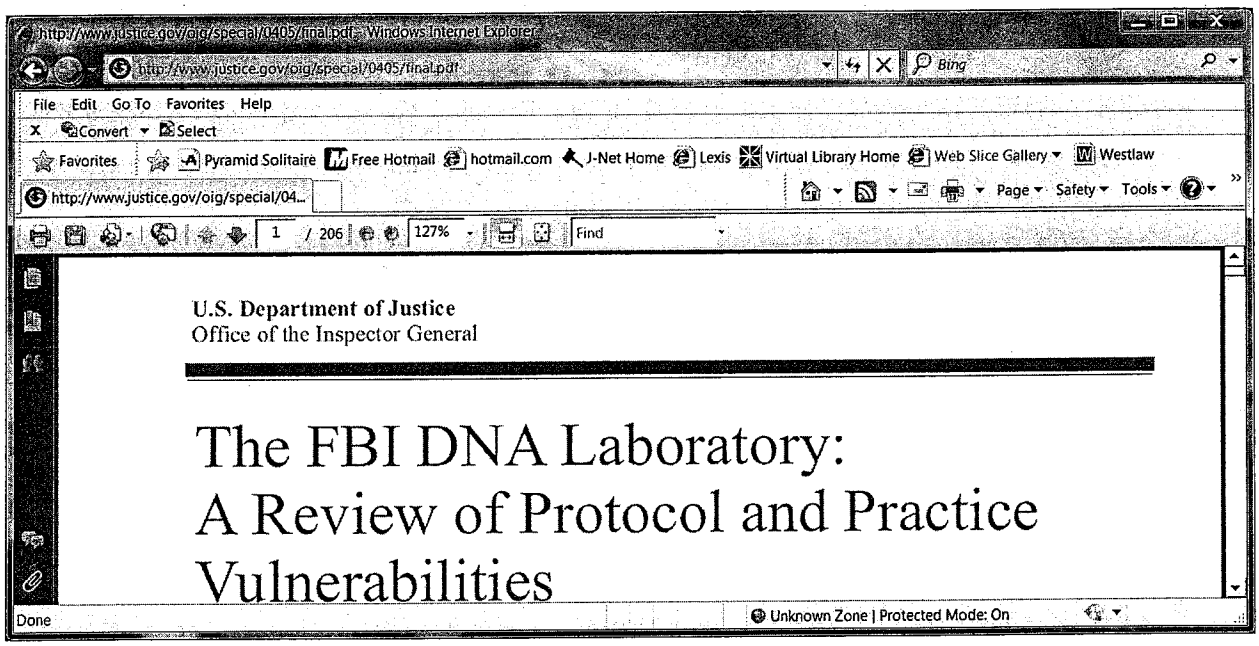
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Office of the Inspector General

The FBI DNA Laboratory: A Review of Protocol and Practice Vulnerabilities

Office of the Inspector General
May 2004

TABLE OF CONTENTS

LIST OF APPENDICIES

THE FBI DNA LABORATORY: A REVIEW OF PROTOCOL AND PRACTICE VULNERABILITIES

EXECUTIVE SUMMARY

I. BACKGROUND

Deoxyribonucleic acid, or DNA, is a molecule that contains the genetic code for living organisms. Within the last 15 years, researchers gained the ability to produce a computerized record containing a person's DNA characteristics (a DNA profile), a development with far-reaching forensic implications. Through comparison of DNA samples, investigators now reliably can conclude whether a particular suspect is or is not the source of DNA found at a crime scene. The Federal Bureau of Investigation's (FBI) Laboratory Division has played an important role in the development of DNA science to solve crimes.

From August 1988 to June 2002, Jacqueline M. Blake was employed in a DNA analysis unit of the FBI Laboratory. Starting in March 2000, she worked as a Polymerase Chain Reaction (PCR) Biologist and was responsible for performing tests on DNA from crime scenes and convicted offenders. Laboratory Examiners used her analyses to reach conclusions regarding the characteristics and sources of DNA profiles obtained from evidence items, and testified in court in reliance on the integrity of the procedures that she employed. During her tenure as a PCR Biologist, Blake performed analyses on evidence from crime scenes in slightly more than 100 cases.

An important step in the DNA testing procedures that Blake was obligated to follow is the processing of control samples that identify whether contamination has been introduced during the testing process, called negative control tests. Starting in the late stages of her training to become a PCR Biologist and for more than two years thereafter, Blake consistently failed to complete these control tests. Her omissions rendered her work scientifically invalid and unusable in court. Without proper processing of the negative controls, a Laboratory Examiner is not able to rule out the possibility that contamination, rather than the evidence under examination, is the source of the testing results. By itself, however, the failure to process the negative controls does not change the test results or lead to a particular testing outcome (e.g., creating a match between a known and unknown evidence sample). The retesting of evidence in Blake's cases to date indicates that, while she did not properly conduct the contamination testing, the DNA profiles that she generated were accurate.

In addition to omitting the negative control tests, Blake falsified her laboratory documentation to conceal the shortcut she was taking to generate

contamination-free testing results. Blake later told the Office of the Inspector General (OIG) investigators: "I knew that when I did not properly prepare the negative control samples for injection but initialed the related injection sheet anyway, I was misrepresenting that the negative control samples were properly prepared. . . ."

Blake generated more than two years' worth of testing results before her omissions were finally caught, and even then her discovery was accidental. In April 2002, a colleague of Blake was working late one evening after Blake had left the Laboratory for the day, and noticed that the testing results displayed on Blake's computer were inconsistent with the proper processing of the control samples. Further inquiry by Laboratory personnel led to the discovery that Blake had failed to complete the negative control testing in the vast majority of her cases. Blake later resigned from the Laboratory and was investigated by the Department of Justice (DOJ or Department) for her misconduct. On May 18, 2004, Blake pled guilty in the United States District Court for the District of Columbia to a misdemeanor charge of providing false statements in her laboratory reports.

Blake's actions have caused many problems. Although the FBI Laboratory has not identified a case where Blake's misconduct interfered with the content of a DNA profile, Blake's failure to process the negative controls rendered all of her DNA analyses scientifically invalid. We found that her actions caused substantial adverse effects in at least five respects. First, it required the removal of 29 DNA profiles from the national registry of DNA profiles, known as NDIS, 20 of which have yet to be restored as of March 2004.[1] Until these profiles are restored there will be an ongoing risk that an investigative agency will submit a DNA profile and not generate a match with a corresponding Blake profile because the Blake profile has been removed from NDIS. Past crimes thus may remain unsolved. Second, Blake's misconduct has delayed the delivery of reliable DNA reports to contributors of DNA evidence. Retesting in many of Blake's cases has taken upwards of two years to complete, leaving evidence contributors without information that they should have had long ago. Third, in a limited number of cases, Blake's faulty analysis is the only DNA information that is available. The previously submitted evidence was consumed in the testing process and new evidence samples cannot be obtained. Fourth, Blake's misconduct has adversely impacted the resources of the FBI and DOJ. The efforts that the FBI Laboratory and DOJ have had to expend on the corrective measures needed to address Blake's actions have been substantial. Both organizations have devoted thousands of hours of work to deal with the consequences of Blake's

[1] Of the 20 cases for which profiles have yet to be restored, no DNA remains for retesting in 2 cases, the Laboratory is awaiting the resubmission of evidence for reanalysis in 13 cases, and the Laboratory states it has completed reanalysis on an additional 4 cases. Reanalysis is being completed in one case.

failure to comply with the FBI Laboratory's DNA protocols, a cost that does not include the funding expended for contractor support to retest evidence. State and local investigators and prosecutors who were notified of Blake's misconduct and instituted corrective measures in their cases also have had to expend additional resources. And lastly, we believe that Blake's misconduct, and the Laboratory's failure to detect it for a period exceeding two years, has damaged intangibly the credibility of the FBI Laboratory. The Blake controversy has fed into a perception that the Laboratory has unresolved management and employee oversight issues.

The FBI's Office of Professional Responsibility notified the OIG approximately one month after the FBI discovered Blake's omission of the control tests. The OIG began an investigation of Blake and interviewed Laboratory staff members, analyzed documents, and met with representatives of the FBI's Office of General Counsel. The OIG investigation resulted in Blake signing an affidavit confessing to her misconduct. In addition, because the FBI Laboratory's application of its protocols did not lead to Blake's early detection, the OIG initiated this review of the FBI Laboratory's DNA protocols to assess whether the protocols were vulnerable to other abuse and instances of noncompliance.

This report describes the results of the OIG's review. Our objectives were twofold: 1) to analyze the vulnerability of the protocols in the FBI Laboratory's DNA Analysis Unit I (DNAUI) – the unit where Blake worked – to undetected inadvertent or willful noncompliance by DNAUI staff members; and 2) to assess the DNAUI's application of the protocols identified as vulnerable.[2] The report also examines and notes several areas of concern with regard to FBI management's response to Blake's misconduct.

II. METHODOLOGY OF THE OIG'S VULNERABILITY ASSESSMENT

The OIG's vulnerability assessment proceeded in two phases. In the first phase, the OIG team reviewed the DNAUI's protocols for vulnerabilities. The second phase consisted of OIG fieldwork at the DNAUI laboratory.

To facilitate our examination, particularly the review of the protocols, we recruited three scientists from the national DNA community to consult with our assessment team. OIG staff provided the scientists with the most current version of each of the written protocols governing DNAUI activities and requested that they identify any weaknesses in them that would render the Unit vulnerable to undetected wrongdoing by staff members. The scientists

[2] The DNAUI identifies and characterizes body fluids and body fluid stains recovered as evidence in crimes using traditional serological techniques and related biochemical analysis. It generates DNA profiles from the nuclei of cells recovered from such evidence.

reviewed the protocol documents and then met with the OIG assessment team to discuss the vulnerabilities identified.

With input from the scientists, OIG staff members then designed fieldwork to verify actual laboratory practices for the protocols deemed problematic, and to assess whether these practices served to mitigate any of the vulnerabilities identified. Our fieldwork consisted of interviews of more than 20 staff members within the DNAUI and the Laboratory Division and tours of the DNAUI facility, first at FBI Headquarters in Washington, D.C., and later at the new DNAUI facility in Quantico, Virginia. In addition to interviews, we also reviewed FBI documentation regarding: 1) the factors considered in the design of the new DNA facility; 2) the training curriculum and methods used within the DNAUI, along with various staff training records; and 3) the status of development of a computerized tracking system to be used by the Laboratory for evidence, samples, and other information. We also examined documents and interviewed personnel from the Laboratory, FBI OGC, and the Counterterrorism Section at the Department regarding FBI management's response to Blake's misconduct.

We compared the results of our fieldwork with the vulnerabilities detected by the scientists to determine whether any information gathered during fieldwork affected the extent and nature of the scientists' conclusions. We then discussed our results with the scientists. Generally, they did not make any changes to the areas they previously identified as vulnerabilities.

III. SUMMARY OF FINDINGS AND RECOMMENDATIONS

Our findings and recommendations focus on two general types of vulnerabilities that became apparent during our assessment: protocol vulnerabilities and practice or operational vulnerabilities.

A. Protocol Vulnerabilities

Our textual analysis of the FBI protocols that govern the DNAUI concluded that 31 out of 172 topical sections are significantly vulnerable to inadvertent or willful noncompliance by DNAUI staff members. One of four reasons typically accounted for each of the vulnerabilities: 1) the protocol lacks sufficient detail; 2) the protocol fails to inform the exercise of staff discretion; 3) the protocol fails to ensure the precision of manual note taking; and 4) the protocol is outdated. In addition, in the course of completing fieldwork that examined how staff members implement the protocols that we identified as problematic, we discovered operational vulnerabilities in the areas of team functions, training, information sharing, and evidence tracking. However, our review did not identify any protocol violations in the DNAUI regarding the failure to process negative control samples, other than the failure

of Jacqueline Blake. It also is important to note that our identification of a "vulnerability" should not be misconstrued as an invalidation of the science or techniques used by the DNAUI, or as an indication of the inadequacy of the entirety of DNAUI policies on a particular subject. Our use of the term "vulnerability" is limited to its definition as set forth in Chapter Five, Section I.C.

Approximately 20 percent of the written procedure and protocol sections we examined lacked the detail necessary for a technically qualified DNA scientist to reproduce all aspects of the analysis procedures in use in the DNAUI without the potential for variation. Protocols that lack essential detail can create a work environment that encourages use of disparate and unproven laboratory practices, can foster disregard for protocols, and can make it difficult for staff members and management to identify instances of protocol noncompliance. Accordingly, we recommend that DNAUI management ensure that the document sections we identified as vague describe completely and accurately management expectations, Unit procedures and policies, and "best practices" currently in use in the DNAUI.

Our review also identified protocols that do not describe adequately the decision criteria Laboratory staff should employ when their duties require them to exercise discretion in the testing process. Greater risk of abuse and error is present when testing procedures call upon the use of such judgment. If staff members are not equipped with sufficient guidance to exercise their discretion properly, they could prematurely halt the testing process when a probative DNA result might otherwise have been obtained. To address this deficiency, we believe that DNAUI management should add decision aids to its protocols, such as workflow diagrams and decision trees, that identify the factors that staff should consider when using judgment during the DNA testing process. These aids would help to structure decision-making and to ensure that staff members do not overlook relevant information.

We also determined that certain protocols lack comprehensive guidance on notetaking methods, even though compliance with the documentation requirements in those protocols depends heavily upon Laboratory staff implementing the methods properly. The DNAUI team structure makes it especially important that all staff members have a comprehensive and consistent understanding of how to record information as they complete their work, since Examiners draw their conclusions and testify in court based upon the work of the Serologists and PCR Biologists as reflected in the case file documentation. If staff members are allowed to delay recording observations and test results, their documentation of that information may not be fully accurate, may be unduly influenced by what they know should have occurred pursuant to the applicable protocols, and thus may compromise the accuracy of the resulting analytical conclusions. Therefore, we believe that the DNAUI should provide sufficient guidance to its employees to ensure that case

documentation meets quality assurance requirements, and it should also guarantee that the Unit's protocols provide comprehensive guidance on notetaking requirements.

Lastly, our review of protocol vulnerabilities identified several protocols that are outdated and no longer reflect current procedures in use in the DNAUI. By retaining outdated protocols, DNAUI management risks the chance that some staff members might not be aware of new requirements and rely inadvertently upon standards that have been superseded. While the staff we interviewed were aware of the new requirements, we recommend that these protocols be revised promptly.

We found that the work practices of the DNAUI's staff members served to mitigate, at least to some degree, the effects of the protocol vulnerabilities outlined above. In other words, the practices described to us by staff members indicated that they rely upon internal controls and an understanding of management expectations, not reflected in the protocols, that diminish the risks posed by the weaknesses in the written documents. However, we believe that until the DNAUI revises its protocols in accordance with the recommendations in this report, the Unit needlessly will remain subject to an increased risk of employee error and inadvertent protocol noncompliance. Because of the importance of the DNAUI's work, we believe this problem merits significant attention from the Laboratory and should be resolved promptly.

B. Practice Vulnerabilities

In terms of practice vulnerabilities, we recommend that the DNAUI should work to: 1) promote greater consistency in DNAUI team operations; 2) develop a comprehensive, written training curriculum; 3) improve management and staff communications; and 4) complete implementation of an information management system to improve efficiency and evidence tracking capabilities.

During our interviews with DNAUI staff members we received many comments that highlighted the need to ensure that the DNAUI's protocols are comprehensive and address all aspects of the Unit's operations. As the interviewees explained, variations exist in staff member work practices because the Unit's written guidance is silent on many subjects. These variations can diminish staff and management sensitivity to protocol noncompliance. Therefore, to promote greater consistency and accountability in DNAUI functions, we recommend that Laboratory management document and standardize the best practices of the Unit's teams and incorporate them in protocols.

Our review of DNAUI training revealed that the Unit lacks a comprehensive, written curriculum and that training consists largely of

individual discussions with a mentor and presentations given by various experienced staff members. Without a comprehensive, written curriculum, mentors and trainers can blur the distinction between team or individual preferences and the requirements of the protocols, leaving trainees unclear about which methods are mandatory and which are merely suggested. In our view, such an environment leaves the Unit vulnerable to inadvertent protocol noncompliance, since staff members may choose to alter their methods in ways that unwittingly contradict Unit requirements. To enhance the quality of its training program, we recommend that DNAUI management convert its "oral tradition" of training and other informal training methods into a comprehensive, written curriculum to ensure that trainees receive consistent instruction that comports with the Unit's protocols.

Further, our interviews revealed that the dissemination and solicitation of protocol-related information to and from DNAUI staff members are inconsistent and ineffective. Interview responses from staff members at all levels within the DNAUI revealed that the flow of information often is erratic and impeded by an incorrect management assumption that communications within the DNAUI, and between the DNAUI and Laboratory management, are functioning well. These types of communication weaknesses pose a risk to the efficiency and effectiveness of the Unit's operations and should be addressed. Consequently, we make several recommendations to Laboratory and DNAUI management that we believe will facilitate the exchange of protocol-related information.

During our review we also observed many DNAUI operations that could be made more efficient through use of a Laboratory Information Management System (LIMS). A LIMS is a computerized system of databases that track, organize, and link the information that must be maintained to document the receipt, handling, and disposition of each case and evidence item. The Laboratory currently lacks a LIMS, and therefore does not have the benefit of greater efficiency, increased detail and timeliness in documentation, and the reduced potential for human error or abuse. Accordingly, Laboratory management should ensure that a LIMS is implemented successfully and that its full utilization remains a top administrative priority of the Laboratory.

C. FBI Response to Blake's Misconduct

Finally, our review identified several issues of concern regarding the management response of the FBI to Blake's misconduct. These include: 1) the timeliness of the retesting of evidence and of written notifications to DNA contributors and prosecutors; 2) the sufficiency of the legal analysis provided by the FBI OGC in the months immediately following the discovery of Blake's misconduct; and 3) the scope of the Laboratory's remedial actions. We also believe that given Blake's prior work history and training experiences, the Laboratory should have paid more careful attention to her performance on her

initial PCR qualifying and proficiency tests and on the first several profiles she generated after she became a PCR Biologist.

As of February 2004, nearly two years after Blake's detection, of the 90 cases where Blake did not properly complete DNA testing, the FBI Laboratory had failed to provide direct, written notification to evidence contributors in 42 of those cases that Blake failed to process properly the evidence they submitted. Of this number, 20 contributors had received no notification at all concerning Blake's processing of their evidence.[3] We found that the FBI disregarded the views of the Department that written disclosures in these cases should have been completed much earlier. It also has taken nearly two years since the discovery of Blake's wrongdoing for the Laboratory to complete DNA retesting in her cases, with the result that some of these cases have languished at the Laboratory for more than four years. [4]

Our review further revealed that FBI OGC failed to ensure that its staff attorney assigned to the Blake matter through the fall of 2002: 1) conducted a comprehensive legal analysis of the Blake situation, and 2) fully assisted the Laboratory to provide sufficient notice to evidence contributors and prosecutors.

We also found that the Laboratory's remedial actions were too narrowly conceived in two respects. First, we believe that the Laboratory erred when it limited its review of Blake's work to the last 2 years of her 14-year career at the FBI. Second, the DNAUI should have taken steps soon after the discovery of

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[3] According to the FBI, notification of these contributors can wait until evidence retesting is complete because, with two exceptions, the cases where notice has not been furnished are ones in which no report has issued from the DNAUI, a suspect has not been identified, and therefore there is no possibility that an evidence contributor would unwittingly rely upon Blake's invalid test results. We believe that this view overlooks the important interest that victims of crime have in the timely testing of evidence. All evidence contributors should have been notified directly in writing during the summer of 2002 that Blake had failed to process their evidence properly. At that juncture the evidence contributor would have had the ability to make an informed decision whether to resubmit new evidence or to seek testing services from another laboratory. Because 20 of these contributors were not informed, however, they were deprived of the opportunity to make this decision. We also believe that it is inappropriate for these contributors to learn about Blake's misconduct indirectly through public reports, rather than directly from the FBI. As explained in text below and in Chapter Six of this report, to avoid these problems in the future we recommend that, in circumstances where a protocol violation renders the Laboratory's testing results scientifically invalid, the Laboratory promptly notify the evidence contributor of the anticipated time needed to complete any necessary retesting.

[4] Of the 90 cases where Blake failed to process the negative controls, the FBI Laboratory, with the assistance of its contractors, intends to complete evidence retesting in 64 cases. In the remaining 26 cases, retesting has been deferred pending the resubmission of evidence from the original evidence contributor. As of February 2004, evidence retesting had been completed in only 27 cases.

her misconduct to reassess comprehensively its protocols for vulnerability to abuse.

In light of the management problems above, we recommend the following three corrective measures. First, the Laboratory should maintain basic case data and contact information for evidence contributors and associated prosecutors in an electronic format that can be shared conveniently as needed with other FBI components (such as FBI OPR and FBI OGC) and the Department. This step will facilitate prompt communications with evidence contributors and prosecutors in the event of future testing problems. Second, in circumstances where a protocol violation renders testing results scientifically invalid and a report from the Laboratory is not expected to issue within 180 days from the violation's discovery, the Laboratory should provide the evidence contributor with information about the violation, including whether any remedial measures have been instituted and the anticipated time to complete evidence retesting if necessary, within 90 days of the violation's detection. Lastly, the Laboratory should perform a file review of a sample of cases that Blake is known to have worked on prior to becoming a PCR Biologist to reconfirm that the procedures that were required in fact are documented as appropriate in the case files.

CHAPTER ONE
INTRODUCTION

The Federal Bureau of Investigation's (FBI) Laboratory Division has played an important role in the development of the use of deoxyribonucleic acid, or DNA, in the investigation of crimes. The DNA analysis units at the FBI Laboratory screen evidence from crime scenes for potential sources of DNA. When DNA is identified, FBI forensic scientists isolate and characterize the DNA to produce a profile that can be linked to a particular individual. The Laboratory relies upon written procedures and protocols to govern the testing techniques that are used to produce DNA profiles and to ensure that its DNA testing results are scientifically valid.[5]

The impetus for this review was the FBI's discovery that one of its DNA analysis unit staff members, Jacqueline Blake, disregarded an important step in the DNA testing process and produced dozens of DNA profiles that are scientifically invalid and unusable in court. Our review examines the vulnerability of the protocols in the unit where Blake worked – the DNA Analysis Unit I (DNAUI or Unit) – to undetected inadvertent or willful noncompliance by DNAUI staff members.[6]

Blake was employed in the DNAUI and its predecessor unit from August 1988 to June 2002. Starting in March 2000, she worked as a Polymerase Chain Reaction (PCR) Biologist and was responsible for performing tests on DNA from crime scenes and convicted offenders. Laboratory Examiners testified in court in reliance on the integrity of the procedures that she employed. During her tenure as a PCR Biologist, Blake performed analyses in slightly more than 100 cases.

Starting in the late stages of her training to become a PCR Biologist and for more than two years thereafter, Blake consistently failed to complete tests that identify whether contamination has been introduced during the DNA testing process, called negative control tests. Her failure called into question the integrity of the DNA profiles that her analyses generated, since it was not possible to confirm that her results were a true reflection of the evidence analyzed, unadulterated by contamination introduced in the Laboratory. Blake falsified her laboratory documentation to conceal the shortcut she was taking to generate contamination-free testing results.

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[5] Unless otherwise indicated, our references to the Laboratory's protocols also include its written procedures. The standards that govern DNA analysis at the FBI Laboratory are found in procedure manuals and protocol documents, as well as other sources. See discussion infra at Chapter Two, Section II and Chapter Three, Section II of this report.

[6] The DNAUI identifies and characterizes body fluids and body fluid stains recovered as evidence in crimes using traditional serological techniques and related biochemical analysis. It generates DNA profiles from the nuclei of cells recovered from such evidence.

Blake generated more than two years' worth of testing results before the FBI Laboratory realized that Blake had failed to complete the negative control testing in the vast majority of her cases. Blake later resigned from the Laboratory and currently is under criminal investigation by the Department of Justice (DOJ or Department) for her misconduct.

Blake's actions have rendered all of her DNA analyses for which she failed to complete the negative controls scientifically invalid. In addition, we found that her conduct caused substantial adverse effects in at least five respects: 1) it required the removal of 29 DNA profiles from NDIS, 20 of which have yet to be restored;[7] 2) it delayed the delivery of reliable DNA reports to contributors of DNA evidence in Blake's cases; 3) her testing consumed all the available DNA evidence in several cases, leaving only her suspect DNA profiles as a basis on which to draw conclusions; 4) the corrective action necessary to address Blake's misconduct has consumed substantial resources of the FBI Laboratory and DOJ, as well as the resources of state and local investigators and prosecutors who were notified of her misconduct and had to take corrective measures in their cases; and 5) the controversy surrounding Blake has caused some measure of credibility loss to the FBI Laboratory.

Following notification from the FBI's Office of Professional Responsibility (OPR), the OIG began an investigation of Blake and interviewed Laboratory staff members, analyzed documents, and met with representatives of the FBI's Office of General Counsel (OGC). The OIG investigation resulted in Blake signing an affidavit confessing to her misconduct. In addition, because the FBI Laboratory's application of its protocols did not lead to Blake's early detection, the OIG initiated this review of the FBI Laboratory's DNA protocols to assess whether the protocols were vulnerable to other abuse and instances of noncompliance.

This report describes the results of the OIG vulnerability assessment. Our primary objectives were twofold: 1) to analyze the vulnerability of the protocols in the DNAUI to undetected inadvertent or willful noncompliance by DNAUI staff members; and 2) to assess the DNAUI's application of the protocols identified as vulnerable. The report also notes several areas of concern with the management response of the FBI to Blake's misconduct.

The OIG's vulnerability assessment proceeded in two phases. In the first phase, the OIG team reviewed the most current version of each of the written protocols governing DNAUI activities for vulnerabilities. The second phase consisted of OIG fieldwork at the DNAUI laboratory.

To facilitate our examination, we recruited three scientists from the national DNA community to consult with our assessment team. The scientists

[7] DNA is not available for retesting for two of these profiles.

were responsible for reviewing the DNAUI protocols and identifying any weaknesses in them that would render the Unit vulnerable to undetected wrongdoing by staff members. The scientists also assisted OIG staff members in designing fieldwork to verify actual laboratory practices for the protocols deemed problematic, and in assessing whether these practices served to mitigate any of the vulnerabilities identified.

The fieldwork conducted by OIG staff consisted of interviews of more than 20 staff members within the DNAUI and the Laboratory Division and tours of the DNAUI facility, first at FBI Headquarters in Washington, D.C., and later at the new DNAUI facility in Quantico, Virginia. In addition to interviews, we also reviewed FBI documentation regarding: 1) the factors considered in the design of the new DNA facility; 2) the training curriculum and methods used within the DNAUI, along with various staff training records; and 3) the status of development of a computerized tracking system for evidence, samples, and other information. We then analyzed the DNAUI staff practices described during this fieldwork to identify whether vulnerabilities existed in staff practices, in addition to the protocol vulnerabilities already identified. Finally, we examined documents and interviewed personnel from the Laboratory, FBI OGC, and the Counterterrorism Section at the Department regarding the management response to Blake's misconduct.[8]

The report is divided into six chapters. Following this Chapter, we provide an overview in Chapter Two of the DNA testing process and the national standards that govern it. In Chapter Three we describe the FBI Laboratory, including operations in the DNAUI, and the FBI's protocols for DNA analysis. Chapter Four details Blake's misconduct and the FBI's response to it. In Chapter Five we describe the protocols and practices that we believe are vulnerable to abuse, and lastly, in Chapter Six we provide recommendations to enhance protocol compliance in the DNAUI.

[8] A more detailed explanation of our assessment methodology is provided in Chapter Five, Section I of this report.

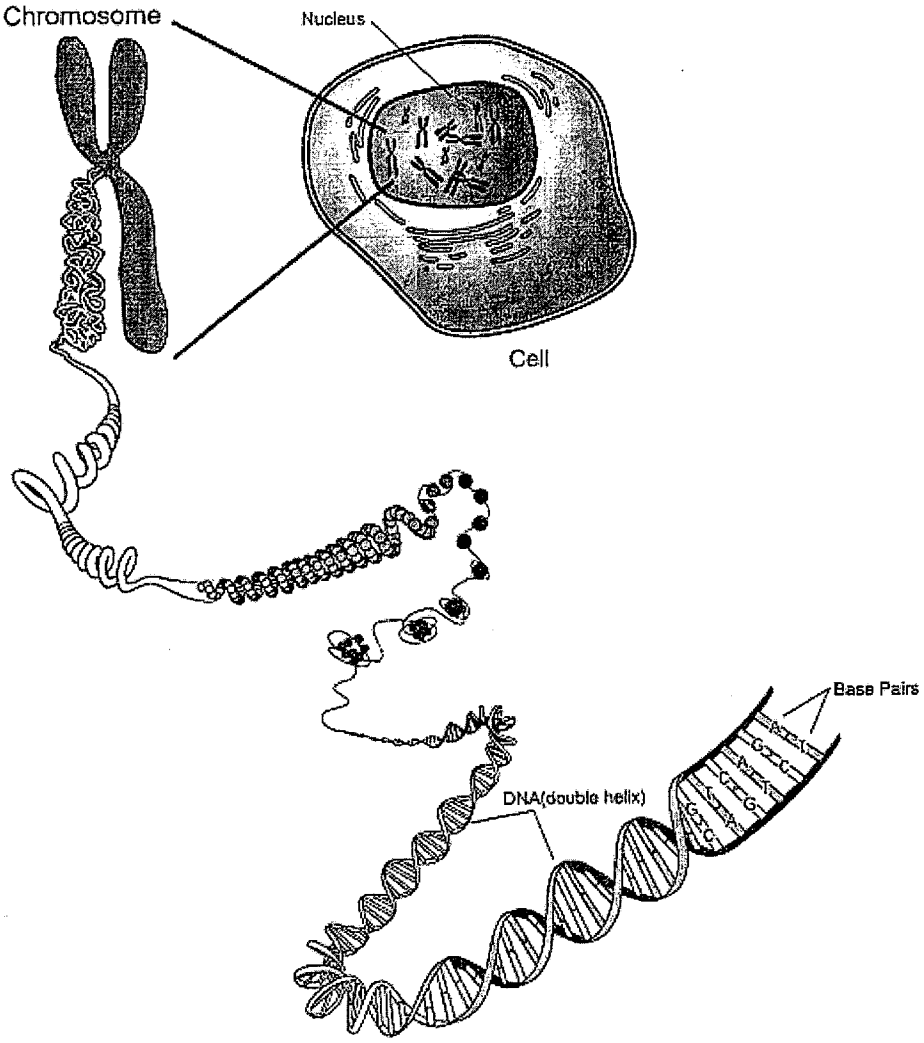
CHAPTER TWO
THE ANALYSIS OF DNA

In order to understand the nature of Blake's misconduct and the deficiencies this review identified in the FBI Laboratory's DNA protocols and practices, we first describe in this Chapter the basic characteristics of DNA and the work of forensic DNA scientists. We describe below the physical structure of DNA, testing methods, and the standards that govern DNA analysis.

I. GENERAL PRINCIPLES OF DNA ANALYSIS

A. The Structure of DNA

All living things are composed of cells, which typically have a nucleus that regulates metabolism, growth and/or reproduction. In human beings, the nucleus contains chromosomes composed of DNA that encode all of the information necessary to produce a complete human body. Chromosomes store information in the chemical structure of DNA much like a book or a compact disk. The nucleus contains 46 chromosomes, two copies of each of the 23 different human chromosomes. One copy of each chromosome is inherited from an individual's mother and one copy is inherited from an individual's father, giving a child DNA characteristics of both its mother and father.



Source: National Human Genome Research Institute, by artist Darryl Leja at www.accessexcellence.org/AB/GG/chromosome.html

Approximately 99.9 percent of human DNA is the same. Forensic DNA scientists are only interested in the 0.1 percent of the DNA that varies among people. The human traits that result from the variations in this part of the DNA can be obvious, like different eye color or different blood types, but may also be so subtle that only laboratory testing can detect them.

Each chromosome contains many genes, which are the portions of the chromosome that code for personally identifying characteristics, like hair color or eye color. The characteristics of a specific gene, or of a specific location on a DNA strand, is referred to as an allele. For example, if two people both have blue eyes, then they have the same alleles for their eye-color gene. It has been estimated that only 2 to 3 percent of the information in a chromosome is

organized into genes. While the function of the DNA between the genes is unknown, scientists currently believe that it does not code for anything. Since it varies widely among individuals, scientists examine the DNA located between the genes to determine a person's DNA profile. Examining this DNA allows scientists to determine an individual's unique DNA profile (except for identical twins), without that profile revealing personally identifying characteristics or medical conditions.

Even though forensic DNA scientists focus their analyses on specific chromosomal locations that vary widely between individuals, it is not necessary to examine every one of these locations to develop a unique DNA profile for an individual. Rather, scientists need only examine enough locations to virtually eliminate the possibility that two unrelated people have the same DNA profile purely by chance. Under current DNA standards applicable in the United States, an individual's DNA profile consists of the alleles present at 13 specified chromosomal locations. Scientists have determined that, in general, when DNA profiles consist of the alleles present at these locations the probability that two unrelated individuals will have the same DNA profile purely by chance is less than 1 in 200 billion. As a result, except for identical twins, examining the 13 locations produces a DNA profile that is essentially unique to an individual. See Appendix 1 (which contains an example of a complete DNA profile).

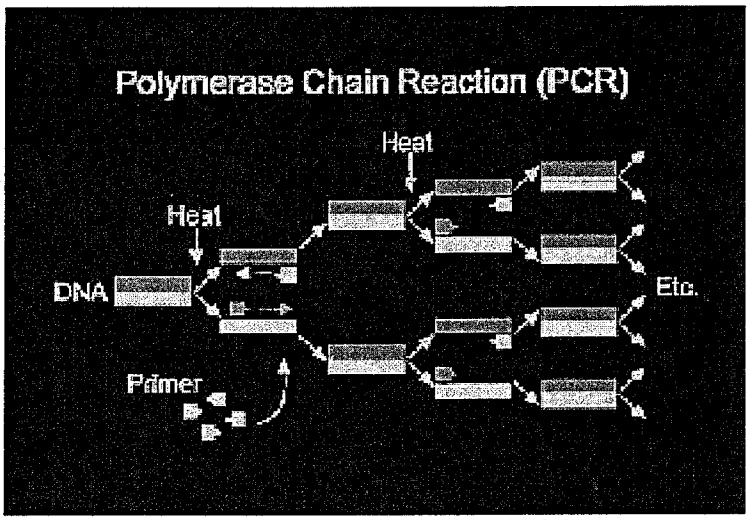
B. Overview of the DNA Testing Process

Law enforcement personnel who submit crime scene evidence for DNA analysis must package and seal the evidence and then arrange for its secure delivery to a DNA laboratory. Upon receipt of the evidence, forensic scientists first determine if the evidence might provide DNA by visually examining it for indications of body fluid stains, and then performing testing to determine whether specific body fluids that might contain DNA are present.

When possible, forensic scientists analyze only a portion of the stains on the evidence and save the remainder in case future testing is necessary. Generally, stains on fabric are cut out of the item and the DNA is extracted from the cuttings. If the stains are on a hard object, such as a knife, some of the dried body fluid is removed from the object with a cotton swab (known as swabbing an item) and the DNA is extracted from the cotton swab. The process used to extract the DNA varies depending on the organic source of the stain and the material containing the stain.

Once the DNA is extracted from the evidence, it undergoes a process known as polymerase chain reaction (PCR), which is also referred to as amplification. This process, often analogized as biological photocopying, allows scientists to make copies of specific chromosomal segments. The amplification process gives forensic scientists the ability to analyze minute DNA samples,

and has allowed DNA analysis to become a much more useful tool for forensic scientists. The diagram below illustrates the PCR process:

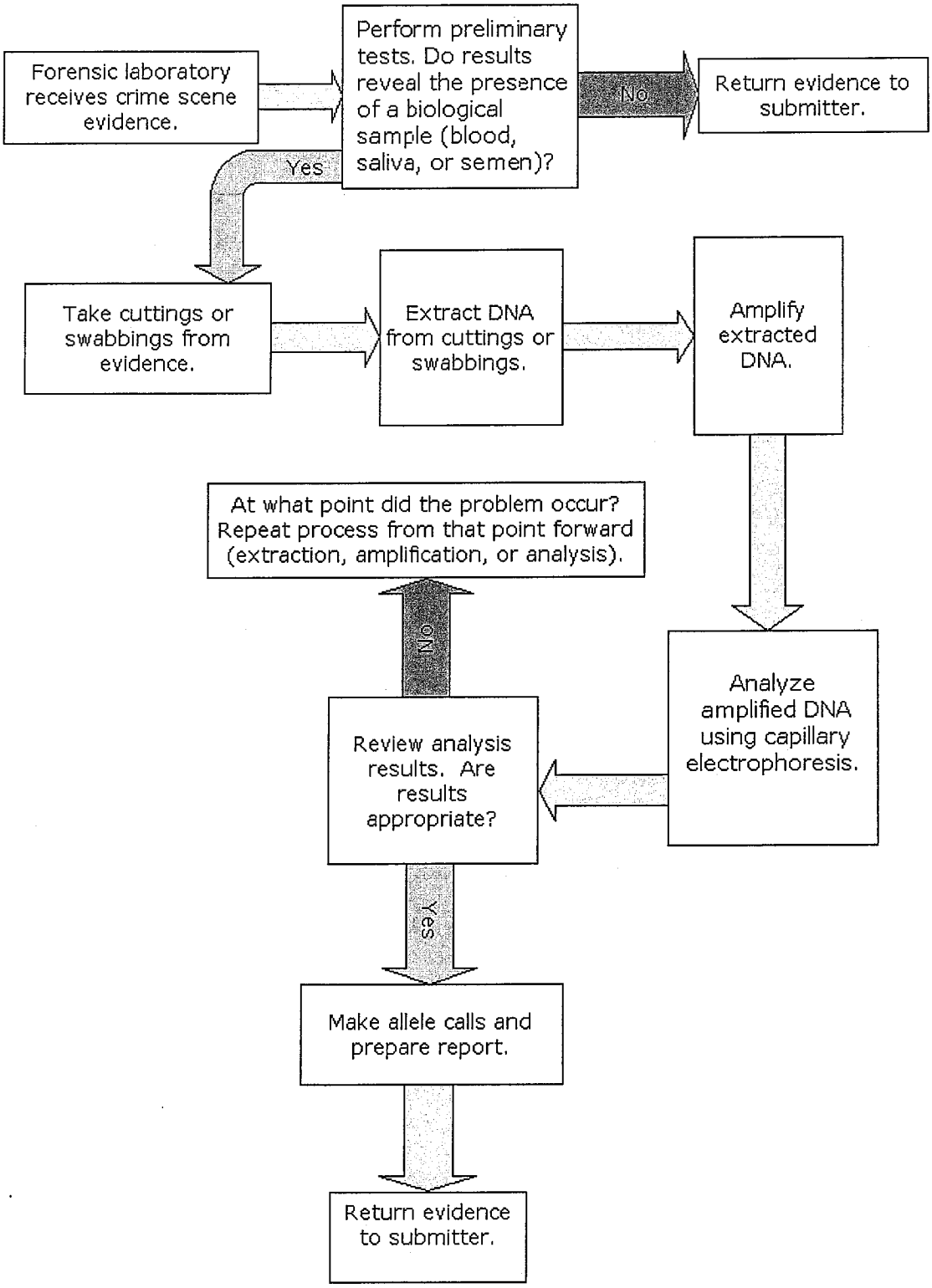


Source: Federation of American Societies for Experimental Biology at www.faseb.org/opar/bloodsupply/pcr.html

After amplification is complete, the DNA is analyzed using a machine that separates the DNA fragments present in the sample. This process is known as electrophoresis. Special software then measures the length of the DNA fragments, determines the alleles that correspond to the fragments, and compiles a DNA profile for the sample. The DNA testing process is summarized in the diagram on the following page.[9]

[9] Information concerning the final steps described in the diagram (i.e., data analysis and allele calls) is presented in Chapter Two, Section I.D of this report.

Steps in the Analysis of DNA



C. Short Tandem Repeat (STR) Analysis

As the name implies, short tandem repeat (STR) analysis is a method of determining an individual's DNA profile by counting the number of times a small DNA sequence (short tandem repeat unit) is repeated at a specific chromosomal location. STR analysis consists of three processes: amplification, electrophoresis, and interpretation.

In amplification, extracted DNA is added to chemical reagents and heated, causing the two strands that compose the DNA molecule (they resemble two sides of a "ladder," as seen in the graphic on page 5) to separate. Each of the two strands then can be used as a template to make (or synthesize) a new double-stranded DNA molecule.

The reagents in which the DNA is heated contain markers that identify the starting and ending points of the DNA fragment that is duplicated. The markers also are called primers because they prime (or stimulate) the synthesis reaction. Primers are short synthetic pieces of DNA designed to match the regions of human DNA which are highly variable. As the DNA and chemicals begin to cool, the primers attach to the single-stranded DNA. The primers contain fluorescent labels so that they may be detected by lasers later in the testing process.

Once the primers have bound to the beginning and end of the segment being copied, individual building blocks of DNA from the reagents fill in the rest of the empty spots on the single-strand. See diagram supra at page 7 describing the PCR process.

The heating and cooling of the DNA is accomplished by a machine called a thermal cycler, in which a tray of capped tubes containing the DNA and chemical reagents are placed. The thermal cycler can be programmed to heat and cool repeatedly for specific amounts of time. At the end of many repetitions, millions of copies of the original DNA section are created.

Any DNA present in a tube when the amplification process begins, whether from evidence or introduced through contamination, will be amplified.[10] To ensure that the DNA profile generated from the amplified DNA is representative of the DNA from the evidence sample and not from contamination, and to verify that the testing process is accurate, DNA protocols require forensic DNA scientists to analyze a series of control samples. For each batch of samples processed, at least one positive control, one negative control,

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[10] DNA from contamination usually can be differentiated from crime scene DNA because it is miniscule in comparison to the amount of DNA that is present from the evidence. In other words, DNA from contamination typically will be "drowned out" by the DNA that is included from the evidence sample.

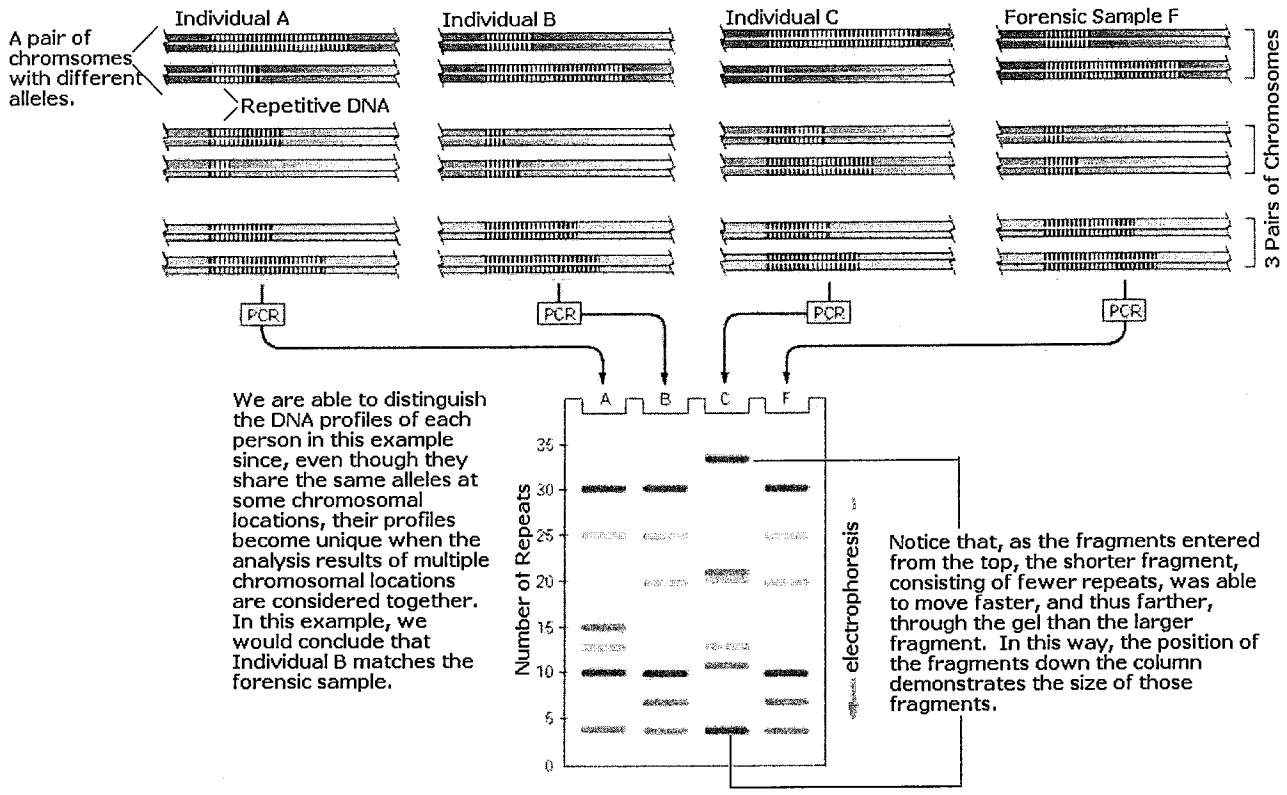
and one reagent blank are analyzed along with the DNA samples. The positive control tube contains the reagents necessary for amplification plus DNA from a source for which the DNA profile is known. Since the scientists know the correct test results for the positive control, it allows them to determine the accuracy and performance of the amplification and analysis processes. The negative control tube contains all of the reagents used for amplification. The reagent blank contains all of the reagents used to process an item of evidence from extraction through electrophoresis. DNA from the evidence is not added to these controls, though their contents are amplified. The purpose of the negative control and the reagent blank is to reveal any contamination that is present in the reagents or introduced during the testing process.[11]

TYPES OF DNA CONTROLS

	Positive Control	**Reagent Blank**	**Negative Control**
Material Tested	Amplification reagents and known DNA	All reagents	Amplification reagents
Reveals	Accuracy and performance of the amplification and analysis processes	Presence of contamination introduced at any point in the analysis process	Presence of contamination introduced during the amplification process

After the DNA has been amplified, the newly formed DNA fragments are sorted according to length (i.e., number of short tandem repeats) using electrophoresis. In general, electrophoresis is performed by adding DNA to one end of a piece of gelatinous material which contains tiny holes that allows the material to function as a molecular sieve. An electric current is applied across the material, causing the DNA fragments to move. Since it is easier for smaller fragments to move through the material, the smaller fragments move farther than the larger fragments. As a result, at the end of electrophoresis the DNA fragments are sorted by size. The size of the DNA fragments is determined by comparing the distance each fragment moved to the distances moved by the fragments of known size. The results of electrophoresis are illustrated in the following graphic.

[11] Unless otherwise noted, references to "negative controls" also include reagent blanks.



Source: www.accessexcellence.org/AB/GG/forensci_PCR.html ©1998 by Alberts, Bray, Johnson, Lewis, Raff, Roberts, Walter. Published by Garland Publishing, a member of the Taylor and Francis Group.

D. Capillary Electrophoresis

The principles described above also apply to capillary electrophoresis, a form of electrophoresis employed by the DNAUI. Its distinguishing characteristic is that the electrophoresis occurs inside a capillary tube (a very thin glass tube, comparable to a human hair) with a sieving material inside, rather than on a piece of gelatinous material. Capillary electrophoresis is an automated process that analyzes many DNA samples and requires minimal involvement by DNA scientists after the initial set-up procedures are completed. These procedures include cleaning and calibrating the electrophoresis machine and preparing the amplified DNA for analysis.

To prepare amplified DNA for capillary electrophoresis, the DNA scientist:

- Places a sufficient number of empty tubes in a rack;

- Adds water for dilution and internal size standard[12] to each of the empty tubes;

- Adds an appropriate amount of one of the following to the tubes containing the internal size standard:

  - amplified DNA from known samples, unknown or evidentiary samples, or the positive control;

  - amplified negative control or reagent blank; or

  - an allelic ladder,[13] which contains the more common alleles in the general population for specific chromosomal locations; and

- Seals the tubes with soft rubber caps.

Once the tubes are sealed, the rack is ready to be placed on the capillary electrophoresis machine. A sample list is prepared which identifies the location of each sample on the rack and makes it possible for the machine's computer to locate a specific sample. An injection list is also prepared which tells the computer the order in which the samples are to be analyzed. The capillary electrophoresis machine has a probe that punctures the soft rubber caps on the tubes and withdraws a specific amount of sample. The sample is drawn up into the capillary tube (referred to as injecting the sample) where the electrophoresis is completed.

As mentioned previously, the primers used during amplification contain fluorescent markers that allow the DNA fragments to be detected by lasers. The manufacturer of the capillary electrophoresis machine has developed proprietary software to display the test results and to aid in their interpretation. Using this software, the capillary electrophoresis machine determines the size of the DNA fragments in a sample based on the information detected by the lasers. The machine and the software then represent the lengths of the various fragments as peaks on a graph as illustrated on the following page:

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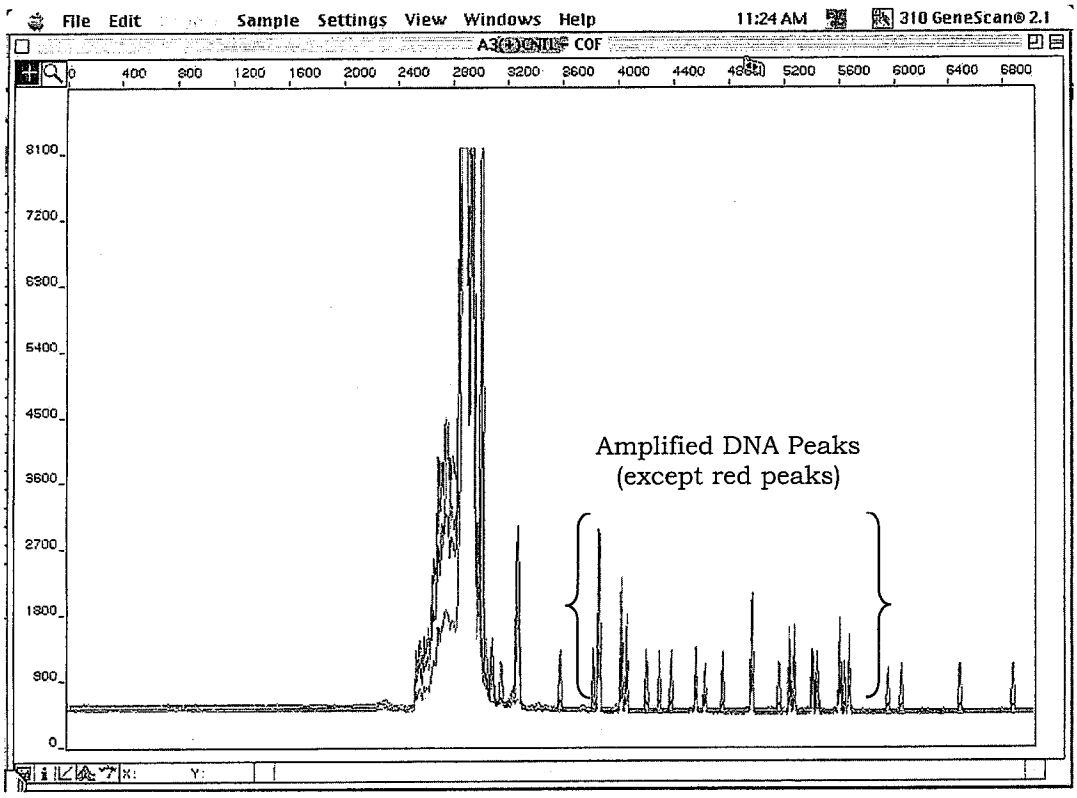
[12] The internal size standard contains DNA fragments of known sizes that provide reference points for determining the length of the sample's DNA fragments.

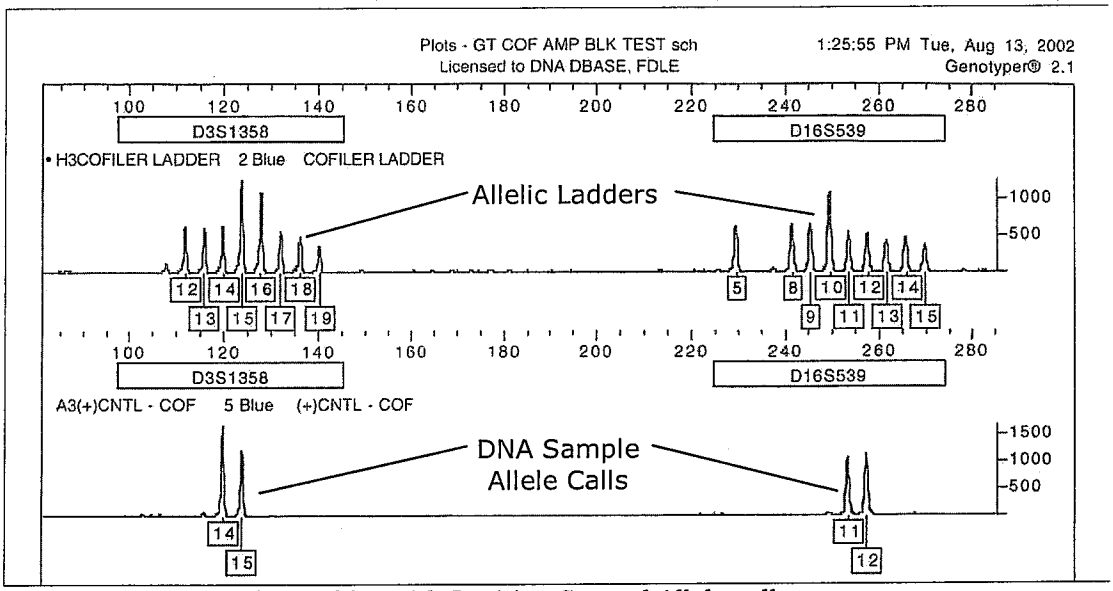
[13] Allelic ladders are used like molecular rulers to help "measure" the lengths of the fragments in the reference and evidentiary samples.



GeneScan® View: raw data for a Positive Control (9947A) prepared according to protocol. Peaks depicted in red originate from the internal size standard added to each sample.

The proprietary software has two components, GeneScan® and Genotyper®.[14] Data viewed in GeneScan®, as appears above, is the raw, unanalyzed, collection data that reflects everything the laser detects, including interference that is common in electrophoresis instruments (Genescan® data). Genotyper® allows forensic scientists to take GeneScan® data and display it in a format that conceals background noise and peripheral information, and to focus their review on the results of the control and evidence samples. An example of a Genotyper® display is presented on the following page:

[14] We provide additional information regarding this software in Appendix 2.



Genotyper® View: COFiler Ladder with Positive Control Allele call

Information collected during these analyses is used to assemble the DNA profile. As mentioned previously, two points of reference are used to help the software as it determines the lengths of the DNA fragments detected during electrophoresis: 1) the GeneScan® software uses the internal size standard, which contains DNA fragments of known sizes; and 2) the Genotyper® software uses allelic ladders as a point of comparison for the designation of the number of repeats in the DNA sample at particular chromosomal locations, since the peaks within the allelic ladder correspond to known fragment lengths at those locations. The DNA Examiner then works with the Genotyper® graphs, similar to the one above, looking for any peripheral information that should be considered. Unless contamination is detected or other complications disrupt the testing, the Examiner then documents what the allele values are at each of the chromosomal locations analyzed (usually 13 chromosomal locations are examined), which, once compiled, constitute a DNA profile. See Appendix 1 for an example of a complete DNA profile and the corresponding GeneScan® and Genotyper® graphs.

II. STANDARDS GOVERNING FORENSIC DNA ANALYSIS

The creation of national standards for DNA analysis played a pivotal role in establishing the integrity of the DNA testing process. In addition, by adhering to these standards, DNA laboratories, including the FBI's DNAUI, have been able to attest to the validity and reliability of their DNA testing results.

A. Sources of DNA Standards

Forensic DNA laboratories, particularly those participating in the FBI's Combined DNA Index System (CODIS),[15] have relied upon three primary sources of operational standards since the first forensic DNA laboratories were established in the late 1980's: 1) the Technical Working Group on DNA Analysis Methods (TWGDAM); 2) the DNA Advisory Board; and 3) the FBI's National DNA Index System (NDIS) program office.

TWGDAM was one of several technical working groups sponsored by the FBI. The goal of the working groups was to improve communication between the various scientific disciplines and to build consensus within the federal, state, and local forensic communities. TWGDAM was established in 1989 with representatives from 12 federal, state, and local laboratories, and focused specifically on the development of forensic DNA methods. Later that same year, TWGDAM developed and published in the *Crime Laboratory Digest*[16] a set of quality guidelines for forensic DNA laboratories.[17] TWGDAM expanded these guidelines in 1991 and in 1995.[18] In addition, TWGDAM worked with the National Institute of Standards and Technology (NIST) to develop model reference material that laboratories across the country could use to gauge the reliability of their equipment and DNA testing processes. In January 1999, TWGDAM was renamed the Scientific Working Group on DNA Analysis Methods (SWGDAM),[19] and in that capacity produced additional guidance for the forensic community, including guidelines for data interpretation, training, quality assurance, and health and safety audits.

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[15] For a description of CODIS, see discussion in Chapter Three, Section I.B.1. CODIS is a national DNA information repository that allows public laboratories across the country to store and compare DNA profiles from crime scene evidence, from convicted offenders, and from unidentified remains.

[16] The *Crime Laboratory Digest* was superseded by *Forensic Science Communications* in April 1999. *Forensic Science Communications* is a peer-reviewed forensic science journal published quarterly in January, April, July, and October by FBI Laboratory personnel.

[17] Technical Working Group on DNA Analysis Methods, "Guidelines for a quality assurance program for DNA restriction fragment length polymorphism analysis," *Crime Laboratory Digest*, Vol. 16, 1989, pp. 40–59.

[18] Technical Working Group on DNA Analysis Methods, "Guidelines for a quality assurance program for DNA analysis," *Crime Laboratory Digest*, Vol. 18, 1991, pp. 44-75; Technical Working Group on DNA Analysis Methods, "Guidelines for a quality assurance program for DNA analysis," *Crime Laboratory Digest*, Vol. 22, 1995, pp. 21–43.

[19] TWGDAM was renamed SWGDAM after the Department of Justice, Office of Justice Programs, created short-term technical working groups that began to be confused by members of the DNA community with the FBI's long-term technical working groups.

While no formal legal authority was granted to TWGDAM and SWGDAM, the guidelines they produced were accepted by the Laboratory Accreditation Board of the American Society of Crime Laboratory Directors as the benchmark for DNA laboratory accreditation. Further, when Congress authorized the creation of CODIS in the DNA Identification Act of 1994,[20] it provided that the guidelines issued by TWGDAM would be deemed to be national standards until the FBI issued its own standards pursuant to the Act.

The second source of DNA standards is the FBI DNA Advisory Board (Board). In the DNA Identification Act, Congress required that the FBI establish an advisory board to develop national quality assurance standards governing all CODIS participants.[21] As a result, the FBI established the Board, which was formally constituted on March 10, 1995.[22] Its members were appointed by the FBI Director based upon nominations from a variety of forensic and science organizations,[23] and included forensic scientists from state, local, and private forensic laboratories; molecular and population geneticists; a NIST scientist; a quality control specialist; an ethicist; and a judge. The Board's mission was to develop and revise, as necessary, standards for quality assurance, including proficiency testing standards for laboratories and analysts that examine DNA. The Board members acknowledged that TWGDAM had begun this work and that the Board should build upon it.

The Board fulfilled its mission with the submission to the FBI Director of quality assurance standards for two types of DNA laboratories:

- *Quality Assurance Standards for Forensic DNA Testing Laboratories* (Forensic Standards), effective October 1998.

- *Quality Assurance Standards for Convicted Offender DNA Databasing Laboratories* (Offender Standards), effective April 1999.

Amendments to these standards must be approved by the FBI Director. Recommendations for changes can be requested through SWGDAM.

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[20] Section 210301 to 210306 of Title XXI of Pub. L. 103-322, September 13, 1994, 108 Stat. 2065.

[21] 42 U.S.C. 14131(a)(1).

[22] The Board was dissolved in December 2000 after a several month extension of its original charter of 5 years.

[23] These organizations included the American Academy of Forensic Scientists, the American Board of Criminalists, the American Society of Crime Laboratory Directors, and the National Academy of Sciences.

The third source of DNA standards is the FBI NDIS program office, currently within the Laboratory Division's CODIS Unit (see the organization chart on page 24 for the placement of the CODIS Unit within the Division). The NDIS office has issued programmatic rules that govern the exchange of information for NDIS participants and has established standards for the submission of DNA data, collectively referred to as NDIS Requirements.

B. Overview of Applicable DNA Standards

At present, three sets of standards govern the DNA activities of the DNAUI: 1) Quality Assurance Standards; 2) NDIS Requirements; and 3) Accreditation Standards. These standards are interrelated: to comply with the Quality Assurance Standards, a laboratory is supposed to pursue accreditation actively; to become accredited, a laboratory must demonstrate compliance with the Quality Assurance Standards; and to become a participant in NDIS, a laboratory must demonstrate compliance with both the Quality Assurance Standards and the NDIS Requirements. We describe each of the standards below.

1. Quality Assurance Standards

Quality Assurance Standards consist of two sets of standards: 1) Forensic Standards that govern the activities of DNA laboratories that analyze crime scene evidence, and 2) Offender Standards that govern the activities of DNA laboratories that analyze samples from convicted offenders. The Forensic Standards contain 155 requirements organized under 15 headings, and the Offender Standards contain 136 requirements also organized under 15 headings.[24] For complete versions of the Forensic and Offender Standards, see Appendix 3.

The key categories of requirements addressed in the two sets of Standards, which correspond to section headings in the Standards, are the following:

- Quality Assurance Program: written guidelines should be adopted and should contain the required categories of standards.

- Organization and Management: key roles and duties should be described in writing, as should the interrelation between the personnel involved in DNA analysis.

[24] A high degree of overlap exists between the two sets of standards. A total of 119 requirements are shared (identical or similar), 36 requirements are unique to the Forensic Standards, and 17 requirements are unique to the Offender Standards.

- Personnel: personnel filling key roles should be properly educated, trained, and should perform duties appropriate to their position.

- Facilities: the design of the laboratory should ensure security and minimize contamination.

- Evidence Control (Forensic Standards only) and Sample Control (Offender Standards only): to ensure the integrity of evidence and of offender samples, and their proper disposition, the laboratory should have a documented control system and adequate implementing procedures.

- Validation: the laboratory should demonstrate that its analysts are capable of using certain equipment and methods properly.

- Analytical Procedures: every procedure used by the laboratory in DNA analysis should be described in detail in writing and formally approved by laboratory management.

- Equipment Calibration and Maintenance: the laboratory should establish a written program for ensuring that equipment used for DNA analysis receives regular calibration and maintenance in accordance with recognized national standards.

- Reports: the laboratory should have written guidelines for maintaining documentation that supports reported conclusions regarding case evidence. Reports should describe with specificity the information collected and written policies should exist to govern the release of such information.

- Review: administrative and technical reviews should be conducted of all reports and supporting documentation for all evidence. The testimony of analysts in court should also be reviewed.

- Proficiency Testing: scientists performing DNA analysis should complete an external proficiency test (a test from an outside agency or commercial test provider that measures an analyst's skill in performing DNA analysis correctly) every 180 days, which should be reviewed and documented.

- Corrective Action: written procedures should exist governing a laboratory's documentation and resolution of errors made during proficiency testing and DNA analysis.

- Audits: the laboratory should undergo an audit every year, and at least every other year this audit should be conducted by an external entity.

- Safety: the laboratory should have and follow a written environmental health and safety plan.

- Subcontractor of Analytical Testing for Which Validated Procedures Exist: a laboratory making use of a subcontractor for any part of the DNA analysis process should establish certain specified controls to ensure the integrity of the subcontractor's work and results.

2. NDIS Requirements

NDIS Requirements are found in the Memorandum of Understanding (MOU) signed by the FBI and each NDIS participant. The MOU requires that signatories comply with general requirements already established (i.e., federal legislation, the Forensic and Offender Standards) as well as requirements specific to the national index that accompany the MOU in three appendices: NDIS Responsibilities (Appendix A); NDIS Data Acceptance Standards (Appendix B); and the NDIS Procedures Manual (Appendix C).[25]

3. Accreditation Requirements

The primary accreditation or certification entities for forensic and offender DNA laboratories are the American Society of Crime Laboratory Directors – Laboratory Accreditation Board (ASCLD-LAB) and the National Forensic Science Technology Center (NFSTC). Both groups draw upon the requirements set forth in the Forensic and Offender Standards for their evaluation of a public DNA laboratory's operations.

III. ACCREDITATION AND STANDARDS COMPLIANCE

While TWGDAM/SWGDAM and the Board were pivotal in creating standards for DNA laboratories, they lacked the means to enforce them. To compensate for this shortcoming, the Board adopted an "Accreditation Premise" which set forth the Board's expectation that standards compliance would be assured through the process of accreditation. Accrediting organizations would need to adopt and hold laboratories accountable for compliance with the Board's standards. The Board acknowledged that a weakness in this approach was the lack of any enforceable requirement that

[25] We provide a detailed description of these appendices in Appendix 4.

laboratories be accredited, even for CODIS participation. In an attempt to address this problem, the Board passed a resolution in February 1999 stating that unaccredited laboratories should seek accreditation "with all deliberate speed." In addition, this language was used in the preface to the Forensic and Offender Standards to emphasize the importance of accreditation.[26]

Compliance with DNA-related standards is an issue previously examined by the OIG. In 1999, the OIG performed an audit of CODIS to determine the extent of state and local CODIS participation and to verify compliance with the FBI's quality assurance standards and national index requirements.[27] In the report summarizing its findings,[28] the OIG explained that the FBI's practice at the time of audit fieldwork was to allow CODIS and NDIS participants to self-certify their compliance with the Quality Assurance Standards and with NDIS Requirements. Because the OIG believed this system of self-certification posed a high risk of undetected noncompliance, the OIG undertook compliance testing of various CODIS participants and subsequently identified multiple instances where the participants were not fully complying with national standards. In addition, while the OIG noted that all audited laboratories had complied with the Forensic and Offender Standards' annual audit requirement,[29] weaknesses were noted with some of the external audits: 1) audit findings were not binding on the laboratories (they could disregard them if they wanted); 2) although accreditation and certification agencies had the authority to ensure a laboratory took appropriate corrective action, accreditation or certification audits did not typically focus on compliance with the quality assurance standards; and 3) laboratory audits were not always performed consistently. From these observations, the OIG recommended that the FBI develop and implement a process that would ensure that laboratories resolve all deficiencies noted during the external audits.

In response to the OIG's findings and recommendations, the FBI developed a new operational procedure, called *National DNA Index System (NDIS) Review of External Audits*, which provides for the formation of several NDIS Audit Review Panels. Each panel consists of four qualified or previously qualified DNA examiners or analysts selected from the FBI and state or local laboratories, with the chief of the FBI Laboratory's Quality Assurance and

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[26] Despite these efforts, according to an FBI Laboratory study conducted in 1999, of 153 laboratories surveyed (64 local, 87 state, and 2 federal), only 87 were accredited. Of the accredited laboratories, 71 were accredited by ASCLD-LAB.

[27] CODIS is described in greater detail in Chapter Three, Section I.B.1.

[28] The OIG audit report, The Combined DNA Index System," Report No. 01-26, was issued in September 2001. See http://www.usdoj.gov/oig.

[29] The Forensic Standards and Offender Standards both require that laboratories undergo, every other year, a quality assurance audit conducted by external auditors. Internal audits conducted by in-house auditors are required during the alternating years.

Safety Unit serving as chairperson. All panelists are required to have completed successfully FBI quality assurance audit training. Under the new procedure, NDIS participating laboratories must forward to a review panel, via the custodian of the NDIS database, a copy of their external audit report, their response to the report, and corrective action plans that address the audit report recommendations. The panel reviews the audit report and related documents to determine if all findings and recommendations have been addressed adequately and/or resolved. If the audited laboratory does not respond to clarification requests by the panel, does not resolve an audit recommendation, or is determined to be non-compliant with the quality assurance standards, a corrective action and conflict resolution process can be invoked. A laboratory's failure to resolve a panel's concern can result in the termination of its access to NDIS.

In addition to these compliance procedures, the FBI created a standardized DNA audit guide (Guide) with input from the Board, ASCLD-LAB, and NFSTC to ensure that auditors of local, state, and federal DNA laboratories are thorough and interpret the Quality Assurance Standards consistently. The FBI offers Guide training for auditors, including those representing accrediting and certifying organizations such as ASCLD-LAB and NFSTC. For an audit to fulfill the Quality Assurance Standards' external audit requirement, it must be conducted in accordance with the Guide and by an auditor trained in its use. However, as this report details, even with these precautions, internal control weaknesses are not always uncovered in quality assurance audits. In fact, weaknesses in DNAUI procedures and protocols allowed a technician routinely to disregard required steps in the analysis of DNA, even while the Unit received clean audit reports from both internal and external auditors and while the Unit was accredited by ASCLD-LAB.