RESPONSE TO ASCLD/LAB INSPECTORS' JULY 23, 2003, CORRESPONDENCE

NOVEMBER 2002 INSPECTION

SAN DIEGO SHERIFF'S DEPARTMENT REGIONAL CRIME LABORATORY

August 19, 2003

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July 23, 2003

Don Tapper
Supervising Criminalist
San Diego County Sheriff's Crime Laboratory
5255 Mt. Etna Drive
San Diego, CA 92117

Dear Don:

Reference the June 23, 2003 ASCLD/LAB Corrections to Remediation Response that was forwarded to the inspection team by Quality Manager Kathy Wagner. The team has completed its review of the documentation and the following comments are provided on each of the criteria identified in the report:

1.1.2.5: No additional remediation is appropriate at this time.

1.1.2.7: The additional information that has been provided is responsive to the issue identified in the May 6th letter. No further action is required. The revised manual sections will be reviewed at the time of a revisit.

1.3.3.1: The additional information that has been provided satisfactorily addresses the issues identified in the May 6th letter and this criterion is considered by the inspection team to be remediated.

1.4.2.4: Appendix 1 of the package provides "7.20.1 Quality System Review Team." There are no words in italics in the document and the information contained therein still does not appear to reflect what is required to conduct an annual review of the quality system.

Response: Apologies for the missing italics (the missing italics have been restored–see Section 7.20.1). The overall policy has been rewritten to better reflect what is required to conduct an annual review of the quality system. Please see **Appendix 1** for a copy of Section 7.20 ("Quality System Review" policy) and the "Quality System Audit Checklist." Red font indicates the latest revisions.

1.4.2.7: The additional information that has been provided is responsive to the issue identified in the May 6th letter. No further action is required. The revised manual sections will be reviewed at the time of a revisit.

1.4.2.8: In #1, 3 and 4, it is unclear as to the requirements for preparation and documentation of

the specific tests. For example, under section 4, Water chlorides, Sulfates, a known latent impression composed of sweat is to be used. How is this impression to be prepared and documented? As an example of a procedure the team considers to be appropriate, the procedure for bloody component is very specific and requires recording preparation of the test cards.

Response: The Latent Print Development Chemical Processing Manual has been revised to indicate how impressions are made and documented for sections 1, 3, and 4. Please see **Appendix 2** for a copy of the revised manual. Red font indicates added or revised language.

Regarding #1, it is assumed that the examiner's case notes pertaining to the test impressions will reflect when, by whom and the specific test (amino acid or beef bouillon).

Response: A new case notes form has been created. This form has a section for recording which test was used (amino acid or beef bouillon) and a place for date and examiner.

1.4.1.14: 1. The additional information that has been provided satisfactorily addresses the issues identified in the May 6th letter. Appropriate implementation will be further reviewed at the time of a revisit.

1.4.2.19: The response states that words in italics in appendix 6 indicate new or revised language in the manual. The document provided as appendix 6, 7.13.7 Proficiency Test Evaluation Results, does not contain any words in italics. Also, the policy states what must take place when a discrepancy is identified, which includes removing an examiner from casework. It does not identify as to what must take place in order to reinstate the examiner to casework.

Response: Apologies again for the missing italics. The policy has been rewritten to better reflect what must be done when a discrepancy is identified (including the removal of an examiner from casework). Please see **Appendix 3** for a copy of Section 7.13.7 ("Proficiency Test Evaluation Results"). Words in italics indicate the rewritten parts of the section.

All findings appear to be satisfactorily resolved with the exception of those issues commented above relating to criteria 1.4.2.4, 1.4.2.8 and 1.4.2.19. As soon as these remaining three criteria are satisfactorily addressed we will be in a position to schedule a revisit.

In the meantime, if you have any questions please do not hesitate to contact me. Until mid-September, my mailing address is 274 69th Street, Avalon, NJ 08202, and I can be reached by telephone at 609-368-5560.

Sincerely,

Richard S. Frank

cc: Ralph Keaton, ASCLD/LAB Executive Director
Frank Fitzpatrick, ASCLD/LAB Board Coordinator
Each inspector
Kathy Wagner, SDCSCL Quality Manager

APPENDIX 1

ASCLD/LAB STANDARDS AND CRITERIA 1.4.2.4 (E)

7.20 QUALITY SYSTEM REVIEW

The quality system review is an evaluation of the quality assurance policies that apply to the whole laboratory, in contrast to policies that may only apply to specific sections or disciplines within the laboratory. An annual quality system review allows laboratory management to be confident that all measures are being taken to provide the highest-quality service. The quality system review process requires the documentation of all responses and corrections that are made as a result of the quality system audit.

7.20.1 Quality System Review Team

To comply with the quality system review requirement, the laboratory may use either an external review system, where the team members are individuals from cooperating crime laboratories, or an internal review consisting of members of the laboratory's own Executive Management Team (EMT). In either case, the quality system review team will use a checklist and examine the records, documents, and policies of each area of interest of the quality system and compare them to the actual practices of the laboratory. A report is generated and kept on file with the Quality Assurance Manager.

The quality system review is scheduled and announced well in advance of the event.

7.20.2 Quality System Audit Checklist

The quality system review audit checklist is used to answer a number of quality system questions, including the following:

- Does the laboratory have a Quality Manual?
- Is an individual designated as the Quality Assurance Manager?
- Are audits of the management operations and disciplines of the laboratory completed and documented annually?
- Does the laboratory conduct and document an annual review of its quality system?
- Are new technical procedures scientifically validated before being used in casework and is the validation documentation available for review?
- Does the laboratory monitor the testimony of each examiner at least annually and is the examiner given feedback from the evaluation?
- If the laboratory has an indication of a significant technical problem, is there a procedure in writing and in use whereby the laboratory initiates a review and takes any corrective action required?
- Does the laboratory have a documented program of proficiency testing?

- Does the laboratory have and use a documented training program in each functional area for employees who are new, untrained, or in need of remedial training?

7.20.3 Quality System Review Report

After the review is completed, the review team writes a quality system review report, which documents the review and its results. The report, with its recommendations for improvements, forms the basis for changes to the quality system. Changes may include the following:

- New or improved control activities designed to better ensure the quality of the laboratory work product.

- The general acceptance and incorporation of advanced technologies that may require new and specific control activities for ensuring quality.

- Changes in the legal requirements for accepting forensic evidence in the judicial environment in which the laboratory operates.

Any deficiency involving an **essential** criterion will become a corrective action item.

7.20.4 Quality System Review Responses

Each finding of a deficiency during the quality system audit process requires a written response, which must include all measures taken to correct the deficiency.

Deficiencies must be addressed in a timely manner. If necessary, a due date for the response will be set by the Quality Assurance Manager.

QUALITY SYSTEM AUDIT CHECKLIST

1. DOES THE LABORATORY HAVE A QUALITY MANUAL? (E) Y N N/A

___Quality Manual is kept current under the responsibility of a quality manager.

___Quality Manual clearly documents all elements of the quality system.

Quality Manual should contain or reference the following:

___A quality policy statement including objectives and commitments by management.
___The organization and management structure of the laboratory, its place in any parent organization, and relevant organizational charts.
___The relationships and responsibilities of management, technical operations, and support services in implementing the quality system.
___Job descriptions, education, and up-to-date training records of laboratory staff.
___Control and maintenance of documentation of case records and procedure manuals.
___The laboratory's procedures for ensuring that measurements are traceable to appropriate standards, where available.
___The type and extent of examinations conducted by the laboratory.
___Policy for handling evidence items.
___Major equipment and reference measurement standards used.
___Calibration and maintenance of equipment.
___Verification practices for ensuring continuing competence of examiners including interlaboratory comparisons, proficiency testing programs, and internal quality control schemes (e.g., technical peer review).
___Laboratory protocol permitting and departures from documented policies and procedures.
___Policy for dealing with complaints.
___Policy for disclosure of information.

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2. IS AN INDIVIDUAL DESIGNATED AS THE QUALITY MANAGER?(E)
Y N N/A

___Quality Manager is objective and capable of coordinating all of the activities required to implement and maintain quality.

___Quality Manager has direct access to the highest levels of management at which decisions are made regarding laboratory policy and resources.

___The scope of responsibilities and authority of the Quality Manager are clearly articulated.

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3. ARE AUDITS OF THE MANAGEMENT OPERATIONS AND DISCIPLINES OF THE LABORATORY COMPLETED AND DOCUMENTED ANNUALLY? (E) Y N N/A

___There are annual audits in all accredited disciplines and all other aspects of laboratory management and operations.

___Controlled Substances
___Trace Evidence
___Firearms/Toolmarks
___Latent Prints
___DNA (according to DAB standards, and external audit every two years).
___Toxicology
___Serology
___Questioned Documents

___The annual auditors are selected and trained by the quality manager.

___Annual audits are scheduled and announced well in advance.

___An audit checklist is employed.

___There is a report that identifies problem areas and the remedial action required.

___Documentation that management is briefed on audit findings, and that there is follow-up on issues raised in a timely manner.

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4. DOES THE LABORATORY CONDUCT AND DOCUMENT AN ANNUAL REVIEW OF ITS QUALITY SYSTEM? (E) Y N N/A

___Recommendations for improvements in the quality system from audit reports, are evaluated and implemented, as appropriate, to make changes in the quality system.

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5. ARE NEW TECHNICAL PROCEDURES SCIENTIFICALLY VALIDATED BEFORE BEING USED IN CASEWORK AND IS THE VALIDATION DOCUMENTATION AVAILABLE FOR REVIEW? (E) Y N N/A

___The new methods are tested using known samples designed to resemble actual evidence materials as closely as possible.

___Written documentation for each validation study is maintained.

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6. DOES THE LABORATORY MONITOR THE TESTIMONY OF EACH EXAMINER AT LEAST ANNUALLY AND IS THE EXAMINER GIVEN FEEDBACK FROM THE EVALUATION? (E)
Y N N/A

___There is a written procedure regarding testimony monitoring.

___Examiners are given feedback on the positive aspects of their testimony as well as the areas that need improvement.

___Prescribes the remedial action that is to be taken should the evaluation be less than satisfactory.

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7. IF THE LABORATORY HAS AN INDICATION OF A SIGNIFICANT TECHNICAL PROBLEM, IS THERE A PROCEDURE IN WRITING AND IN USE WHEREBY THE LABORATORY INITIATES A REVIEW AND TAKES ANY CORRECTIVE ACTION REQUIRED? (E) Y N N/A

___There is a written procedure used when there is an indication of a significant technical problem.
___The technical procedure involved in the problem is reviewed.
___The technical procedure is withdrawn from service if necessary.
___If the technical procedure is reinstated it is demonstrated that it is not, or is no longer, the source of error.

___Documentation is available for any corrective actions taken.

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8. DOES THE LABORATORY HAVE A DOCUMENTED PROGRAM OF PROFICIENCY TESTING? (E)
Y N N/A

___The lab uses approved external providers where available.

___The lab participates annually in at least one external proficiency test for each discipline in which it provides services.

___Non-DNA Examiners complete at least one proficiency test annually.

___Each DNA examiner participates in at least two external proficiency tests annually from an approved provider.

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9. DOES THE LABORATORY HAVE AND USE A DOCUMENTED TRAINING PROGRAM IN EACH FUNCTIONAL AREA FOR EMPLOYEES WHO ARE NEW, UNTRAINED OR IN NEED OF REMEDIAL TRAINING? (E) Y N N/A

___There is demonstration of successful completion of competency testing prior to assuming casework responsibility.

___There is documentation of completion of training.

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10. Staff Documentation.

___The Lab has available documentation of the educational background of technical and managerial staff.

___The Lab has available documentation of the training received by technical and managerial staff.

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11. Documentation of Manuals.

___The lab has available a distribution list for official copies of unit, technical and quality manuals.

___The lab has available a dated record of any changes in unit, technical and quality manuals.

___The lab has available a dated record on archived unit, technical and quality manuals.

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APPENDIX 2

ASCLD/LAB STANDARDS AND CRITERIA 1.4.2.8 (E)

Reagent/Process Quality Assurance Sample Preparation and Procedures (Quality Control)

General Comments

The following quality control methods are used to ensure that proper techniques are followed, instruments are operable, and that the quality of the reagents being used is adequate for the conditions encountered.

Note: To test the effectiveness of a reagent, a test print is used. The test print method is a competent method of testing a reagent and may be the procedure required when a specific technique has not been developed.

1. Amino Acids/Proteins: for reagents such as Ninhydrin, DFO, or other amino/protein reactive reagents.

Purpose:

To test reagents and methods that enhance impressions composed of amino acid and protein residues.

Use either A or B (below) for test print.

A. Finger Impressions from Individuals.

Equipment Needed to Perform Procedures:

1. Finger impressions containing amino acids or proteins obtained from individuals.
2. Porous item similar to evidence item.

Preparation of Test Impressions:

1. Apply perspiration, saliva, or other secretions to finger by rubbing finger across portions of nose, ears, face, neck, or hands.
2. Place the treated finger on the porous item.
3. To test the porous item, see "Steps for Using Test Impressions" below.
4. If results are negative (no prints developed or no color change), repeat the test impression process using a different subject or the source listed in section B below.

B. Finger Impressions from Prepared Control Papers/Squares.

Equipment Needed to Prepare Control Papers/Squares:

1. Store brand beef bouillon cube or powder.
2. Paper squares (with writing in ink if using non-running ninhydrin).

Preparation of Control Papers/Squares:

1. Mix beef bouillon cube or powder with water. This mixture should have the consistency of thin paint.
2. Dip finger in beef bouillon mixture.
3. Manually place finger impressions on paper squares.
4. Test a paper square (see "Steps for Using Test Impressions" below), and record the positive test results in the Reagent Validation Log ("Amino Acids/Proteins"). The purpose of this step is to confirm that the beef bouillon mixture batch has been tested and is ready for future use. If results are negative, see step #4 below under "Steps for Using Test Impressions."
5. Initial, date, and store the test papers/squares in an envelope, at room temperature, until needed.

Steps for Using Test Impressions:

1. Apply the reagent to the impressions, from either process A or B above, using the appropriate procedure detailed in Section 9.9.14.6 of the Latent Print Development Section Policy and Procedures Manual.
2. A positive result is indicated by the visualization of developed images on the item.
3. Evaluate and record the type of test (either A or B from above), and record the test results in the examiner's case notes.
4. If results are negative (no prints developed), repeat the test. If the re-test is negative, the reagent is not acceptable for use on casework. The reagent is disposed of according to laboratory safety policy, and a new reagent is prepared.

Safety Concerns:

Follow the safety procedures for handling the samples, chemicals, and reagents that are being used.

Storage and Location of Chemicals and Solutions:

The processing reagents and beef bouillon powder or cubes are stored in the Latent Print Development Chemical Processing Room.

2. <u>Bloody Components (blood proteins/hemoglobin</u>): for reagents such as Amido Black, Coomassie Blue, Leuco-Crystal Violet, and other blood-reactive reagents.

Purpose:

To validate the reagents and methods used to process blood-contaminated impressions. Test papers containing dilute concentrations of blood are prepared and processed according to the method being evaluated.

Equipment Needed to Prepare Controls:

1. Ten (10) µL pipette.
2. 1.5 ml microtubes.
3. "Whatman" blood cards.

Chemicals Needed for Preparation of Controls:

1. Fifteen (15) µL of mammalian blood.
2. Three thousand (3000) µL of distilled water.

<u>Directions for Preparation of Control Solutions (1.0%, 0.5%, and 0.05%)</u>

1.0% Blood Solution:

1. Place one thousand (1000) µL of distilled water in a microtube.
2. Add ten (10) µL of mammalian blood to the microtube. Mix thoroughly.
3. Store solution in the refrigerator until needed.

0.5% Blood Solution:

1. Place one thousand (1000) µL of distilled water in a microtube.
2. Add five (5) µL of mammalian blood to the microtube. Mix thoroughly.
3. Store solution in the refrigerator until needed.

0.05% Blood Solution:

1. Place one thousand (1000) µL of distilled water in a microtube.
2. Add ten (10) µL of 0.5% blood solution to the microtube. Mix thoroughly.
3. Store solution in the refrigerator until needed.

Procedure for Test Card Preparation:

1. The "Whatman" blood card is divided into four (4) sections. Label the first section as "1.0%," the second area as "0.5%," the third area as "0.05%," and the fourth area as "Ø."
2. Using the pipette, place ten (10) µL of 1.0% blood solution on area labeled "1.0%." Place ten (10) µL of 0.5% blood solution on area labeled "0.5%." Place ten (10) µL of 0.05% blood solution on area labeled "0.05%." Do not put any solution on the area labeled "Ø."
3. Allow the test cards to dry at room temperature.
4. Test the card with a reagent using the guidelines below and record the test card preparation in the Reagent Validation Log ("Bloody Components Test Cards"), located in the Latent Print Development Chemical Processing Room.
5. Store the cards in an envelope, at room temperature, until needed.

Guidelines for Using Test Cards:

1. For the specific reagent/method being evaluated, follow the appropriate processing procedures, detailed in Section 9.9.14.6 of the Latent Print Development Section's Policy and Procedures Manual.
2. A positive result is indicated by an appropriate color change on the test card in the areas indicated by "1.0%," "0.5%," and "0.05%" without a corresponding color change in the non-stained "Ø" area of the test card.
3. Evaluate and record the test results in examiner's case notes.
4. If there is no color change in the stained areas, the reagent/method being evaluated is not acceptable for use on casework. The reagent is disposed of according to laboratory safety policy and a new reagent is prepared.

Safety Concerns:

Follow the safety requirements for the handling of mammalian blood and for the reagents that are being tested.

Storage and Location of Chemicals and Solutions:

Mammalian blood is stored in a sealed container and refrigerated in the Forensic Biology Section.

Shelf Life:

Mammalian Blood—no expiration date.
Test Cards—no expiration date.
Blood dilutions should be made fresh at the time each new batch of test cards are prepared.

Other Comments:

Test cards are prepared by the Forensic Biology Section laboratory personnel. The date prepared, quantity, person preparing cards, and person testing cards for positive quality control are recorded in the Reagent Validation Log ("Bloody Components Test Cards"), located in the Latent Print Development Chemical Processing Room.

3. <u>Lipids, Fats, Oils, Greases</u>: for reagents such as Crystal Violet, Iodine, Physical Developer, Small Particle Reagent, Sticky Side Powder, Sudan Black, and other sebaceous material reactive reagents.

Purpose:

To test reagents and methods that enhance the lipids, fats, oils, and grease of sebaceous impressions.

Equipment Needed to Perform Procedures:

1. Finger impressions containing components of sebaceous materials.
2. Suitable substrate surface/item—similar to anticipated evidence sample.

Preparation of Test:

1. Rub finger across portions of nose, ears, face, neck, or hands.
2. Place fingerprint impression containing sebaceous residues on the item(s).

Steps for Using Test:

1. Apply the reagent solution to the fingerprint impression on the item, using the appropriate processing procedure detailed in Section 9.9.14.6 of the Latent Print Development Section's Policy and Procedures Manual.
2. A positive result is indicated by the visualization of fingerprint impression on the item.
3. Evaluate and record the test results in the appropriate portion of the Reagent Validation Log (if reagent was prepared for single use), and in the examiner's case notes.
4. If results are negative (no prints developed), repeat the test by rubbing finger across portions of nose, ears, face, neck, or hands of a different subject. If the re-test is negative, the reagent is not acceptable for use on casework. The reagent is disposed of according to laboratory safety policy, and a new reagent is prepared.

Safety Concerns:

Follow the safety procedures for handling the samples, chemicals and reagents that are being used.

Storage and Location of Chemicals and Solutions:

The reagents are stored in the Latent Print Development Chemical Processing Room.

4. <u>Water, Chlorides, and Sulfates</u>: for reagents such as Dusting Powders, Cyanoacrylate Ester Fuming, Fluorescent Powders, Silver Nitrate, and other liquid and/or dissolved salts reactive reagents.

Purpose:

To test reagents and methods that enhance impressions consisting of water with both inorganic and organic contaminants.

Equipment Needed to Perform Procedures:

1. Finger impressions composed of sweat.
2. Non-porous test substrate.

Preparation of Test Impressions:

1. Rub finger across portions of nose, ears, face, neck, or hands.
2. Manually place finger impressions on the test substrate.

Steps for Using Test Impressions:

1. Apply the processing procedure being evaluated, as detailed in Section 9.9.14.6 of the Latent Print Development Policy and Procedures Manual, to the impressions on the test substrate.
2. A positive result is indicated by the visualization of developed images on the test substrate.
3. Evaluate and record the test results in the appropriate portion of the Reagent Validation Log (if reagent was prepared for single use), and in the examiner's case notes.
4. If results are negative (no prints developed), repeat the test by rubbing finger across portions of nose, ears, face, neck, or hands of a different subject. If the re-test is negative, the reagent is not acceptable for use on casework. The reagent is disposed of according to laboratory safety policy, and a new reagent is prepared.

Safety Concerns:

Follow the safety procedures for handling the samples, chemicals, and reagents that are being used.

Storage and Location of Chemicals and Solutions:

The processing reagents are stored in the Chemical Processing Room.

5. Cyanoacrylate Ester Residues (Dye Stains): for reagents such as Rhodamine 6G, Ardrox, Basic Yellow, and other Cyanoacrylate Ester reactive reagents.

Purpose:

To validate the reagents, equipment operability, and methods used to dye-stain cyanoacrylate ester developed impressions. To satisfy this requirement, test squares containing previously superglued impressions are prepared and processed according to the method being evaluated.

Equipment Required:

1. Pieces of plastic.
2. Superglue.
3. Superglue chamber.

Preparation of Test Squares:

1. Rub finger across portions of nose, ears, face, neck, or hands.
2. Place at least one finger impression on each plastic square.
3. Place pieces of plastic in superglue chamber, and process with cyanoacrylate fumes until prints are visible.
4. Remove from superglue chamber and evaluate the results.
5. Test the squares following the steps below, and record in the Reagent Validation Log ("Cyanoacrylate Ester Residues") located in the Latent Print Development Chemical Processing Room.
6. Store these positive control cards/squares in a labeled package in the Chemical Processing Room.

Steps for Evaluating Prepared Test Squares:

1. Select the dye stain or method to be evaluated.
2. Apply the selected dye stain to the test square prints, and process according to the documented method, as described in Section 9.9.14.6 of the Latent Print Development Section's Policy and Procedures Manual.
3. Observe test square with an alternate light source.
4. The test is considered positive with the observation of test print fluorescence.
5. Evaluate and record the test results in the User's/Maintenance Log for the ALS and in the examiner's case notes.
6. If results are negative (no prints fluoresce), repeat the test on a different square. If the re-test is negative, the reagent is not acceptable for use on casework. The reagent is disposed of according to laboratory safety policy, and a new reagent is prepared.

Safety Concerns:

Follow the safety requirements for handling the alternate light source, and for the chemicals/reagents that are being used.

Storage and Location of Chemicals and Solutions:

The superglue and the superglue chamber are stored in the Fingerprint Processing Room. The prepared test squares are stored in the Latent Print Development Chemical Processing Room.

Shelf Life:

Prepared cyanoacrylate ester processed latent impressions—no expiration date.

APPENDIX 3

ASCLD/LAB STANDARDS AND CRITERIA 1.4.2.19 (E)

7.13.7 Proficiency Test Evaluation Results

The Quality Assurance Manager uses the Proficiency Test Evaluation Form to document an examiner's proficiency test results. The Quality Assurance Manager places satisfactory test results in the examiner's proficiency test records file.

Successful completion of a proficiency test occurs when one of the following is true:

- An examiner obtains a correct analytical result, as stated by the test provider.
- An examiner obtains a correct analytical result by a consensus of the Quality Assurance Manager, section supervisor, and section lead.

If test results indicate a discrepancy, the Quality Assurance Manager (the DNA Technical Lead for DNA results) will immediately contact the examiner's supervisor. If the supervisor determines that the examiner has not obtained satisfactory results, the examiner will be contacted and removed from casework immediately. Further corrective measures must be taken pursuant to Proficiency Review Committee directives or the laboratory's written policies. Corrective measures may include any or all of the following:

- *Instruction*
- *Retesting*
- *Retraining*
- *Competency Testing*
- *Proficiency Testing*

One of the following groups of personnel will determine which corrective measures need to be completed by an examiner prior to resuming casework:

- *Quality Assurance Manager and the examiner's supervisor or*
- *A panel composed of the Quality Assurance Manager, the examiner's supervisor, and personnel selected by the Quality Assurance Manager and the examiner's supervisor to help resolve the issue.*

Once the corrective measures have been outlined, the examiner must successfully complete all of these corrective measures before he or she can be reinstated to casework. However, the examiner may not resume casework until the Quality Assurance Manager reviews all corrective measures taken and notifies, in writing, the examiner's supervisor that casework may be resumed.

All corrective measures taken must be documented.