COUNTY OF SAN DIEGO

INTER-DEPARTMENTAL CORRESPONDENCE

January 6, 2008

TO: Kathy Wagner, Quality Assurance Manager

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CC: Byron Sonnenberg, CODIS Manager

SUBJECT: Response to 2008 DNA audit finding

With regard to the finding expressed in our 2008 audit: we have drafted a procedure to address failed critical reagent quality control results, as described in the discussion following Standard 9.2 of the DNA Audit Document (see attachment). This procedure modifies section 9.8.11.1 of the laboratory manual, and has been included in the most recent Forensic Biology manual revision.

Attachment – modification to manual section 9.8.11.1

9.8.11 QUALITY CONTROL

9.8.11.1 Quality control (QC) of critical reagents

The performance of all critical reagents used in DNA extraction, quantitation and typing will be tested and verified using known samples before distributing them for general use. Generally, the quality control procedure will be run on all purchased or lab-prepared reagents in a single batch. If it becomes necessary to perform QC on single reagents, or small groups of reagents, the procedures listed below can be modified to test only the performance of the pertinent reagents. The performance of each new lot of kits for DNA quantitation or typing will be verified using known samples before it is used in the analysis of casework samples. Analysts who have completed training in DNA extraction, quantitation, and a DNA typing method, or employees who have successfully completed the applicable portions of laboratory support operations training, will be considered competent to perform quality control of critical reagents (see section 9.8.12).

Reagents that meet the criteria for acceptance described in the procedures below can be used for casework analysis after completion of the appropriate quality control procedure. Reagents that do not meet the criteria will not be used for casework analysis. The person conducting the quality control procedure on reagents not meeting acceptance criteria is responsible for reporting this failure to their supervisor or the DNA Technical Manager. The Technical Manager is responsible for taking any necessary remediative steps. These may include repeating the quality control procedure, discarding the reagent or having it replaced by the manufacturer.

Lab-prepared reagents which ultimately do not meet the acceptance criteria will be discarded. Purchased reagents which ultimately do not meet the criteria will not be used in casework, and will either be returned to the manufacturer for replacement or discarded as appropriate. In either case, the DNA Technical Manager will prepare a memorandum detailing the remediative process, including the identity and lot number(s) of the reagent(s), the steps followed, and the ultimate disposition of the reagent(s). This memorandum will be saved in the QC logbook in the laboratory.

Procedure for QC of purchased and lab-prepared reagents:

1. Prepare all reagents that will be included in the QC batch procedure (see reagent specification sheets, section 9.8.5.2).

2. Perform extraction on a known bloodstain using standard extraction protocols. If 1M DTT is included in the batch, also perform extraction on a known semen stain. If reagents for both organic and EZ1 purification procedures are being tested, perform a purification by both methods on each sample. Although no results, per se, are obtained using these procedures, the QC technician should be alert for anything out of the ordinary, such as unexpected colors or odors.

3. Perform quantitation on the samples. If reagents for both yield gel and Quantifiler procedures have been prepared, perform both procedures. If QC samples, standards,

and blanks give the expected results for these procedures, and no unexpected results are obtained, the reagents used can be considered acceptable for casework.

4. Amplify and type the samples with Profiler Plus and COfiler, or with Identifiler, using the standard methods described in the protocol (see section 9.8.6.4). Compare the results to known types. If the types match, and no contamination or other unexpected results are noted, the extraction and typing reagents may be considered acceptable for use in casework.

5. Prepare a quality control worksheet documenting the process (see example, section 9.8.11.7). Save the worksheet in the QC logbook in the laboratory.

Procedure for QC of AmpF*l*STR kits:

1. The QC sample for the AmpF*l*STR kits will consist of a mixture of two known blood samples that together contain a wide range of alleles. Amplify extracted DNA from a QC sample with the kit to be QCed using the standard method (see section 9.8.6.4.2).

2. Analyze and type the QC sample. The QC sample should exhibit interpretable peaks at each amplified locus. These peaks should correspond to the alleles in the known profile of the sample. No other interpretable peaks should be present. If these criteria are met, all kits with the same lot numbers as those tested may be used for casework.

3. Prepare an AmpF*l*STR kit quality control worksheet documenting the process (see example, section 9.8.11.7). Save the worksheet in the QC logbook in the lab.

Procedure for QC of Quantifiler kits:

1. Conduct a qPCR run on the ABI 7500 SDS using the new Quantifiler kit. Include at least two reactions of the prepared DNA quantitation QC sample (Purchased NIST SRM DNA standard with a nominal DNA concentration of 1.0 ng/µL). QC sample aliquots should be taken from a new, unopened vial. Sample vials should be stored at -15º to -25ºC. Each vial should be thawed, used only once and discarded.

2. Evaluate the analysis results. All kits with the same lot number can be considered acceptable for use in casework if:
   a) no reagent blank and no location lacking a sample show significant quantitation results (>/=.023ng/ul).
   b) the results from each of the QC samples run are +/- 1ng/ul of the nominal concentration. At least two interpretable results should be available.

3. Prepare a Quantifiler kit lot quality control worksheet documenting the process (see example, section 9.8.11.7). Save the worksheet in the QC logbook in the lab.