FORENSIC BIOLOGY CODIS MANUAL

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Status:Published		Document ID: 1257
DATE EFFECTIVE	APPROVED BY	PAGE
12/20/2017	CODIS Manager	1 OF 3

8.0 QUALITY ASSURANCE / QUALITY CONTROL

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8.1	Proficiency Testing
8.1.1	Proficiency testing will be conducted as detailed in the <i>Department of Forensic Biology's Administrative Manual</i> .
8.1.2	Proficiency test documentation will be maintained as required by the <i>NDIS Operational Procedures Manual</i> . Documentation is available from a database maintained by the QA group within the lab.
8.1.3	Issues related to proficiency testing will be addressed as detailed in the <i>Department of Forensic Biology's Administrative Manual</i> .
8.2	Audits
8.2.1	Audits of the laboratory will be conducted as detailed in the Department of Forensic Biology's Administrative Manual.
8.2.2	Audit documentation will be maintained and provided annually to NDIS as required by the NDIS Operational Procedures Manual. Audit documentation will be provided yearly to the SDIS custodian for submission to the NDIS custodian in the form of a Laboratory Audit Certification accompanied by a letter signed by the Laboratory Director.
8.2.3	The Department of Forensic Biology and its CODIS program will be audited as required by "The Quality Assurance Standards for DNA Testing Laboratories and Convicted Offender DNA Databasing Laboratories", the national standards issued by the Director of the FBI.
8.3	9947A and Other Positive and Negative Control Monitoring
8.3.1	9947A and other applicable positive control STR profiles will be compared to the appropriate positive control profile(s) at the time the data is analyzed.
8.3.2	Negative controls will be examined at the time the data is analyzed.
8.3.3	A Positive Control Certification letter will be sent to the SDIS custodian annually as required by the <i>New York State Combined DNA Index System Procedures</i> .

FORENSIC BIOLOGY CODIS MANUAL

(
Status:Published		Document ID: 1257
DATE EFFECTIVE	APPROVED BY	PAGE
12/20/2017	CODIS Manager	2 OF 3

8.4 Monthly database QA/QC checks

- 8.4.1 Each month, a series of checks are performed as a quality measure. The checks are designed to ensure that the profiles in LDIS are allowable and proper, and include the use of queries ("views" in CODIS language).
- Profiles that need fixes may be referred to the interpreting analyst or supervisor, or may be dealt with by the CODIS group.
- 8.4.3 The list of checks includes the following; documentation will be maintained in the CODIS area.
- 8.4.3.1 Specimen Manager views covering the entire database
- 8.4.3.2 Run the following views, evaluate the results, and take appropriate actions:
 - Marked Specimens with Unmarked Uploadable Loci (should not have any; mark any affected loci)
 - Microvariant (.x) Alleles present (fix if any are found)
 - New NDIS ladders check (fix any off-ladder alleles such that they comply with official allelic ladder)
 - Specimens assigned to no indexes (should not have any; investigate and fix)
 - Specimens Violating (the former) 4x4 Rule (there are a handful which have been granted exceptions, as noted in comment boxes; investigate and fix any others)
 - Specimens Unmarked for Upload (disregarding suspects and patterns; investigate and fix any others)
- 8.4.3.3 Match Manager views covering the entire database:

Run the following views, evaluate the results, and take appropriate actions:

- Matches with Disposition Discrepancies
- Overdue Dispositions
- 8.4.3.4 Spot check of profiles entered during a month:

To do this, create a view in specimen manager for all samples "assigned" in desired time frame (e.g. 8/1/17 to 8/31/17). It is preferable to wait 2-3 months for ease of obtaining the case file.

- Highlight non-suspect profiles. These will be the pool to examine.
- Scroll through and select every 12th specimen ID; pull as many of these files as can be easily found. The goal is to have a minimum of a 5% (one in every 20) review rate.

FORENSIC BIOLOGY CODIS MANUAL

Status:Published		Document ID: 1257
DATE EFFECTIVE	APPROVED BY	PAGE
12/20/2017	CODIS Manager	3 OF 3

- Examine all selected CODIS profiles in a case for eligibility, correctness, and Match Estimation compliance; complete the LDIS Audit Form designed for this process.
- Fix problems found, as needed.
- A CODIS supervisor will put a note into the comment box of all specimens examined that the profile was inspected during a database QA/QC check on (date) and that the profile is eligible for the database at this time, then sign off on the LDIS Audit Form. The form is added to the case record.

8.4.3.5 Spot check for modifications done during a month:

This is performed by the QA/QC group on behalf of CODIS, as an external check to ensure that modifications to profiles are done in accordance with protocols of the lab. A minimum of 10% of the modifications for each month will be checked.

Documentation of these checks will be kept by the CODIS group and added to the respective case files.

- The case record should contain documentation of the reason(s) the profile was changed (reinterpretation, correction of a discovered error, changed specimen ID, etc.)
- CODIS' audit trail for the sample should reflect the same change(s)
- CODIS group's modifications binder should contain documentation of the change(s) made

8.4.3.6 Spot check for expungements done during a month:

This is performed by the QA/QC group on behalf of CODIS, as an external check to ensure that removals of profiles are done in accordance with protocols of lab. A minimum of 10% of the expungements for each month will be checked.

Documentation of these checks will be kept by the CODIS group and added to the respective case files.

- The case record should contain documentation of the reason(s) the profile was removed (matches a victim, too many candidate matches, body was identified, etc.)
- CODIS deletion report (because there is no CODIS audit trail once the sample is removed)