
Procedure for Performance Check of Qiagen BioRobot® Universal

- 1.0 Purpose** –To set forth testing methods and acceptance criteria for the performance check of the Qiagen BioRobot® Universal System used for the extraction of Database samples. The performance check shall be conducted (at a minimum) after repair, service or calibration or to QC a new lot of QIAamp® Media MDx Kit.
- 2.0 Scope** – This procedure applies to the DNA Database Section of the State Crime Laboratory. The Technical Leader shall be responsible for the protocol coordination and completion. The Technical Leader and qualified DNA Database Forensic Scientists who have completed the Qiagen BioRobot® Universal Training section of the DNA Database Section Procedure for DNA Database Training shall complete the sections of this procedure.
- 3.0 Definitions** – See the DNA Database Section Procedure for definitions applicable for this procedure.
- 4.0 Equipment** – This document provides an overview to procedures that are written in additional detail in specific DNA Database documents. To see equipment required for particular procedures, reference the appropriate document listed in the references section.
- 5.0 Procedure**
- 5.1 Operation of Robot**
- 5.1.1** Obtain at least one DNA sample with known alleles.
- 5.1.2** Using the DNA Database Section Procedure for Qiagen BioRobot® Universal, extract, amplify, run, and analyze at least two known DNA samples (may use the same known sample, extracted two separate times).
- 5.2 Criteria for Success**
- 5.2.1** Negative extraction control samples must not produce detectable peaks.
- 5.2.2** If multiple positive extraction controls are run, at least one must give a complete profile.
- 5.2.3** Database samples may be processed during the performance check. The database samples shall be accepted for use only after the performance check/QC samples have been analyzed and approved by the Technical Leader.
- 5.3 Actions to be Taken if Failure Occurs**
- 5.3.1** If any instrument (e.g., Qiagen BioRobot®, thermal cycler, 3130XL) fails during the test, the root cause shall be investigated and documented by the Technical Leader. The test may be repeated.
- 5.3.2** If one or more of the performance check samples fails to amplify or fails to generate a full profile, the root cause shall be investigated and documented by the Technical Leader on the Performance check/QC worksheet. If the cause is determined not to be the Qiagen BioRobot®, the results may be used and/or the test may be repeated at the discretion of

the Technical Leader. If the performance samples are retested and pass, the database samples processed with the first run may be used for CODIS purposes.

5.3.3 If the Qiagen BioRobot® does not pass the performance check, the root cause shall be determined. In these cases, any data from database samples processed with the performance check shall not be analyzed or used. The Qiagen BioRobot® shall be posted as not in use until such time as the root cause is determined and the Qiagen BioRobot® passes a performance check.

5.3.4 The Technical Leader shall perform corrective action in the case of a failed criterion.

5.4 Performance Check/QC Worksheet

5.4.1 A final performance check/QC worksheet shall be generated and approved by the Technical Leader prior to analysis/acceptance of any database sample profiles.

5.4.2 Standard documentation shall be included (e.g., extraction sheets, amplification sheets, etc.) with the Performance Check/QC worksheet. The robot batch number for all additional documentation is noted on the Performance Check/QC worksheet for reference.

5.4.3 Electropherograms of the appropriate ladders and controls shall be included with the Performance Check/QC worksheet.

5.4.4 All documentation may be maintained in hard copy or electronic format as authorized by the record retention schedule as set forth by the North Carolina Department of Cultural Resources.

6.0 Limitations – N/A

7.0 Safety – This document provides an overview to procedures that are written in additional detail in specific DNA Database documents. To see safety hazards for particular procedures, reference the appropriate document listed in the references section.

8.0 References

State Crime Laboratory Safety Manual

DNA Database Section Administrative Policy and Procedure

DNA Database Section Administrative Procedure for Safety and Hazardous Waste Disposal

DNA Database Section Procedure for DNA Database Training

DNA Database Section Procedure

DNA Database Section Procedure for Qiagen BioRobot® Universal

DNA Database Section Procedure for PCR Amplification with Identifiler™

DNA Database Section Procedure for Use of the 3130XL Genetic Analyzer

DNA Database Section Procedure for GeneMapper ID

DNA Database Section Procedure for DNA Database Analysis and Technical Review of Database Samples

DNA Database Section Procedure for DNA Reagent Preparation and Quality Control

DNA Database Section Procedure for Calibration and Equipment Maintenance

ABI Prism® 3100/3130/XL Data Collection Software, Applied Biosystems

Qiagen BioRobot® 8000 User Manual

Protocols for Sample ID Scan and Process Sheets, Pre-Offline Lysis Procedure, QIAamp DNA Swab and BloodCard UNIV rcV9, and Amplification Reaction Setup NCSBI

QIAsoft 5 Operating System User Manual

QIAamp® Media MDx Handbook

North Carolina Department of Cultural Resources Record Retention Schedule

9.0 Records

- Performance Check QC Documentation Notebooks
- BioRobot® Log Notebooks

10.0 Attachments – N/A

Revision History		
Effective Date	Version Number	Reason
12/18/2013	1	Original Document