9.1 Purpose

Only suitable and properly operating equipment and software/macros are used for casework and database. This protocol is to ensure that the correct parameters are monitored and equipment maintenance and performance checks are performed on critical equipment and software/macros.

9.2 Responsibility

DNA Section Personnel.

9.3 Equipment Inventory

An inventory for equipment and software/macros is maintained for the DNA section (see appendix for the software/macros). In addition, the Division of Scientific Services maintains a general laboratory inventory.

Annual: Once a calendar within ± 30 days.

Semi-Annual: Two times a calendar year within 6 months ±1 month.

Quarterly: Once every three months within ± 2 weeks

Monthly: Once a month within ± 7 days

Weekly: Once a week within ± 3 days.

9.3.1 Broken Equipment Notification

If a piece of equipment is not working properly, notification (visible sign) will be placed on the piece of equipment. The issue will be investigated to try to correct the problem. The equipment will remain out of use until it is deemed operational. Broken, out of service, and in need of repair equipment should be documented on its maintenance log. Notification to the Assistant Director or Deputy Director will be made. Performance checks or QC measures will be completed prior to release for casework, if equipment is critical (see DNA SOP-6.3.4) and can influence the test results.

9.4 Centrifuges

Centrifuges (used for Microcon purification and concentration, see DNA SOPs 2 and 20) will be annually performance checked on site by a qualified vendor. Records will be kept by the Quality Section. If a centrifuge needs repair, it will be put out of use and sent out for repair. Quarterly cleaning of centrifuges will be documented on DNA QR-290.

9.5 Thermometer Performance Check (Verification)

Performance Check each thermometer against a NIST traceable thermometer prior to its first use and annually thereafter.

The actual NIST traceable thermometers used for critical temperature checks and used to performance check other thermometers (i.e. for temperatures such as 56°, 70°, 80º) will also be performance checked annually unless new NIST thermometers are purchased each year to replace the previous year's set. If performance check is to occur in-house, the thermometers will be checked by placing them in boiling water, at room temperature, and in ice or dry ice as necessary by the thermometer's reading capabilities. An acceptable difference between readings from the two thermometers is ±2ºC. If readings do not meet acceptable requirements, notification to the DNA TL and a Section Manager will be made and a new thermometer may need to be purchased.

9.5.1 The annual performance check of thermometers (non-NIST) will be done following the directions below:

Each thermometer will be verified against a NIST traceable thermometer prior to its first use and then annually. The thermometer may be checked by placing the NIST traceable thermometer and the thermometer being verified in the freezer, refrigerator, heat block or incubator, leaving them in for at least one hour, and recording the temperature of both thermometers. An acceptable difference between readings from the two thermometers is ±2ºC. If the thermometer being performance checked does not read ± 2ºC of the NIST traceable thermometer, continue to monitor for another day. If required, discard it in the proper manner and replace it with an acceptable one.

Note: If multiple temperatures are set on the equipment depending on the method used (i.e. thermomixers), then the thermometers will be performance checked all those temperatures.

9.5.2 Following the performance checks, mark the top of the thermometers to indicate that they had acceptable results. Please refer to GL-21 and GL-21.3 for documentation. A memo will be written documenting the results of the performance check.

9.6 Refrigerators/Freezers

9.6.1 An assigned thermometer is inside each refrigerator/freezer.

9.6.2 Log the temperature weekly on the appropriate sheet (DNA QR-200a/b).

9.6.3 If the temperature in the unit is more than ± 5°C (freezer) or ± 3°C (refrigerator) above the set temperature, perform appropriate maintenance measures. Such measures would include readjusting the temperature settings, defrosting the unit, or having the unit serviced.

9.6.4 Record any maintenance or adjustment to each unit on the appropriate log sheet. Please use DNA QR-200a and 200b.

9.7 Pipettes

Pipettes used for DNA amplification will be annually performance checked and calibrated or repaired by an ISO 17025 calibration vendor. Repair and calibrations will be noted on certificate from vendor if performed. Records will be kept by the Quality Section in Qualtrax.

9.7.1 Pipettes are individually identified and tracked (pipette log) either by serial number or numeric designation and are generally assigned to a specific workspace. Pipettes will have colored lab tape to represent their location.

9.7.2 If a pipette in the DNA Unit is found "out of tolerance" during the annual performance check, and is found to be greater than 20% out of tolerance, a QAR will be opened to investigate this incident.

9.8 Constant Temperature Incubators

9.8.1 All ovens have assigned thermometers.

9.8.2 Before each use: turn the oven on (if necessary). Set the oven to the desired temperature. After ~10 minutes, check the thermometer reading.

9.8.3 If the actual temperature of an oven has deviated from the set temperature by more than ±2°C the temperature is readjusted. DNA TL and a Section Manager will be notified.

9.8.4 Each time the oven is used, any maintenance and adjustments are logged on to the appropriate sheet. (See DNA QR-204)

9.8.5 Annual Performance Checks: All incubators in use are performance checked (PC) annually for each temperature applicable to the incubator (see steps 9.8.1-3 above) using a NIST-traceable thermometer to monitor the temperature. New incubators are performance checked prior to being put into service. The results of the performance check (pass/fail) are documented on DNA QR-344. Following the performance check, the incubator is marked to indicate that it gave acceptable results and a memo is written to document the performance check.

9.9 Mettler Balance

9.9.1 Before each use, verify that the unit is level and clean.

9.9.2 The Mettler must be calibrated once a year by an authorized service representative; Service dates are on the label on the balance. Certificates are kept with the Quality Section.

9.10 Denver Instrument UltraBasic pH Meter

9.10.1 The pH meter is standardized prior to each use. Prior to each new standardization, previous standardizations will be cleared.

9.10.2 Please refer to DNA WI-29 (pH Meter) for further instruction.

9.10.3 Each standard reading is logged onto the proper log sheet (please use DNA QR-206a and 206b).

9.10.4 If the instrument does not standardize properly, follow the troubleshooting guidelines found in the Operational Manual. If problems persist the instrument will be returned to the manufacturer for service. Notify the DNA TL and a Section Manager.

9.10.5 Electrode is stored in a 3M KCL solution. The KCL can be in-house formulated or commercially purchased. Please refer to WI-29 (pH Meter) and QR-267 (3M KCL).

9.11 DNA Thermal Cycler

9.11.1 Log each use of a thermal cycler on the appropriate case amplification worksheet.

9.11.2 Each Thermal Cycler will be performance checked annually by a qualified outside vendor using a NIST traceable temperature measuring device. Certificates will be maintained for each thermal cycler by the Quality Section.

9.11.3 If a Thermal Cycler needs repair or further adjustment, it will be quarantined and sent out for repair. It will be shipped in an appropriate box with padding to prevent any damage. Upon return, the vendor certificate will be maintained to show the thermal cycler left repair acceptable for use and to show the probe used was NIST traceable. An additional performance check will be done before the instrument is reinstated for casework (Please use DNA QR-259).

9.11.4 Each Thermal Cycler's block (including wells) will be cleaned approximately every three months. This is documented on DNA QR-288.

9.12 ABI 3500xL Genetic Analyzer

9.12.1 The ABI 3500xL Genetic Analyzers are serviced annually by factory service contract. The ABI service department is contacted for repairs and the annual service. A performance check will be done following repair or annual service and before the instrument is reinstated for casework. The performance check will include the methodologies that represent the different types of dye sets used for casework. (Document Performance Check by using DNA QR-260). Acceptable parameters can be found on the DNA Quality Record (QR). If acceptable parameters are not met, notify DNA TL and a Section Manager.

9.12.2 During periods of operation, additional maintenance is performed on the ABI 3500xL Genetic Analyzers and is documented on the appropriate quality record (QR-318 and kept in a maintenance binder by the DNA section. Please refer to DNA SOP-38 for more detailed information on maintenance and cleaning.

9.13 ABI 7500 Real-Time Instrument Maintenance

9.13.1 The ABI 7500 Real-Time instruments are serviced annually by factory service contract. The ABI service department is contacted for repairs and the annual service. Records are maintained in 7500 Performance Check Notebook.

9.13.2 Annually: Instrument performance is verified following the annual service using an ABI TaqMan RNase P verification plate per manufacturer's protocols and documented on DNA QR-262. Records are maintained in Performance Check Notebook.

9.13.3 During periods of operation, additional maintenance is performed on the ABI 7500 instruments by the Division of Scientific Services and is documented on the appropriate log sheet (DNA QR-18).

9.13.4 Approximately every 2 months: background check and block cleaning as necessary (DNA QR-18).

9.13.5 Semi-annually (twice a year): spectral calibrations (Pure Dye) per manufacturer's protocols. (One is performed in association with the annual service). Documented on DNA QR-18.

9.13.6 A performance check will be done before the instrument is reinstated for casework as follows:

Following the annual preventative maintenance (performed by an ABI service engineer), the performance check is as described in 9.13.2 and is documented using DNA QR-262. Following an instrument repair (performed by an ABI service engineer at any other time that

year) or following the spectral calibrations (Pure Dye) (performed by laboratory personnel at the 6-month interval following the annual PM), the performance check is done by running a "Quality Controlled Passed" set of DNA standards and a no template control and documented using DNA QR-34 for Quantifiler Trio.

9.13.7 Please refer to ABI 7500 User's Manual for instructions for performing maintenance procedures.

9.13.8 Acceptable parameters can be found on the DNA Quality Record(s) (QR). If acceptable parameters are not met, notify DNA TL and a Section Manager.

9.14 BSD Duet/BSD Plus

Preventative Maintenance occurs at least once a year. This may be performed by an analyst or vendor. A performance check is completed after the instrument has been serviced or moved and before the instrument is used for casework. See DNA SOP-28 and use DNA QR-265 for performance checking and DNA QR-296 for maintenance documentation. Acceptable parameters can be found on the DNA Quality Record(s). If acceptable parameters are not met, notify DNA TL and a Section Manager.

9.15 EZ1 Advanced XL

The Qiagen EZ1 Advanced XL Extraction Instrument is serviced annually by factory service contract. The service department is contacted for repairs and the annual service. A performance check is completed after the instrument has been serviced and before its use for casework. For documentation of a performance check use DNA QR-277. Records are maintained in the EZ1 Performance Check/Maintenance/Service Notebook.

Acceptable parameters can be found on the DNA Quality Record(s). If acceptable parameters are not met, notify DNA TL and a Section Manager.

9.16 Heat Blocks

9.16.1 Each dry heat block has a thermometer assigned to it.

9.16.2 Before each use: turn on the heat block and wait approximately 10 minutes for the unit to reach the required temperature (±2°C). The temperature is determined using the thermometer assigned to the unit and not the temperature displayed by the unit.

9.16.3 If the heat block is not at the required temperature, wait an additional 10 minutes to determine if the unit will reach the set temperature.

9.16.4 If the unit is still not at the required temperature, adjust the temperature settings of the unit and wait an appropriate amount of time until the temperature on the thermometer becomes stable at the required temperature (±2°C).

9.16.5 The temperature of the thermometer is logged each time the unit is used on the appropriate log sheet (DNA QR-201a/b).

9.16.6 Keep a record of any maintenance or adjustment of each unit on the appropriate log sheet (DNA QR-201a/b).

9.16.7 Annual Performance Checks: All heat blocks in use are performance checked annually for each temperature applicable to the heat block (see steps 9.16.1-4 above) using a NIST-traceable thermometer to monitor the temperature. New heat blocks are performance checked prior to being put into service. The results of the performance check (pass/fail) are documented on DNA QR-344. Following the performance check, the heat block is marked to indicate that it gave acceptable results and a memo is written to document the performance check.

9.17 Hoods

9.17.1 An outside vendor checks laminar flow hoods and other hoods with airflow annually. The UV bulbs in hoods equipped with them are also checked at this time. The laboratory QC manager maintains the documentation of these results.

9.17.2 The pre-filters in the hoods used for DNA extraction, amplification, and PCIA extraction are changed as needed. The pre-filter in the bone/teeth extraction hood is changed after each use and these changes are documented in the appropriate log sheet located on the hood (DNA QR-331). The pre-filter in the bone/teeth PCR Workstation is changed quarterly and these changes are documented in the appropriate log sheet located on the hood (DNA QR-333). HEPA filters are changed as needed in hoods equipped with them.

9.18 Spectrolinkers

9.18.1 The UV bulb intensities in the Spectrolinker XL-1000s and XL-1500 are checked quarterly by performing the self-diagnostic intensity check as described in the operator's manual. Bulbs will be replaced if the intensity falls below 1500 $\mu W/cm^2$. The bulbs should also be visually inspected through the instruments' windows to confirm that the bulbs are on. Maintenance is documented in the appropriate log sheet (DNA QR-332). See DNA WI-41 for further instructions on Spectrolinker maintenance.

9.19 Software/Macros: See the Appendices below for details

9.19.1 Analysis Software/Statistic Macros Performance Check

GeneMarker HID, GeneMapper ID-X, STRmix, Sequencing Analysis, Sequencher, DNA-QR-46 Probability of Kinship Worksheet, Y-Mix, YHRD Database, DNA QR-44 Match Probability of Parentage Worksheet, DNA QR-307 Deconvolution Workbook, DNA QR-342 Supplementary GlobalFiler Stutter Filter and DNA QR-345 YFP Stutter Filter are software/macros used in the DNA Unit for analysis and statistics. A set of data with the expected results for each of the above software/macros will be kept on the U: Drive and used to conduct the performance check on the above software/macros semi-annually (approximately every 6 months). See Appendix below for corresponding Quality Records for the various performance checks. Further guidance and details can be found on these DNA QRs. QRs can be found in Qualtrax or if they are macro workbooks, on the Shared drive in the Controlled Document Folder under DNA. Acceptable parameters can be found on the DNA Quality Record(s). If acceptable parameters are not met, notify DNA TL and a Section Manager.

9.19.1.1 STRmix Performance Check

For STRmix, performance checks will be run with the same seed using samples from GF. If there is an upgrade or software patch for STRmix, the performance check will follow the recommendation of the manufacturer. The results will be documented on DNA QR-306. Further guidance/direction is located in the DNA QR-306 workbook. Acceptable parameters can be found on the DNA Quality Record(s). If acceptable parameters are not met, notify DNA TL and a Section Manager.

9.19.2 Processing Macros Performance Check

For macros used throughout the case flow and database process, a performance check will be performed semi-annually. A DNA analyst (other than the macro's creator) may conduct the performance check during his/her proficiency testing from the beginning of the DNA extraction to issuing the DNA report (if applicable). The results will be documented on DNA QR-292 (nuclear/database). Further guidance and details can be found on this DNA QR. See Appendix below for corresponding macros that will be performance checked on DNA QR-292. DNA QRs can be found in Qualtrax or if they are macro workbooks; on the Shared drive in the Controlled Document Folder under DNA.

For the STRmix Known Input File Generator (DNA QR-304), a performance check will be done semi-annually by an analyst in the Database Unit. Please refer to DNA QR-282 for details. Acceptable parameters can be found on the DNA Quality Record(s). If acceptable parameters are not met, notify DNA TL and a Section Manager.

9.19.3 Software/Macros Updates

After a software/macro update, upgrade or software patch and prior to casework commencing, a performance check will be conducted. For software, performance checks will be conducted by any DNA analysts. For excel macros, performance checks will be conducted by any DNA analyst other than the macro's creator. The results of the performance check will be documented on the appropriate QR (see appendix) and notes will describe reasons the performance check was performed. Acceptable parameters can be found on the DNA Quality Record(s). If acceptable parameters are not met, notify the DNA TL and a Section Manager.

9.19.4 Out of Service Software/Macros Notification

If a software/macro is not working properly, notification will be sent out to the DNA Unit through email by the Assistant Director, or designee. The issue, such as a bug in the macro code, will be investigated to try to correct the problem. The software/macro will remain out of use until it is deemed operational. Appropriate performance check will be conducted by the DNA analysts. For macros, performance checks will be conducted by the DNA analysts and the macro's creator. Documentation will be made on the appropriate QR sheet. After the issue has been remedied, the Assistant Director, or designee will notify the DNA Unit that the software/macro is fit for use in casework.

9.19.5 CODIS

There will be a quarterly performance check of the CODIS software following the directions on DNA QR-291 and the results will be documented on DNA QR-291. See DNA QR-291 for further details and guidance.

A semi-annual check of the CODIS search parameters will also be performed. An email will be sent by the CODIS administrator or alternate after the completion of this check. The Quality Manager maintains a copy of this email.

The integrity of the backup files will be verified on a quarterly basis. An email will be sent by the CODIS administrator or alternate after the completion of this check. The Quality Manager maintains a copy of this email. The CODIS administrator or alternate maintains all File Hash Comparison Reports in a designated binder.

9.19.6 DNA Software Risk Assessment

9.19.6.1 All software and software tools (e.g., macros, workbooks, databases)--whether internally or externally developed--have been evaluated to assess the suitability of the software for its intended use in the DNA Unit and to determine the necessity/extent of validation studies or software testing prior to its use in casework or database processing/analysis when software revisions are made. The evaluation, conducted according to forensic QAS standards 8.8 and

8.9/database QAS standards 8.9 and 8.10 and GL 22 has been documented and includes a risk assessment outlining which validation studies/software testing will be conducted for software revisions (see Appendix 2).

9.19.6.2 Software has been characterized as A) a component of instrumentation, B) used for analysis and/or interpretation of DNA data, C) used for statistical calculations, and/or D) not impacting the analytical process/interpretation/statistical calculations. Software in categories A, B, and C is generally considered "high risk" to DNA testing/analysis, while software in category D is typically "low risk". Validation of new software will include functional testing, reliability testing, accuracy and precision studies, sensitivity studies, and specificity studies, as described in forensic QAS standard 8.8/database QAS standard 8.9, wherever applicable to the particular software and to the extent that it does not interfere with the current analytical process. If any of these studies are not applicable to a software program, this will be documented. Data sets for future regression testing may be developed during validation. New software that does not impact the analytical process, interpretation, and/or statistical calculations will undergo at minimum a functional test prior to its use.

9.19.6.3 Revisions to software currently in use will be characterized as "Major" or "Minor" based on the nature and extent of the modification. For external software, release notes may assist in this characterization. Minor revisions will require only functional testing of the modified feature, if applicable. Major revisions will require at minimum functional testing, reliability testing, and regression testing for the program. The Technical Leader will approve whether a revision is considered Major or Minor.

9.20 **Autoclave**

Log each use of the autoclave on DNA QR-343. Notify the TL and the Maintenance Coordinator if there are any issues.

Appendix 1

Analysis and Statistic Software/Macros

Name	Description	QR	Location of QR
GeneMarker	Data analysis as needed (per guidance from TL)	DNA QR-294	Qualtrax
GeneMapper ID-X, including DNA QRs 330	Data analysis as needed (per guidance from TL)	DNA QR-294	Qualtrax
STRmix	Deconvolution and HPD calculation	DNA QR-306	S: Drive
Sequencing Analysis	Mitochondrial DNA Analysis	DNA QR-294	Qualtrax
Sequencher	Mitochondrial DNA Analysis	DNA QR-294	Qualtrax
DNA QR-44 Parentage Worksheet	Match Probability of Parentage Worksheet	DNA QR-280	Qualtrax

Y-Mix/YHRD	Y-STR Statistics	DNA QR-280	Qualtrax
DNA-QR-46 Probability of Kinship Worksheet	Kinship Probability workbook	DNA QR-278	Qualtrax
DNA-QR-307 Deconvolution Workbook – F6C	Deconvolution workbook - F6C	DNA QR-309	Qualtrax
DNA-QR-318 Deconvolution Workbook - GF	Deconvolution Workbook - GF	DNA QR-309	Qualtrax
DNA-QR-319 Deconvolution Workbook - YFP	Deconvolution Workbook - YFP	DNA QR-309	Qualtrax
DNA-QR-342 Supplementary GlobalFiler Stutter Filter	Supplementary GlobalFiler Stutter Filter	DNA QR-292	Qualtrax
DNA-QR-345 YFP Stutter Filter	YFP Stutter Filter	DNA QR-292	Qualtrax

Processing Macros

Name	Description	QR	Location of QR
DNA-QR-25,26,27 EZ1 Extraction Worksheets	EZ1 Worksheet - Knowns	DNA QR-292	Qualtrax
DNA-QR-25,26,27 EZ1 Extraction Worksheets	EZ1 Worksheet - Non Differentials	DNA QR-292	Qualtrax
DNA-QR-25,26,27 EZ1 Extraction Worksheets	EZ1 Worksheet - Differentials	DNA QR-292	Qualtrax
DNA-QR-314 Male Screen Extraction Worksheet	Extraction - Male Screen	DNA QR-292	Qualtrax
DNA-QR-313 Male Screen Concentration	Concentration Worksheet	DNA QR-292	Qualtrax
DNA-QR-24 Quantifiler Trio Worksheet	Quantifiler Trio Worksheet	DNA QR-292	Qualtrax
DNA-QR-22c,32 Dilution Worksheet and Quant Trio Report	Dilution Worksheet - GF	DNA QR-292	Qualtrax
DNA-QR-323 GlobalFiler Amplification Worksheet	GF Amplification Worksheet	DNA QR-292	Qualtrax
DNA-QR-324 Yfiler Plus Amplification Worksheet	YFP Amplification Worksheet	DNA QR-292	Qualtrax
DNA-QR-325 GlobalFiler Injection/Analysis Worksheet	GF/GFE Injection Worksheet	DNA QR-292	Qualtrax
DNA-QR-328 Yfiler Plus Injection/Analysis Worksheets	YFP Injection Worksheet	DNA QR-292	Qualtrax
DNA QR-326 GlobalFiler Express Amplification Worksheet	GFE Amplification Worksheet	DNA QR-292	Qualtrax
DNA-QR-327 GlobalFiler Injection/Analysis Worksheet - Database	GF Injection Worksheet for DB samples	DNA QR-292	Qualtrax
DNA-QR-20 Staff Search Worksheet	Staff Search	DNA QR-292	Qualtrax
Cross-Comparison & Staff Search Tool	Cross-Comparison/Staff Search	DNA QR-292	Qualtrax
DNA-QR-37 Concordance Checker	Positive Control Concordance Checker	DNA QR-292	Qualtrax
DNA-QR-301 Project Comparison Tool	Project Comparison Tool	DNA QR-292	Qualtrax
DNA-QR-302 Contributor Estimation Worksheet	Contributor Estimation Worksheet	DNA QR-292	Qualtrax
DNA-QR-303 STRmix Secondary Diagnostic Output Review	STRmix Secondary Diagnostics	DNA QR-292	Qualtrax
DNA-QR-304 STRmix Known Input File Generator	CO to STRmix Converter/Input file generator	DNA QR-282	Qualtrax
DNA-QR-346 Male Screen Results Worksheet	Male Screen Results and Testing	DNA QR-292	Qualtrax
DNA-QR-348 Allele Table Workbook	Allele Table Workbook	DNA QR-292	Qualtrax

Appendix 2. DNA Software Risk Assessment

Software	Source	QR(s)	Category*	Risk Assessment
Male Screen Worksheets	In-House	313,314	B	High
LIMS Worksheet	In-House	N/A	B	Low
EZ1 Extraction Worksheets	In-House	25,26,27	B	High
Quant Trio Worksheet	In-House	24	B	High
7500 Quant Software	Commercial	N/A	A	High
Quant Trio Report	In-House	32	B	High
Extraction Pos Tracker	In-House	N/A	D	Low
Halt at Quant List	In-House	48	D	Low
Dilution Worksheet	In-House	22c	B	High
Concentration Worksheet	In-House	28	B	High
Amplification Worksheets	In-House	323,324,326	B	High
Injection Worksheets	In-House	325,327,328	B	High
3500 Collection Software	Commercial	N/A	A	High
GeneMarker	Commercial	N/A	B	High
GeneMapper ID-X	Commercial	N/A	B	High
Stutter Macros	In-House	342,345	B	High
Concordance Checker	In-House	37	B	High
GMID-X Edit Record	In-House	330	B	High
Known PHR Filter	In-House	N/A	B	Low
DB Analysis Comment Chart	In-House	14h	D	Low
Project Comparison Tool	In-House	301	B	High
Contributor Estimation Tool	In-House	302	B	High
Cross-Comparison	In-House	N/A	B	High
Staff Search Form	In-House	20	D	Low
Staff Index Key	In-House	N/A	D	Low
Batch Review Spreadsheets	In-House	N/A	D	Low
Known Input File Generator	In-House	304	B	High
STRmix	Commercial	N/A	B,C	High
Secondary Dx Worksheet	In-House	303	B	High
STRmix Performance Check	In-House	309	D	Low
Deconvolution Workbooks	In-House	307,318,319	B,C	High
YHRD	Website	N/A	C	High
Y-Mix	External Lab	N/A	C	High
Parentage Stats Worksheet	In-House	44	C	High
Kinship Probability	In-House	46	C	Low

DB Match Estimator	In-House	N/A	B	High
CODIS	FBI	N/A	B,C	High
CODIS Maintenance Log	In-House	N/A	D	Low
DNA Report	In-House	N/A	D	High
Male Screen Results	In-House	346	D	Low
Allele Table Workbook	In-House	348	D	Low

***Categories:** **A** Component of Instrumentation **B** Used for Analysis/Interpretation
C Used for Statistical Calculations **D** Does not impact Analytical Process

Testing

Functional: Works correctly for task being automated.
Reliability: Works for multiple users/on network. Works up to identified limits.
Accuracy/Precision: Measurements and numerical values are correct.
Sensitivity: Identification of upper and lower limits.
Specificity: Robustness over different samples types, true and non-contributors.
Regression: Performance over same data set as previous version.