

Validation of RapidHIT® ID and Assessment of the ACE and EXT Cartridges

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ABSTRACT

The Richland County Sheriff's Department (RCSD) forensic lab has been using Rapid DNA analysis tools for routine testing of forensic DNA for several years. RCSD was one of the first labs to use Rapid DNA platforms for matching criminal evidence to a suspect, and has used Rapid DNA data (for suspects) in a court of law. The RapidHIT System has enhanced the level of service the forensic DNA lab is able to provide to investigators by automating the steps of conventional DNA analysis.



Figure 1: RapidHIT-200 in routine use at RCSD

RCSD has been using the RapidHIT-200 System for Rapid DNA analysis since March 2014. The system is capable of producing up to 7 DNA profiles in a single run.



Figure 2: RapidHIT ID

Recently, IntegenX introduced a new sample-to-answer Rapid DNA platform, RapidHIT ID. The RapidHIT ID also provides a testing modality for forensic DNA samples in a very compact (<11" wide) footprint. With RapidHIT ID a user can test a single cartridge at a time.

In addition to the sample to answer cartridge (RapidHIT ACE), the manufacturer also developed a second cartridge (RapidHIT EXT) that allows a user to run a forensic DNA profile from extracted, quantified DNA in less than 90 minutes.



Figure 3: RapidHIT EXT Cartridge

In this poster, we describe selected studies from the internal validation of the RapidHIT ID using buccal samples in the complete sample to answer format (ACE), as well as data generated on the cartridge using extracted and quantified DNA (EXT). The RapidHIT ID had 100% correlation to conventional bench methods for both the ACE and the EXT cartridge.

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RESULTS

CONCORDANCE

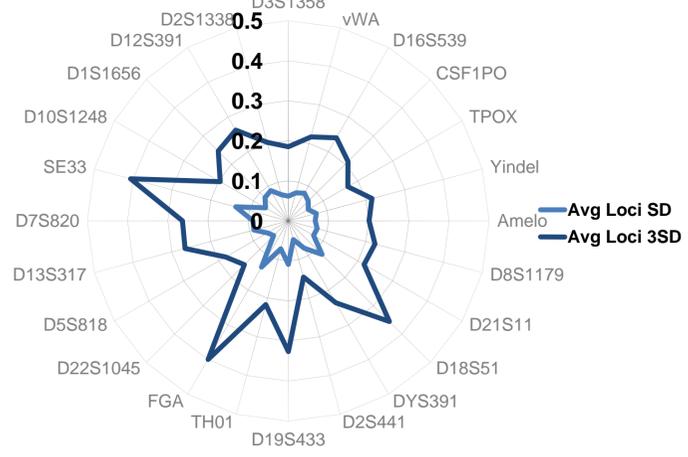
Table 1: 100% Concordance Between Conventional Process and Validated RapidHIT Systems. Four sets of blood samples were prepared from a female donor by applying fresh whole blood in varying amounts to sterile swabs. All common loci in GlobalFiler® Express were concordant across all four runs.

Varying Amounts of Whole Blood Applied to Swabs	Conventional Bench Method ¹	RapidHIT 200	RapidHIT ID Instrument 1	RapidHIT ID Instrument 2
3 uL	✓23	✓22	✓22	✓22
6 uL	✓23	✓22	✓22	✓22
12 uL	✓23	✓22	✓22	✓22
24 uL	✓23	✓22	✓22	✓22
48 uL	✓23	✓22	✓22	✓22

¹ DNA Quantitated on QuantiFiler® (Applied BioSystems), amplified on PowerPlex Fusion® (Promega), and typed on a 3130xl Genetic Analyzer (Applied BioSystems)

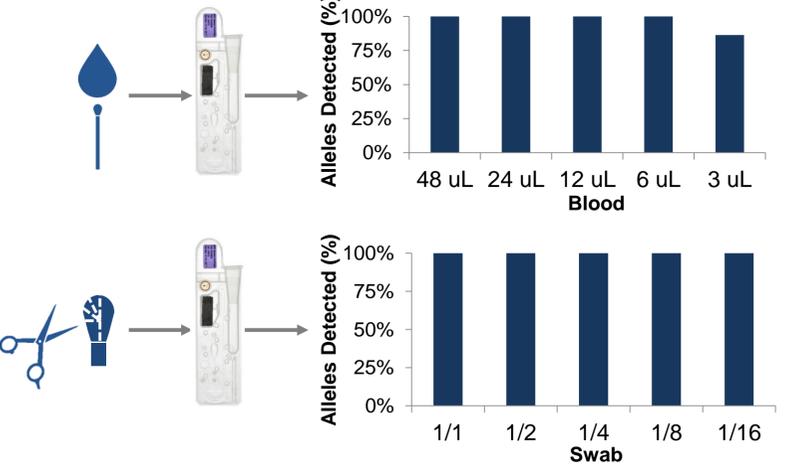
PRECISION

Figure 4: Sizing Variability of All GlobalFiler Alleles Within 3 Standard Deviations. Ten RapidHIT GlobalFiler Express Control Cartridges were analyzed for run-to-run variation on the RapidHIT ID instrument. A +/- 0.5 base pair window was examined for designation of alleles at any particular locus. Standard deviations calculated for each allele at each locus indicated all alleles fell within the 1 base pair window. Therefore, the RapidHIT ID demonstrated required precision within a +/- 0.5 base pair window for all alleles tested.



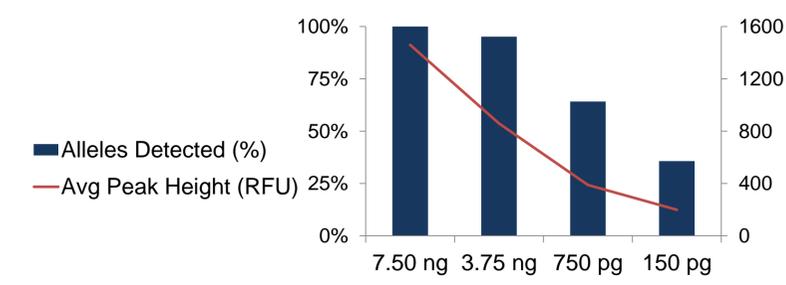
ACE SENSITIVITY

Figure 5: Sensitivity of RapidHIT ACE Sample Cartridge. A set of blood samples was prepared by applying fresh whole blood to sterile swabs. A second set of buccal swabs were collected and cut. Both sets were analyzed with the ACE Cartridge. Number of loci with correct genotypes are noted below.



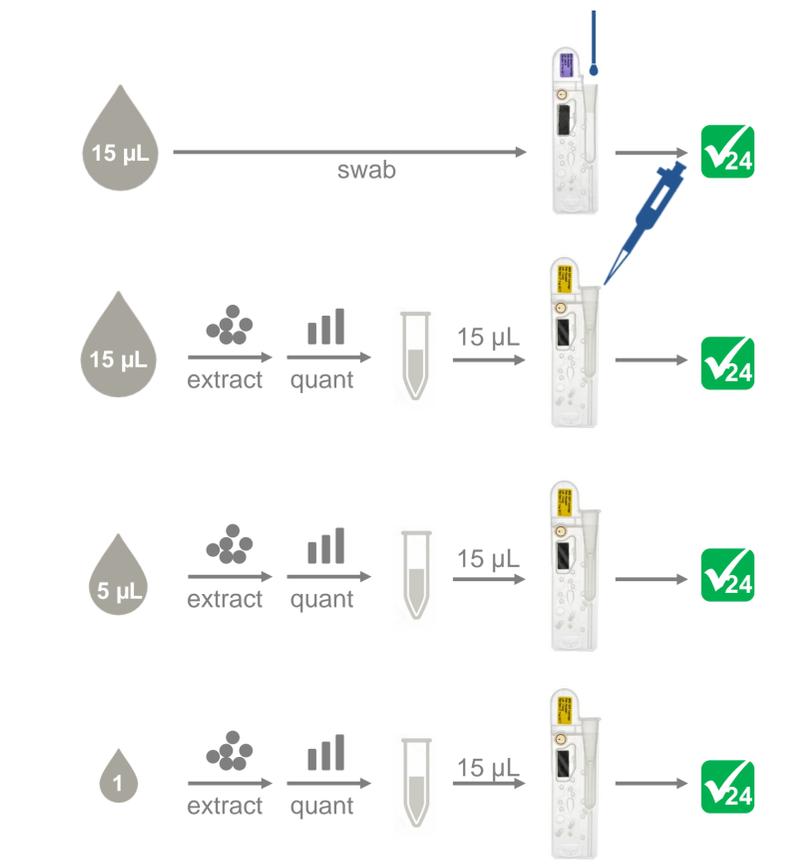
EXT SENSITIVITY

Figure 6: High sensitivity of EXT Sample Cartridge. It is important that the system analyzing unknown samples from crime scenes can produce profiles from low template samples. A study of varying DNA concentrations with 15 uL input volume yielded profiles with as little as 150 pg of DNA.



ACE and EXT CARTRIDGES

Figure 7: Concordant Results Between ACE and EXT Sample Cartridges. Four whole blood samples of varying volume from the same donor, were processed with the RapidHIT ID ACE and EXT cartridges. One sample was applied directly to the swab and run with the ACE cartridge. Three samples were extracted, quantified, and run with the EXT cartridge. All 24 common loci in GlobalFiler Express chemistry were concordant across all runs.



CONCLUSIONS

Internal validation of the RapidHIT ID System with varying DNA samples produced accurate, high quality, forensic DNA profile concordant to those generated using traditional bench methods. There is a significant advantage associated with Rapid DNA methods saving a significant amount of labor, freeing RCSD staff to concentrate on other activities, including analysis. Results from samples run on the rapid

platform with the EXT Cartridge post-evaluation were uploaded to our state database (SDIS), and ultimately to CODIS. The new RapidHIT ID cartridge system is an accurate, reproducible, cost-effective method when compared to our conventional bench methods, and offers certain flexibility even beyond the established RapidHIT-200.