Procedure for Samples Analyzed In-House

1.0 Purpose – To outline the procedures for samples processed in the DNA Database Section.

2.0 Scope – The procedures in this document apply to the DNA Database Section at the State Crime Laboratory.

3.0 Definitions

- **NDIS Specimen Manager Module** – The CODIS program used to gain access to samples that have been uploaded to CODIS.
- **Technical Review** – An evaluation of reports, notes, data, and other documents to ensure there is an appropriate and sufficient basis for the scientific conclusion.

4.0 Equipment – N/A

5.0 Procedure

5.1 In-House Run Sample Processing

5.1.1 Database samples shall be processed in batches. Samples for in-house analysis shall be assigned a batch after its eligibility has been verified. This batch number shall be located on all documents generated as part of that batch process, along with the date the document was produced. Any batch in the "Stored – Pending Analysis" or "Stored – Pending Confirmation" status shall be available for analysis.

NOTE: In-house runs of samples that do not originate from Convicted Offender or Arrestee collection, or samples selected for re-analysis, will not be tracked in SpecMan. These samples may be run as a batch and, at a minimum, shall be named with the Forensic Scientist's initials and the date of punching.

5.1.2 A previously run sample may be run to update locus information. The sample may be added to the end of an in-house run plate. All data will be stored with that run, but the sample will not be part of the batch and will remain located in its original storage area. The following note shall be listed on the punch/amp worksheet and in sample record in SpecMan.

5.1.2.1 Sample (list sample number) was run with batch (list batch number). The sample data and run documentation is located with this batch. See the SpecMan record for the sample's storage location.

5.1.3 Before analysis, the DNA Database Forensic Scientist shall change the batch status to "Extraction and Amplification." SpecMan does not allow a batch to be saved in "Extraction and Amplification" status if the eligibility of any Database sample within that batch has not been verified.

5.1.4 The DNA Database Section shall process Database samples robotically or manually following section procedures.

5.1.5 Once the lab work has been completed, the batch status shall be changed to "In

Analysis." Database samples run in house shall be analyzed per section procedures.

5.1.6 Samples that require rerun or rejection as well as any notes about samples shall be listed on the Exceptions/Notes report.

5.1.7 For samples that require rerun or rejection, put a note into both the SpecMan batch record and the SpecMan sample record explaining the reason for rerun or rejection.

5.1.8 Once analysis has been completed, the Forensic Scientist shall change the batch status to "Analysis Complete – Pending Review" in SpecMan and assign the batch to the technical reviewer.

5.2 In-House Run Documentation

5.2.1 In-house run files shall include but are not limited to the following:

5.2.1.1 Punch/Amplification worksheet

5.2.1.2 Qiagen Amplification Report (if robotic amplification)

5.2.1.3 3500xL setup sheet

5.2.1.4 Exceptions/Notes report

5.2.1.5 Edited GeneMapper ID-X file

5.2.1.6 Raw Data

5.2.1.7 CMF 3.2 (.xml) file generated for all samples to be uploaded/updated. The CMF file shall be deleted after successful upload of all samples to CODIS.

5.2.1.8 All unused data including raw data folders and GeneMapper ID-X files for each project.

5.2.1.9 PowerPlex® Fusion Technical Review Sheet

NOTE: All finalized items in the in-house run file shall be in a non-editable format. The name of each item shall include the batch number. All items shall be retained on the section shared drive.

5.3 In-House Run Technical Reviews

5.3.1 A second, qualified Forensic Scientist shall technically review all samples. The technical review shall be documented on the PowerPlex® Fusion Technical Review Sheet and shall include at a minimum:

5.3.1.1 A review of the in-house run file to ensure that it includes all required documentation listed in the previous section.

5.3.1.2 A review of all worksheets to include verification of completion and the use of proper lot numbers.

5.3.1.3 A review of all electronic data (used and unused) to include all controls, internal lane standards, and allelic ladders to verify that the scientifically expected results were obtained.

5.3.1.4 A review of all samples to ensure proper interpretation.

5.3.1.5 A review of any reworked samples to confirm that the samples have the required controls.

5.3.1.6 A review for sample entry eligibility into CODIS.

5.3.1.7 A review of the CMF file to ensure that the specimen category is correct and that only the sample numbers reported are present in the file.

5.3.2 If the reviewer determines any corrections are needed, the corrections shall be listed in the Reviewer Notes section of the PowerPlex® Fusion Technical Review Sheet. The original Forensic Scientist shall make corrections and then initial and date the Reviewer Notes section. The reviewer shall then review the updated items for accuracy and complete the PowerPlex® Fusion Technical Review Sheet.

5.3.3 If the reviewer determines that a sample is not acceptable during the review process, the following steps shall be completed:

5.3.3.1 The reviewer notes the specimen number and reason for rejection on the PowerPlex® Fusion Technical Review Sheet. Samples shall be reprocessed as outlined in the Rerun Samples section of this document.

5.3.3.2 The reviewer ensures the original Forensic Scientist corrects the CMF file and the edited GeneMapper ID-X project. Corrections and modifications shall be made in accordance with **5.3.2**.

5.3.4 Technical Issues: If during the course of a review, the reviewer and Forensic Scientist are unable to resolve a technical issue, the Technical Leader shall be notified of the issue. The Technical Leader shall then determine and/or approve the appropriate course of action.

5.3.5 Once the review has been completed, the reviewer shall change the batch status to "Review Complete" in SpecMan signifying that the above criteria have been completed. The reviewer shall reassign the batch to the original Forensic Scientist.

5.4 Rerun Samples

5.4.1 Samples that do not produce full profiles or samples that require additional information may be run up to three times unless otherwise approved by the Technical Leader. Samples may be rerun robotically or manually.

5.4.2 After the technical review is complete, samples to be rerun shall be placed in the SpecMan status of "Rejected – Reprocess." The batch information (batch number and sequence number) shall be removed from both the Processing and Admin sections of the SpecMan sample record.

5.4.3 Samples/cards shall be removed from the current batch and set aside to be rebatched and rerun following section procedures.

5.4.4 Samples/cards shall be stored with the batch in which their profiles are reported.

5.5 Rejected Samples

5.5.1 If resubmission is required, a rejection reason(s) shall be added to the SpecMan sample record.

For rejected samples, see the Rejection Processing section of the Procedure for Sample Accessioning and Processing Samples. Cards shall be stored with the final batch in which the sample was run.

5.6 Uploading and Completing an In-House Run File

5.6.1 Once the technical review is complete, batches that will be uploaded to CODIS shall be set to the SpecMan batch status of "Reviewed – Pending CODIS Upload." Individual samples that will be uploaded to SDIS shall be set to the SpecMan status of "Reviewed – Pending SDIS Upload." For confirmation batches, refer to the Completing a Confirmation Batch section of this procedure.

5.6.2 The CMF file shall be uploaded following CODIS procedures.

5.6.3 Perform a CODIS autosearch for arrestee and convicted offender duplicates following CODIS procedures.

5.6.4 For individual samples that were uploaded to SDIS, the Forensic Scientist shall add the upload date and set the sample to the SpecMan status of "Stored – Entered in SDIS." The DNA Database Forensic Scientist shall add the CODIS upload date to the remainder of the batch and change the batch status to "Stored – Entered in CODIS" in SpecMan.

5.6.5 The PowerPlex® Fusion Technical Review Sheet shall be dated and initialed by the DNA Database Forensic Scientist indicating upload and specimen manager system update were completed. This file shall be printed to PDF so that it is in a non-editable format.

5.6.6 The in-house run file shall be stored on the server.

5.7 Completing a Confirmation Batch

5.7.1 Once the SpecMan batch is in the status of "Review Complete," the identifying information and profile from each sample in the reanalysis shall be compared to the identifying information and profile of the suspected duplicate sample that was previously uploaded to CODIS. To determine if the SpecMan resubmission option shall be changed

to "no," refer to the Rejection Processing portion of the DNA Database Section Procedure for Sample Accessioning and Processing.

5.7.2 If a sample is not a duplicate of the corresponding sample in CODIS, the sample shall be processed following the Rerun Samples section of this procedure.

5.7.3 If any other two profiles are not concordant or there are any other problems encountered related to the confirmation, the Forensic Scientist Manager/designee shall be notified. The Forensic Scientist Manager/designee shall determine the correct course of action.

5.7.4 If a sample is a true duplicate of the corresponding sample in CODIS, the sample shall remain in the batch and the SpecMan batch status shall be changed to "Stored – Confirmed."

6.0 Limitations – N/A

7.0 Safety - N/A

8.0 References

DNA Database Administrative Policy and Procedure

DNA Database Administrative Policy and Procedure for Safety and Hazardous Waste Disposal

DNA Database Section Procedure for DNA Reagent Quality Control

DNA Database Section Procedure for GeneMapper® ID-X and STR Interpretation with PowerPlex® Fusion

DNA Database Section Procedure for Instrument and Equipment Quality Control

DNA Database Section Procedure for PCR Amplification with PowerPlex® Fusion

DNA Database Section Procedure for Qiagen BioRobot® Universal Using PowerPlex® Fusion

DNA Database Section Procedure for Sample Accessioning and Processing

DNA Database Section Procedure for Sample Processing Quality Control

DNA Database Section Procedure for Use of the 3500xL Genetic Analyzer

Procedure for CODIS-DNA Database

State Crime Laboratory Quality Manual

State Crime Laboratory Safety Manual

9.0 Records – N/A

10.0 Attachments – N/A

Revision History		
Effective Date	Version Number	Reason
03/03/2017	1	Original Document
03/12/2018	2	Added 5.1.2 and subsection regarding running samples for locus updating; 8.0-Updated CODIS procedure name