Procedure for DNA Database Review of Contractor Data

1.0 Purpose – The purpose of this document is to provide a procedure for the review of database sample profiles generated by a contractor lab prior to upload of Database sample DNA profiles into CODIS.

2.0 Scope – The procedures in this document apply to the DNA Database Unit of the Forensic Biology Section at the North Carolina State Crime Laboratory (State Crime Laboratory). Qualified DNA Database Forensic Scientists/DNA Database Analysts and Qualified Contract Employees who have completed the Outsource Lab Review Training portion of the DNA Database Training Program shall complete the responsibilities outlined in this procedure.

3.0 Definitions – See the DNA Database procedures for definitions applicable to this procedure.

4.0 Equipment

- Applied Biosystems Genemapper ID® Software.

5.0 Procedure

5.1 Data Interpretation – The Outsourcing Technical Review Sheet shall be used as a reference to conduct the review as explained in **5.3**. Data provided by the outsourcing lab is retrieved via a secure website and shall be imported into Genemapper ID® and reviewed (not analyzed) using applicable sections of the Forensic Biology Section Procedure for Genemapper ID Analysis.

5.2 Data Analysis

5.2.1 Electropherogram Review

5.2.1.1 Artifacts: An artifact (e.g., spikes, pull up from another color, etc.) may be present in the electropherogram. Samples with allele calls that are affected by an artifact shall be re-run to confirm the presence of a true allele prior to acceptance. Samples may be re-run in-house or by the vendor.

5.2.1.2 Positive and Negative Controls: Examine positive controls and ensure correct allele calls were obtained. Positive controls must yield a complete profile. If multiple 9947A controls are run, only one must yield a complete profile. Negative controls must be void of alleles above the RFU threshold.

5.2.1.3 Ladders: Visually inspect the ladder at each locus to ensure all alleles are present. If multiple ladders are run, one may be chosen for analysis.

5.2.1.4 LIZ: Visually examine the LIZ for each sample to ensure the proper base pair range of 75-450 is present. Calculate the average 250 bp peak size of all ladders. Ensure the 250 bp peak for each sample is within +/- 0.5 of the averaged ladders.

5.2.2 Sample Analysis Review

5.2.2.1 Balance: Each sample shall be examined for balance at each locus. If excessive heterozygote imbalance occurs (< 50 %), then the sample shall be rejected and rerun if the imbalance does not allow for proper interpretation by the DNA Database Forensic Scientist/DNA Database Analyst.

All copies of this document are uncontrolled when printed.

5.2.2.2 Allele Drop Out: Each sample shall be examined for allele drop out. If drop out is suspected or observed, then the sample shall be rejected.

5.2.2.3 Microvariants: Examine samples for the presence of microvariants. If a microvariant is observed, ensure that the microvariant has been sized properly.

5.2.2.4 Off-Ladder/Out-of-Bin Alleles

5.2.2.4.1 If the allele in question lies between two loci, the DNA Database Forensic Scientist/DNA Database Analyst shall attempt to determine to which locus the allele should be assigned based upon the presence or absence of heterozygosity at the loci in question.

5.2.2.4.2 If one locus exhibits homozygosity and the second heterozygosity, then the off ladder allele shall be assigned to the homozygous locus.

5.2.2.4.3 If both loci exhibit homozygosity or heterozygosity, the DNA Database Forensic Scientist/DNA Database Analyst shall document that the allele was observed, but not assign the allele to a particular locus, and mark the allele as inconclusive (INC). The called (non off ladder) alleles at these loci shall be reported and uploaded into CODIS.

Note: In some instances, an off ladder allele from one locus may appear within an adjacent locus (i.e., appears to be a potential triallele next to a homozygous locus). If based on training and experience, the Forensic Scientist/Database Analyst believes such a situation has occurred, the entire locus containing that allele may be marked as inconclusive.

5.2.2.4.4 If the off ladder allele can be assigned to a locus, the allele shall be designated as either greater than (>) or less than (<) the last respective allele for that locus called by the allelic ladder. For CODIS eligibility, refer to CODIS Procedures.

5.2.2.5 Triallelic Samples: Examine each tri-allelic sample and ensure correct call and allelic designation. Samples exhibiting tri-allelic patterns shall be confirmed by re-extraction and re-run by the vendor.

5.2.2.6 Quality Control Samples: Examine QC sample(s) and ensure concordant results were obtained with corresponding sample.

5.3 Conducting File Review

5.3.1 The DNA Database Forensic Scientist/DNA Database Analyst shall ensure that the Vendor Batch Number has been entered into the Vendor Batch Number field for each specimen in the file.

5.3.2 The Vendor Batch Number Report shall be run in SpecMan for the vendor batch number. This Report shall display the samples selected for QC analysis and show the associated QC number for each sample.

Note: This report does not apply when analyzing QC samples themselves.

All copies of this document are uncontrolled when printed.

5.3.3 Each file received from the vendor shall include the following documentation:

5.3.3.1 Lot numbers of reagents.

5.3.3.2 Extraction sheets, if performed

5.3.3.3 PCR Setup/Amplification sheets, if performed

5.3.3.4 Electrophoresis set up sheets.

5.3.3.5 Scanned Tray Sheets

Note: The lot numbers of reagents, extractions sheets, (if performed), the PCR set up/ amplification sheets, (if performed) and electrophoresis set up sheets are contained within the scanned tray sheets as provided by the vendor.

5.3.3.6 . Edited Genemapper ID file (.ser), project file as reported including edits.

5.3.3.7 Notes on failed samples

5.3.3.8 Raw data

5.3.3.9 Summary Table

5.3.3.10 Sample History Report

5.3.3.11 Scanned Chain of Custody

5.3.3.12CMF files

5.3.3.13 Allele calls/data table for each sample.

5.3.4 Each run sheet shall be dated and identified with the name of the vendor examiner/analyst.

5.3.5 The DNA Database Forensic Scientist/DNA Database Analyst shall complete the following:

5.3.5.1 Print the data table (allele call table) and compare the allele calls to the electropherograms for concordance.

5.3.5.2 Review 100 % of the data by comparing the actual allele calls between the hard copy data table (allele call table) and the electronic data (CMF).

5.3.5.3 Review the samples for eligibility into CODIS. The specimen category for each sample shall be appropriately identified as “Convicted Offender” or “Arrestee” in the CMF file.

Note: QC samples shall not be uploaded to CODIS.

5.3.6 Once all samples are reviewed for quality as described above, the corresponding Outsourcing Technical Review Sheet shall be completed (dated/initialed by reviewer). This shall occur prior to import into CODIS.

All copies of this document are uncontrolled when printed.

5.3.7 The status of the offender/arrestee samples that have passed review shall be changed to "Review Complete" in SpecMan using the "Change Specimen Status to Review Complete" workflow. The workflow takes a moment to run and may be monitored by clicking the refresh button in the top right of the screen. If this is a QC batch, the batch status shall be changed to "Reviewed – Ready to Use in QC" instead.

5.3.8 The status of the associated QC samples that are concordant with their corresponding offender/arrestee samples shall be individually changed to "QC Complete."

Note: The DNA Database Manager and Technical Leader shall be notified in the event of interpretation or technical issues. The Technical Leader shall determine the appropriate course of action.

5.4 Rejected Samples

5.4.1 For each specimen (not QC) that needs to be rejected and rerun, the following steps shall be completed:

5.4.1.1 A note shall be added to the specimen record in SpecMan describing, in detail, the reason for rejection.

5.4.1.2 The specimen status shall be changed to "Rejected – Reprocess."

5.4.1.3 The designated DNA Database Forensic Scientist/DNA Database Analyst shall be notified that the specimen requires reanalysis.

5.4.2 If the sample has an associated QC sample and the profiles are not concordant, the DNA Database Manager shall be notified. The DNA Database Manager shall determine the root cause.

5.4.2.1 If the root cause is a vendor problem, the samples shall not be uploaded to CODIS. The manifest status shall be changed to "Failed QC." The non-QC batches in the manifest shall be changed to "Stored – Pending Analysis" so they may be reanalyzed either in-house or by the vendor. A note shall be added to the manifest record describing the issue.

5.4.2.2 If the root cause is not a vendor problem and is able to be resolved, a note shall be added to the specimen record and the review process shall continue.

5.5 Documentation

5.5.1 The electronic data shall be stored on the Database server.

5.5.2 All documentation from analysis and review shall be retained.

5.6 Upload

5.6.1 Once the manifest status has been changed to "Reviewed – Pending CODIS Upload" using the DNA Database Procedures, the vendor-generated CMF file confirmed in review shall be uploaded following CODIS Procedures.

All copies of this document are uncontrolled when printed.

5.6.2 Review the SDIS Import Reconciliation Report. If it indicates any problems, the CODIS Administrator shall be responsible for ensuring that all problems are resolved according to NDIS requirements.

5.6.3 The DNA Database Forensic Scientist/DNA Database Analyst shall add CODIS upload date to the manifest record and change the manifest status to "Stored – Entered in CODIS." Ensure that all samples that were returned with the current manifest (that were originally sent on a prior manifest) are also updated in SpecMan with the "Change Specimen Status to Stored – Entered in CODIS" workflow and that CODIS upload date is added to the specimen record.

5.6.4 The Outsourcing Technical Review Sheet shall be dated and initialed indicating upload was completed.

5.6.5 The DNA Database Manager or a qualified DNA Database Forensic Scientist/DNA Database Analyst shall verify the allele calls in CODIS if the calls are entered manually by a DNA Database Forensic Scientist/DNA Database Analyst.

6.0 Limitations – N/A

7.0 Safety – N/A

8.0 References

State Crime Laboratory Safety Manual

Forensic Biology Section Administrative Policy and Procedure

Forensic Biology Section Administrative Procedure for Safety and Hazardous Waste Disposal

Forensic Biology Section DNA Database Training Program

Forensic Biology Section Procedure for DNA Database

Forensic Biology Section Procedure for Genemapper ID

Forensic Biology Section Procedure for CODIS

9.0 Records

- BODE Review Binders
- Electronic Documentation Provided by Vendor
- Outsourcing Technical Review Sheet

10.0 Attachments – N/A

All copies of this document are uncontrolled when printed.

Revision History		
Effective Date	Version Number	Reason
09/17/2012	1	Original Document

All copies of this document are uncontrolled when printed.