DEVELOPMENTAL VALIDATION OF THE RAPIDHIT™ 200 SYSTEM

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As Rapid DNA technology is poised to become an effective investigative tool for the identification of individuals through DNA profiling, the efficacy and reliability of Rapid DNA systems must be validated before they can be adopted into routine usage. Validation of integrated, sample-to-answer systems, such as the RapidHIT™ 200 Human DNA Identification System, involves careful determination of the relevant validation studies to perform and the appropriate number of samples for each study in the context of the intended use of the system. For end users in law enforcement, forensics and government agencies, the RapidHIT 200 System is designed for easy and fast generation of DNA profiles for STR-based human identification. From swab-in to profile-out, processes performed by the instrument can be broadly classified into cell lysis, DNA extraction and normalization, STR amplification, capillary electrophoresis (CE) and software processing of data to generate genotype. Using microscale fluid manipulations, the steps of cell lysis, extraction and amplification are integrated into disposable cartridge consumables, pre-loaded with assay reagents. Samples are transferred to a CE array for injection and separation, and software processes electrophoresis trace data to accurately size amplified fragments and identify the alleles present in the sample. Processed electrophoresis traces are reviewed by the expert user to confirm genotype calls. Developmental validation of the RapidHIT 200 System for analysis of buccal swab reference samples has been performed based on the requirements outlined in the Scientific Working Group on DNA Analysis Methods (SWGDAM) validation guidelines (December 2012) . The developmental validation was conducted with expert review of electrophoresis traces using an interpretation guide for analysis developed specifically for the RapidHIT 200 System. Data on species specificity, sensitivity, stability, reproducibility, precision and accuracy, and PCR-based studies will be presented along with data to address some of the unique aspects of validating an integrated sample-to-answer system. Details of the trace interpretation guide will also be presented.