NORTH CAROLINA
STATE BUREAU OF INVESTIGATION
DEPARTMENT OF JUSTICE

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ROY COOPER
ATTORNEY GENERAL

ROBIN P. PENDERGRAFT
DIRECTOR

January 28, 2009

Dr. Douglas Hares
NDIS Custodian
FBI Laboratory
Room 1120
2501 Investigation Parkway
FBI Academy Complex
Quantico, VA 22135

Dear Dr. Hares:

I am writing to notify you that an external ASCLD-LAB audit was conducted of the North Carolina State Bureau of Investigation on January 12-16, 2009. The audit was conducted by Jonathan Newman, Chris Tomsey, and Denise Rankin.

The audit report and any clarifications, responses, and/or corrective action plan/documents shall be forwarded to you within thirty days of our receipt of such report.

If you have any questions, I can be reached at 919-662-4509 ext. 2527.

Sincerely,

SAC Michael Budzynski
North Carolina State Bureau of Investigation

2009036

NORTH CAROLINA
STATE BUREAU OF INVESTIGATION
DEPARTMENT OF JUSTICE

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ROY COOPER
ATTORNEY GENERAL

ROBIN P. PENDERGRAFT
DIRECTOR

March 24, 2009

Dr. Douglas Hares
NDIS Custodian
FBI Laboratory
Room 1120
2501 Investigation Parkway
FBI Academy Complex
Quantico, VA 22135

Dear Dr. Hares:

I am writing to notify you that an external QAS audit in conjunction with an ASCLD/LAB inspection was conducted of the N.C. State Bureau of Investigation Forensic Biology Section on January 12-16, 2009. The audit was conducted by Chris Tomsey (Lead), Jonathan Newman and Denise Rankin.

The audit report and responses are attached.

If you have any questions, I can be reached at 919-662-4500 (ext. 2527).

Sincerely,

Michael J. Budzynski
NCSBI Crime Laboratory

U.S. Department of Justice

Federal Bureau of Investigation

Washington, D. C. 20535-0001

March 31, 2009

Michael J. Budzynski
North Carolina State Bureau of Investigation
Department of Justice
3320 Garner Road
PO Box 29500
Raleigh, NC 27626-0500

Dear Mr. Budzynski:

This is to acknowledge receipt of your DNA Quality Assurance Standards (QAS) Audit Report for the North Carolina State Bureau of Investigation Laboratory, dated January 12 to 16, 2009, for the external audit for 2009. As you are aware, participation in the National DNA Index System (NDIS) requires an external audit on a bi-annual basis. An audit committee will be selected and copies of your audits will be submitted to them for review. Upon completion of this review, their copies of the audit documents will be returned to the FBI. All copies will be shredded and the originals will be returned to you.

For tracking purposes your audit has been assigned a number. Your number will be 2009036. Please refer to this number if you have any inquiries concerning this particular audit document.

It should be noted the Audit Review Panel Chair will be on maternity leave until April. Your patience is appreciated for delays in processing the above audits are inevitable. If you have any questions, please call me at (703) 632-7576.

Thank you for you assistance in this matter. If you have any questions, please call me at (703) 632-8302.

Sincerely,

Douglas R Hares /dlb

Douglas R. Hares, PhD
NDIS Custodian
CODIS Unit
Laboratory Division

1-Ms. Amanda Fox (Information only)

QUALITY ASSURANCE AUDIT

FOR

FORENSIC DNA AND CONVICTED OFFENDER

DNA DATABASING LABORATORIES

IN ACCORDANCE WITH

THE QUALITY ASSURANCE STANDARDS

FOR

FORENSIC DNA TESTING LABORATORIES

AND

CONVICTED OFFENDER DNA DATABASING LABORATORIES

ISSUED BY

THE FBI DIRECTOR

An Audit of: North Carolina SBI Laboratory, Raleigh NC

Dates of Audit: January 12 – 16, 2009

Auditor(s):

(Name)	(Signature)
Jonathan Newman	
Denise Rankin	
Christine Tomsey	

Table of Contents

Introduction

The *DNA Identification Act of 1994* required the formation of a panel of distinguished professionals from the public and private sectors to address issues relevant to forensic DNA applications. This panel, titled the DNA Advisory Board, first convened in 1995. An early mission of the DNA Advisory Board was to develop and implement quality assurance standards for use by forensic DNA testing laboratories. The scope was quickly expanded to include forensic DNA databasing laboratories. The DNA Advisory Board fulfilled this role, recommending separate documents detailing quality assurance standards for both applications. The *Quality Assurance Standards for Forensic DNA Testing Laboratories* and the*Quality Assurance Standards for Convicted Offender DNA Databasing Laboratories* were issued by the Director of the Federal Bureau of Investigation in October 1998 and April 1999, respectively. Both documents have become benchmarks for assessing the quality practices and performances of DNA laboratories throughout the country.

The *DNA Identification Act of 1994* also required the FBI Laboratory to ensure that all DNA laboratories that are federally operated, receive federal funds, or employ software prepared for the Combined DNA Index System (CODIS) demonstrate compliance with the standards issued by the FBI. Additional programs, such as the National DNA Index System, added further requirements for DNA laboratories that wish to enter data into the national DNA database also demonstrate compliance with such standards. Typically, documentation of a laboratory's compliance with a stated standard has been measured through an audit process. Such audits have been performed by forensic scientists, either internal or external to the laboratory, and serve to identify compliance with established standards.

Since the issuance of both quality assurance documents, confusion regarding the intent and subsequent interpretation for various standards has existed in the forensic science community. The lack of a defined, uniform interpretation guide for such standards has presented a potential problem among laboratories and auditors attempting to determine levels of compliance. In an effort to satisfy the responsibilities assigned through the *DNA Identification Act of 1994* and attempt to minimize interpretation variability, the FBI Laboratory has developed an audit document for assessing compliance with the required standards of both documents. Recognizing the broad application of such an undertaking, the FBI Laboratory has solicited input from many forensic DNA laboratories over the past year to assist in the document's design. This has included collaborating with members from two prominent international inspection/accreditation entities, the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB) and the National Forensic Science Technology Center. To this end, the audit document has been created by the FBI Laboratory with the input, guidance, and consensus from the above-mentioned groups. The document defines and interprets each standard, with added discussion points clarifying the criteria necessary for compliance. Additionally, the document is structured such that criteria, which overlap between the FBI-issued standards and the corresponding ASCLD/LAB elements, share a consistent interpretative view.

Regarding the format of the audit document, each standard is listed numerically, combining the quality standards of the forensic DNA laboratories and the convicted offender DNA databasing laboratories into one document. Standards that apply exclusively to one application are identified as such, with the designation of either FO or CO, parenthetically adjacent to the standard. The absence of a designation identifies a shared application. Instances in which the wording of a standard is the same for both applications (FO and CO), but the corresponding number of the standard differs, the FO number will be parenthetically adjacent to the standard, and the CO designation, with its corresponding number, will follow the narrative of the standard. The rating system for assessing the laboratory with each standard is listed by the choices of Yes, No, or Not Applicable (N/A). As indicated earlier, discussion sections follow standards, as appropriate, and serve to clarify the interpretation necessary for compliance. Specific passages are bold to add emphasis to the intent associated with a standard. A comment section is also provided following the discussion areas, affording auditors the opportunity to reference information that may have value in the audit process (such as listing the reason for a Yes, No, or N/A).

Finally, in Appendix A, the findings associated with the audit will be detailed and summarized by the auditor, with an area available for response to such findings by the laboratory. Notes or comments, including observations and recommendations are better suited to be mentioned during the exit briefing with

laboratory personnel or in a separate letter/memorandum to the laboratory so that these comments are not confused with comments relating to a finding or an explanation of why a particular standard is not applicable.

The revised discussions are not to be applied retroactively and will take effect upon the approval of the FBI Director.

The following checklist should be completed and placed after the coversheet of the report:

INTRODUCTION HISTORY Revision 6 Issue Date July 1, 2004

- Added instructions regarding notes and comments
- Added sentence regarding effective date of revisions
- Added "Checklist of General Laboratory Information"
- Added instruction for checklist placement

Checklist of General Laboratory Information

1. Name of Laboratory **NORTH CAROLINA SBI LABORATORY**

2. Federal/State/Regional/County/Local/Other **_STATE__** Laboratory (Circle one)

3. Covering Population of **__APPROXIMATELY - 9.1 million_____**

4. **CASEWORK AND OFFENDER DATABASE SAMPLES** (Circle those that apply)

5. Uses a Contract Laboratory **YES** (Circle those that apply)
   Casework Samples **No**
   Offender Database Samples **YES**
   Name of Contract Laboratory **_BODE TECHNOLOGY GROUP_____**

6. National DNA Index System Participant: **YES** (Circle one)

7. Applying for National DNA Index System Participation -**N/A** (Circle one)

8. Technologies Used (Circle those that apply and indicate if for casework or offender databasing)
   STRs: **CASEWORK AND Offender Databasing**
   YSTRs: **YES CASEWORK**
   MtDNA: **N/A**
   RFLP: **N/A**
   Other **__N/A_____**: Casework or Offender Databasing

9. Number of staff
   DNA analysts/examiners---**28**
   DNA trainees--- **5**
   DNA technicians--- **0**
   DNA technical leader/manager--- **1**
   On-site - **YES – David Freeman, Ph.D.**
   CODIS Manager **YES – Amanda FOX**

10. Last audit conducted on **___DECEMBER 8, 2008 - INTERNAL**

References

American Society of Crime Laboratory Directors/Laboratory Accreditation Board, *ASCLD/LAB Accreditation Manual*. ASCLD/LAB, Garner, North Carolina, 2003.

Federal Bureau of Investigation DNA Advisory Board. Quality assurance standards for forensic DNA testing laboratories, (1998) Forensic Science *Communications* [Online]. (July 2000). Available: www.fbi.gov/hq/lab/fsc/backissu/july2000/codispre.htm.

Federal Bureau of Investigation DNA Advisory Board. Quality assurance standards for convicted offender DNA databasing laboratories, (1999) *Forensic Science Communications* [Online]. (July 2000). Available: www.fbi.gov/hq/lab/fsc/backissu/july2000/codispre.htm.

International Standards Organization/International Electrotechnical Commission. *ISO/IEC Guide 25:1990*. (1990) American National Standards Institute, New York.

Technical Working Group on DNA Analysis Methods. Guidelines for a quality assurance program for DNA analysis, *Crime Laboratory Digest* (1995) 22:(2)21-43.

42 Code of Federal Regulations, Chapter IV (10-1-95 Edition), Health Care Financing Administration, Health and Human Services.

REFERENCE HISTORY Revision 6 Issue Date July 1, 2004

- Changed version year of ASCLD/LAB Accreditation Manual

Definitions

As used in this document, the following terms have the meanings specified:

(a) Administrative review is an evaluation of the report (if applicable) and supporting documentation for consistency with laboratory policies and for editorial correctness.

(b) Amplification blank control consists of only amplification reagents without the addition of sample DNA. This control is used to detect DNA contamination of the amplification reagents.

(c) Analytical procedure is an orderly step-by-step procedure designed to ensure operational uniformity and to minimize analytical drift.

(d) Audit is an inspection used to evaluate, confirm, or verify activity related to quality.

(e) Batch is a group of samples analyzed at the same time.

(f) Calibration is the set of operations that establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system or values represented by a material and the corresponding known values of a measurement.

(g) CODIS is the Combined DNA Index System administered by the FBI. It houses DNA profiles from convicted offenders, forensic specimens, population samples, and other specimen types.

(h) Commercial test kit is a preassembled kit that allows the user to conduct a specific DNA identification test.

(i) Convicted offender is an individual who is required by statute to submit a standard sample for DNA databasing.

(j) Convicted offender database (CODIS) manager or custodian (or equivalent role, position, or title as designated by the laboratory director) is the person responsible for administration and security of the laboratory's CODIS.

(k) Convicted offender standard sample is biological material collected from an individual for DNA analysis and inclusion into CODIS. See also database sample.

(l) Critical equipment or instruments are those requiring calibration prior to use and periodically thereafter.

(m) Critical reagents are determined by empirical studies or routine practice to require testing on established samples before use in order to prevent unnecessary loss of sample.

(n) Database sample is a known blood or standard sample obtained from an individual whose DNA profile will be included in a computerized database and searched against other DNA profiles.

(o) Examiner/analyst (or equivalent role, position, or title as designated by the laboratory director) conducts and/or directs the analysis of samples, interprets data, and reaches conclusions.

(p) Forensic DNA testing is the identification and evaluation of biological evidence in criminal matters using DNA technologies.

(q) Known samples are biological material whose identity or type is established.

(r) Laboratory is a facility where forensic DNA testing and/or convicted offender DNA testing is performed or a government facility that contracts with a second entity for such testing.

(s) Laboratory support personnel (or equivalent role, position, or title as designated by the laboratory director) are individuals who perform laboratory duties and do not analyze samples.

(t) NIST is the National Institute of Standards and Technology.

(u) Polymerase chain reaction (PCR) is an enzymatic process by which a specific region of DNA is replicated during repetitive cycles that consist of (1) denaturation of the template, (2) annealing of primers to complementary sequences at an empirically determined temperature, and (3) extension of the bound primers by a DNA polymerase.

(v) Proficiency test sample is biological material whose DNA type has been previously characterized and that is used to monitor the quality performance of a laboratory or an individual.

(w) Proficiency testing is a quality assurance measure used to monitor performance and identify areas in which improvement may be needed. Proficiency tests may be classified as:

(1) Internal proficiency test is one prepared and administered by the laboratory.

(2) External proficiency test, which may be open or blind, is one that is obtained from a second agency.

(x) A qualifying test measures proficiency in both technical skills and knowledge.

(y) Quality assurance includes the systematic actions necessary to demonstrate that a product or service meets specified requirements for quality.

(z) A quality manual is a document stating the quality policy, quality system, and quality practices of an organization.

(aa) Quality system is the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

(bb) Reagent blank control consists of all reagents used in the test process without any sample. This is to be used to detect DNA contamination of the analytical reagents.

(cc) Reference material (certified or standard) is a material for which values are certified by a technically valid procedure and accompanied by or traceable to a certificate or other documentation that is issued by a certifying body.

(dd) Restriction fragment length polymorphism (RFLP) is generated by cleavage by a specific restriction enzyme, and the variation is due to restriction site polymorphism and/or the number of different repeats contained within the fragments.

(ee) Review is an evaluation of documentation to check for consistency, accuracy, and completeness.

(ff) Second agency is an entity or organization external to and independent of the laboratory and that performs DNA identification analysis.

(gg) Secure area is a locked space (e.g., cabinet, vault, room) with access restricted to authorized personnel.

(hh) Subcontractor is an individual or entity having a transactional relationship with a laboratory.

(ii) Technical manager/leader (or equivalent position or title as designated by the laboratory director) is the individual who is accountable for the technical operations of the laboratory.

(jj) Technical review is an evaluation of reports, notes, data, and other documents to ensure an

appropriate and sufficient basis for the scientific conclusions. This review is conducted by a second qualified individual.

(kk) Technician (or equivalent role, position, or title as designated by the laboratory director) is an individual who performs analytical techniques on samples under the supervision of a qualified examiner/analyst and/or performs DNA analysis on samples for inclusion in a database.

(ll) Traceability is the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons.

(mm) Validation is a process by which a procedure is evaluated to determine its efficacy and reliability for DNA analysis and includes

(1) Developmental validation is the acquisition of test data and determination of conditions and limitations of a new or novel DNA methodology for use on samples.

(2) Internal validation is an accumulation of test data in the laboratory to demonstrate that established methods and procedures perform as expected in the laboratory.

Standard 3: Quality Assurance Program

		Yes	No	N/A
3.1	Does the DNA laboratory have an established and maintained documented quality system that is appropriate to the testing activities?	☒	☐	☐

Discussion

The laboratory must have a documented (hard copy or electronic copy) quality system, typically identified as a quality manual. The laboratory must demonstrate that it has maintained its quality system by conducting an annual review of that system. An annual review of the quality system is important for ensuring that measures are being taken by the laboratory to continually provide the highest quality of service. This review must include the review of the quality manual and standard operating procedures used by the laboratory and must be independent of the required annual audit. Audit reports may identify areas in need of attention and provide the basis for changes to the quality system. Such changes may include new or improved quality control activities for monitoring the quality of the laboratory work product. Additionally, significant modifications of forensic DNA testing, such as the incorporation of a new technology, may necessitate a review or updating of the quality system. The annual review must be documented (hard copy or electronic copy).

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Replaced "generally directed" with "must"
- Added wording that the quality manual review is independent of annual audit
- Added "hard copy or electronic copy" to last sentence

Comment

		Yes	No	N/A
3.1.1	Does the quality manual address (at a minimum) the following:			
a.	Goals and objectives	☒	☐	☐
b.	Organization and management structure	☒	☐	☐
c.	Personnel qualifications and training.	☒	☐	☐
d.	Facilities	☒	☐	☐
e.	Evidence control	☒	☐	☐
f.	Validation	☒	☐	☐
g.	Analytical procedures	☒	☐	☐
h.	Calibration and maintenance	☒	☐	☐
i.	Proficiency testing	☒	☐	☐
j.	Corrective action	☒	☐	☐
k.	Reports	☒	☐	☐
l.	Review	☒	☐	☐
m.	Safety	☒	☐	☐
n.	Audits	☒	☐	☐

Discussion

The DNA laboratory quality system or quality manual must contain or reference each of the above listed criteria. Individual sections that deal with subject areas that are defined through laboratory-wide policies or procedures (e.g., evidence control, safety) may be located in documents that are separate from the quality manual; however, such information should be referenced in the quality manual. If such sections have been supplemented by DNA laboratory-specific practices, the quality manual must reflect such additions.

Any document that is referenced in the laboratory's DNA quality manual must be available on-site. Documents may be in hard copy, electronic files, or a combination of both formats.

Additionally, the quality system/quality manual must contain or reference practices that address continuing education (Standard 5.1.3) and monitoring court testimony (Standard 12.2).

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Added paragraph requiring on-site availability of any referenced laboratory quality manual documents
- Added "monitoring" to last sentence

Comment

Standard 4: Organization and Management

		Yes	No	N/A
4.1.a	Has the managerial staff of the laboratory been provided the authority and resources needed to discharge their duties and meet the requirements of the standards in this document?	☒	☐	☐

Discussion

Evidence of meeting this standard is assessed through interviews of staff and the review of laboratory documents such as job descriptions and organizational charts.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Deleted last sentence of paragraph

Comment

		Yes	No	N/A
4.1.b	Does the laboratory have a designated technical manager/leader who is accountable for the technical operations?	☒	☐	☐

Discussion

The role of a technical manager/leader does not preclude, for example, the existence of additional program managers, each of whom may be assigned a subset of clearly defined duties (e.g., training program manager, quality assurance program manager). The technical manager/leader will retain, however, the ultimate responsibility for such programs.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Replaced "specific" with "clearly defined"

Comment

		Yes	No	N/A
4.1.c	Does the laboratory specify and document the responsibility, authority, and interrelation of all personnel who manage, perform, or verify work affecting the validity of the DNA analysis? (CO4.1c)	☒	☐	☐
4.1c(CO)	Does the laboratory have a CODIS manager or custodian who is accountable for CODIS operations?	☒	☐	☐

Discussion

As a tool in the evaluation of the management standards, laboratories must maintain a current organizational chart, referencing the members of the laboratory with their specific position assignments (e.g., technical manager/leader, CODIS manager). Additionally, current job descriptions must be available for all laboratory personnel, accurately defining the technical and/or administrative responsibilities associated with each position (Standard 5 - Personnel).

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Deleted "various"

Comment

Standard 5: Personnel

		Yes	No	N/A
5.1	Do laboratory personnel have the education, training, and experience commensurate with the examination and testimony provided?	☐	☒	☐

Discussion

To successfully satisfy Standard 5.1, compliance must be demonstrated with all of the subcategories of Standard 5. A list of the individuals in compliance with Standard 5.1 will be incorporated by the auditor into the Comment section below. The credentials for those individuals found to be in compliance with Standard 5.1 after two successive external audits do not need to be reviewed.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Deleted reference to specific subcategories
- Added a sentence requiring a list of standard compliant individuals be placed in comment section
- Added statement that credentials of compliant listed individuals need not be reviewed after two successive external audits

Comment:

5.1 was a no finding in reference to substandard 5.2.3.2 (b-1) – see comment under 5.2.3.2.

The following analysts' education, training and experience qualifications were reviewed and found to be in compliance:

<u>DNA CASEWORK: Second Review</u>
Amanda Thompson
Sarah Johnson

<u>DNA CASEWORK: First Review</u>
Jody West
Kristin Hughes
Suzi Barker

<u>DNA DATABASE: Second Review</u>
Tanisha Ray

<u>DNA CASEWORK: First Review</u>
Jessica Badger
Stephen Henderson
Tabitha Mickelson – education only - still in training
Tonya Rush
Jessica Posto

The following technician education, training and experience qualifications were reviewed and found to be in compliance with duties performed: to date.

		Yes	No	N/A
5.1.1	Does the laboratory have written job descriptions for all personnel to include responsibilities, duties, and skills?	☒	☐	☐

Discussion

Written job descriptions that are augmented by other documentation to include responsibilities, duties, and skills are acceptable.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Changed wording

Comment

		Yes	No	N/A
5.1.2	Does the laboratory have a documented training program for qualifying all technical laboratory personnel?	☒	☐	☐

Discussion

A laboratory's training program must teach and assess the skills and knowledge required to achieve the minimum standards of competence and good laboratory practice in a specific area of work. Training must include all methods that the analyst will use in casework and/or convicted offender analysis.

The laboratory must have a documented training program that includes a training manual and training records for each trainee available for review. Additionally, the laboratory must have documentation that provides a formal means for recognizing an individual's successful completion of the training program (e.g., certificate, letter, memorandum) and demonstration of competency, typically through a test. For further information, refer to the discussion following Standard 5.3.3.

It is management's responsibility to establish and document the adequacy of the training of any staff member who has not completed the laboratory's formal training program. Examples may include (but are not limited to) the acquisition of fully trained personnel from a separate organization or the assignment of experienced forensic DNA caseworking examiners/analysts to validate a new DNA testing procedure. All individuals, regardless of previous training and experience, must successfully complete a qualifying test for the specific DNA technology to be used at the current laboratory prior to assuming convicted offender and/or casework responsibilities. Successful completion of an individual's qualifying test must be documented by the laboratory.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Changed wording, added sentence defining training and clarified document training program
- Deleted the SWGDAM note
- Added "convicted offender and/or" to last paragraph

Comment

		Yes	No	N/A
5.1.3	Does the laboratory have a documented program to ensure that technical qualifications are maintained through continuing education?	☒	☐	☐

5.1.3.1(a)	Over the last year has the technical manager/leader read current scientific literature?	☒	☐	☐
5.1.3.1(b)	Over the last year has the technical manager/leader attended at least one seminar, course, professional meeting, or training session/class that addresses subject matter related to DNA analysis?	☒	☐	☐
5.1.3.1(c) (CO)	Over the last year has the CODIS manager read current scientific literature?	☒	☐	☐
5.1.3.1(d) (CO)	Over the last year has the CODIS manager attended at least one seminar, course, professional meeting, or training session/class that addresses subject matter related to DNA analysis?	☒	☐	☐
5.1.3.1(e)	Over the last year has each examiner/analyst read current scientific literature?	☒	☐	☐
5.1.3.1(f)	Over the last year has each examiner/analyst attended at least one seminar, course, professional meeting, or training session/class that addresses subject matter related to DNA analysis?	☒	☐	☐

Discussion

The laboratory's continuing education program must be documented, such as in the quality manual or training manual. To comply with this standard, laboratory management must provide technical personnel with the opportunity to stay abreast of new developments and issues in the field of DNA analysis. The laboratory must provide the technical manager/leader, CODIS manager, and all examiner/analysts with continuing education in a subject area related to DNA analysis annually as defined by the laboratory (e.g., fiscal or calendar). Continuing education shall be no less than a cumulative total of eight hours on an annual basis. While such continuing education should be formalized, requirements do not necessarily include earned credit hours or grade evaluations, although this would be acceptable. Participation and completion of programs based on multimedia or Internet delivery must be formally recorded and approved by the technical manager/leader. This documentation must include the time required to complete the program.

For laboratory external continuing education programs, a variety of methods may be used including attending local, national, and international meetings or symposia or external training courses. The laboratory must maintain documentation of such attendance.

For internal continuing education programs, the title, a record of the presentation, date of training, attendance list, and curriculum vitae of presenter(s) must be documented and retained by the laboratory.

The laboratory must maintain or have access (e.g., Internet) to a collection of current books, journals, or other literature applicable to DNA typing. The laboratory must have an established system that tracks reading of scientific literature.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Deleted wording.
- Added sentence defining number of hours of continuing education
- Added clarification of use of multimedia or Internet delivery for continuing education
- Added definitions for required internal and external continuing education documentation
- Changed wording and deleted last sentence of last paragraph

Comment

		Yes	No	N/A
5.1.4	Does the laboratory maintain records on the relevant qualifications, training, skills, and experience of all technical personnel?	☒	☐	☐

Discussion

The laboratory must verify the degree and course work for technical personnel. Transcripts must be available to the auditors for assessing an individual's qualifications. Technical personnel skills and experience must be documented through a curriculum vitae or other means, such as a statement of qualifications. Compliance with this standard is assessed through a review of documentation and staff interviews.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Deleted "curriculum vitae"

Comment

		Yes	No	N/A
5.2	Does the technical manager/leader satisfy the degree/educational, experience, and duty requirements as listed in Standards 5.2.1 through 5.2.3?	☒	☐	☐

		Yes	No	N/A
5.2.1	Does the technical manager/leader of the laboratory meet the following degree/educational requirements or have a waiver as stated in Standard 5.2.1.1?	☒	☐	☐
	A. A graduate degree in a biology, chemistry, or forensic science-related area	☒	☐	☐
	B. A minimum of 12 credit hours or its equivalent including a combination of graduate and undergraduate course work or classes covering the subject areas of			
	(a) Biochemistry	☒	☐	☐
	(b) Genetics	☒	☐	☐
	(c) Molecular biology	☒	☐	☐
	(d) Statistics and/or population genetics	☒	☐	☐

Discussion

A minimum of 12 semester or equivalent credit hours must be completed successfully (college- or university-determined passing grade) that address the general subject areas of biochemistry, genetics, molecular biology, as well as statistics and/or population genetics, or other subjects that provide a basic understanding of the foundation of forensic DNA analysis. **The 12 semester or equivalent credit hours requirement (5.2.1 B) must include, at a minimum, one graduate level class registering three or more semester or equivalent credit hours.** A variety of college course work may apply toward satisfying this standard and is not limited exclusively to the subject categories listed. However, the specific subjects area(s) listed must constitute an integral component of any class or course work for compliance with this standard. Individuals who have completed course work with titles other than those listed above must demonstrate compliance with this standard through transcripts, a letter from a university professor verifying course content, a course syllabus, or other appropriate documentation. The DNA training program previously offered by the FBI Laboratory, with graduate credit hours from the University of Virginia, may be applied toward the molecular biology course work requirement associated with this standard. However, courses such as the FBI's Basic Serology course or the FBI's Biochemical Methods of Bloodstain Analysis course would not be applicable toward the 12-hour credit requirement.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Wording changes
- Added last sentence of paragraph defining courses not applicable toward 12-hour credit requirement

		Yes	No	N/A
5.2.1.1	Does the technical manager/leader possess a waiver from the American Society of Crime Laboratory Directors or other organization designated by the Director of the FBI?	☐	☐	☒

Discussion

Compliance with Standard 5.2.1.1 is necessary only if Standard 5.2.1 has not been satisfied. Otherwise the response to 5.2.1.1 is Not Applicable (N/A). Documentation of the waiver must be available.

DISCUSSION HISTORY Revision 8 Issue Date July 1, 2004

- Changed wording to require waiver documentation

Comment

5.2.1.1 graded N/A – Technical leader has a Ph.D. Degree – no waiver was necessary.

		Yes	No	N/A
5.2.2	Does the technical manager/leader of the laboratory have a minimum of three years forensic DNA laboratory experience?	☒	☐	☐

Discussion

The technical manager/leader of the laboratory must have a minimum of three years forensic DNA laboratory experience. This experience must have been gained at a facility where forensic DNA testing was performed for the identification and evaluation of biological evidence in criminal matters. This would include agencies where research/training and caseworking laboratories are separate entities but reside under the same facility-wide organizational umbrella. It should be noted that the experience time frame is measured not by the number of years with any particular employer, but rather by the number of years in a position specific for gaining the experience necessary to satisfy this standard. Although not required, the technical manager/leader should have successfully completed the DNA Auditing Workshop sponsored by the FBI.

DISCUSSION HISTORY Revision 8 Issue Date July 1, 2004

- Added last sentence in paragraph recommending that a technical manager/leader successfully complete the FBI DNA Auditing Workshop

Comment

		Yes	No	N/A
5.2.3	Does the technical manager/leader of the laboratory meet the duty requirements of this standard?	☒	☐	☐
5.2.3.1	Does the technical manager/leader manage the technical operations of the laboratory?	☒	☐	☐

5.2.3.2 (a-1)	Is the technical manager/leader responsible for evaluating all methods used by the laboratory?	☒	☐	☐
5.2.3.2 (a-2)	Is the technical manager/leader responsible for proposing new or modified analytical procedures to be used by the examiners?	☒	☐	☐
5.2.3.2 (b-1)	Is the technical manager/leader responsible for technical problem solving of analytical methods?	☐	☒	☐
5.2.3.2 (b-2)	Is the technical manager/leader responsible for the oversight of training, quality assurance, safety, and proficiency testing in the laboratory?	☒	☐	☐
5.2.3.3	Is the technical manager/leader accessible to the laboratory to provide on-site, telephonic, or electronic consultation as needed?	☒	☐	☐

Discussion

Auditors may assess whether a laboratory has satisfied the requirements listed in Standard 5.2.3 through a review of laboratory documentation (e.g. protocols, quality manual), staff interviews, and/or on-site evaluations. The technical manager/leader is not required to occupy physical (on-site) facility space. However, the technical manager/leader must demonstrate knowledge and oversight of the DNA program to ensure the laboratory is following standards and written protocols. If the laboratory system contracts for an off-site technical manager/leader, the laboratory must ensure that the technical manager/leader makes an initial on-site visit. The frequency of additional visits should be regular but not less than once a year and as needed, based on quality issues, after the initial visit. This individual must be readily accessible to the laboratory (telephonically or electronically) to fulfill the responsibilities and requirements of this position in an effective manner.

For compliance with the duty requirements of Standard 5.2.3, it is not necessary for the technical manager/leader to function (or to have functioned) as a qualified examiner/analyst. For those instances in which the technical manager/leader has an experience base in a specific DNA technology, which is different from the DNA technology currently used in convicted offender or casework analysis, the laboratory must demonstrate that the technical manager/leader has fulfilled his/her defined duties and keeps abreast of technical developments.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Added requirements and responsibilities of off-site managers/leaders
- Deleted second sentence of second paragraph
- Deleted reference to RFLP testing
- Deleted last two sentences of second paragraph

Comment5.2.3.2 (b-1) was a no finding. Corrective Action Reports are not being sent to the Technical Leader for review as per Section Policy 10.1.2 of the DNA Database Policy and Procedures Manual. This included several issues of contamination. Staff interviews revealed that the Technical Leader was not always informed of Corrective Action Reports initiated in the DNA laboratory. Contamination issues are reported to the direct supervisor who sends a memo to the Deputy Assistant Director and Quality Assurance Manager. It is the Deputy Assistant Director who decides whether the section manager or the technical leader is informed. Consequently, the technical leader cannot monitor quality issues or conduct technical problem solving if he is not informed of quality issues they arise in the DNA laboratory.

		Yes	No	N/A
5.3	Does each examiner/analyst satisfy the degree/educational, experience, and duty requirements as listed in Standards 5.3.1 through 5.3.3 (CO5.4)?	☒	☐	☐

5.3.1	Does each examiner/analyst meet the following degree/educational requirements:	☒	☐	☐
	A. B.A./B.S. degree or its equivalent in a biology, chemistry, or forensic science-related area	☒	☐	☐
	B. College course work or classes covering the subject areas of			
	(a) Biochemistry	☒	☐	☐
	(b) Genetics	☒	☐	☐
	(c) Molecular biology	☒	☐	☐
	C. College course work or training that covers the subject area of statistics and/or population genetics	☒	☐	☐

Discussion

A variety of college course work may apply toward satisfying this standard and is not limited exclusively to the subject categories listed. However, the specific subjects area(s) listed must constitute an integral component of any class or course work to satisfy this standard. Analysts who become qualified after the effective date of this document must have a minimum of six cumulative semester hours or equivalent that covers the required subject areas. Individuals who have completed course work with titles other than those listed above must demonstrate compliance with this standard through transcripts, a letter from a university professor verifying course content, a course syllabus, or other appropriate documentation. The technical leader must document his/her approval of compliance.

The DNA training program previously offered by the FBI Laboratory, with graduate credit hours from the University of Virginia, may be applied toward the molecular biology course work requirement associated with this standard. However, courses such as the FBI's Basic Serology course or the FBI's Biochemical Methods of Bloodstain Analysis course would not be applicable.

Examiners/analysts may satisfy the statistics and/or population genetics course work or training requirement (5.3.1) through internal or external training.

For external statistics and/or population genetics training, a variety of methods may be used including workshops at local, national, or international meetings or symposia or external training courses. The laboratory must maintain documentation of such attendance.

For internal statistics and/or population genetics training, the title, a record of the presentation, date of training, attendance list, and curriculum vitae of presenter(s) must be documented and retained by the laboratory.

STANDARD 5.3 HISTORY Revision 6 Issue Date July 1, 2004

- Deleted "(FO)"
- Added "(CO 5.4)"

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Changed wording in first paragraph and added sentence requiring six cumulative semester hours of course work in required subject areas
- Added sentence requiring technical leader's approval of compliance
- Added sentence defining nonapplicable courses for molecular biology course requirements
- Added statements requiring documentation of external and internal statistics and/or population genetics training

Comment

		Yes	No	N/A
5.3.2(a)	Does each examiner/analyst have a minimum of six months forensic DNA laboratory experience?	☒	☐	☐

5.3.2(b)	Does the experience of each examiner/analyst include the successful analysis of a range of samples typically encountered in forensic casework prior to undertaking independent casework analysis using DNA technology?	☒	☐	☐

Discussion

An examiner/analyst must have a minimum of six months forensic DNA laboratory experience gained at a facility where forensic DNA testing was performed for the identification and evaluation of biological evidence in criminal matters. The experience time frame is measured not by the length of time spent with

any particular employer but rather by the number of months/years in a position specific for gaining the experience necessary to satisfy this standard. The experience gained by an individual must include the successful analysis of a range of samples typically associated with forensic casework. An individual's participation in a formal forensic DNA training program is acceptable for fulfilling or being applied toward fulfilling the experience requirement of this standard.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Wording changes

		Yes	No	N/A
5.3.3	Has each examiner/analyst successfully completed a qualifying test before beginning independent casework responsibilities?	☒	☐	☐

Discussion

A qualifying test or competency test serves to test an individual's knowledge, skills, and abilities as they relate to his/her individual position. A laboratory may select from a variety of approaches for administering a qualifying test, including but not limited to a written, oral, or practical examination. If a laboratory uses an internal or external proficiency test as a qualifying test, the laboratory must have phenotyping/genotyping results to assess an individual's performance. The date of qualification of an individual must be documented. The qualification date has particular relevance to proficiency testing requirements discussed in Standard 13 (Proficiency Testing), which requires newly qualified individuals to participate in an external proficiency test within six months of their initial qualification date.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Wording changes
- Replaced "180 days" with "six months"

Comment

		Yes	No	N/A
5.3(CO)	Does the CODIS manager or custodian satisfy the degree/educational, experience, and duty requirements as listed in the convicted offender Standards 5.3.1 through 5.3.3?	☒	☐	☐
5.3.1	Does the CODIS manager or custodian possess a Bachelor's degree in a natural science or computer science?	☒	☐	☐
5.3.2(a)	Does the CODIS manager or custodian have a working knowledge of the following:			
	(a) Computers	☒	☐	☐

	(b) Computer networks	☒	☐	☐
	(c) Computer database management	☒	☐	☐
5.3.2(b)	Does the CODIS manager or custodian have an understanding of DNA profile interpretation?	☒	☐	☐
5.3.3	Does the CODIS manager or custodian meet the duty requirements of this position?	☒	☐	☐
5.3.3(a-1)	Does the CODIS manager or custodian function as the system administrator of the laboratory's CODIS network?	☒	☐	☐
5.3.3(a-2)	Is the CODIS manager or custodian responsible for the security of the DNA profile data stored in CODIS?	☒	☐	☐
5.3.3(b)	Is the CODIS manager or custodian responsible for oversight of CODIS computer training and quality assurance of data?	☒	☐	☐
5.3.3(c-1)	Does the CODIS manager or custodian have the authority to terminate the laboratory's participation in CODIS in the event of a problem until the reliability of the computer data can be assured?	☒	☐	☐
5.3.3(c-2)	Does the state CODIS manager or custodian have this authority over all CODIS sites under his/her jurisdiction?	☒	☐	☐

Discussion

A qualifying test is not required for the CODIS manager unless the CODIS manager performs examiner/analyst duties such as interpretation of data. Examiner/analysts and technicians associated with the convicted offender program are required to successfully complete a qualifying test specific to their duties prior to participating in DNA typing responsibilities. The responsibilities and authority of the CODIS manager must be documented.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Deleted first sentence of paragraph
- Wording changes

Comment:

		Yes	No	N/A
5.4	Does each technician meet the training and qualification requirements as stated in Standards 5.4.1 and 5.4.2 (CO5.5)?	☒	☐	☐
5.4.1	Did each technician receive on-the-job training specific to the job function?	☒	☐	☐
5.4.2	Did each technician successfully complete a qualifying test before participating in forensic DNA typing responsibilities?	☒	☐	☐
5.5	Do all laboratory support personnel meet the requirements as stated in Standard 5.5.1 (CO5.6)?	☒	☐	☐
5.5.1	Do all laboratory support personnel possess the training, education, and experience commensurate with their responsibilities as outlined in their job descriptions?	☒	☐	☐

Comment

Discussion

Technicians associated with the convicted offender program and/or casework are required to successfully complete a qualifying test specific to their duties prior to participating in DNA typing responsibilities.

STANDARD 5.4 HISTORY Revision 6 Issue Date July 1, 2004

- Added "(CO5.5)"

STANDARD 5.5 HISTORY Revision 6 Issue Date July 1, 2004

- Added "(CO5.6)"

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Added discussion paragraph requiring a qualifying test

Standard 6: Facilities

		Yes	No	N/A
6.1	Is the laboratory designed to provide adequate security and minimize contamination?	☒	☐	☐
6.1.1	Is access to the laboratory controlled and limited?	☒	☐	☐

Discussion

To successfully satisfy Standard 6.1, compliance must be demonstrated with all of the subcategories of Standard 6.

Clearly written and well-understood procedures must exist for laboratory security. The laboratory's security system must control access and limit entry to the operational areas. All exterior entrance/exit points to the facility must be secured and controlled in a manner to prevent access by unauthorized personnel. Internal controlled areas should limit access to only authorized personnel. The distribution of all keys and combinations must be limited to appropriate laboratory personnel as designated by laboratory management. The distribution system must be current, accurate, clearly documented, and available for review. Many other control systems, which include card keys, surveillance cameras, and intrusion alarms, are acceptable when they complement the laboratory's security system by controlling unauthorized access and/or limiting authorized access to the operational laboratory and evidence storage areas.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Wording changes
- Replaced "should" with "must" as it applies to criteria for security access distribution systems

Comment

		Yes	No	N/A
6.1.2	Are evidence examinations, DNA extractions, and PCR setup conducted at separate times or in separate spaces?	☒	☐	☐
6.1.2(CO)	Are evidence examinations, liquid sample examinations, DNA extractions, and PCR setup conducted at separate times or in separate spaces?	☒	☐	☐
6.1.3	Is amplified DNA product generated, processed, and maintained in a room(s) separate from the evidence examination, DNA extractions, and PCR setup areas?	☒	☐	☐
6.1.3(CO)	Is amplified DNA product generated, processed, and maintained in a room(s) separate from the evidence examination, liquid sample examinations, DNA extractions, and PCR setup areas?	☒	☐	☐
6.1.4(CO)	If a robotic workstation is used to carry out DNA extraction and amplification in a single room, can it be demonstrated that contamination is minimized and equivalent to that when performed manually in separate rooms?	☒	☐	☐

Discussion

Through a combination of clearly written technical procedures, casework notes, and/or personal observation, the laboratory's approach to sample processing for PCR-based procedures (extraction and amplification) must demonstrate a separation in time or physical space for each activity. The laboratory's design must demonstrate that evidence flow, through the various steps of DNA processing, does not compromise the integrity of the sample. The amplification room must be enclosed with walls from the floor to the ceiling and door(s) for passage. The amplification room(s) must physically separate amplified DNA from all other areas of the laboratory by maintaining doors in the closed position.

When robotic workstations are used to carry out DNA extractions through PCR setup on casework samples (Standards 6.1.2 and 6.1.3) a single room may be used. Internal validation must show that if contamination occurs, it is minimized, addressed, and less than or equivalent to that observed when these procedures are performed manually in separate rooms.

To successfully satisfy Standard 6.1.4(CO), robotic workstations may be used to carry out DNA extraction through amplification in a single room provided that they are separated from the casework extraction and casework amplification areas and that it can be demonstrated through internal validation that if contamination occurs, it is minimized, addressed, and less than or equivalent to that observed when these procedures are performed manually in separate rooms.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Added clarification to description of amplification areas
- Added clarification to use of robotic workstations as they apply to casework contamination

Comment

		Yes	No	N/A
6.1.4	Does the laboratory follow written procedures for monitoring, cleaning, and decontaminating facilities and equipment?	☒	☐	☐

Discussion

A laboratory may employ a variety of methods to monitor its facilities, such as the use of appropriate controls in the analysis process. Whichever approach(es) the laboratory selects to use, the method(s) must be documented. This may be accomplished through a variety of ways at the discretion of the laboratory.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Deleted third sentence

Comment

Standard 7: Evidence or Sample Control

		Yes	No	N/A
7.1	Does the laboratory have and follow a documented evidence control system or sample inventory control system (convicted offender) for handling and preserving the integrity of physical evidence?	☒	☐	☐
7.1.1	Is each evidence sample (including convicted offender samples) labeled with a unique identifier in accordance with established agency policy?	☒	☐	☐

Discussion

To successfully satisfy Standard 7.1, compliance must be demonstrated with all of the subcategories of Standard 7.

Convicted offender samples are not considered evidence for the purposes of this document.

The DNA laboratory must have clearly written, well-understood procedures that address handling and preserving of the integrity of evidence and convicted offender samples. Key components of an evidence sample control procedure include proper labeling and sealing of evidence, a documented chain-of-custody record, and a secure area designated for evidence storage. Key components of a convicted offender sample control procedure include proper labeling and sample storage. Each item of evidence and each convicted offender sample (and/or its container) must be marked with a unique identifier.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Added reference to convicted offender samples

Comment

		Yes	No	N/A
7.1.2	Does the laboratory maintain a chain of custody for all evidence?	☒	☐	☐

Discussion

A written chain-of-custody record must include the signature or initials (written or electronic) of each individual receiving or transferring evidence, with the corresponding date for each transfer with a corresponding identifier that specifies each evidentiary item. This record must provide a comprehensive, documented history for each evidence transfer over which the laboratory has control. Electronic tracking of evidence is an acceptable alternative to a written record if the computerized data are sufficiently secure, detailed, and accessible for review and can be converted to a hard copy when necessary.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Added " (written or electronic)" to first sentence

Comment

		Yes	No	N/A
7.1.2(CO)	Does the laboratory document and maintain the identity, collection, receipt, storage, and disposition for samples?	☒	☐	☐
7.1.3	Does the laboratory follow documented procedures that minimize loss, contamination, and/or deleterious change of evidence?	☒	☐	☐
7.1.4	Does the laboratory have secure areas for evidence storage?	☒	☐	☐
7.1.4(CO)	Does the laboratory have secure areas for sample storage including environmental controls consistent with the form or nature of the sample?	☒	☐	☐

Discussion

The laboratory must ensure that evidence stored under its custody is properly sealed and protected from loss, contamination, and/or deleterious change. An evidence container is properly sealed if its contents cannot readily escape and if entering the container results in a detectable alteration to the container or seal. The seal must be labeled in a manner that identifies an individual responsible for sealing the evidence. The immediate container need not be sealed (but securely closed) if it is enclosed in a larger container that meets the requirements of a proper seal. In such instances, the container must be securely closed so that its contents are protected from loss, contamination, and/or deleterious change. Secure areas for evidence storage must exist in the laboratory. This may include the use of temporary or short-term storage, demonstrating proper security through defined, controlled access to the evidentiary storage area. Short-term storage areas may vary from a locked file cabinet to an entire secured examination room housing large or bulky items of evidence on a temporary basis.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Replaced "desirable" with "must" in third sentence
- Added "secured" to last sentence

Comment

		Yes	No	N/A
7.2(FO)	Does the laboratory retain or return a portion of the evidence sample or extract when possible?	☒	☐	☐
7.2.1(FO)	Does the laboratory have a procedure requiring that evidence samples/extract(s) be stored in a manner that minimizes degradation?	☒	☐	☐

COMMENT:

Standard 8: Validation

		Yes	No	N/A
8.1	Does the laboratory use methods and procedures for forensic DNA analysis that have been validated prior to casework implementation?	☒	☐	☐

Discussion

To successfully satisfy Standard 8.1, compliance must be demonstrated with all of the subcategories of Standard 8.

Validation is the process used by the scientific community to acquire the necessary information for accessing a procedure's reliability to obtain a specific, desired result. The validation process also serves to identify critical aspects of a procedure that must be controlled and monitored, while defining the limitations of the procedure.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Changed wording in first sentence of first paragraph

Comment

		Yes	No	N/A
8.1.1	Have developmental validation studies been conducted and appropriately documented?	☒	☐	☐

Discussion

Developmental validation must precede the introduction of a novel methodology for forensic DNA analysis. A novel methodology may include an existing technology or testing procedure that has been developed for a specific technology (e.g., medical testing, genetic analysis) that is not currently applied to forensic DNA analysis. Citations in peer-reviewed scientific journals that provide the underlying scientific basis for a novel methodology should be available.

		Yes	No	N/A
8.1.2	Have novel forensic or database DNA methodologies used by the laboratory undergone developmental validation to ensure the accuracy, precision, and reproducibility of the procedure?	☐	☐	☒
8.1.2.1	Is there documentation and is it available that defines and characterizes each locus?	☒	☐	☐
8.1.2.2(FO)	Have species' specificity, sensitivity, stability, and mixture studies been conducted?	☒	☐	☐
8.1.2.3(FO)	Does the laboratory have access to a population database that is documented and available for use in population statistics?	☒	☐	☐
8.1.2.3.1(FO-a)	Where appropriate, has the database been tested for independence expectations?	☒	☐	☐
8.1.2.3.1(FO-b)	Does the database information include allele and frequency distributions for the locus or loci obtained from relevant populations?	☒	☐	☐
8.1.3	Has the laboratory completed and documented internal validation studies?	☒	☐	☐

Discussion

To successfully satisfy Standards 8.1.2 and 8.1.3, compliance must be demonstrated with all of the

subcategories of these standards.

Prior to implementing a new DNA analysis procedure or an existing DNA procedure developmentally validated by another laboratory, the forensic or database laboratory must first demonstrate the reliability of the procedure internally. The internal validation studies conducted by the forensic laboratory should be sufficient to document the reliability of the technology as practiced by that laboratory. Summaries must be written for all internal validation studies and approved by the technical manager/leader.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Changed wording in first paragraph
- Added sentence requiring internal validation summaries.

Comment :

8.1.2 given a N/A since it does not use any novel technologies.

		Yes	No	N/A
8.1.3.1(a)	Has the procedure been tested using known and nonprobative evidence samples?	☒	☐	☐
8.1.3.1 (CO-a)	Has the procedure been tested using known samples?	☒	☐	☐
8.1.3.1(b)	Has the reproducibility and precision of the procedure been monitored and documented using human DNA control(s)?	☒	☐	☐
8.1.3.2 (FO)	Based on empirical data, have match criteria been established and documented?	☒	☐	☐
8.1.3.3	Has the analyst or examination team successfully completed a qualifying test using the DNA analysis procedure prior to its incorporation into casework or database applications? (CO8.1.3.2)	☒	☐	☐
8.1.3.4	Have material modifications to analytical procedures been documented and subjected to validation testing?	☒	☐	☐
8.1.4(FO)	If methods are not specified, does the laboratory, wherever possible, select methods that have been published by reputable technical organizations or in relevant scientific texts or journals or that have been appropriately evaluated for a specific or unique application?	☐	☐	☒

Discussion

For laboratory systems that consist of more than one laboratory, each of the laboratories must complete and maintain performance-based validations (e.g., sensitivity and precision), while basic validation studies may be shared among all locations in a laboratory system. The internal validation materials must be documented, summarized, and approved by the technical manager/leader. Summaries of a system's internal validation studies must be available at all sites.

Each new instrument or performance-based software change (including upgrades) requires a performance check. A performance check is an evaluation of a validated procedure existing in the laboratory system to ensure that it conforms to specifications and may include such studies as reproducibility and sensitivity.

However, if acquisition of new equipment leads to a method change (e.g., DNA detection from a gel-based to capillary-based system), internal validation studies must be performed.

A list of the validation studies in compliance with Standard 8.1 will be incorporated by the auditor into the comment section below. The validation studies found to be in compliance with Standard 8.1 after one external audit do not need to be reviewed.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Added clarification to validation studies
- Added paragraph requiring performance checks
- Deleted note referencing SWGDAM
- Added paragraph requiring auditors to list validation studies reviewed. When compliant with standard, validation studies need not be reviewed in future audits

Comment:

8.1 The following validation studies were reviewed and found to be in compliance with the Standard:

Validation of the ABI 3130XL (SN# 17208-005) using the ABI Identifiller amplification kit.

Validation of Quantifiler Y and AmpliSTR Y Filer

Validation of the Qiagen BioRobot Universal System (SN# A4178) using the QIAamp Media MDx kits.

8.1.4 (FO) The laboratory does not use unspecified technologies

Standard 9: Analytical Procedures

		Yes	No	N/A
9.1	Does the laboratory have and follow written analytical procedures approved by laboratory management/technical manager/leader?	☐	☒	☐
9.1.1	Does the laboratory have a documented standard operating protocol for each analytical technique used?	☒	☐	☐
9.1.2	Do the analytical procedures describe reagents, sample preparation, extraction, equipment, and controls that are standard for DNA analysis and data interpretation?	☒	☐	☐
9.1.3(FO)	Does the laboratory have a procedure for the differential extraction of stains that contain semen?	☒	☐	☐

Discussion

To successfully satisfy Standard 9.1, compliance must be demonstrated with all of the subcategories of Standard 9.

Technical protocols for each analytical technology must be approved by the technical manager/leader. This approval must be documented. Technical protocols must be readily available to laboratory personnel and reflect the current practices employed by the laboratory.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Changed wording

Comment

9.1 was a no finding. The DNA QA Manual states that for mixtures, Combined Probability of Exclusion (CPE) statistic may be calculated independently for each reference sample not excluded from the mixture. When calculating separate CPE's values for each reference sample on the mixture, the manual states the report will (Appendix F – 4.4.3.7) indicate the number and the identity of loci used for the each of the calculations. The reports reviewed using more than one CPE value for a mixture did not indicate the loci or the number of loci used in the calculations.

			Yes	No	N/A
9.2	Does the laboratory use reagents that are suitable for the methods employed?		☒	☐	☐
9.2.1	Does the laboratory have written procedures for documenting commercial supplies and for formulating reagents?		☒	☐	☐
9.2.2	Are reagents labeled with the identity of the reagent, the date of preparation or expiration, and the identity of the individual preparing the reagent?		☒	☐	☐
9.2.3(a)	Has the laboratory identified and evaluated the reagents critical to the analysis process prior to use in casework?		☒	☐	☐
9.2.3(b)	Has the laboratory identified and evaluated the following critical reagents:				
	(a)	Restriction enzyme	☐	☐	☒
	(b)	Commercial kits for performing genetic typing	☒	☐	☐
	(c)	Agarose for analytical RFLP gels	☐	☐	☒
	(d)	Membranes for Southern blotting	☐	☐	☒
	(e)	K562 DNA or other human DNA controls	☒	☐	☐
	(f)	Molecular weight markers used as RFLP sizing standards	☐	☐	☒

(g)	Primer sets	☒	☐	☐
(h)	Thermostable DNA polymerase	☒	☐	☐

Discussion

To successfully satisfy Standard 9.2, compliance must be demonstrated with all of the subcategories of Standard 9.2.

Reagents must be labeled with the identity of the reagent and a tracking mechanism identifying preparation or expiration date and component sources. Records must be maintained that identify the preparer of the reagent and the quality control measures (if any) used to check the reliability of the reagent. The laboratory must identify the reagents critical to the analytical processes used and evaluate each, prior to their use on evidence and convicted offender samples. This list must include, at a minimum, those critical reagents listed in Standard 9.2.3(b). Laboratories must have written procedures detailing the quality control measures in place for evaluating reagents and materials, the acceptable range of results, procedures for acting upon data that are unacceptable, and the mechanisms used for documentation and the subsequent approval/rejection of quality control data. The critical reagents listed in Standard 9.2.3(b) are not applicable universally to all types of DNA methodologies.

Standard 9.2.3(b), part(a), (c), (d), and (f) refer to RFLP-based technology.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Changed wording in first paragraph
- Added reference to convicted offender samples
- Added sentence defining minimum requirements for listing critical reagents
- Replaced last sentence of paragraph with a reference to Standard 9.2.3(b)

Comment

9.2.3(b) a, c, d and f graded N/A - This laboratory does not conduct RFLP analysis.

		Yes	No	N/A
9.3(FO)	Does the laboratory have and follow a procedure for evaluating the quantity of human DNA in samples?	☒	☐	☐

Discussion

When using PCR-based analysis techniques for nuclear DNA, the presence or absence of detectable human DNA must also be assessed with regard to the unknown evidentiary samples for compliance to Standard 9.3.

A less direct method for estimating or controlling the amount of recovered DNA, such as control of sample size (e.g., size of a hole punch, volume and length of a hair shaft) is an acceptable approach. These methods are suitable for use on known reference samples from casework, database samples, and evidentiary items that are subjected solely to mitochondrial DNA analysis. In such instances, the response to Standard 9.3 would be Not Applicable.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Deleted first sentence in first paragraph
- Added reference to nuclear DNA in first paragraph
- Changed wording in second paragraph
- Deleted last paragraph

Comment

		Yes	No	N/A
9.3.1	Does the laboratory use procedures for establishing the presence of high molecular weight DNA from RFLP casework samples?	☐	☐	☒
9.4	Does the laboratory monitor the analytical procedures using appropriate controls and standards? (CO9.3)	☒	☐	☐
9.4.1	Does the laboratory use the following controls for RFLP casework analysis? (CO9.3.1)	☐	☐	☒
9.4.1.1	Quantitation standards that estimate the amount of DNA recovered by extraction (CO9.3.1.1)	☐	☐	☒
9.4.1.2	K562 as a human DNA control (CO9.3.1.2)	☐	☐	☒
9.4.1.3	Molecular weight size markers at defined intervals for bracketing known and evidence samples (CO9.3.1.3)	☐	☐	☒
9.4.1.4	Procedure to monitor the completeness of restriction enzyme digestion (CO9.3.1.4)	☐	☐	☒

Discussion

Standards 9.4.1 through 9.4.1.4 apply to RFLP-based technology.

For database laboratories (convicted offender), pertaining to Standard 9.3.1.3, no more than five lanes may exist between marker lanes. Additionally, regarding Standard 9.3.1.4, these laboratories may monitor the completeness of a restriction enzyme digest through a test gel or other method.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Added a standards reference line
- Changed wording
- Deleted reference to database laboratories and autoradiogram/lumigraph assessment methods
- Deleted last sentence of paragraph

Comment

9.3.1 and 9.4.1 through 9.4.1.4 graded N/A - This laboratory does not perform RFLP analysis.

		Yes	No	N/A
9.4.2	Does the laboratory use the following controls for PCR casework or database analysis? (CO9.3.2)	☒	☐	☐
9.4.2.1	Quantitation standards that estimate the amount of human nuclear DNA recovered by extraction (CO9.3.2.1)	☒	☐	☐
9.4.2.2	Positive and negative amplification controls (CO9.3.2.2)	☒	☐	☐
9.4.2.3	Reagent blanks (CO9.3.2.3.1)	☒	☐	☐
9.4.2.4	Allelic ladders and/or internal size markers for variable number tandem repeat sequence PCR-based systems (CO9.3.2.4)	☒	☐	☐

9.5	Does the laboratory check its DNA procedures annually or whenever substantial changes are made to the protocol(s) against an appropriate and available NIST standard reference material (SRM) or standard traceable to a NIST standard? (CO9.4)	☐	☒	☐

Discussion

Standards 9.4.2 through 9.4.2.4 apply to PCR-based technology.

Laboratories have the option of using one sample from the NIST SRM or to create/purchase a NIST traceable standard for the annual check of typing results for each genetic system (e.g., STRs, Y-STRs, mtDNA) used by the laboratory. Laboratories are not required to purchase a NIST SRM kit each year to comply with Standard 9.5. Laboratories may identify controls and run these against the NIST SRM, which in turn makes these controls NIST traceable. For those laboratories that use a bloodstain control, a "lot" is identified as the bloodstain(s) that is tested against the NIST SRM, not the person from whom the blood was drawn. This lot can be used annually to verify the controls and DNA procedures in use by the laboratory.

STANDARD 9.4.2.3 HISTORY Revision 6 Issue Date July 1, 2004

- Deleted "(FO)"
- Added "(CO9.3.2.3.1)"

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Added standards reference paragraph
- Deleted first two paragraphs
- Added new paragraph regarding NIST SRMs

Comment

9.5 is a no finding. The laboratory has used a sample MJB 062304 since 2005 as their NIST traceable sample for their annual check. However, there is no direct documentation to support traceability to a NIST standard. Review of the documentation available for the comparison of the check of sample MJB062304 completed in 2004 lacks the naming of the lot number of MJB used and a verification of the results obtained from the comparison to the NIST published values.

In addition, the methodology using the Qiagen BioRobot Universal System using the QIAamp Media MDx kits on database samples was not checked against the NIST or NIST traceable standard in 2008.

		Yes	No	N/A
9.6	Does the laboratory have and follow written general guidelines for the interpretation of data? (CO9.5)	☒	☐	☐
9.6.1	Does the laboratory verify that all control results are within established tolerance ranges? (CO9.5.1)	☒	☐	☐
9.6.2	Where appropriate, are visual matches supported by a numerical match criterion?	☐	☐	☒
9.6.3	Has the 1996 National Research Council Report and/or a court-directed method been used for the statistical interpretation of a DNA profile for a given population and/or hypothesis or relatedness and are these calculations derived from an established population database appropriate for the calculation?	☒	☐	☐

Discussion

For Standard 9.6.1, laboratories using RFLP-based technology must verify and document that controls fall within established tolerance ranges. For PCR-based technologies, laboratories must verify and document that the types of controls are correct.

Standard 9.6.2 applies to RFLP-based technology.

Standard 9.6.3 does not apply to mitochondrial or Y-STR DNA testing.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Discussion paragraph deleted
- Added new discussion paragraph regarding verification and documentation of controls
- Added two sentences regarding application of Standards 9.6.2 and 9.6.3

Comment

9.6.2 graded N/A. This laboratory does not conduct RFLP analysis.

Standard 10: Equipment Calibration and Maintenance

		Yes	No	N/A
10.1	Does the laboratory use equipment that is suitable for the methods employed?	☒	☐	☐
10.2	Does the laboratory have a documented program for calibration of equipment and instruments?	☒	☐	☐
10.2.1	When available and appropriate, are standards traceable to national or international standards used in the calibration of equipment?	☒	☐	☐
10.2.1.1	Where traceability to a national standard of measurement is not applicable, does the laboratory provide satisfactory evidence of correlation of results?	☒	☐	☐
10.2.2	For each instrument requiring calibration, has the frequency of calibration been documented and has such documentation been retained in accordance with applicable federal or state law?	☒	☐	☐
10.3	Does the laboratory have a documented program to ensure that instruments and equipment are properly maintained?	☒	☐	☐
10.3.1	Have new instruments and equipment, or instruments and equipment that have undergone repair or maintenance, been calibrated before being used in casework analysis?	☒	☐	☐
10.3.2	Have written records or logs been maintained for maintenance service performed on instruments and equipment and has such documentation been retained in accordance with applicable federal or state law?	☒	☐	☐

Discussion

To successfully satisfy Standards 10.2 and 10.3, compliance must be demonstrated with all of the subcategories of both standards.
To successfully satisfy the requirements listed in Standard 10.2, the laboratory's documentation must include the identification of all critical equipment and instruments that require calibration. The laboratory's documentation must include the schedules for and records of all calibrations for the critical equipment and instruments. Critical equipment or instruments are those requiring calibration prior to use and periodically thereafter when the accurate calibration of that instrument directly affects the results of the analysis. Critical equipment, calibration, and traceability are defined at the beginning of this document. Standard 10.3.1 does not apply to instruments and equipment that cannot be calibrated by laboratory personnel (e.g. fluorescence based detection instruments).

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Changed wording in first paragraph.

- Changed wording in second paragraph and defined requirements for equipment calibration.
- Added sentence regarding application of Standard 10.3.1.

Comment

Standard 11: Reports

		Yes	No	N/A
11.1(FO)	Does the laboratory have and follow written procedures for taking and maintaining case notes to support the conclusions drawn in laboratory reports?	☐	☒	☐
11.1(CO)	Does the laboratory have and follow written procedures for generating and maintaining documentation for database samples?	☐	☒	☐
11.1.1(FO)	Does the laboratory maintain in a case record all documentation generated by examiners related to case analyses?	☒	☐	☐
11.1.1(CO)	Does the laboratory have written procedures for the release of database sample information?	☒	☐	☐

Discussion

The release of database sample information in Standard 11.1.1(CO) is specifically limited to database applications and does not apply to forensic (anonymous) population databases that are used by caseworking laboratories to estimate allele frequency information.

Laboratory case records may be in hard copy, electronic files, or a combination of both formats.

Materials contained in case records must demonstrate compliance with this standard.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Added sentence defining formats for case records
- Added sentence requiring materials in case records to be in compliance with standard

Comment

11.1 (FO) is a no finding. The laboratory STR Interpretation Guideline, Appendix F , section 4.4.2.2.3 specifically states that if alleles are not present at one or more loci then there must be a compelling reason for "NOT" excluding a standard (e.g. allelic dropout and/or inhibition).There is no documentation in the case files reviewed as to why the analyst selected loci to be excluded.

11.1 (CO) is a no. The laboratory DNA Database Unit Standard Operating Procedure(December 15, 2008) in Section 3.3.3 requires that additions to records generated should not only initial the form where required but also date the entry. The DNA Database Collection Card is not dated or initialed when the technician adds information. The card is initialed and dated when changes or corrections are made. In addition, the required format for the naming of the batch for in house processing of convicted offender samples is not being used. This was corrected on site with an updated of a version (Jan 9, 2009) of the manual.

	Yes	No	N/A

11.1.2(FO)	Do the laboratory reports include the following criteria:			
	(a) Case identifier	☒	☐	☐
	(b) Description of evidence examined	☒	☐	☐
	(c) Description of methodology	☒	☐	☐
	(d) Locus	☒	☐	☐
	(e) Results and/or conclusions	☒	☐	☐
	(f) Interpretative statement (either quantitative or qualitative)	☒	☐	☐
	(g) Date issued	☒	☐	☐
	(h) Disposition of evidence	☒	☐	☐
	(i) Signature and title or equivalent identification of the person(s) accepting responsibility for the content of the report	☒	☐	☐
11.1.3(FO)	Does the laboratory have written procedures for the release of case report information?	☒	☐	☐

Discussion

The laboratory must generate sufficient documentation for each technical analysis to support the reported conclusions such that in the absence of the examiner/analyst who directed the analysis, another qualified individual could evaluate and interpret the resulting data.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Replaced "assay" with "analysis"

Comment

Standard 12: Review

		Yes	No	N/A
12.1(FO)	Does the laboratory conduct administrative and technical reviews of all case files and reports to ensure conclusions and supporting data are reasonable and in the constraints of scientific knowledge?	☒	☐	☐
12.1(CO)	Does the laboratory have and follow written procedures for reviewing database sample information, results, and matches?	☒	☐	☐

12.1.1	Does the laboratory have a mechanism in place to address unresolved discrepant conclusions between analysts and reviewers?	☒	☐	☐

Discussion

The laboratory must have written procedures defining the elements associated with both administrative and technical reviews. The laboratory must define the qualifications and responsibilities of the administrative reviewer and technical reviewer. The administrative reviewer is not required to be a current or former qualified DNA examiner/analyst.

All individuals who perform technical reviews on DNA casework must have been previously qualified in the specific DNA technology that the review is encompassing. The laboratory must demonstrate that the technical reviewer has a basis of knowledge that will allow him/her to ensure the conclusions and supporting data are reasonable and within the constraints of scientific acceptance. The laboratory must describe the documentation method used for demonstrating completion of each review, as well as a procedure that defines the course of action necessary in the event of an unresolved discrepancy. This applies to both forensic casework as well as database laboratories.

To comply with Standard 12.1(CO) laboratories must demonstrate 100 percent review of database samples. A National DNA Index System-approved and internally validated expert system can be used to interpret and review.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Deleted "frequency" and "required" from first paragraph and changed wording
- Added paragraph requiring 100 percent database review for compliance with Standard 12.1(CO) and approval for use of expert systems to interpret and review

Comment

		Yes	No	N/A
12.2	Does the laboratory have and follow a written program that documents the annual monitoring of the testimony of each examiner?	☒	☐	☐
12.2(CO)	Does the laboratory have and follow a written program that documents the annual monitoring of the testimony of laboratory personnel?	☒	☐	☐

Discussion

In forensic DNA and convicted offender database laboratories, the testimony of individuals who provide expert witness testimony as part of their current positions must be monitored at least once annually. Several methods of monitoring are possible, and laboratories may select an appropriate approach. Laboratories must define the elements and standardize the method for capturing information necessary to review an individual's testimony. Supervisors must review the testimony monitoring results with each individual, serving to identify areas of strengths and weaknesses. The laboratory must provide clear documentation identifying individuals who did not testify over the course of the year.

Comment

Standard 13: Proficiency Testing

		Yes	No	N/A
13.1	Do examiners and other personnel designated by the technical manager/leader who are actively engaged in DNA analysis undergo open external proficiency tests at regular intervals not to exceed 180 days?	☒	☐	☐

Discussion

All technical personnel who participate in DNA analysis (casework or convicted offender) must undergo two external proficiency tests per year. One test must be performed in the first six months of the calendar year and the second in the last six months of the calendar year. The interval between consecutive tests must be at least four months and not to exceed eight months. The laboratory must define and consistently use the date that the proficiency test is performed as the received date, submitted date, or the due date. An external proficiency test is defined as a test provided by a second agency. An external proficiency test provider must demonstrate compliance with the proficiency testing manufacturing guidelines established by the Technical Working Group on DNA Analysis Methods and American Society of Crime Laboratory Directors/Laboratory Accreditation Board (*Guidelines for DNA Proficiency Test Manufacturing and Reporting*, Technical Working Group on DNA Analysis Methods Quality Assurance Subcommittee and American Society of Crime Laboratory Directors/Laboratory Accreditation Board DNA Proficiency Review Committee Volume 21, Number 2, April 1994). Alternatively, the external proficiency test provider must demonstrate compliance with the International Standards Organization Guide 43.

The test results from each participant in the laboratory must be returned to the provider by the specified due date to ensure incorporation into the provider's external summary report. All external proficiency tests must have defined due dates for the return of testing information to the test provider. Regardless of whether the test provider is one who provides an external summary report or not, the laboratory must not have access to the proficiency test results until all participants have completed the test.

Newly qualified technical personnel must enter into the external proficiency testing program within six months of the date of qualification.

Technical personnel must be externally proficiency tested on an annual basis in each DNA technology (RFLP, PM/DQA1, STRs, mtDNA) to the full extent in which they perform casework examinations. Each qualified analyst must be assigned and complete his/her own proficiency test set. The laboratory must handle proficiency test samples in the same manner as their casework or database samples. Laboratories that routinely employ a team approach for conducting DNA examinations (such as several technicians, each performing a separate, dedicated aspect of the DNA process on evidentiary materials) may likewise employ a team approach for performing proficiency tests. However, all technical personnel must be proficiency tested in each aspect of the DNA process in which they performed DNA testing over the course of a year.

Individuals who perform both RFLP- and PCR-based analyses in casework or database applications must be externally proficiency tested for each method. One test may include only RFLP analysis with a second test that is limited to PCR analysis. This does not preclude the possibility that both technologies (RFLP and PCR) may be administered on a single proficiency test. In either case, the two external tests per year are required.

Individuals who perform multiple PCR testing methodologies (e.g., PM/DQA1, STR, mtDNA) in casework or database applications must be externally proficiency tested for each method. This does not preclude the possibility that all PCR methodologies may be administered on a single proficiency test. As stated previously, two external tests per year are required.

There are no proficiency test requirements for individuals who function solely as the technical manager/leader or the CODIS manager.

The laboratory's proficiency testing program must include testing for all genetic loci used by the laboratory in casework and database applications. For example, laboratories that conduct STR analysis at 13 genetic loci

must include characterizations (or attempts at characterization) for all 13 genetic loci.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Added clarification to the time interval between proficiency tests
- Added a statement requiring a defined and consistent date that a proficiency test is performed
- Changed wording that requires new technical personnel to be proficiency tested within six months after being qualified
- Changed wording that requires technical personnel to be proficiency tested annually
- Added statements that further clarify the handling of proficiency test samples in accordance with casework/database samples
- Deleted "180 day(s)"

Comment

		Yes	No	N/A
13.1.1	Does the laboratory maintain the following records for proficiency tests and is such documentation retained in accordance with applicable federal or state law?			
	(a) Test set identifier	☒	☐	☐
	(b) Identity of the examiner	☒	☐	☐
	(c) Date of analysis and completion	☒	☐	☐
	(d) Copies of all data and notes supporting the conclusions	☒	☐	☐
	(e) Proficiency test results	☒	☐	☐
	(f) Any discrepancies noted	☒	☐	☐
	(g) Corrective action taken	☒	☐	☐

		Yes	No	N/A
13.1.2	Has the laboratory established at a minimum the following criteria for evaluating proficiency tests:			
	(a) All reported inclusions are correct or incorrect.	☒	☐	☐
	(b) All reported exclusions are correct or incorrect.	☒	☐	☐
	(c) All reported genotypes and/or phenotypes are correct or incorrect according to consensus genotypes/phenotypes or within established empirically determined ranges.	☒	☐	☐
	(d) All results reported as inconclusive or uninterpretable are consistent with written laboratory guidelines. The basis for inconclusive interpretations in proficiency tests must be documented.	☒	☐	☐
	(e) All discrepancies/errors and subsequent corrective actions must be documented.	☒	☐	☐
	(f) All final reports are graded as satisfactory or unsatisfactory. A satisfactory grade is attained when there are no analytical errors for the DNA profile typing data. Administrative errors shall be documented and corrective actions taken to minimize the error in the future.	☒	☐	☐
	(g) All proficiency test participants shall be informed of the final test results.	☒	☐	☐

Discussion

The laboratory must have and use a documented program for evaluating proficiency testing data as listed in Standard 13. This must include documentation (such as a summary report) that addresses the evaluation of all participants. Additionally, such evaluations should identify any levels of administrative, analytical, or systemic errors and define what (if any) corresponding corrective actions are necessary. Such evaluations must be available to the participants.

Comment

Standard 14: Corrective Action

		Yes	No	N/A
14.1	Does the laboratory have and follow written procedures for taking corrective action whenever proficiency testing discrepancies and/or casework errors are detected?	☐	☒	☐
14.1(CO)	Does the laboratory have and follow written procedures for taking corrective action whenever proficiency testing discrepancies and/or analytical errors are detected?	☒	☐	☐
14.1.1	Does the laboratory maintain documentation for corrective actions and is such documentation retained in accordance with applicable federal or state law?	☒	☐	☐

Discussion

The elements listed for Standard 14 may be assessed through a review of existing laboratory documentation.

Comment

14.1 Is a no finding. Section 10.1. 2 of the DNA Policy and Procedure Manual states that the Special Agent In Charge and the Technical Leader will be notified anytime questions arise concerning discrepancies or the efficacy of a technical procedure using casework analysis. This section also states the technical leader should then immediately investigate. This section of the manual is in conflict with the laboratory's corrective action plan (Procedure 39) which states that the individual recognizing a quality problem immediately notifies the supervisor who in turn notifies the Laboratory Director Quality Manager and the Assistant Deputy Director(Procedure 39). There is no requirement for the Assistant Laboratory Director to inform the Technical Leader. In addition, the DNA Quality Assurance Policy Section 2.1.5.7 states that the technical leader will be informed of any anticipated problems.

Standard 15: Audits

			Yes	No	N/A
15.1	Are audits of the laboratory completed and documented annually?		☒	☐	☐
15.1.1	Did the audit procedures address the following:				
	(a)	Quality assurance program	☒	☐	☐
	(b)	Organization and management	☒	☐	☐
	(c)	Personnel	☒	☐	☐
	(d)	Facilities	☒	☐	☐
	(e)	Evidence control	☒	☐	☐
	(f)	Validation	☒	☐	☐
	(g)	Analytical procedures	☒	☐	☐
	(h)	Calibration and maintenance	☒	☐	☐
	(i)	Proficiency testing	☒	☐	☐
	(j)	Corrective action	☒	☐	☐
	(k)	Reports	☒	☐	☐
	(l)	Review	☒	☐	☐
	(m)	Safety	☒	☐	☐
	(n)	Previous audits	☒	☐	☐
15.1.2	Has the laboratory retained all documentation pertaining to audits in accordance with relevant legal, agency, and state requirements?		☒	☐	☐
15.2	Did a second agency (external) participate in an annual audit of the laboratory at least once every two years?		☒	☐	☐

Discussion

The DNA laboratory must be audited annually. Every other year a qualified auditor from an external agency must conduct the audit. At least one participant of the external auditing team must be or have been a previously qualified analyst in the specific DNA technology (e.g., STRs, mtDNA) in which the external audit is encompassing. A qualified auditor is an individual who has successfully completed the DNA Auditing Workshop sponsored by the FBI. At least one participant in an internal audit must be a qualified DNA analyst or technical manager/leader. One of the individuals must be a qualified auditor.

Audits must be conducted once per calendar year, with the interval between audit dates not less than six months and not exceeding 18 months.

After the audit is completed, the auditor briefs DNA laboratory management regarding the results. This briefing should detail specific areas of findings (noncompliance), observations (general comments and/or recommendations), as well as recognitions of commendable performances.

A written report should be prepared within 30 days of an audit. The audit report consists of the completed checklist, with any areas of noncompliance listed under the findings section of Appendix A. All findings must be clearly identified and referenced to the appropriate standard. Recommendations must not be

included in the audit document. The laboratory must ensure that an adequate response has been generated with regard to all findings, detailing any incorporated corrective actions if appropriate within the response section of Appendix A. Prior audit reports must be available to auditors as a measure of the laboratory's response to previous findings. It is critical that findings identified in a previous audit report are thoroughly addressed and resolved (if possible) within the DNA laboratory's capabilities. **To fulfill the requirements associated with Standard 15.2, the laboratory must show evidence of an adequate response to all findings detailed in the previous audit.** A laboratory's written course of action or response to the findings in an audit report (document) should be maintained as part of the audit report (document).

The audit process criteria listed in Standard 15.1.1 must also include an evaluation of the laboratory's practices that relate to individual qualifications, training, continuing education, and court testimony.

Note: National DNA Index System participating laboratories must refer to the National DNA Index System - Laboratory Audits and External Proficiency Testing Operational Procedures.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Changed wording in first paragraph
- Added statements for qualification requirements of members of the external audit team
- Added wording to define a time frame of 30 days after the audit for the written report to be prepared
- Added sentence requiring that recommendations must not be included in the audit document
- Added note for National DNA Index System participating laboratories

Comment

Standard 16: Safety

		Yes	No	N/A
16.1	Does the laboratory have and follow a documented environmental health and safety program?	☒	☐	☐

Discussion

All information addressing environmental health and safety must be current and available to laboratory staff. At a minimum, the laboratory must have bloodborne pathogen and chemical hygiene plans. This information must be updated to reflect changes in a technical procedure (e.g., radioisotopes) or the remodeling of laboratory space (e.g., changed evacuation plans) that may have an effect on the laboratory's environmental health and safety program. To fulfill the requirements associated with Standard 16.1, the laboratory must provide documentation that its environmental health and safety program has been reviewed to ensure that all practices are appropriate and contemporary.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Added sentence requiring bloodborne pathogen and chemical hygiene plans

Comment

Standard 17: Subcontractors of Analytical Testing for Which Validated Procedures Exist

		Yes	No	N/A
17.1	Does the laboratory require certification of compliance with these standards when a subcontractor performs forensic DNA analyses for the laboratory?	☒	☐	☐
17.1.1	Has the laboratory established and does the laboratory use appropriate review procedures to verify the integrity of the data received from the subcontractor?	☒	☐	☐
17.1.1(CO)	Has the laboratory established and used review procedures that include but are not limited to each of the following:			
	(a) Random reanalysis of samples	☒	☐	☐
	(b) Visual inspection and evaluation of results/data	☒	☐	☐
	(c) Inclusion of quality control samples	☒	☐	☐
	(d) On-site visits	☒	☐	☐

Discussion

A subcontractor, as a forensic DNA laboratory or a convicted offender laboratory, must demonstrate compliance with Standard 17.1 by undergoing an audit with respect to the elements listed in this document. Compliance with Standard 17 is required if the forensic or convicted offender laboratory pays for a subcontractor to perform analysis using analytical methods currently employed by the forensic or convicted offender laboratory or the laboratory enters into an agreement (direct or indirect) with another laboratory for forensic DNA testing (e.g., criminal casework, paternity testing in criminal matters, convicted offender/database testing), in which the forensic or convicted offender laboratory will maintain "ownership" of the case. The forensic or convicted offender laboratory is said to maintain "ownership" and must comply with Standard 17.1.1, if any of the following criteria are applicable:

(a) The forensic/convicted offender laboratory will use any samples, extracts, or any materials from the subcontractor for the purposes of forensic testing (i.e., a subcontractor prepares an extract that will be analyzed by the forensic/database laboratory).

(b) The forensic/convicted offender laboratory will interpret the data generated by the subcontractor.

(c) The forensic/convicted offender laboratory will issue a report on the results of the analysis.

(d) The forensic/convicted offender laboratory will enter a DNA profile into CODIS from data generated by the subcontractor.

To minimize the redundancy of multiple audits (each requiring the same quality assurance elements as listed in this document) of the same subcontractor over the course of the year, contracting laboratories may elect to accept the audit documentation generated from an external audit conducted on the subcontractor laboratory. The audit documentation must include the audit checklist, audit report, and the subcontractors' responses, and/or follow-up actions to any findings detailed in the report. Such documentation or copies must be retained by the contracting laboratory. It is noted that an on-site visit is different from an external audit.

To minimize the redundancy of multiple on-site visits to the subcontracting laboratory (CO17.1.1[d]), contracting laboratories may elect to accept information/documentation generated from an on-site visit conducted on the subcontracting laboratory by a National Institute of Justice/Federal Bureau of Investigation-sponsored laboratory assessment team or public laboratory with similar analysis/contract criteria.

On-site visits (CO17.1.1[d]), if conducted following the external audit on database laboratories or as a component of the review process on a forensic DNA laboratory (FO Standard 17.1.1), should include a

reevaluation of any findings detected during the audit. A minimum of one on-site visit is required per contract period.

All reviews associated with the criteria listed in Standard 17.1.1 (a-d) must be sufficient to thoroughly assess the integrity of the subcontractor's data. A National DNA Index System-approved and internally validated expert system can be used to interpret and review data.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Added statements clarifying a subcontractor's compliance with Standard 17
- Added a list of criteria that defines a forensic/convicted offender laboratory maintaining ownership of a case
- Changed wording in second paragraph
- Added paragraph giving direction on minimizing redundancy of multiple on-site visits to subcontracting laboratories
- Added a sentence requiring one on-site visit minimum per contract period
- Deleted last sentence of second paragraph
- Added sentence approving the use of expert systems for data interpretation and review

Comment

Appendix A: Findings and Responses

Note: Auditors should reference any standard found to be in noncompliance in the findings section below. Directly under the standard, describe the finding of noncompliance in terms of the standard. Recommendations must not be included in the audit document.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

Findings:

5.1 was a no finding in reference to substandard 5.2.3.2 (a-1) – see comment under 5.2.3.2.

5.2.3.2 (b-1) was a no finding. Corrective Action Reports are not being sent to the Technical Leader for review as per Section Policy 10.1.2 of the DNA Database Policy and Procedures Manual. This included several issues of contamination. Staff interviews revealed that the Technical leader was not always informed of Corrective Action Reports initiated in the DNA laboratory. Contamination issues are reported to the direct supervisor who sends a memo to the Deputy Assistant Director and Quality Assurance Manager. It is the Deputy Assistant Director who decides whether the section manager or the technical leader is informed. Consequently, the technical leader cannot monitor quality issues or technical problems if he is not informed of quality issues as they arise in the DNA laboratory.

9.1 was a no finding. The DNA QA Manual states that for mixtures, Combined Probability of Exclusion (CPE) statistic may be calculated independently for each reference sample not excluded from the mixture. When calculating separate CPE's values for each reference sample on the mixture, the manual states the report will (Appendix F – 4.4.3.7) indicate the number and the identity of loci used for the each of the calculations. The reports reviewed using more than one CPE value for a mixture did not indicate the loci or the number of loci used in the calculations.

9.5 is a no finding. The laboratory has used a sample MJB 062304 since 2005 as their NIST traceable sample for their annual check. However, there is no direct documentation to support traceability to a NIST standard. Review of the documentation available for the comparison of the check of sample MJB062304 completed in 2004 lacks the naming of the lot number of MJB used and a verification of the results obtained from the comparison to the NIST published values.

In addition, the methodology using the Qiagen BioRobot Universal System using the QIAamp Media MDx kits on database samples was not checked against the NIST or NIST traceable standard in 2008.

11.1 (FO)is a no finding. The laboratory STR Interpretation Guideline, Appendix F , section 4.4.2.2.3 specifically states that : if alleles are not present at one or more loci then there must be a compelling reason for "NOT" excluding a standard (e.g. allelic dropout and/or inhibition).There is no documentation in the case files reviewed as to why the analyst selected loci to be excluded.

11.1 (CO) is a no. The laboratory DNA Database Unit Standard Operating Procedure(December 15, 2008) in Section 3.3.3 requires that additions to records generated should not only initial the form where required but also date the entry. The DNA Database Collection Card is not dated or initialed when the technician adds information. The card is initialed and dated when changes or corrections are made. In addition, the required format for the naming of the batch for in house processing of convicted offender samples is not being used. This was corrected on site with an updated of a version (Jan 9, 2009) of the manual.

14.1 is a no finding. Section 10.1. 2 of the DNA Policy and Procedure Manual states that the Special Agent in Charge and the Technical Leader will be notified anytime questions arise concerning discrepancies or the efficacy of a technical procedure using casework analysis. This section also states the technical leader should then immediately investigate. This section of the manual is in conflict with the laboratory's corrective action plan (Procedure 39) which states that the individual recognizing a quality problem immediately notifies the supervisor who in turn notifies the Laboratory Director Quality Manager and the Assistant Deputy Director(Procedure 39). There is no requirement for the Assistant Laboratory Director to inform the Technical Leader. In addition, the DNA Quality Assurance Policy Section 2.1.5.7 states that the technical leader will be informed of any anticipated problems.

Responses

META Tags

Quality Assurance Audit for Forensic DNA and Convicted Offender DNA Databasing Laboratories

Scientific Working Group on DNA Analysis Methods

SWGDAM

Findings:

5.1 was a no finding in reference to substandard 5.2.3.2(a-1) – see comment under5.2.3.2.

5.2.3.2 (b - 1) was a no finding, Corrective Action Reports are not being sent to the Technical Leader for review as per Section Policy 10.1.2 of the DNA Database Policy and Procedures Manual. This included several issues of contamination. Staff interviews revealed that the Technical leader was not always informed of Corrective Action reports initiated in the DNA laboratory. Contamination issues are reported to the direct supervisor who sends a memo to the Deputy Assistant Director and Quality Assurance Manager. It is the Deputy Assistant Director who decides whether the section manager or the technical leader is informed. Consequently, the technical leader cannot monitor quality issues or technical problems if he is not informed of quality issues as they arise in the DNA laboratory.

Response: The copy of Procedure 39 dated April 1, 2008 that was given to the ASCLD-LAB/QAS inspection team was a draft, but recognized as the most "official' version to that date. Due to the inconsistencies that were noted during the inspection, a new draft of Procedure 39 dated February 1, 2009 was created to address these issues and is highlighted with the changes. This new draft is the most "official" version to date.

Copies of both drafts are attached.

9.1 was a no finding. The DNA QA Manual states that for mixtures, Combined Probability of Exclusion (CPE) statistic may be calculated independently for each reference sample not excluded from the mixture. When calculating separate CPE's values for each reference sample on the mixture, the manual (Revision 9) states the report will (Appendix F-4.4.3.7) indicate the number and the identity of loci used for the each of the calculations. The reports reviewed using more than one CPE value for a mixture did not indicate the loci or the number of loci used in the calculations.

Response: In Revision 10 of the Interpretation Guidelines (Appendix F-4.4.3.7) the wording has been changed from "the report wording will be as follows" to "the report may be worded as follows."

Copies of revision 9 and 10 are attached.

9.5 was a no finding. The laboratory has used a sample MJB 062304 since 2005 as their NIST traceable sample for their annual check. However, there is no direct documentation to support traceability to a NIST standard. Review of the documentation available for the comparison of the check of sample MJB 062304 completed in 2004 lacks the naming of the lot number of MJB used and a verification of the results obtained from the comparison to the NIST published values.

Response: On June 23, 2004, a bloodstain from Mike Budzynski was prepared for the intent of making a NIST traceable standard. On June 24, 2004, it was extracted along with components from the NIST kit. At that time the stain was identified as MJB 062304, but when the extraction worksheet was prepared it was identified as 'MJB." As a result of this inspection, this extraction worksheet has been updated with the extended terminology (See Attached). As for the verification of the results obtained from comparisons to the NIST published values, a checkmark was placed above the allele calls for each sample to show that they were reviewed and provided the correct results (See Attached allele call form).

In addition, the methodology using the Qiagen BioRobot Universal System using the QIAamp Media MDx kits on database samples was not checked against the NIST or NIST traceable standard in 2008.

Response: A NIST traceable standard was run against the robot on January 28, 2009. A copy of the documentation is provided as well as confirmation that the allele values provided the correct results. This procedure has been scheduled on a calendar, so that it will be performed on a routine basis in the future.

11.1 (FO) is a no finding. The laboratory STR Interpretation Guideline, Appendix F, Revision 9, section 4.4.2.2.3 specifically states that: if alleles are not present at one or more loci then there must be a compelling reason for "NOT" excluding a standard (e.g. allelic dropout and/or inhibition). There is no documentation in the case files reviewed as to why the analyst selected to be excluded.

Response: In Revision 10 of the Interpretation Guidelines, Appendix F, section 4.4.2.2.3, the statement, "If alleles are not present at one or more locus, then there must be a reason for NOT excluding a standard (e.g. allelic dropout and/or inhibition)," has been deleted.

Copies of revision 9 and 10 are attached.

11.1 (CO) is a no. The laboratory DNA Database Unit Standard Operating Procedure (December 15, 2008) in Section 3.3.3 requires that additions to records generated should not only initial the form where required but also date the entry. The DNA Database Collection Card is not dated or corrections are made. In addition, the required format for the naming of the batch

for in house processing of convicted offender samples is not being used. This was corrected on site with an updated of a version (Jan 9, 2009) of the manual.

Response: Once this issue was pointed out, during the inspection, the database supervisor held a meeting with the individuals assigned to the DNA database unit and instructed them to initial and date any additions made to the DNA Database Collection Cards.

14.1 is a no finding. Section 10.1.2 of the DNA Policy and Procedure Manual states that the Special Agent in Charge and the Technical Leader will be notified anytime questions arise concerning discrepancies or the efficacy of a technical procedure using casework analysis. This section of the manual is in conflict with the laboratory's corrective action plan (Procedure 39) which states that the individual recognizing a quality problem immediately notifies the supervisor who in turn notifies the Laboratory Director Quality Manager and the Assistant Deputy Director (Procedure 39). There is no requirement for the Assistant Laboratory Director to inform the Technical Leader. In addition, the DNA Quality Assurance Policy Section 2.1.5.7 states that the technical leader will be informed of any anticipated problems.

Response: The copy of Procedure 39 dated April 1, 2008 that was given to the ASCLD-LAB/QAS inspection team was a draft, but recognized as the most "official' version to that date. Due to the inconsistencies that were noted during the inspection, a new draft of Procedure 39 dated February 1, 2009 was created to address these issues and is highlighted with the changes. This new draft is the most "official" version to date.

Copies of both drafts are attached.

DRAFT

3.2.3.2(b-1)

14.1

pg 1 of.

STATE BUREAU OF INVESTIGATION PROCEDURE 39
POLICY AND PROCEDURE MANUAL
APRIL 1, 2008

SUBJECT: LABORATORY QUALITY SYSTEM

CONFIDENTIALITY OF COMPETENCY AND PROFICIENCY TEST RESULTS

The results of all competency and proficiency tests shall be treated with strict confidence and shall be discussed only with the individual, his/her Special Agent in Charge or Training Officer, the Quality Manager, or the Assistant Director of Crime Laboratory Services.

MINOR OR SUBSTANTIAL DISCREPANCIES DEFINED

Minor Discrepancies generally:

- are foreseeable,
- have a clear-cut immediate cause,
- have a defined straightforward corrective action, which can be adequately
- documented by a simple entry on the examination documentation, or utilizing the Technical Review Form.
- can be corrected on the spot by the individual who discovers them, and
- have not and will not in any way compromise the quality of work if properly addressed.

Substantial discrepancies generally:

- are unexpected,
- require an inquiry to determine their root cause,
- require elaborate or intensive action with extensive documentation,
- must be addressed by more than one individual, and
- have compromised the quality of work.
- usually include missed identifications (failing to identify something present) and erroneous identifications (identifying something not present).

CORRECTIVE ACTIONS AS THE RESULT OF MINOR DISCREPANCIES

Corrective actions of minor discrepancies are made by examiners and are considered normal operating procedures. Staff may take on-the-spot or immediate corrective action to correct or repair non-conforming data, reporting or equipment, that are actions routinely made by analysts, technicians and supervisors.

CORRECTIVE ACTIONS AS THE RESULT OF SUBSTANTIAL DISCREPANCIES

A. The individual who identifies a potential substantial discrepancy shall inform their supervisor in a timely manner. The supervisor shall briefly but clearly document the discrepancy and method of identification in an e-mail to the Laboratory Director, Deputy Assistant Director, and Quality Manager within 2 business days of the identification of the discrepancy.

B. The Deputy Assistant Director will determine if the discrepancy is substantial, and if so, will assign a two-person inquiry team to evaluate the discrepancy. The team shall

SUBJECT: LABORATORY QUALITY SYSTEM

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- are unexpected,
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- must be addressed by more than one individual, and
- have compromised the quality of work.
- usually include missed identifications (failing to identify something present) and erroneous identifications (identifying something not present).

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CORRECTIVE ACTIONS AS THE RESULT OF SUBSTANTIAL DISCREPANCIES

A. The individual who identifies a potential substantial discrepancy shall inform their supervisor and/or Technical Leader in a timely manner. The supervisor and/or Technical Leader shall briefly but clearly document the discrepancy and method of identification in an e-mail to the Laboratory Director, Deputy Assistant Director, and Quality Manager within 2 business days of the identification of the discrepancy.

B. The Deputy Assistant Director will determine if the discrepancy is substantial, and if so, will assign a two-person inquiry team to evaluate the discrepancy. The team shall generally include the Section Supervisor and a designated Technical Leader. The Quality

N.C. Black: 1 in 1,070
N.C. Hispanic: 1 in 235
N.C. Lumbee Indian: 1 in 394"

4.4.3.3 Allele Dropout: If there are signal intensities that do not meet the criteria set forth by the laboratory protocols (i.e. activity below RFU cutoff threshold) and there are clearly approved allele calls within the same locus, the entire locus may be excluded from the calculation. Note that only those loci in which an individual is not excluded may be used for statistical calculations.

4.4.3.4 Predominant Profile with Minor Alleles of Interest:

Example: A predominant profile with 5 minor alleles at 4 loci is obtained and the suspect cannot be excluded at the minor alleles. CPE may be performed on the mixture, but only at the 4 loci.

4.4.3.5 Intimate Samples with No Predominant Profile: If a mixed profile is obtained from an Intimate Sample with no Predominant profile, CPE must be calculated on the entire sample. Alleles from the "owner" of an Intimate Sample cannot be pulled out of Mixture.

4.4.3.6 Complex Mixtures: If a complex mixture with multiple contributors is observed and individuals cannot be excluded, then CPE may be performed on entire profile. However, if a single individual is being considered, then CPE calculations should be performed on loci where that individual cannot be excluded.

4.4.3.7 Mixture of Two (or More) Individuals: If two or more individuals cannot be excluded from a mixture, then multiple CPE calculations may be performed.

Example: The following profile is obtained from a swabbing from the handle of a gun used to rob a bank. The following profile was observed:

Item	D21	D7	D3	CSF	D5	THO1	D13	D16	D2	D19	TWA	TPOX	D18	Am	D8	FGA
Gun	(13) 14 (15)	29	8 12	(10) 11 (12)	14 15	6 (7)	11 12 13	9	17 23 24	13 14 15	(14) 16 (17)	10, 11	12 (15) 17	XY	10 (11) (12)	(22) (23) 24
Susp 1	13 14	29 30	Inc	10 12	14 17	6 9.3	11 12	12 13	19 23	13 14	14 17	10, 11	12 17	XY	10 12	24
Susp. 2	14 15	29	8 12	11	15 16	6 7	12 13	9	17 24	14 15	16	9, 11	15 17	XY	9, 11	22, 23

Allele dropout was noted D21, D7, D3, THO1, D16, D2, TPOX, and D5. Suspect # 1 cannot be excluded as a contributor to the DNA mixture at 10 genetic markers. Suspect # 2 cannot be excluded as a contributor to the DNA mixture at 13 genetic markers. The report wording will be as follows:

"The DNA profile obtained from the gun (Item 1) is CONSISTENT WITH A MIXTURE. The DNA profile obtained from Suspect #1 cannot be excluded as a contributor to this DNA mixture at 10 genetic markers. The DNA profile obtained from Suspect #2 cannot be excluded as a contributor to this DNA mixture at 13 genetic markers.

Suspect #1 cannot be excluded as a contributor to this DNA mixture at 10 genetic markers. The estimates of the combined probability of inclusion (i.e. the chance of selecting an unrelated individual at random that would be expected to be included) for the observed DNA mixture profile is approximately:

N.C. Caucasian: 1 in 5,340
N.C. Black: 1 in 7,990
N.C. Hispanic: 1 in 11,210
N.C. Lumbee Indian: 1 in 4,100

(Note: D21, D7, D3, THO1, D16, and D2 were not used in the calculations.)

Suspect #2 cannot be excluded as a contributor to this DNA mixture at 13 genetic markers.

4.4.3.6 Complex Mixtures: If a complex mixture with multiple contributors is observed and individuals cannot be excluded, then CPE may be performed on entire profile. However, if a single individual is being considered, then CPE calculations should be performed on loci where that individual cannot be excluded.

4.4.3.7 Mixture of Two (or More) Individuals: If two or more individuals cannot be excluded from a mixture, then multiple CPE calculations may be performed.

Example: The following profile is obtained from a swabbing from the handle of a gun used to rob a bank. The following profile was observed:

Item	D8	D21	D7	CSF	D3	TH01	D13	D16	D2	D19	vWA	TPOX	D18	Am	D5	FGA
Gun	(13) 14 (15)	29	8 12	(10) 11 (12)	14 15	6 (7)	11 12 13	9	17 23 24	13 14 15	(14) 16 (17)	10, 11	12 (15) 17	XY	10 (11) (12)	(22) (23) 24
Susp 1	13 14	29 30	Inc	10 12	14 17	6 9.3	11 12	12 13	19 23	13 14	14 17	10, 11	12 17	XY	10 12	24
Susp. 2	14 15	29	8 12	11	15 16	6 7	12 13	9	17 24	14 15	16	9, 11	15 17	XY	9, 11	22, 23

Allele dropout was noted D21, D7, D3, THO1, D16, D2, TPOX, and D5. Suspect # 1 cannot be excluded as a contributor to the DNA mixture at 10 genetic markers. Suspect # 2 cannot be excluded as a contributor to the DNA mixture at 13 genetic markers. The report may be worded as follows:

"The DNA profile obtained from the gun (Item 1) is CONSISTENT WITH A MIXTURE.

Suspect #1 cannot be excluded as a contributor to this DNA mixture. The estimates of the combined probability of inclusion (i.e. the chance of selecting an unrelated individual

at random that would be expected to be included) for the observed DNA mixture profile is approximately:

N.C. Caucasian: 1 in 5,340
N.C. Black: 1 in 7,990
N.C. Hispanic: 1 in 11,210
N.C. Lumbee Indian: 1 in 4,100

Suspect #2 cannot be excluded as a contributor to this DNA mixture.

The estimates of the combined probability of inclusion (i.e. the chance of selecting an unrelated individual at random that would be expected to be included) for the observed DNA mixture profile is approximately:

N.C. Caucasian: 1 in 15.3 Million
N.C. Black: 1 in 1.96 Million
N.C. Hispanic: 1 in 15.8 Million
N.C. Lumbee Indian: 1 in 8.97 Million"

PAGE NUMBER	
SBI LAB FILE NUMBER	R2004-NIST
ANALYST	SRW
DATE	June 24, 2004

DNA Extraction Worksheet

NOTE: Extractions for Question and Known Samples are separated by time or space.

Question Samples	Date/ Time	Extraction Type	Final Volume	Area and Equip. Decon.
				SW

Known Samples	Date/Time	Extraction Type	Final Volume	Area and Equip. Decon.
K, 11,12, MJB (lot # MJB 062304) SH 2/24/05	8:35am 6/24/2004	Organic	100ul	SW
				SW

Phenol/Chloroform Lot # 024K0017

Extracted with following Cases SW

Notes:

Date: 6/28/2004 Case Number: 2004-NIST

Item Number	1 ✓				2 ✓			
Item Description								
Markers	Allele Call				Allele Call			
AMEL	X	Y	-	-	X	-	-	-
CSF1PO	12	-	-	-	11	12	-	-
D13S317	11	13	-	-	8	11	-	-
D16S539	12	14	-	-	12	-	-	-
D18S51	14	-	-	-	10	14	-	-
D19S433	13	16.2	-	-	14	16	-	-
D21S11	29	33.2	-	-	29	30	-	-
D2S1338	17	23	-	-	17	26	-	-
D3S1358	14	17	-	-	15	16	-	-
D5S818	12	-	-	-	12	-	-	-
D7S820	9	10	-	-	9	10	-	-
D8S1179	13	-	-	-	11	16	-	-
FGA	21	22	-	-	20	22	-	-
TH01	6	7	-	-	8	9.3	-	-
TPOX	8	11	-	-	8	10	-	-
vWA	17	-	-	-	14	16	-	-

Item Number	3 ✓				4 ✓			
Item Description								
Markers	Allele Call				Allele Call			
AMEL	X	Y	-	-	X	-	-	-
CSF1PO	11	12	-	-	11	12	-	-
D13S317	11	12	-	-	12	-	-	-
D16S539	11	12	-	-	9	10	-	-
D18S51	16	20	-	-	18	-	-	-
D19S433	12	14	-	-	11	13	-	-
D21S11	28	31.2	-	-	28	30	-	-
D2S1338	20	24	-	-	17	23	-	-
D3S1358	15	-	-	-	15	17	-	-
D5S818	11	-	-	-	11	-	-	-
D7S820	12	13	-	-	8	10	-	-
D8S1179	14	16	-	-	14	-	-	-
FGA	23	25	-	-	18	22	-	-
TH01	9.3	-	-	-	7	9	-	-
TPOX	8	11	-	-	8	9	-	-
vWA	18	19	-	-	17	-	-	-

Item Number	5 ✓				6 ✓			
Item Description								
Markers	Allele Call				Allele Call			
AMEL	X	-	-	-	X	-	-	-
CSF1PO	10	12	-	-	10	13	-	-
D13S317	11	12	-	-	12	13	-	-
D16S539	9	11	-	-	12	13	-	-
D18S51	14	16	-	-	18	-	-	-
D19S433	12.2	14	-	-	12	14	-	-
D21S11	28	30	-	-	28	29	-	-
D2S1338	17	19	-	-	25	-	-	-
D3S1358	15	18	-	-	14	17	-	-
D5S818	11	12	-	-	12	-	-	-
D7S820	8	10	-	-	8	11	-	-
D8S1179	15	16	-	-	10	16	-	-
FGA	23	26	-	-	21	26	-	-
TH01	7	-	-	-	9	9.3	-	-
TPOX	10	11	-	-	8	-	-	-
vWA	16	20	-	-	16	18	-	-

Item Number	7 ✓				8 ✓			
Item Description								
Markers	Allele Call				Allele Call			
AMEL	X	Y	-	-	X	-	-	-
CSF1PO	10	11	-	-	10	12	-	-
D13S317	11	12	-	-	9	13	-	-
D16S539	10	-	-	-	9	11	-	-
D18S51	13	16	-	-	15	18	-	-
D19S433	13	15.2	-	-	12.2	15	-	-
D21S11	28	31.2	-	-	30	31	-	-
D2S1338	17	22	-	-	22	-	-	-
D3S1358	14	15	-	-	15	18	-	-
D5S818	11	12	-	-	12	13	-	-
D7S820	9	-	-	-	9	10	-	-
D8S1179	13	15	-	-	12	14	-	-
FGA	23	24	-	-	24	28	-	-
TH01	6	7	-	-	7	8	-	-
TPOX	8	11	-	-	8	12	-	-
vWA	16	-	-	-	15	17	-	-

Date: 6/28/2004 Case Number: 2004-NIST

Item Number	9 ✓				10 ✓				Item Number	11 ✓				12 ✓			
Item Description									Item Description								
Markers	Allele Call				Allele Call				Markers	Allele Call				Allele Call			
AMEL	X	-	-	-	X	Y	-	-	AMEL	X	-	-	-	X	Y	-	-
CSF1PO	10	12	-	-	10	11	12	-	CSF1PO	10	12	-	-	10	11	12	-
D13S317	11	-	-	-	11	-	-	-	D13S317	11	-	-	-	11	-	-	-
D16S539	11	12	-	-	11	-	-	-	D16S539	11	12	-	-	11	-	-	-
D18S51	15	19	-	-	15	18	-	-	D18S51	15	19	-	-	15	18	-	-
D19S433	14	15	-	-	13	14	-	-	D19S433	14	15	-	-	13	14	-	-
D21S11	30	-	-	-	29	30	-	-	D21S11	30	-	-	-	29	30	-	-
D2S1338	19	23	-	-	23	-	-	-	D2S1338	19	23	-	-	23	-	-	-
D3S1358	14	15	-	-	15	17	-	-	D3S1358	14	15	-	-	15	17	-	-
D5S818	11	-	-	-	11	13	-	-	D5S818	11	-	-	-	11	13	-	-
D7S820	10	11	-	-	11	-	-	-	D7S820	10	11	-	-	11	-	-	-
D8S1179	13	-	-	-	12	13	-	-	D8S1179	13	-	-	-	12	13	-	-
FGA	23	24	-	-	24	26	-	-	FGA	23	24	-	-	24	26	-	-
TH01	8	9.3	-	-	6	9.3	-	-	TH01	8	9.3	-	-	6	9.3	-	-
TPOX	8	-	-	-	8	9	-	-	TPOX	8	-	-	-	8	9	-	-
vWA	17	18	-	-	17	-	-	-	vWA	17	18	-	-	17	-	-	-

Item Number	MJB ✓				blank				Item Number	blank				blank			
Item Description									Item Description								
Markers	Allele Call				Allele Call				Markers	Allele Call				Allele Call			
AMEL	X	Y	-	-	-	-	-	-	AMEL	-	-	-	-	-	-	-	-
CSF1PO	10	12	-	-	-	-	-	-	CSF1PO	-	-	-	-	-	-	-	-
D13S317	8	9	-	-	-	-	-	-	D13S317	-	-	-	-	-	-	-	-
D16S539	12	-	-	-	-	-	-	-	D16S539	-	-	-	-	-	-	-	-
D18S51	13	16	-	-	-	-	-	-	D18S51	-	-	-	-	-	-	-	-
D19S433	13	14	-	-	-	-	-	-	D19S433	-	-	-	-	-	-	-	-
D21S11	29	30	-	-	-	-	-	-	D21S11	-	-	-	-	-	-	-	-
D2S1338	17	24	-	-	-	-	-	-	D2S1338	-	-	-	-	-	-	-	-
D3S1358	15	17	-	-	-	-	-	-	D3S1358	-	-	-	-	-	-	-	-
D5S818	11	-	-	-	-	-	-	-	D5S818	-	-	-	-	-	-	-	-
D7S820	8	10	-	-	-	-	-	-	D7S820	-	-	-	-	-	-	-	-
D8S1179	11	13	-	-	-	-	-	-	D8S1179	-	-	-	-	-	-	-	-
FGA	20	23	-	-	-	-	-	-	FGA	-	-	-	-	-	-	-	-
TH01	8	9.3	-	-	-	-	-	-	TH01	-	-	-	-	-	-	-	-
TPOX	8	11	-	-	-	-	-	-	TPOX	-	-	-	-	-	-	-	-
vWA	17	-	-	-	-	-	-	-	vWA	-	-	-	-	-	-	-	-

9.5 part 2

ROBOT-NIST-2009
page 1 of 22

QIAGEN

Result documentation

NCSBI DNA Data Base Identifiler Punch/Extraction Sheet JRM

File Name:JRM2009prof-1

Extraction Table Worksheet

Row	1	2	3	4	5	6	7	8	9	10	11	12
A		DNAF-01		MJB-062304-1								
B		DNAF-01	UNIDENTIFIED	MJB-062304-2								
C		DNAF-02	UNIDENTIFIED	MJB-062304-3								
D		DNAF-02	UNIDENTIFIED	MJB-062304-1								
E		DNAF-03	UNIDENTIFIED	MJB-062304-2								
F		DNAF-03	UNIDENTIFIED	MJB-062304-3								
G	NegExt	UNIDENTIFIED	UNIDENTIFIED	UNIDENTIFIED								
H	NegExt	UNIDENTIFIED	UNIDENTIFIED	UNIDENTIFIED								

Extraction Worksheet Info

Punch/Cut	*Info*	*Off-Line Lysis*	*Date/Time/Initials*	*DNA Extraction Info*	*Number / Date/time/Initials*
Analyst	JRM	Reagents added	1-27/1:35p/jrm	Q-card number	9800101013 0159229070 9000
Witness	TAR	Start thermomixer	1-27/1:40p jrm	Ethanol Lot number	01133MH
Date	1-27-09	Stop thermomixer	1-28/5:40a jrm	Extraction Start	1-28/5:45a jrm
Punch Size	1/8 inch				

Comments:

Comment [1]: |CheckSum|59B9FA0F

Robot-NIST-2009
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Result documentation

QIAGEN

Operator: jmatthews
Date: 2009 01 28
Start time: 05:58:32
Run time: 98 min
Kit name: QIAamp Media MDx Kit
Number of processed samples: 32

Bar code of Elution Microtubes CL (EMT): 10137400127151159032 30
Q-Card bar code: 9800101013015922907090 00
Kit catalog number: 0965752
Kit lot number: 0130159229
Kit expiration date: 2009 7 31

BioRobot UNIV ID: BR8R_UNIV_Sn4178
QIAsoft 5 version: 5.0.1-1800
Protocol version: QIAamp DNA Swab and BloodCard UNIV rcV9 (protected)
Robot Configuration: BR8R_UNIV_SN4178

Message log file name: 090128AB.msl
Message log file directory: C:\Program Files\QIAsoft\UserData\LogFiles\
Report log file name: QIAamp DNA Swab and BloodCard UNIV rcV9 2009 01 28 05 58 32.rtf
Report directory: C:\Program Files\QIAsoft\UserData\ReportData\

Maintenance: The protocol was executed with no open maintenance action(s)

Process information:

Technical process check: PASSED
General Results:

Position	Barcode	Result (1 = valid, 0 = invalid)
A1		1
B1		1
C1		1
D1		1
E1		1
F1		1
G1	NegExt	1
H1	NegExt	1
A2	DNAF-01	1
B2	DNAF-01	1
C2	DNAF-02	1
D2	DNAF-02	1
E2	DNAF-03	1
F2	DNAF-03	1
G2	UNIDENTIFIED	1
H2	UNIDENTIFIED	1
A3		1
B3	UNIDENTIFIED	1
C3	UNIDENTIFIED	1
D3	UNIDENTIFIED	1
E3	UNIDENTIFIED	1
F3	UNIDENTIFIED	1
G3	UNIDENTIFIED	1
H3	UNIDENTIFIED	1
A4	MJB-062304-1	1
B4	MJB-062304-2	1
C4	MJB-062304-3	1
D4	MJB-062304-1	1
E4	MJB-062304-2	1
F4	MJB-062304-3	1
G4	UNIDENTIFIED	1
H4	UNIDENTIFIED	1

Comment [1]: CheckSum[B6B7147E

Result documentation

QIAGEN

ROBOT-NIST-2009
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NCSBI DNA Data Base Identifiler Amplification Sheet

File Name: JRM2009prof-1
Number of Punches to be Amplified: 12 – 6 ROBOT, 6 MANUAL

Row	1	2	3	4	5	6	7	8	9	10	11	12
A	Ladder	DNAF-01	Ladder	MJB062 304-1D								
B	NegAmp	DNAF-01 D	NegAmp	MJB062 304-2D								
C	NegAmp	DNAF-02	NegAmp	MJB062 304-3D								
D	9947A	DNAF-02 D	9947A	MJB062 304-1								
E	9947A	DNAF-03	9947A	MJB062 304-2								
F	9947A	DNAF-03 D	9947A	MJB062 304-3								
G	NegExt		NegExt									
H	NegExt		NegExt									

Component	Lot #	ul	No Rxn + 1	Vol Total
PCR Rxn Mix	J10416	5.25	30	150.75
Identifiler Primer Set	0802057	2.75	30	82.5
Taq Gold	0802127	0.25	30	7.5

Negative Amplification Control	ul/Rxn
Volume MasterMix / Rxn	7.5
TE: 032909	5.0
Sample Template	0.00
Volume Total / Rxn	12.5

Positive Amplification Control	ul/Rxn
Volume MasterMix / Rxn	7.5
9947A: 0802057	5.0
Volume Total / Rxn	12.5

ThermalCycler: 19
Program: Identifiler

Comments: MMX, TE robot transferred thru well 2F, manual thereafter. D samples were diluted (as per robot protocol) with 100ul TE before adding to amp reaction. All samples were manually pipetted into reaction plate due to robot malfunction during the amp protocol.

Comment [1]: CheckSum2009678

3100 Tray Setup

Instrument: Lane4 Date: 01-28-09 Analyst: JRM Run Number(s): 73, 74 Plate Name: JRM0128

	1	2	3	4	5	6	7	8	9	10	11	12
A	LADDER	DNAF-01	LADDER	MJB062304-1D								
B	NEGAMP	DNAF-01-D	NEGAMP	MJB062304-2D								
C	NEGAMP	DNAF-02	NEGAMP	MJB062304-3D								
D	9947A	DNAF-02-D	9947A	MJB062304-1								
E	9947A	DNAF-03	9947A	MJB062304-2								
F	9947A	DNAF-03-D	9947A	MJB062304-3								
G	NEGEXT		NEGEXT									
H	NEGEXT		NEGEXT									

Run with the following cases: N/A

Formamide lot #: 0711659 Ladder lot#: 0711010 Liz size standard lot #: 0801082

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NCSBI [redacted]
Laurel

ROBOT-NIST [redacted]

JRM [redacted]
01-28-200[redacted]

Sample File	Sample Name	Sample Type	Analysis Method	Panel	Size Standard	Instrument Type
D03_9947A.fsa	9947A	Positive Control	NCSBI Robot	Identifiler_v2	GS500_Advanced	ABI3130
E03_9947A.fsa	9947A	Positive Control	NCSBI Robot	Identifiler_v2	GS500_Advanced	ABI3130
F03_9947A.fsa	9947A	Positive Control	NCSBI Robot	Identifiler_v2	GS500_Advanced	ABI3130
A03_LADDER.fsa	LADDER	Allelic Ladder	NCSBI Robot	Identifiler_v2	GS500_Advanced	ABI3130
D04_MJB02304-1.fsa	MJB062304-1	Sample	NCSBI Robot	Identifiler_v2	GS500_Advanced	ABI3130
A04_MJB062304-1D.fsa	MJB062304-1D	Sample	NCSBI Robot	Identifiler_v2	GS500_Advanced	ABI3130
E04_MJB062304-2.fsa	MJB062304-2	Sample	NCSBI Robot	Identifiler_v2	GS500_Advanced	ABI3130
B04_MJB062304-2D.fsa	MJB062304-2D	Sample	NCSBI Robot	Identifiler_v2	GS500_Advanced	ABI3130
F04_MJB062304-3.fsa	MJB062304-3	Sample	NCSBI Robot	Identifiler_v2	GS500_Advanced	ABI3130
C04_MJB062304-3D.fsa	MJB062304-3D	Sample	NCSBI Robot	Identifiler_v2	GS500_Advanced	ABI3130
B03_NEGAMP.fsa	NEGAMP	Negative Control	NCSBI Robot	Identifiler_v2	GS500_Advanced	ABI3130
C03_NEGAMP.fsa	NEGAMP	Negative Control	NCSBI Robot	Identifiler_v2	GS500_Advanced	ABI3130
G03_NEGEXT.fsa	NEGEXT	Sample	NCSBI Robot	Identifiler_v2	GS500_Advanced	ABI3130
H03_NEGEXT.fsa	NEGEXT	Sample	NCSBI Robot	Identifiler_v2	GS500_Advanced	ABI3130

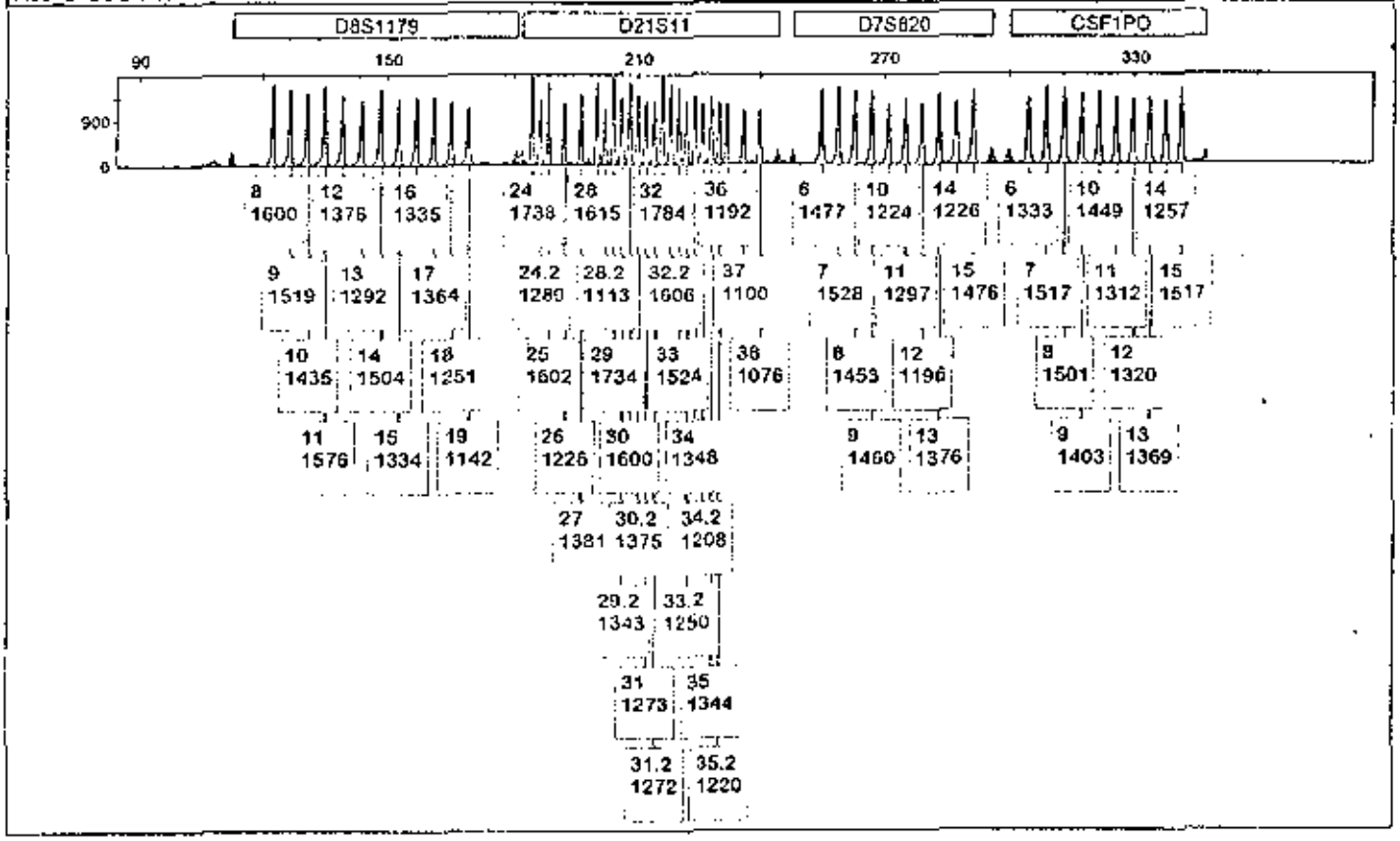
Analysis on JRM computer

Applied Biosystems

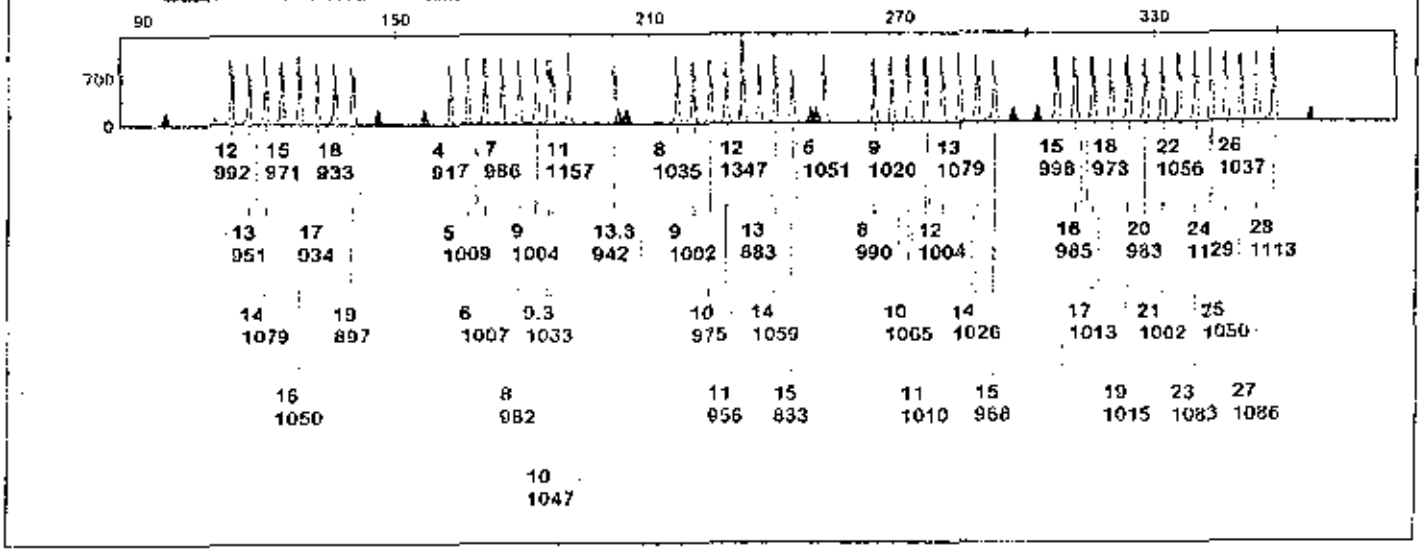
GeneMapper ID v3.2.1

ROBOT-NIST-2009

Sample File	Sample Name	Panel	SQO	SQ
A03_LADDER.fsa	LADDER	Identifiler_v2		



A03_LADDER.fsa	LADDER	Identifiler_v2



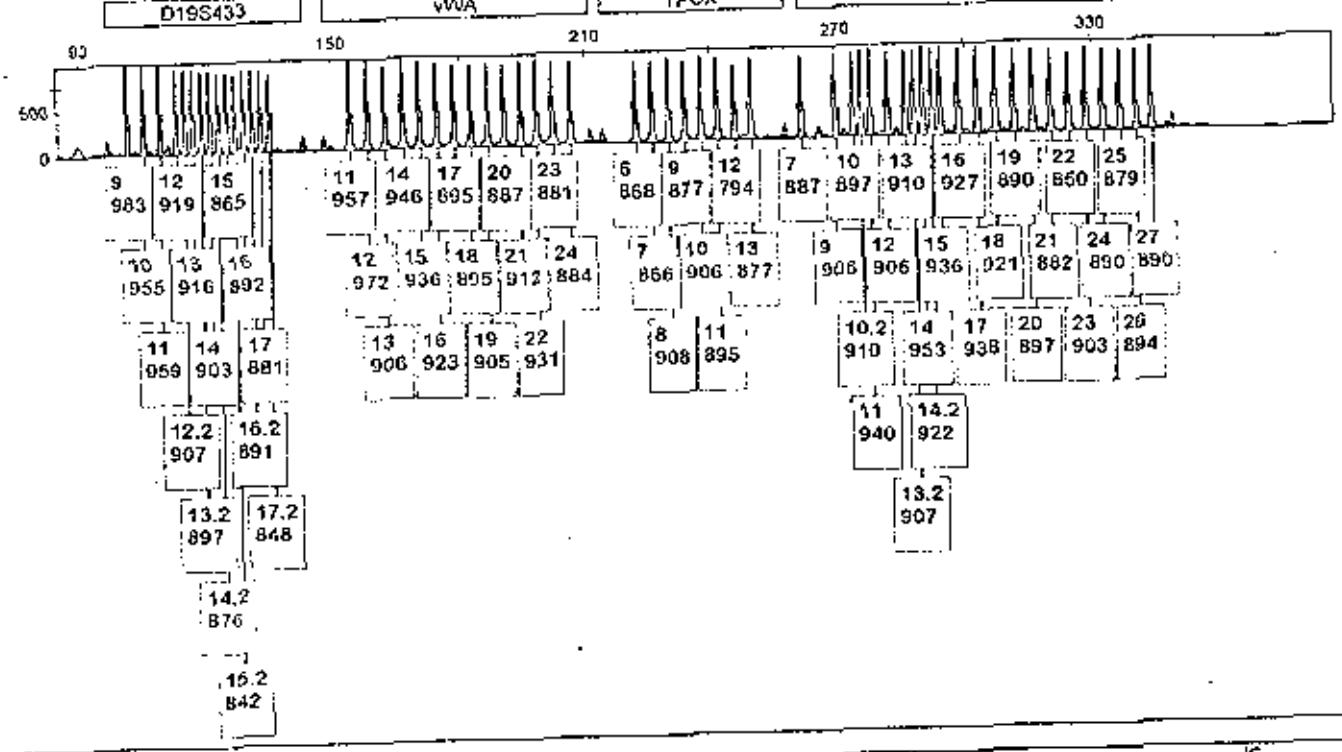
Applied Biosystems

GeneMapper ID v3.2.1

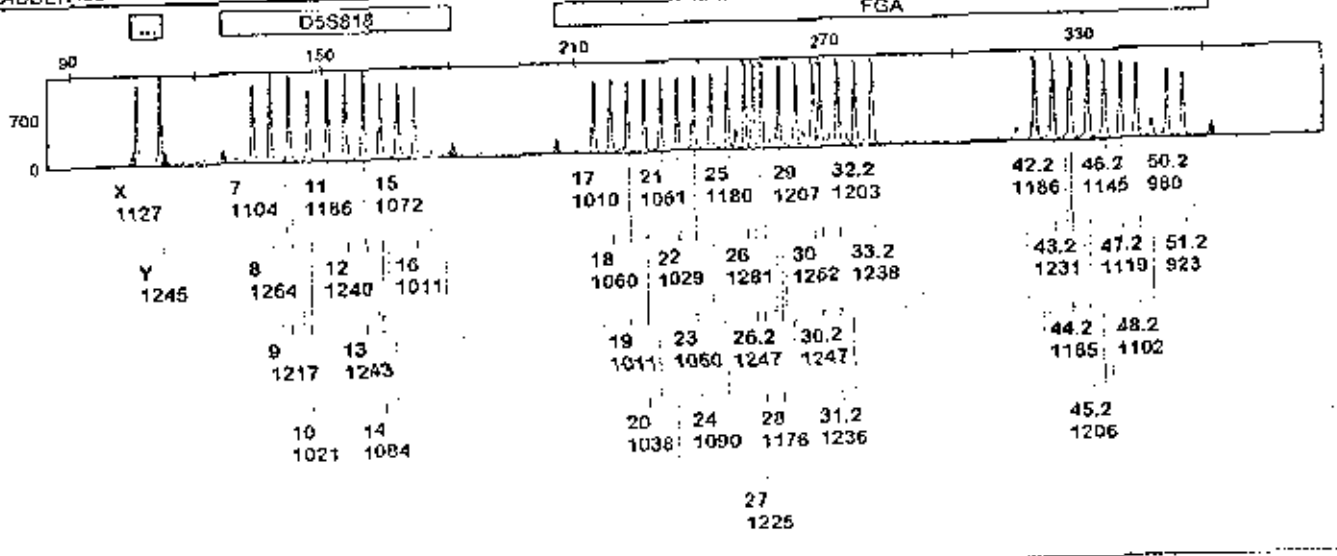
ROBOT-NIST-2009

Sample File | Sample Name | Panel | SQO | SQ

A03_LADDER.fsa | LADDER | Identifiler_v2



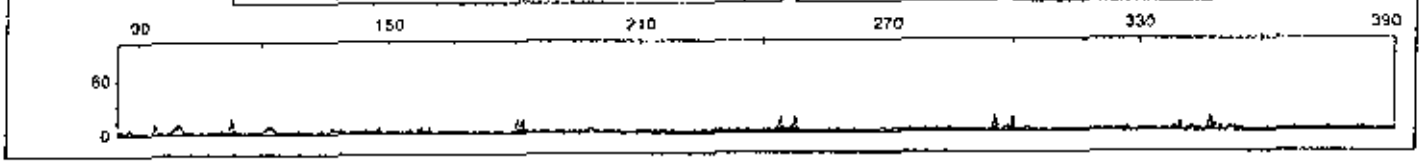
A03_LADDER.fsa | LADDER | Identifiler_v2



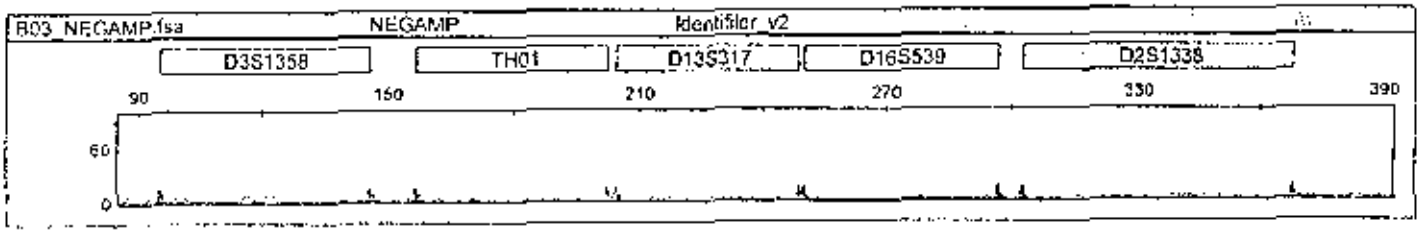
Applied Biosystems
GeneMapper ID v3.2.1

ROBOT-NIST-2009

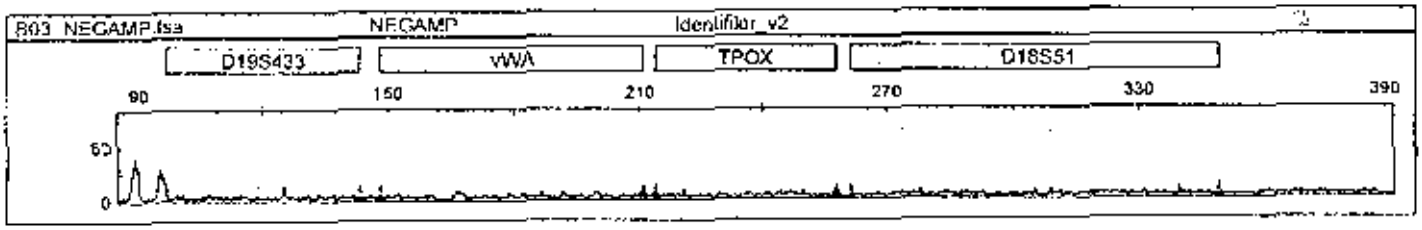
Sample File	Sample Name	Panel	SQO	SQ
B03_NEGAMP.fsa	NEGAMP	Identifiler_v2		



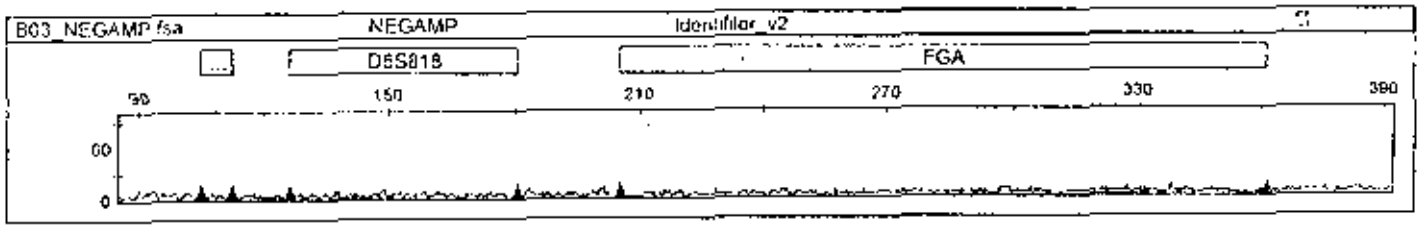
B03_NEGAMP.fsa NEGAMP Identifiler_v2



B03_NEGAMP.fsa NEGAMP Identifiler_v2



B03_NEGAMP.fsa NEGAMP Identifiler_v2

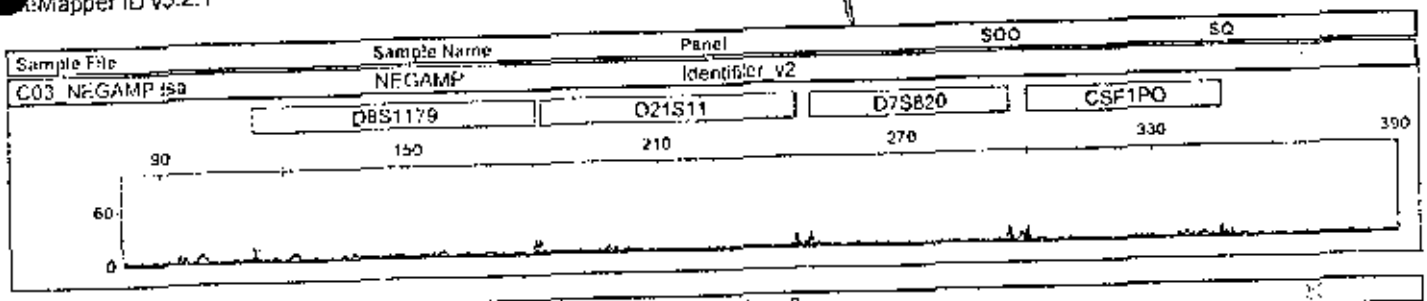


Applied Biosystems

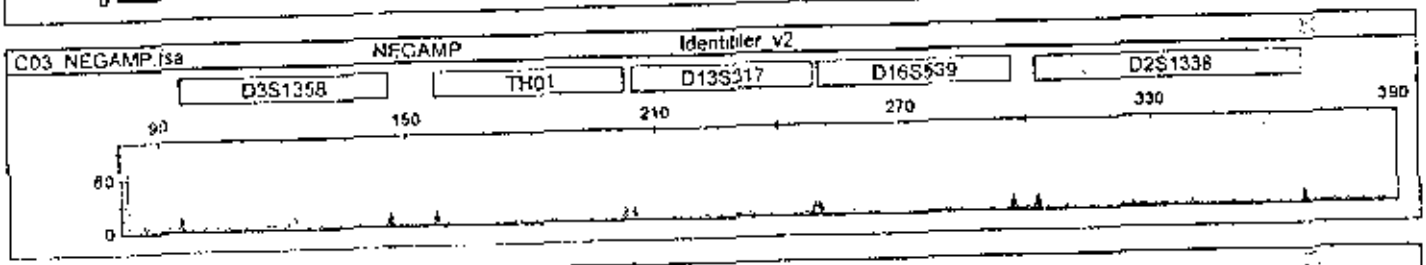
GeneMapper ID v3.2.1

ROBOT-NIST-2009

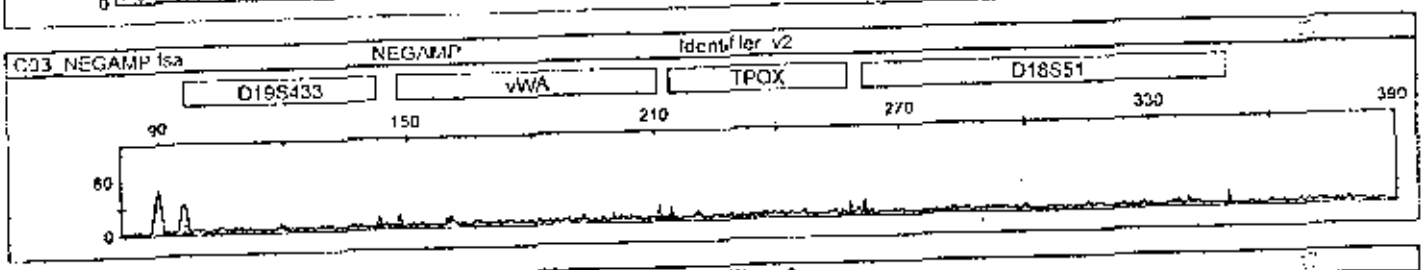
Sample File	Sample Name	Panel	SOO	SQ
C03_NEGAMP.fsa	NEGAMP	Identifiler_v2		



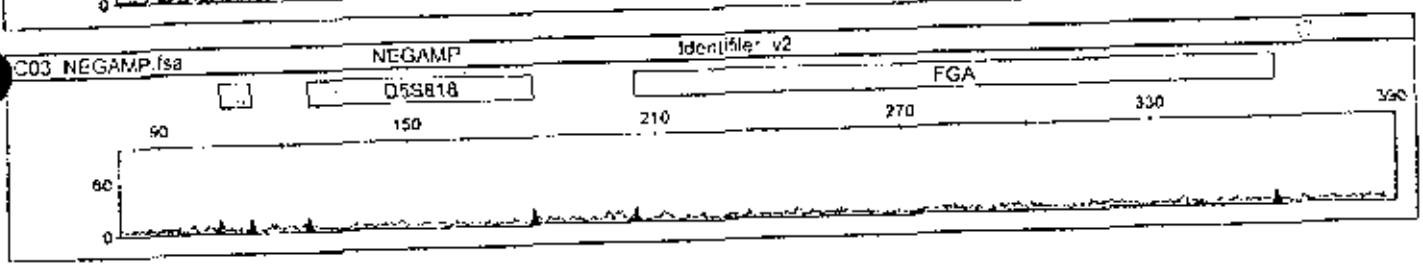
C03_NEGAMP.fsa NEGAMP Identifiler_v2



C03_NEGAMP.fsa NEGAMP Identifiler_v2



C03_NEGAMP.fsa NEGAMP Identifiler_v2



Applied Biosystems

GeneMapper ID v3.2.1

ROBOT-NIST-2009

Sample File	Sample Name	Panel	SQO	SQ
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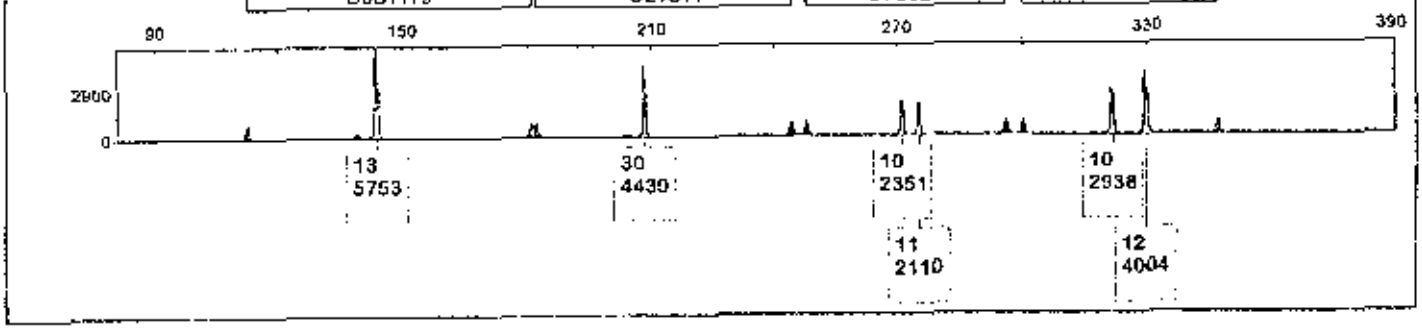
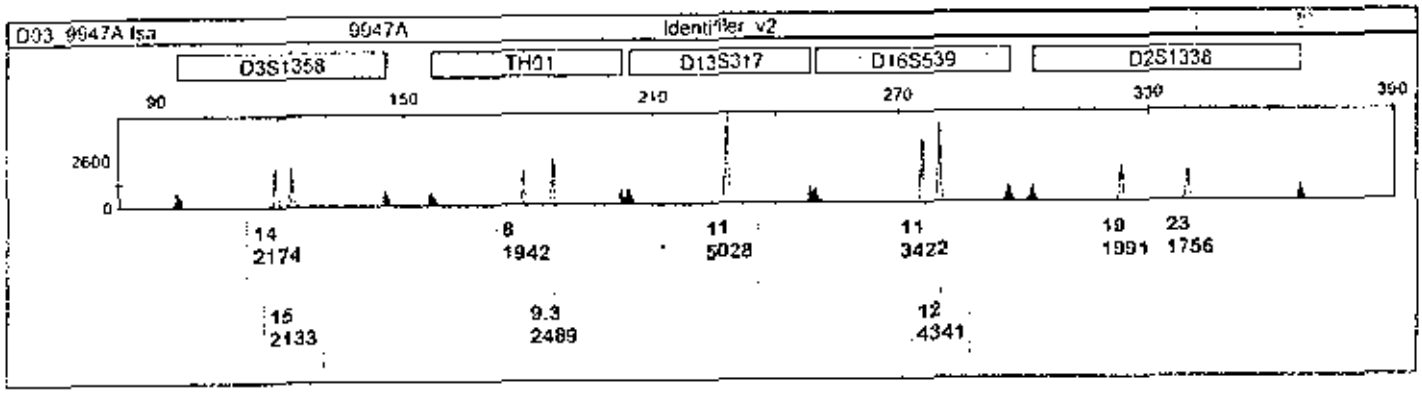
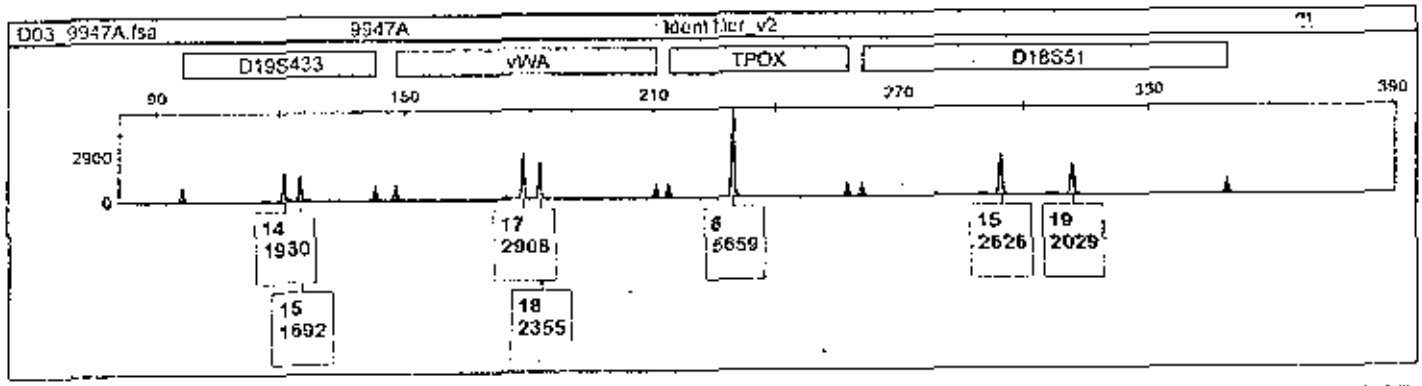


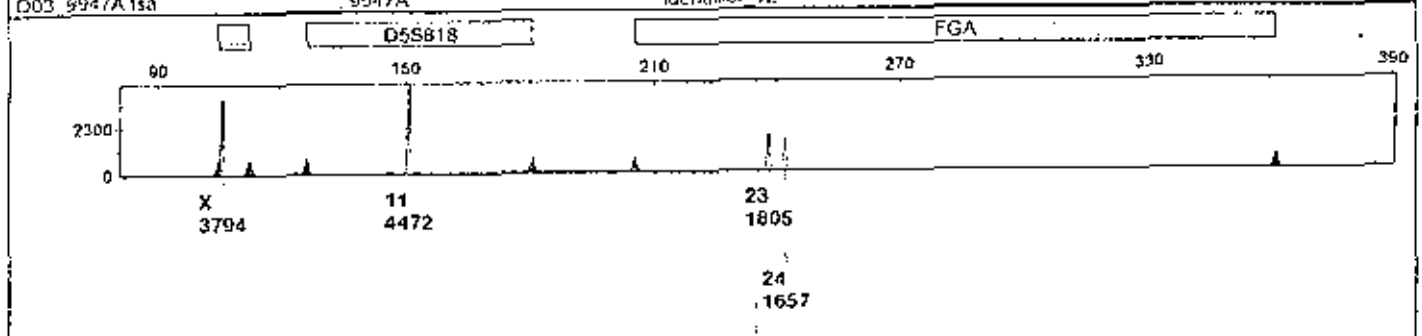
D03_9947A.fsa 9947A Identifiler_v2



D03_9947A.fsa 9947A Identifiler_v2



D03_9947A.fsa 9947A Identifiler_v2



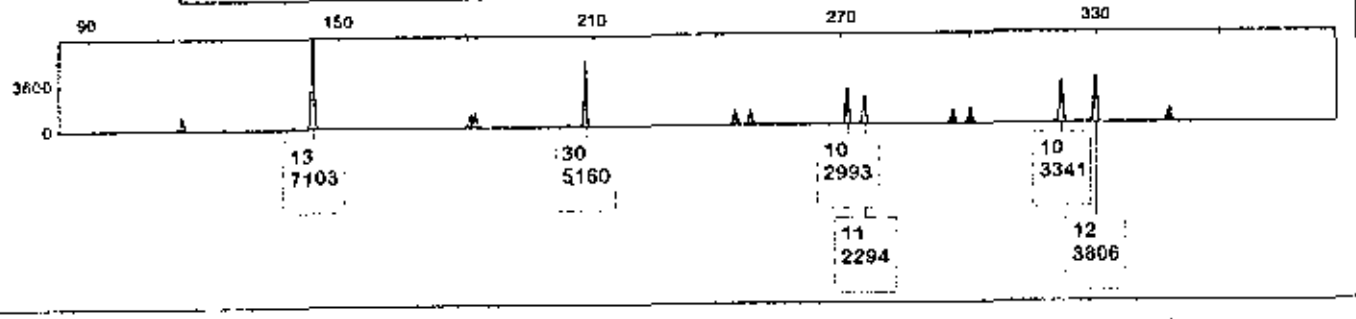
Applied Biosystems

GeneMapper ID v3.2.1

ROBOT-NIST-2009

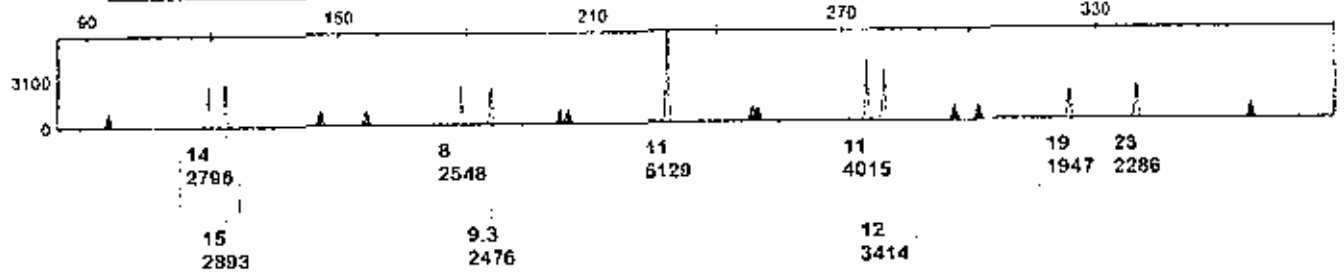
Sample File	Sample Name	Panel	SQO	SQ
E03_9947A.fsa	9947A	Identifiler_v2		

D8S1179 | D21S11 | D7S820 | CSF1PO



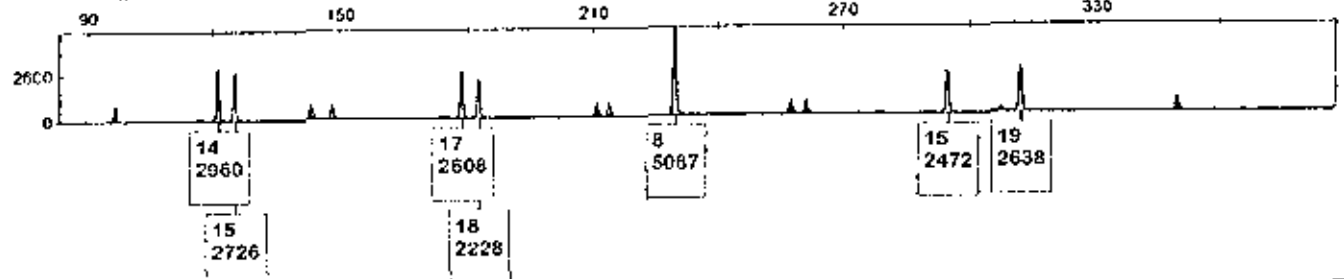
Sample File	Sample Name	Panel
E03_9947A.fsa	9947A	Identifiler_v2

D3S1358 | TH01 | D13S317 | D16S539 | D2S1338



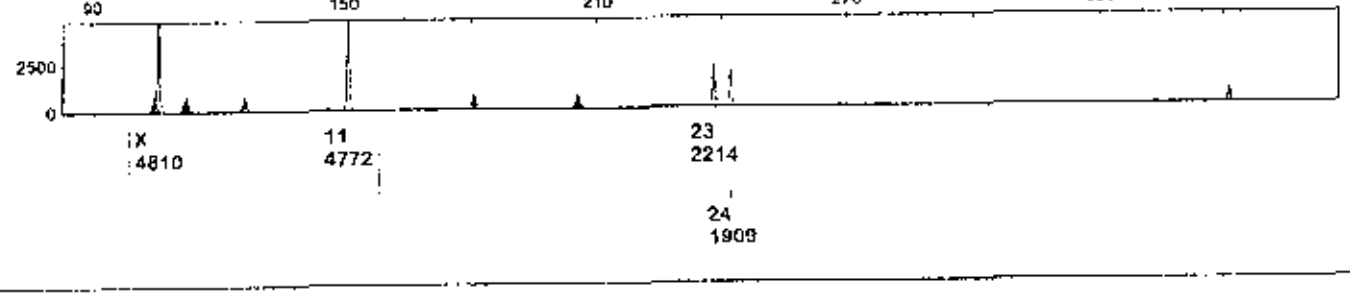
Sample File	Sample Name	Panel
E03_9947A.fsa	9947A	Identifiler_v2

D19S433 | vWA | TPOX | D18S51



Sample File	Sample Name	Panel
E03_9947A.fsa	9947A	Identifiler_v2

... | D5S818 | FGA

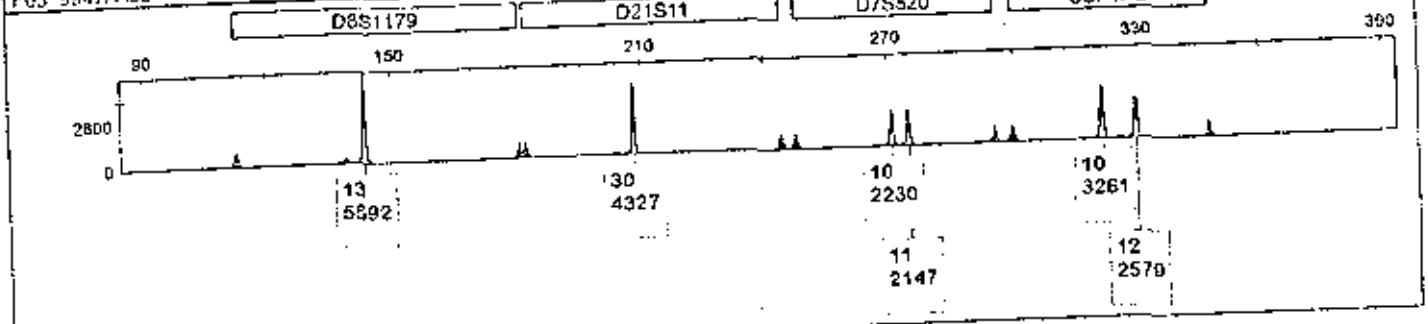


Applied Biosystems

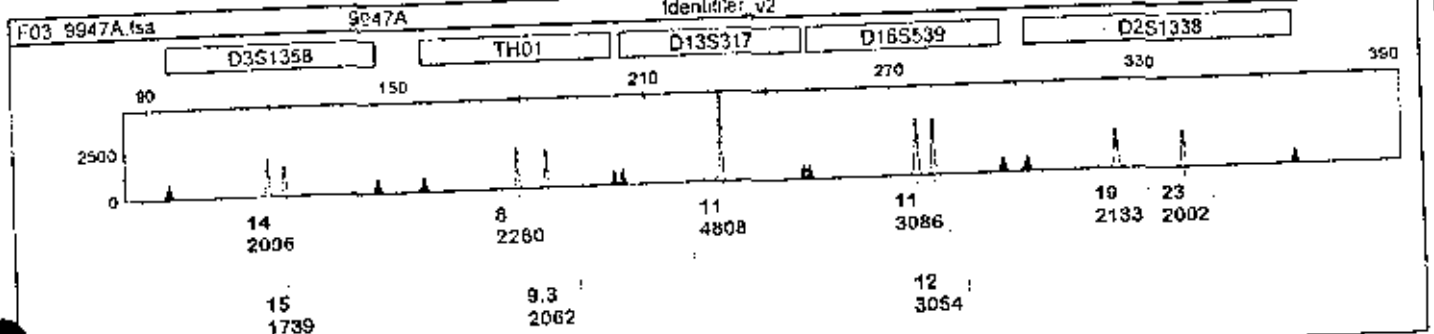
GeneMapper ID v3.2.1

ROBOT-NIST-2009

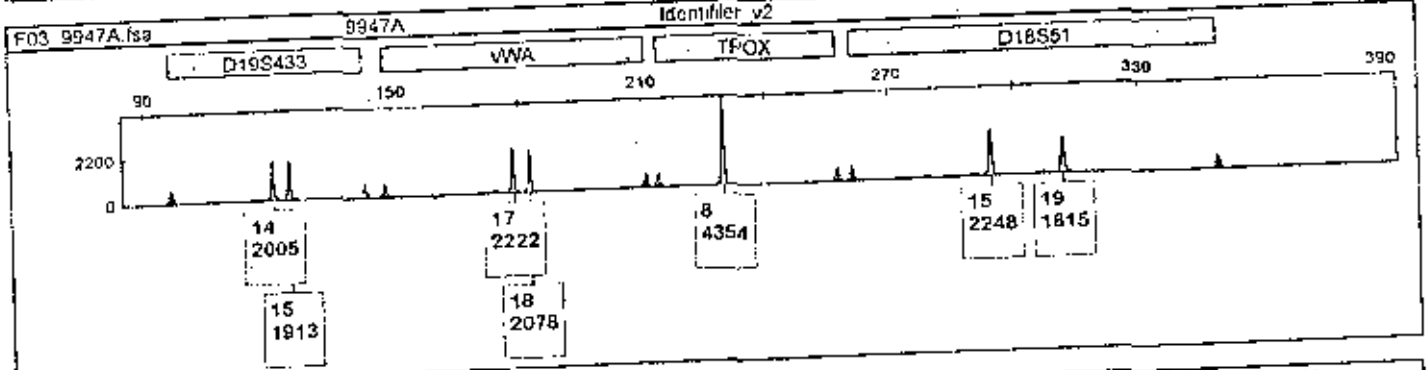
Sample File	Sample Name	Panel	SQO	SQ
F03_9947A.fsa	9947A	Identifiler_v2		



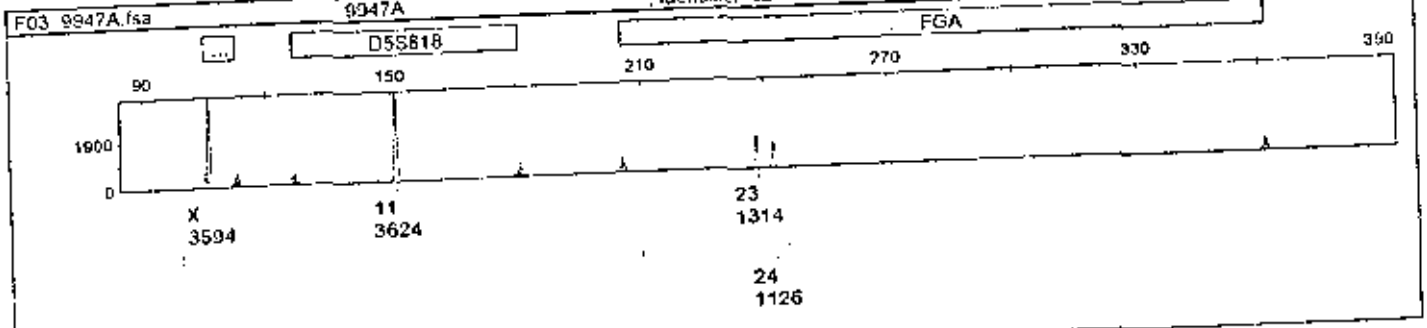
F03_9947A.fsa | 9947A | Identifiler_v2



F03_9947A.fsa | 9947A | Identifiler_v2



F03_9947A.fsa | 9947A | Identifiler_v2



Printed by: jrmatthews

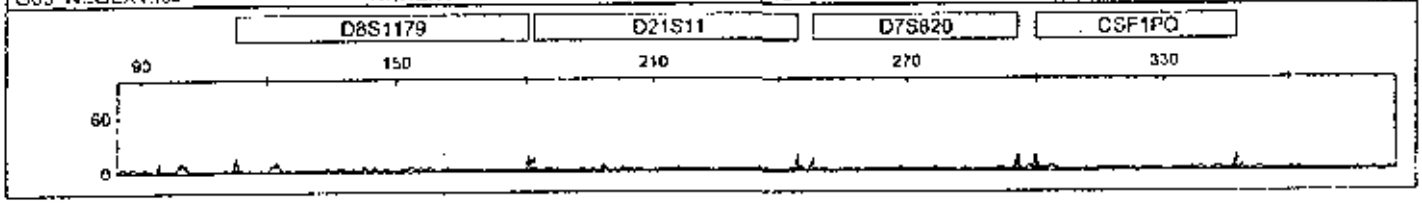
Wed Jan 28,2009 03:17PM, EST

Applied Biosystems

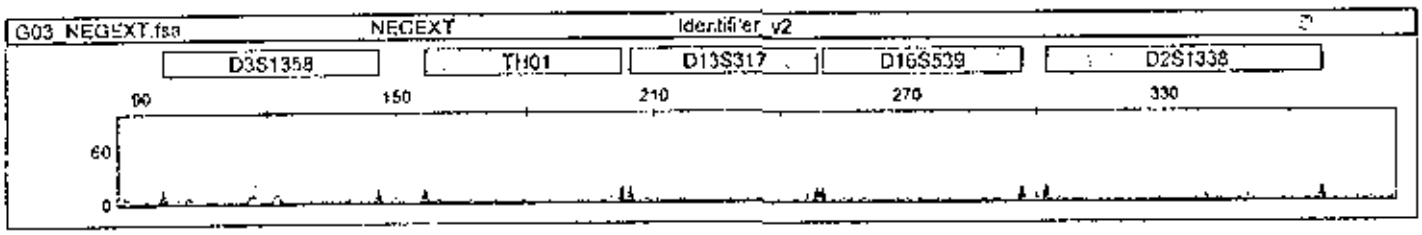
GeneMapper ID v3.2.1

ROBOT-NIST-2009

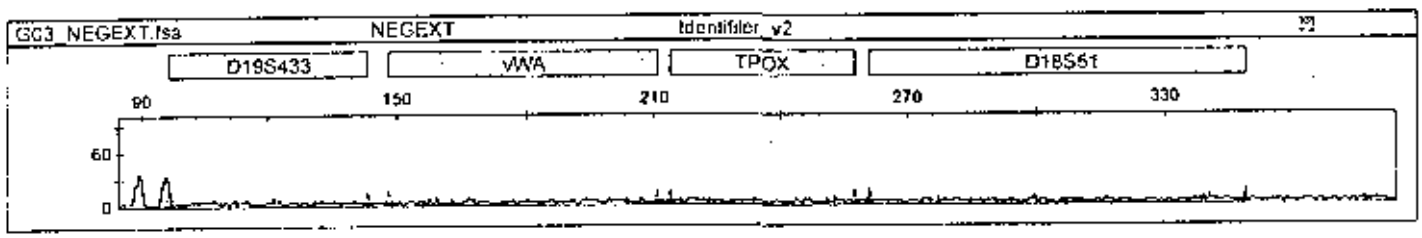
Sample File	Sample Name	Panel	SQO	SQ
G03_NEGEXT.fsa	NEGEXT	Identifiler_v2		



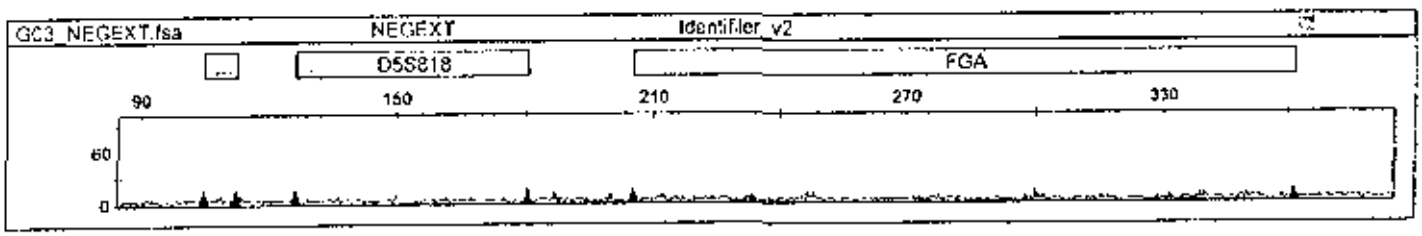
G03_NEGEXT.fsa NEGEXT Identifiler_v2



G03_NEGEXT.fsa NEGEXT Identifiler_v2



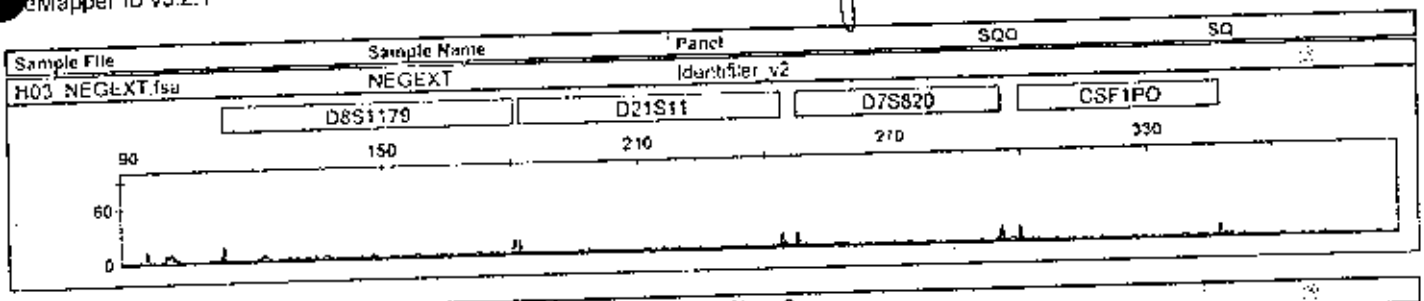
G03_NEGEXT.fsa NEGEXT Identifiler_v2



Applied Biosystems
GeneMapper ID v3.2.1

ROBOT-NIST-2009

Sample File	Sample Name	Panel	SQO	SQ
H03_NEGEXT.fsa	NEGEXT	Identifiler_v2		



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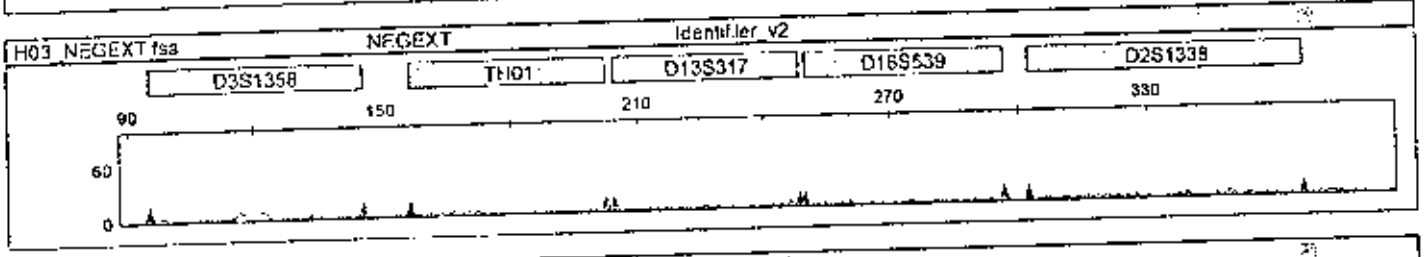
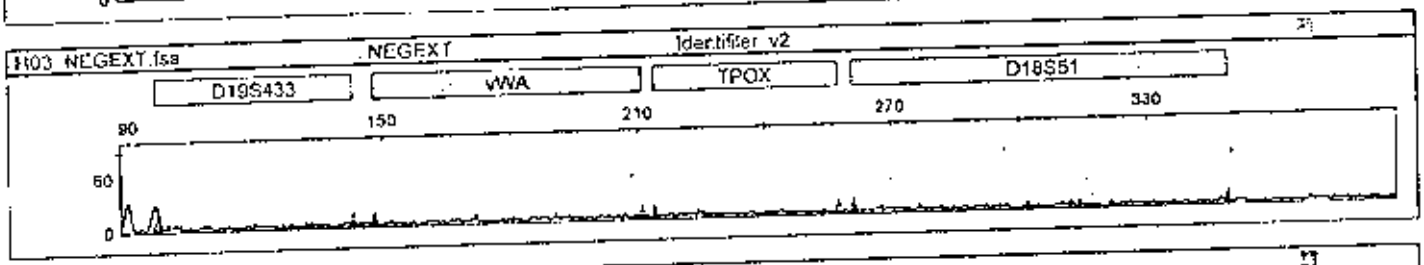
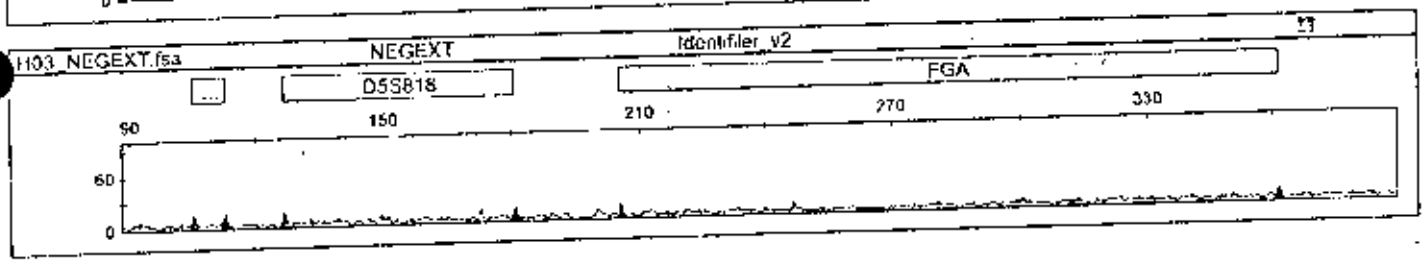


H03_NEGEXT.fsa NEGEXT Identifiler_v2



H03_NEGEXT.fsa NEGEXT Identifiler_v2



Applied Biosystems

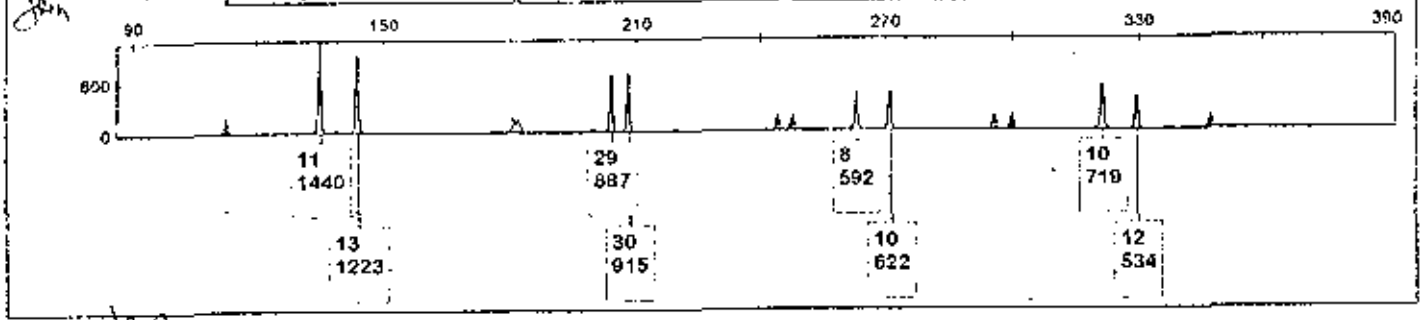
GeneMapper ID v3.2.1

ROBOT-NIST-2009

Sample File	Sample Name	Panel	SQO	SQ
D04_MJB02304-1.fsa	MJB02304-1	identifiler_v2		

MJB0623041

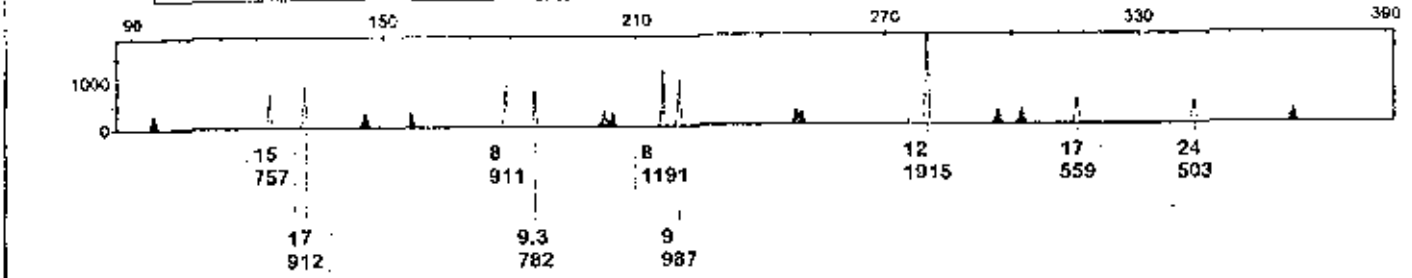
D8S1179 | D21S11 | D7S820 | CSF1PO



D04_MJB02304-1.fsa | MJB02304-1 | identifiler_v2

MJB0623041

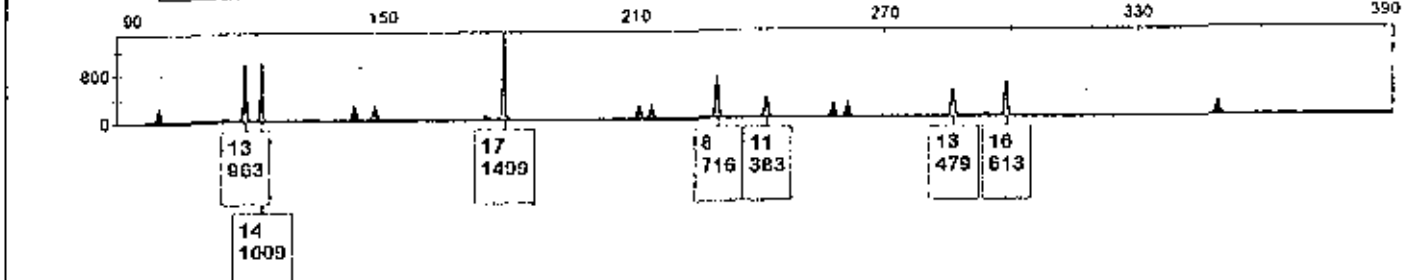
D3S1358 | TH01 | D13S317 | D16S539 | D2S1338



D04_MJB02304-1.fsa | MJB02304-1 | identifiler_v2

MJB0623041

D19S433 | vWA | TPOX | D18S51



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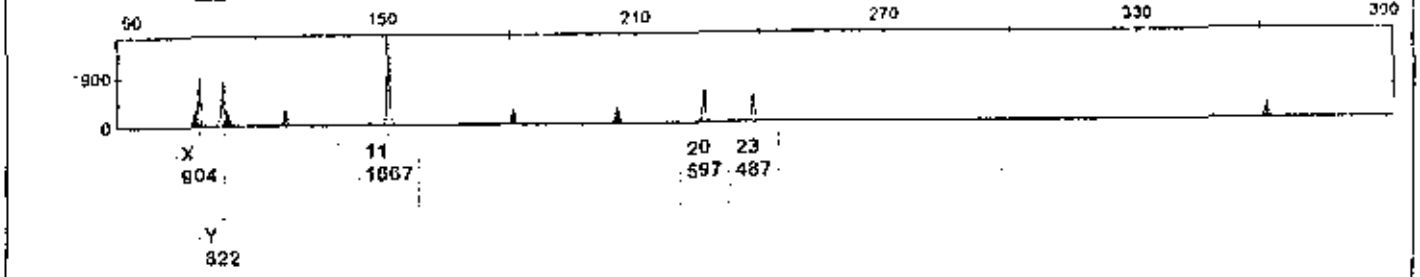
MJB0623041

D5S818 | FGA



Applied Biosystems

GeneMapper ID v3.2.1

ROBOT-NIST-2009

Sample File	Sample Name	Panel	SQO	SO
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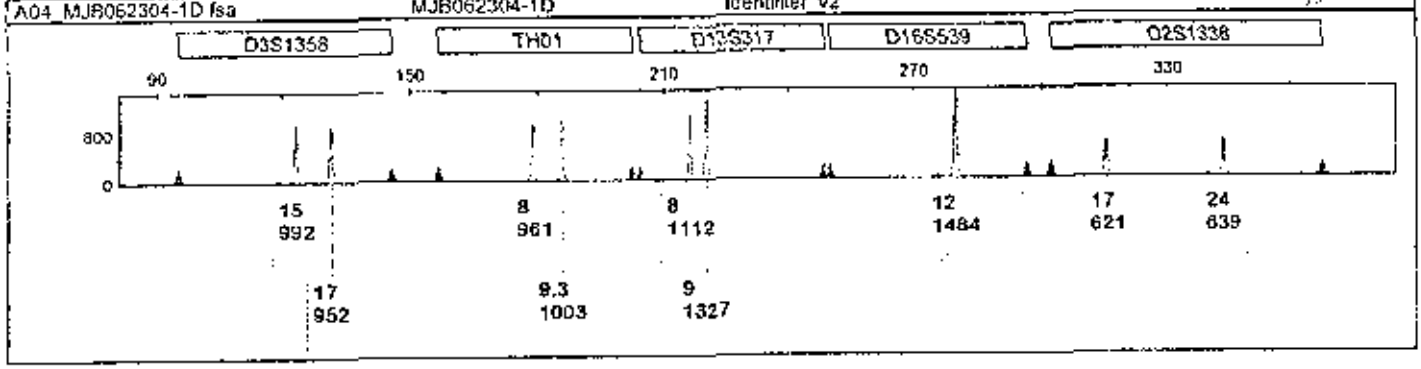
A04_MJB062304-1D.fsa MJB062304-1D Identifiler_v2



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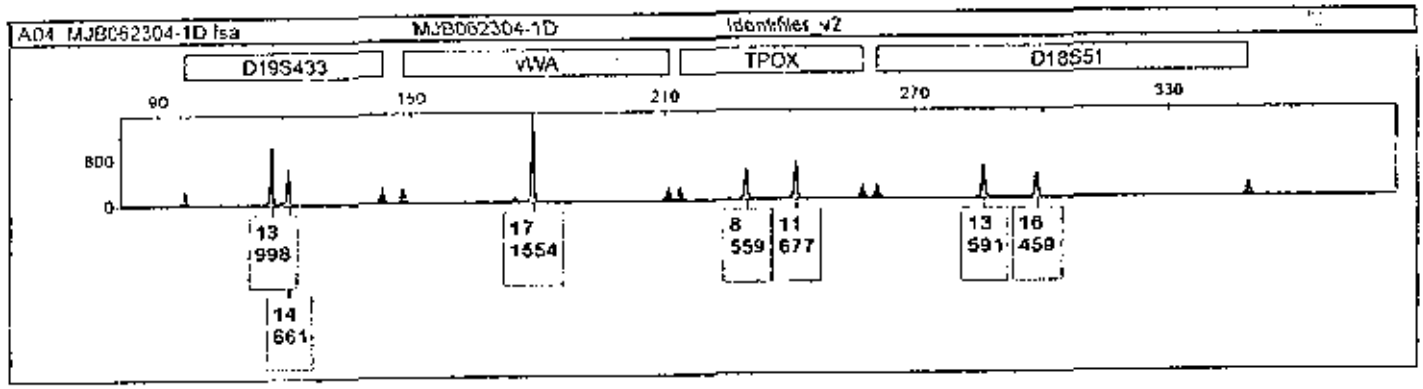

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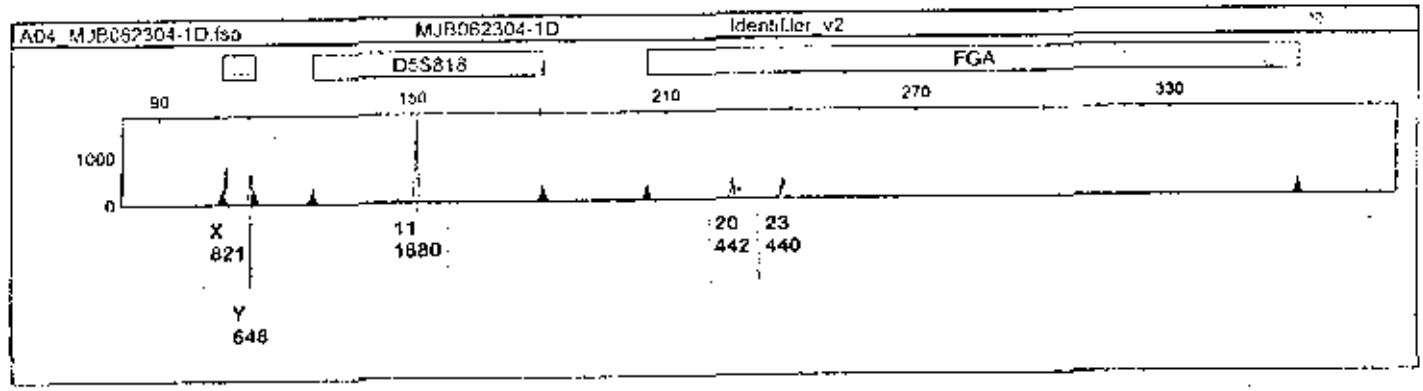


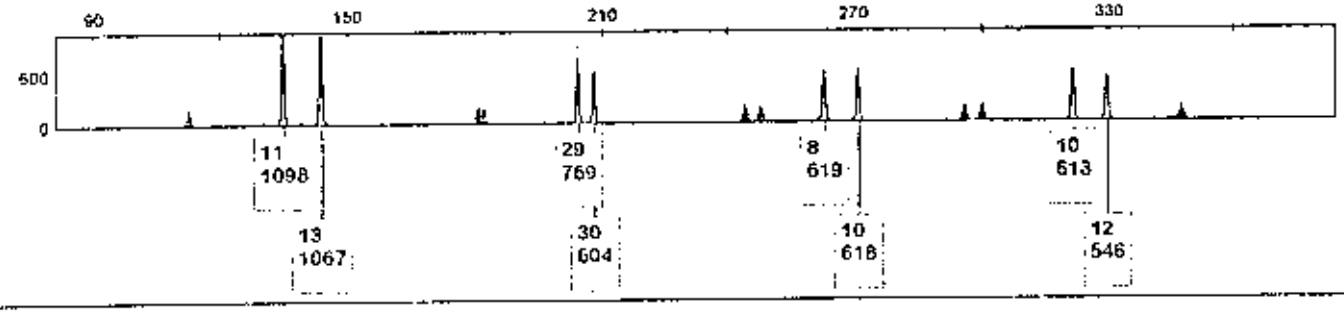
Applied Biosystems

GeneMapper ID v3.2.1

ROBOT-NIST-2009

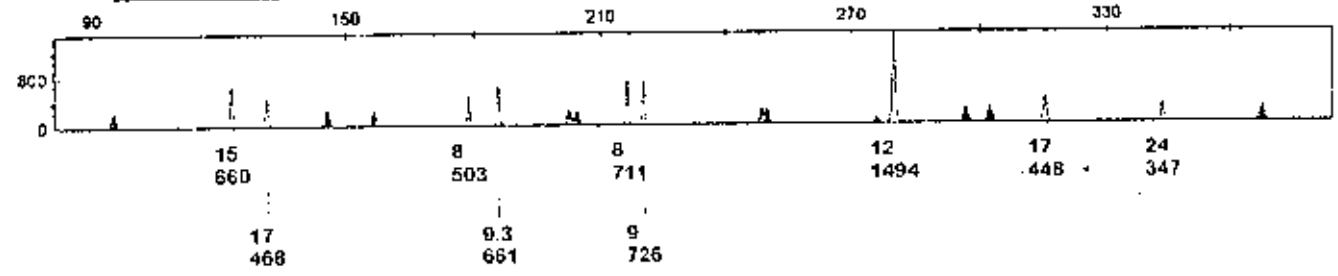
Sample File	Sample Name	Panel	SQO	SD
E04_MJB062304-2.fsa	MJB062304-2	Identifiler_v2		

D8S1179 | D21S11 | D7S820 | CSF1PO



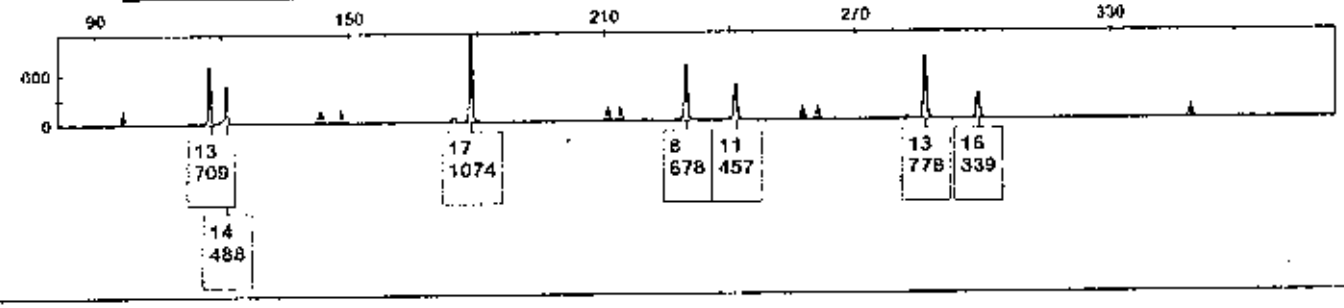
E04_MJB062304-2.fsa	MJB062304-2	Identifiler_v2

D3S1358 | TH01 | D13S317 | D16S539 | D2S1338



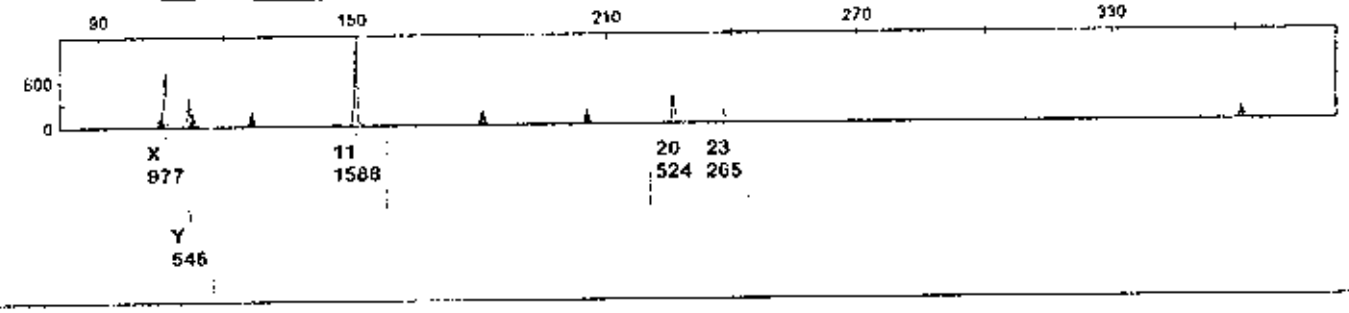
E04_MJB062304-2.fsa	MJB062304-2	Identifiler_v2

D19S433 | vWA | TPOX | D18S51



E04_MJB062304-2.fsa	MJB062304-2	Identifiler_v2

... | D5S818 | FGA



Applied Biosystems

GeneMapper ID v3.2.1

ROBOT-NIST-2009

Sample File	Sample Name	Panel	SQ	SQ
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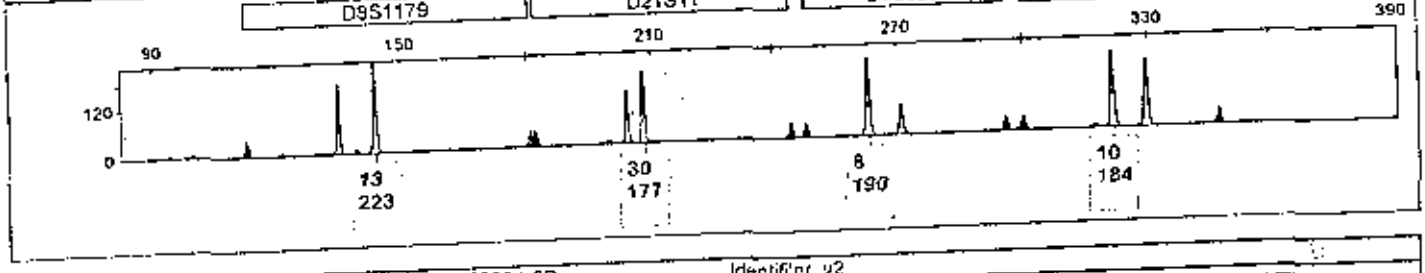

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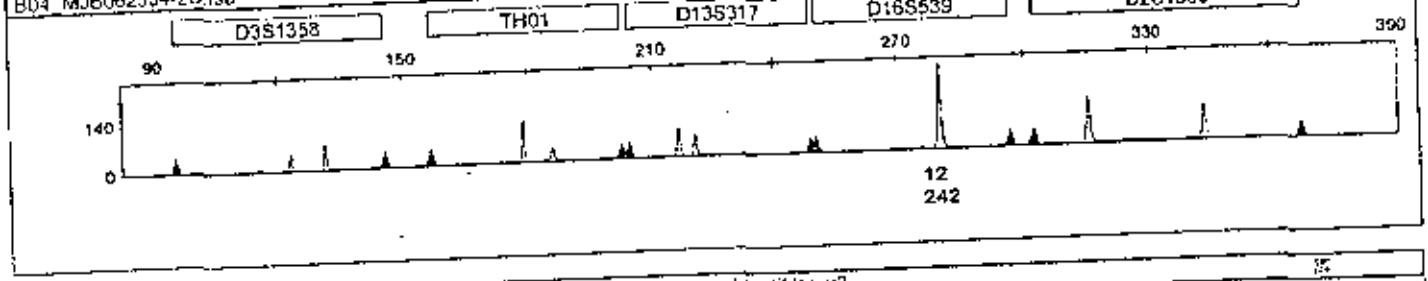

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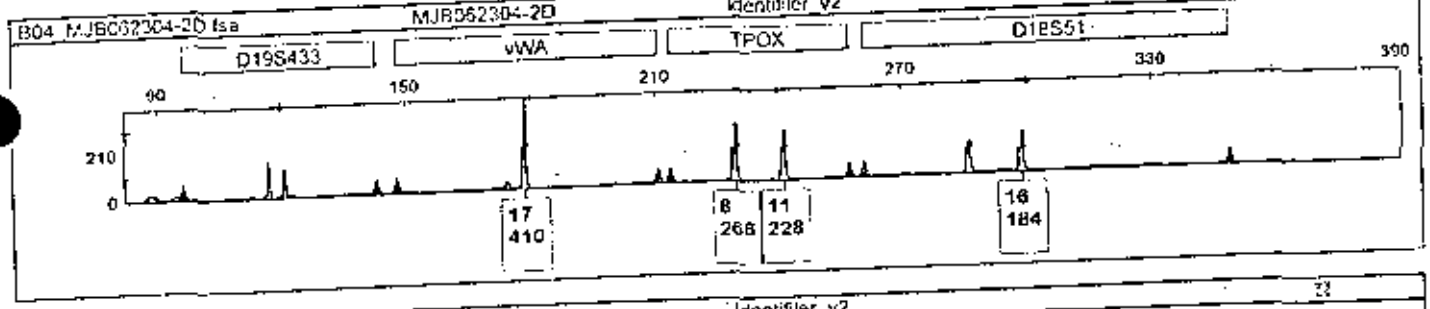

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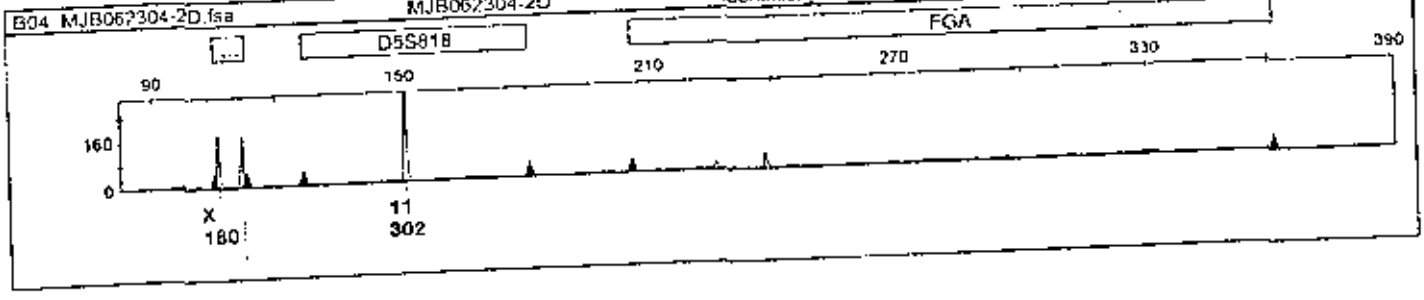


Diluted sample - allelic dropout seen.
See previous page for un-diluted
sample e-gram

JM

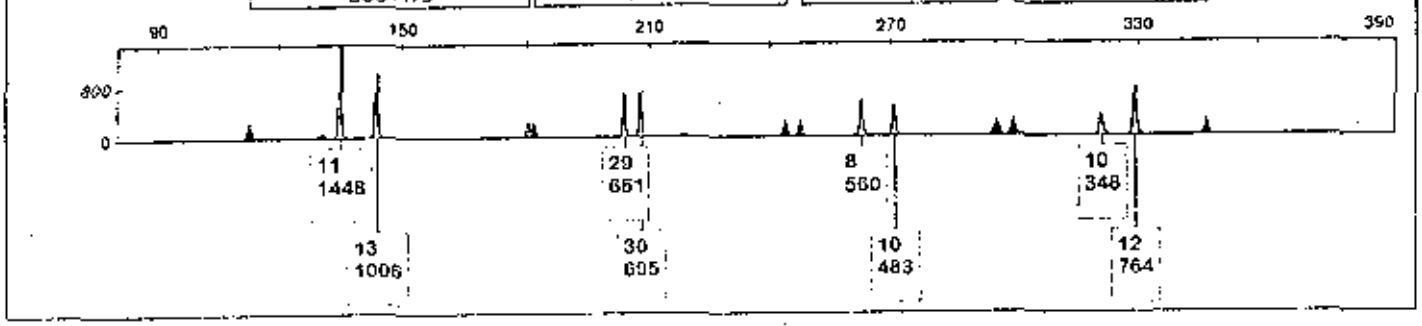
Printed by: jrmatthews

Wed Jan 28,2009 03:21PM, EST

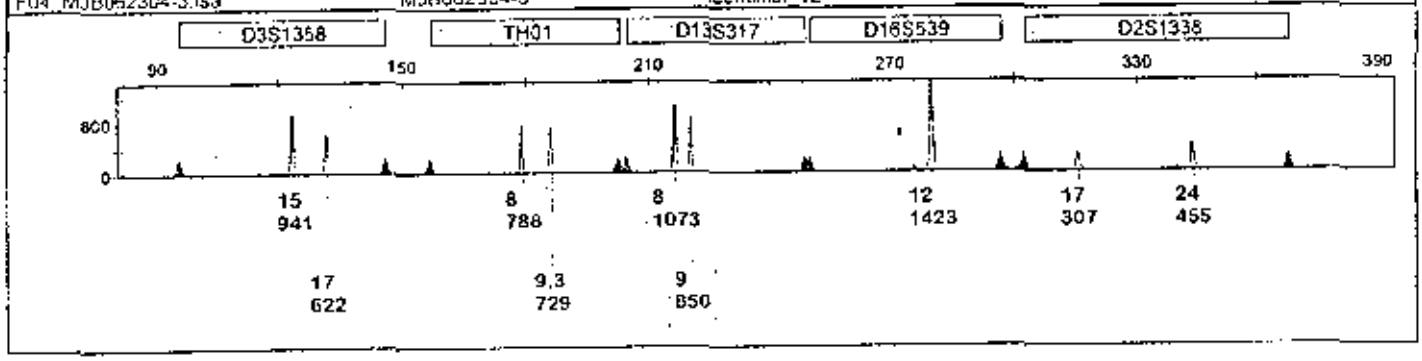
Applied Biosystems
GeneMapper ID v3.2.1

ROBOT-NIST-2009

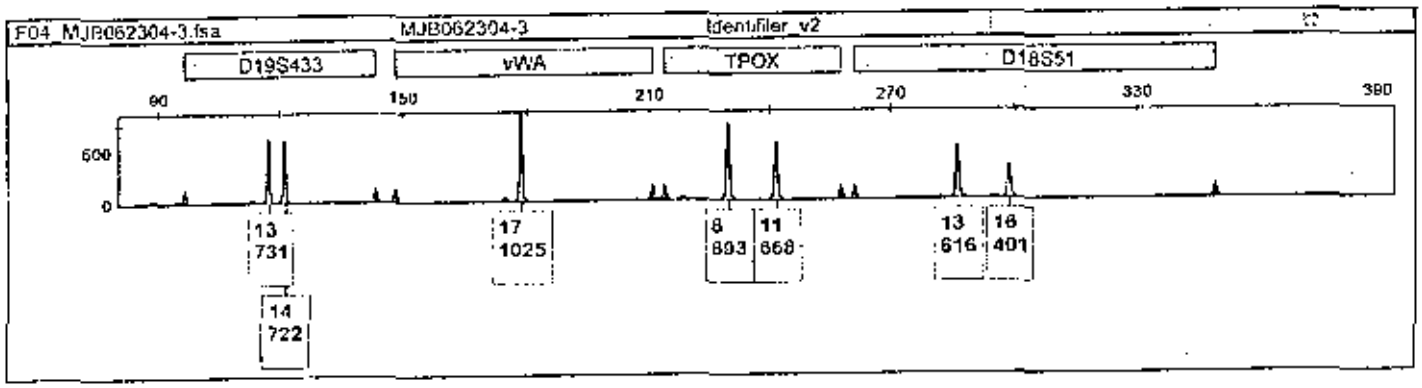
Sample File	Sample Name	Panel	SQ0	50
F04_MJB062304-3.fsa	MJB062304-3	Identifiler_v2		



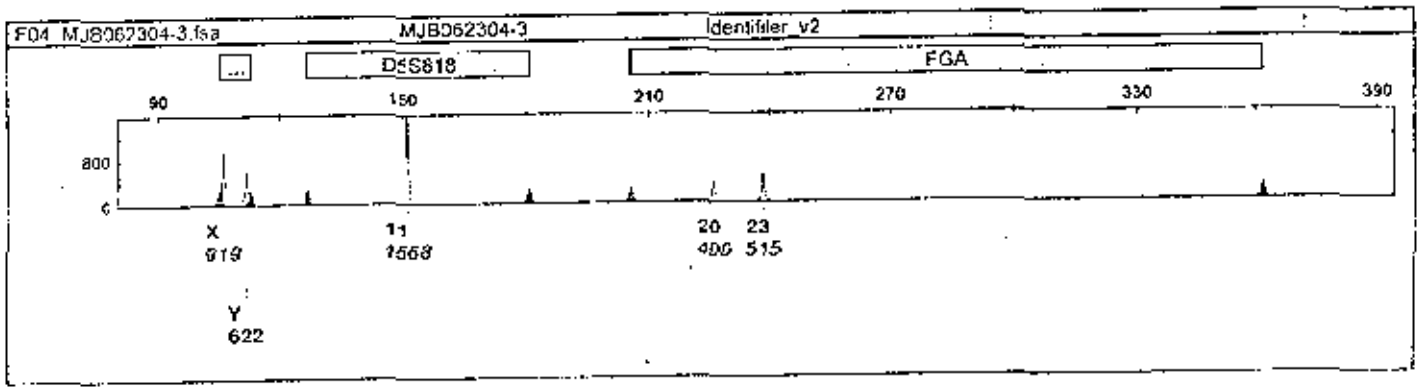
F04_MJB062304-3.fsa MJB062304-3 Identifiler_v2



F04_MJB062304-3.fsa MJB062304-3 Identifiler_v2



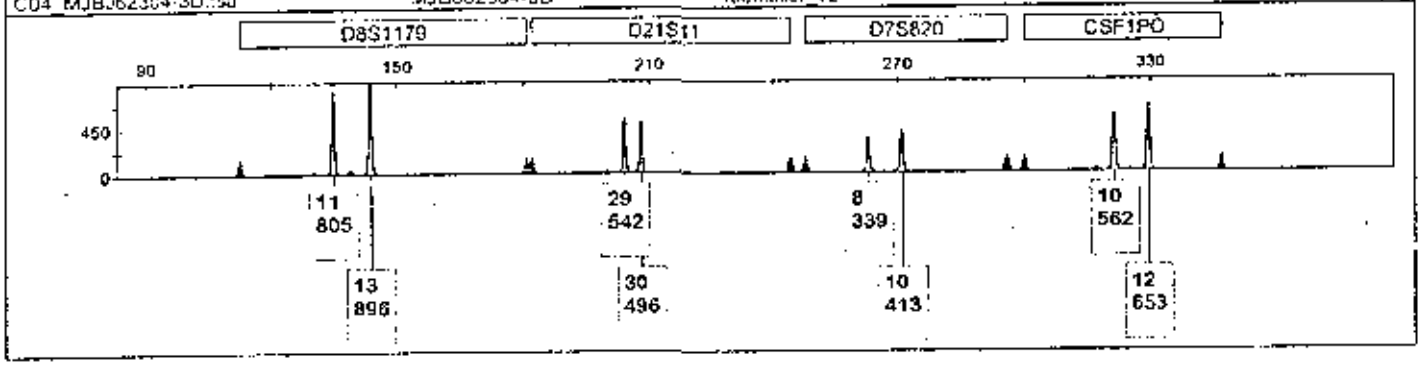
F04_MJB062304-3.fsa MJB062304-3 Identifiler_v2



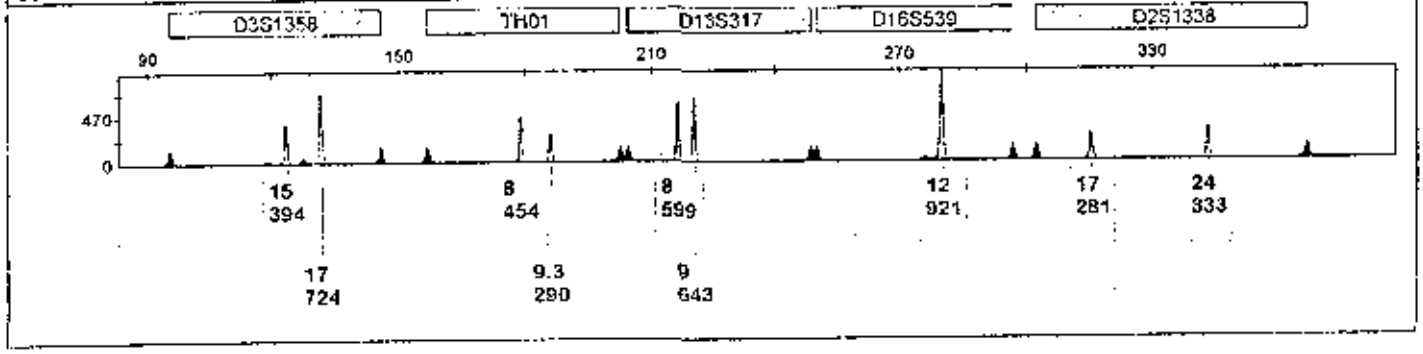
Applied Biosystems
GeneMapper ID v3.2.1

ROBOT-NIST-2009

Sample File	Sample Name	Panel	SQO	SO
C04_MJB062304-3D.fsa	MJB062304-3D	Identifiler_v2		



C04_MJB062304-3D.fsa MJB062304-3D Identifiler_v2



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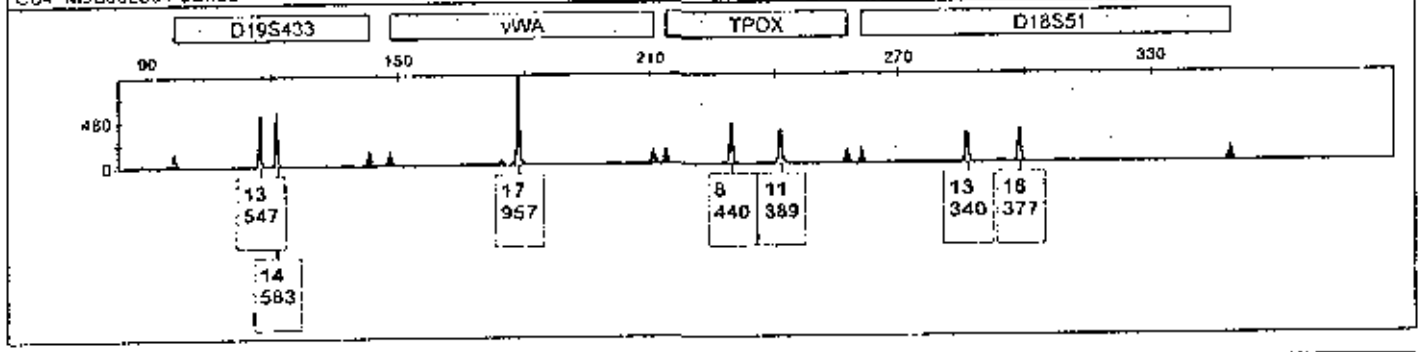

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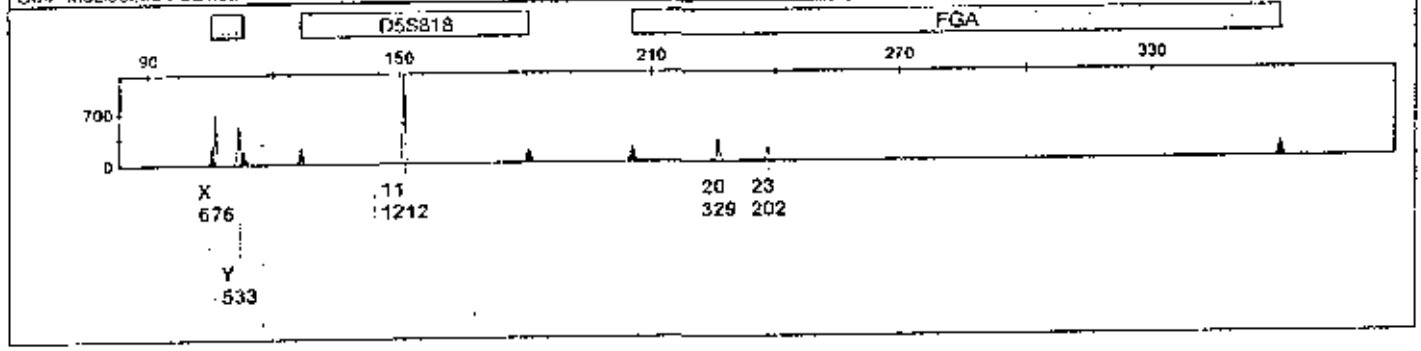

NCSBI
Laurel

ROBOT NIST-2009

JRM
01-28-2009
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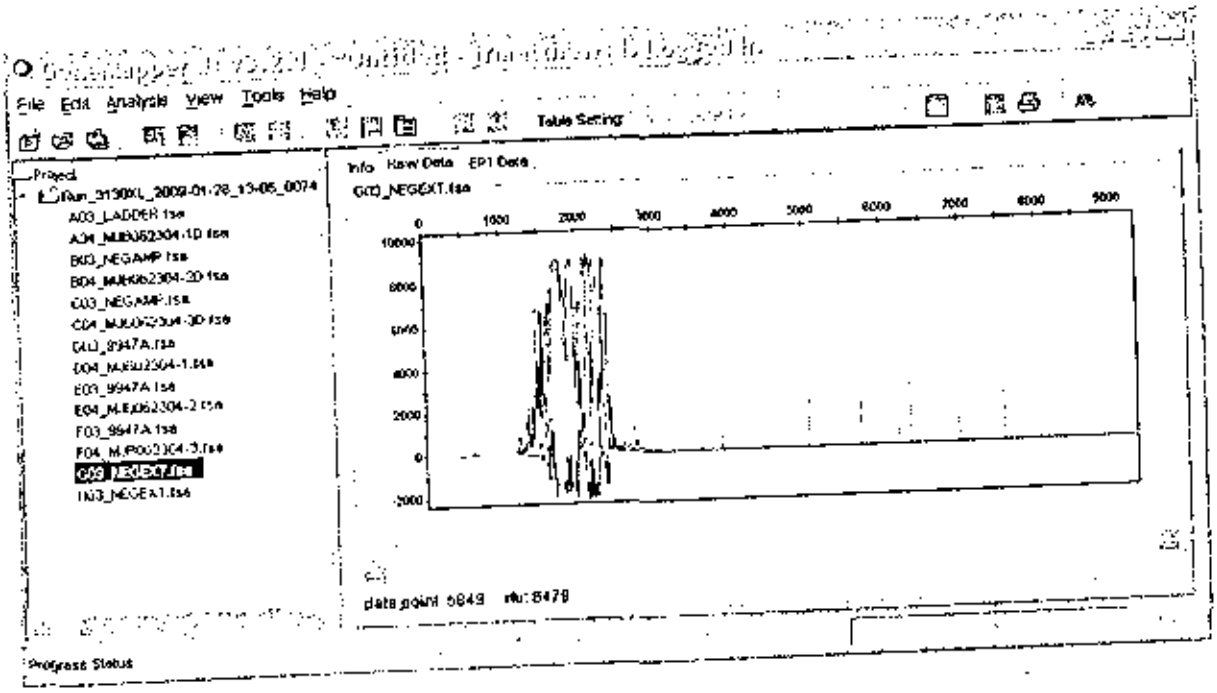
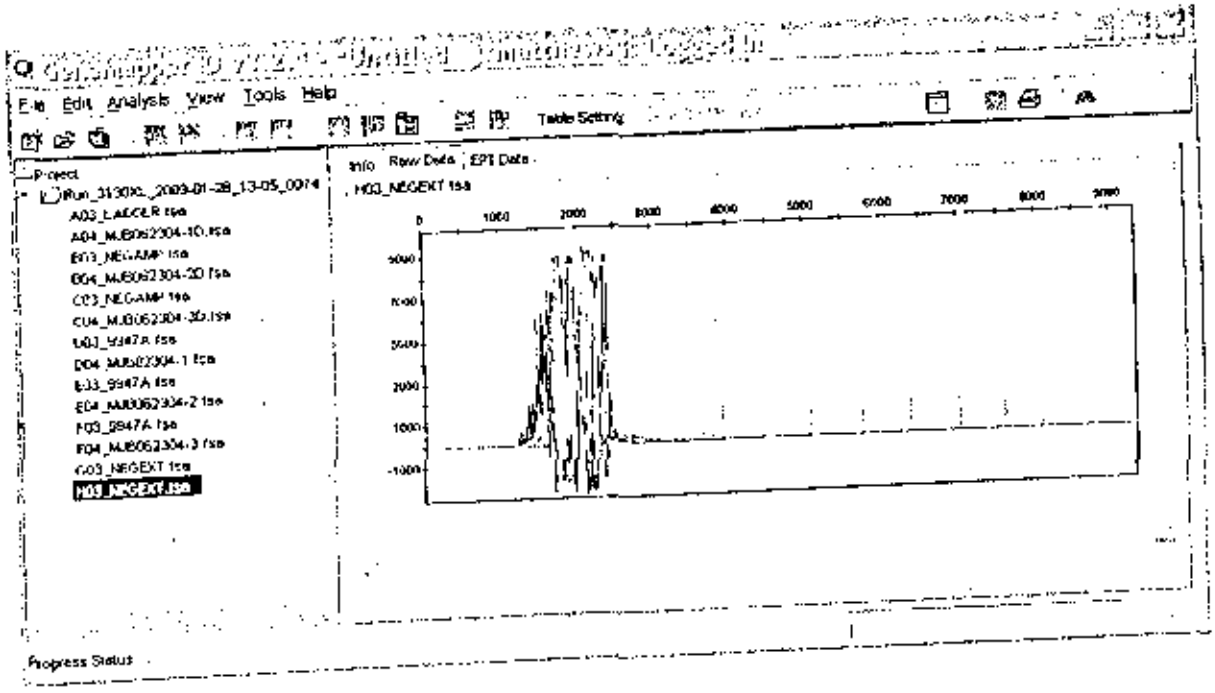
Neg Exts





NCSBI
Laurel

ROBOT NIST-2009

JRM
01-28-2009
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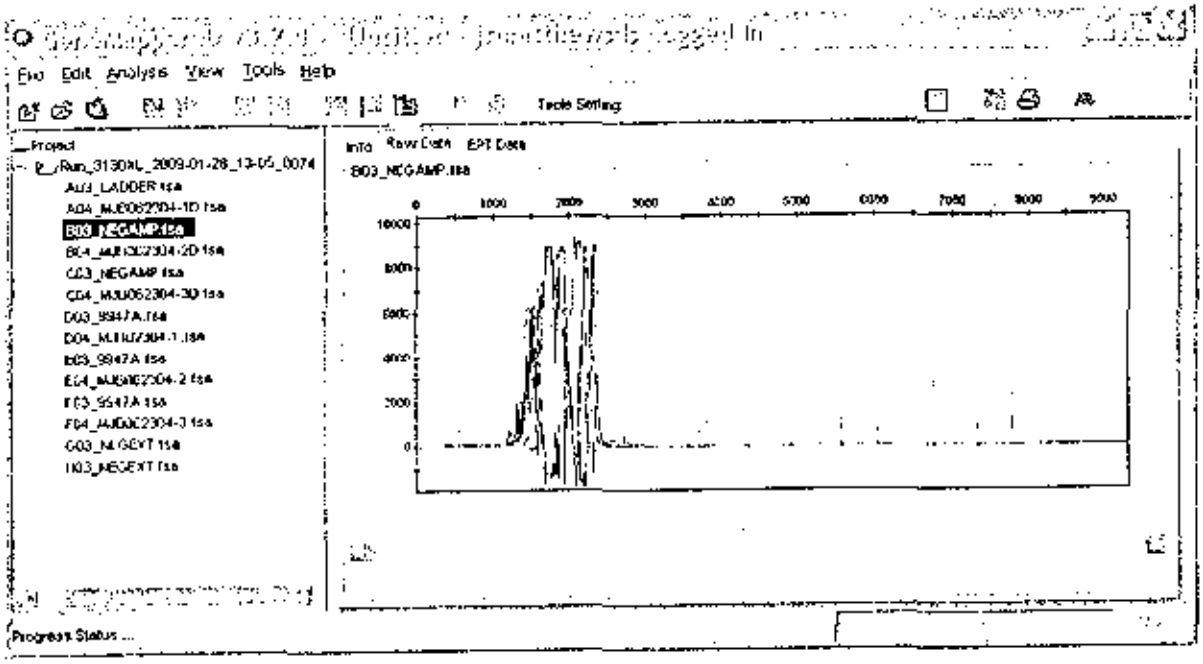
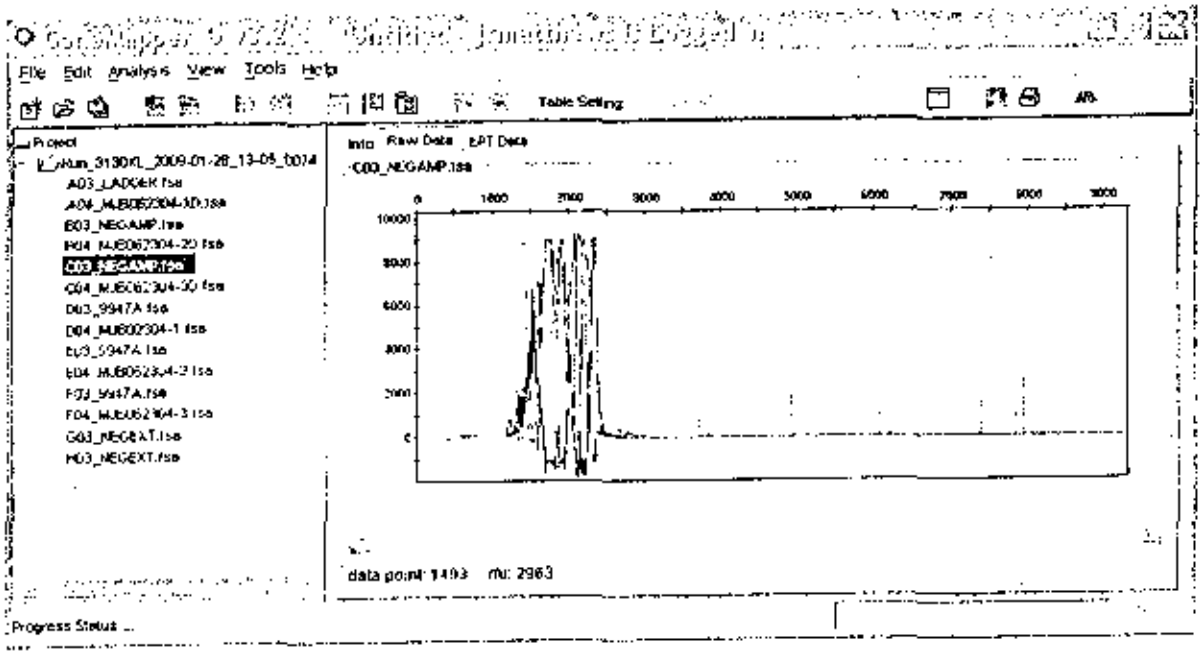
Neg Amps





NCSBI
Abbott

ROBOT-NIST-2009 JRM

JRM
01-28-2009

Sample	D8S1179	D21S11	D7S820	CSF1PO	D3S1358	TH01	D13S317	D16D539	D2S1338	D19S433	vWA	TPOX	D18S51	Amel	D5S818	FGA
9947A	13	30	10,11	10,12	14,15	8,9.3	11	11,12	19,23	14,15	17,18	8	15,19	X	11	23,24
9947A	13	30	10,11	10,12	14,15	8 9.3	11	11,12	19,23	14,15	17,18	8	15,19	X	11	23,24
9947A	13	30	10,11	10,12	14,15	8,9 3	11	11,12	19,23	14,15	17,18	8	15,19	X	11	23,24
MJB062304-1	11,13	29,30	8,10	10,12	15,17	8,9 3	8,9	12	17,24	13,14	17	8,11	13,16	X,Y	11	20,23
MJB062304-1D	11,13	29,30	8,10	10,12	15,17	8,9 3	8,9	12	17,24	13,14	17	8,11	13,16	X Y	11	20,23
MJB062304-2	11,13	29,30	8,10	10,12	15,17	8,9 3	8,9	12	17,24	13,14	17	8,11	13,16	X,Y	11	20,23
MJB062304-2D	13	30	8	10				12			17	8,11	16	X	11	
MJB062304-3	11,13	29,30	8,10	10,12	15,17	8,9.3	8,9	12	17,24	13,14	17	8,11	13,16	X,Y	11	20,23
MJB062304-3D	11,13	29,30	8,10	10,12	15,17	8,9.3	8,9	12	17,24	13,14	17	8,11	13,16	X,Y	11	20,23

allele calls verified by JRM 2/2/09

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Samples with D suffix were diluted per robot amp protocol; samples without D were run un-diluted.

mixture profile, each locus must be considered independent of the DNA Standards from suspects and victims.

4.4.2.2.3 Determine if the standard(s) can be excluded. If alleles are not present at one or more locus, then there must be a reason for NOT excluding a standard (e.g. allelic dropout and/or inhibition).

4.4.2.2.4 If the standard(s) cannot be excluded, perform the CPE calculation using the NCSBI CPE Mixture Program.

4.4.2.3 All alleles detected at a particular locus must be included in the CPE calculation unless there is a compelling reason to exclude the alleles.

4.4.2.4 Intimate sample alleles may not be subtracted from a CPE calculation.

4.4.2.5 Frequencies for the Amelogenin locus will not be computed.

4.4.2.6 If the DNA profiles from two (or more) individuals cannot be excluded from the profile and the DNA from the individuals is not present at all genetic markers, multiple CPE/CPI calculations may be performed. When performing statistics to determine the probability of an individual being included in a mixture, only the genetic markers where that individual CANNOT be excluded shall be used in the CPE calculations.

4.4.2.7 CPE on minor components: If a DNA profile from an evidentiary sample is a mixture of contributors whose genotypes can be separated based on allele intensities and a major profile discerned, the report must state that a major profile is evident. In this case, a statistic for the major DNA profile may be calculated using Random Match Probabilities. When a Major

profile will be evaluated to determine whether an individual (e.g. suspect or victim) is included or excluded as a possible contributor to the mixture. Only if the individual cannot be excluded will a CPE calculation be performed. The possibility of allelic dropout must be considered in determining whether an individual may be excluded or included in the mixed profile.

4.4.2.2 Basic Steps

4.4.2.2.1 Examine the electropherogram of the mixture. Note any inhibition, allelic dropout, and/or artifacts on the electropherogram.

4.4.2.2.2 Compare the DNA profile obtained from the standards with the mixture. When determining the contributors to a DNA mixture profile, each locus must be considered independent of the DNA Standards from suspects and victims.

4.4.2.2.3 Determine if the standard(s) can be excluded.

4.4.2.2.4 If the standard(s) cannot be excluded, perform the CPE calculation using the NCSBI CPE Mixture Program.

4.4.2.3 All alleles detected at a particular locus must be included in the CPE calculation unless there is a compelling reason to exclude the alleles.

4.4.2.4 Intimate sample alleles may not be subtracted from a CPE calculation.

4.4.2.5 Frequencies for the Amelogenin locus will not be computed.

4.4.2.6 If the DNA profiles from two (or more) individuals

Overman, Amanda

From: Dahl, Jodi M. [Jodi.Dahl@ic.fbi.gov]
Sent: Monday, August 10, 2009 3:27 PM
To: Fox, Amanda
Subject: RE: Audit Follow-up

We do not usually send a formal letter indicating the outcome of the review panel. It is usually done by email correspondence with the laboratory. I work with the laboratories to get all audit issues resolved before sending the final audit packet to the NDIS Custodian for a closing review. Any replies can be sent to my attention.

Jodi

-----Original Message-----
From: Fox, Amanda [mailto:Afox@ncdoj.gov]
Sent: Monday, August 10, 2009 3:22 PM
To: Dahl, Jodi M.
Subject: RE: Audit Follow-up

I will forward this email to our Special Agent in Charge and our Tech Leader. Will there be something in writing that they need to formally reply to?

Amanda L. Fox
Special Agent -- Forensic Biologist
North Carolina State Bureau of Investigation
[redacted]21 East Tryon Road
Raleigh, NC 27626
(919) 662-4509 ext 2643
Afox@ncdoj.gov

-----Original Message-----
From: Dahl, Jodi M. [mailto:Jodi.Dahl@ic.fbi.gov]
Sent: Monday, August 10, 2009 3:21 PM
To: Fox, Amanda
Subject: FW: Audit Follow-up

Amanda - The audit has come back from the review panel. There is one issue that needs to be resolved before we can close the audit. It is in regards to 5.1/5.2.3.2(b-1) and 14.1. The panel felt the remediation for these did not address the finding. The addition of the "and/or"
still allows analysts to bypass the technical leader and only go to the supervisor.
Suggestions from the panel included making the statement just "and".

Please let me know if you have any questions.

Jodi Dahl
CODIS Auditor / Chair, NDIS Audit Review Panel FBI - Laboratory Division
2501 Investigation Parkway
Quantico, VA 22135
[redacted]703-632-8425 (voice)
703-632-8305 (fax)

-----Original Message-----

From: Hares, Douglas R.
Sent: Monday, August 10, 2009 1:17 PM
To: Dahl, Jodi M.
Subject: Fw: Audit Follow-up

Jodi - can you check status and get back to Amanda. Thanks.

Doug

Sent via BlackBerry

Douglas Hares
NDIS Custodian
FBI Laboratory
CODIS Unit
2501 Investigation Parkway
Quantico, VA 22135
703.632.7576
Fax 703.632.8305

From: Fox, Amanda <Afox@ncdoj.gov>
To: Hares, Douglas R.
Cc: Budzynski, Mike <Mbudzynski@ncdoj.gov>
Sent: Mon Aug 10 13:10:42 2009
Subject: Audit Follow-up

Hi Doug,

I enjoyed your scenarios at the software training class. Some were oldies but goodies. I'm glad nobody took it too far off the wall - I think we were tired by that point J

Mike has asked me to follow up with you on our January 2009 Audit. Our audit number is 2009036. We just wanted to see if the review had been completed and if there were any additional actions required on our part.

Thanks,

Amanda

Amanda L. Fox

Special Agent -- Forensic Biologist

North Carolina State Bureau of Investigation

121 East Tryon Road

Raleigh, NC 27626

(919) 662-4509 ext 2643

Afox@ncdoj.gov

NORTH CAROLINA
STATE BUREAU OF INVESTIGATION
DEPARTMENT OF JUSTICE

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ROY COOPER
ATTORNEY GENERAL

ROBIN P. PENDERGRAFT
DIRECTOR

Crime Laboratory Directive No. 07-01
Effective Date: October 15, 2009

TO: Laboratory SACs and Supervisors

FROM: Assistant Director Jerry Richardson JR

SUBJECT: Laboratory Quality System and Corrective Action (REVISED)

The following Crime Laboratory Directive No. 07-01 was initially issued, and then incorporated into the SBI Policy and Procedures as part of Procedure 39. This Directive is hereby being REVISED as follows:

The maintenance of the overall quality of scientific findings needs to be of the utmost importance in a Forensic Science laboratory. To this end, the position of Quality System Manager (Deputy Assistant Director) was established prior to the Laboratory's last accreditation. The position of Quality Control Manager (QCM) was created in March 2006 to assist the Quality System Manager. The scope of the responsibilities of both of these positions includes maintenance of quality manuals, administration of the proficiency testing program, monitoring of the court testimony program, etc.

Also included among the scope of these positions is the control of non-conforming work and corrective action procedures. As noted in the SBI Policy and Procedure Manual, "any problems or deficiencies identified through the quality control checks shall be brought to the attention of the Laboratory Quality Manager (DAD) and fully investigated by the Special Agent in Charge and Quality Manager." As the Crime Laboratory's quality system evolves toward the ISO system, Corrective Action Reports will be used to identify non-conformity, examine extent, and document the necessary corrective action. Prior to the ISO Program being implemented, **all SACs, Supervisors and staff are directed to adhere to the following Quality Guidelines:**

1. Definitions

A. Cause - A cause is a fundamental deficiency that results in a non-conformance and is to be corrected to prevent reoccurrence of the same, or similar, non-conformance.
B. Corrective action - This is an endeavor taken to eliminate the causes of a detected non-conformance, defect or other undesirable situation in order to prevent reoccurrence.

C. *Minor Discrepancies generally:*

- are foreseeable,
- have a clear-cut immediate cause,
- have a defined straightforward corrective action, which can be adequately documented by a simple entry on the examination documentation, or utilizing the Technical Review Form.
- can be corrected on the spot by the individual who discovers them, and
- have not and will not in any way compromise the quality of work if properly addressed.

D. Substantial discrepancies generally:

- are unexpected,
- require an inquiry to determine their root cause,
- require elaborate or intensive action with extensive documentation,
- must be addressed by *more than one individual, and*
- have compromised the quality of work.
- usually include missed identifications (failing to identify something present) and erroneous identifications (identifying something not present).

E. Non-conformance - This is non-fulfillment of a specified, or implied, requirement of the Quality Management System or of a quality work product.

2. Corrective Actions – Minor Discrepancies

A. Corrective actions of minor discrepancies are made by examiners and are considered normal operating procedures.
B. Staff may take on-the-spot or immediate corrective action to correct or repair non-conforming data, reporting or equipment, that are actions routinely made by analysts, technicians and supervisors

3. Corrective Actions - Substantial Discrepancies

A. The individual who identifies a potential substantial discrepancy shall inform their supervisor and Technical Leader in a timely manner. The supervisor and Technical Leader shall briefly but clearly document the discrepancy and method of identification in an e-mail to the Laboratory Director, Deputy Assistant Director, and Quality Manager within 2 business days of the identification of the discrepancy.
B. The Deputy Assistant Director will determine if the discrepancy is substantial, and if so, will assign a two-person inquiry team to evaluate the discrepancy. The team shall generally include the Section Supervisor and a designated Technical Leader. The QCM will oversee this process, will be notified of the team composition and will assign a corrective action *tracking designator.*
C. The inquiry team will confer with the QCM and the Deputy Assistant Director to develop an approach and establish deadlines for the inquiry. A tentative corrective action plan or interim status report will be developed by the team and QCM and provided to the Deputy Assistant Director within 30 days of the assignment. Prior to implementation of

any corrective action plan, the investigators will determine and document the following for review by the QCM and subsequent approval by the Deputy Assistant Director:

- The discrepancy itself.
- The specific event(s) which identified the discrepancy.
- The extent of the discrepancy.
- The effect(s) of the discrepancy on the quality of work.
- Any necessary short term response.
- The root cause of the discrepancy.
    i. Root cause identification is commonly perceived as determining assignment of blame. In many cases, an individual may be held responsible for causing a discrepancy, but that is a byproduct of the corrective action process.
    ii. Root cause determination could involve multiple immediate factors.
    iii. Examples of findings or root causes may include but are not limited to:
        - equipment failure;
        - incomplete or nonexistent procedures;
        - non-compliance with procedures and regulations;
        - improper collection, storage, handling, or preparation;
        - calculation errors or transcription errors; and
        - lack of training.
- A recommended course of action.
- A recommended course of follow-up activities.

D. If the inquiry and/or corrective action plan extends over a protracted time period, the team will generate regular progress reports to the Deputy Assistant Director and QCM, particularly on completion of milestones.

E. On completion of the follow-up assessments, the investigators will review the follow-up documentation, confer with the QCM and Deputy Assistant Director, and make a recommendation in a written summary report to the Laboratory Director as to the status of the corrective action plan.

F. The Laboratory Director either will deem the corrective action completed or specify further action.

G. If deemed necessary, follow-up actions will be identified by the QCM and/or the Deputy Assistant Director and a new date for completion set and approved.

H. When there is objective evidence that the actions are completed and effective, the Laboratory Director approves and closes the corrective action.

I. The QCM will maintain all original documentation on substantial discrepancies.

4. Special Audit

A. If the findings of the inquiry indicate that there may be a systemic problem of non-compliance at a laboratory-wide or a Section level, the QCM will initiate an appropriate audit. The QCM, in consultation with the Deputy Assistant Director, will assign one or more experienced persons from outside of the Section or laboratory to perform a special audit.

B. A report from the audit team will be made to the Deputy Assistant Director who will determine what follow-up action or actions will be carried out.

5. Completed Cases Released To Clients

A. Data, reports, and actions are not released until the problem is resolved and verified by the Section Supervisor and/or QCM. If unable to resolve the problem, the submitting agency will be notified that the Section or laboratory data cannot be reported or accepted, with disclaimers made that the product did not meet quality standards.
B. In the event that a non-conformity has been identified and that a discrepancy has affected a Laboratory (Case File) Report that has already been furnished to submitting agency, the agency will be notified and the Laboratory Director will request resubmission of the appropriate evidence for reanalysis. If in error, an amended report will then be issued.

It is anticipated that with increased familiarity with this system of addressing discrepancies, examination of the root cause, and determination of corrective action, attending to quality issues will presently be more uniform and the transition to the ISO standards will be straightforward in the future.

U.S. Department of Justice

Federal Bureau of Investigation

Washington, D. C. 20535-0001

January 22, 2010

Michael J. Budzynski
NCSBI Crime Laboratory
3320 Garner Road
Raleigh, North Carolina 27626-0500

Dear Mr. Budzynski:

This is in response to the external Quality Assurance Standard audit conducted for the North Carolina State Bureau of Investigation, Raleigh, North Carolina in Raleigh, North Carolina from January 12 to 16, 2009.

A review of your audit documentation, which is enclosed, found your laboratory to be in compliance with the external audit requirement and the FBI Director's Quality Assurance Standards.

Thank you for you assistance in this matter.

Sincerely,

Douglas R. Hares, PhD
NDIS Custodian
CODIS Unit
Laboratory Division

Enclosure

1 - Ms. Amanda Overman (no enclosure)