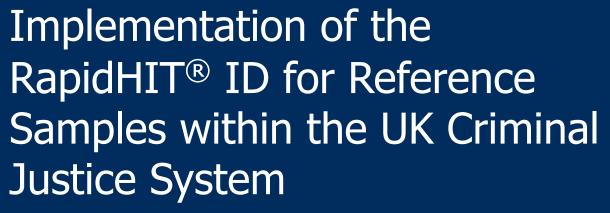




David Shackleton



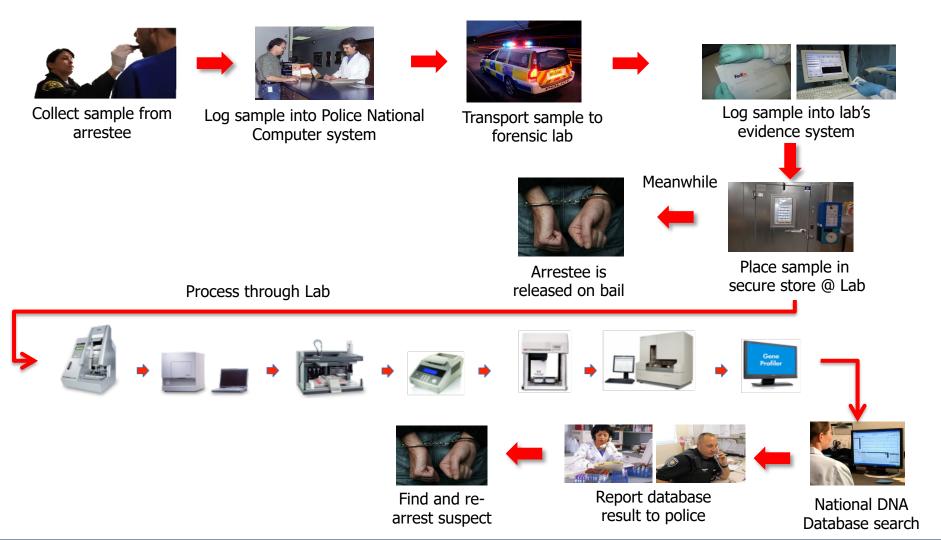


Human Identification Solutions (HIDS) Rome, May 2018





Life of a PACE Sample





Aims for Technology

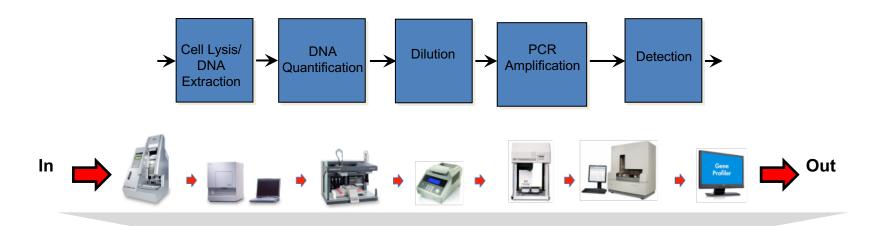
- Rapid DNA process in less than 90 minutes
- Fully concordant DNA17 profiles

Aims for Implementation

- At least 95% of buccal profiles suitable for loading to the National DNA Database without reworking
- Instrument suitable for deployment in custody suite and other, non-laboratory, environments
- Data handling and KFS processes compliant with the relevant legislation (PoFA, CPIA, Data Protection Act, etc.)
- All tracking measures are in place to ensure that chain of custody and process pathways can be identified for all samples processed using the RH-ID technology



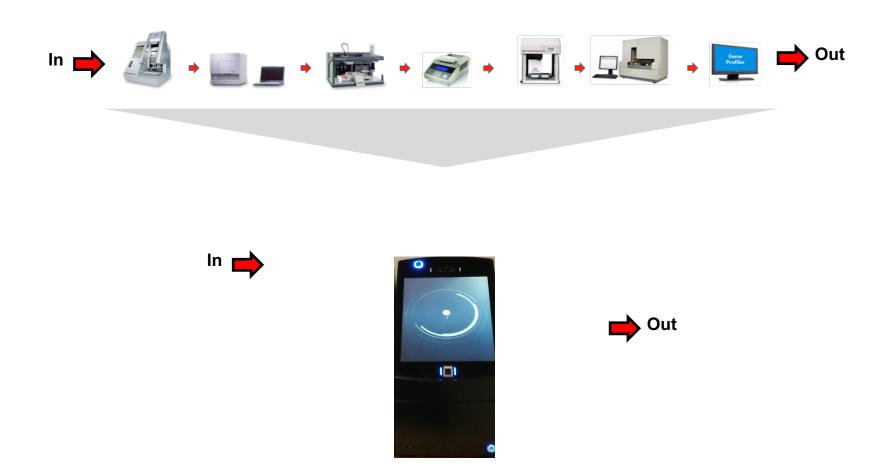
What is the RapidHIT® ID?







What is the RapidHIT® ID?





Sample Cartridges

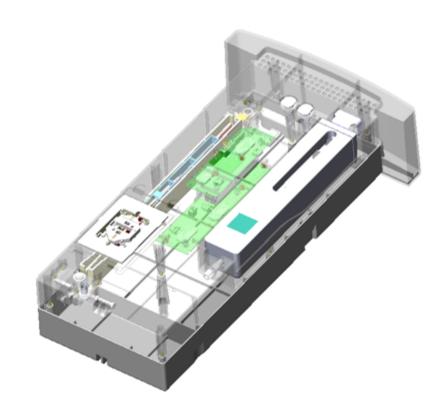


- Single Use
- RFID tagged (Expiry/Usage/Chemistry)
- Contains
 - PCR reagents (2x vials)
 - CE Loading cocktail (1x vial)
 - Absorbent waste pad



Sample Cartridge & Primary Cartridge

- 150 or 250 samples
- RFID tagged (Expiry/Usage)
- Contains
 - Lysis Buffer
 - Capillary array
 - Gel syringe
 - CE Buffers
 - Waste



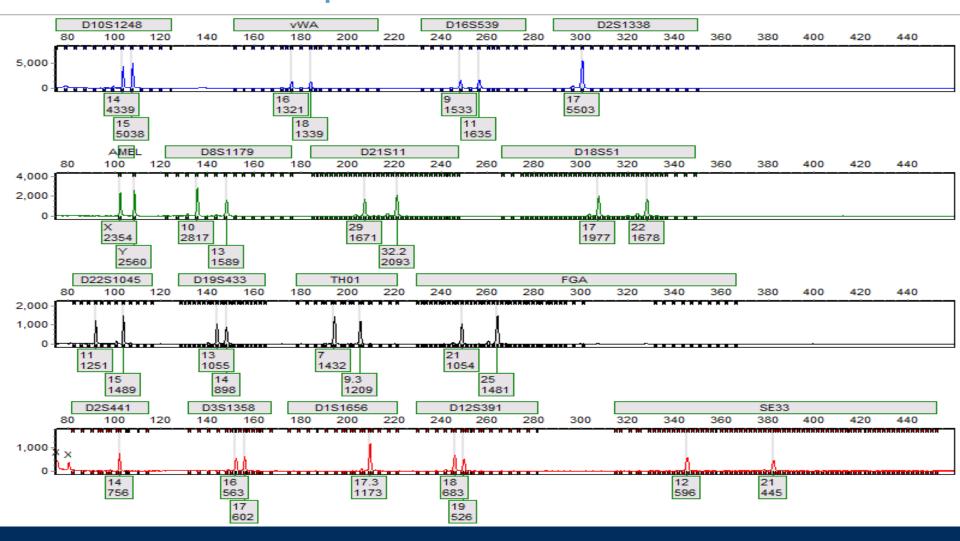


KFS Development – Optimisation

- Lysis
 - Volume (completed by IntegenX)
 - Temperature
 - Time
- PCR
 - All Parameters
- CE
 - Injection time
 - Injection Voltage

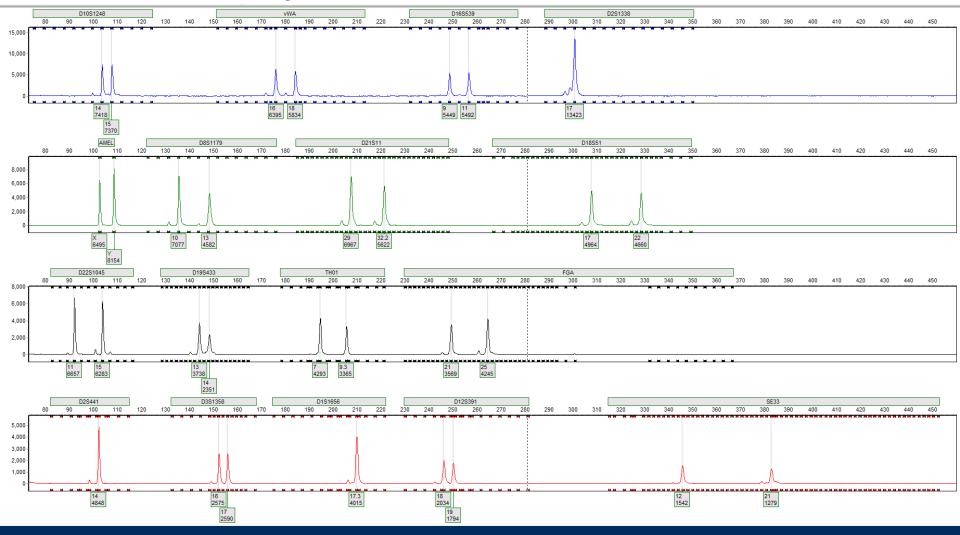


Profile Before Optimisation



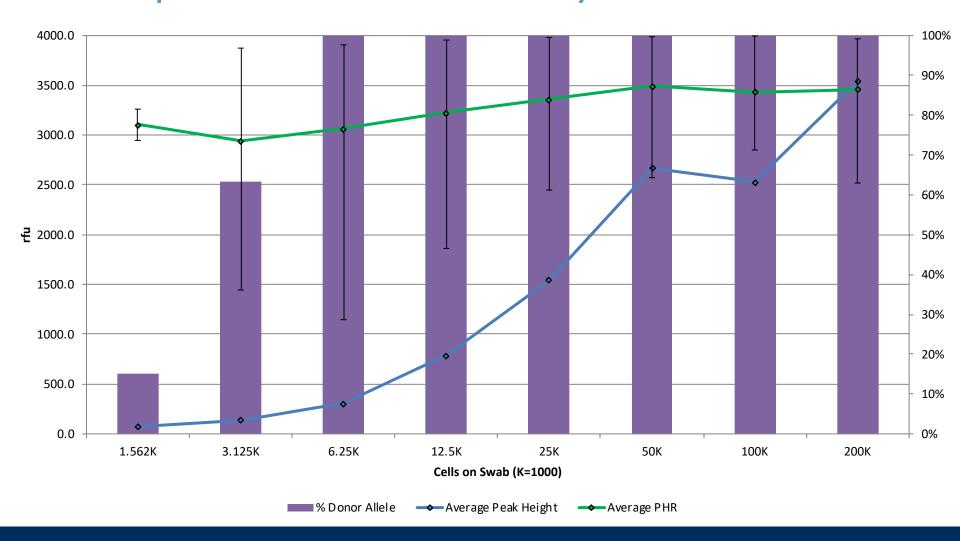


Profile Post Optimisation





Development Work – Sensitivity





Development & Validation Work – Profile Success & Concordance

Manual review thresholds set

Limit of detection 35rfu

Homozygotes 350rfu

Peak height ratio 40%

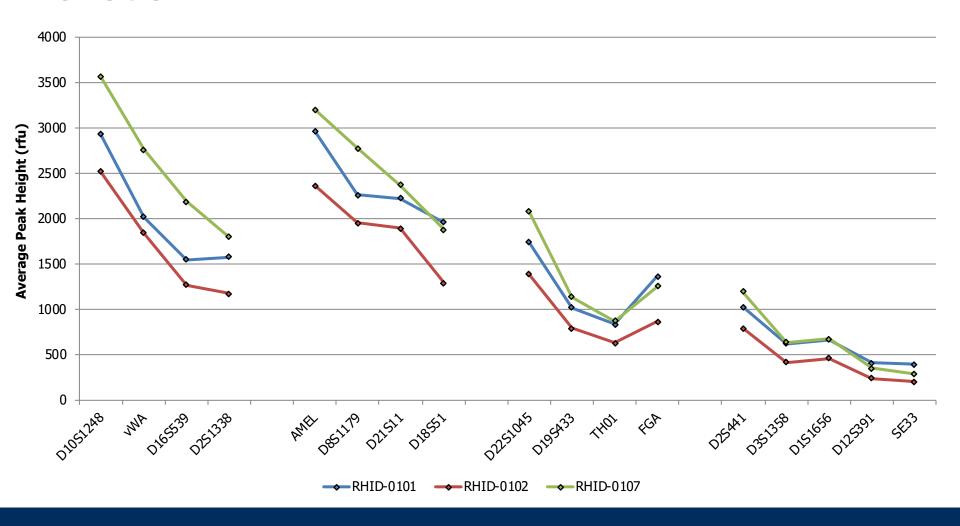
± Stutter
 Variable by locus

96.8% Full profile
 (150/155 sample on final method/analysis parameters)

All labelled peaks were concordant with the expected donor profile

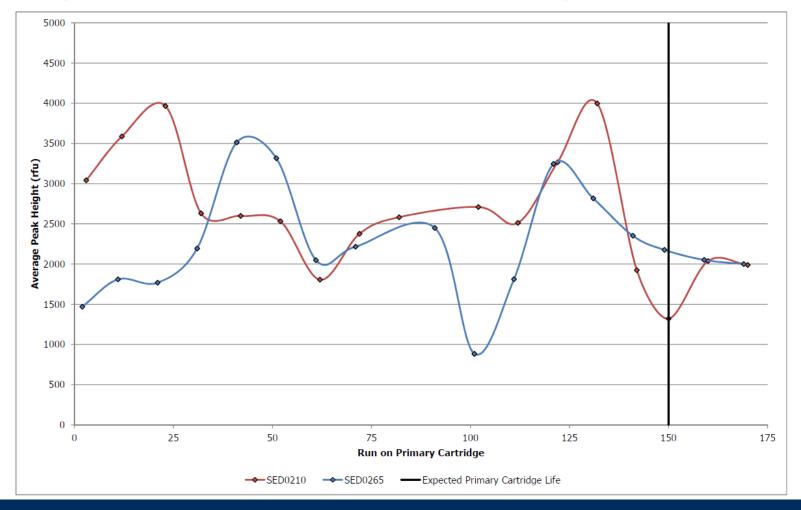


Development & Validation Work – Inter Instrument Variation





Development & Validation Work – Variation Throughout Life of Primary Cartridge





Development & Validation Work – Cross Contamination

Three studies

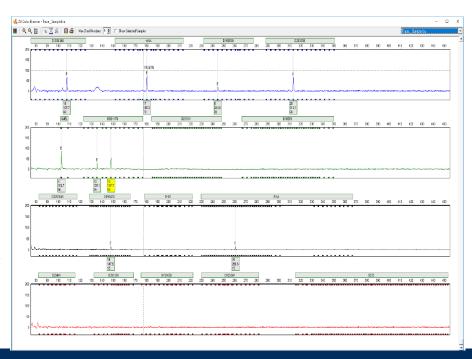
- 'Blank' swab processed with 1 extra PCR cycle
- 'Blank' swab processed after each run in development work (74 samples)
- 'Blank' swab processed every 10 runs in validation (15 samples)

Results

- Extra cycle showed no peaks over analytical threshold
- Between other studies 6 samples showed peaks about analytical threshold
- Majority single peak

Risk Assessment:

Deemed as low as these profiles are low level and no contamination was observed in samples containing DNA





Development & Validation Work – Implementation

- ISO17025/UKAS Sign Off
 - Received Jan 2018
- KFS to process PACE and reference samples through RapidHIT™ ID at Norwich site
- First PACE sample processed in 2 hours from receipt at lab to NDNAD report received; eliminating a suspect
- Beginning verification work of other KFS sites May '18



Aims for Technology

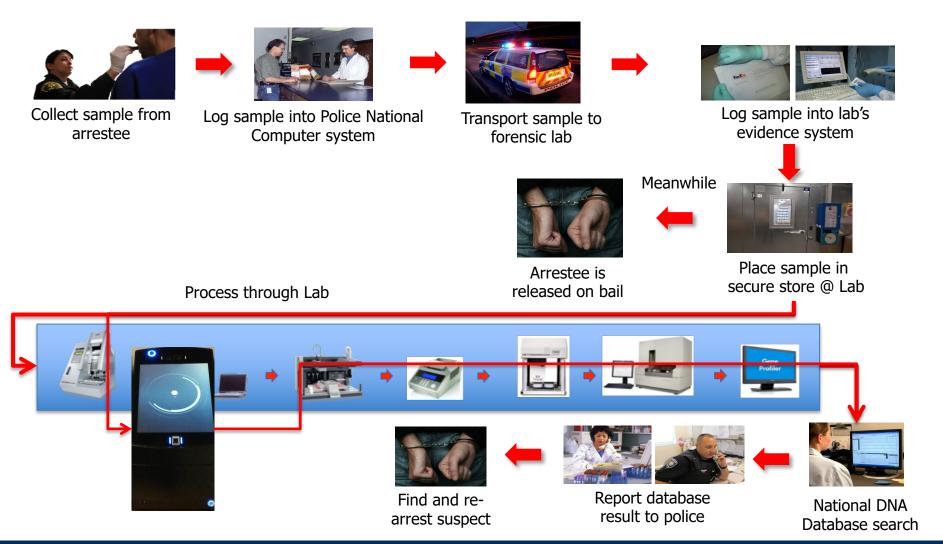
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Life of a PACE Sample





Putting the Instruments in Custody

Advantages

- Major time saving can be made by placing instrument in custody environment
- Potential to get matches back from database before suspects are released
 - Saving time and money re-arresting
 - Preventing further offending

Potential Issues

- Taking the experience away from the sample processing
- Remote control of instruments, troubleshooting and support required
- Transfer of responsibility for sample integrity and compliance
- IT Security



Operator Experience

Instrument Operation

- Simplistic, user friendly, interface
- On instrument instructions
- User levels to restrict advanced function to suitably trained users

Training

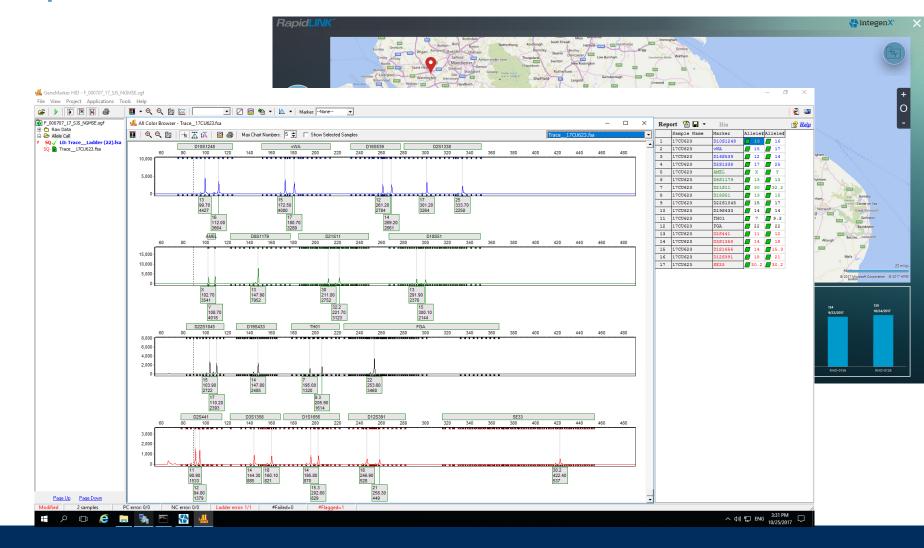
- Use experienced trainers to train relevant police staff
- Use a train the trainer model going forward
- Ensure that training includes all relevant information
 - Process
 - Legislation (e.g. PoFA, COSHH)
 - Explain wider implications of the technology

On-going Competence

- User tracking on instrument to ensure suitable usage within timeframe
- Use QC or PT samples



RapidLINK – Remote Control





Troubleshooting & Support

Live Help & Remote Assistance – Already discussed

Hot Swap

- Validating 'Hot swap' model
 - If an instrument fault is not repairable remotely it is swapped for spare working instrument
 - No further verification needed as spare is verified
 - Instruments shipped ready to run



Transfer of Responsibility

Training – Already discussed

Legislation

- Protection of Freedoms Act (PoFA)
 - Log in at end of run to record operator removing cartridge/responsible for A-Scrape destruction
 - Mark samples in RapidLINK for retention (CPIA rules)
 - Produce list of B-Scrapes for destruction and send to SPOC in custody
 - SPOC uses RapidHIT™ ID to mark as destroyed
 - Data delink function in RapidLINK removes profile data

Accreditation

UKAS for ISO/ILAC/FSR codes of deployment model



IT Security

Issues

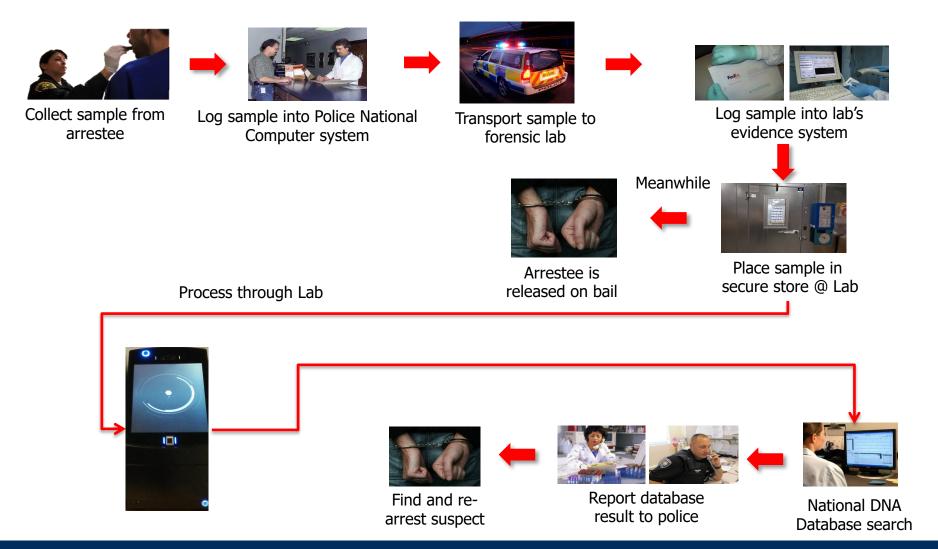
- RHID supplied 'Open'
- Uses internet to transmit data to RapidLINK
- Has camera, facial recognition, microphone and fingerprint reader (Biometrics)

Solutions

- Hardened Mode
 - Domain joined instruments
 - Windows Kiosk mode
 - Data encryptions three modes employed
 - Antivirus and Windows Update Server
 - Option to remove camera, disable finger print reader
 - This reduced functionality, in particular live help on instrument



Life of a PACE Sample





Life of a PACE Sample – A New Story



Collect sample from arrestee



Log sample into Police National Computer system



Run sample on RapidHIT ID in Custody



Expert profile analysis





Suspect still in custody!!



Report database result to police



National DNA Database search



Real Life?

- KFS using the RapidHIT ID for live case work in laboratory environment
- Two large scale trials undertaken with UK forces
- Promising data on success rates, turnaround times and impact on the CJS
- Other trials and implementations underway and in discussion with several UK Police Forces
- Fastest turn around time achieved 92 minutes!
 Instrument start to NDNAD load received



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