

VALIDATION OF THE APPLIED BIOSYSTEMS RAPIDHIT ID INSTRUMENT AND ACE GLOBALFILEREEXPRESS SAMPLE CARTRIDGE

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Forensic geneticists have continually worked towards reducing the amount of time and labor needed to generate STR profiles when processing biological evidence. Today, Rapid DNA platforms offer the forensic community a fully automated system capable of processing DNA from biological samples and interpreting the results in approximately 90 minutes with minimal human intervention. Operators of these Rapid DNA instruments can have widely varying backgrounds. Because there is a greater reliance on the system than on the analyst, data are needed to thoroughly define the performance and limitations of commercially available Rapid DNA systems. The RapidHIT ID System (Thermo Fisher Scientific) has been modified compared with the previous version of the instrument. Thus, the reliability and efficacy of the current RapidHIT ID System need to be evaluated.

Validation studies of a Rapid DNA workflow consisting of the Applied Biosystems RapidHIT ID Instrument and RapidLINK software with a focus on the ACE GlobalFiler Express Sample Cartridge and reference buccal swabs were completed at UNTHSC's Center for Human Identification (UNTCHI) in accordance with SWGDAM Validation Guidelines. Sensitivity studies demonstrated the dynamic range and limit of detection with buccal swab collections ranging from two to ten swipes. A contamination assessment was completed by interspersing un-used swabs in sample cartridges processed throughout the study. Swabs from 50 different individuals were processed on the RapidHIT ID instrument and on the 3500 Genetic Analyzer to evaluate concordance with traditionally used methodologies. Reproducibility and repeatability were assessed by processing replicate swabs in one day, across multiple primary cartridges, and across multiple instruments. Stability was evaluated by processing swabs that had been stored at time points ranging from zero to 12 weeks. The effect of common inhibitors was assessed by processing swabs collected from individuals immediately after consuming coffee or mouthwash, and after smoking a cigarette. Mixtures with contributor ratios ranging from 1:1 to 1:9 were also processed to determine the system's ability to differentiate between single-source and mixed samples. Due to the ability to remove the swab from the sample cartridge after processing, a study to assess the extent and success of reprocessing was performed. Performance metrics, including peak heights, peak height ratios, and profile completeness, were generated and collated from each study. Additionally, data from each of these studies were used to generate an overall first-pass success rate, assess precision, and identify artifacts.

Overall, the current Applied Biosystems RapidHIT ID Instrument with the ACE GlobalFiler Express sample cartridge was found to be a reliable tool for generation of STR profiles from reference-type buccal swabs. Data and resources generated at UNTCHI during the course of these validation studies could assist other forensic laboratories or agencies considering the use of RapidDNA technologies within a laboratory setting or remotely.