buccal collection kit is a fraction of the cost of most kits currently used by CODIS laboratories. OSBI is currently seeking opportunities to make this new buccal collection kit available to CODIS, forensic, and paternity testing laboratories.”

As far as OSBI's second EIP objective, the laboratory was able to test many different techniques that would allow for the direct amplification of buccal swabs. OSBI's results indicated the following:

“Some techniques tested worked well, others did not. However, it was demonstrated that direct amplification of buccal swabs is possible, thus eliminating the time and cost associated with the extraction step of the DNA analysis process.”

It is the hope of OSBI management that the EIP activities will assist other laboratories in furthering their efficiencies by reducing labor and costs associated with DNA analysis. ABSciex recently reported at a DNA conference that their internal research has successfully allowed the use of the Identifiler® Direct kit on buccal swabs, and they anticipate the release of a validated procedure to the forensic community soon. If this occurs, a significant impact on the overall backlog of criminal cases will be realized.

3.3.5.4 Budget and Timeline

OSBI's EIP was completed within budget on October 2011. The project was originally scheduled to end on December 31, 2010, but was delayed due to variables such as NIJ's delayed release of funds, late release of the amplification kit, and delayed optimization of amplification procedures. OSBI was granted an NCE of 10 months. The Identifiler® Direct kits were expected to be available in mid-October 2009, but were not commercially available until January 2010. OSBI ordered the kits in March 2010, and the validation started in May 2010 and was completed in October 2011. During the performance period of July through December 2010, OSBI received another NCE. During this reporting period, a GAN was approved that extended the end of the award through September 30, 2011. This extension was requested and approved to provide OSBI sufficient time to complete the research testing and submit the final write-up to NIJ for approval. One final NCE was approved for the period of performance to end December 31, 2011. The

remaining time in the performance period was used to document and report the results.

Laboratory performance metrics were collected during April 2010 through April 2011.

3.3.6 Impact of EIP on Laboratory Operations

The results from this research demonstrated that, although the buccal samples showed good results from direct amplification, the FTA showed better results. Due to the limitations of the research study, several additional buccal swab methods have been suggested for future research studies. In addition, the FTA samples worked very well with the Identifiler® Direct kit, with 100% of the samples tested yielding a full DNA full profile (i.e., CODIS uploadable) on the first analysis attempt. To date, the use of Identifiler® Direct kit on cotton swabs has not been implemented at OSBI. Several years of FTA® collection kits were previously purchased to EIP result; hence, switching to cotton swabs at this time would not be cost effective to the laboratory. The implementation of cotton swab collection devices for CODIS samples may be considered in the future at the discretion of the OSBI CODIS manager and laboratory administration.

3.4 Palm Beach Sheriff's Office (PBSO) Crime Laboratory

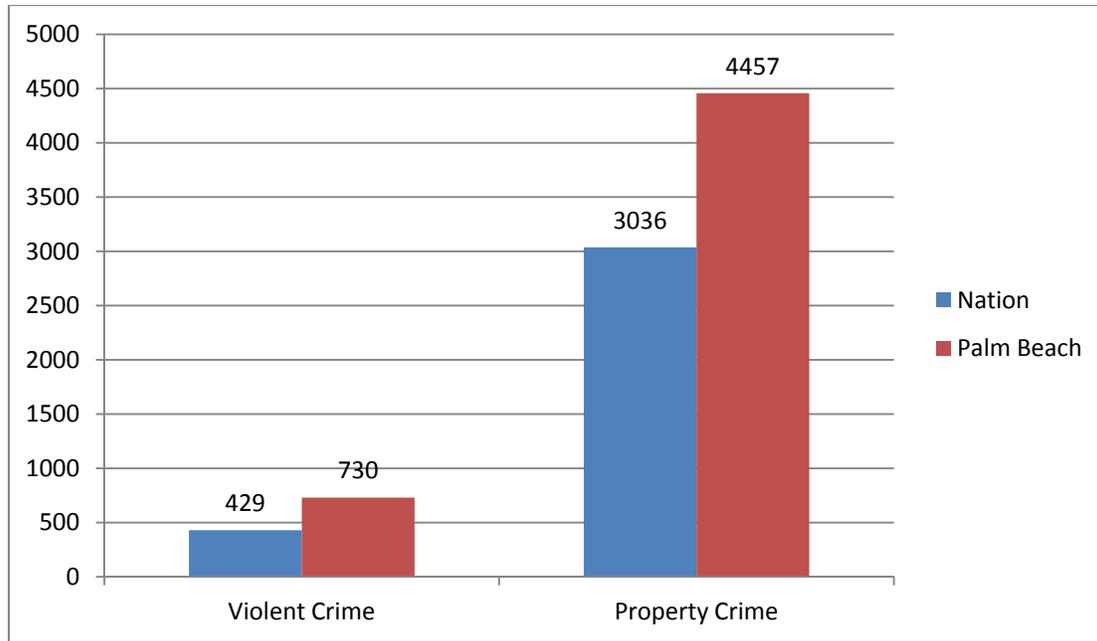
The Palm Beach Sheriff's Office (PBSO) proposed to develop a central Biology Processing Laboratory (BPL) in an existing space within the Boca Raton Police Services Department (BRPSD) to pre-screen crime scene evidence for southern Palm Beach County law enforcement agencies. PBSO received \$519,544 to cover salary and benefits for two laboratory analysts, additional laboratory equipment and supplies, and the renovation of the BPL space. The BPL would be responsible for processing evidence for the confirmation of blood and semen; determining, through microscopic analysis of hair, if DNA analysis should be attempted; and swabbing items for touch DNA evidence. All informative evidence would then be submitted to

the PBSO Forensic Biology Unit (FBU) for DNA analysis. This will allow BRPSD to know within days if their evidence may provide a biological investigative lead and if stains should be submitted for DNA analysis. Further, the FBU will prioritize pre-screened cases, providing faster casework turnaround times.

3.4.1 Context

3.4.1.1 Setting

PBSO serves citizens in the county of Palm Beach, Florida. The American Community Survey estimated Palm Beach's population to be 1,268,601 in 2009. Three-quarters (75%) of the population identified themselves as white, and 16% identified themselves as black. Less than one in five Palm Beach residents indicated they were of Hispanic or Latino ethnicity (17%). In 2009, the combined crime rate of the cities in Palm Beach was higher than the national average, with 5,186 violent crimes (730 per 100,000 residents) and 31,655 property crimes (4457 per 100,000 residents) (UCR, 2010) (**Figure 3-4**).



NOTE: Based on summed UCR statistics and population estimates for the following cities: Atlantis, Belle Glade, Boca Raton, Boynton Beach, Delray Beach, Greenacres City, Gulf Stream, Highland Beach, Juno Beach, Jupiter, Lake Clarke Shores, Lake Park, Lake Worth, Lantana, Manalapan, Mangonia Park, North Palm Beach, Ocean Ridge, Pahokee, Palm Beach, Palm Beach Gardens, Palm Beach Shores, Riviera Beach, Royal Palm Beach, South Bay, South Palm Beach, Tequesta, Wellington, West Palm Beach.

Figure 3-4. Crime rate per 100,000 residents.

The state of Florida has several law enforcement agencies with forensic DNA capabilities, including the Florida Department of Law Enforcement (FDLE), which services over 60 counties. There are also six counties with their own DNA laboratories, including PBSO. The Sheriff's Department, including the laboratory, is funded entirely out of the county general fund. The laboratory serves nearly 30 agencies, including city police departments in Palm Beach, county agencies (e.g., Palm Beach County Animal Control and Palm Beach County School Police), state agencies (e.g., Florida Highway Patrol, Florida Marine Patrol, State Attorney's Office, FDLE), and the Florida Atlantic University Police Department.

3.4.1.2 History of Program

The PBSO laboratory was established in the early 1970s. Prior to the 2009 DNA Unit EIP, PBSO had extensive experience managing NIJ grant awards. For example, they have

received federal funding for other laboratory projects since 1996, including the Forensic DNA Laboratory Improvement Program; No Suspect Casework DNA Backlog Reduction Program; Crime Laboratory Improvement Program; Paul Coverdell National Forensic Science Improvement Act Grant; DNA Capacity Enhancement Program; Forensic Casework DNA Backlog Reduction Program; and Solving Cold Cases with DNA.

3.4.1.3 Laboratory

The PBSO laboratory was built for DNA analysis in 1992 and expanded in September 2006; construction on the Boca Raton BPL began in September 2011, with completion expected in mid-March 2012. The PBSO laboratory encompasses 8,141 square feet (2,660 square feet of which is used for administrative purposes and 5,481 square feet used for forensic biology), and the BPL is expected to be approximately 1,800 square feet. The laboratory currently has five extraction robots (one BioMek, and two Qiagen EZ1 Mini-Robots), two ABI Real Time PCR 7500 units, two ABI 3130XLs, and an Eppendorf thermocycler.

In 2005, PSBO used grant monies to hire a company to conduct process mapping before construction began for the new FBU. All suggestions from the process mapping were implemented by the construction company and the laboratory. For example, the design of the laboratory traffic pattern is based on size, specialized areas, and compliance with SWGDAM FBI National Standards and ISO standards. The plans for the BPL build-out look functional; there is ample space and a well-conceived workflow. The screening workflow for the BPL will be modeled after PBSO procedures because these procedures are established and efficient.

3.4.1.4 Decision to Develop the EIP

The idea for this EIP was generated in a DNA/Law Enforcement Working Group assembled by the Palm Beach County Law Enforcement Planning Council (LEPC) in January 2009. LEPC members were aware that screening evidence for biological material is the most labor-intensive process in DNA analysis and is largely responsible for the increase in caseload backlogs. Thus, prescreening evidence for biological material prior to laboratory submission would help greatly reduce both the backlog and turnaround time. The Working Group proposed to develop the central BPL to prescreen crime scene evidence for three law enforcement agencies in southern Palm Beach County. Further, BPLs have been successfully developed in Seminole and Marion counties, and the advantages of doing screening at the local level were noted. Chief Alexander offered existing space within the BRPSD training facility to construct the BPL.

3.4.2 Goals and Objectives

The three goals of this EIP were to provide (1) timely serological data to southern Palm Beach County law enforcement agencies; (2) pre-screened evidence so DNA processing may begin upon submission of evidence; and (3) a template for other jurisdictions interested in increasing efficiency. PBSO anticipated that this EIP would result in a reduction in turnaround time, or the number of days from the date a case is requested and when the report is released. The goal was to accomplish a 30-day turnaround for both violent and property crimes; when their proposal was written, the turnaround time averaged about 6 months for violent crimes and 15 months for property crimes. To meet this goal, PBSO proposed the development for a BPL in an existing space within BRPSD that would serve three jurisdictions in the southern part of the county.

3.4.3 Staffing

The FBU is staffed by one forensic biology manager, 1 CODIS manager, 1 DNA technical leader, 3 senior forensic scientists, 2 laboratory analysts, and 6 forensic scientists. As part of the EIP, two additional laboratory analysts were hired by BRPSD to screen evidence in the BPL.

3.4.4 Proposed Activities

PBSO proposed the development of a BPL in an existing space within a training facility already acquired by BRPSD. Renovations to the existing space were anticipated to take between 9 and 12 months. The BPL would include an evidence reception area, evidence vault, report writing stations, and a laboratory (i.e., reagent preparation room, dark room, and main laboratory). BRPSD would also post a job announcement and hire two new laboratory analysts to staff the BPL. After the analysts are selected, they would be trained by the PBSO DNA technical lead within the FBU facility. After successful completion of training, the analysts would transfer to the BPL and begin doing casework. Hiring and training were expected to take approximately 10 months. Once renovations are completed and the new analysts complete their training, the BPL would serve as an axis laboratory for southern Palm Beach law enforcement agencies, including Boca Raton, Boynton Beach, and Delray Beach.

3.4.5 Implementation

3.4.5.1 Actual Activities

The activities conducted by PBSO fall into three categories: legal paperwork and agency relationships, BPL staffing and processes, and laboratory renovation.

Legal Paperwork and Agency Relationships

A meeting of all grant partners was convened on October 23, 2009, to outline how each project goal would be met, establish timelines, and identify points of contact. A follow-up meeting was held on December 16, 2009, to discuss ordering equipment, supplies, and materials required for training the BPL analysts and conducting laboratory analyses. Grant monies were not made available until legal approval processes were completed, including the generation and approval of Memorandums of Understanding (MOU) between the BRPSD and PBSO. The grant monies were made available for use after Palm Beach County Commissioners accepted the award (10/15/09), the Boca Raton City Council accepted the award (7/10), and the MOU between BRPSD and PBSO was signed by Boca Raton City attorneys (9/10). Additionally, MOUs between BRPSD and Delray Beach and Boynton Beach were completed by the Executive Management in September 2010. However, these agencies will need to establish protocols for coordinating evidence submission, prioritization of cases, and other collaborative process (e.g., shared funding, reporting, decision making). Furthermore, the roles and responsibilities of each partnering agency will need to be developed.

BPL Staffing and Processes

In November 2010, BRPSD posted job announcements for two laboratory analysts. Over 100 applications were received; 15 candidates were interviewed and background checks were performed. Two analysts were selected and began training in early April 2011. The hiring process took approximately 4 months to complete. The BRPSD crime scene manager and two PBSO technical leads prepared a 3-month calendar for training the new analysts. The training was based on similar materials that new PBSO analysts are required to complete and covered the

following topics: safety, quality assurance/quality control (QA/QC), ISO Standards, evidence handling, serological analysis, ethics training, and court testimony.

While the new analysts are BRPSD employees, the training was completed at PBSO. In order to be considered competent in PBSO serological techniques, each analyst was required to complete laboratory bench training (which included conducting approximately 200 serological tests), passing a competency exam, and participating in a courtroom mock trial. Both analysts successfully completed their training in early July 2011. As part of their training outside the OCCL laboratory and while awaiting BPL renovations, these analysts shadowed Boca Raton Crime Scene personnel for a few weeks, prepared the BPL Quality Assurance and Methods Manuals for the new BPL facility, and completed a LIMS training module required of all BRPSD personnel. While temporarily located at PBSO, the BPL analysts are only screening evidence for the three law enforcement agencies that the BPL will serve (Boca Raton, Delray Beach, and Boynton Beach). The BPL analysts' job responsibilities include locating biological stains; performing presumptive and confirmatory tests; swabbing for touch or wear; collecting hair, fiber or debris; documentation (e.g., stain location, descriptions, labeling); and communicating with detectives about the probative evidence decision tree.

The BPL will follow a number of processes developed by PBSO. For example, the BPL analysts will use PBSO forms, conduct evidence screening per PBSO protocols, and write reports as per PBSO protocols. Stain cuttings and swabs processed by BPL analysts will be submitted to the PBSO evidence custodian. To prioritize BPL cases, they were given their own Casework Request tab, and analysts must choose from that tab when they need cases. However, it was challenging to figure out the chain of custody for the BPL analysts and the three agencies.

Renovation of BPL

Soon after the project was awarded, BRPSD began working with an architect to design the BPL. The building permit was applied for in February 2011, and the final architectural designs were approved in March 2011. BRPSD had a contractor in place when the grant was awarded and originally determined that no formal bid system was necessary. However, due to the amount of time needed to complete the legal paperwork, new contractor bids were required. The bid was awarded to a general contractor in late June 2011. The renovation is still in progress and is expected to complete in March 2012.

The BPL is being constructed in an existing space in the Boca Raton Training and Administration Building, where over 1,800 square feet of space were dedicated for the BPL. The building also holds extensive training rooms and training support; a gym; and the Boca Raton Fire Department Administration office. Additionally, plans are in place to build an Emergency Operations Center for Boca Raton, Delray Beach, and Boynton Beach in the same facility. Renovation will include moving existing plumbing from the building; building out the air conditioning system; establishing a hurricane reinforced entrance/exit door; adding additional venting for fumes; moving additional electrical power panels to the area; adding a telephone system, computer lines, and fire and burglar alarms, a card access system, and additional security locks for the storage of DNA evidence; installing industrial vinyl flooring; painting; upgrading lighting; and building three offices.

3.4.5.2 Consideration for the PBSO EIP Process

There were several considerations that the PBSO laboratory had to face over the course of their EIP process (Table 3-6). A lack of realization on the time required for legal processing, collection of EIP evaluation metrics, and fully executing collaborative agreements led to a 1-year

delay before the EIP could get started. There also appeared to be limited understanding of the roles and responsibilities for each of the collaborative partners. Additionally, the BRPSD procurement process was initially not well understood by the stakeholders. The personnel hiring process was also delayed, thus interfering with the training schedule and staff availability. While PBSO and BRPSD have a good working relationship, there was a learning curve for BRPSD to understand the full scope of their responsibilities in running an independent laboratory. Understanding the processes, approvals, and QA, agreements became clearer to the Boca Raton staff as the EIP progressed.

PBSO proposed to prioritize cases screened at the BPL. However, the system for doing so has yet to be developed. PBSO has a performance system that tracks cases that can provide a separate list of cases that were screened at the BPL. At this time, stain cuttings submitted by the BPL will be assigned per current protocol.

Table 3-8. PBSO Considerations Encountered during the EIP

Category	Consideration/Issue	Comments
Partnering	Organization and role responsibilities among PBSO and BRPSD had to be addressed	
	Organization and role responsibilities among BRPSD and Delray Beach and Boynton Beach had to be addressed	
	BRPSD procurement process was not well understood	
	PBSO proposed to prioritize cases screened at the BPL, but the system for doing so has yet to be developed	
Personnel- Hiring, training, reassigning, retention	BRPSD needed to hire two laboratory analysts to staff the BPL	Hiring process took approximately 4 months after job posting
	New hires required training	Training was completed in 3 months
	Hiring was delayed, which impacted scheduling of PBSO staff who were to provide training	
Construction	Renovation of the BPL was delayed is not complete	Completion is expected in March 2012

3.4.5.3 Modifications to Original Implementation Plan

The scope of the PBSO EIP as presented to NIJ in the proposal has not changed. The only modifications have involved the timeline (described below).

3.4.5.4 Budget and Timeline

While the original end date for the EIP was March 31, 2011, PBSO requested and received two NCEs, first through September 30, 2011, and subsequently through September 30, 2012. There were initially administrative delays in formalizing the financial relationship between PBSO and BPRSD and in preparing bids for the contractors. Both major components of the project—renovating the BPL and hiring two laboratory analysts—were also delayed. Originally, the BPL was expected to be ready for occupancy in November 2010; the renovations are now expected to be completed by the end of March, 2012. Similarly, the laboratory analysts were originally expected to complete training in June 2010, and training completion was delayed until July 2011. Because the renovations were delayed longer than staffing, the BPL analysts will conduct casework at PBSO until the BPL is ready for occupancy.

The delay in the implementation of building the BPL was due to the additional time that was required for review and approval by the administration of the City of Boca Raton, as well as the initiation and implementation of internal policies.

3.4.6 Impact of EIP on Laboratory Operations

Implementation of the EIP will impact operations at the PBSO. Because the renovations to the BPL were significantly delayed, PBSO housed two additional laboratory analysts in their facilities until construction was complete. While at PBSO, the analysts were able to assist in two

evidence screening procedures. After training, they assisted BRPSD crime scene personnel, which provided the analysts with an awareness of the evidence collection process.

Prior to this EIP, PBSO prioritized all cases by the date the evidence was submitted; all law enforcement agencies were treated the same. After implementation, PBSO developed a process for prioritizing cases that were screened at the BPL.

The impacts of the EIP are yet to be fully realized because the screening laboratory was not operational in their own facilities at the time of this report. Once the BPL is operating at the BRPSD facility, it is anticipated that the PBSO DNA analysts will spend less time screening cases for evidence and will be able to initiate a case with the DNA protocols. A summary of impacts of the EIP for PBSO are in **Table 3-9**.

Table 3-9. PBSO Impacts of EIP Process

Category	EIP Impacts	Comments
Partnering	MOUs between partnering agencies have been implemented	The BPL will pre-screen evidence from three southern jurisdictions prior to submission to PBSO
		BRPSD will accept evidence from Boynton Beach and Delray Beach for pre-screening
Personnel- Hiring, training, reassigning, retention	Two new laboratory analysts were hired	Needed to be trained on safety, QA/QC, ISO Standards, evidence handling, serological analysis, ethics training, and court testimony
	Because the renovations to the BPL were significantly delayed, PBSO housed two additional laboratory analysts in their facilities until construction was complete	While at PBSO, the analysts were able to assist in two evidence screening procedures. After training, they assisted BRPSD crime scene personnel, which provided the analysts with an awareness of the evidence collection process

3.5 University of North Texas Health Science Center Department of Forensic and Investigative Genetics (UNTHSC)

The University of North Texas Health Science Center Department of Forensic and Investigative Genetics (UNTHSC) proposed to develop an expert system to automate routine and repetitive tasks in interpreting mitochondrial DNA, or mtDNA, sequence analysis. If successful, this expert system would improve laboratory efficiency while also reducing variability in data

analysis decision. Funds were requested in the amount of \$265,393 to cover software development and validation, two work stations, labor, travel, office supplies, and academic materials.

3.5.1 Context

3.5.1.1 Setting

This EIP was conducted at a research and development laboratory that does not conduct actual casework. The Laboratory for Molecular Identification, located on UNTHSC campus in Fort Worth, Texas, has both a Forensic Casework division and a Research division, which has been involved with the development, testing, and validation of several procedures and commercial kits currently used in forensic laboratories and the development of databases used by the forensic community. The purpose and mission of the Research and Development Laboratory (RDL) is to support the advancement of technology in the areas of human identification through DNA-based testing for the Center's Missing Persons, Forensic, and Relationship Testing laboratories. The laboratory is also available to assist in the training of graduate students wishing to conduct DNA technology-based research, as well as serving as a collaborator for genetic testing studies being conducted by UNTHSC researchers and faculty. Although the laboratory is not a "core-facility" that processes samples on a contract basis, the researchers overseeing the RDL will assist in feasibility assessment. The RDL analyzes mtDNA, autosomal STRs, and/or Y-STRs. mtDNA can be used to examine the DNA from samples that cannot be analyzed by RFLP or STR. In contrast, nuclear DNA must be extracted from samples for use in RFLP, PCR, and STR. Older or anucleated biological samples, including hair, bone, and teeth, can be invaluable in a forensic case because often times these cases do not have nucleated cells for autosomal testing. The "mtDNA sample" is a buccal swab submitted as a family reference

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specimen to be compared to missing persons cases for upload into one or more CODIS applications (LDIS, SDIS, and NDIS). Assay development is completed by faculty and students at UNTHSC. The RDL has worked with industry leaders in the development of many DNA testing technologies and actively collaborates with researchers and visiting scientists at the national and international level.

3.5.1.2 History of Program

The RDL was established in 2006. For more than 10 years, the principal investigator (PI) at the RDL has worked with software development teams and evaluated expert systems for forensic DNA analysis, as well as conducted research for the Missing Persons Program at the UNT Center for Human Identification (CHI), including automation, method development, and mtDNA research. She also helped develop GeneMapper ID (Applied Biosystems, Foster City, CA). Furthermore, the PI was the Technical Director for NIJ's Expert System Testbed Project, which was publically introduced in 2005 to support the national forensic DNA community in the review of data (Roby et al., 2005).

3.5.1.3 Laboratory

The RDL is housed in 1022 square feet of newly remodeled laboratory space on the UNTHSC campus. The laboratory is a state-of-the-art facility, with research capabilities in DNA sequencing and sequence analysis, SNP detection and genotyping, real-time PCR/qPCR, and Affymetrix microarray-based genome analysis. The facility also houses a culture laboratory to support the Center's Tick-Bourne Disease Research Center. The RDL operates under the same stringent QA standards, ISO 75025, adhered to by the casework laboratories of the UNT CHI. An overview of UNT's laboratory equipment is included in **Table 3-10**.

Table 3-10. UNT Laboratory Equipment

Equipment	Quantity	Location
Nuaire Biological Safety Cabinet	2	UNT CHI
LabConco Biological Safety Cabinet	1	UNT CHI
Airclean 3000 Fume Hood	1	UNT CHI
SPEX Freezer Mill 6750	3	UNT CHI
Tecan Freedom EVO 100	1	UNT CHI
Agilent 2100 Bioanalyzer	1	UNT CHI
ABI GeneAMP PCR System 9700	10	UNT CHI
ABI 3130xl Genetic Analyzer	3	UNT CHI
Jouan Centrifuge C4.12	1	UNT CHI
ABI Real Time 7500	1	UNT CHI
ABI 3130xl Genetic Analyzer	1	RDL
ABI GeneAMP PCR System 9700	2	RDL
ABI 7500 Real Time	1	RDL
Tecan MiniPrep 75	2	RDL
TECAN Evo 200	1	RDL
ABI 3500 xl	1	RDL
ABI GeneAMP PCR System 9700	3	RDL
Promega Maxwell 16	2	RDL

3.5.1.4 Decision to Develop the EIP

Expert systems have been used to reduce backlogs of nuclear DNA samples; however, no expert system was available for mtDNA. Processing mtDNA sequence data is a time-consuming manual task that requires at least a two-tier review by extensively trained and experienced analysts (i.e., several hours for typing of each sample). Independent results are compared and reconciled in order to create the reported profile. As a continuation of UNTHSC 2008 DNA Unit EIP, which increased the laboratory's throughput with development of more automated sample processing and increased sequencing capabilities, the laboratory proposed a subsequent EIP (this 2009 NIJ award) to improve data analysis by developing a mtDNA sequence analysis expert system.

3.5.2 Goals and Objectives

The overarching goal of this EIP was to create an expert system that will automate the routine and repetitive tasks in interpreting mtDNA sequence analysis. The expert system was anticipated to have two impacts: (1) improve the capacity to analyze DNA and (2) reduce the backlog of DNA analysis requests. The objectives of UNTHSC's DNA Unit EIP are to assist the casework laboratory, as well as other forensic laboratories that conduct mtDNA testing nationally.

3.5.3 Staffing

The UNTHSC RDL, also referred to as the Field Testing Unit, is one of the five units within the UNT CHI. Within this unit is a UNTHSC co-director, who is also the PI of the 2009 DNA Unit EIP award from NIJ; 1 field testing manager; 6 forensic technicians; 1 CODIS project coordinator; 1 graduate student; and 1 post-doctorate candidate. The staffing for this EIP included the PI, 1 research analyst, 1 technologist (10% of time not paid with EIP funding), and 2 graduate students from the RDL. In addition, 2 or 3 casework analysts participated in several of the outcome evaluation studies for the expert system software.

3.5.4 Proposed Activities

Expert system software will be developed to fully automate the analysis of high-quality mtDNA data, including its ability to direct the analyst to specific areas where further review is necessary and profile decisions can be made (i.e., data resolved and result reported or reanalysis). UNTHSC partnered with Mitotech, LCC, a DNA software company, to build the automation of the current visual manual evaluations using sophisticated signal-to-noise analysis of trace files. The created software is expected to provide more information about the DNA peaks and traces

than is produced by base-calling software. The software will also evaluate the quality of the data. Examples of its capabilities include automated conflict resolution, automated identification of suspected heteroplasmy, and automated rule firings for those bases that do not meet minimum thresholds in the process of creating a consensus assembly trace (UNTHSC 2009 EIP proposal).

Throughout the project, opportunities to automate routine and repetitive tasks will be identified. Proposed automation includes the following:

- Automated consensus assembly and review
- Automated trimming of low-quality redundant regions in a trace
- Expert rules specific for dye chemistry, instrumentation, and primers
- Expert rules to automatically resolve some assembly conflicts and dye artifacts
- Automated assessment of heteroplasmy
- Automated identification of sequences exhibiting a mixture of two or more contributors
- Automated detection and evaluation of length heteroplasmy
- Seamless integration with the Mitotype rules and ‘linking’ the consensus sequence to the haplotype for efficient review and comparison

In addition to opportunities to automate the Mitotyper review rules of the expert system, steps to address data integrity and quality were also included:

- Automated organization files
- Automated analysis of the Positive Controls, Negative Controls, and Reagent Blank Controls with the pass/fail rules
- A reloadable archive files containing the data, analyses, and results for each sample
- Automated assessment of regions of low quality and regions of low and no coverage
- Automated analysis of the statistical rarity of the types generated to identify improbable polymorphisms for further review (UNTHSC 2009 EIP Proposal)

Another proposed activity of UNTHSC was to develop performance metrics and a Data Collection Plan to effectively measure improved performance. This activity would be planned in conjunction with the external evaluator, RTI. The last planned activities for UNTHSC's 2009 EIP were validation of the expert system software and dissemination of the findings to the forensic community.

3.5.5 Implementation

3.5.5.1 Actual Activities

UNTHSC secured a subcontract agreement with Mitotech, LLC, the company that developed the software packages that would be integrated, in the first half of 2010. Two MTexpert™ workstations were purchased and setup in 2010. One forensic scientist was trained by Mitotech on the workstation, and training was initiated for the other forensic scientist. UNTHSC regularly met with Mitotech to discuss software specifications and identify any bugs they might encounter.

UNTHSC worked with three software packages with the goal of linking them all: eFAST, Sample Trace Assessment Tool and Integrated Summary (STATIS), and MTexpert™. Two forensic scientists developed specifications for the software packages and submitted them to Mitotech. When the specified software was delivered, they compiled samples to run through the program and evaluate the software. They initially identified about 45 bugs with MTexpert™ and suggested changes to Mitotech. As part of the validation, a forensic scientist processed 1000 samples for the "Chilean Database" and ran them against the new Mitotyper rules. The software caught several instances of human error and ambiguity, demonstrating the power of using software to make calls.

By October 2011, UNTHSC will have developed more than 29 versions of eFAST; 4 versions of MTextpert™; and 6 versions of STATIS. eFAST and STATIS are now routinely used in the RDL. In addition, a User Guide has been drafted for eFAST 2.0 and a User Manual for MTextpert™.

3.5.5.2 Consideration for EIP Implementation

The primary problems encountered involved the considerable amount of time that was required to develop software, test and reports bugs, and incorporate additional features.

3.5.5.3 Modifications to Original Implementation Plan

UNTHSC modified their original implementation plan to include designing a batch management software program that links eFAST Software and MTextpert™. No other modifications were made. Two GANs were submitted to NIJ and received approval. The GANs were submitted for NCEs, first to a completion date of December 2011 and ultimately to a completion date of September 2012. The reasons for the NCEs were that the programming was not complete and that the testing exchange takes time.

3.5.5.4 Staff and Management Perceptions of Project Progress

At the time of this report, EIP implementation is within budget and is not projected to exceed budget. While this project has been delayed from its original completion date, the laboratory staff and management are content with the project's progress. With 9 months left before completion of this EIP, it is difficult to know if the final progress will be acceptable to the laboratory.

3.5.5.5 Budget and Timeline

While the project is still operating within its original budget, UNTHSC requested two NCEs (December 2011 and September 2012). The extensions were needed because programming was not complete and testing the software is time consuming.

3.5.6 Impact of EIP on Laboratory Operations

This EIP has the potential to impact both casework laboratories and forensic laboratories that conduct mtDNA testing. Thus far, casework laboratory operations have demonstrated interest in the EIP by requesting RDL's assistance in Mitotyper rules, a component in MTextpert™. As MTextpert™ is not yet complete, laboratory operations have not been trained on this software package, so the impact cannot be fully realized.

4. OUTCOME TO EVALUATION

4.1 Orange County Crime Laboratory (OCCL)

4.1.1 Overview

OCCL's EIP involved two primary components: (1) the case submission triage system and (2) the Property Crime DNA Program with high-throughput DNA analysis line. These components were implemented at different times during the performance period, and it is important to consider the date when the triage system was fully implemented with a Web-based work request system (November 2010) and the date when the high-throughput DNA analysis line became fully operational (April 2011). Since the EIP was implemented for only 6 months prior to the end of the evaluation, only short-term outcomes have been assessed. Performance metrics were collected throughout the evaluation using both the OCCL LIMS and RTI Microsoft (MS) Excel spreadsheets (**Appendix C**). The MS Excel spreadsheets captured additional data not routinely entered into LIMS, such as sample type, quantity of DNA recovered, and type of DNA result obtained (e.g., major contributor versus unresolved mixture). The MS Excel spreadsheets also included a list of all cases where a suspect was identified from the questioned sample, either through the submission of a standard or by a CODIS cold hit.

Since the emphasis of the OCCL EIP was on property crime, metrics specific to property crime are presented, when available. To fully evaluate the impact of the EIP on outcomes, these metrics should continue to be calculated and tracked until the end of the grant's performance period.

During the EIP, RTI designed monthly data collection spreadsheets that were used to report laboratory metrics before, during, and after the EIP implementation. The metrics were

identified as baseline data (pre-implementation), implementation period, and post-implementation stages of the EIP.

For OCCL, the pre-implementation (or baseline) was the period from May 2009 to November 2010. The implementation period was from December 2010 to March 2011. The triage system was fully implemented with a Web-based work request system in November 2010; the high-throughput DNA analysis line was fully implemented in April 2011 with the first team of analysts. Since the first team was composed of existing OCCL staff, required training was limited. For the purpose of this report, the post-implementation data collection period is from April 2011 to September 2011..

4.1.2 Average Monthly Turnaround Time

Unlike most laboratories, the OCCL turnaround time starts when the first examination is scheduled in the LIMS and concludes with the final report. As shown in **Figure 4-1**, the turnaround time was fairly stable over the data collection period. The average turnaround time appears to begin to decline during the post-implementation period for all crimes and for property crimes only (**Table 4-1**); however, this will need to be tracked for a longer period of time before conclusions can be drawn about whether turnaround time has actually decreased. In fact, the average monthly turnaround time in September 2011, the last month RTI collected data, was the lowest in the 2 years of data collection of this laboratory metric.

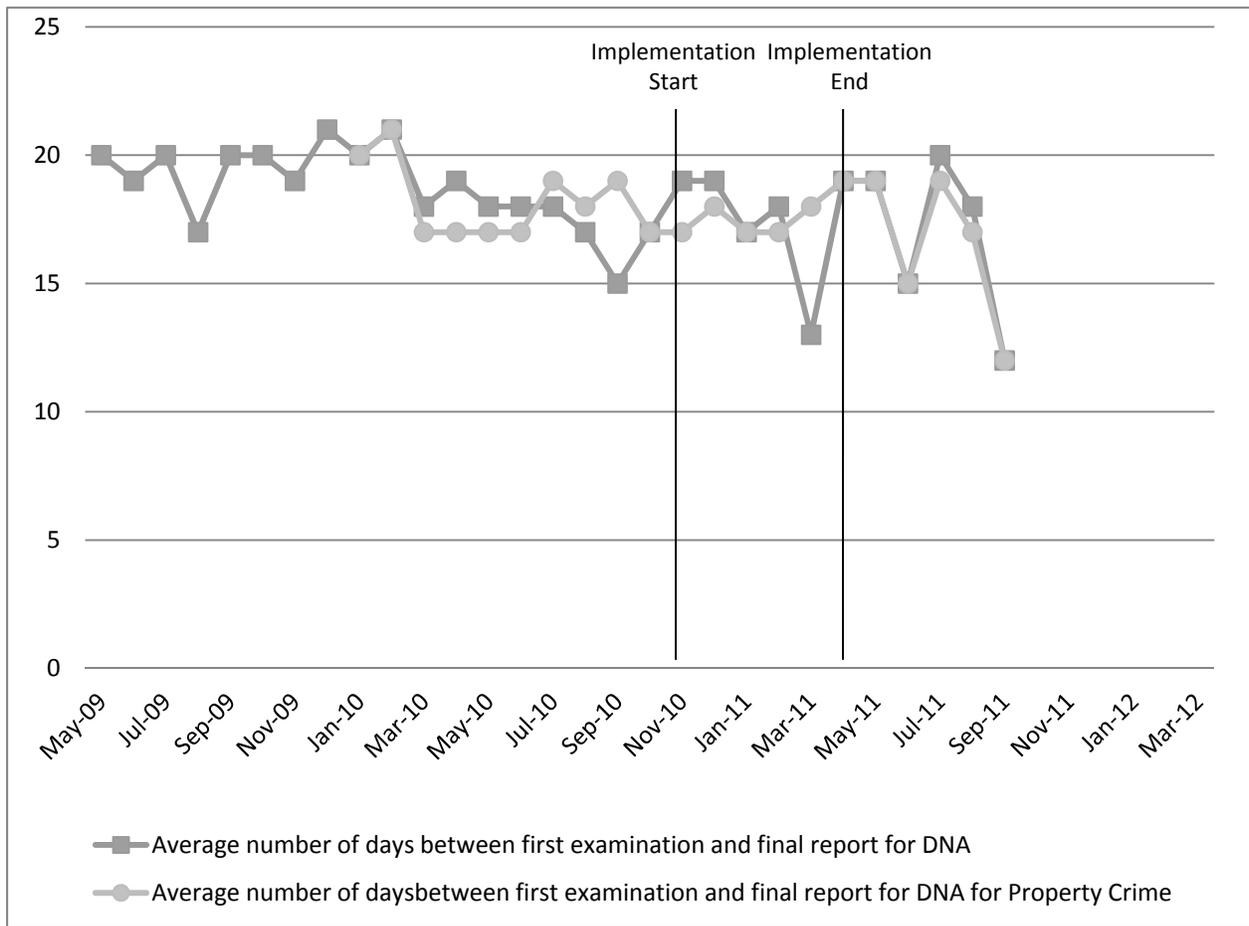


Figure 4-1. Turnaround time.

Table 4-1. Summary of Turnaround Time

Metric	Mean	Pre-implementation Mean (May 2009–November 2010)	Implementation Mean (December 2010–March 2011)	Post-implementation Mean (April 2011–September 2011)
Average number of days between first examination and final report for DNA	18	19	17	17
Average number of days between first examination and final report for DNA for Property Crime	18	18	18	17

The OCCL turnaround time for all DNA cases and property cases fluctuated between September 2010 and September 2011. For all cases, the longest turnaround time was 20 days (July 2011) and the shortest turnaround time was 12 days (September 2011). For property crime

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cases, the longest turnaround time was 19 days (4 different months) and the shortest turnaround time was 12 days (September 2011). These turnaround times can be affected by instrument validations, analyst training, holidays, vacations, and professional seminars and courses. As the second team of high-throughput DNA analysis line analysts completes their training (end of 2011), the TAT for property crime cases should level out and remain stable.

The turnaround times presented in the paragraph above appear reasonable, but only represent the time that a sample spends on the high-throughput DNA analysis line; it does not reflect how long it takes to triage a work request and assign a case to an analyst. According to OCCL, it takes approximately 1 month from the time a work request is received, triaged, and accepted by the Orange County District Attorney's Office (OCDA) and OCCL and the evidence is submitted to the laboratory. It can then take an additional 2 to 3 months for the cases to be assigned to an analyst. However, these data are not specifically tracked by OCCL.

4.1.3 Cases Analyzed Per Analyst

The analyst caseload was calculated by dividing the number of cases assigned to analysts by the number of analysts employed. The Forensic Biology caseload only refers to property crimes that require forensic biology tests (such as presumptive blood analyses or amylase presumptive tests) and does not include major crime cases (which would increase the number of forensic biology tests done). As shown in **Figure 4-2**, the Forensic Biology caseload remained fairly stable, while the DNA Unit caseload fluctuated over the tracking period. On average, DNA analysts were assigned more cases during and after implementation than they were during the pre-implementation period (**Table 4-2**).

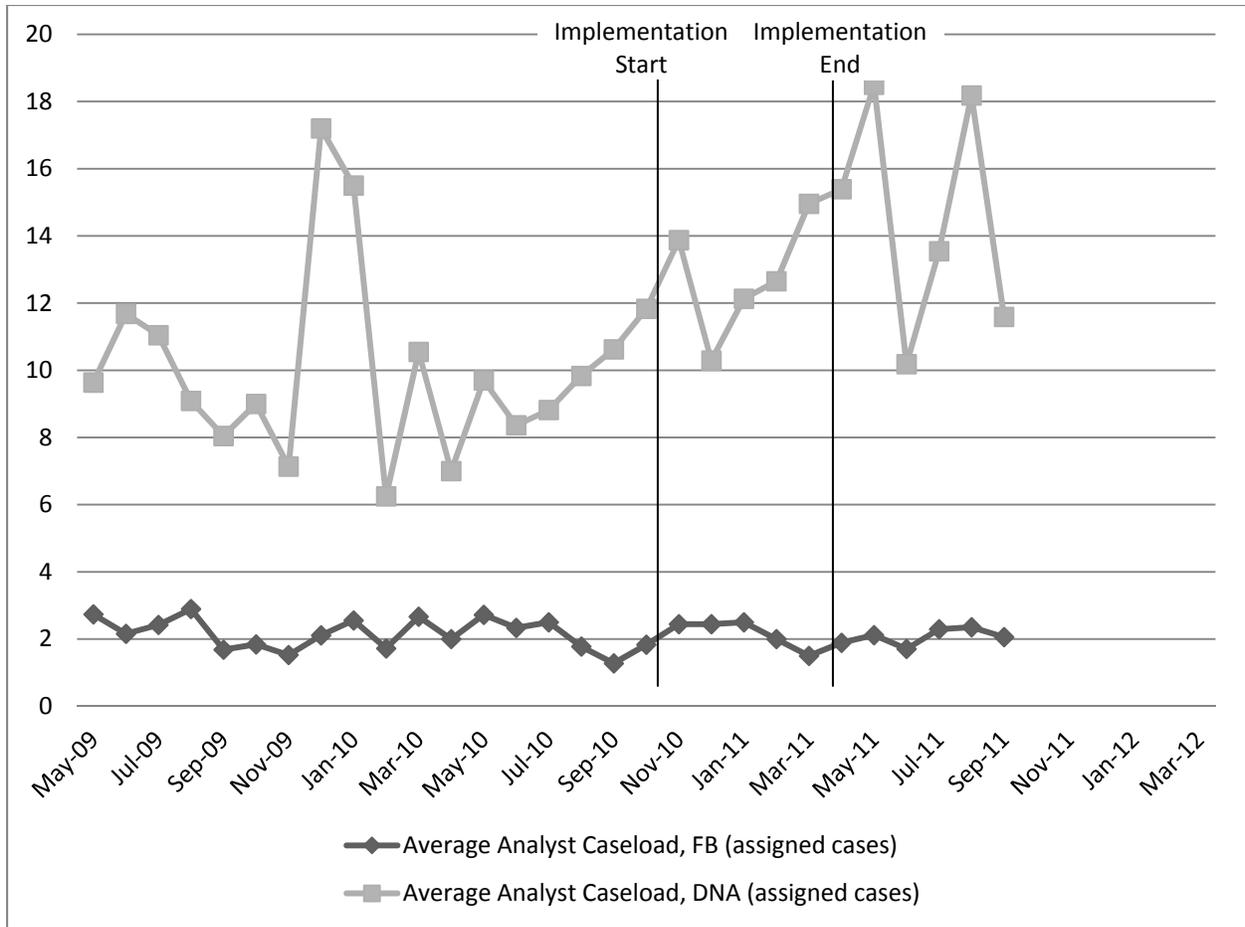


Figure 4-2. Analyst caseload.

Table 4-2. Summary of Analyst Caseload

Metric	Mean	Pre-implementation Mean (May 2009–November 2010)	Implementation Mean (December 2010–March 2011)	Post-implementation Mean (April 2011–September 2011)
Average analyst caseload, forensic biology (assigned cases)	2	2	2	2
Average analyst caseload, DNA (assigned cases)	11	10	13	15

The number of cases completed by OCCL DNA analysts between September 2010 and September 2011 also fluctuated. The analysts were assigned 255 cases and completed 295 cases in September 2010. They were assigned 255 cases and completed 314 cases in September 2011. The “high point” during this period was August 2011, when 400 cases were assigned and 443

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cases were completed. This high point corresponds to 2,015 total DNA samples and 950 property crime samples.

As with the turnaround time, the number of cases examined per analyst depends on the same influences provided in **Section 4.1.2**. OCCL does not track the number of completed cases per analyst because much of the process consists of team batching.

4.1.4 DNA Case Backlog

As shown in **Figure 4-3**, OCCL's DNA case backlogs had steadily declined prior to this EIP. The number of backlogged cases declined each month between May 2009 and September 2010. After a slight increase between September 2010 and October 2010, the backlog appeared to stabilize. As shown in **Table 4-3**, the average number of cases in the DNA backlog was smaller during implementation than during pre-implementation; however, it increased post-implementation.

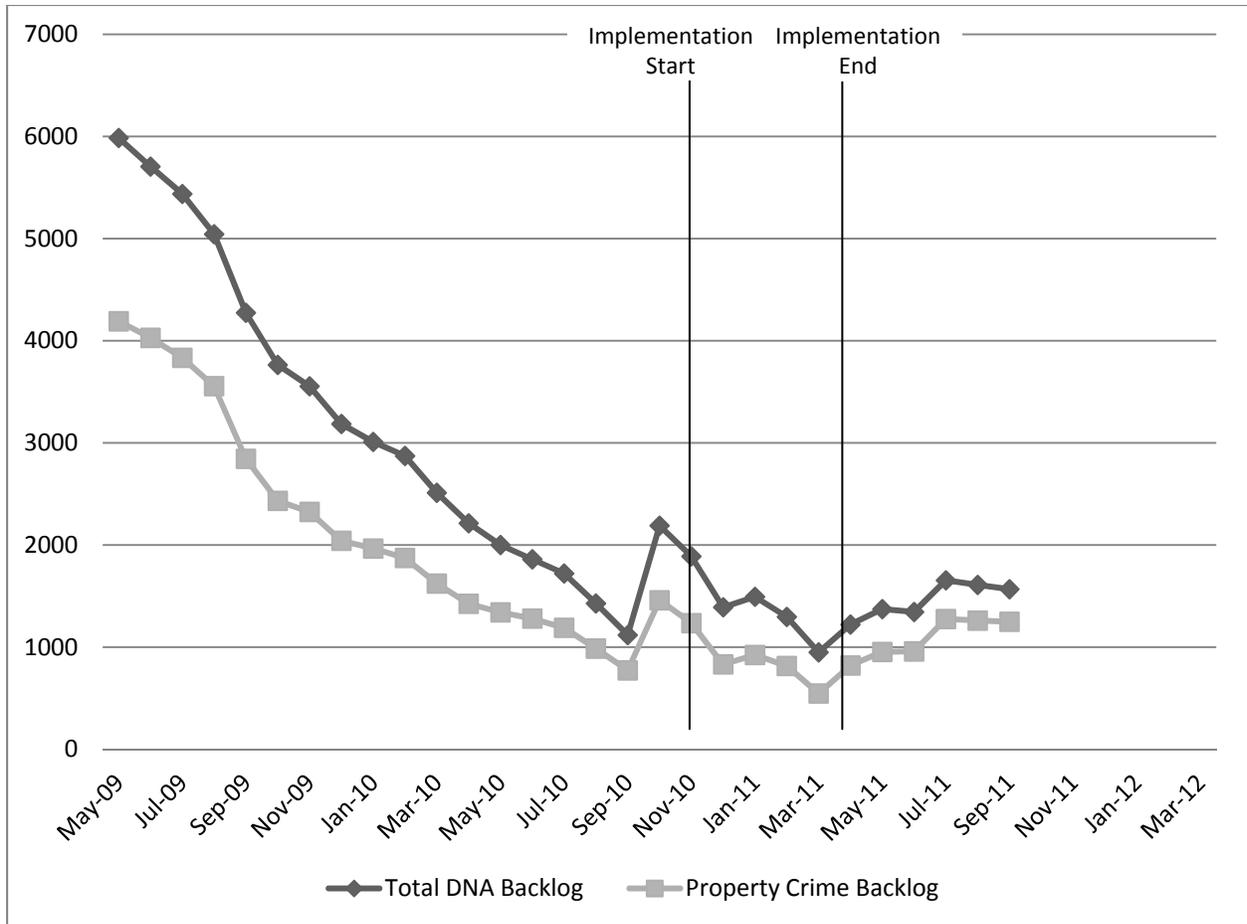


Figure 4-3. Backlogged cases.

Table 4-3. Summary of Backlog

Metric	Mean	Pre-implementation Mean (May 2009–November 2010)	Implementation Mean (December 2010–March 2011)	Post-implementation Mean (April 2011–September 2011)
Total DNA backlog	2,648	3,146	1,283	1,313
Property crime backlog	1,779	2,127	780	911

The property crime backlog was 672 cases in September 2010 and was 983 cases in September 2011. The backlog reached its lowest point (559 cases) in March 2011 and the highest point (1,023 cases) was in August 2011.

The number of cases being submitted is increasing, which adds to the backlog.

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4.1.5 CODIS Matches

Table 4-4 and **Figure 4-4** summarize the OCCL Property Crime CODIS matches for EIP pre-implementation, implementation, and post-implementation periods. As shown in **Figure 4-4**, the number of property crime cases that CODIS assisted through verified matches of convicted offenders fluctuated over the data collection period, whereas the number of property crime cases CODIS assisted through matches of crime scene evidence remained fairly stable. Additionally, property crimes consistently yielded a greater number of offender matches than major crimes.

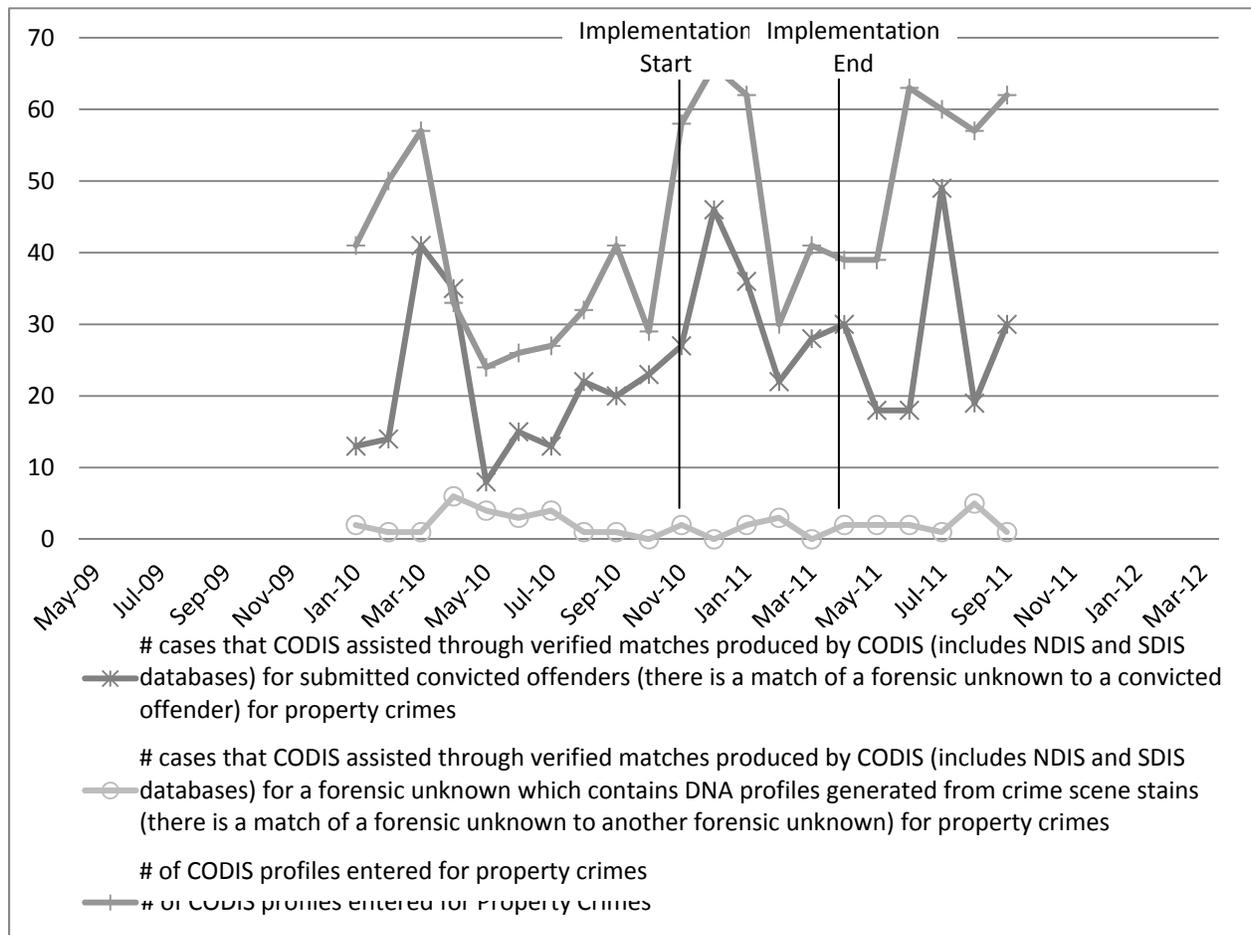


Figure 4-4. Property crime CODIS matches.

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Table 4-4. Summary of Property Crime CODIS Matches

Metric	Mean	Pre-implementation Mean (May 2009–November 2010)	Implementation Mean (December 2010–March 2011)	Post-implementation Mean (April 2011–September 2011)
Number of cases that CODIS assisted through verified matches produced by CODIS (includes NDIS and SDIS databases) for submitted convicted offenders (there is a match of a forensic unknown to a convicted offender) for property crimes	25	21	33	27
Number of cases that CODIS assisted through verified matches produced by CODIS (includes NDIS and SDIS databases) for a forensic unknown, which contains DNA profiles generated from crime scene stains (there is a match of a forensic unknown to another forensic unknown) for property crimes	2	2	1	2
Number of CODIS profiles entered for property crimes	45	38	50	53

In September 2010, there were 41 property crime DNA profiles entered into CODIS. In September 2011, there were 62 profiles entered into CODIS. The month with the lowest number of CODIS entries was October 2010 (29 entries) and the month with the highest number was December 2010 (66 entries). OCCL anticipates that the number of DNA profiles entered into CODIS will continue to increase as the laboratory's capacity increases. With the current Property Crime DNA Program with high-throughput DNA analysis line it appears that about 50% of the hits has led to a CODIS filing which is a significant result.

4.1.6 Improved Capacity or Other Benefits

4.1.6.1 Training and Triage

Orange County law enforcement agencies were given EIP-initiated training to provide information on (1) the value of DNA evidence, (2) how to properly submit work requests and evidence to the laboratory, and (3) the feedback regarding their own agency's use of DNA

evidence to solve crimes. This training, combined with the triage process, gave the laboratory a process so that the DNA supervisors and the OCDA personnel could limit the number the evidence items submitted or could reject a case entirely, based on the information provided. This has resulted in higher-quality cases and evidence, which subsequently allows for the generation of more probative CODIS profiles.

4.1.6.2 High-throughput DNA Analysis Line

Developing a high-throughput DNA line and dedicated analysts to process property crime should also yield an increase in the laboratory's throughput, or the number of samples analyzed. There is some evidence that throughput may be increasing. Although the average throughput varies each month (**Figure 4-5**), it was highest in the post-implementation time period (**Table 4-5**).

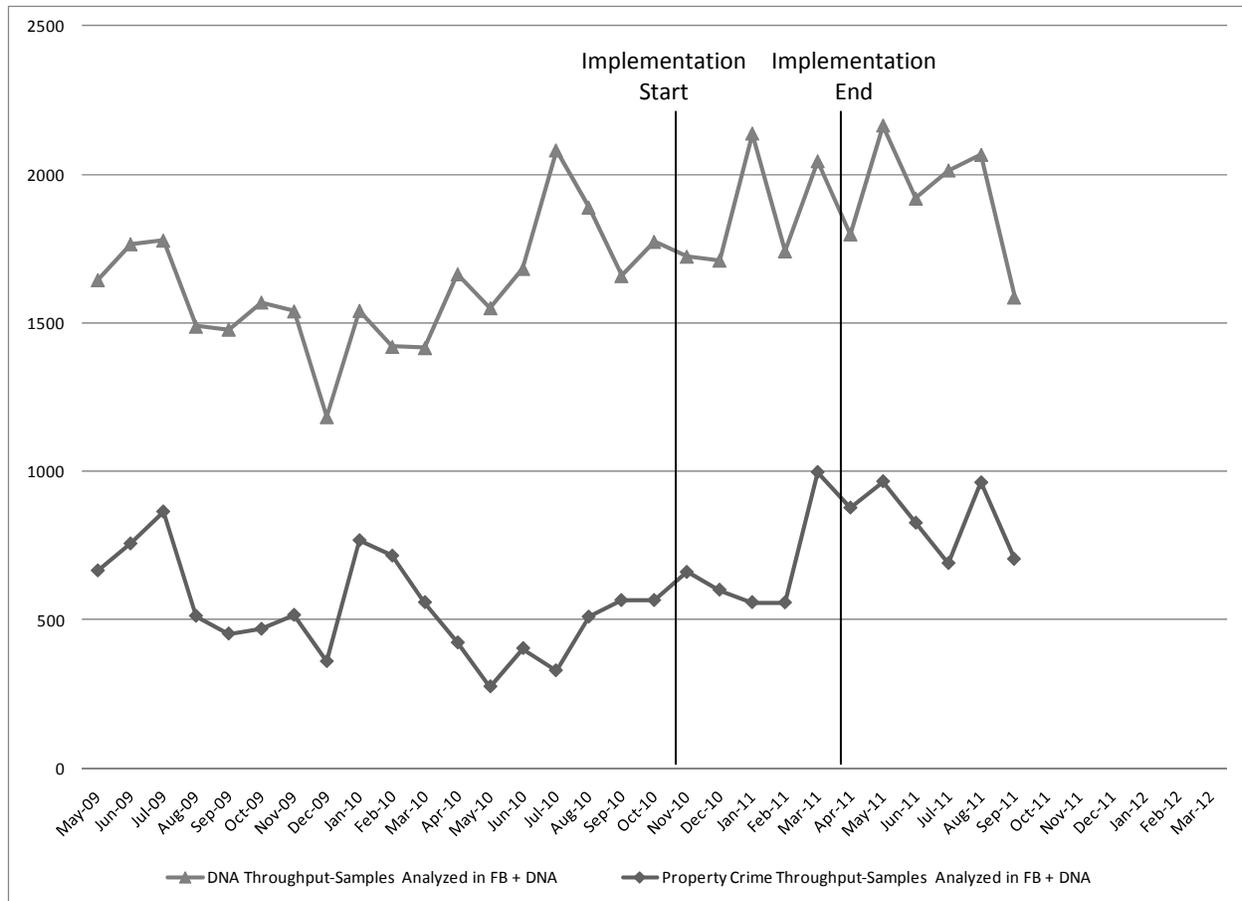


Figure 4-5. DNA Throughput.

Table 4-5. Summary of Throughput

Metric	Mean	Pre-implementation Mean (May 2009–November 2010)	Implementation Mean (December 2010–March 2011)	Post-implementation Mean (April 2011–September 2011)
DNA Throughput – samples analyzed in FB + DNA	1,706	1,623	1,908	1,960
Property crime throughput – samples analyzed in FB + DNA	605	545	678	890

The number of cases in the analysis process each month is steadily increasing. There were 100 cases being processed in September 2010 and 269 cases being processed in September 2011. These numbers indicate that OCCL’s capacity is increasing and a higher number of samples are being processed through the high-throughput DNA analysis line.

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Case triage and increased efficiency should also improve the OCDA's ability to prosecute and convict offenders. DNA evidence should result in a higher felony conviction rate. In April 2011, the OCDA began tracking the felony dispositions and sentences with DNA evidence. Between April 2011 and September 2011, the OCDA completed 21 felony dispositions with DNA evidence; 17 resulted in felony convictions and 4 were reduced to misdemeanors. Seven of the offenders were sentenced to prison, 10 to jail, and 3 to probation; 1 offender received another sentence. These statistics should continue to be monitored to assess any potential impact of the EIP on the laboratory. Later in this section, the limitations of these statistics will be addressed in more detail.

4.1.7 Orange County District Attorney Performance Metrics

As part of the outcome evaluation, the OCDA was also asked to provide some performance measures to help understand the impact of the 2009 DNA Unit EIP grant with OCCL. RTI participated in a conference call with OCDA staff to request performance measures. To assist with this process, RTI categorized the metrics, and the OCDA agreed with the dates when these metrics could potentially be calculated, as shown in **Table 4-6**. However, it was later determined that it was too early to calculate many of these metrics, but it is something that OCCL and the OCDA could possibly continue to collect and report as part of the laboratory's final report to NIJ.

Table 4-6. Proposed Orange County District Attorney's Office Performance Metrics

High Priority (Collection Dates)	Medium Priority (Collection Dates)	Low Priority (Collection Dates)
Number or percentage of property crime cases charged (April 2010 to April 2011)	Number or percentage of property crime cases that result in conviction (April 2011 to September 2011)	Number of OCDA office labor hours committed to property crimes (or estimated percentage); Too difficult to collect

High Priority (Collection Dates)	Medium Priority (Collection Dates)	Low Priority (Collection Dates)
Number or percentage of property crime cases charged that had DNA evidence (available April of 2011)	Number or percentage of property crime cases resolved prior to jury (April 2011 to September 2011)	Number of restitution cases for property crime (April 2011 to September 2011)
Number of property crimes reported to authorities	Number or percentage of property crime cases resolved prior to jury that used DNA evidence (April 2011 to September 2011)	Qualitative metrics for victim satisfaction for property crime. This was part of original OCCL proposal as results collected by a large-scale survey by OCDA. Determined that these data could not be easily collected again.
Orange County annual population pre-EIP and during EIP	Number of DAs working property crime cases (full- or part-time) (#9–11) Qualitative information	
	Number of training, resources, and technical assistance programs that the DA's office has provided or has assisted with for property crime (community outreach, law enforcement, laboratory).	
	Number of property crime initiatives for the DA's office (e.g., Repeat Burglar Initiative for crime pattern analysis, career criminals, non-violent repeat drug offenders)	

The OCDA used the following methodology to collect these metrics and provided a Microsoft Excel spreadsheet with the DNA evidence accepted and analyzed from January 2011 through September 2011. Data were extracted from the office's Case Management System on October 2011, in addition to other resources (California Department of Justice, 2010a, 2010b; California Criminal Justice Statistics Center, 2011; CDR, 2010). The OCDA uses the same penal codes as the state to categorize property crime. Felony filings are reported the year the case was filed. This statistic is a case count. Felony case disposition and sentences are reported the year the defendant's legal proceedings were completed. These statistics are defendant counts. The conviction could be for something other than the property crime that resulted in a charge in the case. For example, defendants who had the charges dismissed due to a California Penal Code 1203.4 motion are not included in the disposition statistics. In these cases, defendants are

originally found guilty of the charges, but the charges are dismissed at a later date due to no new violations or successful completion of probation. Sentences are mutually exclusive, and the highest level of sentences is recorded. **Table 4-7** summarizes the legal definitions and case dispositions as followed by the California Penal Code.

Table 4-7. Legal Definitions and Case Dispositions as Followed by the California Penal Code

Dispositions	
Completed	Conviction on felony + reduced to misdemeanor + dismissals + acquittals (Statistics on dismissals and acquittals are not included as part of report.)
Conviction on felony	Defendant received a felony disposition or pleaded to a felony (includes trials)
Reduced to misdemeanor	Defendant's felony case was reduced to a misdemeanor or felony charges were dismissed, and the defendant was only found guilty/pleaded to a misdemeanor charged on the case (includes trials)
Diversions	Defendant received a disposition from the court or pleaded (felony or misdemeanor) and sentenced to diversion (includes Proposition 36, PC 1000, Deferred Entry of Judgment). If a defendant successfully completes requirements of diversion, the charges can be dismissed. Diversion cases are not included in completed statistics.
Trial count	Separate count of trials (guilty and acquitted)
Sentences	
Prison	Defendant sentenced to state time
Jail	Defendant sentenced to county time
Probation	Defendant sentenced to traditional probation supervision
Other	Defendant sentenced to community service, or payment of fines or restitution, or other programs
Restitution included	Separate count of restitution ordered (defendant could be included in a sentence category previously listed and be counted in the restitution included statistic)

4.1.7.1 Implications of OCDA Performance Metrics

The OCCL provided the following DNA EIP data to the OCDA: police agency information, laboratory report numbers, incident dates, criminal charges, exam dates, sample types, analysis results, and turnaround times. The data provided were collected during an 8-month period (March 2011 to October 2011).

Using the data from this 8-month time period, the OCDA examined the correlation between criminal case filings and DNA EIP cold hits. One hundred twenty-seven crimes were identified that met both of the following criteria: (1) that crime scene evidence was analyzed

using the OCCL high-throughput DNA analysis line, and (2) that a criminal case was filed by the OCDA. Fifteen of these cases were filed before DNA reports were issued by the OCCL, indicating that a suspect was identified by non-forensic DNA means. The remaining 112 cases were filed after OCCL DNA reports were issued and after DNA database hits occurred. This strongly suggests that a DNA database hit identifying a suspect was frequently a necessary component for initiating a criminal filing.

The OCDA also examined the rate of occurrence of DNA database hits before and after the implementation of the OCCL high-throughput DNA analysis line in April 2011. During the 3-month period that preceded the implementation (January 2011 to March 2011), 53 DNA hits were reported by the OCCL. In contrast, 162 DNA hits were obtained during the 6-month period that followed (April 2011 through September 2011), representing a 56% increase.

4.1.8 Qualitative Outcomes from the Orange County Police Agencies

The Orange County Police Agencies were surveyed by the OCDA's office to inquire how their DNA collection and follow up has changed since the awarding of the 2009 DNA Unit EIP Grant. Many of the responding agencies indicated that they have increased collections or submissions to the crime laboratory due to the knowledge of the high-throughput DNA analysis line. The agencies have been very satisfied with the promptness of the processing since this went online.

Most of the agencies that attended training provided by the OCCL and the OCDA's Office indicated that the training had a positive impact on the collection of probative biological evidence and increased their submissions to the OCCL. With more submissions resulting in uploadable profiles, the outcome is likely to be an increase in CODIS hits, which has been observed in other jurisdictions.

With low funding issues across the county, most of the agencies report that personnel numbers have either dropped or remained stagnate. In spite of the staffing issues, the agencies' report that they are coping with higher caseloads resulting from increased cold hits.

4.1.9 Future Directions and Considerations for OCCL and EIP

Growth of crime and case submissions to a forensic laboratory has always required strategic planning and forward thinking. The preliminary success of the EIP has demonstrated that there will likely be increases in DNA case submissions, CODIS hits, and prosecutions and convictions. This trend will have future implications for the various stakeholders of Orange County, including OCCL, the OCDA, the Orange County Government, and law enforcement agencies, and the citizens served by these agencies. Continued collaborative and individual efforts will be necessary to accommodate increases in services. These are summarized in **Table 4-8**.

Table 4-8. Future EIP Implications for Orange County Agencies

Agency	Impact of EIP	Future Considerations
OCCL	<ol style="list-style-type: none"> 1. Increased capacity for DNA Analysis 2. Increased submission of DNA cases 3. Increases in technical personnel 4. Increases in supplies and reagents 5. Increases in CODIS hits 6. High-throughput results in less time being spent on analysis, resulting in more time available for DNA Interpretation, report writing, and review 7. Increased training provided to first responders/LE agencies 	<ul style="list-style-type: none"> ▪ Will a third team of analysts be required to address the increasing volume of property case submissions? ▪ How will funding be maintained for potential increases in <ul style="list-style-type: none"> ○ Personnel ○ Expanded laboratory facilities ○ Instrumentation ○ Computers and software ○ Reagents and supplies ○ Evidence Control Unit staffing and storage ▪ Potential for shift work ▪ Should the high-throughput DNA analysis line be instituted for violent crimes?
Orange County District Attorney's Office	<ol style="list-style-type: none"> 1. More time involved in case evaluation (triage) 2. Increased CODIS hits 3. Increased Prosecutions 	<ul style="list-style-type: none"> ▪ Funding for potential increase in staff to handle increased prosecutions

Agency	Impact of EIP	Future Considerations
Orange County Government	<ol style="list-style-type: none"> 1. Has Increased budget by taking over funding of grant-funded analytical personnel required to maintain program 2. Has not funded the temporary support personnel 	<ul style="list-style-type: none"> ▪ Additional future increases in budget and funding for an expanded program ▪ Implications to weigh public safety against budget increases
Law Enforcement Agencies	<ol style="list-style-type: none"> 1. Increased collection and submission of DNA cases, especially property crimes 2. Increased storage 	<ul style="list-style-type: none"> ▪ Increased number of investigators trained in DNA collection, submission, and knowledge of probative value ▪ Increased storage capabilities

Future research includes examining the outcome of the cases such as petty theft, vehicle burglaries, and recovered stolen vehicles that have CODIS hits to determine if these cases have been prosecuted. Results of this investigation will allow the laboratory and the communities it serves the ability to reevaluate the utility of DNA testing for property crimes and their specific needs.

Using DNA and DNA databases as investigative tools may be cost effective on a per-case basis by reducing the amount of time performing traditional investigative legwork; however, many property crimes were probably not thoroughly investigated prior to the laboratory increasing its capacity for performing DNA on these cases.

In Orange County, investigators and CSI staff are noticing the increase in the number of cases that have been solved with DNA and are therefore motivated to collect and submit more evidence from both property and major crimes. Ultimately, this work will solve crimes and increase public safety.

4.2 Denver Police Department (DPD) Crime Laboratory Bureau

4.2.1 Overview

Although the primary aim of DPD's EIP was to use SIMUL8 software to develop and validate a process map of both forensic biology and DNA work flows, DPD also identified opportunities for improvement and generated innovations prior to software validation (described

in **Section 3**). Given the ongoing nature of identifying and addressing problems, two implementation dates are used for the purpose of examining outcomes: the date the first innovation was implemented (implementation start date) and the date the SIMUL8 was finalized (implementation end date). DPD identified and developed its first efficiency issue solution in July 2010; the SIMUL8 software had not been validated at the time of writing this report, but was anticipated to be complete in late November 2011. Metrics are summarized for these separate time periods in the figures and tables below.

Because the EIP was not fully implemented when the evaluation ended, performance metrics are only available prior to and during the implementation. As such, the evaluation team was unable to conduct a complete outcome evaluation. However, performance metrics were collected throughout the evaluation and are presented below for descriptive purposes. To evaluate the impact of the EIP on outcomes, these metrics should be calculated and tracked for a period after the implementation is complete (i.e., the SIMUL8 software has been validated and DPD has implemented innovations based on the results).

4.2.2 Average Monthly Turnaround Time

As shown in **Figure 4-6**, below, the turnaround time, measured as the number of days between the date when a case was submitted to the laboratory and when a report of the results was administratively approved, varied over the entire data collection period. The mean turnaround time for the entire period was 108 days for forensic biology and 160 days for DNA (**Table 4-9**). The mean turnaround time for both forensic biology and DNA were slightly higher in the implementation period than in the preceding months.

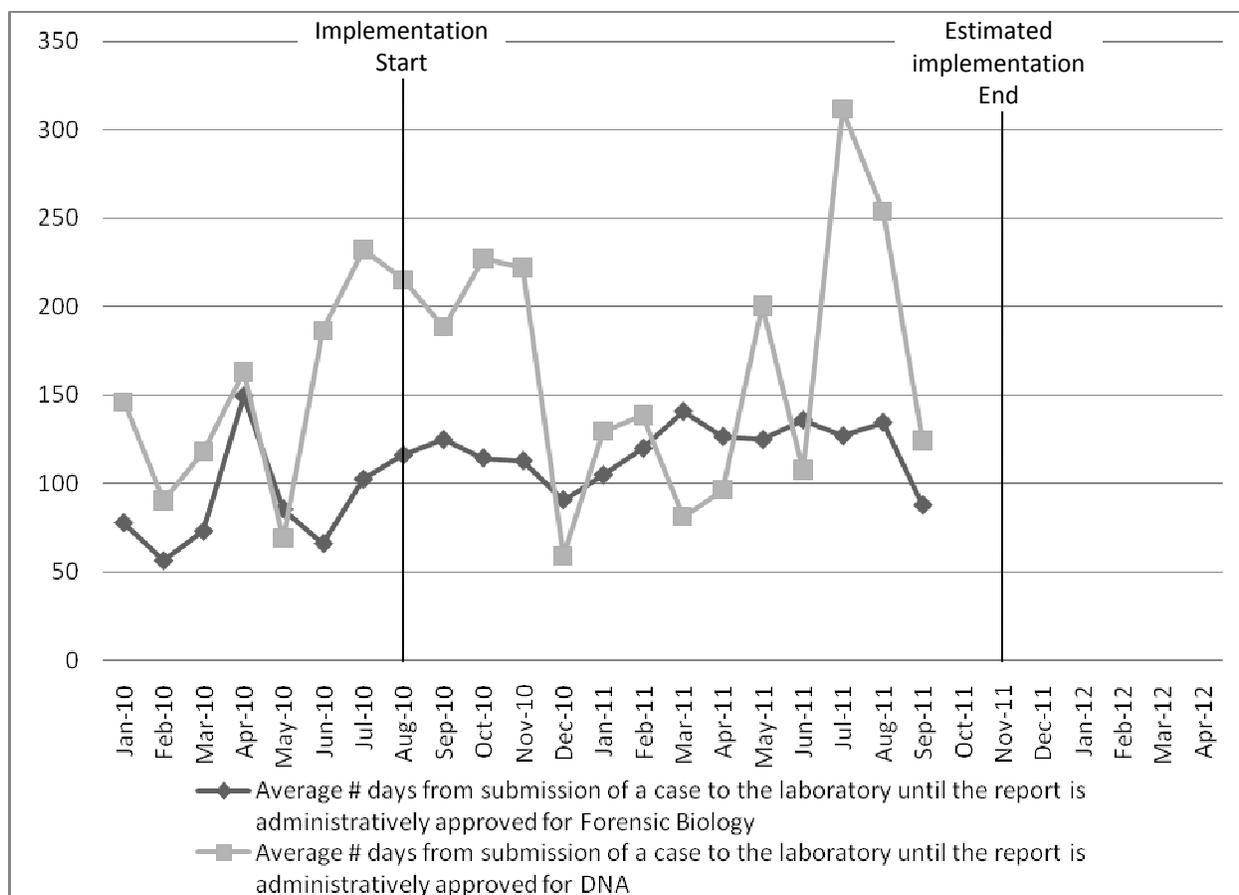


Figure 4-6. Turnaround time.

Table 4-9. Summary of Turnaround Time

Turnaround Time	Mean	Pre-implementation Mean (Jan. 2010–July 2010)	Implementation Mean (Aug. 2010–Sep. 2011)
Average number of days from submission of a case to the laboratory until the report is administratively approved for forensic biology	108.1	87.2	118.5
Average number of days from submission of a case to the laboratory until the report was administratively approved for DNA	160.1	143.7	168.3

4.2.3 Cases Analyzed Per Analyst

As shown in **Figure 4-7**, analyst caseload, which was calculated by dividing the number of cases that analysts were assigned by the number of analysts employed, remained fairly steady over the data collection period with the exception of a spike in forensic biology caseload

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occurring in February 2011. This spike appears to be related to staffing issues during this month. For example, one forensic biologist was out of the office for that month and three others were undergoing training. The mean analyst caseload for the entire period was 20 cases for forensic biology analysts and 12 cases for DNA analysts (**Table 4-10**). The mean analyst caseload for both forensic biology and DNA were higher in the implementation period than in the preceding months.

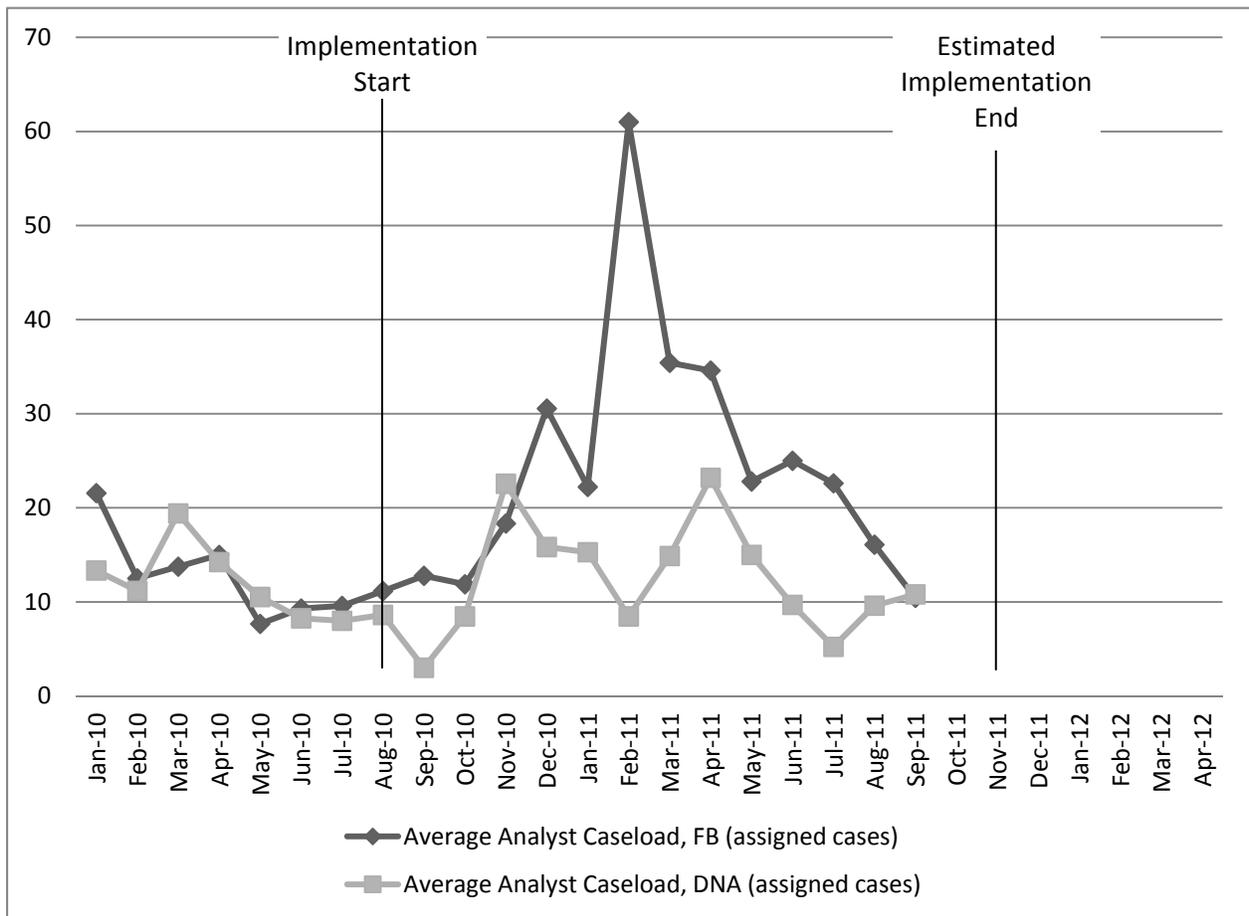


Figure 4-7. Analyst caseload.

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Table 4-10. Summary of Analyst Caseload

Calculated Performance Metrics	Mean	Pre-implementation Mean (Jan. 2010–July 2010)	Implementation Mean (Aug. 2010–Sep. 2011)
Average Analyst Caseload, FB (assigned cases)	20.2	12.8	23.9
Average Analyst Caseload, DNA (assigned cases)	12.2	12.1	12.2

4.2.4 DNA Case Backlog

The total DNA case backlog for the DPD laboratory was calculated by summing the number of cases that have not been assigned to either a forensic biologist or DNA analyst and cases in which the forensic biological analysis has been completed and is waiting assignment to a DNA analyst. As shown in **Figure 4-8**, there was a larger number of backlogged DNA cases at the end of the data collection period than the beginning. The mean number of total backlogged cases was 475, and the mean number of backlogged property crime cases was 180 (**Table 4-11**). Although the mean of the total backlog was essentially the same in both the pre-implementation and during implementation time periods, the mean number of cases in the property crime backlog more than doubled from 90 prior to implementation to 193 during implementation.

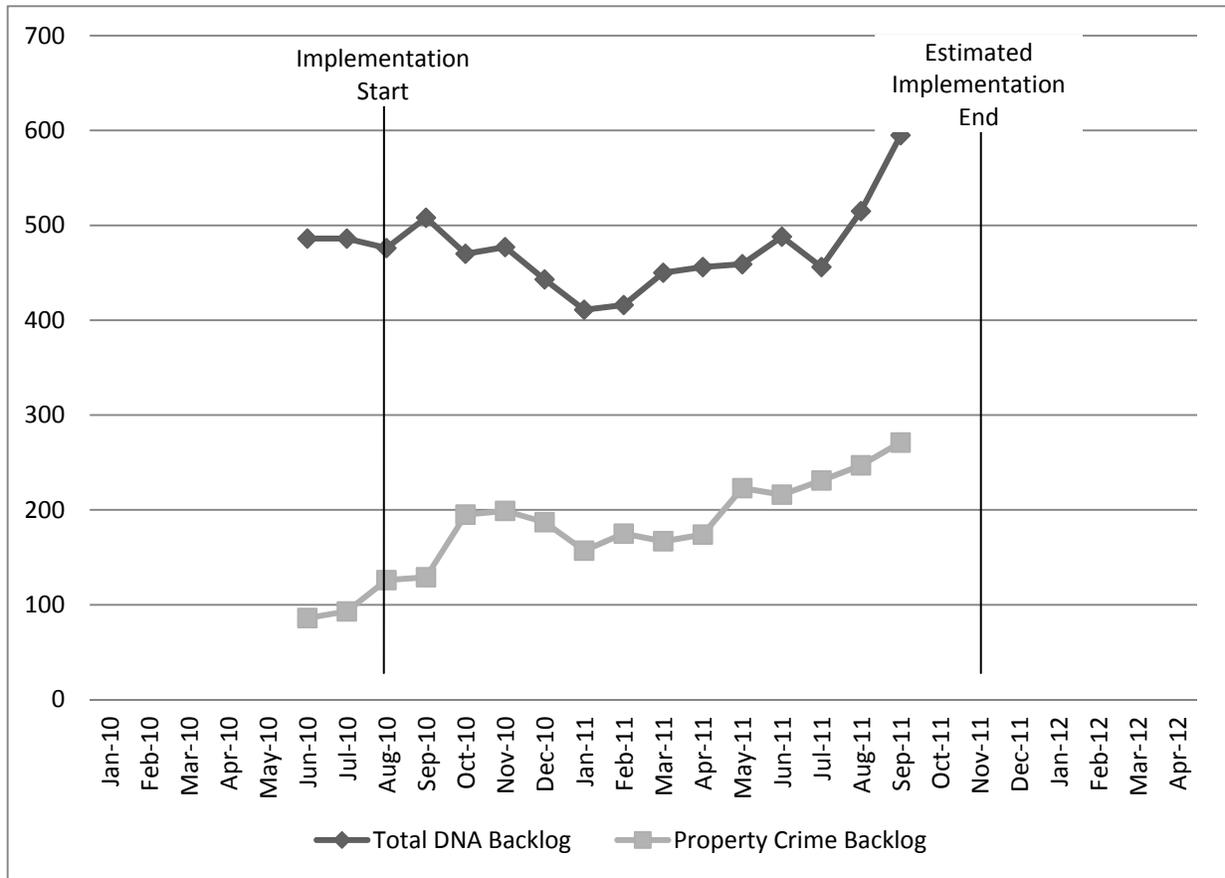


Figure 4-8. Backlogged cases.

Table 4-11. Summary of Backlog

Calculated Performance Metrics	Mean	“Implementation Start” and “Implementation End” (respectively)	“Implementation Start” and “Implementation End” (respectively)
Total DNA backlog	474.5	486.0	472.9
Property crime backlog	179.8	89.5	192.6

4.2.5 CODIS Matches

CODIS outcomes were measured as the number of matches between: (1) convicted offender and forensic unknown, and (2) crime scene stain and forensic unknown. As shown in **Figure 4-9**, the number of CODIS hits varied over the entire data collection period, with a spike in November 2010. The mean number of CODIS matches for the entire period was 19 for convicted offender matches and 6 for crime scene stain matches (**Table 4-12**). The mean

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numbers of matches for both convicted offender and crime scene samples were slightly higher in the implementation period than in the preceding months.

Additionally, DPD staff felt that the efficiency gained through the 13 mini-EIPs indirectly resulted in more CODIS entries. The CODIS report was revised to be more user-friendly, which made it easier (and quicker) to complete.

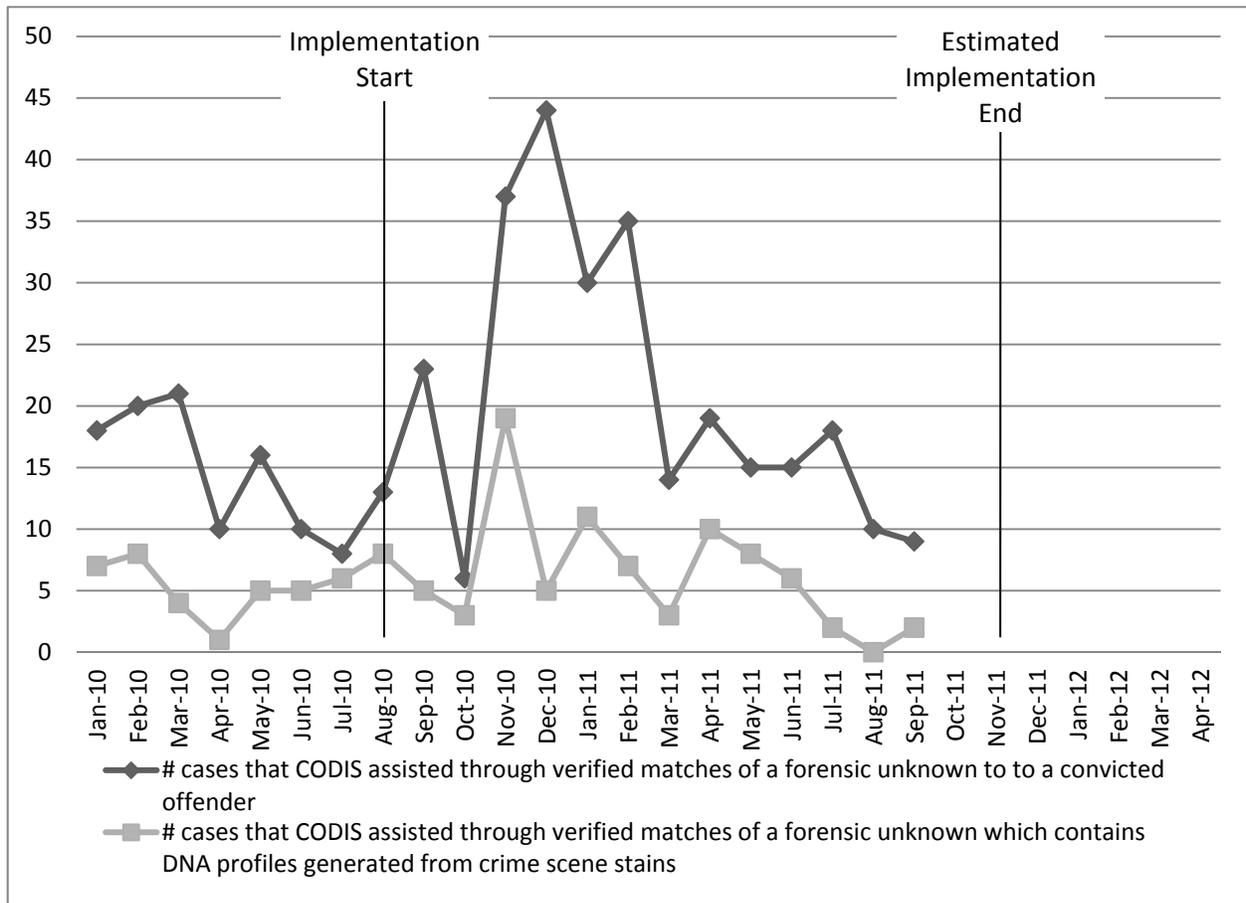


Figure 4-9. CODIS Matches

Table 4-12. Summary of CODIS Matches

Metric	Mean	“Implementation Start” and “Implementation End” (respectively)	“Implementation Start” and “Implementation End” (respectively)
Number of cases that CODIS assisted through verified matches produced by CODIS (includes NDIS and SDIS databases) for submitted convicted offenders (there is a match of a forensic unknown to a convicted offender)	18.6	14.7	20.6

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Metric	Mean	“Implementation Start” and “Implementation End” (respectively)	“Implementation Start” and “Implementation End” (respectively)
Number of cases that CODIS assisted through verified matches produced by CODIS (includes NDIS and SDIS databases) for a forensic unknown, which contains DNA profiles generated from crime scene stains (there is a match of a forensic unknown to another forensic unknown)	6.0	5.1	6.4

4.2.6 Improved Capacity or Other Benefits

DPD adopted 13 mini-EIPs during the implementation phase of their project, resulting in a range of improvements (see Table 3-2).

4.3 Oklahoma State Bureau of Investigation (OSBI)

4.3.1 Overview

OSBI’s EIP involved optimizing and validating the use of Applied Biosystem’s Identifiler® Direct amplification kit for use on buccal swabs; however, this use was not actually implemented in the laboratory. Because the new technique was not used on actual cases, the standard set of performance metrics developed for this evaluation (i.e., turnaround time, analyst caseload, backlogged cases, and CODIS matches) are not relevant to measuring the impact of this EIP. The evaluation team collected these metrics in the event that the amplification kit would be adopted. If OSBI decided to adopt the Identifiler® Direct amplification kit for use on buccal swabs in the future, an evaluation of its performance in real-world conditions could be conducted. For example, OSBI could continue to calculate and track this standard set of metrics for a period before and after the amplification kit is adopted. Although this EIP was not adopted, it does shed light on the plausibility of directly amplifying DNA samples collected on buccal swabs.

4.3.2 Average Monthly Turnaround Time

Not applicable.

4.3.3 Cases Analyzed Per Analyst

Not applicable.

4.3.4 DNA Case Backlog

Not applicable.

4.3.5 CODIS Matches

Not applicable.

4.3.6 Improved Capacity or Other Benefits

As a final study, OSBI completed a parallel study of the selected optimized method (Method 16) using the laboratory's current sample collection device (FTA card) and the proposed EIP sample collection device (buccal swabs). This side-by-side comparison (**Table 4-13**) was made between buccal samples lysed using Method 16 and FTA cards amplified according to the Identifiler® Direct recommended procedures using two separate genetic analyzers.

Table 4-13. Summary OSBI Side-by-Side Comparison Study

Sample Type	Genetic Analyzer	Average RFU (5 seconds)	Average RFU (10 seconds)	Average PHR (5 seconds)	Average PHR (10 seconds)	% Pass	% Artifacts
Buccal swab	3130	1257	2039	85.34%	85.64%	63	17
FTA Card	3130	2836	4420	87.19%	88.42%	88	58
Buccal swab	3730	725	1327	86.69%	86.34%	58	4
FTA Card	3730	1892	3483	87.31%	87.64%	100	0

Source: Modified from OSBI Final Report.

RFU = Relative Fluorescent Unit or peak height scale. Higher value better resolution of sample peak above background signal (better detection threshold).

PHR = Peak Height Ratio. Defined by SWGDAM as the Intra-locus, PHRs are calculated for a given locus by dividing the peak height of an allele with a lower RFU value by the peak height of an allele with a higher RFU value, and then multiplying this value by 100 to express the PHR as a percentage (closer to 100%, good DNA profile of one contributor; usually set at greater than 60% and determined for each loci). Higher value better resolution of sample peak above background signal (single DNA contributor). PHRs become more varied and have a lower value as the amount of DNA decreases.

The FTA samples had a better pass rate using both genetic analyzers, with 100% of the samples tested providing a full DNA profile (i.e., CODIS uploadable) on the first analysis attempt. For both buccal swab and FTA samples, the best overall results were obtained on the 3730 DNA analyzer. Although the swab samples only had a 58% pass rate on that analyzer, the majority of samples that did not pass were due to allelic dropout. This can be expected because the overall average Relative Fluorescent Unit (RFU) value for these samples was less than half the FTA samples. When examining the quantitation results for the optimized method (Method 16), the average amplification target range was 0.321 ng, which is much lower than the typical recommended range of 0.5–1.0 ng. OSBI recommends additional research to include an increase in the amplification template volume to 5.0 μ L to encourage the peak heights for the buccal samples to increase, thus providing an increased number of samples that should produce a full DNA profile and more consistent results between the buccal swabs and the FTA samples.

4.4 Palm Beach Sheriff's Office (PBSO) Crime Laboratory

PBSO's EIP is only partially implemented at this time. Although two laboratory analysts were hired, trained, and began conducting casework, renovation of the BPL is not complete, and the analysts are currently working out of PBSO. Given this partial implementation, two implementation dates are used for the purpose of examining outcomes: the date when the analysts began conducting casework at PBSO (July 2011) and the date when the BPL is completed (expected in March 2012). Metrics are presented below for the pre-implementation

(October 2009 to June 2011) and during implementation (July through September 2011) periods in the figures below.

Because the EIP was not fully implemented when the evaluation ended, performance metrics are only available prior to and during the implementation. As such, the evaluation team was unable to conduct a complete outcome evaluation. However, performance metrics were collected throughout the evaluation and are presented below for descriptive purposes. Performance metrics are only available for one quarter after the analysts began casework, which is not a sufficient period of time to assess outcomes. To evaluate the impact of the EIP on outcomes, these metrics should be calculated and tracked for a period after the implementation is complete (i.e., the BPL is up and running).

4.4.1 Average Turnaround Time

One of the primary anticipated outcomes of this EIP was a reduction in turnaround time. As shown in **Figure 4-10**, the turnaround time, measured as the number of days between the date when a case was submitted to the laboratory and when a report of the results was administratively approved, varied over the entire data collection period. The mean turnaround time for the entire period was 109 days; the mean turnaround time was slightly lower after initial implementation (**Table 4-14**).

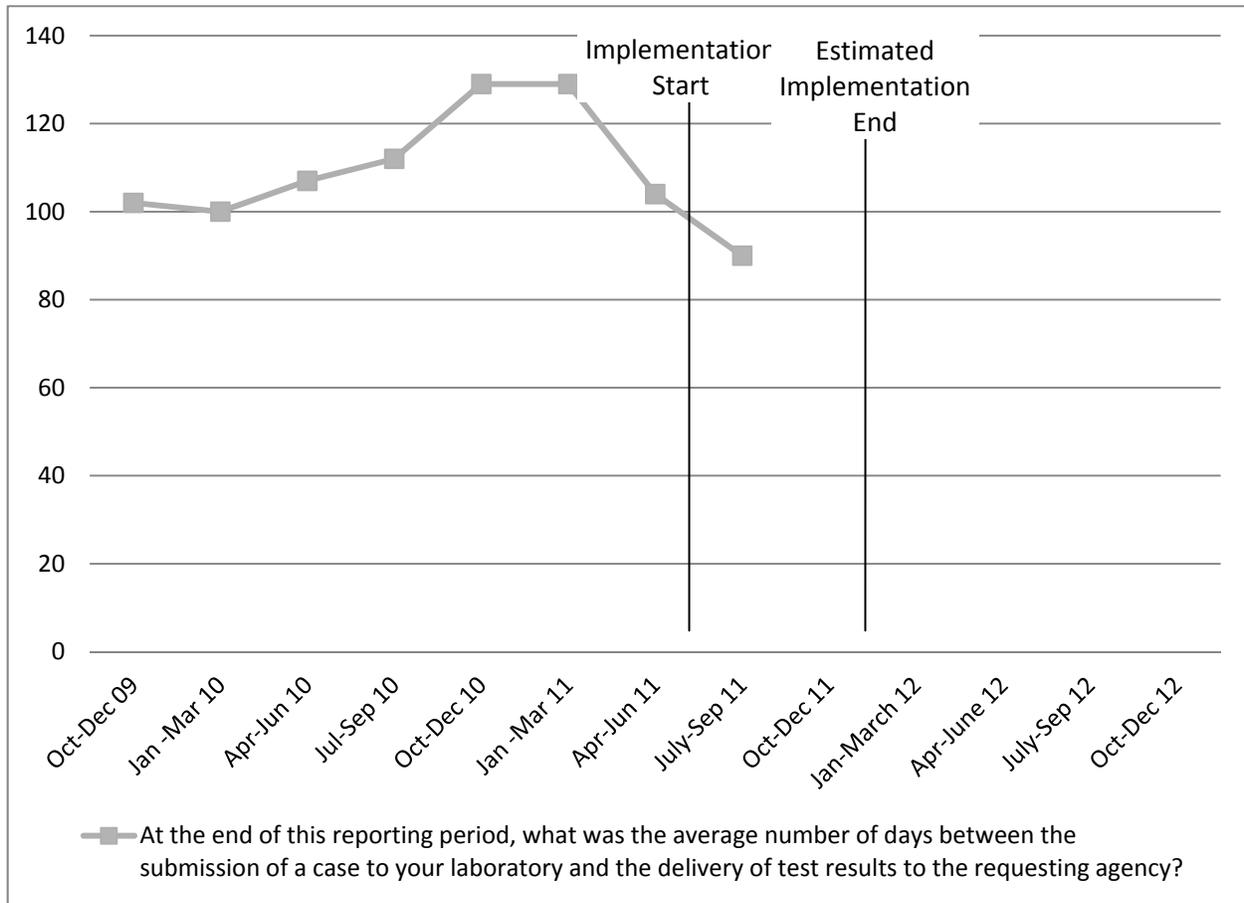


Figure 4-10. Turnaround time.

Table 4-14. Summary of Turnaround Time

Turnaround Time	Mean	Pre-implementation Mean (Oct 2009–June 2011)	Implementation Mean (July 2011–Sept. 2011)
At the end of this reporting period, what was the average number of days between the submission of a case to your laboratory and the delivery of test results to the requesting agency?	109	112	90

4.4.2 Case Requests

As shown in **Figure 4-11**, the number of cases that were requested for analysis by the law enforcement agencies to be served by the BPL (i.e., Boca Raton, Boynton Beach, and Delray Beach) steadily increased through 2011. The mean number of cases requested for the entire period was 55. On average, 50 cases were requested each quarter prior to implementation, but an

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average of 85 cases was requested after the BPL analysts began performing casework (Table 4-15). It is plausible that law enforcement officers at the BPL jurisdictions became more aware of PBSO due to the development of its BPL and contributed to this increase.

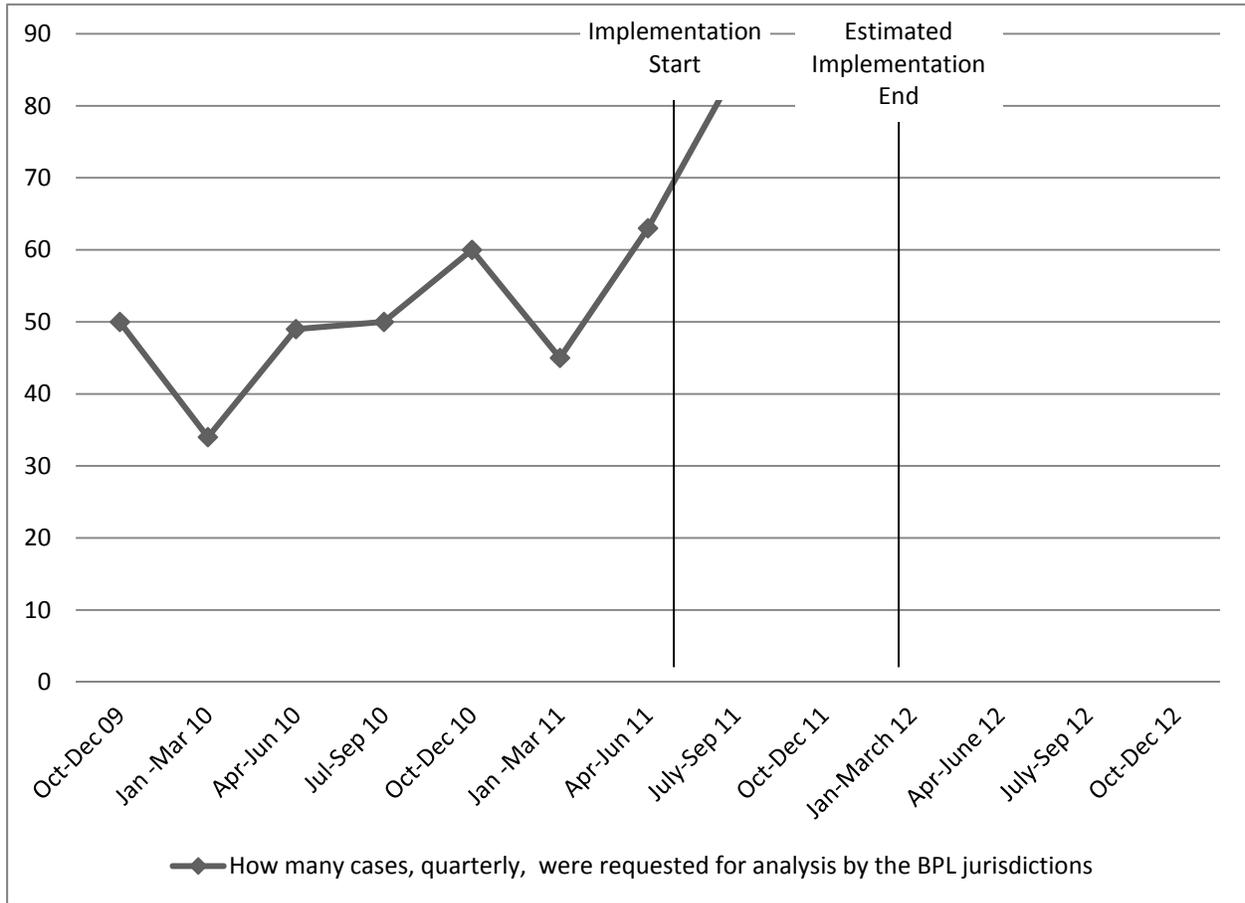


Figure 4-11. BPL Case requests.

Table 4-15. Summary of BPL Case Requests

Calculated Performance Metrics	Mean	Pre-implementation Mean (Oct 2009–June 2011)	Implementation Mean (July 2011–Sept. 2011)
How many cases (quarterly) were requested for analysis by the BPL jurisdictions?	55	50	85

4.4.3 DNA case backlog

Not applicable at this time.

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4.4.4 CODIS

CODIS outcomes were measured as the number of profiles entered and the number of hits. As shown in **Figure 4-12**, the number of profiles entered varied over the data collection period, whereas the number of CODIS hits was fairly stable. The mean number of CODIS matches for the entire period was 19 for convicted offender matches and six for crime scene stain matches (**Table 4-16**).

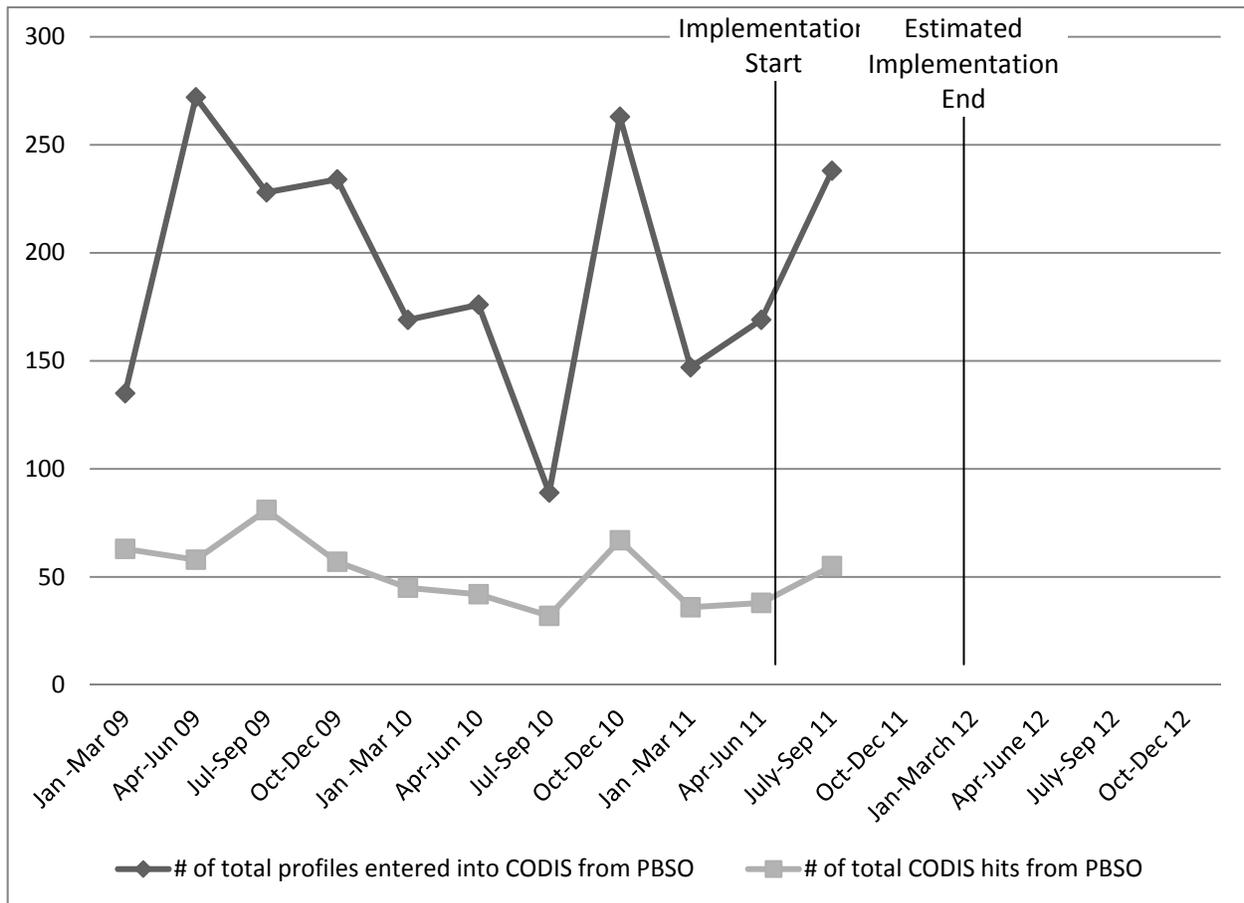


Figure 4-12. CODIS profiles and hits.

Table 4-16. Summary of CODIS Profiles and Hits

CODIS Matches	Mean	Pre-implementation Mean (Oct 2009– June. 2011)	Implementation Mean (July 2011– Sept. 2011)
Number of total profiles entered into CODIS from PBSO	193	194	238
Number of total CODIS hits from PBSO	52	51	55

4.5 University of North Texas Health Science Center (UNTHSC)

This evaluation report is premature for the completion of UNTHSC's 2009 EIP; therefore, it does not include a complete outcome evaluation. Currently, traditional performance metrics such as turnaround time, case backlog, analyst caseload, and CODIS matches were not collected for this EIP. It was determined that these metrics will only be applicable once software revisions are complete and training of laboratory staff is conducted. Instead, other performance metric studies were included as a preliminary evaluation effort.

4.5.1 Overview

The goal of the 2009 UNTHSC EIP is to integrate eFAST software of Mitotech into the newly developed expert system and enhance both software tools for mtDNA testing.

Additionally, a batch management software program (STATIS) was developed as the middleware that links eFAST software and the created expert system, MTexpert™. The system will automate the routine and repetitive tasks in interpreting mtDNA sequence analysis. One of the difficulties of evaluating the 2009 EIP was that it dovetailed with the 2008 EIP, making timing and many of the outputs and outcomes not easily separated.

The 2008 EIP Grant award focused on increased mtDNA processing efficiency through robotics, chemistry, and software. A reagent chemistry cost analysis showed an 11% decrease (\$3,127.17 to \$2,793.50) in cost for processing a batch of 86 samples with EIP improvements.

Changes in robotics and software development amounted to another 22% reduction (\$1051.29 to \$819.78) after implementation of the EIP. The improvement also produced consistent, high-quality sequence data, thereby increasing work flow efficiency. The eFAST software automated control analysis at the plate level, trace quality assessment, trace file management, and sample tracking, and it alerted the analyst of failed controls and overall plate performance. During the UNTHSC site visit by the RTI evaluation team, UNTHSC staff gave a demonstration of the robotics and eFAST v1.2 software.

With the continued development of the eFAST 2.0 software in the 2009 EIP, this automated software application will allow automatic review of the DNA Continuous Read Length (CRL) and Traces Sequences (TS) of the mtDNA sequence data. The MTexpert™ system for the 2009 EIP will be exploring software programming that performs all analysis and review functions without human intervention. The expert system will allow accurate sorting of traces and facilitate downstream processing and analysis.

Ultimately, the MTexpert™ system will replace the required “second read” by a qualified analyst. This system will automatically evaluate DNA sequences and pass only those that meet all of the required set standards and flag those that do not. Those samples that fail will then be subjected to a manual second read by a qualified analyst. Those that pass review will continue through the administrative review by an analyst and will be entered into the FBI’s CODIS database system. This MTexpert™ system is designed to dramatically improve sample turn-around times. **Table 4-17** summarizes the development goals and capabilities of the MTexpert™ software.

Table 4-17. Development Goals of the MTextpert™ Software

2009 EIP Software	
What MTextpert™ Can Do	What MTextpert™ Cannot Do
<ul style="list-style-type: none"> Identifies peaks and bands Assigns alleles Ensures that data meet laboratory-defined criteria (trims traces based on quality value thresholds) Describes the rationale behind the decisions (calls bases with an associated quality value) Ensures that there will be no incorrect calls (assemble traces to a reference) 	<ul style="list-style-type: none"> Call polymorphisms (i.e., differences) according to designated nomenclature Alert the analyst of a specific data issue (e.g., homopolymeric regions, heteroplasmy, mixtures, rare variants) Replace the analyst review completely Automatically check for concordance of calls and agreement between two reviews (“reads”)

At this time, traditional performance metrics cannot be measured as part of the outcome evaluation, but other evaluation studies are included. **Figure 4-13** shows data obtained in the initial stages of development for samples during eFAST version 1.0 verification. At the time of this report, the current versions of the expert system software are eFAST version 1.2 and MTextpert™ version 2.0.

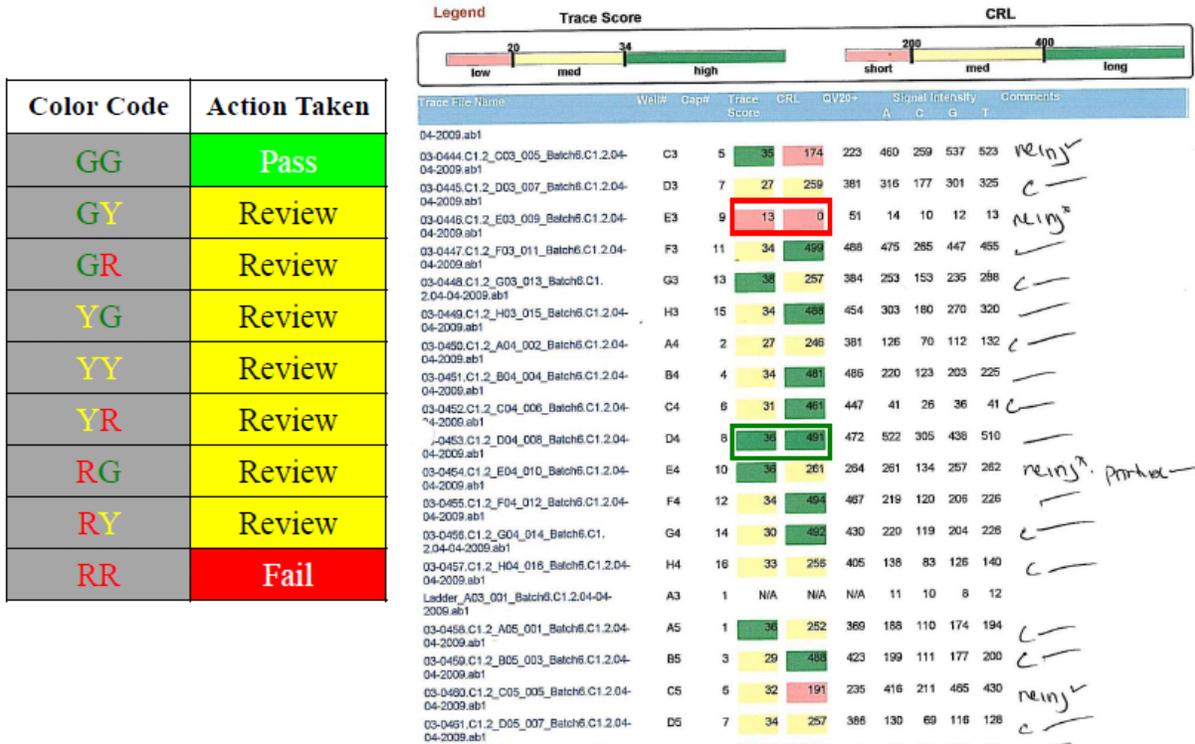


Figure 4-13. Example of eFAST v1.0 verification data.

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4.5.2 Average Monthly Turnaround Time

Not applicable at this time.

4.5.3 Cases Analyzed Per Analyst

Not applicable at this time.

4.5.4 DNA Case Backlog

Not applicable at this time.

4.5.5 CODIS Matches

Not applicable at this time.

4.5.6 UNTHSC Outcome Studies

Because the traditional laboratory performance metrics were not applicable at the time of this report, RTI and UNTHSC looked at other ways to evaluate the progress of the software development. These traditional performance metrics should be collected once the software revisions are complete and DNA samples can be effectively processed by eFAST and MTextpert™. Four metric studies were proposed as outcome measures for the evaluation. At this time, one of the four studies has been completed; the other three studies are still in progress. The laboratory started to conduct several of the metric studies discussed below, but the time savings was not accurate with the current software “glitches” that remain unresolved. RTI will not report on these, but this information can be reported in UNTHSC’s final report.

4.5.6.1 Study #1: Calculate consistency and time savings for MTextpert™ version 2.0.

Normal procedures within UNTHSC CHI require two casework analysts to review family reference samples (FRS) data independently and save their reviews in a shared drive on the

network. Analysts will discuss (by e-mail or in person) and review conflicts of a batch. The time for the total review and follow up will be documented for one or more batches (86 samples) along with the review data. Upon completion by the casework analyst, a UNTHSC RDL laboratory analyst will take profiles from Analyst 1 and Analyst 2 and run with Mitotyper software, documenting the required time to complete. The time and discrepancies on these batches will be compared as an additional evaluation of MTexpert™ version 2.0. It is expected that there will be minimal or no discrepancies and that the time reduction for MTexpert™ will be small. There are no current metrics to report at this time.

4.5.6.2 Study #2: Evaluate the time savings achieved using MTexpert™ software by having three casework analysts review three batches of FRS data for second reads.

The time required for the initial review of each batch will be documented. Similarly, the same FRS batches will be reviewed with MTexpert™, and the time to complete will be recorded. It is expected that a time savings will be demonstrated with MTexpert™ review. There are no current metrics to report at this time.

4.5.6.3 Study #3: Evaluate concordance with challenging casework samples.

All analysts training at UNTHSC process challenge samples or samples known to be complex and more difficult to review (for competency). This study evaluation determines if challenging samples would be called correctly with MTexpert™ system in comparison to casework analysts. Original sequence files were obtained for 29 challenged samples. These files were imported into MTexpert™ and analyzed using the Mitotyper rules by Analyst 1 (Budowle, 2010; Wilson, 2002). The profiles obtained by MTexpert™ were reviewed and compared by

Analyst 2, a UNTHSC CHI casework analyst, using Sequencher. Results of this study are summarized as follows by UNTHSC in a report (dated August 8, 2011) sent to RTI:

- 25 mtDNA profiles were concordant (in agreement)
 - **Samples 1–23:** Same differences reported in HV1 and HV2 DNA regions by both analysts.
 - **Sample 24:** Length heteroplasmy in HV1 reported by MTextpert™ Analyst, but not Analyst 2. HV2 was concordant.
 - **Sample 25:** Identified as a mixture by both Analysts.
- Three samples were called incorrectly by Analyst 2 (casework analyst), but correctly by MTextpert™ according to Mitotyper rules
 - **Sample 26:** Analyst 1 (MTextpert™) called a length heteroplasmy that was not reported by Analyst 2
 - **Sample 27:** Analyst 1 (MTextpert™) called an insertion at Position 58; Analyst 2 called this insertion at Position 56
 - **Sample 28:** Analyst 1 (MTextpert™) called an insertion at Position 57.2 and a deletion at 66; Analyst 2 called this insertion at Position 60.1 and a deletion at 71.
- One Sample (**Sample 29**) not properly aligned by MTextpert™ due to homopolymeric C-stretch in HV1. The software was updated based on this finding.

Thus, these data demonstrated a high concordance between current review procedures used in the casework laboratory and reviews performed with new MTextpert™ software. Only one call made by MTextpert™ was questionable and resulted in a software update.

DNA Expert Systems should:

- Meet the NDIS DNA Data Acceptance Standards (Appendix B4, www.fbi.gov)
- Be commercially available
- Be configurable off-the-shelf (COTS) software
- Be fully accommodated within the laboratory facility
- Not require user to know or self-program computer code

4.5.6.4 Study #4: Calculate the time for analysts to process three batches (86 samples with at least one-third of the batch containing mtDNA) and compare the time for MTexpert™ to process the same batches.

Although the current software already demonstrates a time savings, this calculation is being postponed until final software revisions and implementations can occur. This implementation did not occur by September 2011. Follow up of this metric will be performed by UNTHSC and could be reported as part of the laboratory's EIP, which will end in June 2012, based on UNTHSC's current NCE.

4.5.7 Improved Capacity or Other Benefits

The development of this expert system software has the potential to greatly enhance the review process of mtDNA testing in much the same way that expert systems for nuclear DNA revolutionized laboratory practices. Upon completion, this mtDNA Expert system should meet the requirements (see inset box) set forth by the NEXT project for autosomal DNA. As part of the final EIP evaluation of this expert system, other judgment criteria should include the ease of the purchasing process, vendor optimization of the general analysis parameters and laboratory-specific analysis parameters, the vendor's customer service and training record, and software characteristics such as utility, processing speed, analysis speed, and appropriateness of available system parameters (e.g., flags, rules, criteria, features) (Roby & Jones, 2005).

Casework review by the analyst is by far one of the continued bottlenecks for mitochondrial testing, because more DNA regions must be evaluated. Efficient data analysis software systems such as eFAST, STATIS, and MTexpert™ will improve laboratory workflow by reducing data review time, implementing additional and automated quality control parameters, and improving the integrity of forensic data. This improved capacity will impact the community as the ability of a forensic laboratory to process an increasing numbers of samples

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with the same or less resources in a shorter amount of time will greatly enhance the criminal investigative process.

5. COMPARISON OF FINDINGS ACROSS EIP SITES

The comparison of laboratories for this EIP was complicated. The laboratories are diverse, and many metrics and outcomes used to evaluate an EIP could not be used appropriately to compare across laboratories. Characterizations of the laboratories, such as the type of DNA testing performed, the types of samples collected, size and type of EIP efficiency, definitions used for laboratory metrics, timelines of EIPs, and other challenges, were important to consider during the evaluation process.

5.1 Comparison of EIP Laboratories

Four of the laboratory EIPs involve casework testing, and one laboratory (UNTHSC) is a research laboratory that does not analyze forensic DNA cases as a “core facility.” The four EIP laboratories performing casework did so using nuclear (autosomal) DNA, and the research laboratory analyzes primarily mtDNA, but can also perform STR and Y-STR (standard tandem repeats) analysis. The type of casework included violent crime and property crime cases. Violent crimes (i.e., major crimes) include forced crimes against a victim, such as homicide, non-negligent manslaughter, aggravated (physical) and sexual assault, and robbery. Property crime (i.e., minor crime, “victimless” crime) is non-violent and includes vandalism, burglary, and grand theft, where only physical “property” is affected. One laboratory’s EIP (OCCL) was specific to property crime. Another laboratory’s EIP (OSBI) was specific to offender sample analysis, although this EIP was a method validation that was not ultimately implemented or tested on actual casework. One laboratory (UNTHSC) analyzed family reference samples for missing and unidentified remains cases. Two EIP laboratories (PBSO and DPD) performed both violent and property crime casework.

Laboratories vary in defining terms for the work that is implemented. This is particularly true for defining turnaround times, DNA backlogs, and casework per analyst. For consistency in evaluation, it is important that definitions and terms be the same for all laboratories. RTI, using input from all EIP laboratories and DNA consultants, developed a list of standardized definitions that were included as part of the data collection of performance metrics (this list is provided in **Appendix C**). Unfortunately, the effort to have shared definitions proved to be difficult to achieve and created stress on the laboratories to collect data within the framework of the proposed definitions. Hence, some laboratories opted to use their established definitions as this could be collected more readily and was less of a burden (e.g., OCCL average analyst caseload), while other laboratories (UNTHSC) could not collect the requested performance metrics. Still other laboratories (OSBI, DPD, PBSO) collected the requested performance metrics, but the metrics were not affected by the implemented EIP (i.e., OSBI did not casework samples for the EIP) or at the time of this report.

Due to the variety of sizes and types of EIP efficiencies, there were not enough consistent variables to compare and contrast from one EIP to the next. Instead of a traditional outcome evaluation, RTI has included longitudinal overviews outlining the strengths, weaknesses, and unique aspects of the EIP at the point at which the final evaluation report was prepared on November 15, 2011. In almost all instances, qualitative findings, not quantitative metrics, were most appropriate. This evaluation method was used as an improved way of documenting findings and exploring potential efficacies.

5.2 Challenges to Comparison of Findings for EIP Sites

The previous section described the variability of the EIP laboratories and their process and purpose of testing specific to their EIP. In addition to these barriers for comparing EIP

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across laboratory sites, there are a number of challenges to our ability to synthesize and compare findings across the five sites, as shown in Table 5-1.

Table 5-1. Challenges for Comparison of DNA Unit Laboratory EIP

Challenge	Characteristic	Example
Unique EIPs	Focus	
	Strategies	Process mapping/simulation
		Adding BPL and analysts dedicated to evidence screening
		Dedicating staff to specific crime type
		Triaging cases
		Developing high-throughput DNA analysis line
		Eliminating extraction step
	Validating expert systems	
Casework Involvement		Three EIPs involved casework samples; two did not
Timing of Completion of EIP Evaluation vs. EIP Implementation		Two EIPs implemented at time of this report; three not fully implemented

In reality, these EIPs cannot be compared to each other in totality because each is distinctly different in its processes (see **Table 5-2** for a summary of processes by EIP). Considering all the findings, each EIP has an application that could be valid for another laboratory, given the appropriate circumstances. For instance, here is a case scenario of a hypothetical Full-Service DNA Analytical Laboratory (FSDAL) that could ideally explore all of the evaluated EIP given their explicit needs:

*Use SIMUL8 (per the EIP of **DPD**) to create the optimum laboratory – facility, equipment, supplies, personnel, etc. Then the FSDAL could use the EIP developed by **OSBI** to perfect their CODIS Unit. If the FSDAL also was in an area experiencing a large number of burglaries, then it could also choose to establish a separate property crime analysis line, as delineated by the EIP developed by **OCCL**. Since FSDAL services multiple high-volume agencies, then it may benefit them and their agencies to allow the agencies to develop a regional type*

*screening laboratory that would process evidence before sending it to FSDAL, thereby minimizing FSDAL's burden based on the EIP developed by **PBSO** to maximize that potential. As FSDAL is a full-service laboratory, its mitochondrial testing could also benefit from the expert system used by the EIP developed by **UNTHSC**.*

Thus, the EIPs developed by these laboratories can have application to other laboratories if they also have these particular scenarios, but the EIPs do not have a commonality amongst themselves that could be effectively compared and contrasted. However, this evaluation describes how the EIPs can benefit other laboratories and how the documented lessons learned could be prevented or taken into account during subsequent EIP implementation to add further efficiency and understanding of the processes.

The compilation of these lessons learned are the basis and focus of the next section, *Implications and Recommendations*, for laboratories to consider for their EIPs.

Table 5-2. Summary of DNA Unit EIP Laboratory Process

Process	DPD ^b	OCCL	OSBI ^c	PBSO ^d	UNTHSC ^e
Staff for the EIP	3 + Bio staff input (12)	8 + 2 if needed	7	2 + administrative staff	4 at UNT; unknown at Mitotech
Sample Types	All types	Swabs, property, blood, saliva	Buccal swabs	All types	Blood, bones, teeth, tissue
Sample Preparation	Bio screening: cuttings, swabs, reference samples	Cutting swabs	Cutting swabs	Bio screening: cuttings, swabs, reference samples	Physical removal of bone marrow or root pulp, cut tissue
Extraction ^a	Qiagen EZ1 extraction robots	Qiagen EZ1 extraction robots & Tecan HID EVOLution robot	Lysis step only	N/A	Tecan Freedom EVOLution 200 robot Promega Maxwell 16
Quantitation setup	Corbett CAS 1200 robot	Qiagen Universal BIORobot	N/A	N/A	N/A
Quantitation ^a	AB 7500	AB 7500	N/A	N/A	AB 7500
Amplification setup ^a	QiaSymphony robot	Qiagen Universal BIORobot & Tecan HID EVOLution robot	Biomek 3000 & Biomek FX robots	N/A	Tecan MiniPrep robot Promega Maxwell 16
Amplification (thermocyclers) ^a	AB 9700	AB 9700	AB 9700	N/A	AB 9700
Post amplification setup	Corbett CAS 1200 robot or QiaSymphony robot	Corbett CAS 1200 robot or QIAgility robot	Biomek 3000 & Biomek FX robots	N/A	Tecan MiniPrep robot Promega Maxwell 16
Allele Detection	AB 3130xl CE	AB 3130xl CE AB 3500 CE	AB 310 CE AB 3130xl CE AB 3730 CE	N/A	AB 3130xl CE AB 3500 CE
Data Interpretation	GeneMapper IDX	GeneMapper IDX	GeneMapper IDX	N/A	eFAST & MTextpert™
Data Review	Scientists	Scientists	Scientists	Scientists	Scientists

^a The use of robotics by each laboratory was not defined or designated for which process they were being used in. Robotics are interchangeable and can be used in the extraction, quantitation, amplification, and post-amplification stages.

^b Equipment was not purchased under this EIP other than a computer and the SIMUL8 software. The rest of the EIP funds were for personnel, including a new hire specific to EIP funding. The use of the DNA equipment listed is just for illustrative purposes.

^c The EIP funding was for overtime and supplies, not equipment. The use of the DNA equipment listed is just for illustrative purposes. The swabs underwent a lysis step but no extraction or quantitation.

^d The “not applicable,” or N/A, is more for the DNA analysis portion as the PBSO BRL is a bio-screening lab and no DNA equipment was purchased.

^e Equipment was not purchased under this EIP other than the developed eFAST, and MTextpert™ software. The use of the DNA equipment listed is just for illustrative purposes. The swabs underwent a lysis step but no extraction or quantitation.

6. IMPLICATIONS AND RECOMMENDATIONS

6.1 *Recommendations for Implementing EIPs*

Developing a successful efficiency model for forensic laboratories can have a direct impact on criminal justice practice and policy. If laboratories become more efficient in processing and analyzing DNA samples, direct benefits can be realized in criminal investigations and prosecutions, as well as in exonerating innocent people convicted of serious crimes. While this project was intended to identify promising approaches for improving laboratory functioning and reducing DNA case backlogs, laboratory delays in getting the EIPs up and running made it impossible to assess change in key performance metrics at the time of this report. Either insufficient time has elapsed since DNA Unit EIP implementation, or EIP implementations were not fully implemented. However, laboratories attempting to improve efficiency should be aware of the challenges some of the laboratories faced in implementing these EIPs.

The implementation of any new process, new hires, laboratory equipment or software, or policies necessitates the optimization of communication. Whether it is between management and laboratory personnel, team members, partners, and/or stakeholders of the EIP, the success of all five of the evaluated EIPs was heavily determined by communication before, during, and after EIP implementation. While all five laboratories experienced some delays in their EIPs, it was clear that those laboratories that fostered more communication were often much faster and efficient at resolving issues and implementing solutions.

Laboratory managers should be aware that making changes within a laboratory may take more time than originally expected. All five laboratories in this evaluation were not able to implement their EIPs according to their original schedule. Realistic timelines with achievable milestones should be developed at the outset. This would alleviate the necessity to ask for

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repeated time extensions. Research and planning of an EIP prior to its implementation minimizes or eliminates project delays, team member frustration, under budgeting, and incomplete or abandoned EIPs.

Approaches that involve coordinating with other partnering agencies (e.g., District Attorney's offices or multiple law enforcement agencies) may require significant administrative effort. Finalizing legal processing and executing collaborative agreements may take a significant amount of time. Furthermore, the roles and responsibilities of each party should be determined early on in the process, and it is essential that they are agreed upon and understood by all parties involved.

Additionally, if efficiency strategies involve the use of new software or equipment, laboratory managers should be aware that there may be a significant learning curve in fully understanding its potential in the laboratory. Managers should plan for adequate time and funds to support staff that will be using new technologies.

The success of implementing any changes in a laboratory setting hinges on the staff's willingness and ability to accept and adapt to these changes. Before undertaking any major change, it is important to engage the staff that will be affected and involve them in the process of proposing solutions and providing feedback about plans for change. The value of defining challenges and proposing solutions supports an organizational culture of continuous improvement and of openness to change.

Similar to staff acceptance of an EIP, it is also essential that laboratory management accept and promote an EIP. If the Criminal Justice System leaders and laboratory management are actively involved with the EIP during planning and execution, their ability to promote and route it through the system is much greater. It is always important to keep in mind the possibility

for unanticipated changes within the laboratory, some of which may impact the success of a plan to improve efficiency. Changes in staffing or funding levels, for example, may impede the ability of a laboratory to implement desired improvements.

6.2 Recommendations for Evaluating EIPs

Evaluating EIPs is an essential step toward identifying strategies that have demonstrable impacts in improving laboratory efficiency. Based on our experiences conducting this evaluation, RTI has several suggestions for future work in this order.

First, in order to assess the impact of an EIP on various outcomes, the evaluation performance period must be longer than that of the laboratory in order to collect data post-implementation, conduct analyses, and report the results. This evaluation was limited in this regard because, while the laboratories were funded as grants and were allowed NCEs to complete EIPs, the evaluation was funded as a contract with a maximum extension of 6 months. This limited the evaluation to primarily focusing on the process component of the evaluation. While process is certainly important, the results would have been more useful had outcomes been assessed as well.

Second, it is also challenging to generalize findings from an evaluation of a small number of unique EIPs. As described in **Section 5**, the five EIPs evaluated herein cannot be compared to each other in totality as each is distinctly different. Given the composition of EIPs here (and the lack of post-implementation outcomes for most laboratories), we are unable to determine whether a specific type of EIP has the potential for success at the point of this evaluation report as too little time has passed since implementation of the one laboratory that has completed their EIP. In these types of situations, conducting a series of case studies for each laboratory is more appropriate. However, if EIPs are similar and a large number are awarded, then a multi-site

evaluation that includes comparison sites should be conducted. This would allow for more generalizable findings about the impact of a particularly efficiency strategy.

Third, careful and thoughtful planning of an EIP evaluation is another consideration that should be included as early as possible in an EIP process. There are many reasons why an EIP should be evaluated, and the timing of the evaluation is a key component. The laboratory can include an internal evaluation that helps them document the process and its outcomes to management and key stakeholders, as well provide insight into how to improve an EIP in the future. Similarly, an external evaluation performed independently of the EIP allows the laboratory to focus on the EIP purpose and goals and can minimize laboratory biases. Prospective evaluations that occur simultaneously with the EIP can often times have a greater impact, questions can be answered much earlier, and EIP and evaluation findings can allow for interventions and streamlining of the EIP process.

Fourth, it is a good practice to define terms for the EIP process and any performance metrics to be collected. For example, turnaround times, DNA backlogs, and case work per analyst are not standardized from one laboratory to the next. For consistency in evaluation, it is important that definitions and terms be the same for all laboratories. Unfortunately, the effort to have shared definitions under the current evaluation proved to be difficult to achieve and created stress on the laboratories to collect data within the framework of the proposed definitions.

Fifth, due to the variety of sizes and types of EIP efficiencies, there were not enough consistent variables to compare and contrast from one EIP to the next. Instead of an outcome evaluation, longitudinal overviews outlining the strengths, weaknesses, and unique aspects of the EIP would be an improved way of documenting findings and exploring potential efficacies.

This report also has some consideration for guidelines and recommendations for making an EIP evaluation more successful. RTI recommendations to improve an EIP evaluation include the following:

- **Agreement of Project Extension Requirements for EIP Grants and Evaluation**

Project—The deliverables of this contract were significantly impacted because the outcome evaluations could not be completed in the time allowed by NIJ. While RTI was only granted one 6-month NCE to January 14, 2011, all five laboratories were allowed NCEs up to the month before RTI’s completion date (one laboratory) or 3 to 12 months beyond RTI’s completion date (four laboratories). As such, the deliverables of the RFP and proposal could not be met. **Table 6-1** highlights the current status of the EIPs in relation to the evaluation type that RTI can complete, as well as and EIP implementation and NCE dates.

Table 6-1. 2009 DNA Unit EIP Status and Planned Evaluation Type

Laboratory	EIP Implementation Date	NIJ Approved No Cost Extension Date	Evaluation Type
DPD	9/1/11 (estimated)	5/31/2012	Process only. Software will be validated, but not fully implemented into the laboratory casework
UNTHSC	3/1/12 (estimated)	12/30/2012	Partial process only (software design will not be completed or validated in 2011)
OCCL	4/1/11	6/30/2012	Process and short-term outcomes
OSBI	3/1/11 (estimated)	12/31/2011	Process and outcome specific to EIP, but not implemented in laboratory (ongoing research project)
PBSO	1/15/12 (estimated)	9/30/2012	Partial process only (BPL will not be built before final report is due)

- **Optimization of Communication**—Regular communication between the evaluation team and the key laboratory staff participating in the EIP is critical to performing and documenting a process and outcome evaluation. RTI chose to have, at a minimum, one

monthly scheduled call with each laboratory once laboratories moved well into their pre-implementation activities and continued these calls until 1 month before the draft final report was due to NIJ. These scheduled meetings could have begun sooner in the process because we found that, after we had a kickoff meeting with the laboratories and then did not talk to them on a regular schedule for the 6 months after the meetings (pre-implementation period), updates and communications were limited and an EIP, in some cases, appeared to be slow to progress. Perhaps scheduled meetings could have improved the process of the pre-implementation period. During these scheduled conference calls, the evaluation team undoubtedly received much information that may have gone undocumented otherwise.

- **Adequate Time for Outputs and Outcomes**—Once an EIP is implemented, it takes some time to adequately measure the impacts of the EIP to the laboratory (sometimes years). Premature expectations of these measurements can limit the use of the measures and sometimes even penalize the laboratory if the EIP is considered unsuccessful by management and policy makers. During the outcome evaluation, the goal should be to clearly identify and collect both short-term and long-term outcomes.

RTI used findings from the process and outcome evaluations to construct a preliminary model of effectiveness for future replication of EIPs for DNA laboratories (**Figure 6-1**). Once the 2009 DNA Unit EIPs are completed by the remaining laboratories, this model can be further developed as lessons learned are finalized and quantitative metrics are collected and analyzed over an appropriate period of time.

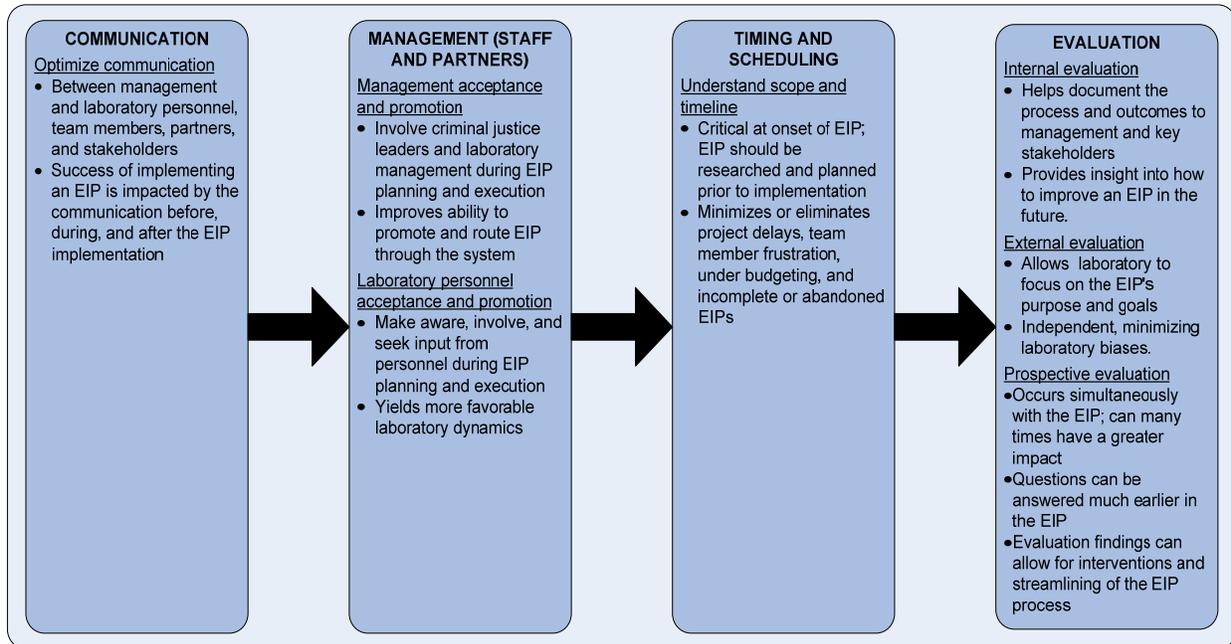


Figure 6-1. Model of effective DNA Unit EIP.

This process and outcome evaluation identified and examined the EIP approaches and elements by which the 2009 DNA Unit EIPs were initiated and carried out in the laboratories. The process evaluation collected information on the EIPs' progress, challenges, and barriers to EIP implementation and developed solutions to identify "lessons learned." Ultimately, these guidelines and recommendations are direct results of a better understanding of how a forensic laboratory can successfully plan and execute an improvement that provides efficiency in both time and cost. Consequently, more samples and cases can be analyzed, and the criminal justice system can be more expedient.

7. TASK ORDER MANAGEMENT AND TIMELINE

This section includes further details of RTI’s management of this task order and the timeline for the project (**Figure 7-1**).

	'09	2010												2011												'12	
	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	
Project Start-Up Activities																											
Develop Pre-assessment checklist																											
Make initial contact with grantee laboratories																											
Obtain IRB exemption																											
Implementation Activities																											
Grantee Proposals-- review and data extraction																											
Conduct semi-structured telephone interviews																											
Prepare laboratory profiles																											
Conduct Process and Outcome Evaluation																											
Research design and data collection protocols submitted to IRB																											
Conduct Laboratory monthly conference calls																											
Conduct laboratory site visits ^a								1	2			1			1												
Define implementation measures and expected products																											
Collect and track performance measures																											
Analysis and Reporting																											
Interpretation of data																											
Site visits report																											
Laboratory assessment summary report																											
Process evaluation report- Pre-Assessment Lab Profiles & Conference Call Minutes																											
Outcome evaluation PM Excel reports																											
Project Management (NIJ Deliverables)																											
Submit monthly progress report	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Submit monthly financial reports	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Submit draft final report																										■	
Submit revised final report																											

^a Number of site visits.

Figure 7-1. Project timeline.

Appendix D presents the project’s required Task Activity Summary. Also, required by NIJ and included as **Appendix E** presents the List of Inventory of Project Data/Information Stored on CD (EIP Project Bibliography), which was delivered to NIJ at project completion simultaneously with this final report.

7.1 Task Management

The goal of the EIP evaluation was to include both a process evaluation and an outcome evaluation. The process evaluation provided an ongoing assessment and feedback on the EIP implementation to laboratory staff and NIJ. The triad of the external evaluator (RTI), the laboratory, and NIJ worked together to identify problem areas and obstacles, assist in making modifications to the EIP when warranted, and assist in the development of the measurements to be used in evaluating the success of this program. The outcome evaluation was to assess the EIP after implementation to laboratory staff and NIJ. It was to be a mixture of qualitative and quantitative methods of measuring the success of the DNA Unit EIP. To achieve the goal of the EIP evaluation, an Evaluation Plan was developed that included 10 project tasks, as summarized in **Table 7-1**.

Table 7-1. 2009 DNA Unit EIP Evaluation Plan

Objective	Task	Deliverables
1. Plan and execute project startup	<ul style="list-style-type: none"> ▪ Project startup activities <ul style="list-style-type: none"> – Hold kickoff meeting with COTR and NIJ grant managers (for evaluation project and for each EIP laboratory) ▪ Make initial contact with laboratories <ul style="list-style-type: none"> – Develop a pre-assessment checklist of items to request from EIP laboratories – Complete the Institutional Review Board (IRB) process 	<ul style="list-style-type: none"> ▪ Pre-assessment checklist ▪ EIP evaluation letter to grantee laboratories ▪ IRB exemption

(continued)

Table 7-1. 2009 DNA Unit EIP Evaluation Plan (continued)

Objective	Task	Deliverables
2. Document the implementation of the Forensic DNA Unit EIP grants	<ul style="list-style-type: none"> ▪ Review grantee proposals; extract information on <ul style="list-style-type: none"> – Laboratory configuration and characteristics of EIPs ▪ Conduct semi-structured telephone interview(s) with key laboratory personnel <ul style="list-style-type: none"> – Verify and document laboratory operations – Verify or update planned efficiency improvements ▪ Prepare laboratory “profiles” using pre-assessment data collection instrument (Appendix A) and interview follow ups 	<ul style="list-style-type: none"> ▪ Preliminary laboratory profiles (e.g., type and number of cases, number of clients, process maps, current performance indicators) ▪ Final planned approaches to efficiency improvements, including solutions, timeline, and performance measures ▪ Reviewer’s checklist for site visits; personnel interviews ▪ Electronic files containing profiles, improvements, and performance measures for EIP laboratories
3. Conduct a process and outcome evaluation of each grantee’s EIP	<ul style="list-style-type: none"> ▪ Conduct a Web meeting with laboratories to describe planned evaluation activities ▪ Conduct site visits <ul style="list-style-type: none"> – Tour the laboratory – Collect baseline data defining laboratory characteristics or “inputs” – Conduct semi-structured interviews with key staff ▪ Collect monthly performance metrics or other metric studies as appropriate for each laboratory ▪ Conduct semi-structured monthly telephone meetings to document progress, discuss metrics, and determine if evaluation is going as planned, including the timeline 	<ul style="list-style-type: none"> ▪ Meeting minutes ▪ Site visit agenda; preliminary list of performance measures ▪ Site Visit Interview Tool (Appendix B) ▪ Minutes of pre-site-visit meeting ▪ Documentation of laboratory operations, EIP plans, and progress, activities that may impact the outcome of the EIP and ability to report proposed performance measures ▪ Performance Metrics Spreadsheets (Appendix C) ▪ Monthly progress reports describing implementation issues, performance measures, current project activities, and planned activities for next month ▪ Document changes in laboratory operations, EIP progress, activities that impacted the outcome of the EIP, and ability to report performance measures
4. Produce a report that documents the results of the evaluation and provides recommendations of models to be considered by other forensic science laboratories	<ul style="list-style-type: none"> ▪ Draft and revise the final report <ul style="list-style-type: none"> – Analyze process data – Analyze outcome data – Identify lessons learned and recommendations – Propose models and guidelines 	<ul style="list-style-type: none"> ▪ Final report ▪ Task Activity Summary (Appendix D) ▪ List of Data/Documents developed and collected during evaluations (Appendix E and CD Diskette of all project files submitted to NIJ)

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7.1.1 Task 1. Project Start-Up Activities

7.1.1.1 Project Kick-Off Meeting

RTI contacted the NIJ Contracting Officer's Technical Representative (COTR) immediately upon notification of award to make arrangements for a project kickoff meeting and also to request copies of the grant applications for the five laboratories selected for EIP grants. RTI held a kickoff meeting with NIJ staff in Washington, DC, in November 2009, during which the general project design and proposed work plan were discussed. Following the meeting, RTI revised the Evaluation Plan and submitted the revised Evaluation Plan to the COTR and Contracting Officer for approval.

7.1.1.2 Initial Contact with Laboratories

After NIJ's introduction of RTI as the external evaluator to the laboratories, RTI prepared an email correspondence to the EIP project manager (and the laboratory director if it was a different individual) for each of the grantees. The letter (1) introduced and outlined the components of the evaluation, stressing the importance of the evaluation to the forensics field; (2) requested verification of the name of a laboratory contact; and (3) requested availability to schedule a conference call to discuss the plans of the EIP and evaluation and to make further introduction of EIP staff from the laboratory and RTI.

7.1.2 Task 2. Document Review and Information Extraction

This task extracted qualitative and quantitative information from the grantees' applications. The initial profiles of the laboratories and their EIP implementation plans were developed from the data extracted from the laboratories' grant applications and the auxiliary materials. A laboratory checklist was prepared to ensure that a standardized review occurred.

The extraction focused on developing information on laboratory characteristics (e.g., staffing, workload and processing metrics, clients, performance measures) and the proposed EIP.

7.1.3 Task 3. Conduct Semi-structured Telephone Interviews

Verification and augmentation of the data extracted in Task 2 was accomplished through a semi-structured telephone interview (Months 2 to 3) with a representative of each laboratory. One of the key goals of this task was to develop a comprehensive understanding of the policies and operation of the laboratory. Laboratories were asked questions about implementation plans for efficiency improvement processes, including estimated initiation date. The laboratory contacts were also asked to provide a basic overview of the EIP, identify any changes since the application phase, and answer other questions RTI found following our review of the laboratory's proposal.

7.1.4 Task 4. Prepare Laboratory Profiles

Using the information developed in Tasks 2 and 3, a laboratory profile was prepared on each laboratory that was distributed to the RTI project team to give all team members an understanding of the laboratory's overall operation. These laboratory profiles were collected as part of the pre-assessment process using the Pre-Assessment Data Collection Instrument. The profiles include information on the laboratory characteristics and EIP. They are provided on the CD diskette submitted to NIJ.

7.1.5 Task 5. Prepare and Submit Human Subjects' Application

A human subjects' application package was prepared and submitted to an RTI Institutional Review Board (IRB) within 2 weeks of the completion of the final evaluation design plan. RTI operates three IRBs under a Federal-wide Assurance (FWA #3331 effective until

March 5, 2012) from the Office for Human Research Protections (OHRP) to RTI. Based on past experience, we anticipated that the data collection activities under this study would be exempt.

Appendix F is the approved IRB document for this project.

7.1.6 Task 6. Conduct Web Meeting with Laboratories

A Web-based meeting was conducted during Month 3 with the laboratories to discuss site visit plans and to identify common performance measures. A site visit agenda was discussed, and a needs assessment for preparing the laboratory and RTI project team for the site visit was conducted. During this meeting, the team and laboratory representatives discussed a preliminary assessment of the performance measures identified by laboratories for the outcome evaluation. The discussion included questions about the quality and consistency of these measures, as well as steps for extracting the data from the LIMS (including periodicity of reporting so that RTI could obtain standard measures at consistent points over time).

7.1.7 Task 7. Conduct Site Visits

The RTI evaluation team conducted site visits to each of the laboratories. The purpose of the site visits was to collect data defining laboratory characteristics, which allows for a baseline determination of the laboratory's current operating capacity. The site visit's main objective was to collect or review the baseline data. An RTI team of two to three staff members (e.g., Project Director, forensic scientist, senior advisor, DNA analyst) traveled to each laboratory site for a 2-day site visit. Another important aspect of these site visits was to identify current functioning of the laboratory prior to or directly after implementation of the EIP, along with obtaining specific details on how the program or technology was intended to be implemented. Specific questions were drafted for each construct and provided flexibility to probe for more detailed responses. A

single interview guide was developed, although each interview was tailored to the interviewees' laboratory role. For example, questions related to specific procedures were only asked of laboratory analyst staff involved in preparing and analyzing samples, whereas more general questions about laboratory capacity and backlogs were asked of laboratory directors and managers.

The interviews were semi-structured and lasted up to 60 minutes. Representative staff included management, the EIP project manager, analysts, an evidence technician (sample collection and system input), a quality assurance officer, and a LIMS operator. The site team also obtained written program documentation to assist in subsequent evaluations.

7.1.8 Task 8. Monthly Data Collection

7.1.8.1 Data Collection

MS Excel Spreadsheets (**Appendix C**) with performance metrics and calculations were collected monthly (or quarterly if laboratory requested) and were used to inform the outcome evaluation and give the EIP project team insight into questions to ask during scheduled monthly conference calls to document progress. The spreadsheets were used to collect metrics that were baseline, pre-implementation, and post-implementation data. At least 6 months of baseline data was requested to help with analysis of laboratory metrics.

7.1.8.2 Preliminary Analysis and Reporting

As data collection for the process and outcome evaluations was completed, the evaluation team performed analyses, met with NIJ, and documented in the monthly reports to NIJ a summary of ongoing progress and findings. For qualitative data associated with process evaluation, RTI used techniques for interpreting data and identifying key clusters or themes

across laboratories (e.g., grouping of data by similarities and/or hierarchy). In addition, RTI created open-ended questions as part of the on-site visit Interview Guide for laboratories to provide information on laboratory operations and the perceptions of laboratory staff of the EIP.

Because the EIPs were not fully implemented, outcome evaluations were not conducted for each laboratory. For the outcome evaluation, we calculated changes related to the central tendency of specific measures at the laboratory level, examining changes from pre-implementation to specific points of time post-implementation for those laboratories that reached this stage of their EIP. All outcome performance measures were collected at 1- to 3-month intervals; however, because the EIPs were not implemented according to schedule, we were unable to analyze intermediate and longer-term changes in laboratory capacity. We were also unable to analyze changes across laboratories. The results from the impact analysis, coupled with the process evaluation results, were used to develop conclusions and recommendations for effective preliminary models that should be considered by other forensic laboratories.

7.1.9 Task 9. Conduct Semi-structured Telephone Interviews

Semi-structured interviews (conference calls) were conducted with the laboratory director, laboratory manager, IT manager, and laboratory QA manager. The purpose of these interviews was to update information identified in the baseline data collection. Prior to the interviews, the respondents were sent copies of the interview and a checklist of items to be provided to the evaluation. The interviews were conducted by forensic scientists and research analysts familiar with DNA laboratory procedures and the profiles and EIP of each of the participating laboratories.

7.1.10 Task 10. Draft and Revise Final Report

To document findings of this project during milestones, some interim reports were completed. A laboratory pre-assessment instrument tool, site visit reports, and conference call meeting minutes were used to detail these important steps. This in-depth final report synthesizes all project activities, including the study design and methodology, evaluation results, and recommendations for laboratory policy and practice. In addition, this report contains an Executive Summary that highlights the main findings of the study. A draft of the final report was submitted 60 days before the end of the grant (November 15, 2011); the final version, incorporating NIJ feedback, will be submitted electronically and in hard copy by the end date of the project.

7.2 Strategies for Ameliorating Weaknesses and Potential Pitfalls

This project required effective communication among all parties in order to achieve a timely and accurate evaluation of the EIP project. The project's timeline, especially early on, was intense, and coordination with the laboratories during these initial phases was crucial. Poor communication resulted in delays that impacted specific components of the project (e.g., not conducting a planned site visit before the implementation of the efficiency improvement measure). Similarly, RTI maintained a feedback loop with the laboratories to ensure that results were documented correctly and that the laboratories agreed with the recorded performance measures. If there was a disagreement, we immediately followed up with laboratory staff to clarify and resolve matters

We were careful to ensure that the definition of measures was similar across laboratories. RTI developed a list of definitions as part of the pre-assessment collection tool. The evaluation

team met with laboratories to discuss and finalize these standardized definitions for the EIP evaluation and used these definitions as part of the ongoing data collection efforts.

Perhaps the largest challenge for this EIP evaluation was the ability to generalize findings from this evaluation to DNA laboratories nationwide because the small number of evaluation sites and lack of control sites are factors that limit our ability to draw inferences from the findings. As such, the evaluation focuses more on changes within the laboratory (pre-implementation and post-implementation) while also taking into consideration how each program was implemented and key characteristics of each laboratory. RTI collected both quantitative (e.g., backlog numbers, CODIS hits, turnaround times) and qualitative data (e.g., conference call notes, progress reports) at a monthly rate to ensure that comparisons across laboratories were consistent and potential trends were more likely to be recognized. Finally, the laboratory EIP and their evaluations did not occur in a “sterile environment.” Other changes to the laboratory that are not specific for the EIP can and will occur concurrently; these changes could impact the outcomes of interest. As such, RTI project staff documented any external variables as well as the laboratory characteristics (e.g., staffing capacity, training, type and size of laboratory) as part of the pre-assessment and ongoing data collection efforts, as many could potential impact the target indicators and outcome measures collected.

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Appendix A

Pre-Assessment Collection Instrument

**Evaluation of EIP
Baseline Data Collection Instrument**

Information Supplied By:

Name	Title		
Agency name			
Number and street or P.O. Box/route number	City	State	ZIP code
E-mail address			
Telephone (area code and number)	Extension	Fax number (area code and number)	

Consent to Participate

Purpose

The 2009 Forensic DNA Unit Efficiency Program is a research study sponsored by the National Institute of Justice (NIJ) under award #2009F_09085. The study is being conducted by RTI International, a nonprofit research organization located in Research Triangle Park, North Carolina.

The objective of the study is to conduct a rigorous process and outcome evaluation of the implementation of the DNA laboratory efficiency programs by assessing their impact of laboratory productivity as measured by DNA case turnaround time, analyses completed per analyst, reduction in DNA case backlogs, Combined DNA Index System (CODIS) hits, and other relevant measures. Our objective is to identify evidence-based approaches that can improve DNA laboratory processes within the broader forensic laboratory community and ultimately to publish one or more successful DNA efficiency improvement program awards as model programs. Such a publication would assist other State and local government forensic DNA laboratories to implement similar strategies and subsequently increase efficiency and capacity.

Study Duration

The pre-assessment data collection instrument will take approximately 30 to 60 minutes to complete.

Your Rights

While you agreed to have an external evaluator into your laboratory as part of your NIJ funding for a DNA Laboratory Efficiency Improvement, your decision to take part in this research study is completely voluntary. You can refuse any part of the study and you can stop participating at any time. You can also refuse to answer any question.

Your Questions

If you have any questions about the study, you may call Dr. Jeri Roper-Miller at (919) 485-5685 or jerimiller@rti.org. If you have any questions about your rights as a study participant, you may call RTI's Office of Research Protection at 1-866-214-2043 (a toll-free number).

By initialing here, respondent agrees to participate in the pre-assessment collection.

SECTION A

DEFINITIONS

Please define the following words as they pertain to your laboratory. Use "n/a" or non-applicable for definitions that do not pertain to your laboratory:

% Backlog Reduction – _____

Analyst Caseload – _____

Cold Hit – _____

DNA Backlog – _____

Elimination Standard – _____

Laboratory Caseload (i.e., Does the clock begin upon “assignment” or upon “submission”?) – _____

Property Crime Throughput – _____

Property Crime Backlog – _____

Reference Standard – _____

Turnaround Time (TAT) – _____

TAT Reduction – _____

Touch DNA – _____

For the remaining sections, please complete the following questions as they pertain to your laboratory. If any question is too difficult for your laboratory to comment on without a considerable time investment, please indicate this for question as your answer. Use “n/a” or non-applicable for questions that do not pertain to your laboratory:

SECTION B.

STAFFING AND JURISDICTION

B1. What is the population base the laboratory serves?

B2. Is your DNA lab currently fully staffed? Yes No

B3. What is the range of experience of staff in your DNA lab?

B4. What is your rate of staff turnover?

B5. Will there be partnering support for the project? Yes No

If yes, describe: _____

B6. Would you be able to provide jurisdictional crime rates? Yes No

If yes, could this be provided for multiple years? Yes No

B7. Would you be able to provide prosecutions and convictions in which DNA evidence was used? Yes No
If yes, could this be provided for multiple years? Yes No

SECTION C	CASELOAD
------------------	-----------------

C1. What is your current DNA backlog?

C2. a. What is your current caseload?

b. How does current caseload compare to 1 year ago?

c. How does current caseload compare to 5 years ago?

C3. a. Does your DNA laboratory have a Convicted Offender Databank Unit for processing and data entry of Convicted Offender profiles? Yes No

b. What is the current yearly submission of samples to the Convicted Offender DNA Databank? _____

c. What is the current backlog of Convicted Offender DNA Databank caseload? _____

C4. a. What is the current average of a DNA case load per Analyst?

b. Do you have a goal of caseload per Analyst? Yes No

If yes, please explain further _____

C5. Does your laboratory perform DNA analysis for property crimes? Yes No

If yes,

a. What is your current DNA caseload for property crimes?

b. What is your current DNA backlog for property crimes?

C6. a. Does your laboratory perform mitochondrial DNA analysis? Yes No

b. What is the average caseload for mitoDNA analysis?

C7. a. What is the current mean DNA Turnaround Time for your laboratory?

b. How does current DNA TAT compare to 1 year ago?

c. How does current DNA TAT compare to 5 years ago?

d. Do you have a goal for your DNA turnaround? Yes No

C8. a. What is the average number of DNA samples per case submitted?

b. Does this differ based on the crime type (e.g., violent crime, property crime)? Yes No

c. Can your laboratory easily track the number of cases worked as well as the number of samples processed before and after the EIP? Yes No

C9. Are there projections of workload increases for DNA testing in the next 5 years (i.e., legislation mandating property crimes DNA collection)? Yes No

If yes, please explain further _____

SECTION D

IMPACTS AND INFLUENCES ON THE LABORATORY

D1. Have all costs been considered within the proposed and awarded budget? Yes No

If not, what is the estimated cost of the total project? _____

D2. How will unexpected costs be tracked?

D3. Are other “innovation projects” being implemented concurrently in the lab? Yes No

D4. Are there any special circumstances, high profile cases, mega-cases, disasters, special laboratory challenges influencing workload? Yes No

D5. a. What type of LIMS system or platform does your laboratory currently use? _____

b. Have there been LIMS changes recently? Yes No

c. Is system modifiable or able to provide quarterly statistics or data? Yes No

D6. Are there any known barriers that may influence your EIP progression and implementation? Yes No

If yes, please explain further _____

D7. Are there cost savings potential for your Lab and partners? Yes No

If yes, please explain further _____

D8. Are there any other impacts this EIP will have on your laboratory and its customers? Yes No
(example: Laboratory Accreditation of a New Laboratory Facility)

Please elaborate further _____

D9. a. Using the calculation formula below, please provide the cost per sample for your DNA laboratory. _____
Total DNA Laboratory Costs for one year includes DNA personnel/staff costs, DNA consumable products and supplies, equipment and instrument costs (include maintenance agreements), and % of the physical facility cost (state % using in formula).

Cost Per Sample = A/B or divide the number of DNA samples analyzed by the laboratory into the total DNA Laboratory costs (A Total) as calculated for each reportable test to include reference materials, controls, and proficiency tests

A Total = DNA Personnel/Staff Costs (All related FTE's) + DNA consumable products and supplies + Equipment and Instrument Costs (Include maintenance agreements) + % of the total physical facility cost (state % of laboratory)

B Total = The number of samples processed in one year

b. What time period did you use to establish this (e.g., 6 months, 1 year)? _____

D10. What is your “projected” or “predicted” DNA caseload for your laboratory after EIP implementation?

SECTION E.**GRANT INFORMATION**

E1. What is the key goal/objective of the innovation?

E2. What is the sustainability of grant funded improvements?

E3. Does your lab have any experience in implementing grants? Yes No

If yes, what is the number of innovation grants implemented in the last 5 years? _____

SECTION F.**REQUESTED MATERIAL CHECKLIST**

The list of materials below will help us better evaluate your EIP. Please provide the following materials to us when returning the pre-assessment.

- Organizational chart and staffing plan (including degree levels, certifications)
- State/Local policy that is considered a key influencer for the EIP submission
- Laboratory mission statement
- Quality Manual and SOPs (as relevant to EIP)
- State CODIS system policies and procedures
- Recent laboratory inspection findings (e.g., internal audits, ASCLD/LAB, State)
- Jurisdiction and/or list of clients (Law Enforcement offices and State prosecutors)

Appendix B

EIP Interview Guide

EIP Project Interview Guide: DNA Forensic Laboratory

(Estimated Interview Duration: 60–90 minutes)

Instructions: Please use the following instructions when conducting the interviews to ensure that each is conducted using a standard approach. Below are recommendations on interacting with participants, location(s) for interviews, and format of the questions to cover. All ***italicized sections*** are example instructions you can read to the interviewee or use to make your own dialogue covering the key points.

Interview Setting: DNA Forensic Laboratory—DNA Laboratory Walk Through and Interview. Two suggested locations for the interviews are (1) a neutral meeting room or (2) the Laboratory management office. Other locations may also be acceptable; however, interviewers should keep in mind obtaining a room that is private and free from outside distractions.

Interview Guide: Interviewers are expected to follow this guide; however, as the situation dictates, it may be necessary to deviate onto other topics or a longer discussion than planned on any one topic. When conducting interviews, it is more important to stay engaged with the interviewee and to understand what feedback he or she is providing. Make sure the interviewee has completely answered the question asked before moving on to an additional question (insert additional question only to clarify details that you are receiving, but not a new topic). Use your judgment to deviate as needed.

A. Evaluation BACKGROUND

Before we begin, I wanted to tell you a little about the project we are conducting on the behalf of the National Institute of Justice.

This process evaluation will be an ongoing assessment and feedback on the EIP implementation to laboratory staff and NIJ. The triad of the external evaluator (RTI), the laboratory and NIJ will work together to identifying problem areas and obstacles, assist in making modifications to the EIP when warranted, and assist in the development and modification of the measurements to be used in evaluating the success of this program. The on-site visit by RTI allows the project team to understand the processes of the laboratory and how the EIP will be implemented and evaluated by the laboratory.

I want to emphasize that the goal of the project is not to criticize or draw attention to the problems of any specific jurisdiction. The names of the individuals providing information in this study will not be mentioned by name in any published reports. Furthermore, we will provide all laboratory participants with a draft of the final NIJ report prior to its release, to allow for your review and comment. As agreed upon in your EIP proposal participation in the evaluation of this project, both internal and external components are essential to the findings, implications, and recommendations. If at any time you feel uncomfortable providing requested information, you can decline to comment, however, this will become part of the project record.

1. **Do you have any questions or something you would like to share before we begin our laboratory tour?**

2. **Overall—how is the project going?**
 - *Why did you decide to implement this EIP (i.e., what factors influenced the decision to focus on this EIP)?*
 - *Would you categorize your EIP program as “UP and running”?*
 - *Is the intended EIP being addressed?*
 - *What has been necessary to get EIP “done?”*

B. DNA LABORATORY Tour and EIP BACKGROUND

Laboratory Tour (1 hour)

To assist the EIP evaluation team in understanding the operation of the DNA laboratory we will begin with a tour of your DNA laboratory; particularly we are interested in the processes related to your innovation project.

Possible probe questions on the tour –

- *Age of Laboratory*
- *Age of equipment*
- *Size of Laboratory*
- *Design/functionality*
- *Capacity*
- *Workflow of EIP reviewed*
- *Overall or specific challenges the lab faces*
- *Laboratory strengths*
- *Background on the decision making to develop the innovation proposal*
- *Outsourcing*

Following the tour, an interview with the Project Manager

I. Review of Baseline Data (30 minutes)

Discuss and review baseline information provided by the laboratory. Details of baseline information for this lab have been collected and collated into one document when possible. These documents can be reviewed separately from the interview guide. The laboratory’s key baseline data:

- Organizational Chart.
- Laboratory QA Manual
- DNA Laboratory Past Laboratory Audit

- Training Program Manuals
- General Pre-Assessment Q&A (Staffing, Caseload, Impacts& Influences)

II. Review Specific Objectives of the EIP:

Discuss the EIP objectives and review how the proposed objectives are being implemented: Review EIP (e.g. EIP activities matrix).

Measurement

- *How is the data being collected for the EIP?*
- *Is that data being collected in an efficient process?*
- *How did the laboratory staff evaluate the completion of the EIP activities?*

Timeline

- *Is the EIP timeline on schedule?*
- *If changes have been made, what is the new projected timeline?*
- *What activities are planned during EIP (e.g. EIP activities matrix) from this point forward?*
- *What activities listed in the EIP activities matrix were/were not completed during EIP period of performance?*
- *What explanation can be offered for the discrepancy between the projected and actual activities?*

Staffing

- *Is the staff identified in the proposal working on the EIP?*
- *Does these staff perform the tasks/duties as specified in the EIP?*

Expenditures

Review and discuss the proposed budget.

- *Are the funds being spent according to the proposed plan?*
- *What percentage was anticipated and is actually being spent on each EIP budgetary item (labor, equipment, facilities, etc) listed in the Statement of Work (e.g. projected budget vs. actual expenses)?*

Partners

- *If working with institutional partners to implement EIP, describe in general how the partnership is being implemented.*
- *Is the partnership being implemented as envisioned?*

- *Are there changes being made in any of the roles and responsibilities of the institutional partners.*
- *Any issues that have arisen during the EIP implementation?*

Barrier and Solutions

- *Have there been any major changes in the scope of your program?*
- *What have been the difficulties and barriers?*
- *Do you foresee any major changes to your program in the future?*
- *Are the EIP grant objectives being achieved?*
- *Are the EIP elements working?*
- *Have there been changes made in the EIP plan?*
- *If there are discrepancies -- what explanation can be offered for the differences between the projected and actual activities?*
- *Did the project encounter any roadblocks during the implementation so far?*
- *Any action items needed?*

Lessons Learned to Date

- *What lessons have been learned thus far?*
- *What feedback can be used to improve the EIP for the future implementations in other laboratories?*

III. Overall Site Visit Summary:

1. Request of Additional Documents to review on site
2. Current issues being addressed
3. List modifications needed in EIP
4. Staff reaction to the progress accomplished to date
5. Projected schedule for completion of EIP
6. Progress indicators

Checklist and Data Matrix:

Collect information here in bulleted format for completion of notes following time in the lab (recommend in direct time period following observations) and as a checklist measure.

Background	Measurement	Timeline	Staffing
Expenditures	Partners	Barriers/Solutions	Action Items
Performance Metrics	Lessons Learned	Future Timeline	Summary
			1. 2. 3. 4. 5. 6.

Appendix C

Performance Metrics and Calculations

Performance Metrics and Calculations

A Element	Staffing and Hours
A1	# Forensic Biology analysts
A2	# DNA analysts
A3	# technicians
A4	# managers (supervisors)
A5	# staff hired specifically for EIP
A6	# trainees
A7	# trainer hours
A8	# expert witness hours
B Element	Turnaround Time
B1	Average # days from submission of a case to the laboratory until the report is administratively approved for Forensic Biology
B2	Average # days from submission of a case to the laboratory until the report is administratively approved for DNA
C Element	Cases
C1	# cases Forensic Biology analysts were assigned
C2	# cases DNA analysts were assigned
C3	# cases completed in DNA
C4	# cases completed in Forensic Biology
C5	# cases that have not been assigned to either a Forensic Biologist (e.g., screening analyst and a serologist) or DNA analyst
C6	# cases in which forensic biological analysis has been completed and is awaiting assignment to a DNA analyst
C7	# DNA cases currently being processed/worked but not completed through final report sent to agency
C8	# FB cases currently being processed/worked
C9	# cold cases (any criminal investigation by a law enforcement agency that has not been solved for (generally) at least one year and, as a result, has been closed from further regular investigations) in backlog
C10	# cold cases (any criminal investigation by a law enforcement agency that has not been solved for (generally) at least one year and, as a result, has been closed from further regular investigations) being worked
C11	# cases projected for next year
C12	# cases with Touch DNA (DNA left behind on an object or surface after it has been touched, handled or held by one or more individuals)
C13	# cases with Touch DNA (DNA left behind on an object or surface after it has been touched, handled or held by one or more individuals) currently being processed/worked but not completed through final report sent to agency

C14	# property crime cases (burglary, theft, theft from motor vehicle, auto theft, criminal trespass, criminal mischief, arson) that have not been assigned to either a Forensic Biologist (e.g., screening analyst and a serologist) or DNA analyst
C15	# property crime cases (burglary, theft, theft from motor vehicle, auto theft, criminal trespass, criminal mischief, arson) in which forensic biological analysis has been completed and is awaiting assignment to a DNA analyst
C16	# property crime DNA cases (burglary, theft, theft from motor vehicle, auto theft, criminal trespass, criminal mischief, arson) currently being processed/worked but not completed through final report sent to agency
D Element	CODIS Hits
D1	# cases that CODIS assisted through verified matches produced by CODIS (includes NDIS and SDIS databases) for submitted convicted offenders (there is a match of a forensic unknown to a convicted offender)
D2	# cases that CODIS assisted through verified matches produced by CODIS (includes NDIS and SDIS databases) for a forensic unknown which contains DNA profiles generated from crime scene stains (there is a match of a forensic unknown to another forensic unknown)
E Element	Samples
E1	# samples analyzed in Forensic Biology
E2	# samples analyzed in DNA
E3	# samples analyzed for property crime cases (residential and commercial burglary, theft, and theft from motor vehicle, auto theft, criminal trespass, criminal mischief and arson) in Forensic Biology
E4	# samples analyzed for property crime cases (residential and commercial burglary, theft, and theft from motor vehicle, auto theft, criminal trespass, criminal mischief and arson) in DNA
F Element	Financial
F1	Total staff salaries (\$)
F2	DNA consumables and supplies (\$)
F3	Major equipment and instrument costs (\$)
F4	Major equipment maintenance agreements (\$)
G Element	Scheduling
G1	Total number of months EIP data collection

Calculated Performance Metrics	
Average Analyst Caseload, FB (assigned cases)	[Formula: C1/A1]
Average Analyst Caseload, DNA (assigned cases)	[Formula: C2/A2]
Average Analyst Caseload, FB + DNA (assigned cases)	[Formula: (C1 + C2)/(A1+A2)]

Laboratory Workload (FB + DNA cases) [Formula: C1+C2]
Case Average, FB (Element C4) [Formula: C3 + C4]
Case Completion, FB + DNA [Formula: C2/A2]
Turnaround Time, FB + DNA [Formula: B1+B2]
Total DNA Backlog [Formula: C5+C6 +C7]
Property Crime Backlog [Formula: C14+C15 +C16]
Investigations Aided, Forensic and Offender Hits [Formula: D1+D2]
DNA Throughput-Samples Analyzed in FB + DNA [Formula: E1+E2]
Property Crime Throughput-Samples Analyzed in FB + DNA [Formula: E3+E4]
Total # of FB Cases [Formula: C5+C8]
Total # DNA Cases [Formula: C5+C6+C7+C8]
Total # Cold Cases [Formula: C9+C10]

Appendix D

Task Activity Summary

2009 Evaluation of Forensic DNA Unit Efficiency Improvement (EIP) Program

NIJ Contract No. GS10F-0097L
Order No. 2009Q_039

TASK ACTIVITY SUMMARY

This task activity summary provides a description the activities undertaken to achieve completion of this project from the task award date to the submission of the final report.

1. GOAL FOR PROJECT:

Our main goal was to help strengthen state and local law enforcement responses to transnational crime. Prior to this project, NIJ sponsored a national survey of law enforcement practitioners. Using the results of this survey and new research, this project has identified some “next steps” to providing local and State law enforcement with tools to identify and respond to transnational crime. This project was designed to help improve local law enforcement’s response to transnational crime, and begin to move the field from research data and constructs to policy-making and practice.

2. OBJECTIVES AND ACCOMPANYING PROJECT TASKS:

The ultimate goal of this evaluation was to help NIJ assist the forensic laboratory community address growing capacity needs by identifying strategies that have quantifiable impacts in terms of improvements in lab efficiency.

2.1 OBJECTIVE 1: Project Start-Up Activities

2.1.1 Project Kick-Off Meeting.

Project Kick-Off Meeting. RTI contacted the NIJ COTR immediately upon notification of award and make arrangements for a project kick-off meeting and also requested copies of the grant applications for five laboratories selected for EIP grants. RTI proposed that the kick-off meeting be accomplished by a telephone conference call or a Web meeting during which the general project design and proposed work plan will be discussed. Following the meeting, RTI revised the evaluation plan and submitted the revised evaluation plan to the COTR and Contracting Officer for approval.

2.1.2. Initial Contact with Laboratories.

Within 2 weeks of award, and with the COTR’s approval, RTI prepared a letter to the program director (and the laboratory director if it is a different individual) for each of the grantees. The

letter, (1) introduced and outline the components of the evaluation, stressing the importance of the evaluation to the forensics field; (2) requested the name of a laboratory contact; and (3) requested that the laboratory provide us with the items included in their proposal that would enable RTI project staff to gain familiarity with the specific processes and operation of their laboratory.

2.1.3 Prepare and Submit Human Subjects' Application

A human subjects' application package was prepared and submitted to an RTI Institutional Review Board (IRB), within two weeks of the completion of the final evaluation design plan. RTI operates three IRBs under a Federalwide Assurance (FWA #3331 effective until March 5, 2012) from the Office for Human Research Protections (OHRP) to RTI. Based on past experience, we anticipate that the data collection activities under this study that will focus on the collection of official data from government personnel will be exempt; however, this is a determination that must be made by the IRB.

2.1.4 Conduct Web Meeting with Laboratories

A Web meeting was conducted during month 3 with the laboratories to discuss site visit plans and to identify common performance measures in addition to the Government Performance and Results Act (GPRA) performance measures that will be applied across all sites. A site visit agenda will be discussed, and a needs assessment for preparing the laboratory and RTI project team for the site visit will be conducted. During this meeting, a preliminary assessment of the performance measures identified by laboratories for the outcome evaluation was discussed. The discussion included questions about the quality and consistency of these measures, as well as steps for extracting the data from the laboratory information system (including periodicity of reporting so that we can obtain standard measures at consistent points over time).

2.2 OBJECTIVE 2: Document the implementation of the Forensic DNA Unit EIPs

2.2.1 Document Review and Information Extraction

This task extracted qualitative and quantitative information from the grantees' applications. The initial profiles of the laboratories and their EIP plans were developed from the data extracted from the laboratories' grant applications and the auxiliary materials. A reviewer's checklist was prepared to ensure that a standardized review occurred. RTI analysts reviewed the materials and extracted data. The extraction focused on developing information on laboratory characteristics (e.g., staffing, workload and processing metrics, clients, performance measures) and the proposed EIP.

2.2.2 Conduct Semi-structured Telephone Interviews

Verification and augmentation of the data extracted in Task 2 was accomplished through a semi-structured telephone interview (months 2 to 3) with a representative of each laboratory. One of the key goals of this task was to develop a comprehensive understanding of the policies and operation of the laboratory. Laboratories were asked questions about implementation plans for efficiency improvement processes, including estimated initiation date. The laboratory contacts were also asked to provide a basic overview of the EIP, identify any changes since the application phase, and answer other questions that RTI may have following our review of the laboratory's proposal.

2.3 OBJECTIVE 3: Conduct a process and outcome evaluation of each grantee's EIP

2.3.1 Prepare Laboratory Profiles

Using the information developed in Tasks 2 and 3, a laboratory profile was prepared on each laboratory that was distributed to the RTI project team to give all team members an understanding of the laboratory's overall operation. The profile included information on the lab characteristics and EIP.

2.3.2 Conduct Web Meeting with Laboratories

A Web meeting was conducted during month 3 with the laboratories to discuss site visit plans and to identify common performance measures in addition to the Government Performance and Results Act (GPRA) performance measures that will be applied across all sites. A site visit agenda will be discussed, and a needs assessment for preparing the laboratory and RTI project team for the site visit will be conducted. During this meeting, a preliminary assessment of the performance measures identified by laboratories for the outcome evaluation was discussed. The discussion included questions about the quality and consistency of these measures, as well as steps for extracting the data from the laboratory information system (including periodicity of reporting so that we can obtain standard measures at consistent points over time).

2.3.3 Conduct Site Visits

Site visits to each of the laboratories were conducted. The purpose of the site visits was to collect data defining laboratory characteristics, which will allow a baseline determination of the laboratory's current operating capacity. The site visit's main objective was to collect or review the baseline data. An RTI team of two to three staff members (e.g., Project Director, Forensic Scientist, Senior Advisor, DNA Analyst) traveled to each laboratory site for a 2-day site visit. Another important aspect of these site visits was to identify current functioning of the laboratory prior to or directly after implementation of the EIP, along with obtaining specific details on how the program or technology was or is intended to be implemented. The interviews were semi-structured and lasted up to 60 minutes. Representative staff included management, EIP project manager, analysts, evidence technician (sample collection and system input), quality assurance officer, and LIMS operator. The site team also obtained written program documentation to assist in subsequent evaluations.

2.3.4 Monthly Data Collection

Data Collection. Surveys were conducted monthly to collect information on performance measures to inform the outcome evaluation and on the progress of implementing the EIP in support of the process evaluation. Specific questions were drafted for each construct and provided flexibility to probe for more detailed responses. A single interview guide was developed, although each interview was tailored to the interviewees' laboratory role. For example, questions related to specific procedures were only asked only of lab analyst staff involved in preparing and analyzing samples, whereas more general questions about lab capacity and backlogs were asked of lab directors and managers.

Preliminary Analysis and Reporting. As data collection for the process and outcome evaluations is completed, we will perform analyses and prepare reports for NIJ summarizing the findings. For qualitative data associated with process evaluation, we will use qualitative data analysis techniques for interpreting data and identifying key clusters or themes across labs (e.g., grouping of data by similarities and/or hierarchy). RTI will explore content analysis of open-ended questions to determine what sorts of clusters of concepts emerge from the self

descriptions of activities and impact. This may better define the EIPs as understood by laboratory staff.

For the outcome evaluation, we will use non-parametric statistics to analyze changes in specific measures at the laboratory level, examining changes from pre-implementation to specific points of time post-implementation. All outcome performance measures will be collected at 3-month intervals to allow us to analyze intermediate and longer-term changes (i.e., 18 months post-implementation) in laboratory capacity. In order to analyze changes across laboratories, we will also use parametric techniques to quantify the average changes in key measures used to capture overall improvements in laboratory capacity (e.g., average turnaround time between sample receipt and return of results to the submitting agency). Changes related to the central tendency and dispersion of these measures will be used for these purposes. The results from the impact analysis, coupled with the process evaluation results, will be used to develop conclusions and recommendations for effective models that should be considered by other forensic laboratories.

2.3.5 Conduct Semistructured Telephone Interviews

Semi structured interviews were conducted with the laboratory director, lab manager, IT manager, and lab QA manager. The purpose of these interviews was to update information identified in the baseline data collection. Prior to the interviews, the respondents were sent copies of the interview and a checklist of items to be provided to the evaluation. The interviews were conducted by forensic scientists and research analysts familiar with DNA laboratory procedures and the profiles and EIP of each of the participating labs.

2.4 OBJECTIVE 4: Produce a report that documents the results of the evaluation and provides recommendations of models to be considered by other forensic science laboratories

2.4.1 Draft and Revise Final Report

To document findings of this project during milestones, some interim reports will be completed. A lab assessment summary report, site visit reports, and process and analysis reports will all be used to detail these important steps. An in-depth final report will synthesize all project activities, including the study design and methodology, evaluation results, and recommendations for lab policy and practice. This report will be accompanied by an executive summary highlighting the main findings of the study. A draft of the final report will be submitted 60 days before the end of the grant; the final version, incorporating NIJ feedback, will be submitted electronically and in hard copy by the end date of the project.

4.5 DELIVERABLES

1. A draft final report and an executive summary to be delivered sixty (60) calendar days from the end date of this award (November 15, 2011).
2. A 2,500-word executive summary should distill the findings of the project, presenting the most significant findings early in the summary. A general description of the methods used should be presented in a non-technical manner. Any policy implications flowing from the findings should also be included. The Contractor may choose to write a somewhat longer executive summary not to exceed 4,000 words. As with the shorter executive summary, key findings and their policy implications should be highlighted here and elaborated later in the document. The type is to be in 12 point font, 1 inch margins throughout. Deliverables shall be submitted for CO/IR approval.

3. Along with the background report, the contractor shall submit a machine-readable diskette of data collected and analyzed in conjunction with this project. This will be made public.
4. Accompanying the final report, the Contractor shall submit a task activity summary. The task activity summary shall address activities undertaken to achieve completion of this project from task award date to the submission of the final report.

Appendix E

List of Inventory of Project Data/Information Stored on CD (EIP Project Bibliography)

Pre-Assessment Data Collection

- Pre-Assessment Collection Instrument.docx
 - Pre-Assessment_LabProfiles_Data.xlsx

Site Visits

- Site Visit Personalized Interview Guides
 - a. DPD_EIP Interview_Guide.docx
 - b. OCCL_EIP Interview_Guide.docx
 - c. OSBI_EIP Interview_Guide.docx
 - d. PBSO_EIP Interview_Guide.docx
 - e. UNT_EIP Interview_Guide.docx
- Site Visit Agendas
 - a. DPDAgenda_Sept20_SiteVisit.docx
 - b. OCCLAgenda_Sept22_SiteVisit_Final.pdf
 - c. OSBI_OnSite Itinerary_FINAL.pdf
 - d. PBSO_BRPSD_Agenda_SiteVisit.pdf
 - e. UNT_Site_Visit_Agenda.pdf
- Site Visit Notes and Follow-up Questions
 - a. OCCL_Site_Visit_Follow-up_Questions_May_2011.docx
 - b. OCCL Final Site Visit Notes_Mar_2011.pdf
 - c. OSBI Final Site Visit Notes.doc
 - d. OSBI Site Visit Follow-up Questions.doc
 - e. DPD Site Visit Notes.pdf
 - f. PBSO Final Site Visit Notes.docx
 - g. UNT Final Site Visit Notes.docx

Data Analysis

- DNA_EIP Evaluation Protocol_ver8.doc
- Performance Metrics and Calculations.docx
- Site Monthly Data Collection Charts
 - a. DPD final report charts.xlsx
 - b. OCCL final report charts.xlsx
 - c. PBSO final report charts.xlsx
 - d. OSBI monthly data as of 070711.pdf

Site Specific Items

- DPD
 - a. DPD_Org Chart.zip
 - b. DPD_DNA Supplemental QA Manual.zip
 - c. DPD_FBIO SOPs.zip
 - d. DPD_QASOPs.zip
 - e. DPD_DNA SOPs.zip
 - f. DPD_CODIS.zip
- UNTHSC
 - a. 0567_001.pdf
 - b. Metric Study for RTI_091411.pdf
 - c. RTI site visit presentation.120710.mod for RTI.pdf
 - d. 2008 Final Report.pdf
 - e. Equipment Inventory.xlsx
 - f. Organizational Chart Institute 01032011.pptx
 - g. Policy 06-001 Mission and Goals, Rev 4 .docx
 - h. Policy 06-009 Interpretation Guidelines for mtDNA, Rev 8.docx
 - i. Accreditation Certificate, exp 2010.pdf
 - j. FQS-I Report_UNT_Final, Responses, 2008.pdf

- OCCL
 - a. QSM 1_5 Org Chart-current.pdf
 - b. DNA 1_4 Organizational Chart-current.pdf
 - c. Final Assessment Report - Orange Co 2008.pdf
 - d. Accreditation Certificate-2010.pdf
 - e. Scope of Accrediation-2010.pdf
 - f. List of Clients.docx
 - g. cases received from OCCL clients_2009.pdf
 - h. DNA NIJ Grant Request.xlsx
 - i. DA data for final report.xlsx
 - j. Methodology - Orange County District Attorney.docx
- OSBI
 - a. Research Results_Final Data_0812_2011.xlsx
 - b. List of Qualifying Offenses.docx
 - c. Title 20 Section 1313.2 (Fine-Penalty-Punishment).docx
 - d. Title 22 Section 18 (Expungement of Criminal Records).docx
 - e. Title 22 Section 152 (Limitations in General).docx
 - f. Title 22 Section 991a (Sentence-Powers of the Court).docx
 - g. Title 74 Section 150.27a (Establishment of OSBI DNA Offender Database).docx
 - h. CODIS Unit Policy and Procedures Manual, Efective 02-15-10 (Revision 0).pdf
 - i. Laboratory Quality Manual Rev 2 (6-9-10).pdf
 - j. Validation Team Organizational Chart.docx
 - k. OSBI_audit.pdf
- PBSO
 - a. Org Chart PBSO.pdf
 - b. FL_PBCSO_WPalmBeach_09_09_DNA-CW_FINAL.pdf
 - c. Jurisdictional List.pdf
 - d. PBSO Laboratory Mission Statement.pdf
 - e. PBSO presentation given at NIJ Grantee Meeting.pdf

Appendix F

IRB Approval Letter

RESEARCH TRIANGLE INSTITUTE
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS
Request for Exemption from IRB Review

To request approval for exemption from Institutional Review Board (IRB) review, the Project Manager (includes Project Director or Leader, Principal Investigator, or Survey Manager) must complete this form and deliver the request to an IRB Administrator. The Project Manager will be notified if more information is necessary and the results of the determination.

Date: 2/5/10

RTI Project/Proposal No.: 0212339

Project Title: Evaluation of Forensic DNA Unit Efficiency Improvement Program

Project Manager: Jeri Roper-Miller Sponsor: Department of Justice National Institute of

Justice

Date Participation of Human Subjects Scheduled to Begin:

A. **Brief Description of Study Procedures and Participant Population:** Using semi-structured interviews and a short web-based survey with key stakeholders, RTI will conduct an evaluation of 5 laboratories funded under NIJ's NDA Unit Efficiency Improvement Program. Respondents will include state forensic Laboratory Directors and their staff. The results of the study will be used by Department of Justice to identify strategies that show promise to help improve efficiency in DNA laboratories and which could be replicated in other labs.

B. **Description of Physical, Psychological, Social or Legal Risks to Participants:** There are no physical, or psychological, or legal risks to the participants. The data collected from laboratory staff will be based on their job responsibilities as this study is for planning strategies, not as an accountability or management tool. The initial baseline data collection (Pre-Assessment Collection List) will be semi-structured interviews (or if requested laboratory can complete document and submit to RTI prior to interview to expedite data collection) by phone and any completed documents will always be in the possession of an RTI employee (locked file cabinet). This data collection will allow us to develop our evaluation plan and site visits that will also be a part of this project, however, we will apply for IRB at a later time to evaluate the participation of human subjects in these activities. No individuals will be identified in the final report by name or title.

C1. For educational tests (cognitive, diagnostic, aptitude, achievement), survey or interview research with adults:

1. Is information recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects?

Yes No NA

If yes, explain: We will collect name, title, agency, e-mail address, and phone from each respondent. This information will be used for follow-up purposes and reported data will not be directly attributed to a particular laboratory employee. Data will be collected from state forensic laboratory directors and their delegates via semi-structured interviews, but data will be confidential and will not be released in a personally identifiable manner. Information will only be reported in aggregate form from each laboratory, as the goal of the study is to assist DOJ in future planning related to DNA Backlogs.

2. Would any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing employability or reputation?

Yes No NA

If yes, explain: _____

C2. For research with existing data, documents, records, pathological or diagnostic specimens:

1. Are the sources of the data publicly available?

Yes No NA

If no, explain: _____

2. Is information recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects?

Yes No NA

If yes, explain: _____

D. Describe other categories of exempt research¹ here:

¹ Note: Categories C1 and C2 above are the most common types of research conducted at RTI that may be exempt from IRB review. For a complete list of exemption criteria, please see below.

-----Space below this line for IRB use only.-----

Decision of IRB Coordinator or Chair

Name of IRB Coordinator or Chair making exemption determination: David Borasky

Please check appropriate answer(s):

I agree that this study is exempt [45CFR46.101(b)] from IRB review based upon the information provided by the Project Manager above. (Check applicable category below.)

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.



02-12-2010

Signature of IRB Coordinator or Chair named above

Date