

Introduction

This protocol outlines the use of the Applied Biosystems™ RapidHIT™ ID System in conjunction with the Applied Biosystems™ INTEL GlobalFiler™ Express STR chemistry (GFE) sample cartridges for RapidHit DNA analysis.

The methods listed in this protocol have been validated to be used with specific crime scene samples assumed to be from a single donor.

Responsibility

Trained Rapid ID Operators.

Safety

The RapidHIT™ ID System will only be operated by qualified personnel who have been appropriately trained.

Improper use of the RapidHIT™ ID System may cause personal injury or damage to the instrument. Personal protective equipment including gloves and face masks must be worn when conducting this procedure.

All waste materials that have come into contact with biological fluids or samples must be disposed of in a biohazard waste container.

All sample cartridges must be disposed of in a biohazard waste container.

Before handling any chemicals, refer to the MSDS provided by the manufacturer and observe all relevant precautions.

Do not lean on any part of the instrument as it can cause damage.

Unless performing maintenance, leave the main power switch (on the back panel) set to “On” at all times. Power is necessary to maintain the temperature control of the primary cartridge.

Procedure

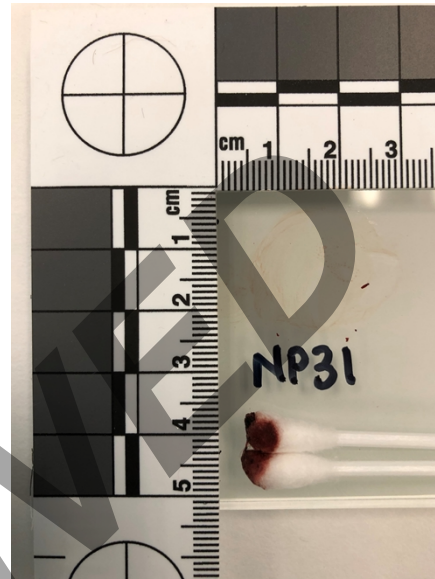
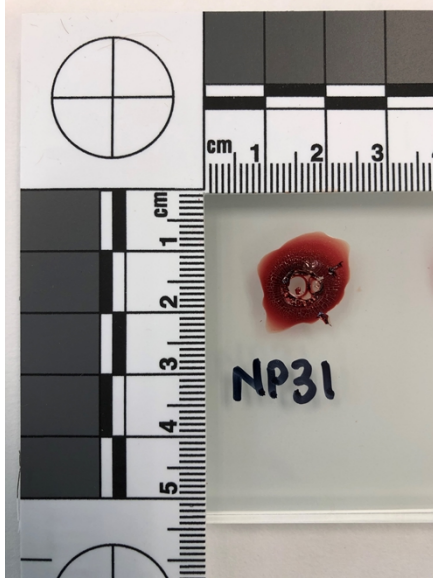
RapidHIT™ ID System Sample Preparation for use with the INTEL cartridge

Sample Selection

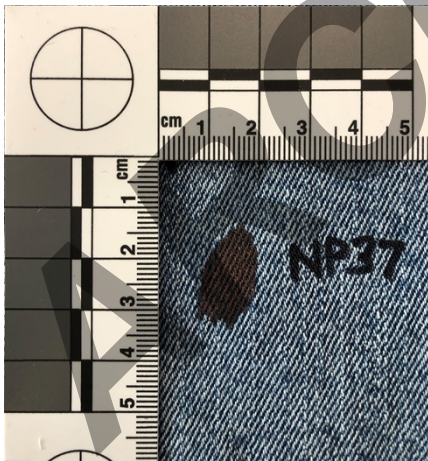
1. Crime scene samples selected for Rapid DNA testing must be believed to originate from one individual.
2. DNA profiles generated on the RapidHIT™ ID System are not eligible for CODIS (Combined DNA Index System) entry. Samples must be collected in duplicate simultaneously (i.e two swabs). While one swab is processed on the RapidHIT™ ID System, the second must be tested at the Division of Scientific Services through traditional DNA testing.
3. The crime scene sample must be sufficient enough to ensure adequate testing material is available for both Rapid and traditional DNA testing.

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Figure 1: Evidence Sample Size



1A. Target Blood Sample – Non-porous Surface - Before and After Collection



1B. Target Blood Sample – Porous Surface – Before and After Collection

Sample Collection

**State of Connecticut Department of Emergency Services and Public Protection
Division of Scientific Services**




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Swabbing:

Note: It is recommended (but not necessary) to use the Puritan 3" Sterile Standard Cotton Swab with Semi-Flexible Polystyrene Handle.

Ref #	Packaging
25-803 2PC	10/100/2 (10 boxes of 100 individually wrapped packages, 2 p/pkg)



1. Moisten the swabs with dH₂O.
2. Swab the area by turning the swabs to ensure that all sides come in contact with the area.

Sample Pre-Processing

1. **Swab:**

Insert one 3-inch sterile cotton swab into the sample cartridge by opening the top of the cartridge (see Figure 2a). Swabs longer than 3" will need to be cut or broken to fit in the sample cartridge. Once inserted, close the sample cartridge.

2. **Cigarette Butt:**

- a. Cut off ¼ inch off end of cigarette butt with sterile scalpel.
- b. Cut that sample in half; take one half and the remainder of the cigarette butt and submit to the Laboratory for conventional DNA testing.
- c. Take the remaining half of the sample and using the scalpel, remove paper around outside of filter.
- d. Moisten a swab with dH₂O and swab the filter paper.
- e. Place the filter paper in cartridge and use the swab to anchor the sample as shown in Figure 2b.



Figure 2a. Sample cartridge showing opening for sample.



Figure 2b. Sterile cotton swab anchoring sample in the INTEL cartridge.

Running the RapidHIT™ ID System

1. Touch the center of the Lock screen (Figure 3) to unlock the instrument.

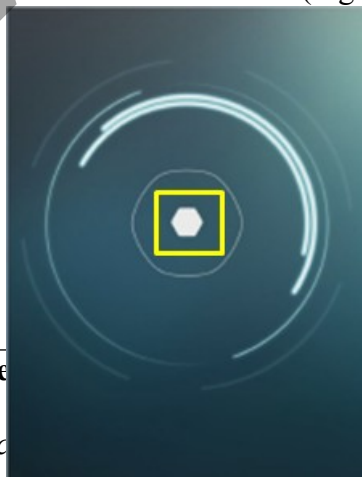
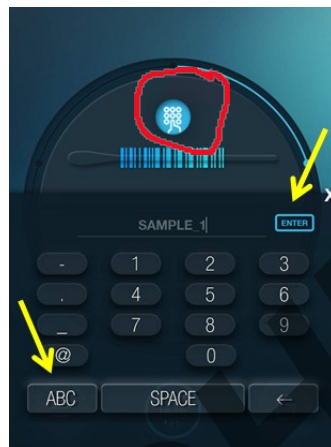


Figure 3. Lock screen (screen saver)

2. Touch the keyboard icon in the lower right corner of the screen.
3. Touch the hand icon in the upper right corner of the screen.
4. Select designated username from the drop down menu.
5. Depending on user; use thumb print verification or face scan to log into the instrument.
6. Select the keyboard icon on the Sample Identification Screen (red circle below)



(Figure 4)

7. Enter the sample identifier formatted as follows: AgencyCode-Case#-Sample# using the keyboard and select “Enter” when finished (Figure 4 yellow arrows).
8. Note: The instrument defaults sample identifiers to all capital letters.
9. Insert the sample into the sample cartridge. If this has already been completed, proceed to step 10. (Figure 5A)

Insert the sample cartridge into the instrument as the instrument (Figure 4B). The run will begin automatically after the cartridge is inserted. Note: The countdown timer will begin at ~110 minutes; typical run time is ~96 minutes. If the instrument requires

priming, the run time can extend up to ~110 minutes. See figure 5C.

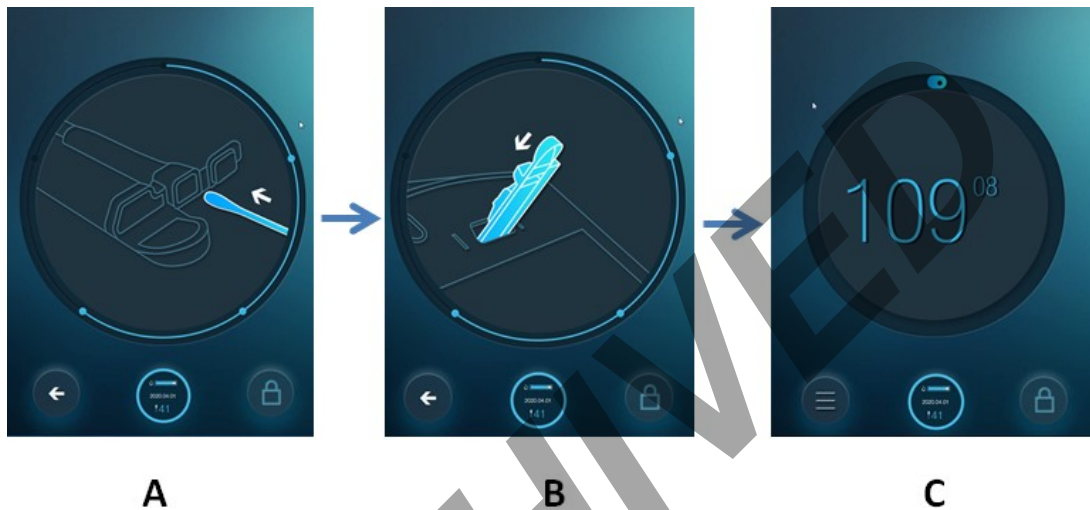


Figure 5. Inserting the sample cartridge into the instrument

10. Complete the **RDNA – 02 Rapid Hit DNA Evidence Sample Run Log** each time a sample is run on the RapidHIT™ ID System and the Case Summary form.
11. After the run has completed, remove the sample cartridge. Note: If the RapidHIT™ ID remains idle following the run, it will default to the Lock screen. Log into the instrument to display the Remove Sample Cartridge screen.
12. When the Remove Sample Cartridge screen is displayed (Figure 6A), remove the sample cartridge from the instrument and the run result will be displayed (Figure 6B). Press “DONE”.

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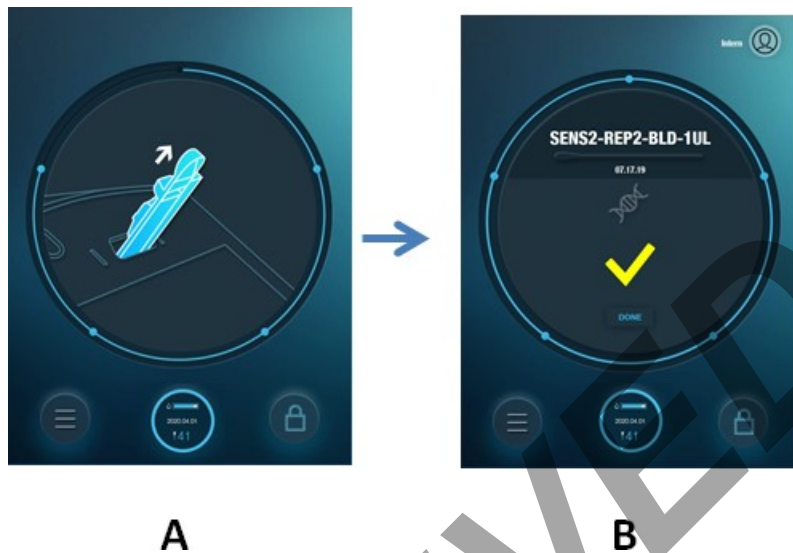


Figure 6. Cartridge removal and run results screen

13. When a sample is removed, the result screen is displayed as shown in Figure 6B. Review the sample status (see Table 1). The laboratory DNA analysts will review data and you will be notified about your results.




Status	DNA profile is generated	Action
Green 	Yes	The DNA profile does not contain quality score flags. The DNA profile is ready for analysis by the RapidLink™ Software. No further action is needed on the instrument.
Yellow 	Yes	The DNA profile generated contains quality score flags. The DNA profile is available for review in the RapidLink™ Software.
Red 	No	The sample failed and no profile was generated.

Table 1. Sample Status Table.

14. Discard the sample cartridge into the red biohazard bucket. The sample is consumed in testing.
15. A green check mark will be a full single source profile, but a DNA analyst will still review.

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16. A yellow check mark will need assistance from a DNA analyst.
17. An email will be sent out communicating if there was a hit in the Small Pond Database to a specific Database ID through CT.RAPIDDNA@ct.gov.
18. The **Offender Collect Search Confirmation Form** will be filled out using the Database ID, signed and sent to the CT.RAPIDDNA@ct.gov email address.
19. After confirming the form is signed, an email will be sent to the user with the information needed for a COLLECT search.
20. A COLLECT search must be done to document that the individual qualifies to be in the Offender Database.

Please see below for CT General Statutes:

Sec. 54-102j. Dissemination of information in DNA data bank. (a) It shall be the duty of the Division of Scientific Services within the Department of Emergency Services and Public Protection to receive blood or other biological samples and to analyze, classify and file the results of DNA identification characteristics profiles of blood or other biological samples submitted pursuant to section 54-102g and to make such information available as provided in this section, except that the division shall analyze samples taken pursuant to subsection (a) of section 54-102g only as available resources allow. The results of an analysis and comparison of the identification characteristics from two or more blood or other biological samples shall be made available directly to federal, state and local law enforcement officers upon request made in furtherance of an official investigation of any criminal offense. **Only when a sample or DNA profile supplied by the person making the request satisfactorily matches a profile in the data bank shall the existence of data in the data bank be confirmed or identifying information from the data bank be disseminated,** except that if the results of an analysis and comparison do not reveal a match between the sample or samples supplied and a DNA profile contained in the data bank, the division may, upon request of the law enforcement officer, indicate whether the DNA profile of a named individual is contained in the data bank provided the law enforcement officer has a reasonable and articulable suspicion that such individual has committed the criminal offense being investigated. A request pursuant to this subsection may be made by personal contact, mail or electronic means. The name of the person making the request and the purpose for which the information is requested shall be maintained on file with the division.

A satisfactory match involves the confirmation of a conviction of a "Serious Felony". A "serious felony" means a violation of section 53a-70b of the general statutes, revision of 1958, revised to January 1, 2019, or section 53a-54a, 53a-54b, 53a-54c, 53a-54d, 53a-55, 53a-55a, 53a-56, 53a-56a, 53a-56b, 53a-57, 53a-59, 53a-59a, 53a-60, 53a-60a, 53a-60b, 53a-60c, 53a-

70, 53a-70a, 53a-72b, 53a-92, 53a-92a, 53a-94, 53a-94a, 53a-95, 53a-100aa, 53a-101, 53a-102, 53a-102a, 53a-103a, 53a-111, 53a-112, 53a-134, 53a-135, 53a-136, 53a-167c, 53a-179b, 53a-179c or 53a-181c.

Sec. 54-102k. Unauthorized dissemination or use of DNA data bank information. Obtaining blood sample without authority. Penalties. Any person who, without authority, disseminates information contained in the data bank shall be guilty of a class C misdemeanor. Any person who disseminates, receives or otherwise uses or attempts to so use information in the data bank, knowing that such dissemination, receipt or use is for a purpose other than as authorized by law, shall be guilty of a class A misdemeanor. Except as authorized by law, any person who, for purposes of having a DNA analysis performed, obtains or attempts to obtain any sample submitted to the Division of Scientific Services for analysis shall be guilty of a class D felony.

21. If the individual is not qualified, the hit **CANNOT** be used any further. Please alert the RAPID DNA administrators at the laboratory immediately if there is no qualifying offense.
22. If the individual is qualified as stated above, the name may be used as an investigative lead. A notification will be sent by email summarizing the hit.

Maintenance and Routine Performance Checks

Routine maintenance

1. At a minimum one sample must be run on the RapidHIT™ ID System weekly.
2. Weekly runs for maintenance or casework runs must be documented on the RapidHIT™ ID System Instrument Log form. Each time a sample is run on the instrument, the Instrument Log must be completed. These logs will be emailed to CT.RAPIDDNA@ct.gov monthly.
3. Maintenance tasks and frequency of task will be conducted as outlined in Table 2.

Table 2. Maintenance tasks and frequency for the RapidHIT™ ID System

Task	Frequency
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State of Connecticut Department of Emergency Services and Public Protection
Division of Scientific Services

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Run a sample cartridge if the instrument is not in use daily	Weekly
Clean the touchscreen. 1. Power off the internal computer (button on the front), hold for several seconds. 2. Power off the main power switch (button on the back). 3. Spray with a non-abrasive glass cleaner, then gently wipe the screen with lint-free lab tissues. 4. Power on the main power switch and the internal computer.	As needed (call Rapid Admins)

4. If needed, the lot numbers and expiration dates can be found on the cartridge itself.
5. The main power switch at the back of the instrument should always be kept on to keep the gel cool in the primary cartridge. If the instrument is powered off for a prolonged period of time, the primary cartridge and gel cartridge may need to be replaced.

Performance Checks

1. If the RapidHIT™ ID System is idle longer than a week, a sample cartridge must be run. The Rapid Admins will review the data but, below is the expected results.
2. The sample cartridge should contain a swab of a known single source.
3. Acceptable performance check results for the positive sample control are a green checkmark indicating a full single source profile has been developed.
4. If an unacceptable performance check result are obtained, the RapidHit Administrator must be notified, the appropriate root cause analysis will be conducted (possibly calling the vendor), and the performance check will be repeated.

5. All performance check test results must be recorded on the maintenance log.
6. The performance check data will be stored electronically.

Maintenance, Service and Repair

1. The DSS Laboratory staff will notify the vendor if maintenance, service, or repair is needed.
2. Following maintenance, service or repair a performance check must be run prior to performing Rapid DNA analysis on casework reference samples. A positive sample control and negative control must be run.
 - a. A positive sample control is a sample that the DNA profile is known.
 - b. A negative control is an empty Rapid DNA cartridge
3. The performance check data must be reviewed by the RapidHit Administrators (DNA Analysts).
4. Acceptable performance results for the positive sample control is a concordant DNA profile.
5. Acceptable performance check results for the negative control is no detection of a DNA profile.
6. Unacceptable performance check results for the positive sample control are a negative DNA profile, a partial DNA profile, or a non-concordant DNA profile.
7. Unacceptable performance check results for the negative control are obtained when DNA is present.
8. If an unacceptable performance check result is obtained for the positive sample control or negative control the Rapid Administrator must be notified, the appropriate root cause analysis will be conducted, and the performance check will be repeated.
9. All performance check test results must be recorded.

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10. If the RapidHIT™ ID System fails to produce acceptable performance check results, the manufacturer must be contacted in to order attempt to resolve the unacceptable performance check results and/or request instrument service.
11. The date of the maintenance, service, or repair will be electronically maintained.

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