A145 Internal Validation of an Automated Extraction Robot

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The goal of this presentation is to describe the internal validation of an automated extraction robot. Attendees of this presentation will learn how the extraction robot provides for an automated extraction using silica-based spin columns and the procedure by which a laboratory may internally validate such an instrument. The parameters used to validate the instrument will be defined and the methods to test them will be demonstrated for attendees. An example of the results of a successful validation of an automated extraction robot will then be given.

This presentation will impact the forensic science community because it will offer an internal validation plan that may serve as a template that can be applied to any automated technology new to forensic DNA analysis.

There are two levels of validation for any new instrumentation in forensic science. Developmental validation, the first level, is conducted by the manufacturer of new instrumentation during the design process. Internal validation, the second level, is performed within individual laboratories to confirm the results of the developmental validation. Protocols for the internal validation of new instruments are necessary so that forensic laboratories maintain a rigorous standard of integrity and credibility. This presentation will thus be beneficial to forensic science because it will offer an internal validation plan that may serve as a template that can be applied to any automated technology new to forensic DNA analysis.

The objective of this study was to validate an automated extraction robot for use in casework at the DNA Section of the Austin Police Department Forensic Science Division. The authors performed several studies within the framework of the validation. Blood and saliva samples were extracted on the extraction robot, quantified, amplified, and separated to verify that the resulting STR profiles were concordant with the known profiles for each sample. This part of the validation was intended to demonstrate the extraction robot's effectiveness at extracting DNA from different sample matrices. A series of four contamination studies were also completed, in which different configurations of alternating blood samples and reaction blanks were extracted on the robot, quantified, amplified, and separated in order to ensure that the instrument does not cause cross-contamination. A set of mixtures were also extracted on the robot and STR profiles developed to ensure that there was no interference in obtaining profiles composed of alleles from both donors. Reference samples traceable to the National Institute of Standards and Technology (NIST) and mock casework samples extracted on the robot were also analyzed with the objective of achieving fully accurate profiles. Finally, a sensitivity study was conducted using a range of DNA dilutions from 1:10 up to 1:200 to determine the lowest concentration of DNA that can be extracted on the robot and still result in a full profile.

The results of all blood and saliva samples achieved full concordance at all loci. All amplified reaction blanks from each of the four contamination studies contained no detectable DNA. Alleles found in all loci of profiles obtained from the mixture samples were consistent with the donors. Profiles from the NIST standards and mock case samples were determined to be fully accurate when verified against the appropriate references. For the sensitivity samples, full profiles were achievable at DNA concentrations with a lower limit of approximately

0.01 ng/µL.

From these results, this research has demonstrated the extraction robot's ability to extract DNA from a variety of sample matrices without introducing contamination, while maintaining a high level of accuracy and sensitivity suitable for forensic casework.

Automation, Validation, Extraction Robot

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