

RapidHIT[®] NEWS

RapidHIT[®] provides DNA processing from sample to profile, in under 2 hours

Key Forensic Services is the First in the World to Purchase Multiple Units of the NEW IntegenX RapidHIT[®] ID System.

KFS is the first organisation in the world to take receipt of the new RapidHIT[®] ID from IntegenX. The multi-unit purchase will enable KFS to offer the second-generation rapid DNA instrument and disposable cartridge system to all of its customers. KFS will validate and accredit the RapidHIT[®] ID System thus introducing an additional platform for fast human identification services to police forces in the UK.

The RapidHIT[®] ID is designed for ease of use, and with a footprint approximately 25% of the size of the original RapidHIT[®] System, the RapidHIT[®] ID system can be utilised in any location. The RapidHIT[®] ID uses leading industry-standard chemistries and generates DNA profiles from mouth swabs that are compatible with the UK National DNA Database[®]. The significant advances in cartridge and instrument design also incorporate numerous efficiencies that make forensic profiling faster and easier than ever, as well as having the potential to be more cost-effective. This should further enable rapid DNA testing to move closer to facilities such as custody suites.

"This is another seismic shift in rapid DNA technology. The smaller, faster and more cost-effective RapidHIT[®] ID system will deliver significant benefits to the UK Criminal Justice System by enabling samples taken from arrestees to be searched against the UK NDNAD before they are released from custody. The cost savings to the UK CJS as a whole may be, at this stage difficult to quantify, but common sense tells us they will be very substantial indeed. In times of austerity this is the type of transformational technology that government, police forces and other law enforcement organisations should be very interested in this technology." Said Paul Hackett, KFS Managing Director.

This new, compact instrument boasts an impressive array of features:

- Incredibly compact footprint, can be placed anywhere.
- NGM SElect[™] or GlobalFiler[®] DNA profiles in less than 90 minutes.
- Intuitive touchscreen interface.
- On board system training videos, experience guide, and ordering information.
- Less than 1 minute of hands-on time using compact, single, room-temp cartridge, providing up to 250 samples per cartridge.
- On-board facial recognition and barcode reading.
- Password protected user access with fingerprint, facial recognition or user input.
- No maintenance required.



RapidHIT[®] ID

integenX



The story so far...

Since the last edition of RapidHIT[®] News some major developments have taken place.

It has been an exciting journey; KFS has devoted the last three years to the validation and accreditation of the RapidHIT[®] technology and to live field-trials with customers.

Working in concert with our colleagues at IntegenX Inc., our dedicated team has worked very hard to validate and fully characterise the performance of the RapidHIT[®] technology for the processing of buccal swabs. The validation work specifically addressed the areas of software performance, profile concordance and success rates. It concluded that the RapidHIT[®] performs to a standard that is comparable to other profiling systems currently in operation within the UK Criminal Justice System.

Alongside the success of the police force trials of the RapidHIT[®] technology, our team was also working on accreditation for the system and we announced the award of ISO17025 accreditation by UKAS in August 2015.

This makes Key Forensic Services the world's first forensic organisation to obtain ISO17025 accreditation for rapid DNA technology, allowing the DNA profiles generated by KFS to be uploaded to the UK National DNA Database[®].

This led to the launch of our new same day DNA profiling service for the processing of mouth swabs. The RapidHIT[®] system takes approximately two hours to produce a DNA profile, which is a radical reduction of the time taken using traditional DNA processing techniques.

KFS is now in the final stages of validating the RapidHIT[®] for a range of other sample types and body fluids and is aiming for ISO17025 accreditation in early 2016.

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Experienced scientists delivering forensic effectiveness, unquestionable integrity, focused customer service and value for money.



Key Forensic
Services Limited

Lancashire and EMSOU Pilot Projects

At the end of last year, Home Office Innovation Funding provided two of our police force customers, Lancashire Constabulary and the East Midlands Special Operations Unit - Forensic Services (EMSOU-FS) with the means to acquire and test the RapidHIT® technology in a live policing environment.

RapidHIT®NEWS takes a look at these two projects:



Lancashire Constabulary

Lancashire Constabulary's Scientific Support Unit has been trialling the RapidHIT® technology since October last year to mostly support the investigation of Volume Crime offences. During this time, around 250 casework samples have been processed using the RapidHIT® instrument.

The majority of samples processed have been blood stains submitted by Lancashire's own screening laboratory. Success rates from these samples have been high and results have been used as intelligence in a wide range of Volume Crime cases.

Some case examples are shown below:

Bicycle Thefts

Since the beginning of May, the South Lancaster area had seen a large amount of burglary offences (over 20 offences with similar MO in close proximity) where expensive pedal bikes were being targeted. No intelligence/evidence existed as to identifying the offender(s).

A shed was broken into overnight at a property and 2 high value mountain bikes stolen (approx. value £3K). Blood was recovered from inside a shed a few hours later by Lancashire's CSI team. The blood swab was processed using the RapidHIT® and an intelligence result was obtained from the National DNA Database on the same day.

A suspect was located and arrested and admitted to carrying out the offence with 2 other unidentified males. He was remanded straight to court and has since been sentenced to 12 weeks imprisonment.

The two bikes from this offence were recovered along with various parts which were identified as being from other bikes stolen in previous burglaries.

The blood recovered in this offence was crucial to the investigation into this series of offences, as a previously unknown offender was identified and charged within 48 hours of the offence being reported. Whilst the offences have still continued, it is believed that one of the main offenders has been removed. In this instance the male was identified in approx. 48 hours from the offence being reported using the RapidHIT® instrument compared with a minimum TRT of 7 days using conventional DNA profiling techniques.

Approx. 2 days from report of incident to offender being charged.



Seen here with the RapidHIT® instrument (in a non-operational environment), is Lancashire's **Dr Kath Mashiter MBE, Scientific Support Manager.**



Vehicle Thefts

Vehicle thieves using glass cutting equipment made a hole in the kitchen door of a dwelling and removed keys to 2 vehicles. Other valuable items were left in situ. Only one of the vehicles was driven away from the property by the offender(s).

Blood was recovered from the kitchen floor and the kitchen door by Lancashire's forensic team and were processed on the RapidHIT® instrument.

The stolen vehicle was located and 3 males were detained prior to any forensic result being obtained.

An intelligence name was obtained from the National DNA Database® from the sample processed using the RapidHIT®. The male that was identified was not one of the 3 males who had been in custody.

The RapidHIT® result was able to quickly identify another individual who was potentially involved in this case. This individual was associated with the 3 males who were previously held in custody, via a drugs connection and lived in close proximity to the burgled property.

Because of the timeliness of the RapidHIT® result (i.e. before the PACE clock expired), the bail applications for the 3 males were avoided, which reduced the amount of officer time required to deal with the bails. This case is still currently under investigation as to the involvement of all 4 males in this offence and no further details are available at present.

Approx. 2 days from crime being reported to identification of a possible additional offender.

Kidnapping

A kidnapping took place in Blackburn, the victim, who owed £20k to a drugs gang, was dragged from a stationary vehicle by named offenders and placed in the boot of a hire car (white Mercedes) being driven by one of the offenders.

Whilst in the boot of the car the kidnap victim spat onto the boot liner in order to mark his presence. He was subsequently stripped of clothing, assaulted and released. The named individuals were later arrested and a white Mercedes was located outside one of the addresses and recovered.

Lancashire's forensic team was asked to screen for the presence of Saliva in the boot of the vehicle and subsequently identified saliva in the same area as described by the victim. The area indicated was processed and an intelligence result was obtained from the database which matched the IP later the same day.

Vehicle keys and a hire car agreement located inside a secure property belonging to one of the named offenders were recovered.

The named offenders were charged prior to the sample being processed. However, by processing the neat saliva sample using the RapidHIT® instrument and obtaining a link between the victim and the vehicle and subsequently the named offenders, a large amount of seized exhibits (drinks containers/offenders clothing etc.) were pended as a result of the RapidHIT® result. This delivered a saving of at least £2.5k on the forensic costs. In addition, the amount of time officers needed to investigate this case was greatly reduced.

Approx. 3 days from report of incident to establishing a link between the victim and vehicle (corroborating victim's and witness' version of events).



Commenting on the deployment of the RapidHIT® technology in these and the numerous other Volume Crime cases, Forensic Specialist Helen Jones said:

"The RapidHIT® instrument has proved to be invaluable in our Volume Crime investigations and as well as bringing offenders to justice, has resulted in a good deal of victims' property being successfully recovered, due to the speed of the results. Thanks to the RapidHIT®, we have been able to intervene before thieves have had a chance to move the goods on."



EMSOU-FS

In October last year the East Midlands Special Operations Unit – Forensic Services (EMSOU-FS) began working in partnership with Key Forensic Services after successfully securing Home Office Innovation Funding to trial RapidHIT® technology. After a period of confidence testing and ensuring compliance with Forensic Science Regulator's Codes of Practice, in February 2015 EMSOU-FS started to process live casework samples utilising RapidHIT®, to date 228 casework samples have been processed from both volume and serious crime, which are currently restricted to blood swabs.

The benefits of rapid DNA technology are of particular interest to the Police Service if 'Faster, Cheaper, Better' outcomes can be achieved in forensic related investigations.

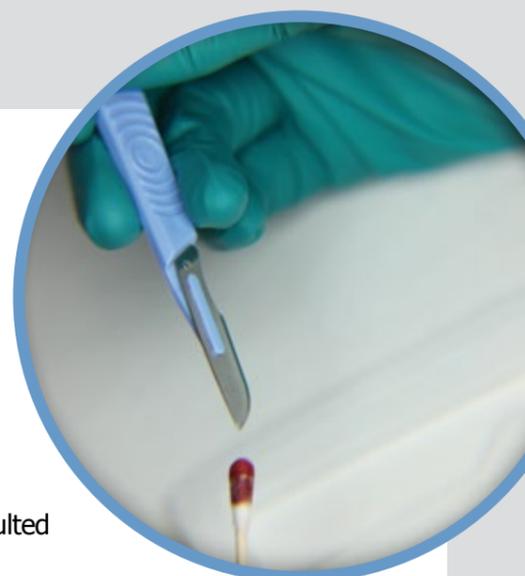
Some case examples are shown below:

Shop Burglary

An unknown suspect smashed glass in a front door of a shop premises. Originally the offence was thought to be connected to a series of Burglary Dwellings. Blood was recovered, by CSI, from the scene, the same day that the offence was reported. This was then submitted as part of the RapidHIT® pilot and a profile suitable for searching the National DNA Database® was obtained, resulting in a positive match. This positive identification was submitted to the investigation team within hours of being received from the NDNAD.

The timely results enabled the DC to eliminate a potential suspect immediately and refocus the investigation. The OIC then checked the suspect against incidents occurring on the night of the alleged offence and obtained a match to other offences. In interview the subject alleged he'd been assaulted whilst high on drink and drugs but admitted he had assaulted a paramedic before going to hospital for maxillofacial treatment.

The subject has been subject of a Voluntary Interview under Caution and Reported for Summons in respect of offences of Criminal Damage and Assault, he received a Community Order, compensation costs to pay of £150.00 and an Unpaid Work Requirement.



Investigative Value – Elimination

A sample recovered from a Burglary Dwelling was processed through RapidHIT® whilst a suspect was in custody. This suspect stated that the blood was not his. A second suspect was known to the investigation team. At 15:52 on 09/03/2015 KFS advised that a partial DNA profile was obtained which was submitted to the NDNAD for an urgent speculative search whilst a suspect was in custody.

A result was received from the NDNAD at 10:03 on 10/03/2015. An intelligence memo was immediately sent to the investigation team at 10:14 the same day.

The match identified the co-accused and not the primary suspect but within the custody time limits. Consequently charge of correct suspect and focus of investigation and enquiries was achieved.



Cannabis Cultivation un-earthed

An offender attempted to gain entry to a dwelling property by kicking and smashing the bottom double glazed unit to a rear UPVC door. After processing the blood swab using the RapidHIT® a positive match was obtained to a subject on the NDNAD. On arrest, officers discovered cannabis cultivation and stolen property from two other burglaries. The offender was charged with attempted burglary from the original blood identification and a further three burglaries, the rapid turnaround had no doubt contributed to this excellent result.

Cost Savings

In order to expand the scope of the RapidHIT® pilot and gain best value from the resources available serious cases are now being considered for processing utilising this rapid DNA technology. In a section 18 GBH offence, a submission requesting the analysis of 8 Blood Swabs recovered from the point of entry was made. At least two offenders were believed to have sustained bleeding injuries. A significant cost saving was made by processing via RapidHIT® and not submitting in the usual manner.

Commenting on the use of the innovative rapid DNA technology in these and other investigations, EMSOU Regional Director of Forensic Services, Jo Ashworth OBE said:

“Myself and the team at EMSOU have been extremely impressed with the results produced by the RapidHIT® instrument. It has provided us with the means to significantly speed up routine and exceptional investigations and get a result, whether that be an early exoneration (saving investigative time) or a timely arrest and charging of a suspect, before they have the opportunity to offend further.”



‘It is vitally important to effective policing to be able to identify and charge a suspect in the shortest possible time so that they can be taken off the streets as soon as possible. RapidHIT® gives us an un-rivalled means to do this and I am delighted that this technology is setting a new benchmark in forensic investigation’”

Commenting on the success of both the Lancashire and EMSOU RapidHIT® trials, KFS Group Managing Director, Paul Hackett said:

“The testing of the RapidHIT® technology in live policing environments has been of immense value, providing us with valuable feedback on the RapidHIT® system and allowing our customers to experience, first hand, the real difference that the technology can make to day to day policing. We are now focused on validating and testing the technology for use in casework, where it can be deployed for use in major investigations, providing tangible benefits in facilitating the early identification of dangerous offenders and providing a financial benefit by significantly reducing the costs of running a major incident room.””



Validation of a Rapid DNA Process Using a Platform Optimized for a Decentralized Environment

RapidHIT® ID

Arnaldo Barican, Jacklyn Buscaino, Kaiwan Chear, Stevan Jovanovich, Jim Klevenberg, David King, Dennis Lehto, Frank Lin, Phong Nguyen, Charles Park, Francesca Pearson, Robert Porporato, Susana Salceda, Sayali Salodkar, Robert Schueren, Corey Smith, Dean Tsou, Mattias Vangbo and Justus Wunderle. IntegenX Inc. 5720 Stoneridge Drive, Pleasanton, CA 94588

Introduction

The FBI vision for Rapid DNA is to collect and test samples at time of arrest. With the introduction of HR320, The Rapid DNA Identification Act of 2015 in Congress and the Maryland. v. King decision, the overall judicial and legislative path is now being cleared at the federal level in the USA. Appropriate quality assurance standards are being worked on and the process to upgrade CODIS is underway. Similar activities are occurring globally.

IntegenX has developed a next generation Rapid DNA instrument, RapidHIT® ID, specifically to meet the needs of decentralized environments. Decentralized environments demand very short sample-to-profile time, e.g. include booking stations, border patrol, small-scale forensic labs. The RapidHIT® ID system is a fully automated, sample-to-CODIS file system for STR-based human identification. RapidHIT® ID processes reference samples and generates CODIS compatible output in less than 90 minutes with less than one minute hands-on time. The system uses a low-cost, single-use consumable for each sample. Bulk reagents and the capillary electrophoresis module are in a 250-use "printer toner"-like cartridge. RapidHIT® ID uses NDIS approved chemistry and an expert data analysis system along with a built-in fingerprint reader and camera for authenticating access and documentation. Ladder and control cartridges are in identical format to a sample cartridge.

More specifically, the RapidHIT® ID makes use of:

- GlobalFiler® Express (Part Numbers 4474665 & 4476609 - NDIS Operational Procedures Manual, Appendix E)
- Capillary gel electrophoresis with optical detection, and
- Expert System allele calling software (GeneMarker® HID, SoftGenetics, LLC)

RapidHIT® ID leverages and improves much technology from the internally-validated RapidHIT® platform (Hennessey et al., 2014). The RapidHIT® system has been used to upload hundreds of rapid DNA profiles into CODIS and NDAD.



Swab Reuse

To demonstrate the simplicity of swab re-use, a buccal swab that had been processed on a RapidHIT® ID was manually removed from the sample cartridge and re-processed on the bench following the package insert for GlobalFiler®

Express: extraction using Prep-N-Go™ (Thermo Fisher), amplification using Applied Biosystems GeneAmp® PCR System 9700 and detection using Applied Biosystems® 3130xl.

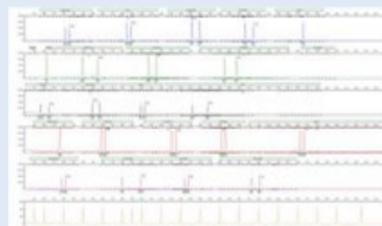


Figure 3. GlobalFiler® Express profile resulting from manual bench processing, demonstrating the ability to produce high-quality profiles from the same swab after processing on the RapidHIT® ID.

Carryover and Concordance

A set of unique donor buccal swabs (10 individuals) was processed on RapidHIT® ID along with 5 blanks in a quasi-checkerboard pattern to determine carryover, contamination and concordance. Genotype concordance was checked against reference profiles generated from the GlobalFiler® Express runs on the ABI 9700/3130xl instruments and analyzed with GeneMarker HID 2.7.2 software. All profiles were fully concordant with their respective genotypes in the reference database. No alleles were called in the blanks. No evidence of contamination or carryover genotypes was detected.

Repeatability

Nine 1000M control swabs loaded with 100,000 cells were processed on RapidHIT® ID by three different operators. All samples were fully concordant with reference profile. This result is largely due to the minimal interaction an operator has with the RapidHIT® ID.

Consumables

The RapidHIT® ID system employs a single-use, disposable sample cartridge that is pre-loaded with all assay reagents (GlobalFiler® Express STR reagents). The GlobalFiler® Express STR reagents enable direct multiplex PCR amplification, eliminating the need to perform DNA extraction or purification steps. In addition, we are developing capability for AmpF!STR® NGM SElect™ (ThermoFisher) and various swab types.



Figure 1. Front and back view of sample cartridge. The bulk reagents, waste and the electrophoresis capillary are housed in a 250-use replaceable

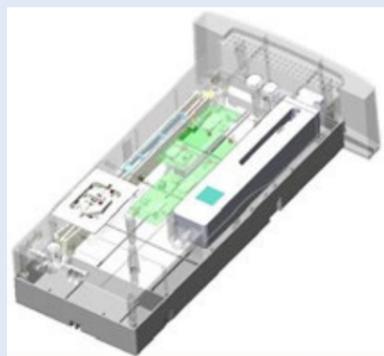


Figure 2. Cut-away view of primary cartridge

Standard deviation of each allele size was measured for approximately one thousand alleles using allelic ladders processed on a RapidHIT® ID.

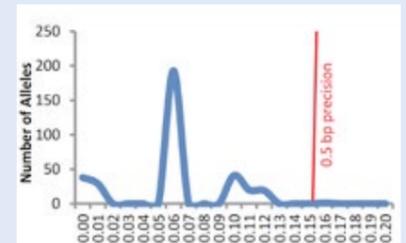


Figure 4. Histogram of all standard deviations measured shows better than 0.5 bp precision assuming three times the standard deviation as the precision limit.

PCR-based Studies

Boundary studies of the optimized thermal cycling parameters were conducted to verify the performance conditions selected for the GlobalFiler® Express assay. Three 1000M control swabs loaded with 100,000 cells were used to test each of the thermal cycling parameters. The following thermal cycling parameters were examined, with the standard conditions indicated in bold: annealing and extension temperature: 58°C, 60°C and 62°C; final extension time: 6 min, 8 min and 10 min; cycle number: 27, 28 and 29 cycles. Final results show robust performance to changes in PCR conditions.

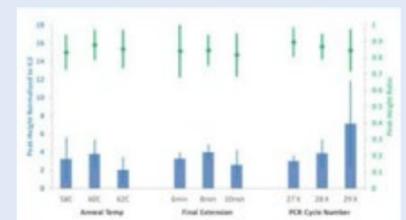


Figure 5. PCR boundary study results show that average peak heights and heterozygote peak height ratios (average ± SD) were not significantly different from optimized PCR conditions.

Conclusions

- The RapidHIT® ID system has completed Developmental Validation for analysis of reference buccal swab samples following current SWGDAM guidelines with 100% genotype concordance.
- The RapidHIT® ID demonstrates highly robust performance over a wide range of operating conditions.
- RapidHIT® ID represents a quantum advance in rapid DNA technology with unparalleled ease-of-use and economics.

References

- National DNA Index System (NDIS) Operational Procedures Manual. FBI Laboratory, Version 3, Effective January 1, 2015
- GlobalFiler® Express PCR Amplification Kit User Guide. Pub. N° 4477672. Thermo Fisher Scientific.
- Hennessey, L. K. et al. Developmental validation of the GlobalFiler® express kit, a 24-marker STR assay, on the RapidHIT® System. Forensic Sci. Int. Genet. (13) 2014 247-258
- Scientific Working Group on DNA Analysis Methods (SWGDAM). Validation Guidelines for DNA Analysis

RapidHIT®



first live sample results in conviction of sex offender, just hours after its UKAS accreditation.

The very first reference sample generated by the RapidHIT® technology, a mere 36 hours after it was accredited to ISO17025, produced a match to DNA recovered from the victim of a serious sexual assault. The suspect's DNA sample was rushed to the KFS laboratory in Warrington, where, using the RapidHIT® instrument, we generated a profile in two hours. His DNA profile was compared against DNA obtained from intimate samples taken from the victim and was found to match.

The suspect was charged and faced with this compelling forensic evidence pleaded guilty to the serious sexual assault. Thanks to our rapid DNA service the offender was prevented from being released on bail, to possibly re-offend. He was sentenced to nine years imprisonment.

RapidHIT®... Rapid Justice.

Fast Exoneration of rape suspect using RapidHIT®

RapidHIT® rapid DNA technology was used to exonerate a suspect, arrested for a vicious stranger rape.

The East Midlands Specialist Operations Unit (EMSOU) submitted a PACE sample to Key Forensic Services, which was analysed and searched against the National DNA Database® in a staggering 3 hours and 8 minutes, from receipt of the sample

at our lab. The arrestee's DNA sample did not produce a match and the suspect was released. East Midlands Region investigators were immediately able to renew their search for the perpetrator, losing only a few hours of pursuit time as opposed to at least 24-48 hours if traditional DNA profiling had been used.

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