appliedbiosystems

RapidHIT™ ID System v2.0 and v2.0.1

USER GUIDE

for use with:

RapidLINK™ Software v2.0.1

Publication Number MAN0026593

Revision C



For Forensic, Human Identification, or Paternity/Kinship Use Only. Not for use in diagnostic procedures.

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For descriptions of symbols on product labels or product documents, go to thermofisher.com/symbols-definition.

Revision history: MAN0026593 C (English)

Revision	Date	Description
C	10 March 2025	Performance verification was added for RapidHIT™ ID System v2.0.1.
B00	18 March 2024	A reference to subsampling procedures was added ("Subsampling" on page 18). The sign-in procedures were updated ("Sign in to the instrument" on page 20). A list of demo mode IDs was added ("Enable demo mode and (optional) perform a simulated run" on page 47). Guidelines for managing workflows were added "Assign an instrument to a workflow (RapidLINK™ Software)" on page 56 and "Manually update a workflow on the instrument" on page 56). Troubleshooting procedures were reorganized and clarified (Appendix A, "Troubleshooting"). Analysis settings were updated ("General analysis settings" on page 95 and "Artifact thresholds and filters for RapidINTEL™ Plus cartridges" on page 102). Validation studies were added (Appendix C, "RapidHIT™ ID System v2.0 validation studies and v2.0.1 performance verification"). The conformity symbols were updated to match the instrument label ("Conformity symbols" on page 152). Minor text updates for clarification were made (throughout the document).
A.0	15 November 2023	New document for RapidHIT™ ID System v2.0.

The information in this guide is subject to change without notice.

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1 Product information

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IMPORTANT! Before using this product, read and understand the information in the "Safety" appendix in this document.

Product description

RapidHIT™ ID System v2.0 and RapidHIT™ ID System v2.0.1

RapidHIT™ ID System v2.0 and RapidHIT™ ID System v2.0.1 use the following components.



- **RapidHIT™ ID sample cartridges**—Self-contained sample cartridges contain reagents and size standard for Applied Biosystems™ STR (short tandem repeat) chemistry.

  The sample is added to the cartridge, then the sample cartridge is inserted into the instrument.

- **RapidHIT™ ID instrument**—The instrument provides an intuitive user interface that guides users through routine use.

  The instrument generates a DNA profile in 90–110 minutes.

- **RapidLINK™ Software**—When an instrument run is complete, the DNA profile is sent to the RapidLINK™ Software. In the RapidLINK™ Software, users can perform the following functions:
  - Review DNA profiles, view electropherograms, and update DNA profiles.
  - Monitor all instruments that contribute DNA profiles to the RapidLINK™ Software.

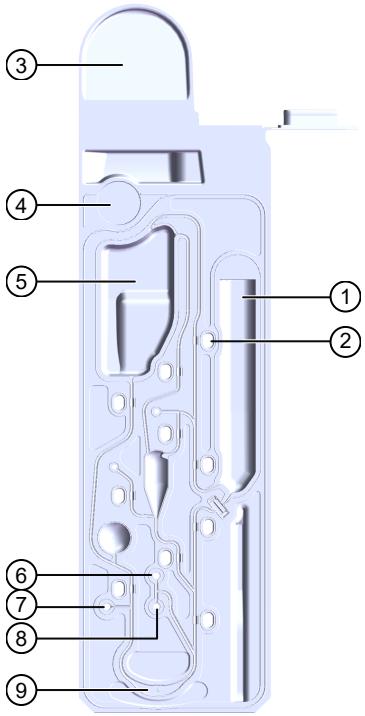
  For information about the RapidLINK™ Software, see the *RapidLINK™ Software v2.0 User Guide* (Pub. No. MAN0030010) and the *RapidHIT™ ID System Software v2.0.1 and RapidLINK™ Software v2.0.1 Release Notes*.

Sample cartridge types

Sample cartridge	Sample type	STR chemistry	Features	More information
RapidHIT™ ID ACE GlobalFiler™ Express Sample Cartridge	Single-source, buccal swab	GlobalFiler™ Express	• Systematic allelic ladder library • Optimized data analysis thresholds	For more information, see: • Appendix B, “Analysis settings” • Appendix C, “RapidHIT™ ID System v2.0 validation studies and v2.0.1 performance verification”
RapidINTEL™ Plus Sample Cartridge	Casework, single-source, blood and saliva samples	RapidINTEL™ Plus	• Systematic allelic ladder library • Optimized data analysis thresholds • Internal Quality Control (IQC) markers to identify samples that contain PCR inhibitors. • Quantification markers to estimate the DNA quantity in the PCR and determine if the sample is degraded. • Master mix and primer mix optimizations for improved DNA profile balance. • PCR optimizations	For more information, see: • Appendix B, “Analysis settings” • *RapidINTEL™ Plus Sample Cartridge User Bulletin* (Pub. No. MAN0026595)

Sample cartridge components

The sample cartridges include the following components.



1. Sample swab chamber
2. Crosshatch cuts in the cartridge film (× 10)
3. Cartridge label
4. RFID tag
5. Waste sponge
6. Pre-mix (clear)
7. Size standard
8. Primer mix (pink)
9. DNA capturing paper

Note: The insertion flag is not visible in this view.

Figure 1 Sample cartridge—front view

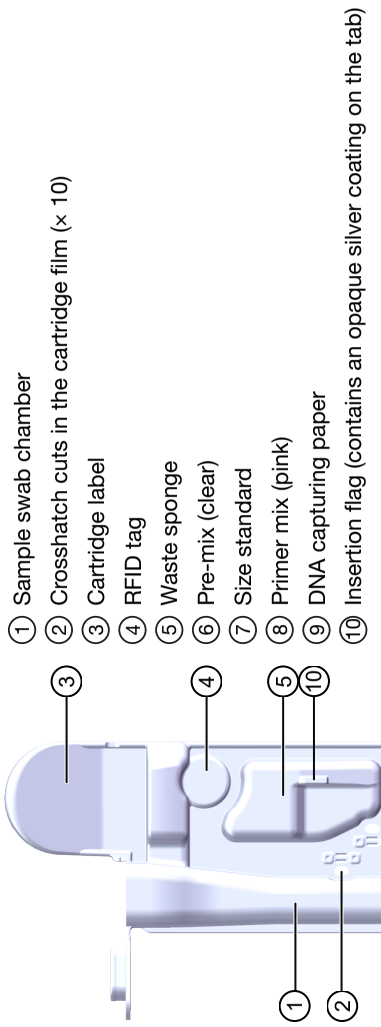


Figure 2 Sample cartridge—back view

Parts of the instrument



1. Camera
2. Sample cartridge port
3. Touchscreen (display screen)
4. Fingerprint reader
5. Primary cartridge (contains gel cartridge)
6. Power button (controls the internal computer)
7. USB port
8. Rear panel with main power switch, USB, and computer connections

The instrument also includes an internal environmental sensor that monitors temperature and humidity.

Do not lean on any part of the instrument. This action could cause damage or breakage, especially to the display screen.

Required materials not supplied

Unless otherwise indicated, all materials are available through **thermofisher.com**. "MLS" indicates that the material is available from **fisherscientific.com** or another major laboratory supplier.

Catalog numbers that appear as links open the web pages for those products.

Primary cartridge kit

Note: For the primary cartridge kit, the allelic ladder, negative control, positive control, and utility cartridges can be ordered separately through your local Thermo Fisher Scientific sales representative. See “Allelic ladder, control, and utility cartridges” on page 13.

Table 1 RapidHIT™ ID Primary Cartridge GlobalFiler™ Express 150 Kit (Cat. No. A53084)

Contents	Amount	Storage
Box 1		
RapidHIT™ ID Primary Cartridge—150 runs	1 (for 150 runs)	Room temperature (15–30°C)
RapidHIT™ ID Utility Cartridge (for installation or primary cartridge replacement)	2	
Box 2		
RapidHIT™ ID Gel Cartridge (for installation or primary cartridge replacement)	1	2–8°C
RapidHIT™ ID ACE GlobalFiler™ Express Control (Ladder) Cartridge (allelic ladder for installation or primary cartridge replacement)	1	4–10°C
RapidHIT™ ID ACE GlobalFiler™ Express Positive Control Cartridge (for installation or primary cartridge replacement)	1	

Sample cartridge kits

Table 2 RapidINTEL™ Plus sample cartridge kits

Kit	Cat. No.	Contents	Amount	Storage
RapidINTEL™ Plus 50 Sample Cartridge Kit	A54338	RapidINTEL™ Plus Sample Cartridge	50	15–25°C for ≤2 months, or 4–10°C until the expiration date on the label
		RapidINTEL™ Plus Negative Control Cartridge	2	
		RapidINTEL™ Plus Positive Control Cartridge	2	
RapidINTEL™ Plus Sample Cartridge Evaluation Kit	A55598	RapidINTEL™ Plus Sample Cartridge	10	

Table 3 RapidHIT™ ID ACE GlobalFiler™ Express sample cartridge kits

Kit	Cat. No.	Contents	Amount	Storage
RapidHIT™ ID ACE GlobalFiler™ Express 50 Sample Kit	A41831	RapidHIT™ ID ACE GlobalFiler™ Express Sample Cartridge	50	15–25°C for ≤2 months, or 4–10°C until the expiration date on the label
		RapidHIT™ ID ACE GlobalFiler™ Express Negative Control Cartridge	2	
		RapidHIT™ ID ACE GlobalFiler™ Express Positive Control Cartridge	2	
RapidHIT™ ID ACE GlobalFiler™ Express Evaluation Kit	400114RH	RapidHIT™ ID ACE GlobalFiler™ Express Sample Cartridge	10	

Allelic ladder, control, and utility cartridges

Table 4 RapidINTEL™ Plus allelic ladder, control, and utility cartridges

Contents	Cat. No.	Amount	Storage
RapidINTEL™ Plus Ladder Cartridge Kit (allelic ladder)	A54344	5	4–10°C
RapidINTEL™ Plus Negative Control Cartridge	A54343	1	
RapidINTEL™ Plus Positive Control Cartridge	A54342	1	
RapidHIT™ ID Utility Cartridge	A42471	1	Room temperature (15–30°C)

Table 5 GlobalFiler™ Express allelic ladder, control, and utility cartridges

Contents	Cat. No.	Amount	Storage
RapidHIT™ ID ACE GlobalFiler™ Express Control (Ladder) 5-Cartridge Kit	400096RH	5	4–10°C
RapidHIT™ ID ACE GlobalFiler™ Express Negative Control Cartridge	A42470	1	
RapidHIT™ ID ACE GlobalFiler™ Express Positive Control Cartridge	A42469	1	
RapidHIT™ ID Utility Cartridge	A42471	1	Room temperature (15–30°C)

Accessories

Table 6 Accessories

Item	Cat. No.
(Optional) Barcode scanner compatible with one of the following formats: GS1-128, Industrial 2 of 5, Interleaved 2 of 5, Code 128, Code 39 **Note:** The instrument must be configured by a Service representative to enable barcode scanning. If you want to add a barcode scanner to the instrument after initial installation, contact Thermo Fisher Scientific Technical Support to request an update to your configuration.	MLS
FLOQSwabs™ 516CS01 Ultra Minitip Flocked Swab with100-mm Breakpoint	516CS01 (Copan)
Puritan™ PurFlock™ Ultra Sterile Flocked Swabs	253318U BT (MLS)
Puritan™ HydraFlock™ 6" Sterile Micro Ultrafine Flock Swab with Polystyrene Handle	25-3318-H (MLS)
Puritan™ 3″ Sterile Standard Cotton Swab with Semi-Flexible Polystyrene Handle	25-803 2PC (MLS)

Network and password security requirements

Network configuration and security

The network configuration and security settings of your laboratory or facility (such as firewalls, anti-virus software, network passwords) are the sole responsibility of your facility administrator, IT, and security personnel. This product does not provide any network or security configuration files, utilities, or instructions.

If external or network drives are connected to the software, it is the responsibility of your IT personnel to ensure that such drives are configured and secured correctly to prevent data corruption or loss. It is the responsibility of your facility administrator, IT, and security personnel to prevent the use of any unsecured ports (such as USB, Ethernet) and ensure that the system security is maintained.

Password security

Thermo Fisher Scientific strongly recommends that you maintain unique passwords for all accounts in use on this product. All passwords should be reset upon first sign in to the product. Change passwords according to your organization's password policy.

It is the sole responsibility of your IT personnel to develop and enforce secure use of passwords.

User role permissions

The procedures that you can perform in the RapidHIT™ ID System depend on the user role permissions assigned to your user account.

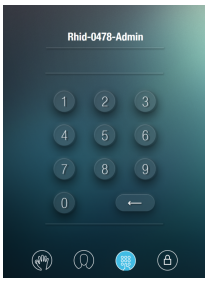
For more information on user role permissions, see “Edit a user role” on page 70.

Workflow

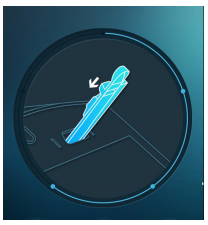
Obtain a swab or substrate sample according to your standard operating procedure.

Insert the swab or substrate sample into a sample cartridge.

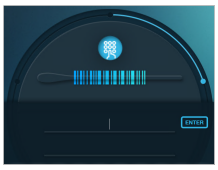
Sign in to the instrument.



Insert the sample cartridge into the instrument.



Enter the sample identification number or scan the sample cartridge barcode.



Select a specimen category

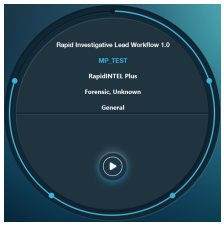
The default specimen categories are **Test** and **Training**. Depending on the workflow for your instrument, more specimen categories may be available.

(RapidINTEL™ Plus sample cartridges only) Select a sample protocol

Depending on the workflow for your instrument, you may be prompted to select a sample protocol.

Start the run

Review the information on the screen, then start the run.



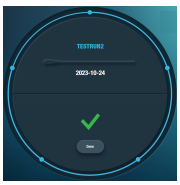
The countdown timer starts at 110 minutes. The typical run time is ~90 minutes.

When the run is complete, the lock screen is displayed.

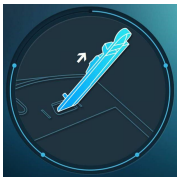
Note: The timer stops when the run is complete. The timer does not decrease to 0 minutes. For more information, see “Run times for different sample cartridges” on page 30.



Sign in, view the result, then tap Done.



Remove the sample cartridge from the instrument.



Review results and run applications in the RapidLINK™ Software.

2 Collect and prepare the sample

Sample collection

Sample cartridges were validated using the following swab types, but other swab types have been used successfully with both cartridges.

- **GlobalFiler™ Express**—Puritan™ 3″ Sterile Standard Cotton Swab with Semi-Flexible Polystyrene Handle
- **RapidINTEL™ Plus**—
  - FLOQSwabs™ 516CS01 Ultra Minitip Flocked Swab with100-mm Breakpoint
  - Puritan™ HydraFlock™ 6" Sterile Micro Ultrafine Flock Swab with Polystyrene Handle
  - Puritan™ PurFlock™ Ultra Sterile Flocked Swabs
  - Puritan™ 3″ Sterile Standard Cotton Swab with Semi-Flexible Polystyrene Handle

IMPORTANT! When you handle buccal swabs, follow your standard operating protocol for the use of safety glasses, lab coats, and chemical-resistant, disposable gloves (powder-free).

Subsampling

For information on subsampling, see the *RapidINTEL™ Plus Sample Cartridge User Bulletin* (Pub. No. MAN0026595).

3 Run the instrument

- Power on the internal computer 19
- Sign in to the instrument 20
- Insert the sample cartridge into the instrument 25
- Enter the sample identification number 25
- Select a sample category 27
- (RapidINTEL™ Plus sample cartridge only) Select a sample protocol 28
- Start the run 30
- View the run results and remove the sample cartridge 31
- Sign out 33

Power on the internal computer

Note: If you are starting the RapidHIT™ ID System instrument for the first time, see "Configure the server connection (at initial startup)" on page 36. If you are starting the instrument after it has been running in standalone mode, see "Configure the server connection (after running in standalone mode)" on page 42.

IMPORTANT! Leave the main power switch (on the back panel) set to On at all times. Power is necessary to maintain the gel temperature.

Press the power button on the front lower-right of the instrument.

The power button changes from green to blue.

The startup screen is displayed until the instrument finishes the following operations.

- System check
- System prime, if needed (≤15 minutes)

The lock screen is displayed after system startup is complete.





Figure 3 Startup and lock screens

1. Startup screen
2. Lock screen

Sign in to the instrument

By default, two-factor authentication (2FA) is enabled. When 2FA is enabled, a password/PIN and one biometric (fingerprint scan or face recognition) are required to sign in.

When 2FA is disabled, only one factor is required to sign in. If your user account is configured with multiple sign-in factors, you can use any one of the factors to sign in.

Note: For more information, see "Configure instrument options" on page 54.

Use one or more factor to sign in to the instrument, as required by your user account configuration.

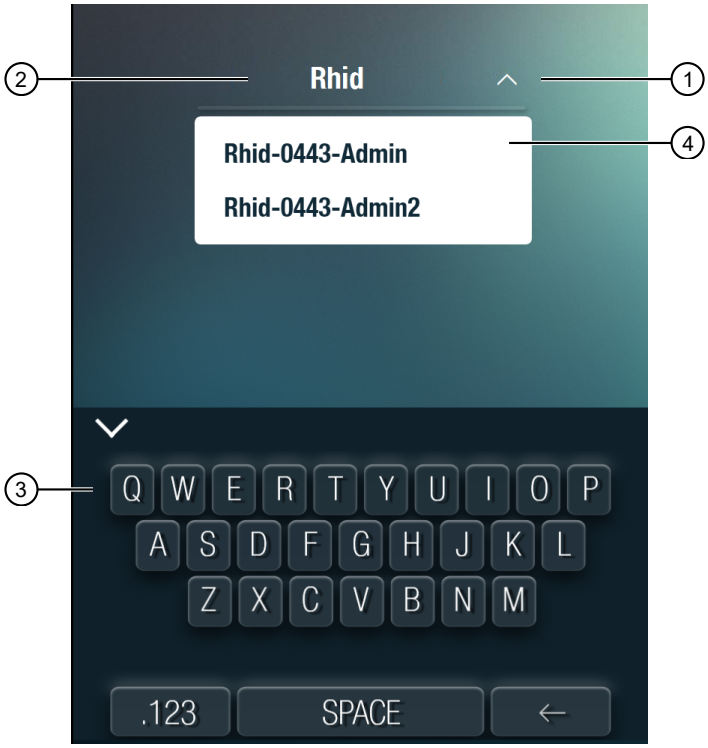
- **Password/PIN**—See page 20.
- **Fingerprint scan**—See page 23.
- **Face recognition**—See page 23.

Sign in to the instrument—Password/PIN

1. Tap the lock screen.



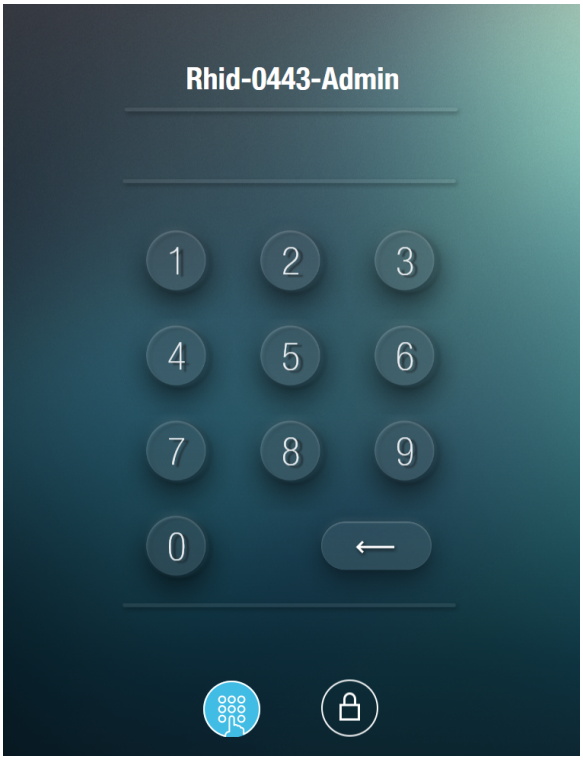
2. *(If your user name is not already displayed)* Select or search for your user name.
   - **Select your user name**—Tap ⌄, then select your user name from the dropdown list.
   - **Search for your user name**—Tap the user name field to display an alphanumeric keypad, begin entering the first characters of your user name, then select your user name from the search results.



① Dropdown list to select your user name
② User name field to search for your user name
③ Alphanumeric keypad to search for your user name
④ Dropdown list or search results

3. At the bottom of the screen, tap to display a numeric keypad, then enter your password/PIN.

Note: If you selected or searched for your user name (step 2), you do not have to tap —the numeric keypad is automatically displayed.

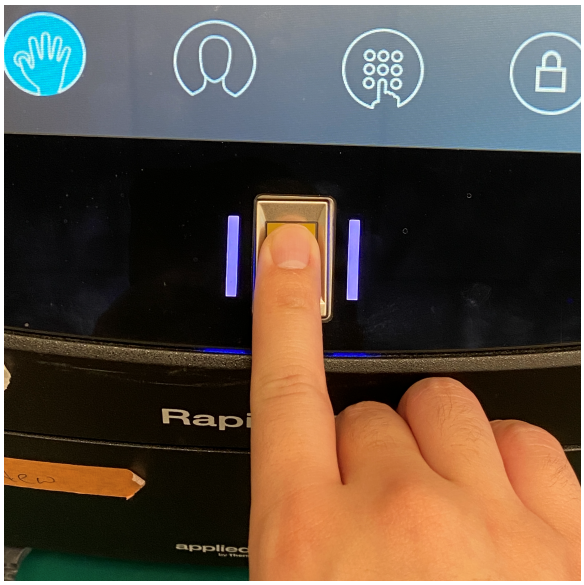


4. *(If needed)* When two factor authentication (2FA) is enabled, a password/PIN and one biometric (fingerprint scan or face recognition) are required to sign in to the instrument. Use the appropriate factor to complete the sign-in process.
   - **Fingerprint scan**—See page 23.
   - **Face recognition**—See page 23.

Proceed to “After signing in—next steps” on page 24.

Sign in to the instrument—Fingerprint scan

1. *(If needed)* When two factor authentication (2FA) is enabled, you must enter a password/PIN before scanning your fingerprint. See “Sign in to the instrument—Password/PIN” on page 20.
2. *(If needed)* At the bottom of the screen, tap .
3. Touch the fingerprint reader.



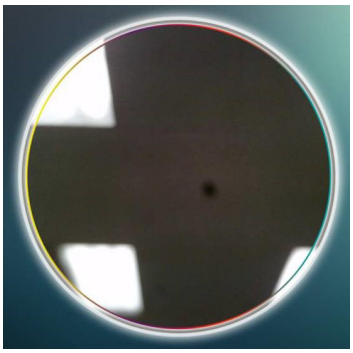
Proceed to “After signing in—next steps” on page 24.

Sign in to the instrument—Face recognition

1. *(If needed)* When two factor authentication (2FA) is enabled, you must enter a password/PIN before using the face recognition factor. See “Sign in to the instrument—Password/PIN” on page 20.
2. Tap the lock screen.



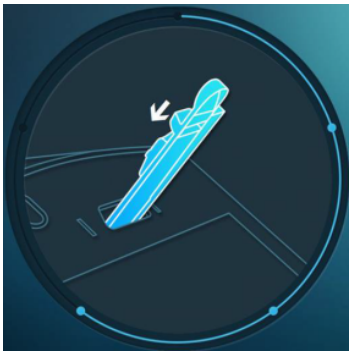
3. At the bottom of the screen, tap , then position your face in front of the camera.



Proceed to “After signing in—next steps” on page 24.

After signing in—next steps

1. After you sign in, the insert cartridge screen is displayed. For a detailed description of this screen, see “Insert cartridge screen” on page 147.

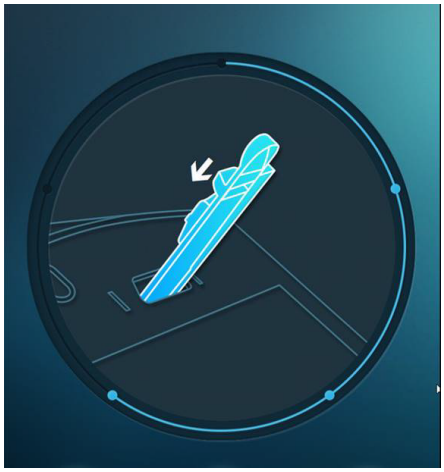


2. If an error code is displayed when you sign in, see “An error code is displayed when you sign in” on page 86.

Proceed to “Insert the sample cartridge into the instrument” on page 25.

Insert the sample cartridge into the instrument

When the insert cartridge screen is displayed, insert the sample cartridge (containing the sample swab) into the sample cartridge port. See the following figures.





The enter sample ID number screen is displayed.

Proceed to “Enter the sample identification number” on page 25.

Enter the sample identification number

You can manually enter the sample identification number, or you can scan a barcode. Proceed to the appropriate procedure:

- “Manually enter a sample ID or barcode” on page 26
- “Scan a barcode with the instrument camera” on page 26

Manually enter a sample ID or barcode

1. In the enter sample ID number screen, use the alphanumeric keypad to enter the sample ID or barcode.

   By default, the enter sample ID number screen displays the alphanumeric keypad. If the screen displays the camera for scanning a barcode, tap the in the center of the screen to display the keypad.



① The enter sample ID number screen, with the alphanumeric keypad displayed. To scan a barcode, tap , then see “Scan a barcode with the instrument camera” on page 26.

Sample ID guidelines:

- The keypad on the instrument touchscreen allows you to include spaces, underscores, periods, hyphens, and alphanumeric characters. If you use an external keyboard attached to the instrument, use only the same characters that are allowed by the touchscreen keypad.
- To create a valid CMF file according to the CODIS CMF file interface specifications, limit the sample ID to 9 characters. The specifications are published by the Federal Bureau of Investigation (FBI).

2. Tap **Enter**.

   The **Sample category** prompt is displayed.

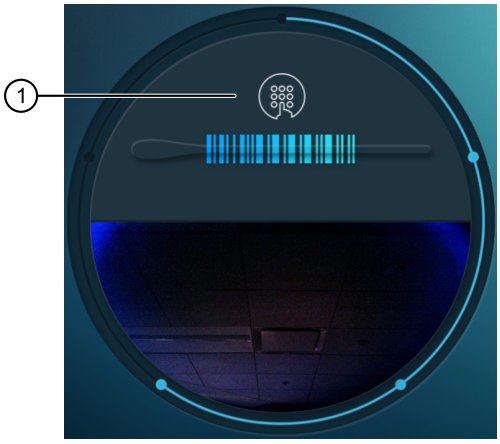
Proceed to “Select a sample category” on page 27.

Scan a barcode with the instrument camera

Note: You can also use a compatible handheld barcode scanner. For information on the compatible scanner, see “Required materials not supplied” on page 12.

1. In the enter sample ID number screen, tap in the middle of the screen to display the camera.

   By default, the enter sample ID number screen displays the keypad. If the screen already displays the camera, proceed to step 2.



① The enter sample ID number screen, with the camera displayed. To manually enter a sample ID or barcode, tap , then see "Manually enter a sample ID or barcode" on page 26.

2. Hold the barcode in front of the camera at the top left of the instrument.
   After the camera reads the barcode, the **Sample category** prompt is displayed.

Proceed to "Select a sample category" on page 27.

Select a sample category

The default sample categories are **Test** and **Training**. Depending on the workflow for your instrument and sample cartridge, more sample categories may be available.

Note: Workflows are configured in the RapidLINK™ Software. For more information, see the *RapidLINK™ Software v2.0 User Guide* (Pub. No. MAN0030010).

Note: Sample categories are not required for allelic ladder, negative control, positive control, or utility cartridges.

At the **Sample category** prompt, select or search for a sample category..

- **Select a sample category**—Tap ⌄, then select a sample category from the dropdown list.
- **Search for a sample category**—Tap the sample category field to display an alphanumeric keypad, begin entering the first characters of the sample category, then select the category from the search results.



① Dropdown list to select a sample category
② User name field to search for a sample category
③ Alphanumeric keypad to search a sample category
④ Dropdown list or search results

Proceed to one of the following, depending on your workflow:

- "(RapidINTEL™ Plus sample cartridge only) Select a sample protocol" on page 28
- "Start the run" on page 30

(RapidINTEL™ Plus sample cartridge only) Select a sample protocol

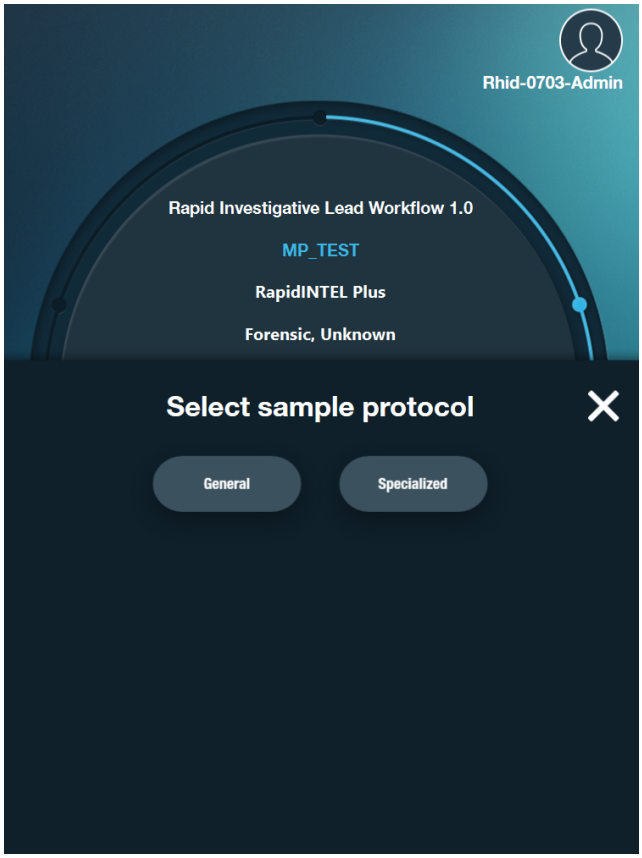
If you are running a RapidINTEL™ Plus sample cartridge, you may be prompted to select a sample protocol, depending on the workflow for your instrument:

- If the workflow specifies the **Dual** protocol, you will be prompted to select an appropriate protocol for your sample. Proceed to step 1.
- If the workflow specifies the **General** or **Specialized** protocol, you will not receive a prompt. Proceed to "Start the run" on page 30.

Note: Workflows are configured in the RapidLINK™ Software. For more information, see the *RapidLINK™ Software v2.0 User Guide* (Pub. No. MAN0030010).

At the **Select sample protocol** prompt, tap the appropriate sample protocol.

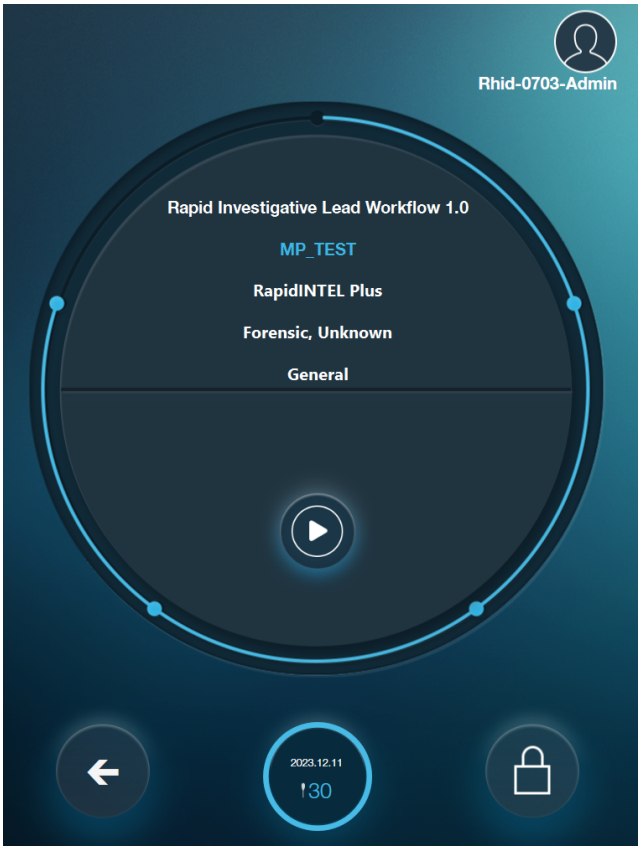
- **General**—The general protocol has a higher lysis volume and is intended for samples that were collected with standard swabs.
- **Specialized**—The specialized protocol has a lower lysis volume and is intended for samples that were collected with mini or micro swabs.



Proceed to “Start the run” on page 30.

Start the run

1. Review the information on the screen.
2. If any of the information needs to be corrected, tap ←.
   You will be prompted to remove the cartridge, re-insert it, then re-enter all of the run information.
3. Tap ▶ to start the run.



A sample cartridge run takes ~90–110 minutes to complete (see "Run times for different sample cartridges" on page 30). When the run is complete, the lock screen is displayed.

Proceed to "View the run results and remove the sample cartridge" on page 31.

Run times for different sample cartridges

- The countdown timer starts at 110 minutes. The typical run time is ~90 minutes.
- The timer stops when the run is complete. The timer does not decrease to 0 minutes.

Cartridge	Run timer stops at
RapidHIT™ ID ACE GlobalFiler™ Express Sample Cartridge	~19 minutes
RapidINTEL™ Plus Sample Cartridge	~19 minutes

View the run results and remove the sample cartridge

1. When the run is complete, the lock screen is displayed. Tap the lock screen, then sign in (see “Sign in to the instrument” on page 20).

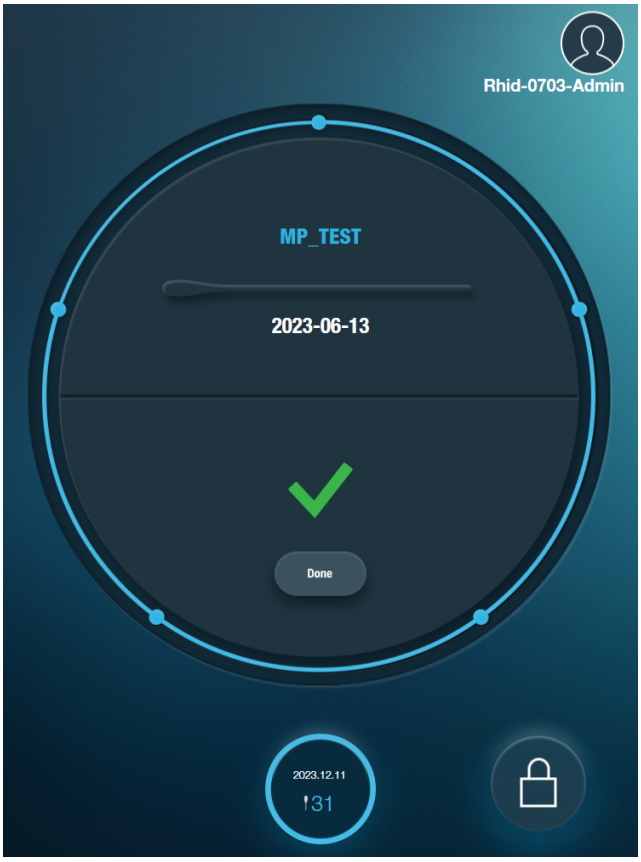
2. In the result screen, view the run result.

   IMPORTANT! If the instrument is restarted for any reason before you are able to sign in and view the run result, the result screen is not displayed. Instead, you are prompted to remove the cartridge (proceed to step 4). To view the run result, access the run log screen (see “View run log” on page 35).

Status	DNA profile was generated	Description	Action
Green 	Yes	The DNA profile does not contain quality flags.	The DNA profile is ready for analysis by the RapidLINK™ Software. No further action is needed on the instrument.
Yellow 	Yes	One of the following: • The DNA profile contains quality flags. • The run result contains only size standard peaks. It does not contain sample peaks.	The DNA profile may be available for review in the RapidLINK™ Software, depending on the workflow for your instrument. Proceed according to your standard operating protocol. **Note:** Workflows are configured in the RapidLINK™ Software. For more information, see the *RapidLINK™ Software v2.0 User Guide* (Pub. No. MAN0030010).
Red 	No	One of the following: • A DNA profile was not generated. • A critical DX code was generated during the run.	A DNA profile is *not* available for review in the RapidLINK™ Software. Proceed according to your standard operating protocol.

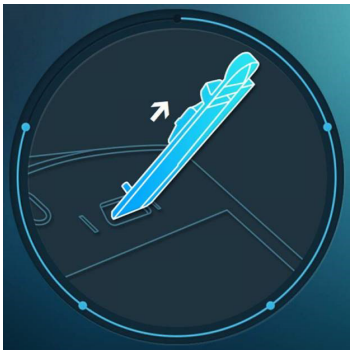
3. When you complete your review, tap **Done** to close the result screen.

   IMPORTANT! After you tap **Done**, the result screen can no longer be viewed. To view the run result again, access the run log screen (see “View run log” on page 35).



4. When the remove cartridge screen is displayed, remove the cartridge from the instrument.

   IMPORTANT! Remove the cartridge only when the remove cartridge screen is displayed. If the lock screen is displayed before you have a chance to remove the cartridge: Sign in again, wait for the remove cartridge screen, then remove the cartridge.



5. Discard the sample cartridge. Use proper precautions for disposal. Follow local, state, provincial and federal regulations for disposal.

Sign out

The signed-in user is automatically signed out in the following instances:

- When a run is completed
- If there is no user activity on the touchscreen for ≥2 minutes

You can manually sign out whenever the lock icon ( ) is displayed.
To sign out manually, tap .
The lock screen is displayed.



IMPORTANT! Leave the main power switch (on the back panel) set to On at all times. Power is necessary to maintain the gel temperature.

4 Manage the instrument and software

- View run log 35
- Configure instrument settings 36
- Configure instrument options 54
- Manage workflows 55

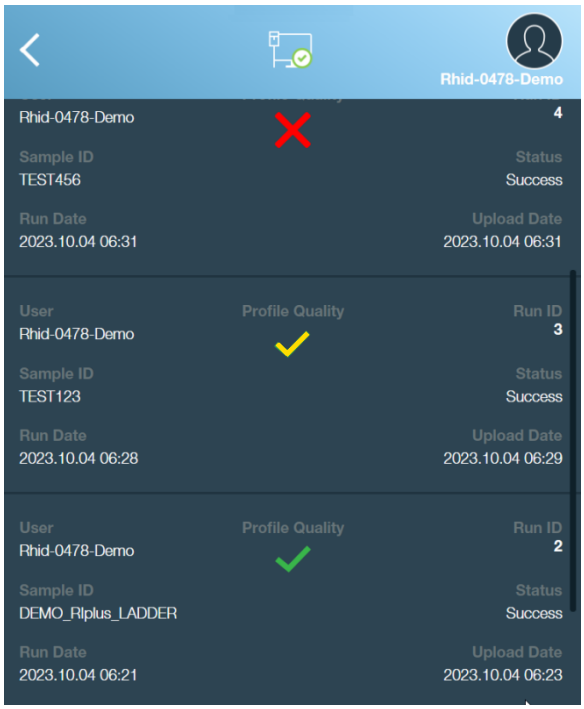
View run log

The run log displays a history of all runs performed on the instrument, including the upload and export status of the run.

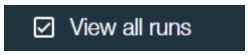
If your user role includes the **View all runs** permission, you can view a run log for all runs performed by all users. Otherwise, you can view only a run log for the runs that you performed. For more information on user role permissions, see “Edit a user role” on page 70.

1. Tap ☰, then tap 📄 to display the run log.

   Depending on your user role permissions, the run log displays only your run results, or the run results for all users. For a description of run results, see “View the run results and remove the sample cartridge” on page 31.



2. *(Optional)* By default, 150 entries are available to view. To view all runs, select the **View all runs** checkbox at the bottom of the screen.



Configure instrument settings

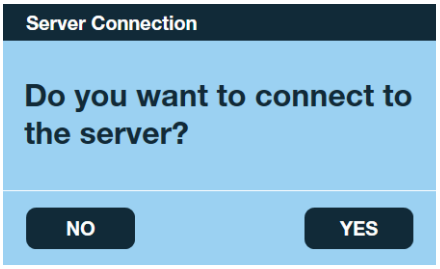
Connect or disconnect (server)

Configure the server connection (at initial startup)

Note: To connect an instrument that has been running in standalone mode, see “Configure the server connection (after running in standalone mode)” on page 42.

Perform this procedure if you are starting the instrument for the first time.

1. Power on the instrument.
2. At startup, you are prompted to select a server connection. Tap the appropriate connection option.



- **RapidLINK™ server**—Tap **YES** to connect the instrument to a RapidLINK™ server, then proceed to step 3.
- **Standalone**—Tap **NO** to operate the instrument in standalone mode (with no connection to a RapidLINK™ server). You are prompted to create the first administrator user account—skip to step 4.

3. Enter the server details provided by your IT administrator, then tap **Connect**.

Note: If the host name of the instrument was added to a host file, you can select the **Resolve to host name** checkbox, then enter the host name in the **IP address/host name** field. Alternatively, if the network DNS is correctly configured, you do not need to update the host file.

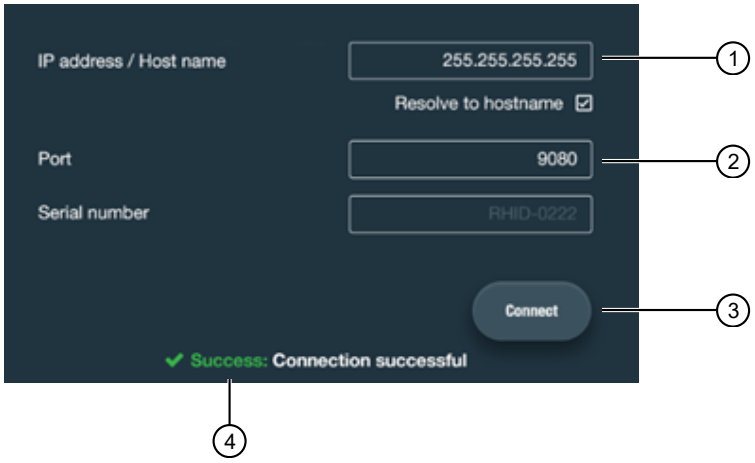


Figure 4

① IP address or host name
② Port
③ Tap to connect to the specified server
④ Connection is successful

Note: If you receive an error message, see “"Failed to connect to server" error message is displayed” on page 87 or “"The instrument is already registered on the server" error message is displayed” on page 87.

4. At the prompt, create the first administrator user account. For information on creating new user accounts, see “Add a user account (new user)” on page 59.
   After the first administrator user account is created, the lock screen is automatically displayed.

5. Sign in as the first administrator, then create new user accounts for the remaining users.

After all user accounts are created, users can begin operating the instrument.

Disconnect from a server (to run in standalone mode or to connect to a different server)

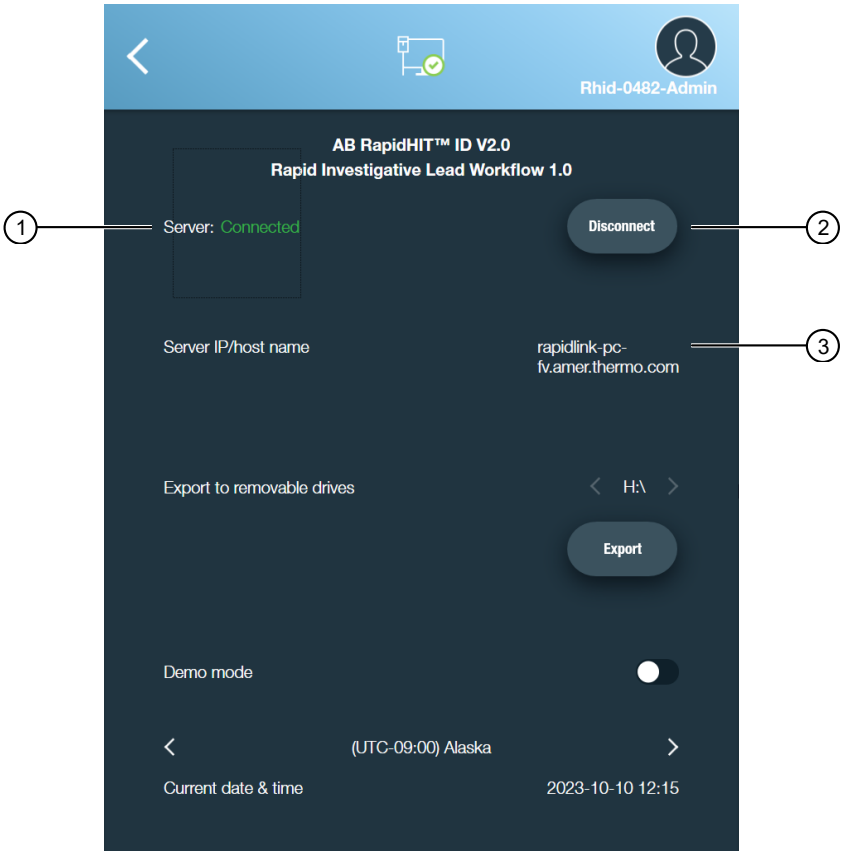
Note: If you are moving the instrument, and do not want to lose the connection to your current RapidLINK™ server, do *not* disconnect the instrument. Instead, unplug the instrument from the network, move the instrument to its new location, then plug the instrument back in.

Perform this procedure to disconnect the instrument from the current RapidLINK™ server. You may want to disconnect the instrument to run in standalone mode or to connect to a different server.

IMPORTANT! Disconnecting from a server removes all user accounts from the instrument, including the RapidHIT™ ID System administrator.

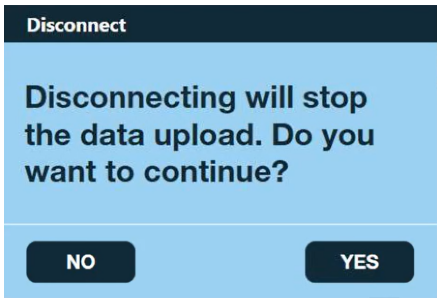
Note: If you disconnect the instrument from a RapidLINK™ server when the instrument is offline, the RapidLINK™ Software will not register the disconnection. A RapidLINK™ Software user must manually disconnect the instrument from within the RapidLINK™ Software. For more information, see the *RapidLINK™ Software v2.0 User Guide* (Pub. No. MAN0030010).

1. Tap ☰, then tap ⚙.
2. Tap **Disconnect**.



① The instrument is currently connected
② Tap to disconnect from the current server
③ When connected, the **Server IP/host name** is displayed

3. If there are runs queued for upload to the RapidLINK™ server, the prompt **Disconnecting will stop the data upload** appears. We recommend that you export the queued runs before continuing.



   a. Tap **NO** to stop the disconnect process.

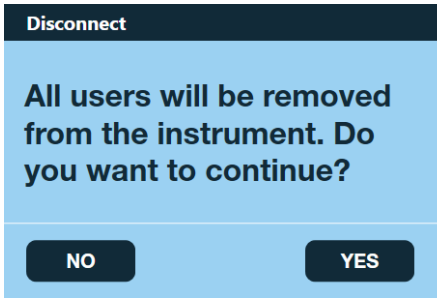
   b. Export the queued runs to a USB device. See “Export data” on page 44.

   c. When the export is complete, try disconnecting again.

Note: If you tap **YES**, the disconnect process continues, and the queued runs are not uploaded to the RapidLINK™ server. The runs are retained on the instrument—the run data will not be lost.

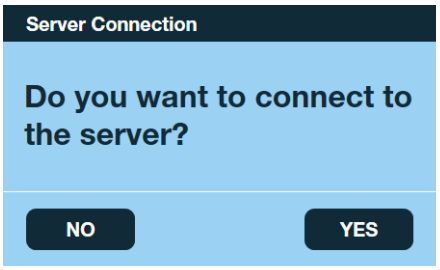
4. At the **All users will be removed from the instrument** prompt, tap **YES** to continue. All user accounts will be removed.

Note: If you do not want the user accounts to be removed, tap **NO** to stop the disconnect process. No user accounts will be removed. No further action is required.



The instrument software automatically restarts (the restart takes ~1–2 minutes).

5. At restart, you are prompted to select a server connection. Tap the appropriate connection option.



- **RapidLINK™ server**—Tap **YES** to connect the instrument to a RapidLINK™ server, then proceed to .step 6.
- **Standalone**—Tap **NO** to operate the instrument in standalone mode (with no connection to a RapidLINK™ server). You are prompted to create the first administrator user account—skip to step 7.

6. Enter the server details provided by your IT administrator, then tap **Connect**.

Note: If the host name of the instrument was added to a host file, you can select the **Resolve to host name** checkbox, then enter the host name in the **IP address/host name** field. Alternatively, if the network DNS is correctly configured, you do not need to update the host file.

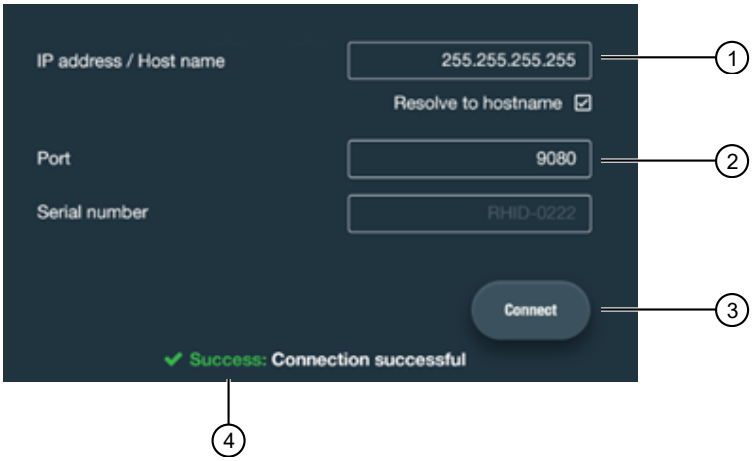


Figure 5

1. IP address or host name
2. Port
3. Tap to connect to the specified server
4. Connection is successful

Note: If you receive an error message, see “"Failed to connect to server" error message is displayed” on page 87 or “"The instrument is already registered on the server" error message is displayed” on page 87.

7. At the prompt, create the first administrator user account. For information on creating new user accounts, see “Add a user account (new user)” on page 59.
After the first administrator user account is created, the lock screen is automatically displayed.

8. Sign in as the first administrator, then create new user accounts as needed.

Connection status	Accounts
Connecting to a RapidLINK™ server	• If the RapidLINK™ server includes any instrument user accounts that are authorized for this instrument, those accounts are automatically downloaded to the instrument. **Note:** The automatic download may take several minutes, depending on the number of user accounts. You can continue using the instrument while the download is in progress. Alternatively, you can manually download the user accounts; see “Manually download user accounts from the RapidLINK™ Software” on page 71. • Create new accounts for the remaining users.
Running the instrument in standalone mode (no connection to a RapidLINK™ server)	Create new accounts for the remaining users.

After all user accounts are created, users can begin operating the instrument.

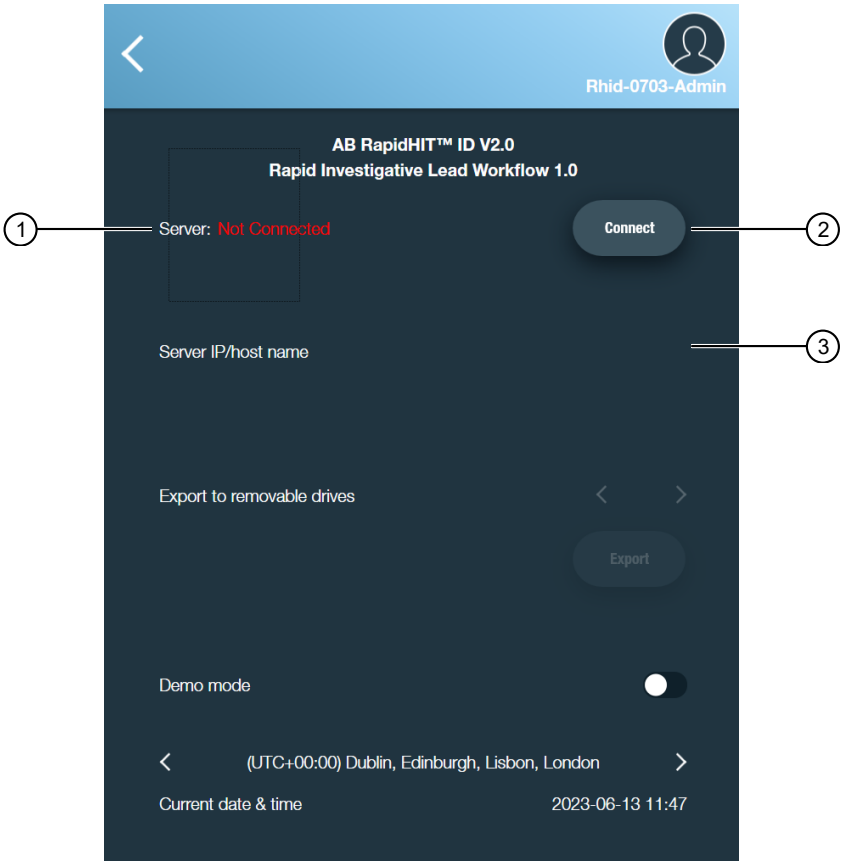
Configure the server connection (after running in standalone mode)

Note: If you are starting the instrument for the first time, see “Configure the server connection (at initial startup)” on page 36.

Perform this procedure to connect to a RapidLINK™ server after the instrument has been running in standalone mode.

IMPORTANT! Connecting to a server removes all user accounts from the instrument, including the RapidHIT™ ID System administrator.

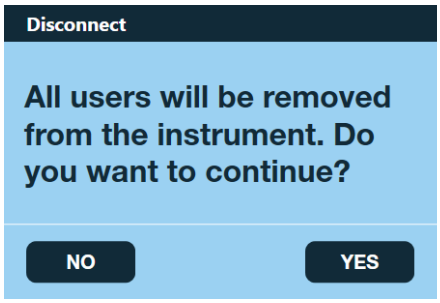
1. Tap ☰, then tap ⚙.
2. Tap **Connect**.



① The instrument is currently disconnected
② Tap to connect to a server
③ When disconnected, the **Server IP/host name** is empty

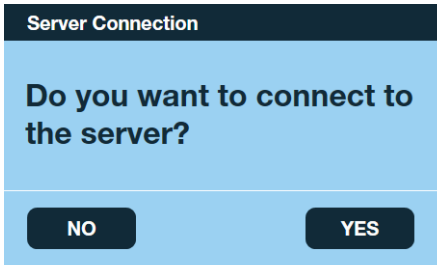
3. At the **All users will be removed from the instrument** prompt, tap **YES** to continue. All user accounts that were created while the instrument was in standalone mode will be removed.

   Note: If you do not want the user accounts to be removed, tap **NO** to discontinue. No user accounts will be removed. No further action is required.



   The instrument software automatically restarts (the restart takes ~1–2 minutes).

4. At restart, you are prompted to select a server connection. Tap **YES** to connect the instrument to a RapidLINK™ server.



5. Enter the server details provided by your IT administrator, then tap **Connect**.

   Note: If the host name of the instrument was added to a host file, you can select the **Resolve to host name** checkbox, then enter the host name in the **IP address/host name** field. Alternatively, if the network DNS is correctly configured, you do not need to update the host file.

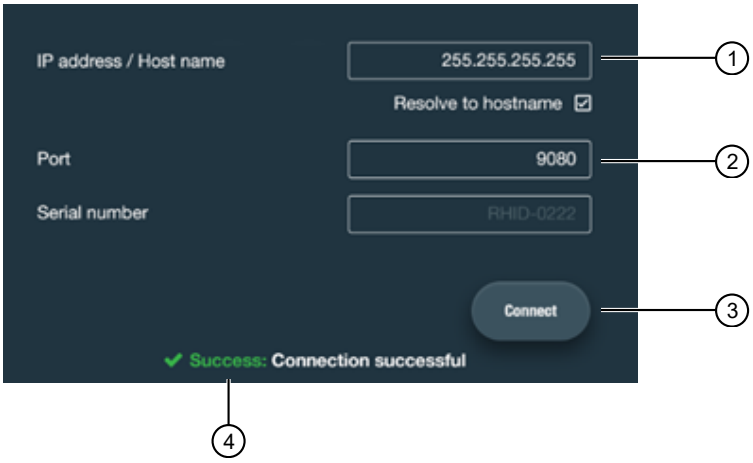


Figure 6

1. IP address or host name
2. Port
3. Tap to connect to the specified server
4. Connection is successful

Note: If you receive an error message, see ""Failed to connect to server" error message is displayed" on page 87 or ""The instrument is already registered on the server" error message is displayed" on page 87.

6. At the prompt, create the first administrator user account. For information on creating new user accounts, see "Add a user account (new user)" on page 59.
   After the first administrator user account is created, the lock screen is automatically displayed.

7. Sign in as the first administrator, then create new user accounts as needed.
   - If the RapidLINK™ server includes any instrument user accounts that are authorized for this instrument, those accounts are automatically downloaded to the instrument.

     Note: The automatic download may take several minutes, depending on the number of user accounts. You can continue using the instrument while the download is in progress. Alternatively, you can manually download the user accounts; see "Manually download user accounts from the RapidLINK™ Software" on page 71.
   - Create new accounts for the remaining users.

After all user accounts are created, users can begin operating the instrument.

Export data

The export function exports a copy of the selected data from the instrument to a USB device.

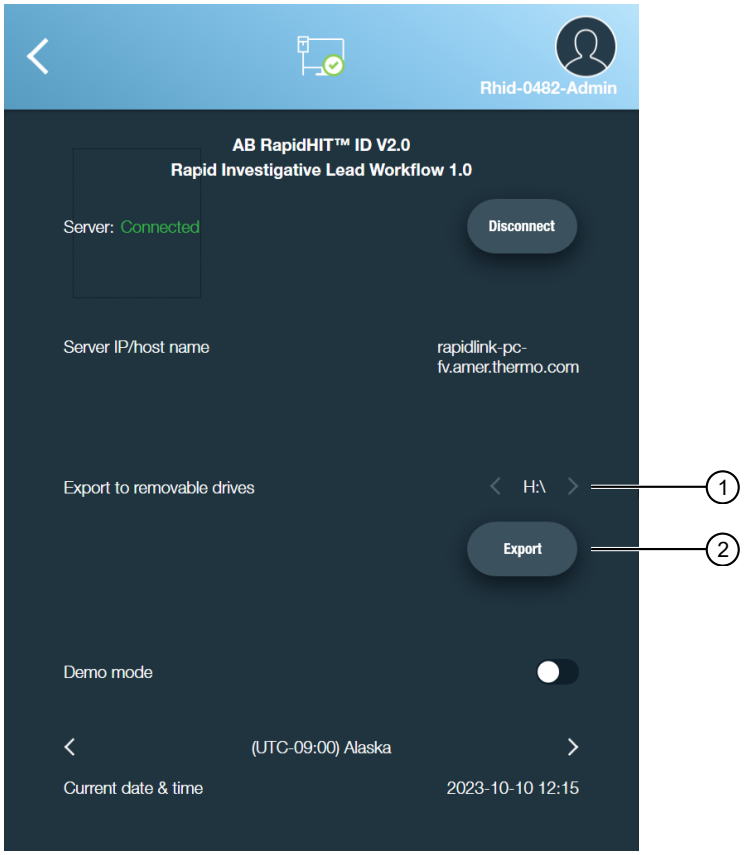
Note: The export function does not allow export of user account information or instrument settings.

1. Tap , then tap .
2. Insert a USB device or external storage device into the appropriate port on the instrument.

3. If multiple devices are inserted in the instrument, tap the left or right arrow to select the appropriate drive.

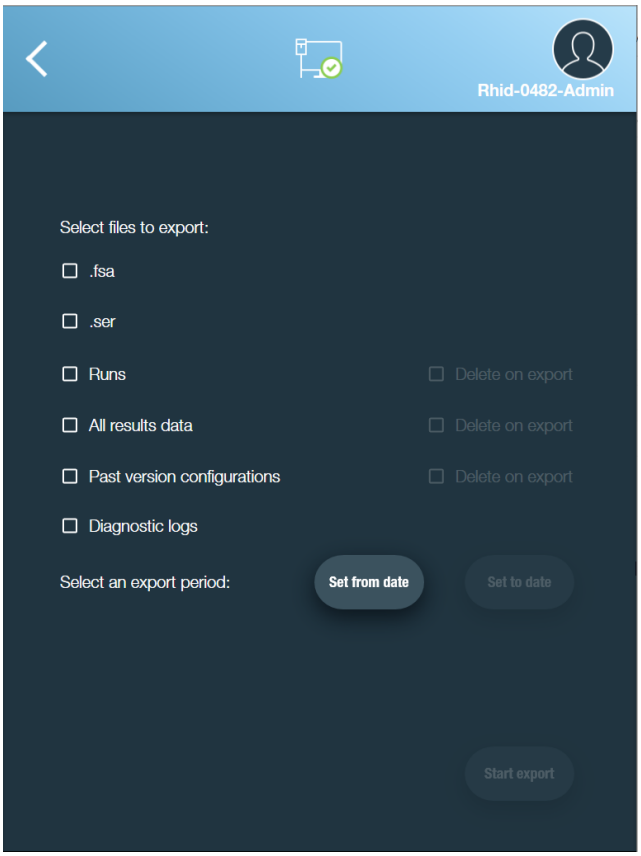
   Note: If only one device is inserted, the correct drive is automatically selected.

4. Tap **Export**.



① Drive selection, if multiple devices are inserted in the instrument
② **Export** button displays export options

5. Select the checkboxes for the data to export.



Item	Description
.fsa	Exports all sample files (FSA).
.ser	Exports all project files (SER).
Runs	Exports all FSA files, SER files, and run folders. Selecting the **Runs** checkbox, automatically selects the **.fsa** and **.ser** checkboxes. You can deselect one or both of those checkboxes.
All results data	Exports the three options above (**.fsa**, **.ser**, **Runs**) and instrument data (for example, maintenance data and BEC insertion data).
Past version configurations	Exports backed up instrument configuration data from earlier versions of the RapidHIT™ ID System.
Diagnostic logs	Exports trending diagnostic information for the past 10 days: • Run logs for the runs performed in the last 10 days • Maintenance logs for maintenance performed in the last 10 days • Instrument script logs for the last 10 days • Windows™ event and firewall logs for the last 10 days

Note: For the **.fsa**, **.ser**, and **Runs** options: If the RapidHIT™ ID Instrument is configured to automatically delete run data after the data are transferred to the RapidLINK™ Software, there may not be any data available to export. See the **Delete run data on upload to server** option in "Configure instrument options" on page 54.

6. If you select **Runs**, **All results data**, or **Past version configurations**, select whether to delete the data on export.

   To maintain space on the instrument, we recommend that you select the option to delete the data on export. By default, the data will be deleted ~1 hour after the export; however, the time can be configured by Service.

   Note: Alternatively, you can configure the instrument to automatically delete run data (FSA files, SER files, and run folders) after the data are transferred to the RapidLINK™ Software. See the **Delete run data on upload to server** option in "Configure instrument options" on page 54.

7. Select an export period.

   Note: If you do not select an export period, only export data for the current date will be exported.

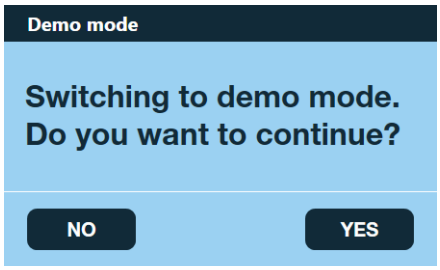
8. Tap **Start export**.

The **Export** button changes to **Abort** and a progress bar is displayed. When the export is complete, a message is displayed.

Enable demo mode and *(optional)* perform a simulated run

When enabled, demo mode allows simulated user accounts and runs that can be used for training purposes.

1. Tap ☰, then tap ⚙.
2. Tap the **Demo mode** toggle button to enable (⬤) demo mode.
3. At the prompt, tap **YES** to switch to demo mode.



The instrument software automatically restarts in demo mode (the restart takes ~1 minute). A yellow banner is displayed on the touchscreen.

4. At the prompt, create a demo administrator account and *(optional)* any other demo user accounts. For information on creating user accounts, see “Add a user account (new user)” on page 59.

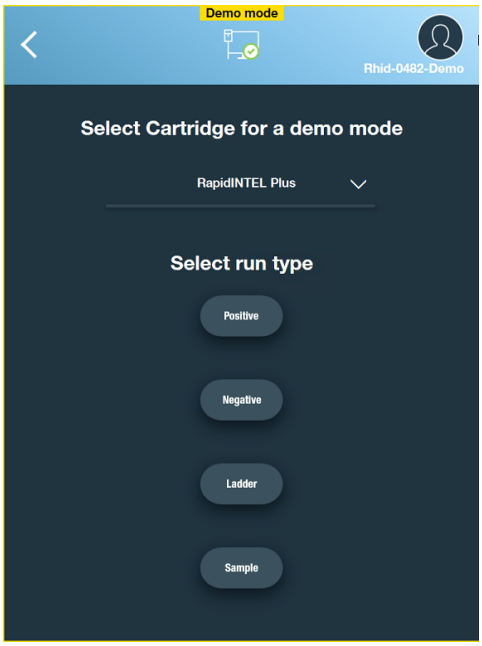
Note: New demo user accounts must be created each time that you enable demo mode. All demo user accounts are removed when you disable demo mode. Demo mode user accounts are not uploaded to the RapidLINK™ Software.

5. Start a simulated run. You can perform the simulated run with or without cartridges.

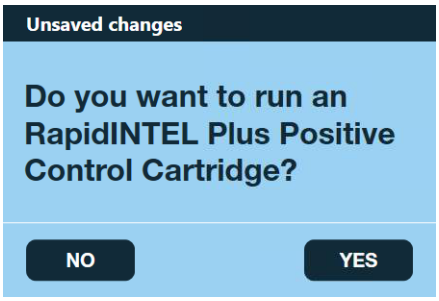
Note: *(Demo mode only)* RapidHIT™ ID System v2.0.1 allows the use of expired sample cartridges.

Action
Perform a simulated run without cartridges

1. Tap **Demo run settings**.
2. Select a cartridge type from the dropdown list, then tap a run type.



3. At the prompt, tap **YES** to start the run.

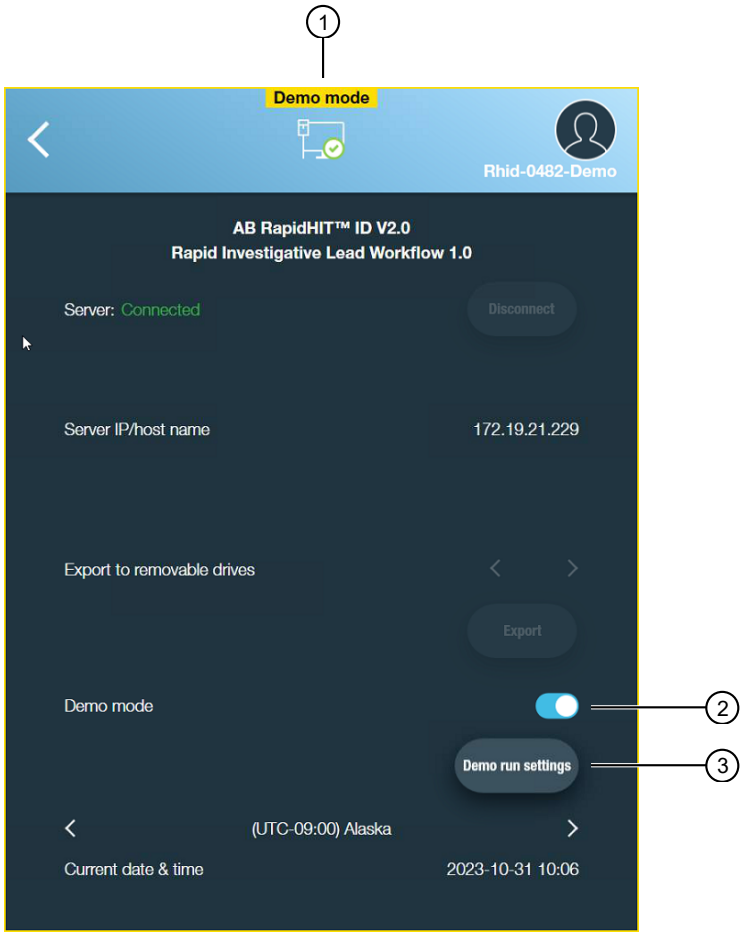


4. At the prompts (for example, insert cartridge), tap the touchscreen to move to the next step in the run.

(continued)

Action
Perform a simulated run with cartridges
Follow the prompts to perform the simulated run. For detailed information on performing a run, see Chapter 3, "Run the instrument". Note the following: • When prompted to insert a cartridge, ensure that you use the appropriate cartridge. **Note:** *(Demo mode only)* RapidHIT™ ID System v2.0.1 allows the use of expired sample cartridges. • When prompted to enter the sample identification number, scan the appropriate barcode or manually enter one of the following IDs to generate the correct results. The instrument software determines the correct chemistry, so you only need to enter the text after the second underscore (for example, you can enter **Fail_Sample** instead of **DEMO_RIplus_Fail_Sample**). **Note:** The cartridge used for simulation is not physically engaged in the instrument. However, you should not remove the cartridge until prompted to do so.

IDs for the RapidINTEL™ Plus chemistry	IDs for the GlobalFiler™ Express chemistry
• DEMO_RIplus_Fail_Sample • DEMO_RIplus_LADDER • DEMO_RIplus_NEGCTRL • DEMO_RIplus_Pass_Sample • DEMO_RIplus_POSCTRL • DEMO_RIplus_QF_Sample	• DEMO_GFE_Fail_Sample • DEMO_GFE_LADDER • DEMO_GFE_NEGCTRL • DEMO_GFE_Pass_Sample • DEMO_GFE_POSCTRL • DEMO_GFE_QF_Sample

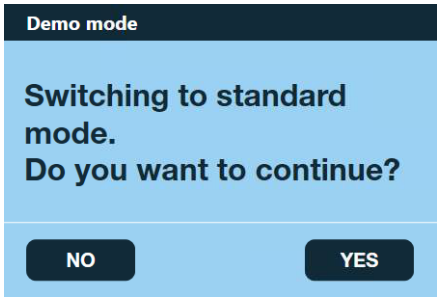


① Yellow **Demo mode** banner is displayed on the touchscreen
② **Demo mode** toggle button—demo mode enabled
③ Opens a settings menu for simulated runs

Demo runs are uploaded to the RapidLINK™ Software, where users can view the demo runs for training purposes.

Disable demo mode

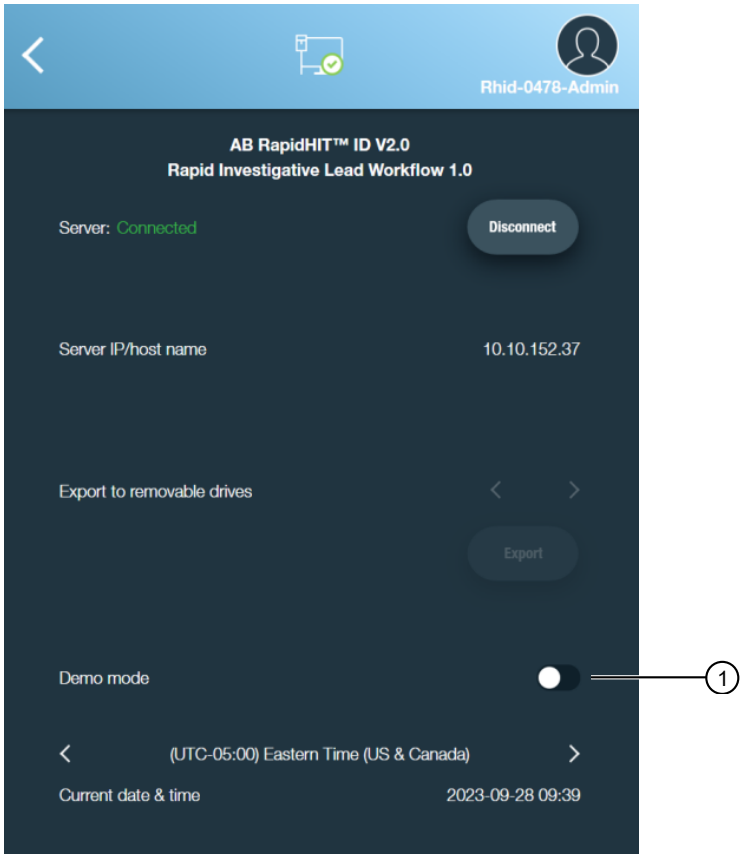
1. Tap ☰, then tap ⚙.
2. Tap the **Demo mode** toggle button to disable (◯) demo mode.
3. At the prompt, tap **YES** to switch to standard mode.



Note: All demo user accounts are removed when you disable demo mode. New demo user accounts must be created each time that you enable demo mode.

The instrument software automatically restarts in standard mode (the restart takes ~1–2 minutes). The yellow banner is no longer displayed on the touchscreen.

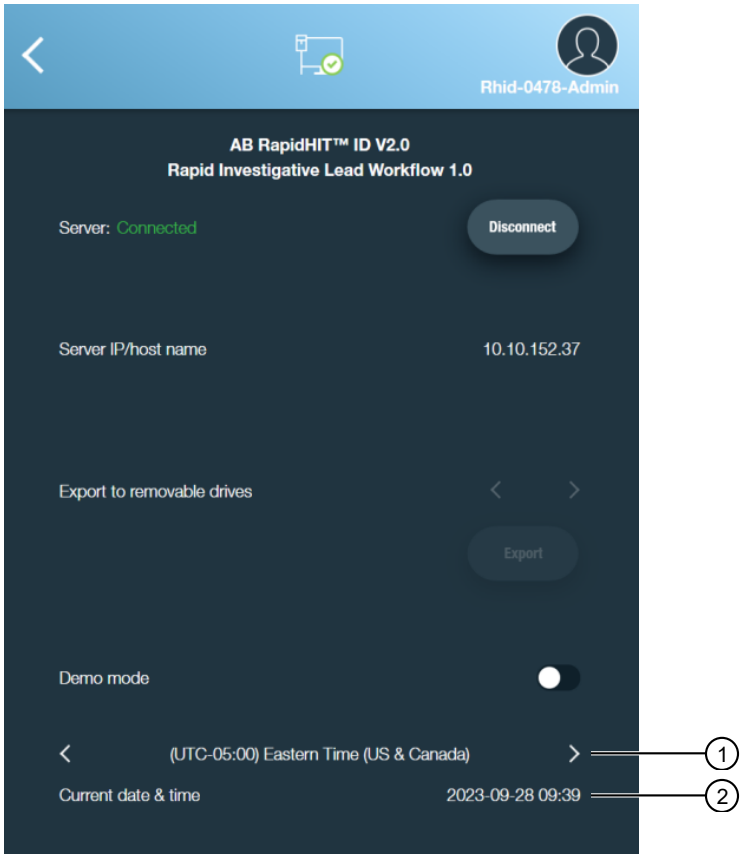
Note: If the instrument has been in demo mode for a long period of time, you may see a **Maintenance in progress** message upon restart. If the maintenance requires a utility cartridge, you will be prompted to insert one (see “Routine maintenance” on page 73). Otherwise, the message automatically disappears after ~1 minute.



① **Demo mode** toggle button—demo mode disabled

Adjust the instrument time zone

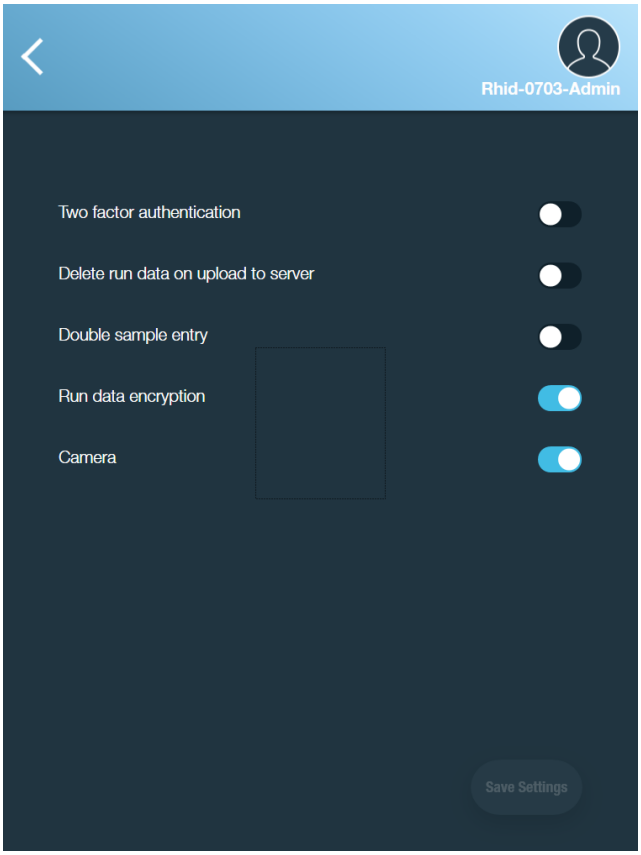
1. Tap ☰, then tap ⚙.
2. At the bottom of the screen, tap the left or right arrow to adjust the time zone of the instrument. The current date and time of the selected time zone is displayed.



① Time zone
② Current date and time

Configure instrument options

1. Tap ☰, then tap ⚙.
2. Configure the instrument options as needed.



Setting	Description	Default
Two factor authentication	When enabled, requires a password/PIN and one biometric (fingerprint scan or face recognition) to sign in. • To enable two factor authentication, an administrator account with at least two factors must already exist on the system. • After two factor authentication is enabled, users with only one factor cannot sign in, and their user accounts are flagged with . Their accounts must be updated to include two factors before they can sign in again. When disabled, requires only one factor to sign in.	Enabled
Delete run data on upload to server	When enabled, deletes run data from the instrument after it has been uploaded to the RapidLINK™ Software. **Note:** Run data includes FSA files, SER files, and run folders. For more information, see the **.fsa**, **.ser**, and **Runs** options in "Export data" on page 44.	Disabled
Double sample entry	When enabled, requires a sample identification number to be entered twice when a sample is run. The double entry helps ensure that the sample identification number is accurate.	Disabled
Run data encryption	When enabled, encrypts run data on the instrument as follows: • Data are automatically encrypted when created. • Data are automatically decrypted when downloaded from the RapidLINK™ Software and when exported to a USB device (see "Export data" on page 44) .	Enabled
Camera	When enabled, allows the instrument camera to be used for facial recognition during sign in and to scan barcodes.	Enabled

3. Tap **Save Settings**.

Manage workflows

Workflows are configured in the RapidLINK™ Software. A workflow provides the following functions:

- On the RapidHIT™ ID instrument, the workflow specifies the instrument run and data analysis parameters.
- In the RapidLINK™ Software, the workflow determines how a run progresses in the software, based on the profile quality and run status.

Methods for assigning an instrument to a workflow

There are three methods for assigning an instrument to a workflow:

- **Default assignment**—Each RapidHIT™ ID instrument is shipped with the default system-defined workflow.
- **RapidLINK™ Software**—A RapidLINK™ Software user can assign an instrument to a new workflow from the RapidLINK™ Software. See “Assign an instrument to a workflow (RapidLINK™ Software)” on page 56.
- **Manual install**—You can assign an instrument to a new workflow by manually installing the workflow on the instrument. See “Manually update a workflow on the instrument” on page 56.

An instrument can be assigned to only one workflow at a time. Different instruments connected to the same RapidLINK™ Software instance can be assigned to different workflows. For example, Instrument 1 can be assigned to Workflow A, but Instrument 2 can be assigned to Workflow B.

Assign an instrument to a workflow (RapidLINK™ Software)

A RapidLINK™ Software user can assign an instrument to a new workflow from the RapidLINK™ Software.

For detailed instructions, see the *RapidLINK™ Software v2.0 User Guide* (Pub. No. MAN0030010).

Note the following:

- When a new workflow is assigned in the RapidLINK™ Software and is ready for download, the instrument touchscreen displays an update available icon ( ).
- For the download to occur on the instrument: All maintenance and sample runs must be complete, the instrument must be idle, and all users must be signed out of the instrument.
- When the download is complete, the instrument software automatically restarts (the restart takes ~1–2 minutes).
- If the download fails, the instrument touchscreen displays an update failed icon ( ).
- The workflow change is applied to all existing and new user accounts the next time that each user signs in.
- The workflow change is applied to all future runs.

Manually update a workflow on the instrument

1. In the RapidLINK™ Software, export a workflow (ZIP file).
   For detailed instructions, see the *RapidLINK™ Software v2.0 User Guide* (Pub. No. MAN0030010).
2. Save the ZIP file to a USB device.
3. Insert the USB device into the appropriate port on the instrument.
   An update available icon ( ) is displayed on the instrument touchscreen.
4. Tap to install the workflow.

The following occurs:

- A progress message is displayed.
- When the install is complete, the instrument software automatically restarts (the restart takes ~1–2 minutes).
- The workflow change is applied to all existing and new user accounts the next time that each user signs in.
- The workflow change is applied to all future runs.

IMPORTANT! The manual update does not change the workflow that the instrument is assigned to in the RapidLINK™ Software. As soon as you remove the USB device, the RapidLINK™ Software will assign the instrument to the workflow that is specified in the RapidLINK™ Software. To prevent this, do one of the following before removing the USB device:

- In the RapidLINK™ Software: Ensure that the RapidLINK™ Software administrator assigns the instrument to the same workflow that you manually updated to on the instrument.
- Disconnect the instrument from the RapidLINK™ Software.

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5 Manage users

- Search for a user account 58
- Add a user account (new user) 59
- Add a user account (existing user) 63
- Edit a user account (includes password/PIN reset) 65
- Edit a user role 70
- Manually download user accounts from the RapidLINK™ Software 71
- Authorize or deauthorize a user account (RapidLINK™ Software) 72

Search for a user account

1. Tap ☰, then tap 👥.
2. Tap the **Search for a user** field to display an alphanumeric keypad, begin entering the first characters of a user name, then select the user account from the search results.
3. To clear the search results, tap **X**.



① **Search for a user** field
② Alphanumeric keypad
③ Search results; scroll down if needed
④ Clear search results

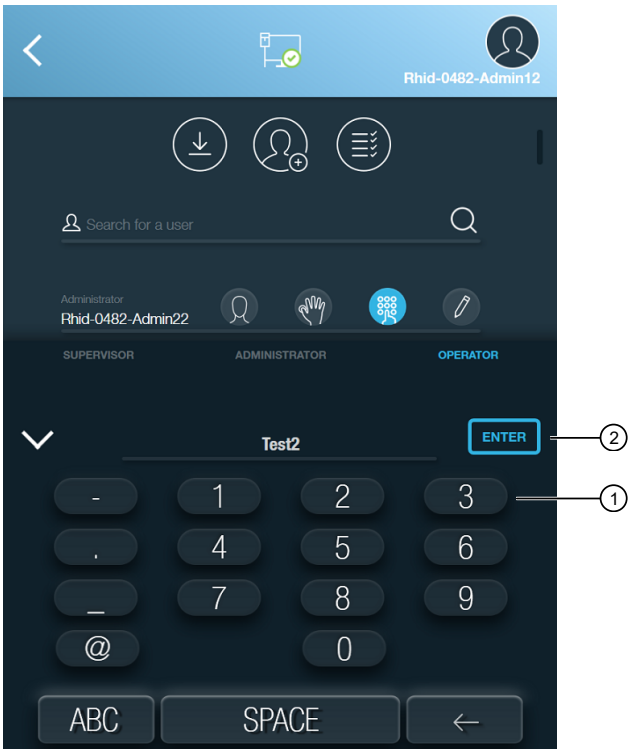
Add a user account (new user)

When a user account is created on one RapidHIT™ ID instrument, that same user account can be authorized for all other instruments connected to the same RapidLINK™ Software instance.

Note: If needed, an administrator can remove the authorization for individual instruments (see "Authorize or deauthorize a user account (RapidLINK™ Software)" on page 72).

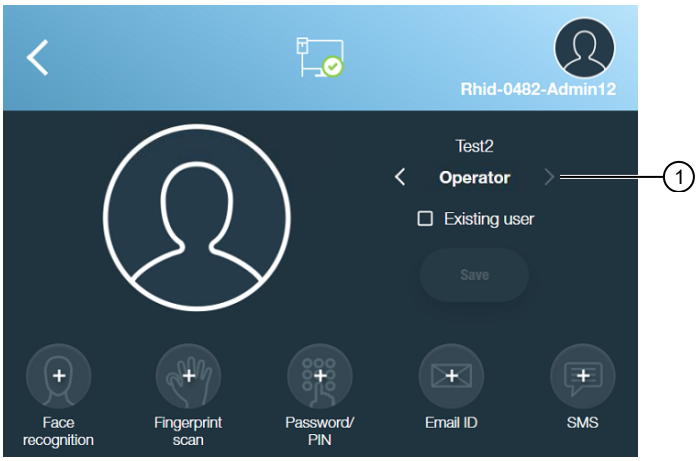
1. Tap , then tap .
2. Tap .

3. Enter a user name with the alphanumeric keypad, then tap **ENTER**.



① Enter a user name with the alphanumeric keypad
② Tap **ENTER**

4. Use the left or right arrow to select a user role **Supervisor**, **Administrator**, or **Operator**.

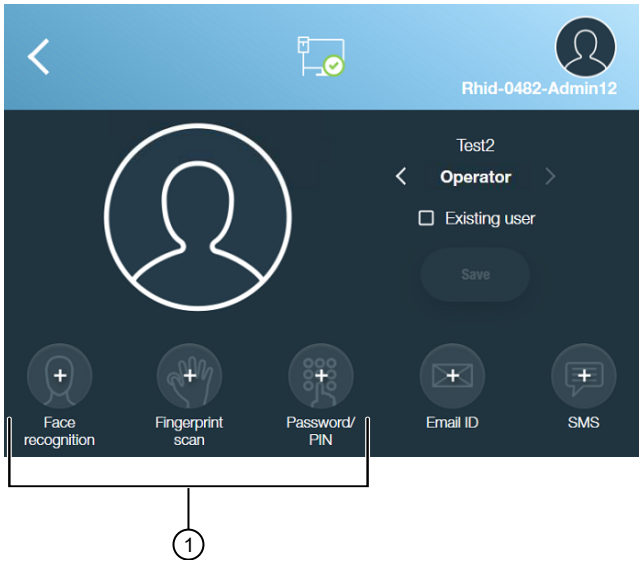


① Arrows to select a user role

IMPORTANT! Do not select the **Existing user** checkbox for new RapidHIT™ ID instrument users. If you need to add an existing user to a new instrument, see “Add a user account (existing user)” on page 63.

5. Select one or more user authentication methods.

Note: You can select 1–3 authentication methods. A password/PIN is always required. If two-factor authentication is enabled on the instrument, a second method is also required (see “Configure instrument options” on page 54).

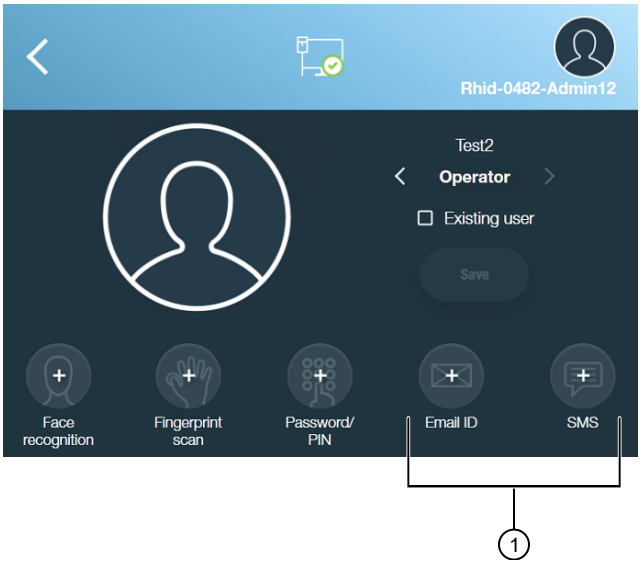


① User authentication methods

Option	Action
Password/PIN	a. Tap . b. Enter a PIN (6 characters) two times with the numeric keypad, then tap . A success message is displayed. The message closes automatically after a few seconds. We recommend that users change their PIN when they initially sign in.
Face recognition	a. Tap . b. Tap **Start face scan**. c. Ask the user to adjust their position so that their face is centered in the live camera view. When the scan is complete, a success message is displayed. The message automatically closes after a few seconds.
Fingerprint scan	a. Tap . b. Tap **Start fingerprint scan**. c. Ask the user to place any finger on the fingerprint pad on the front of the instrument, then remove and touch as instructed by the software. When the scan is complete, a success message is displayed. The message automatically closes after a few seconds.

6. *(Optional)* Add an email address or SMS mobile phone number.

Note: The email address and phone number are for information only—they are not authentication methods for signing in to the instrument

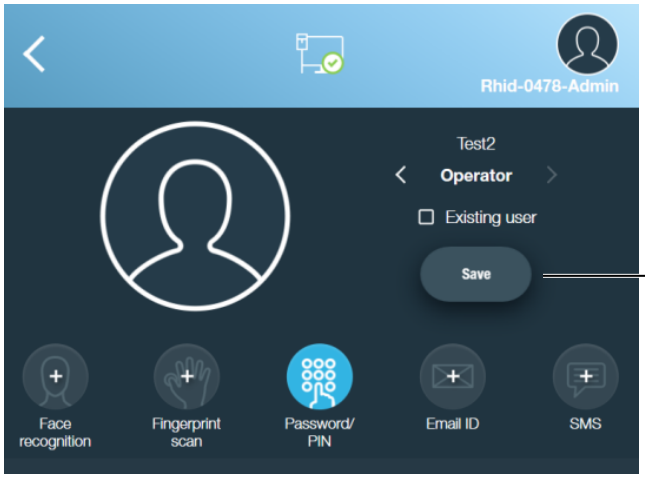


① Email ID and SMS options

Option	Action
Email ID	a. Tap +. b. Tap the **Enter Email ID** field. c. Enter an email address with the alphanumeric keypad, then tap **ENTER**. d. Tap 💾. A success message is displayed. The message closes automatically after a few seconds.
SMS	a. Tap +. b. Tap the **Enter Mobile No.** field. c. Enter a mobile telephone number with the alphanumeric keypad. The format is ***XXX-XXX-XXXX*** (include the hyphens). d. Tap **ENTER**. e. Tap 💾. A success message is displayed. The message closes automatically after a few seconds.

7. Tap **Save**.

IMPORTANT! You must tap the **Save** button, even if you tapped 💾 after previous entries (for example, after entering the password/PIN).



① **Save**

A success message is displayed. The message closes automatically after a few seconds.

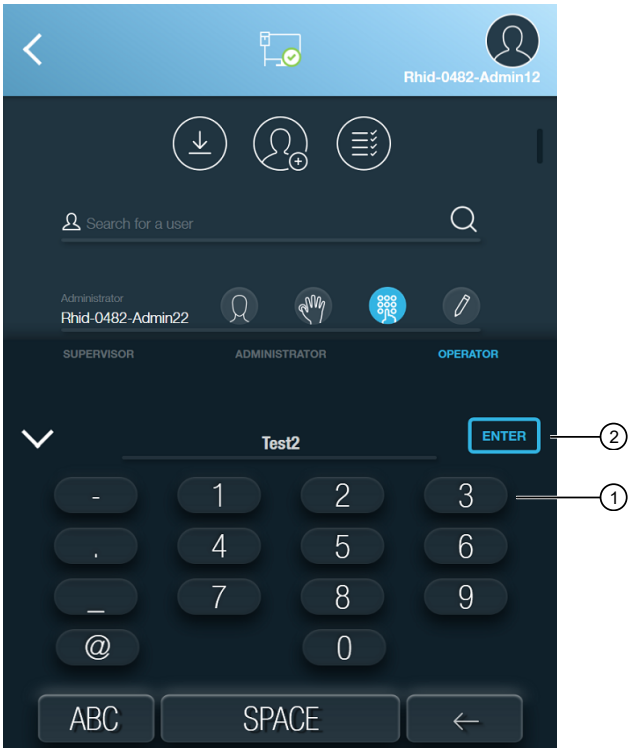
Add a user account (existing user)

This procedure is available only when both of the following circumstances are met:

- The RapidHIT™ ID System user account exists on a different instrument and has already been uploaded to the RapidLINK™ Software.
- You are adding the existing user account to a new instrument that is connected to the RapidLINK™ Software, but the instrument status is currently **Offline**.

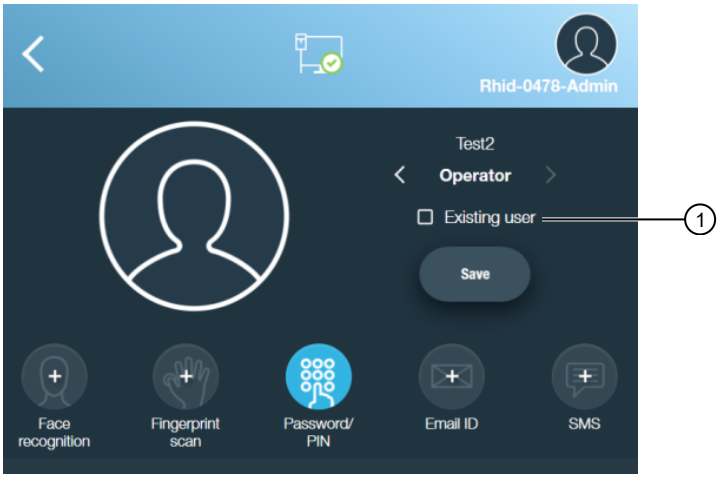
1. Tap , then tap .
2. Tap .
3. Enter the existing user name with the alphanumeric keypad, then tap **ENTER**.

   IMPORTANT! Enter the user name exactly as it appears in the existing user account.



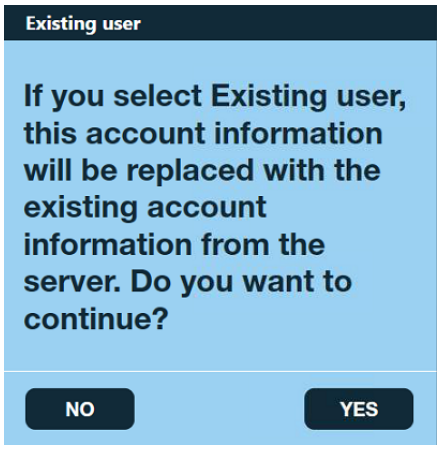
① Enter a user name with the alphanumeric keypad
② Tap **ENTER**

4. Select the **Existing user** checkbox.



① **Existing user** checkbox

5. At the prompt, tap **YES** to confirm.



6. Complete the remaining user account information. For detailed instructions, see “Add a user account (new user)” on page 59.

When the new instrument comes back online, the RapidLINK™ Software recognizes the user account and downloads all of the original user account information to the new instrument. If there are any discrepancies, the user account information in the RapidLINK™ Software overrides the user account information entered on the new instrument.

IMPORTANT! If you do not select the **Existing user** checkbox, when the instrument comes back online, the RapidLINK™ Software determines that there is a duplicate user account and generates a temporary user account. In the RapidLINK™ Software, the temporary account is flagged with ⚠; on the RapidHIT™ ID instrument, the account is flagged with ⚠.

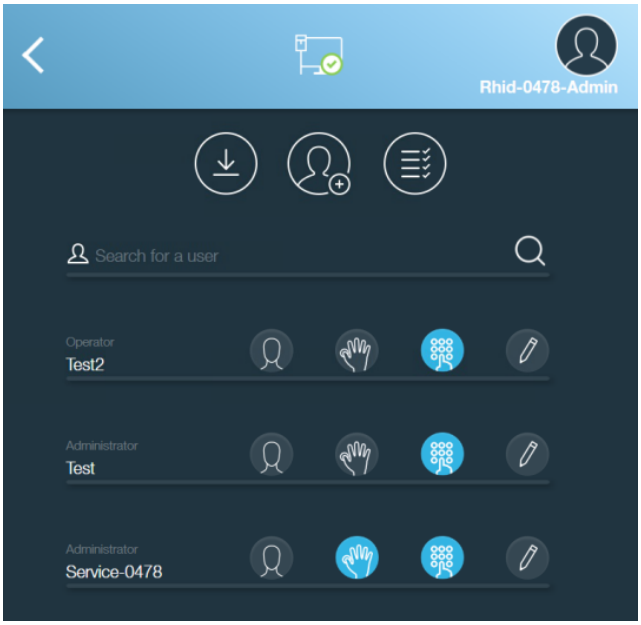
To resolve the duplication, edit the user name from the instrument. This is the only instance that allows a user name to be edited. See “Edit a user account (includes password/PIN reset)” on page 65.

Edit a user account (includes password/PIN reset)

Any user can edit their own account. To edit other user accounts, your user role must include the **Manager users** permission. For more information on user role permissions, see “Edit a user role” on page 70.

1. Tap ☰, then tap 👥.
2. Tap ✎ next to the user account to edit.

Note: If 🔒 is displayed next to a user account, the account cannot be edited. The user was deauthorized for this instrument or inactivated in the RapidLINK™ Software. These users cannot sign in to the instrument.

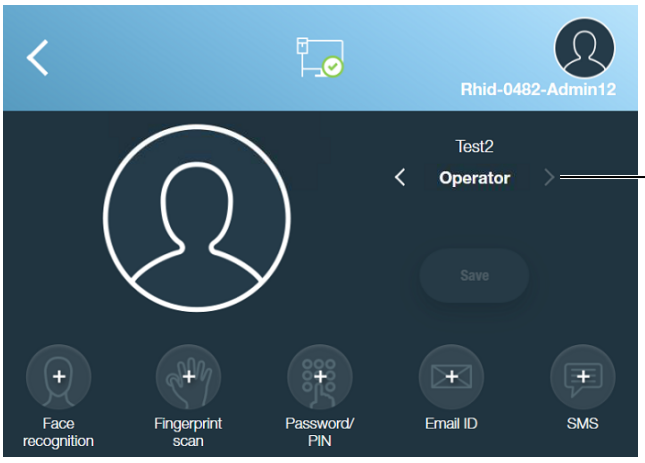


3. *(Duplicate user names only)* If a user account is flagged with ⚠, it indicates that it is a duplicate user account. To resolve the duplication, edit the user name or accept the temporary user name provided.

Note: This is the only instance that allows a user name to be edited. In all other instances, you cannot edit the user name for any existing user account (including your own account).

4. *(If needed)* Edit the user role: Use the left or right arrow to select a user role **Supervisor**, **Administrator**, or **Operator**.

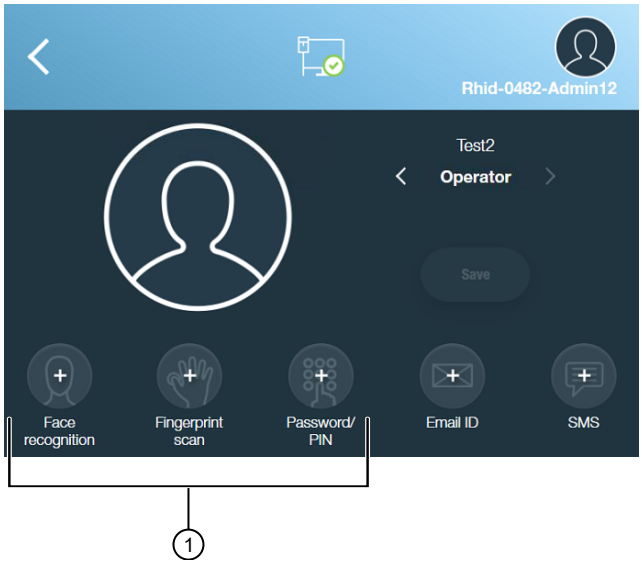
   You cannot edit your own user role unless you have the **Manager users** permission.



① Arrows to select a user role

5. *(If needed)* Edit the authentication methods.

Note: You can select 1–3 authentication methods. A password/PIN is always required. If two-factor authentication is enabled on the instrument, a second method is also required (see “Configure instrument options” on page 54).

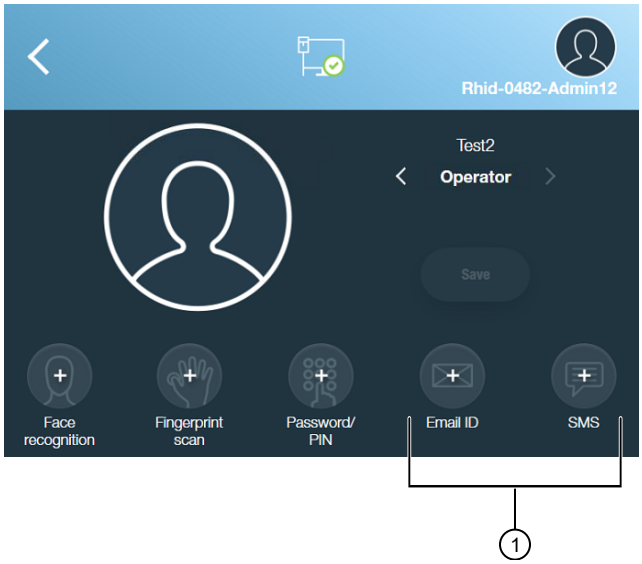


① User authentication methods

Option	Action
Password/PIN	**For users who know their PIN:** 1. Tap ⚙. 2. Enter the user's current PIN (6 characters) with the numeric keypad. 3. Enter a new PIN (6 characters) two times with the numeric keypad, then tap 💾. A success message is displayed. The message closes automatically after a few seconds. We recommend that users change their PIN when they initially sign in.
	For users who do not know their PIN: 1. Tap ⚙. 2. Select the **Reset PIN** checkbox. This allows you to enter a new PIN for the user account without entering the user's current PIN. 3. Enter a new PIN (6 characters) two times with the numeric keypad, then tap 💾. A success message is displayed. The message closes automatically after a few seconds. We recommend that users change their PIN when they initially sign in.
Face recognition	1. Tap ⊕. 2. Tap **Start face scan**. 3. Ask the user to adjust their position so that their face is centered in the live camera view. When the scan is complete, a success message is displayed. The message automatically closes after a few seconds.
Fingerprint scan	1. Tap ⊕. 2. Tap **Start fingerprint scan**. 3. Ask the user to place any finger on the fingerprint pad on the front of the instrument, then remove and touch as instructed by the software. When the scan is complete, a success message is displayed. The message automatically closes after a few seconds.

6. *(If needed)* Edit the email address or SMS mobile phone number.

Note: The email address and phone number are for information only—they are not authentication methods for signing in to the instrument

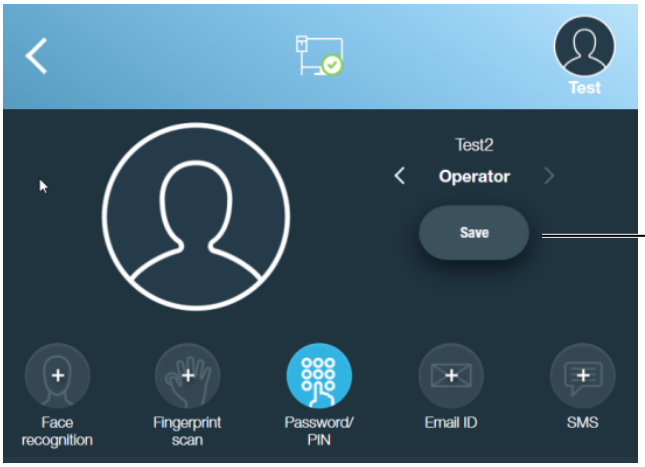


1 Email ID and SMS options

Option	Action
Email ID	a. Tap +. b. Tap the **Enter Email ID** field. c. Enter an email address with the alphanumeric keypad, then tap **ENTER**. d. Tap 💾. A success message is displayed. The message closes automatically after a few seconds.
SMS	a. Tap +. b. Tap the **Enter Mobile No.** field. c. Enter a mobile telephone number with the alphanumeric keypad. The format is ***XXX-XXX-XXXX*** (include the hyphens). d. Tap **ENTER**. e. Tap 💾. A success message is displayed. The message closes automatically after a few seconds.

7. Tap **Save**.

IMPORTANT! You must tap the **Save** button, even if you tapped 💾 after previous entries (for example, after entering the password/PIN).



① **Save**

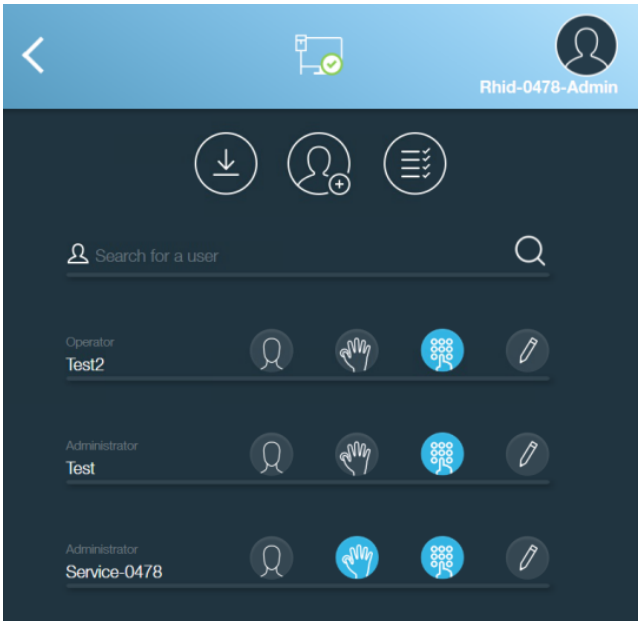
A success message is displayed. The message closes automatically after a few seconds.

Edit a user role

There are three default user roles in the instrument software: administrator, supervisor, and operator.

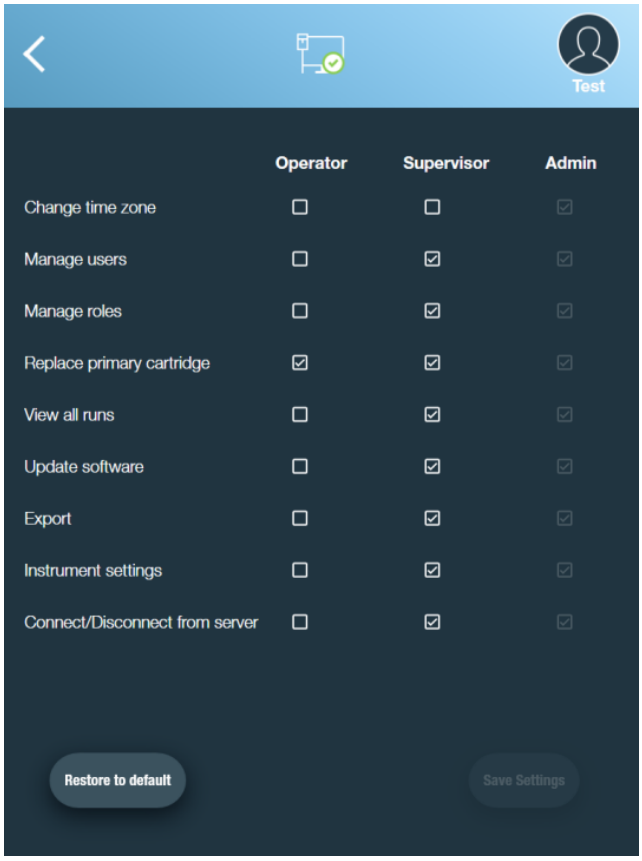
- You cannot delete the default user roles or create new user roles.
- You cannot change the permissions that are assigned to the administrator role.
- You can change the permissions that are assigned to the supervisor and operator roles. Permission changes are applied to all existing and new user accounts the next time that each user signs in.

1. Tap , then tap .
2. Tap .



3. Edit the permissions for the supervisor or operator role: Select and deselect the checkboxes as needed.

   The default permissions for each user role are displayed below.



4. *(If needed)* Tap **Restore to default** to restore the default permissions for the supervisor and operator roles.

5. Tap **Save Settings**.

Manually download user accounts from the RapidLINK™ Software

The RapidLINK™ Software automatically syncs the instrument user accounts on a periodic basis. This manual download procedure only downloads user account changes made in the RapidLINK™ Software to the instrument. It does not upload any user account changes made on the instrument to the RapidLINK™ Software.

Note: The user accounts must be authorized for the instrument.

1. Tap ☰, then tap 👥.

2. At the top of the user account screen, tap ⬇.

Authorize or deauthorize a user account (RapidLINK™ Software)

In the instrument software, users are automatically authorized for the instrument that their user account was created on. Otherwise, authorization and deauthorization must be applied from the RapidLINK™ Software. See the following table for details:

State	Description	Instrument software	RapidLINK™ Software
Authorized	When a user is authorized for an instrument, the user can sign in to that instrument.	• Users are automatically authorized for the instrument that their user account was created on. • Users cannot be authorized for other instruments.	Users can be authorized for any instrument.
Deauthorized	• When a user is deauthorized from an instrument, the user cannot sign in to that instrument. • 🔒 is displayed next to the user account.	Users cannot be deauthorized from any instrument.	Users can be deauthorized from any instrument.

For detailed instructions on using the RapidLINK™ Software to authorize and deauthorize users, see the *RapidLINK™ Software v2.0 User Guide* (Pub. No. MAN0030010).

Note the following:

- Deauthorization applies only to a single instrument. If you want to deauthorization a user from multiple instruments, repeat the procedure for each instrument. Alternatively, you can deactivate a user in the RapidLINK™ Software, which will prevent the user from signing in to all instruments.
- If an instrument is disconnected from the network during the deauthorization process, the user authorization will be removed for that instrument when the instrument is reconnected.

6 Maintain the instrument

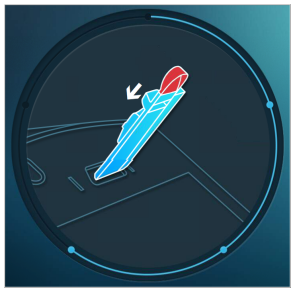
- Routine maintenance 73
- View primary cartridge information 75
- Replace the primary cartridge 76
- Control cartridge results 82

Routine maintenance

Maintenance check

Action	Frequency
If a run has not been performed for 17 hours, the instrument automatically performs a maintenance check. • Approximately 30 minutes before the maintenance check begins, the touchscreen displays a maintenance due icon and the expected time that maintenance will start. • The instrument locks out any signed-in users 1 minute before the maintenance check, and notifies the user that maintenance is about to start. • If the check determines that maintenance is not needed, no user action is required. • If the check determines that maintenance is needed, the insert utility cartridge screen is displayed—a new utility cartridge is required. See “Maintenance (new utility cartridge required)” on page 74. • If the instrument is powered off, the time count is retained when the instrument is restarted. If ≥17 hours have passed, the maintenance check will begin when the instrument is restarted. • The time count is reset if a user performs a run or replaces the primary cartridge.	Every 17 hours

Maintenance (new utility cartridge required)

Action	Frequency
When maintenance is required, the instrument automatically displays the insert utility cartridge screen. **Note:** Utility cartridges can be ordered separately through your local Thermo Fisher Scientific sales representative. See “Allelic ladder, control, and utility cartridges” on page 13. **1.** When the insert utility cartridge screen is displayed, insert a new utility cartridge into the instrument. The utility cartridge has a red label.  The instrument automatically performs the required maintenance, then displays the lock screen when the maintenance is complete. **2.** Sign in (see “Sign in to the instrument” on page 20). **3.** When the remove utility cartridge screen is displayed, remove the utility cartridge from the instrument.  You can bypass maintenance if you start a run 30 minutes before the time displayed below the maintenance due icon ( ). **Note:** If you leave any cartridge in the instrument when maintenance is due, the cartridge will be used for the maintenance run.	Every 15 days[1]

[1] You may need to perform the maintenance sooner, if a maintenance check determines that the instrument requires maintenance before 15 days.

Clean the touchscreen

Action	Frequency
1. Power off the internal computer. **2.** Spray with a non-abrasive glass cleaner, then gently wipe the screen with lint-free lab tissues.	As needed

View primary cartridge information

If the sample identification screen is not displayed, tap ← until it is displayed. The screen displays the following information for the primary cartridge: Expiration date, number of runs performed, and gel volume indicator.



① Expiration date—Indicates the expiration date of the gel or the primary cartridge, whichever is closest to expiration. The primary cartridge, including gel, must be changed when the expiration date is reached.

② Number of runs—The run count for the primary cartridge. The run count indicates the number of runs that have been performed, not the number of runs that are remaining (for example, "70" indicates that 70 runs have been performed).

③ Gel volume indicator—The color of the outer ring indicates the amount of gel remaining in the primary cartridge.

- **Blue ring**—The number of runs remaining is >30 and the amount of gel remaining is >30%.
- **Yellow ring**—The number of runs remaining is ≤30 or the amount of gel remaining is 16–30%.
- **Red ring**—The expiration date has been reached, or the number of runs remaining is ≤15 or the amount of gel remaining is ≤15%.

Replace the primary cartridge

To replace the primary cartridge, your user role must include the **Replace primary cartridge** permission. For more information on user role permissions, see “Edit a user role” on page 70.

This procedure requires ~2 hours to complete.

Parts of the primary cartridge

The following figures illustrate the parts of the primary cartridge. The parts are listed in the order of removal when you prepare a new primary cartridge.

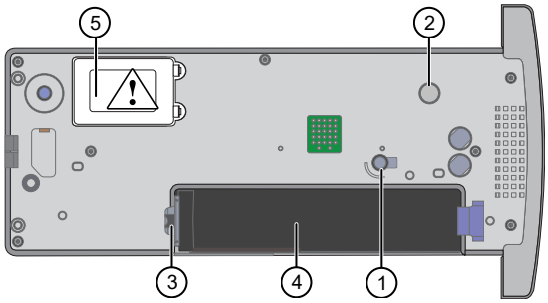


Figure 7 Parts of the primary cartridge before preparation

1. Shipping plug on check valve
2. Shipping plug on cathode block
3. Gel cartridge inlet
4. Gel cartridge slot
5. Shipping cover on capillary

CAUTION! The capillary is fragile. Handle the primary cartridge with care after you remove the capillary cover.

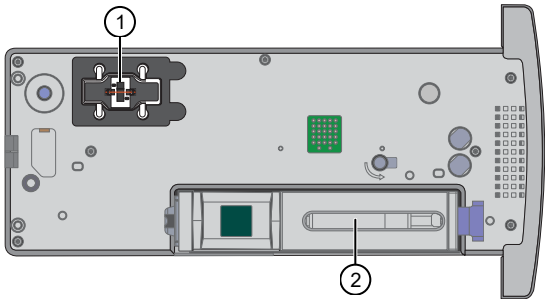


Figure 8 Primary cartridge after preparation

1. Capillary
2. Gel cartridge

Prepare a new primary cartridge

The following components are required for this procedure:

- New primary cartridge
- Gel cartridge that is provided with the new primary cartridge

Note: For RapidINTEL™ Plus applications, use a primary cartridge from the RapidHIT™ ID Primary Cartridge GlobalFiler™ Express 150 Kit.

Prepare the primary cartridge according to the instructions provided with the cartridge.

For the location of the primary cartridge parts, see Figure 7 on page 76.

Immediately proceed to "Run the prepared primary cartridge and the utility cartridge" on page 77.

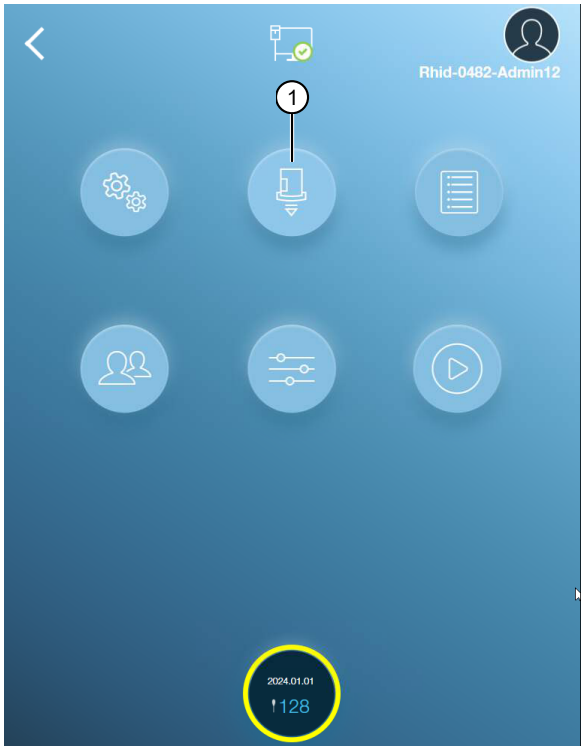
Run the prepared primary cartridge and the utility cartridge

The following components are required for this procedure:

- Prepared primary cartridge (with the gel cartridge inserted)
- Utility cartridge that is provided with the new primary cartridge

1. Tap ☰, then tap 📌.

Note: This procedure starts the primary cartridge replacement from the menu screen. However, if the primary cartridge is empty or there is no primary cartridge in the instrument, 📌 is displayed on the touchscreen. Tap 📌, then skip to step 3.

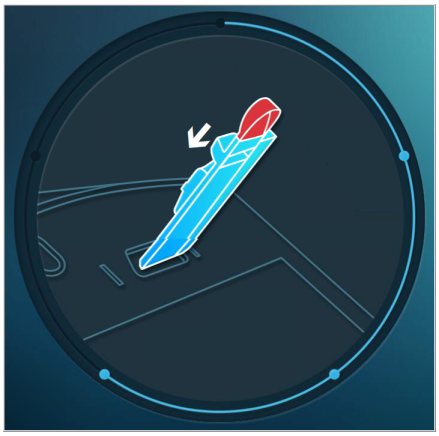


① Primary cartridge replacement

2. Tap **Yes** to confirm that you want to remove the primary cartridge.

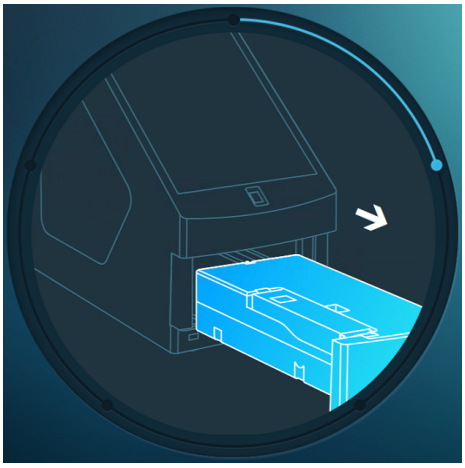


3. When the insert utility cartridge screen is displayed, insert the utility cartridge into the instrument. The utility cartridge has a red label and is provided with the new primary cartridge.



A countdown timer starts at 10 minutes while the instrument disengages the primary cartridge.

4. When the remove primary cartridge screen is displayed (~3 minutes after you insert the utility cartridge), pull the used primary cartridge out of the instrument.



5. When the insert primary cartridge screen is displayed, insert the prepared primary cartridge into the instrument.



CAUTION! The capillary is fragile. Do not let the capillary contact the instrument when you insert the prepared primary cartridge.

A countdown timer is displayed. The instrument performs a full 90-minute run.

6. When the remove utility cartridge screen is displayed, remove the utility cartridge from the instrument.



7. Discard the used primary and utility cartridges. Use proper precautions for disposal. Follow local, state, provincial and federal regulations for disposal.

Immediately proceed to "Run a positive control cartridge" on page 80.

Run a positive control cartridge

For each sample cartridge type that will be used, a positive control cartridge must be run immediately after a new primary cartridge is inserted. For example, if you will be running RapidINTEL™ Plus Sample Cartridges and RapidHIT™ ID ACE GlobalFiler™ Express Sample Cartridges, run a positive control cartridge for both of these chemistries. The positive control cartridge acts as the spectral calibration for the system and is specific to each chemistry and primary cartridge type.

IMPORTANT! The instrument will not accept sample cartridges until the positive control cartridge has been run.

1. When the insert cartridge screen is displayed, insert the positive control cartridge in the instrument.

   The instrument reads the label on the cartridge and automatically assigns the sample identification as **POSCTRL**.

   Note: If you insert the wrong cartridge type, an icon is displayed on the touchscreen: PL indicates a sample cartridge and P indicates an allelic ladder cartridge. Remove the cartridge and replace it with a positive control cartridge. The instrument will not proceed with the run until a positive control cartridge is inserted.

2. Review the information on the screen, then tap ▶ to start the run.

   A positive control cartridge run takes 90–110 minutes to complete. When the run is complete, the lock screen is displayed.

3. Tap the lock screen, then sign in (see “Sign in to the instrument” on page 20).

4. In the result screen, view the run result. See “Control cartridge results” on page 82.

   IMPORTANT! If the instrument is restarted for any reason before you are able to sign in and view the run result, the result screen is not displayed. Instead, you are prompted to remove the cartridge (proceed to step 6). To view the run result, access the run log screen (see “View run log” on page 35).

5. When you complete your review, tap **Done** to close the result screen.

   IMPORTANT! After you tap **Done**, the result screen can no longer be viewed. To view the run result again, access the run log screen (see “View run log” on page 35).

6. When the remove cartridge screen is displayed, remove the cartridge from the instrument.

   IMPORTANT! Remove the cartridge only when the remove cartridge screen is displayed.

7. Discard the used cartridge. Use proper precautions for disposal. Follow local, state, provincial and federal regulations for disposal.

Proceed to “(Recommended) Run an allelic ladder cartridge” on page 81.

(Recommended) Run an allelic ladder cartridge

If the appropriate allelic ladder for the sample cartridge has not been run on the instrument,  is displayed on the touchscreen each time a sample is run. An allelic ladder run is recommended, but not compulsory.

1. When the insert cartridge screen is displayed, insert the allelic ladder cartridge in the instrument.

   The instrument reads the label on the cartridge and automatically assigns the sample identification as **LADDER**.

2. Review the information on the screen, then tap  to start the run.

   An allelic ladder cartridge run takes 90–110 minutes to complete. When the run is complete, the lock screen is displayed.

3. Tap the lock screen, then sign in (see “Sign in to the instrument” on page 20).

4. In the result screen, view the run result. See “Control cartridge results” on page 82.

   IMPORTANT! If the instrument is restarted for any reason before you are able to sign in and view the run result, the result screen is not displayed. Instead, you are prompted to remove the cartridge (proceed to step 6). To view the run result, access the run log screen (see “View run log” on page 35).

5. When you complete your review, tap **Done** to close the result screen.

   IMPORTANT! After you tap **Done**, the result screen can no longer be viewed. To view the run result again, access the run log screen (see “View run log” on page 35).

6. When the remove cartridge screen is displayed, remove the cartridge from the instrument.

   IMPORTANT! Remove the cartridge only when the remove cartridge screen is displayed.

7. Discard the used cartridge. Use proper precautions for disposal. Follow local, state, provincial and federal regulations for disposal.

Control cartridge results

Table 7 Results for allelic ladder, negative control, and/or positive control cartridges

Status	DNA profile was generated	Description	Action
Green 	Yes	• The DNA profile does not contain quality flags. • Expected alleles were called in the positive control or allelic ladder profile. • No alleles were called in the negative control profile. **Note:** Passing allelic ladder profiles are added to the allelic ladder library on the instrument. The passing profile remains in the allelic ladder library until another passing ladder is run.	No further action is needed on the instrument.
Red 	No	One of the following: • A DNA profile was not generated. • A DNA profile was generated, but the results were not as expected. • Expected alleles were not called in the positive control or allelic ladder profile. • Alleles were called in the negative control profile.	Proceed according to your standard operating protocol.
		A critical DX code was generated during the run.	See “DX codes” on page 89.

A Troubleshooting

- Check the RapidLINK™ Software connection 83
- Troubleshooting: Observations, causes, and actions 83
- DX codes 89
- Perform the SCCL recovery procedure 92

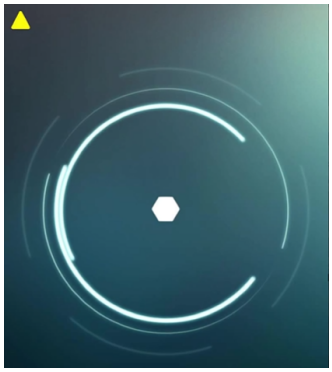
Check the RapidLINK™ Software connection

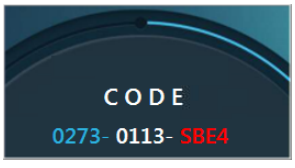
1. At the top of any screen, check the connection status.
   - —The instrument is connected to the RapidLINK™ Software.
   - —The instrument is connected to the RapidLINK™ Software, but is currently offline.
   - No icon—A connection was never initiated between the instrument and the RapidLINK™ Software.
2. If the instrument is not connected to the RapidLINK™ Software, perform the connection steps in “Configure the server connection (at initial startup)” on page 36 or “Configure the server connection (after running in standalone mode)” on page 42.

Troubleshooting: Observations, causes, and actions

Observation	Possible cause	Recommended action
Clock icon is displayed on the remove cartridge screen:  	An expired cartridge is inserted in the instrument.	Obtain and prepare a new cartridge.

Observation	Possible cause	Recommended action
X icon is displayed on the remove cartridge screen 	The cartridge is improperly inserted in the instrument.	Remove the cartridge from the instrument and re-insert.
	The cartridge is not supported by the instrument.	Remove the cartridge from the instrument and insert a supported cartridge. To determine which cartridges are supported, view the workflow settings in the RapidLINK™ Software.
Used cartridge icon is displayed on the remove cartridge screen  	A used cartridge is inserted in the instrument.	Obtain and prepare a new cartridge.
L icon is displayed on the touchscreen 	The appropriate allelic ladder for the current primary cartridge has not been run on the instrument.	Run the appropriate allelic ladder cartridge. See “(Recommended) Run an allelic ladder cartridge” on page 81.

Observation	Possible cause	Recommended action
P icon is displayed on the touchscreen 	A positive control cartridge must be run on the instrument. For each sample cartridge type that will be used, a positive control cartridge must be run immediately after a new primary cartridge is inserted. For example, if you will be running RapidINTEL™ Plus Sample Cartridges and RapidHIT™ ID ACE GlobalFiler™ Express Sample Cartridges, run a positive control cartridge for both of these chemistries. The positive control cartridge acts as the spectral calibration for the system and is specific to each chemistry and primary cartridge type.	Run a positive control cartridge. See “Run a positive control cartridge” on page 80.
PL icon is displayed on the touchscreen 	A positive control cartridge and an allelic ladder cartridge must be run on the instrument. The instrument will not accept sample cartridges until the positive control cartridge has been run.	1. Run a positive control cartridge. See “Run a positive control cartridge” on page 80. 2. *(Recommended)* Run an allelic ladder cartridge. See “(Recommended) Run an allelic ladder cartridge” on page 81.
Yellow triangle icon is displayed on the lock screen  	An instrument error occurred and a DX code was generated.	Tap the lock screen to obtain the DX code. For the **SCCL** error code, see “Perform the SCCL recovery procedure” on page 92. Otherwise, see “DX codes” on page 89.

Observation	Possible cause	Recommended action
Camera icon is displayed on the touchscreen 	The instrument camera is disabled. **Note:** You will also see a "Camera is turned OFF" message when you attempt a scan.	Enable the camera. See “Configure instrument options” on page 54.
	The instrument camera is broken.	Contact Thermo Fisher Scientific Support.
Computer icon is displayed on the touchscreen 	The instrument is connected to the RapidLINK™ Software, but is currently offline.	See “Check the RapidLINK™ Software connection” on page 83.
User icon is displayed next to a user name 	The user account has not been uploaded to the RapidLINK™ Software.	The instrument is offline. When the instrument is back online, the user account will upload automatically.
Red triangle icon is displayed next to a user name 	The user account is a duplicate (that is, the account has the same user name as another user account).	To resolve the duplication, edit the user name from the instrument. This is the only instance that allows a user name to be edited. See “Edit a user account (includes password/PIN reset)” on page 65.
Key icon is displayed next to a user name 	Two-factor authentication is enabled, but the user is missing a biometric credential (face recognition or fingerprint scan).	Edit the user account to add at least one biometric credential. See “Edit a user account (includes password/PIN reset)” on page 65.
Lock icon is displayed next to a user name 	The user account cannot be edited. The user was deauthorized for the instrument or inactivated in the RapidLINK™ Software.	No further action is required. If needed, the user can be authorized or activated again in the RapidLINK™ Software.
An error code is displayed when you sign in 	There is a problem with the instrument.	See “DX codes” on page 89.
		Open the **DX Code Troubleshooting Guide** within the RapidLINK™ Software. For more information, see the *RapidLINK™ Software v2.0 User Guide* (Pub. No. MAN0030010).

Observation	Possible cause	Recommended action
"Failed primary cartridge replacement" message is displayed on the sample identification screen	There is a problem with the instrument or the primary cartridge.	Contact Thermo Fisher Scientific Support.
"Failed to connect to server" error message is displayed	The message may be caused by various communication issues.	Perform any of the following, as needed: • Check the network connection. • Ensure that the ports for the RapidLINK™ Software are open. • Ensure that the DNS is set up correctly; or if you are trying to connect by resolving host names, ensure that the host files are updated. • Ensure that the RapidLINK™ services are running. • Ensure that the instrument is able to ping the RapidLINK™ Software. • Ensure that the firewall is not blocking communication.
"The instrument is already registered on the server" error message is displayed	The instrument connection to the RapidLINK™ Software still persists. A previous disconnection process may have been interrupted.	In the RapidLINK™ Software, check the instrument health status. If the health status displays something other than **Disconnected** or **Never Connected**, perform the following steps: 1. In the RapidLINK™ Software, select the instrument, then click **Disconnect instrument**. 2. Wait for the instrument health status to display **Disconnected** in the RapidLINK™ Software. 3. In the instrument software, try connecting again.

Observation	Possible cause	Recommended action
"Unable to access the removable drive" message is displayed when you attempt to export data	Damaged, malfunctioning, or improperly formatted USB drive.	Select another USB drive, then try exporting again.
A power failure occurs during a run	Various causes.	If the power failure occurs early in the run, the run will stop and it will not be listed in the run log. Obtain a new swab and rerun the sample.
		If the power failure occurs late in the run but before analysis starts, the run will be listed in the run log with a red ✖.
		If the power failure occurs after analysis is complete, the run will be listed in the run log with the run result.
The instrument software crashes	During sign in or when adding or editing a user account, the user quickly switched between the face recognition authentication factor and another authentication factor multiple times.	Press the power button on the front of the instrument to restart the instrument.
	The instrument could not read a cartridge RFID tag.	Press the power button on the front of the instrument to restart the instrument.
	A user inserted a cartridge into the instrument immediately before the instrument was about to auto-lock because of inactivity.	Press the power button on the front of the instrument to restart the instrument.
	While a user account is being edited on the instrument, the same user account is being deauthorized from the RapidLINK™ Software.	Press the power button on the front of the instrument to restart the instrument.

DX codes

DX code[1]	Restart required	Error description	Action
A1	Yes	The ambient temperature is not within specification for running the instrument.	Ensure that the ambient temperature is 15–30°C (59–86°F).
B1	No	The sample injection was not detected.	Contact Thermo Fisher Scientific Technical Support.
B2	No	The sample injection was delayed.	Contact Thermo Fisher Scientific Technical Support.
C4	Yes	The sample cartridge insertion was not detected.	Restart the instrument, then re-insert the sample cartridge.
CL	Yes	A cartridge was compromised.	Perform the SCCL recovery procedure on "Perform the SCCL recovery procedure" on page 92.
CP	Yes	A cartridge was compromised (after SCCL recovery).	Restart the instrument, then perform another run using a blank cartridge or blank swab.
D1	Yes	An internal heater did not reach the set temperature.	Contact Thermo Fisher Scientific Technical Support.
E3	Yes	The gel has expired.	Replace the primary cartridge.
E4	Yes	The gel syringe is empty.	Replace the primary cartridge.
F3	Yes	During primary cartridge installation, the cartridge was not able to prime.	Restart the instrument, then re-insert the sample cartridge. A new utility cartridge will be required.
G1	Yes	Gel refrigeration did not reach the set temperature.	Contact Thermo Fisher Scientific Technical Support.
G2	Yes	The gel temperature probe malfunctioned.	Contact Thermo Fisher Scientific Technical Support.
G3	Yes	Gel refrigeration was not able to maintain the set temperature.	Contact Thermo Fisher Scientific Technical Support.
H3	Yes	An internal heater did not reach the set temperature.	Press the rear button to restart the instrument, then run another blank or control cartridge.

(continued)

DX code[1]	Restart required	Error description	Action
H4	Yes	The heater is not reaching the required temperature in the allotted time frame.	Press the front button to power off the instrument, then press the rear button to restart the instrument. A new primary or mezzanine board may be required. **Note:** The H4 DX code may be observed in conjunction with SBH3 and SBV2 errors. If so, review DX codes H3 and V2 for more information.
K1	No	The amount of sample lysate transferred was low.	Ensure that the substrate did not absorb lysate. For example, a frayed swab or sponge is more likely to absorb lysate.
K2	Yes	The sample lysate transfer did not occur.	Ensure that the substrate did not absorb lysate. For example, a frayed swab or sponge is more likely to absorb lysate.
L3	Yes	An internal heater did not reach the set temperature.	Contact Thermo Fisher Scientific Technical Support.
M6	Yes	During primary cartridge installation, the motor did not move as expected.	Press the rear button to restart the instrument, then try to re-insert the primary cartridge. A new utility cartridge will be required.
P1	No	There is an optics heater thermistor error.	Contact Thermo Fisher Scientific Technical Support.
R0	No	The spectrometer calibration is corrupt or missing.	Contact Thermo Fisher Scientific Technical Support.
R2	No	Raman signal is lower than detected.	Contact Thermo Fisher Scientific Technical Support.
U1	Yes	The current is too high or too low.	Contact Thermo Fisher Scientific Technical Support.
U3	Yes	The current is too high or too low.	Contact Thermo Fisher Scientific Technical Support.
U4	Yes	The current is too high or too low.	Contact Thermo Fisher Scientific Technical Support.
V2	No	The gel recharge volume was lower than expected.	Contact Thermo Fisher Scientific Technical Support.

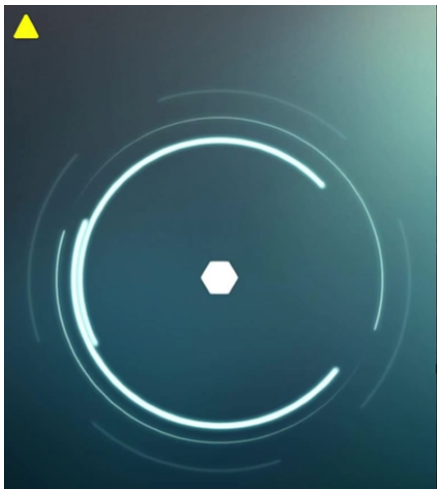
(continued)

DX code[1]	Restart required	Error description	Action
V3	Yes	In the primary cartridge, the gel reprime was lower than expected.	Restart the instrument, then re-insert the primary cartridge. A new utility cartridge will be required.
		In the sample cartridge, the gel reprime was lower than expected.	Restart the instrument, then insert a new sample cartridge.

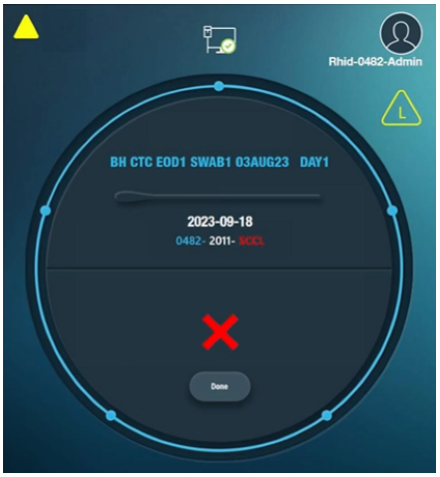
[1] This column lists only the last two characters of each error code. The complete error code also includes characters that identify the instrument and primary cartridge.

Perform the SCCL recovery procedure

If an SCCL error occurs during a run, the lock the screen is displayed with a yellow triangle.

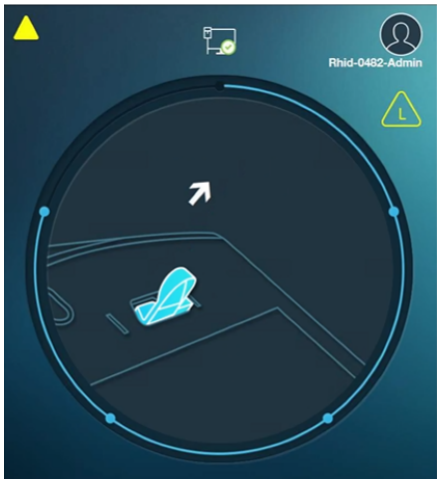


1. Tap the lock screen, then sign in (see “Sign in to the instrument” on page 20).
2. When the SCCL error code is displayed, tap **Done**.

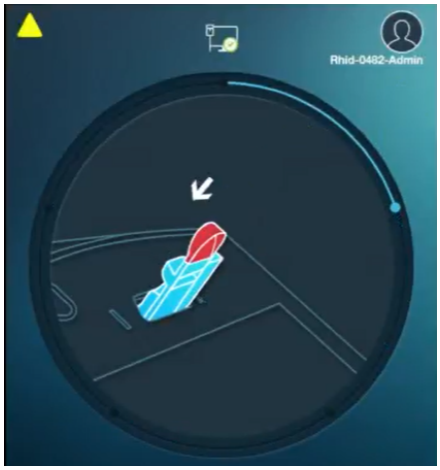


3. When the remove cartridge screen is displayed, remove the cartridge from the instrument.

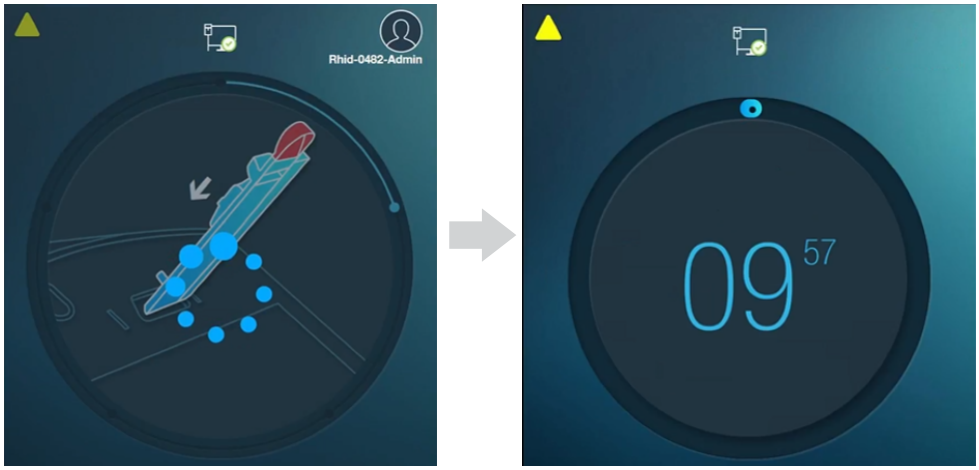
IMPORTANT! Remove the cartridge only when the remove cartridge screen is displayed.



4. When the insert utility cartridge screen is displayed, insert a new utility cartridge into the instrument.



The instrument prepares for the recovery steps, then displays the countdown timer. The recovery can take ~5–10 minutes.



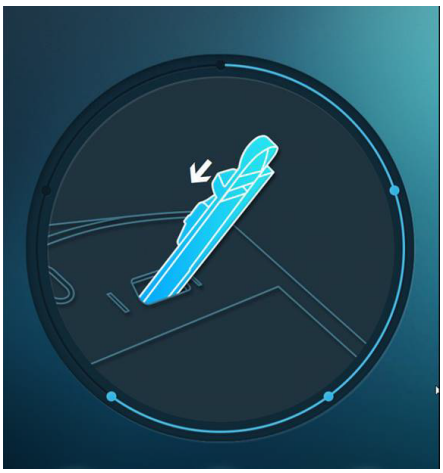
5. When the remove utility cartridge screen is displayed, remove the utility cartridge from the instrument.



6. If the lock screen is displayed, tap the screen, then sign in.

7. When the insert cartridge screen is displayed, insert a new sample cartridge into the instrument to perform a new run. See Chapter 3, “Run the instrument”.

Note: If you are prompted to insert a utility cartridge again, the instrument may not have recovered from the sample leak. Try performing the SCCL recovery procedure again or contact Thermo Fisher Scientific Technical Support.



8. Discard all used cartridges. Use proper precautions for disposal. Follow local, state, provincial and federal regulations for disposal.

B

Analysis settings

- General analysis settings 95
- Marker-specific settings for RapidHIT™ ID ACE GlobalFiler™ Express cartridges 98
- Marker-specific settings for RapidINTEL™ Plus cartridges 99
- Stutter thresholds for RapidHIT™ ID ACE GlobalFiler™ Express cartridges 100
- Stutter thresholds for RapidINTEL™ Plus cartridges 101
- Artifact thresholds and filters for RapidINTEL™ Plus cartridges 102

General analysis settings

Note: For settings marked **Marker-specific**, see "Marker-specific settings for RapidHIT™ ID ACE GlobalFiler™ Express cartridges" on page 98 and "Marker-specific settings for RapidINTEL™ Plus cartridges" on page 99.

Analysis parameter	RapidHIT™ ID ACE GlobalFiler™ Express cartridges	RapidINTEL™ Plus cartridges
Panel file	GFE_BV_ACE_Panel	ABRIplus_GS600_Panel
Bin set	GFE_BV_ACE_Bin	ABRIplus_GS600_Bin
Stutter file	GFE_BV_ACE_Stutter	ABRIplus_GS600_Stutter
Default analysis method name	GFE_BV_ACE_Analysis_Method	ABRIplus_GS600_Analysis_Method
Use marker-specific stutter ratio	True	True
Use allele-specific stutter ratios	False	False
Consider additive stutters	False	False
Cut-off value	0.2	0.2 between markers; marker-specific within markers
MinusA ratio	0.19/0.19 (Tri/Tetra)	0/0
MinusA distance (From/To)	1.5/1.5 (Tri/Tetra)	0/0

(continued)

Analysis parameter	RapidHIT™ ID ACE GlobalFiler™ Express cartridges	RapidINTEL™ Plus cartridges
Amelogenin cut-off	0.2	0.2
Range filter (From/To)	92.0/102.2 (Green)	76.0/91.0 (Blue) 89.7/98.0 (Green)
Use marker-specific thresholds	True	True
Analysis range	Full range	Full range
Sizing range	All sizes	60–460
Smoothing	Light	Light
Baseline window	33	33
Size calling method	Cubic Spline Interpolation	Local Southern Method
Peak amplitude threshold	Marker-specific	Marker-specific
Min. peak half width	2	2
Polynomial degree	3	3
Peak window size	15	11
Slope threshold (Start/End)	0/0	0/0
Use normalization	False	False
Homozygous min peak height	Marker-specific	Marker-specific
Heterozygous min peak height	Marker-specific	Marker-specific
Max peak height	Marker-specific	24,000
Min peak height ratio	Marker-specific	Marker-specific
Max peak width	1.5	1.5
Max expected alleles (Autosomal/Y)	2/1	2/1
Allelic ladder spike detection	Enable	Enable
Sample spike detection	Enable	Enable
Enable pull-up detection	False	False

(continued)

Analysis parameter	RapidHIT™ ID ACE GlobalFiler™ Express cartridges	RapidINTEL™ Plus cartridges
SQ & GQ settings	All default	All default
Size standard definition name	RapidHITID_SS3_Size_Standard	RapidHITID_GS600_Size_Standard

Marker-specific settings for RapidHIT™ ID ACE GlobalFiler™ Express cartridges

Locus	Peak Amplitude Threshold	Hm. Minimum Peak Height	Hz. Minimum Peak Height	Minimum Peak Height Ratio	Maximum Peak Height	Cut-off
D3S1358	35 RFU	130 RFU	35 RFU	0.35	28,374 RFU	0.2
vWA		113 RFU				
D16S539		105 RFU				
CSF1PO		109 RFU				
TPOX		122 RFU				
Y indel		35 RFU				
AMEL		115 RFU				
D8S1179		113 RFU				
D21S11		124 RFU				
D18S51		100 RFU				
DYS391		35 RFU				
D2S441		101 RFU				
D19S433		133 RFU				
TH01		162 RFU				
FGA		100 RFU				
D22S1045		137 RFU				
D5S818		103 RFU				
D13S317		100 RFU				
D7S820		111 RFU				
SE33		179 RFU				
D10S1248		107 RFU				
D1S1656		105 RFU				
D12S391		112 RFU				
D2S1338		151 RFU				

Marker-specific settings for RapidINTEL™ Plus cartridges

Locus	Peak Amplitude Threshold	Hm. Minimum Peak Height	Hz. Minimum Peak Height	Minimum Peak Height Ratio	Maximum Peak Height	Cut-off
QQS	35 RFU	35 RFU	35 RFU	0	24,000 RFU	0
D3S1358		180 RFU	50 RFU	0.2		0.1
vWA		287 RFU				0.13
D16S539		186 RFU				0.11
CSF1PO		219 RFU				0.1
TPOX		164 RFU				0.1
QQL		35 RFU	35 RFU	0		0
Y indel	60 RFU	60 RFU	60 RFU			0.1
AMEL	35 RFU	153 RFU	35 RFU	0.2		0.1
D8S1179		141 RFU	50 RFU			0.1
D21S11		210 RFU				0.1
D18S51		244 RFU				0.1
DYS391		35 RFU	35 RFU	0		0.1
D2S441		300 RFU	50 RFU	0.2		0.11
D19S433		187 RFU				0.2
TH01		209 RFU				0.13
FGA		150 RFU				0.1
D22S1045		269 RFU				0.11
D5S818		235 RFU				0.11
D13S317		213 RFU				0.1
D7S820		299 RFU				0.1
SE33		311 RFU	60 RFU			0.1
D10S1248		215 RFU	50 RFU			0.12
D1S1656		265 RFU				0.1
D12S391		210 RFU				0.11
D2S1338		299 RFU				0.13

Stutter thresholds for RapidHIT™ ID ACE GlobalFiler™ Express cartridges

Note: When not indicated, the stutter threshold is –3.25 to –4.75 nucleotides from the allele peak.

Locus	Stutter threshold
D3S1358	0.17
vWA	0.18
D16S539	0.15
CSF1PO	0.14
TPOX	0.08
Y indel	—
AMEL	—
D8S1179	0.17
D21S11	0.17
D18S51	0.20
DYS391	0.12
D2S441	0.12
D19S433	0.17
TH01	0.14
FGA	0.17
D22S1045	0.22 (–2.25 to –3.75 nucleotides)
D5S818	0.13
D13S317	0.14
D7S820	0.14
SE33	0.22
D10S1248	0.17
D1S1656	0.19
D12S391	0.24
D2S1338	0.19

Stutter thresholds for RapidINTEL™ Plus cartridges

Note: When not indicated, the stutter threshold is ±3.25–4.75 nucleotides from the allele peak.

Locus	Minus stutter threshold	Plus stutter threshold
QQS	0.90 (–0.25 to –4.8 nucleotides)	0.90 (0.25–4.0 nucleotides)
D3S1358	0.22	0.03
vWA	0.22	0.03
D16S539	0.17	0.04
CSF1PO	0.19	0.03
TPOX	0.14	0.03
QQL	0.4 (–0.5 to –12.5 nucleotides)	0.4 (0.5–5.0 nucleotides)
Y indel	0.2 (–1.0 to –3.0 nucleotides)	0.2 (1.0–3.0 nucleotides)
AMEL	0.3 (–0.5 to –4.0 nucleotides)	0.3 (0.5–4.0 nucleotides)
D8S1179	0.19	0.03
D21S11	0.25	0.05
D18S51	0.25	0.05
DYS391	0.18	0.03
D2S441	0.20 0.30 (–0.5 to –1.9 nucleotides)	0.03
D19S433	0.22 (–3.05 to –4.75 nucleotides)	0.03
TH01	0.14	0.03
FGA	0.26	0.03
D22S1045	0.29 (–2.25 to –3.75 nucleotides)	0.12 (2.25–3.75 nucleotides)
D5S818	0.17	0.03
D13S317	0.25	0.03
D7S820	0.19	0.03
SE33	0.33 0.20 (–1.25 to –2.75 nucleotides)	0.06
D10S1248	0.22	0.03
D1S1656	0.29 0.03 (–1.25 to –2.75 nucleotides)	0.03

(continued)

Locus	Minus stutter threshold	Plus stutter threshold
D12S391	0.27	0.03
D2S1338	0.26	0.03

Artifact thresholds and filters for RapidINTEL™ Plus cartridges

The RapidINTEL™ Plus assay requires filters for potential amplification artifacts that may be caused by the quantification markers (QQS 1 and QQL 1) and amplification markers (QQS 2 and QQL 2). We used the filter functions to address the following scenarios:

- The –0.25 to –4.8 bp artifact seen with QQS 2 is filtered at 90% the main peak. The stutter filter is tuned to avoid filtering the QQS 1 peak by the cascading function of the stutter. In addition, a plus stutter threshold of 90% for the range of 0.25–4.0 bp is implemented to filter possible noise peaks generated when the QQS 2 peak reaches saturation levels. Filtering within the QQS locus is difficult because the two targets are unrelated and can have exponentially different amplification.
- The QQL 2 target may produce an artifact at –10.5 bp. A minus stutter filter threshold of 40% for the range of –0.5 to –12.5 bp is implemented to filter this artifact. A plus stutter threshold of 40% for the range of 0.5–5.0 bp is implemented to filter possible noise peaks generated when the QQL 2 peak reaches saturation levels.
- Amelogenin and the Y indel loci are non-STR loci and have no microvariants. To avoid noise generated from saturated alleles or high pull-ups in off ladder (OL) locations of these loci, stutter filter functions are implemented. Amelogenin uses stutter thresholds of 30% from –0.5 to –4.0 bp and 0.5–4.0 bp. Y indel uses stutter thresholds of 20% from –1.0 to –3.0 bp and 1.0–3.0 bp.
- To mitigate noise peaks in non-STR regions following the QQS and Y indel loci, the blackout region filter is used. The 6-FAM™ dye channel blackout range is 76.0–91.0 bp. The VIC™ dye channel blackout range is 89.7–98.0 bp.

RapidHIT™ ID System v2.0 validation studies and v2.0.1 performance verification

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Objective of the validation

The objective of the validation was to assess the performance of RapidHIT™ ID System v2.0 when analyzing a variety of samples with Expert System Software v2.0 (Primary Analysis v1.0 and GeneMapper™ ID-XR v1.0).

The validation studies were performed according to the Scientific Working Group on DNA Analysis Methods (SWGDAM) *Validation Guidelines for DNA Analysis Methods* (December 2016) and the FBI Quality Assurance Standards (July 2020).

The following studies were performed:

- Population
- Precision
- Reproducibility and repeatability (R&R)
- Sensitivity
- Carryover

- Extra negative controls
- Inhibition
- Mixture
- Reliability

Analysis thresholds

Before completing the validation studies, a calibration data set was used to establish various analysis thresholds for RapidHIT™ ID System v2.0. 961 data files that were generated from ACE GFE sample cartridges originally run on RapidHIT™ ID System v1.x were reprocessed through the RapidHIT™ ID System v2.0 analysis pipeline. The data set is described in Table 8. The resulting analysis thresholds are provided in Appendix B, “Analysis settings”.

5 challenging runs were included in the data set:

- Population study—1 partial profile
- Carryover study—2 mock contamination runs and 2 failed runs

Table 8 Calibration data set

Study	Number of runs	Details
Population	587	• Buccal samples from 300 unique genotypes • 1 DNA Control 007 sample • Repeated ≤5 runs per genotype
Carryover	318	• 314 sample cartridges with no sample input (blank), or ACE GFE negative control cartridges • 2 mock contamination runs • 2 failed runs
Sensitivity	56	• DNA Control 007 series: 2,400 ng, 1,200 ng, 600 ng, 300 ng, 150 ng, 75 ng, 37.5 ng, and 18.75 ng. • 7 replicates of each of the 8 concentrations
Total	**961**	—

Analysis thresholds calculated

Analytical threshold (AT)

The AT was determined on a per-locus basis using a Receiver Operator Characteristics (ROC) curve to determine the RFU where the false positive rate drops to 0.00% for peaks in bin (allele calls). ROC analysis was performed using the full calibration data set. False positive allele designations were limited to true system noise that could be misidentified as an allele. As a result, the calculation did not include any allele designations during this analysis caused by dye artifacts, pull-up, stutter, MinusA peaks, or spikes.

When considering the AT for the size standard, peak height distribution was evaluated to find where 99.9% of size standard peaks were called.

Peak height ratio (PHR)

PHR data from the population data set was calculated and plotted for all non-haploid loci. The PHR distribution was analyzed to find the 0.1% quantile and used to establish an acceptable PHR limit for system flagging.

Stochastic threshold (ST)

The population study data set was evaluated to set the ST. The ST was determined on a per-locus basis as follows:

AT + (AT / minimum observed PHR)

Stutter filter

Average per-locus stutter values were calculated from the population data set, excluding stutter peaks in additive stutter or pull-up positions. Marker-specific stutter filters were set as follows:

Average locus stutter + 4 SD

Cut-off filter

The cut-off filter sets a PHR that filters peaks less than or equal to the defined threshold. Within a marker, the height of the peak in question is compared to the peak height of the highest peak in the marker size range. Between markers, the peak height in question is compared to the highest peak in the dye color. The global filter was calculated from the population data set as follows:

Minimum true heterozygote PHR % – 5%

Maximum peak height (MPH) threshold

The MPH setting results in a quality flag for peak heights that is greater than the established threshold. Data from the population study was used to establish an MPH as follows:

Maximum true heterozygote peak height × 2

Threshold results

The thresholds established from the calibration data set for allele calling and quality flagging are summarized in Table 9. These values were implemented for the validation studies.

Details for setting the AT, ST, PHR, and stutter filter values are provided below Table 9.

Table 9 Analysis setting thresholds

Threshold type	Threshold setting in the software	Value
Analytical threshold (AT)	Peak Amplitude Threshold (PAT)	35 RFU, all loci and the size standard
	Low Peak Height Heterozygotes (LPH Hetero)	
Stochastic threshold (ST)	Low Peak Height Homozygote (LPH Homo)	91–179, locus specific
Peak height ratio (PHR)	Peak Height Ratio (PHR)	35%, all loci
Stutter filters	Stutter Ratio	8–24%, locus specific
Global filter	Cut-Off	20%
Maximum peak height (MPH)	Maximum Peak Height (MPH)	28,374 RFU

Analytical threshold (AT)

The AT was set at 35 RFU for all loci, based on ROC analysis from the calibration data set. A heat map view of the false positive % per locus is shown in Figure 9. Evaluation of the size standard peak height distribution showed that 99.9% of size standard peaks were called at 33 RFU.

	AMEL	CSF1PO	D10S1248	D12S391	D13S317	D16S539	D18S51	D19S433	D1S1656	D21S11	D22S1045	D2S1338	D2S441	D3S1358	D5S818	D7S820	D8S1179	DYS391	FGA	SE33	TH01	TPOX	vWA	Yindel
AT	False+%	False+%	False+%	False+%	False+%	False+%	False+%	False+%	False+%	False+%	False+%	False+%	False+%	False+%	False+%	False+%	False+%	False+%	False+%	False+%	False+%	False+%	False+%	False+%
1	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%
2	58.00%	53.24%	42.56%	37.26%	32.13%	54.06%	30.18%	33.63%	38.76%	30.02%	36.17%	40.58%	39.77%	55.93%	35.18%	32.56%	34.93%	28.30%	30.37%	35.90%	31.22%	53.82%	52.47%	37.55%
4	4.00%	2.71%	2.86%	1.19%	0.45%	2.91%	0.79%	1.76%	1.33%	0.69%	1.98%	1.38%	7.25%	6.91%	0.79%	0.40%	2.94%	1.05%	0.80%	0.72%	1.30%	2.14%	2.98%	3.89%
6	0.00%	0.49%	1.13%	0.39%	0.21%	0.50%	0.34%	0.70%	0.52%	0.35%	0.78%	0.53%	3.04%	2.38%	0.32%	0.11%	1.04%	0.41%	0.30%	0.25%	0.63%	0.30%	0.42%	1.95%
8	0.00%	0.37%	0.51%	0.17%	0.10%	0.27%	0.20%	0.38%	0.31%	0.21%	0.35%	0.32%	1.60%	1.09%	0.21%	0.09%	0.51%	0.20%	0.19%	0.17%	0.36%	0.20%	0.29%	1.36%
10	0.00%	0.28%	0.24%	0.02%	0.05%	0.19%	0.11%	0.18%	0.08%	0.16%	0.12%	0.16%	0.85%	0.54%	0.15%	0.06%	0.24%	0.10%	0.12%	0.09%	0.12%	0.03%	0.21%	0.78%
12	0.00%	0.21%	0.21%	0.00%	0.03%	0.06%	0.08%	0.15%	0.08%	0.14%	0.12%	0.12%	0.69%	0.34%	0.12%	0.03%	0.14%	0.10%	0.09%	0.08%	0.09%	0.02%	0.11%	0.58%
14	0.00%	0.15%	0.15%	0.00%	0.03%	0.04%	0.08%	0.06%	0.05%	0.14%	0.12%	0.11%	0.43%	0.29%	0.09%	0.03%	0.12%	0.05%	0.09%	0.06%	0.09%	0.02%	0.10%	0.19%
16	0.00%	0.13%	0.12%	0.00%	0.03%	0.04%	0.07%	0.03%	0.05%	0.09%	0.12%	0.07%	0.32%	0.19%	0.09%	0.03%	0.05%	0.02%	0.08%	0.06%	0.09%	0.00%	0.10%	0.19%
18	0.00%	0.06%	0.09%	0.00%	0.00%	0.04%	0.06%	0.03%	0.05%	0.09%	0.08%	0.04%	0.21%	0.10%	0.03%	0.03%	0.05%	0.02%	0.06%	0.04%	0.06%	0.00%	0.06%	0.19%
20	0.00%	0.04%	0.09%	0.00%	0.00%	0.04%	0.06%	0.03%	0.05%	0.07%	0.00%	0.04%	0.16%	0.07%	0.03%	0.00%	0.05%	0.02%	0.06%	0.02%	0.00%	0.00%	0.04%	0.19%
22	0.00%	0.04%	0.06%	0.00%	0.00%	0.02%	0.04%	0.03%	0.05%	0.05%	0.00%	0.04%	0.05%	0.05%	0.03%	0.00%	0.02%	0.00%	0.06%	0.02%	0.00%	0.00%	0.02%	0.19%
24	0.00%	0.02%	0.03%	0.00%	0.00%	0.02%	0.04%	0.00%	0.05%	0.05%	0.00%	0.03%	0.00%	0.05%	0.03%	0.00%	0.02%	0.00%	0.04%	0.01%	0.00%	0.00%	0.02%	0.00%
26	0.00%	0.00%	0.03%	0.00%	0.00%	0.02%	0.03%	0.00%	0.00%	0.02%	0.00%	0.01%	0.00%	0.05%	0.00%	0.00%	0.02%	0.00%	0.03%	0.01%	0.00%	0.00%	0.00%	0.00%
28	0.00%	0.00%	0.00%	0.00%	0.00%	0.02%	0.01%	0.00%	0.00%	0.02%	0.00%	0.01%	0.00%	0.02%	0.00%	0.00%	0.00%	0.00%	0.03%	0.01%	0.00%	0.00%	0.00%	0.00%
30	0.00%	0.00%	0.00%	0.00%	0.00%	0.02%	0.01%	0.00%	0.00%	0.00%	0.00%	0.01%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.02%	0.01%	0.00%	0.00%	0.00%	0.00%
32	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%	0.00%	0.00%	0.00%	0.00%
34	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%	0.00%	0.00%	0.00%	0.00%
36	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
38	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
40	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

Figure 9 False positive percentage rates per locus The bolded line is between 34 and 35 RFU. The AT setting in Expert System v2.0 is 35 RFU for all loci.

Stochastic threshold (ST)

The ST per locus is provided in Table 9. The minimum peak height ratios used to calculate ST are listed in the **Minimum** PHR column. The **ST** column represents the ST using an analytical threshold (AT) of 35 RFU.

Table 10 ST per locus

ST per locus, based on minimum locus-specific peak height ratios and 35 RFU AT for all loci.

Marker	n	Peak height ratio (PHR)				ST
		Minimum	Maximum	Average	Standard deviation	
D3S1358	467	36.98%	99.93%	86.92%	9.20%	130
vWA	492	45.12%	99.93%	85.67%	9.02%	113
D16S539	462	49.87%	99.88%	85.45%	10.06%	105
CSF1PO	413	47.23%	99.84%	85.70%	9.85%	109
TPOX	381	40.29%	99.92%	86.23%	10.60%	122
AMEL	329	43.95%	99.93%	87.17%	10.32%	115
D8S1179	464	44.62%	99.84%	87.12%	9.38%	113
D21S11	491	39.47%	99.90%	87.56%	9.15%	124
D18S51	510	54.70%	99.89%	87.83%	8.54%	99
D2S441	462	52.67%	99.96%	90.26%	6.75%	101
D19S433	482	35.64%	99.82%	88.14%	8.06%	133
TH01	414	27.59%	99.91%	87.74%	10.56%	162
FGA	510	60.00%	99.96%	89.60%	7.58%	93
D22S1045	417	34.41%	99.86%	82.64%	10.21%	137
D5S818	449	51.79%	99.87%	89.08%	7.66%	103
D13S317	440	56.79%	99.84%	87.47%	8.45%	97
D7S820	479	45.76%	99.93%	86.14%	9.67%	111
SE33	565	24.28%	99.72%	81.50%	12.92%	179
D10S1248	472	48.30%	99.89%	87.66%	8.03%	107
D1S1656	494	50.00%	99.85%	86.79%	8.85%	105
D12S391	512	45.45%	99.88%	86.08%	9.24%	112
D2S1338	492	30.12%	99.83%	84.00%	11.44%	151

Peak height ratio (PHR)

Distribution of the peak height ratios is shown in Figure 10. An evaluation determined that a 35% PHR balanced genotype accuracy and increased system pass rate by reducing false flagging of true heterozygote pairs.

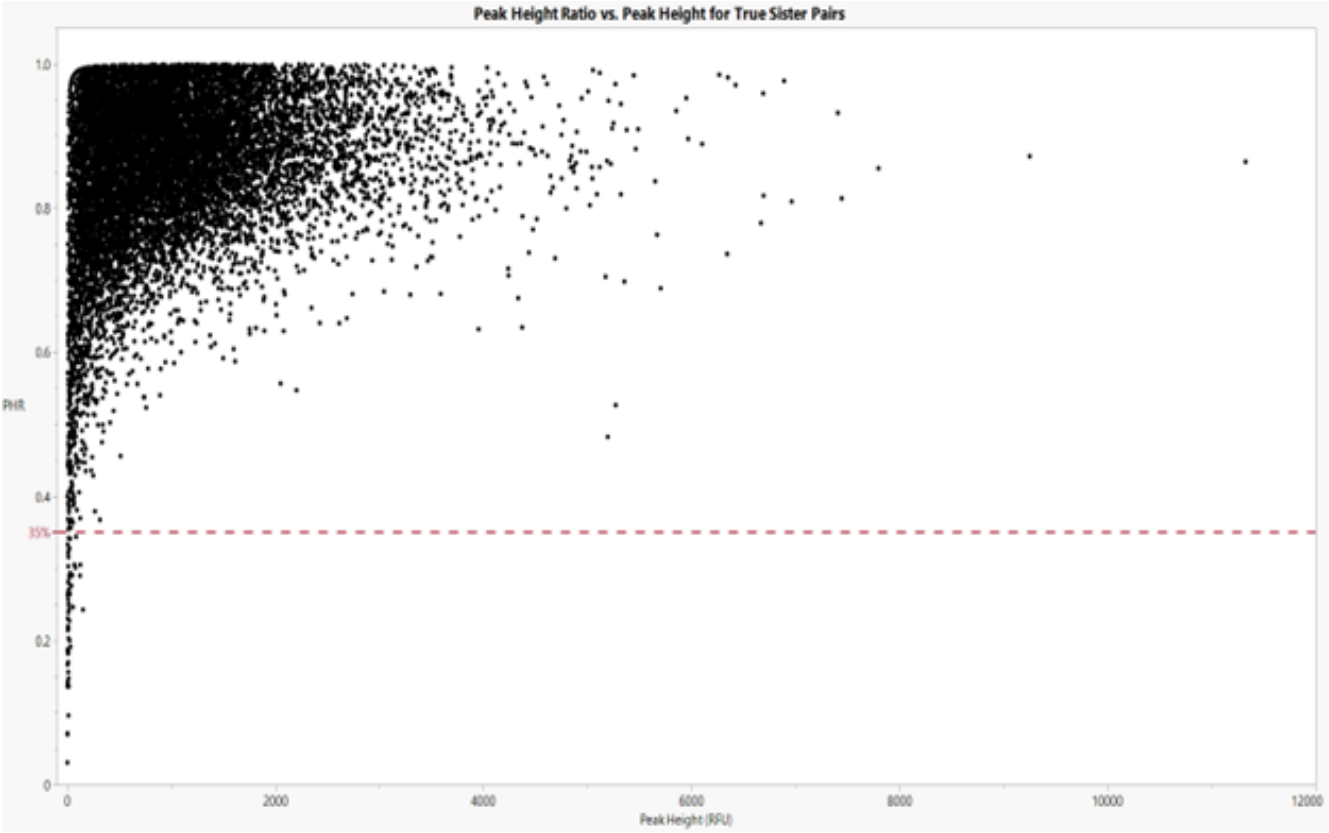


Figure 10 Distribution of PHR The distribution of PHR is graphed by the lower peak height of the 2 heterozygote alleles on the X-axis vs. peak height ratio on the Y-axis. The dotted red line is at 0.35 and represents the 0.1% quantile rounded down to the nearest multiple of 5.

Stutter

Stutter filter settings were calculated per locus and are listed in the **Stutter filter** column in Table 11. The Y indel and Amelogenin markers will be set to 0%; the global filter will apply at these two loci.

Table 11 Stutter filter settings

The **Stutter filter** column shows the filter settings for the n–4 or n–3 (D22S1045 only) stutter positions. The **n** column lists the number of alleles evaluated per marker.

Marker	n	Stutter ratio				Stutter filter
		Minimum	Maximum	Average	Standard deviation	
D3S1358	349	6.0%	14.4%	9.9%	1.7%	17%
vWA	387	2.7%	14.7%	7.9%	2.5%	18%
D16S539	302	2.6%	13.5%	7.1%	2.0%	15%
CSF1PO	291	2.9%	14.4%	7.7%	1.6%	14%
TPOX	173	1.8%	6.0%	3.6%	1.0%	8%
Y indel	N/A					0%
AMEL	N/A					0%
D8S1179	273	3.8%	24.4%	8.1%	2.1%	17%
D21S11	593	2.9%	16.6%	10.1%	1.8%	17%
D18S51	584	2.3%	17.2%	9.2%	2.6%	20%
DYS391	201	5.6%	10.7%	7.6%	1.0%	12%
D2S441	504	2.0%	9.4%	5.8%	1.7%	12%
D19S433	416	2.0%	20.5%	7.8%	2.3%	17%
TH01	111	1.2%	13.9%	4.6%	2.3%	14%
FGA	529	3.2%	17.0%	8.6%	2.1%	17%
D22S1045	446	1.7%	15.3%	8.3%	3.3%	22%
D5S818	298	2.7%	14.1%	6.8%	1.5%	13%
D13S317	466	1.4%	10.8%	5.6%	2.1%	14%
D7S820	383	2.0%	13.7%	5.7%	2.1%	14%
SE33	774	3.1%	20.2%	11.9%	2.7%	22%
D10S1248	318	3.0%	18.2%	9.3%	1.8%	17%
D1S1656	604	4.2%	16.9%	9.6%	2.2%	19%
D12S391	497	4.1%	20.3%	11.5%	3.2%	24%
D2S1338	503	4.7%	17.3%	10.6%	2.1%	19%

Materials used in the validation

Instruments

12 RapidHIT™ ID System v2.0 instruments were used for validation studies. All instruments were not used in every study; however, each instrument was used in at least one study.

Software

Software	Version number
RapidHIT™ ID System Software	v2.0
RapidLINK™ Software	v2.0

Note: Data presented in this appendix were obtained using RapidHIT™ ID ACE GlobalFiler™ Express cartridges run on RapidHIT™ ID System v2.0, then analyzed with RapidLINK™ Software v2.0 or other downstream software applications.

Cartridges

Note: The RapidHIT™ ID ACE GlobalFiler™ Express cartridge types are referred to as "ACE GFE" cartridges throughout this appendix. For example, the RapidHIT™ ID ACE GlobalFiler™ Express Sample Cartridge is referred to as "ACE GFE sample cartridge".

Before validation studies were run, an ACE GFE positive control cartridge and an ACE GFE allelic ladder cartridge were run on all instruments.

Cartridge	Catalog number
RapidHIT™ ID ACE GlobalFiler™ Express Sample Cartridge	A41831
RapidHIT™ ID ACE GlobalFiler™ Express Control (Ladder) Cartridge	400096RH
RapidHIT™ ID ACE GlobalFiler™ Express Positive Control Cartridge	A42469
RapidHIT™ ID ACE GlobalFiler™ Express Negative Control Cartridge	A42470

Samples

Study	Sample	Details
Population	500 ACE GFE sample cartridges—single-source buccal swabs, each with a unique genotype	Single replicates across 11 RapidHIT™ ID instruments
Precision	30 ACE GFE allelic ladder cartridges from the same lot number	5 replicates each on 6 RapidHIT™ ID instruments
Reproducibility and Repeatability (R&R)	30 ACE GFE positive control cartridges from the same lot number	5 replicates each on 6 RapidHIT™ ID instruments

(continued)

Study	Sample	Details
Sensitivity	130 ACE GFE sample cartridges: • 40 buccal swipes (male donor)—1, 5, 10, and 20 • 50 gDNA swabs—500 ng, 250 ng, 125 ng, 62.5 ng, and 31.25 ng of DNA Control 007 • 40 saliva swabs (male donor)—neat, 1:5, 1:10, and 1:20 in PBS	5 replicates of each input amount on 2 RapidHIT™ ID instruments
Carryover	Alternating runs: • 10 ACE GFE sample cartridges, gDNA swabs—2,400 ng of DNA Control 007 • 10 ACE GFE negative control cartridges	10 runs (5 sample cartridges and 5 negative control cartridges) on 2 RapidHIT™ ID instruments (for a total of 20 runs)
Inhibition	The following samples, applied to swabs with 750 ng of DNA Control 007: • 50 tobacco swabs: 0 µL, 2.5 µL, 5 µL, 10 µL, and 20 µL • 50 coffee swabs: 0 µL, 2.5 µL, 5 µL, 10 µL, and 20 µL • 50 mouthwash swabs: 0 µL, 2.5 µL, 5 µL, 10 µL, and 20 µL	5 replicates of each input amount on 2 RapidHIT™ ID instruments
Mixtures	• gDNA (DNA Control 007 to Control DNA 9947A): 1 to 0, 1 to 1, 1 to 2, 1 to 4, 1 to 8, 8 to 1, 4 to 1, 2 to 1, and 0 to 1 • Saliva (male to female): 1 to 0, 1 to 1, 1 to 2, 1 to 4, 1 to 8, 8 to 1, 4 to 1, 2 to 1, and 0 to 1	3 replicates each ratio on 2 RapidHIT™ ID instruments
Extra negative controls	Negative controls were run throughout other studies and between the highest and lowest sensitivity series inputs.	Failed (✖) runs were not repeated

Population study

Cartridge and sample summary

510 ACE GFE sample cartridges were run, each containing a single-source buccal swab.

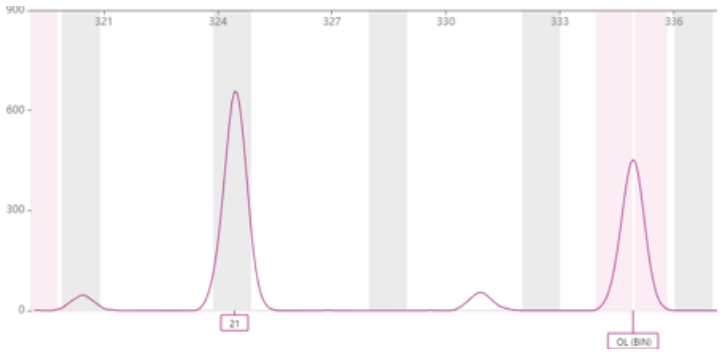
Of the 510 sample cartridges that were run, 10 samples did not generate DNA profiles (the runs failed (✖); for more information, see “Run and analysis summary” on page 112). These 10 samples were then reprocessed with a new swab from the same donors, resulting in 500 profiles from unique donors.

- 457 swabs were from frozen InnoGenomics Technologies collections.
- 43 swabs were from internal donors; 10 of the internal donors were run within 24 hours of collection.

Run and analysis summary

11 RapidHIT™ ID instruments ran a total of 500 samples that gave a profile:

- 440 runs passed with no quality flags (✅). This represented a first pass success rate of 86.3% (440/510). Upon further analysis, all were 100% concordant to the reference truth.
- 44 runs triggered quality flags (✅), but passed with review. This represented a second pass success rate of 94.9% [(440 + 44)/510]. See “Population study: Runs that passed with review (44 runs)” on page 112.
- 16 runs triggered quality flags (✅) and were failed upon review:
  - 9 runs were for a low peak height (LPH) flag on a true homozygote.
  - 6 runs were for dropout.
  - 1 run was for a false off ladder (OL) flag (bin conflict at locus D2S1338).



- 10 runs failed (❌):
  - 9 runs failed because of size quality failure.
  - 1 run failed because of an instrument current issue.

Note: The default workflow for the ACE GFE sample cartridges includes Y indel and DYS391 in the run status evaluation.

Population study: Runs that passed with review (44 runs)

Of the 60 runs that triggered quality flags (✅), 44 runs passed with review. "Passed with review" means that, despite the presence of one or more quality flags in the profile, after review by a trained analyst, the profile was determined to contain a clear, unambiguous full profile.

Reasons for the quality flags for these 44 runs are provided in Table 12.

Table 12 Population study: Reasons for the quality flags—for the 44 runs that passed with review

Reason for quality flag (✅)	Number of samples[1]
D19S433 –3 nt artifact (flagged)	10
Microvariant	9
Y indel to D2S441 pull-up	8
Amelogenin cross-check	6
DYS391 to TPOX pull-up	6

Table 12 Population study: Reasons for the quality flags—for the 44 runs that passed with review *(continued)*

Reason for quality flag (✓)	Number of samples[1]
Stutter at D19S433	3
TH01 –5 nt artifact	3
DYS391 to SE33 pull-up	2
D19S433 –3 nt artifact (unflagged)[2]	2
Y indel artifact	2
D2S441 MinusA	2
Stutter at D22S1045	1
Spike	1
PHR at SE33	1
PHR at Amelogenin	1
Stutter at CSF1PO	1
FGA –5 nt artifact	1

[1] The "Number of samples" column totals more than 44 because some samples had more than one quality flag. 31 of the 44 samples had a single quality flag. 13 samples had two or more.

[2] Both samples that had an unflagged artifact at D19S433 had quality flags at other loci.

Note: For more information on artifacts in RapidHIT™ ID ACE GlobalFiler™ Express chemistry, go to **thermofisher.com**, then search for *Technical Note: Artifacts Identified Post-Developmental Validation: RapidHIT™ ID ACE GlobalFiler™ Express and RapidINTEL™ Sample Cartridges*, or contact your local Human Identification representative.

Stutter

When the locus-specific filter and global cut-off settings were applied, all stutter peaks above the detection threshold were filtered out in 495 of the 500 profiles tested. Calculated stutter is provided in Appendix B, “Analysis settings”.

5 of the 500 profiles (1.0%) triggered quality flags because of stutter:

- As expected, all stutter was flagged with peak height ratio (PHR) and/or allele number (AN).
- The flagged markers were CSF1PO, D19S433, and D22S1045.

See Figure 11 through Figure 15.

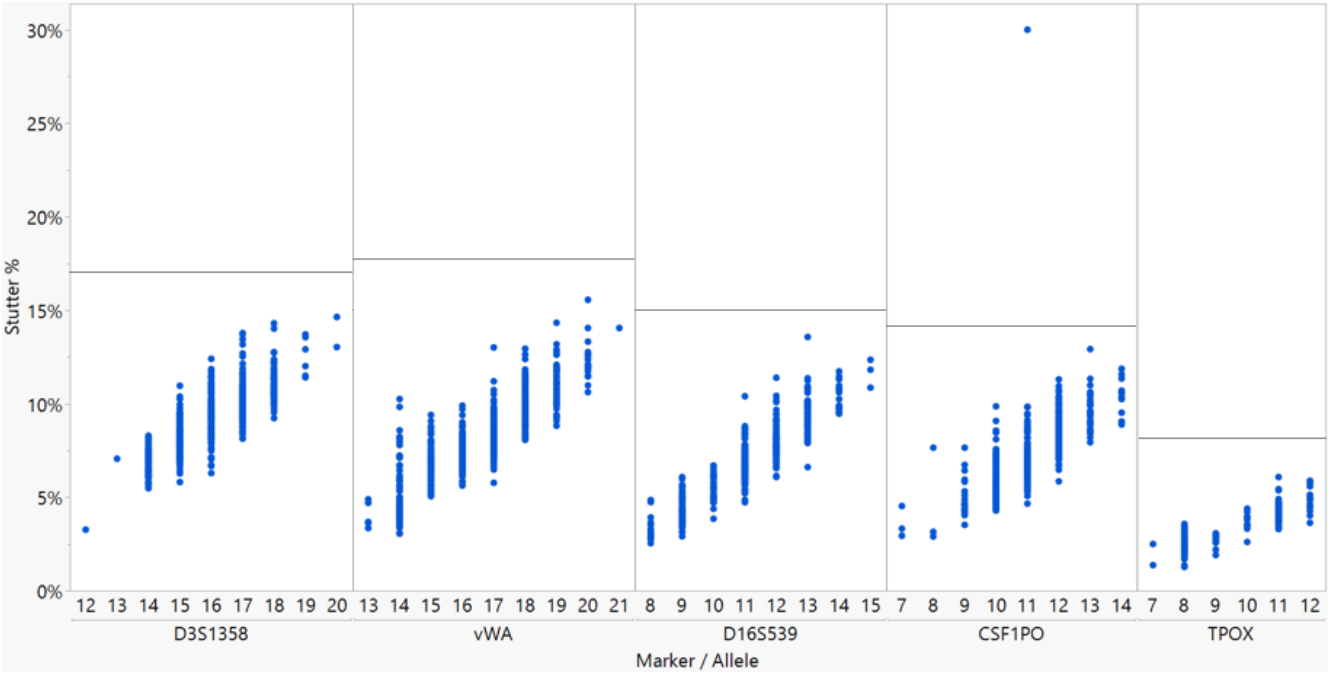


Figure 11 6-FAM™ dye: Stutter percent vs. marker and parent allele The horizontal gray lines represent the stutter filter for each locus. See "Stutter" on page 108 and "Stutter thresholds for RapidHIT™ ID ACE GlobalFiler™ Express cartridges" on page 100.

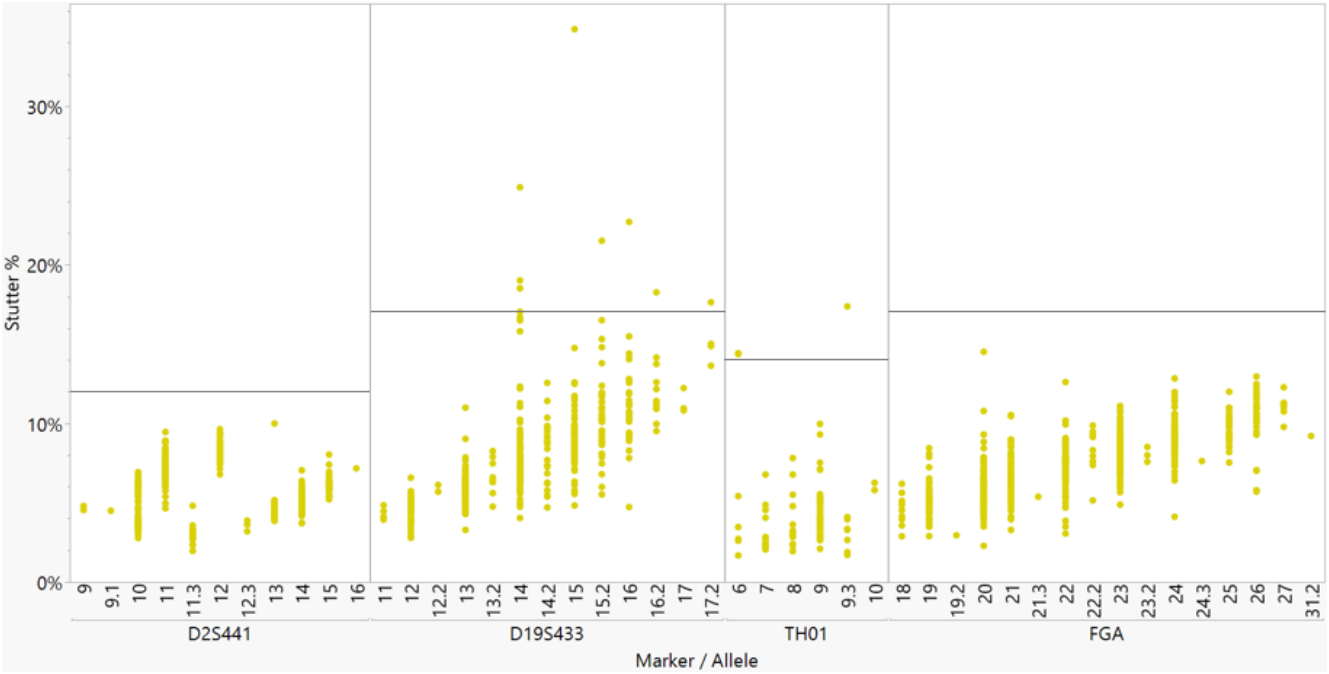


Figure 12 NED™ dye: Stutter percent vs. marker and parent allele The horizontal gray lines represent the stutter filter for each locus. See "Stutter" on page 108 and "Stutter thresholds for RapidHIT™ ID ACE GlobalFiler™ Express cartridges" on page 100.

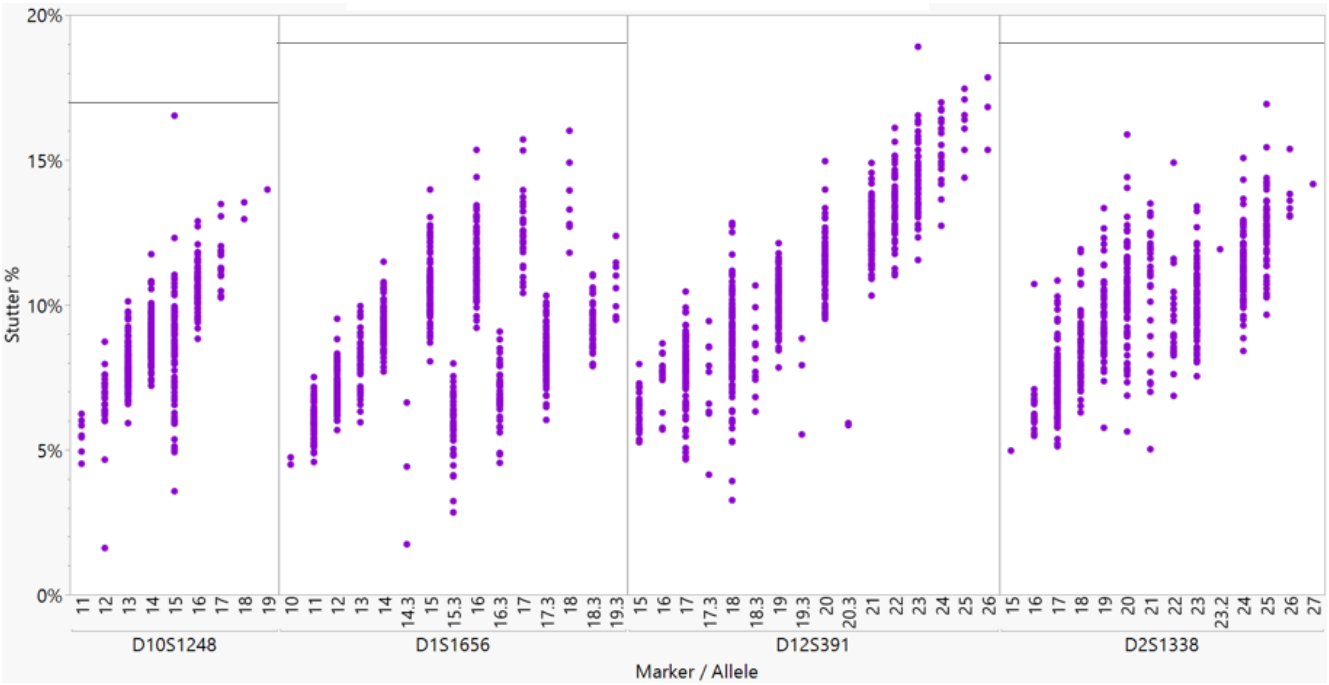


Figure 13 SID™ dye: Stutter percent vs. marker and parent allele The horizontal gray lines represent the stutter filter for each locus. See "Stutter" on page 108 and "Stutter thresholds for RapidHIT™ ID ACE GlobalFiler™ Express cartridges" on page 100. The filter (gray line) does not appear for D12S391 because the stutter threshold for D12S391 is 0.24 (24%).

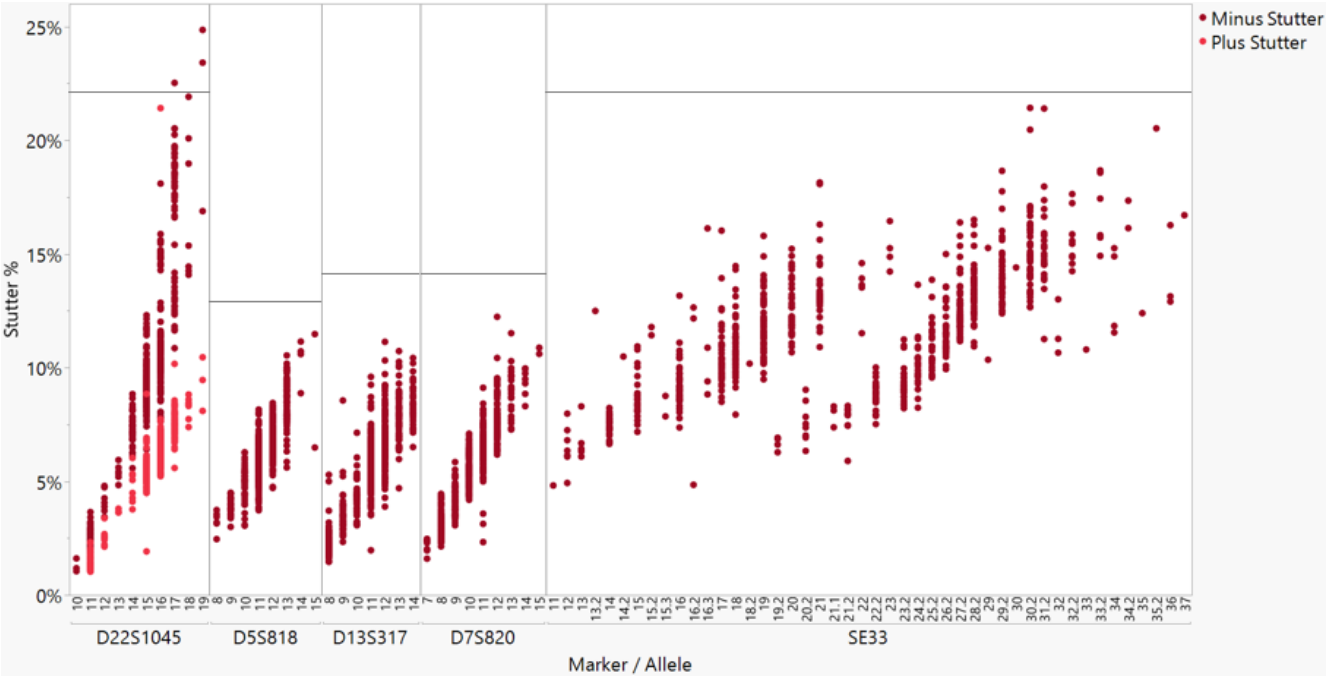


Figure 14 TAZ™ dye: Stutter percent vs. marker and parent allele The horizontal gray lines represent the stutter filter for each locus. See “Stutter” on page 108 and “Stutter thresholds for RapidHIT™ ID ACE GlobalFiler™ Express cartridges” on page 100.

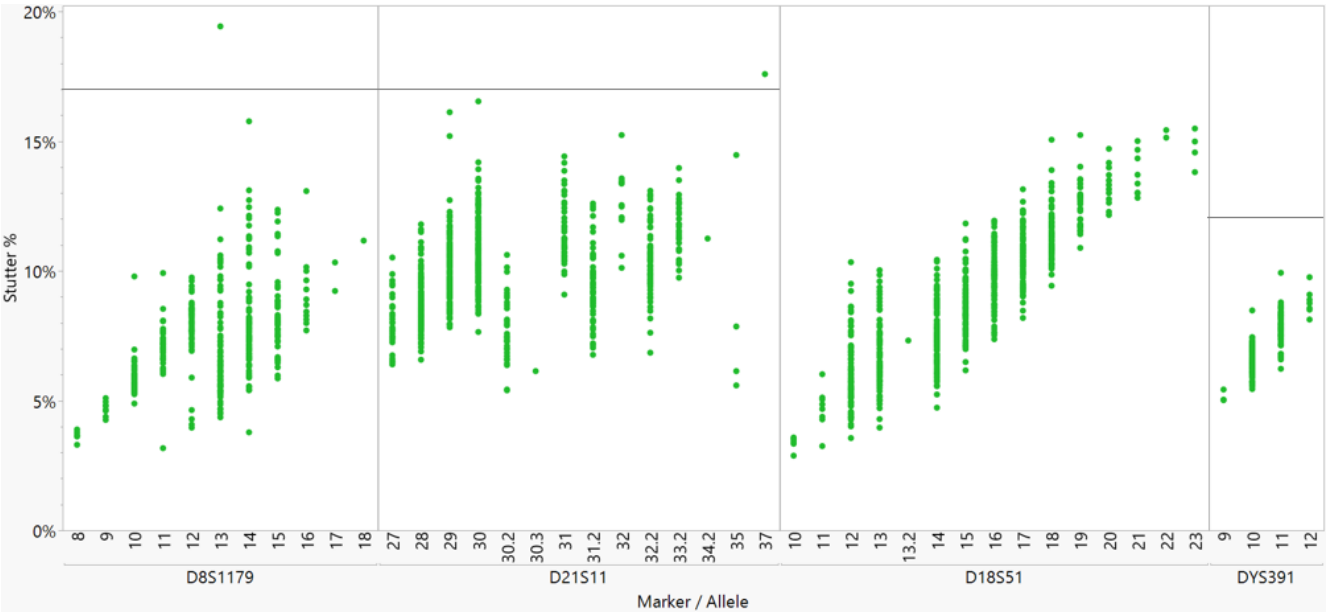


Figure 15 VIC™ dye: Stutter percent vs. marker and parent allele The horizontal gray lines represent the stutter filter for each locus. See “Stutter” on page 108 and “Stutter thresholds for RapidHIT™ ID ACE GlobalFiler™ Express cartridges” on page 100. The filter (gray line) does not appear for D18S51 because the stutter threshold for D18S51 is 0.20 (20%).

Pull-up

When the locus-specific filter and global cut-off settings were applied, all pull-up peaks were filtered out in 484 of the 500 profiles tested.

16 of the 500 profiles (3.2%) triggered quality flags because of pull-up:

- All pull-up was observed in Y indel and/or DYS391.
- The Y indel pull-up came from D2S441.
- The DYS391 pull-up came from TPOX or SE33.

Type	Average %	Minimum %	Maximum %
Y indel pull-up from D2S441	1.5%	0.7%	2.2%
DYS391 pull-up from TPOX	2.3%	1.5%	2.7%
DYS391 pull-up from SE33	1.0%	0.8%	1.2%

Dropout

6 of the 500 profiles (1.2%) triggered quality flags because of dropout:

- 3 runs had sister peak dropout at 1 marker only.
- 1 run had sister peak dropout at 2 different markers.
- 1 run had DYS3691 dropout.
- 1 run had both sister peaks dropout at a marker.
- All dropout was flagged for quality issues at the appropriate marker.
- Locus breakdown: TPOX (1), D8S1179 (1), DYS391 (1), TH01 (1), D10S1248 (1), D2S1338 (2)

Sizing accuracy

Sizing accuracy is defined as the difference in base pairs (bp) between the observed allele size and the mean allele size for all observations of that allele.

The sizing specification is between –0.3 and 0.3 bp.

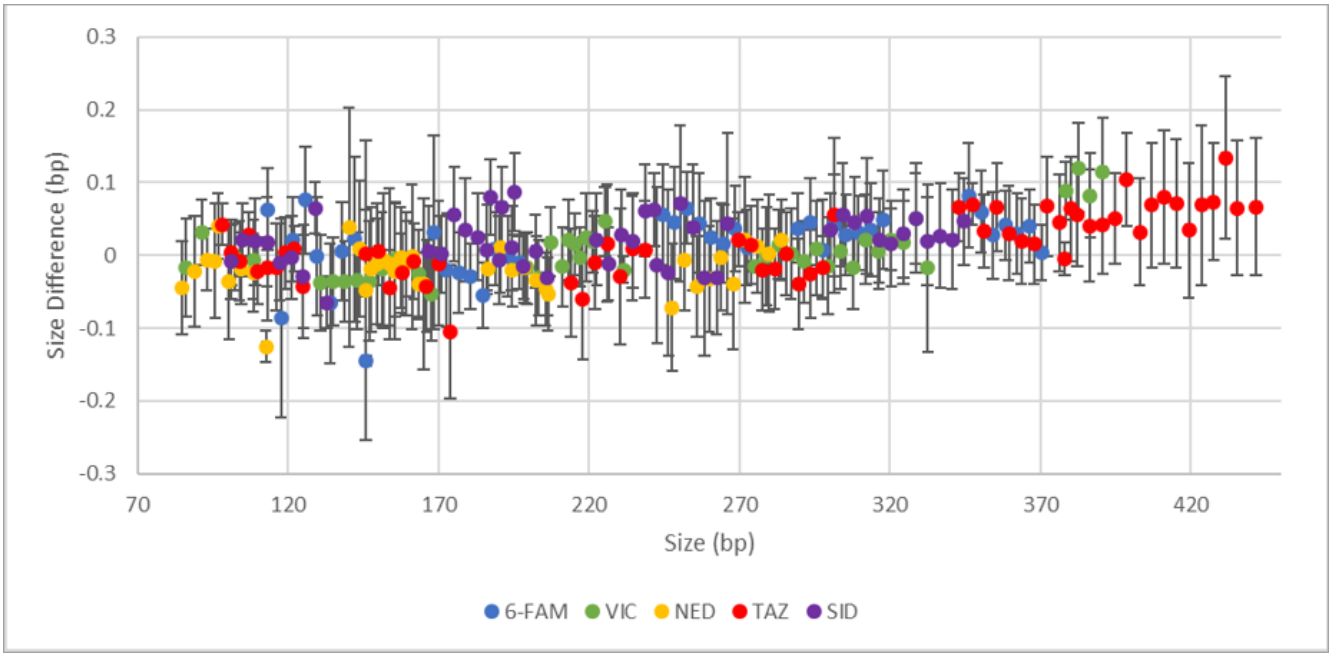


Figure 16 Population study: Size difference vs. mean allele size (500 unique genotypes)

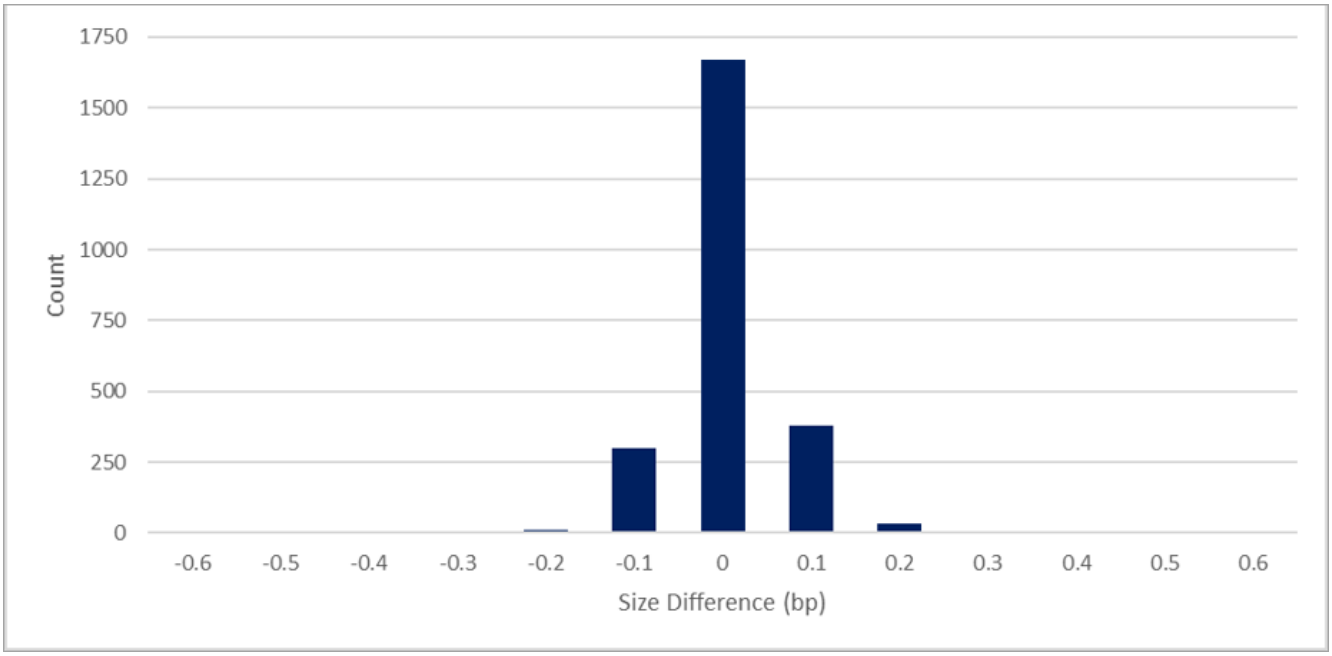


Figure 17 Population study: Distribution of size differences (500 unique genotypes)

Precision study

Precision was measured by calculating and plotting the standard deviation of the size values for each allele. The standard deviations of the size values for 30 allelic ladders run across 6 instruments were all <0.16 bp.

The precision specification is 0.17 bp.

Cartridge and sample summary

30 ACE GFE allelic ladder cartridges from the same lot number were run.

Run and analysis summary

6 RapidHIT™ ID instruments ran 5 allelic ladder cartridges each:

- 30 cartridges passed with no quality flags (✅).

Precision by instrument

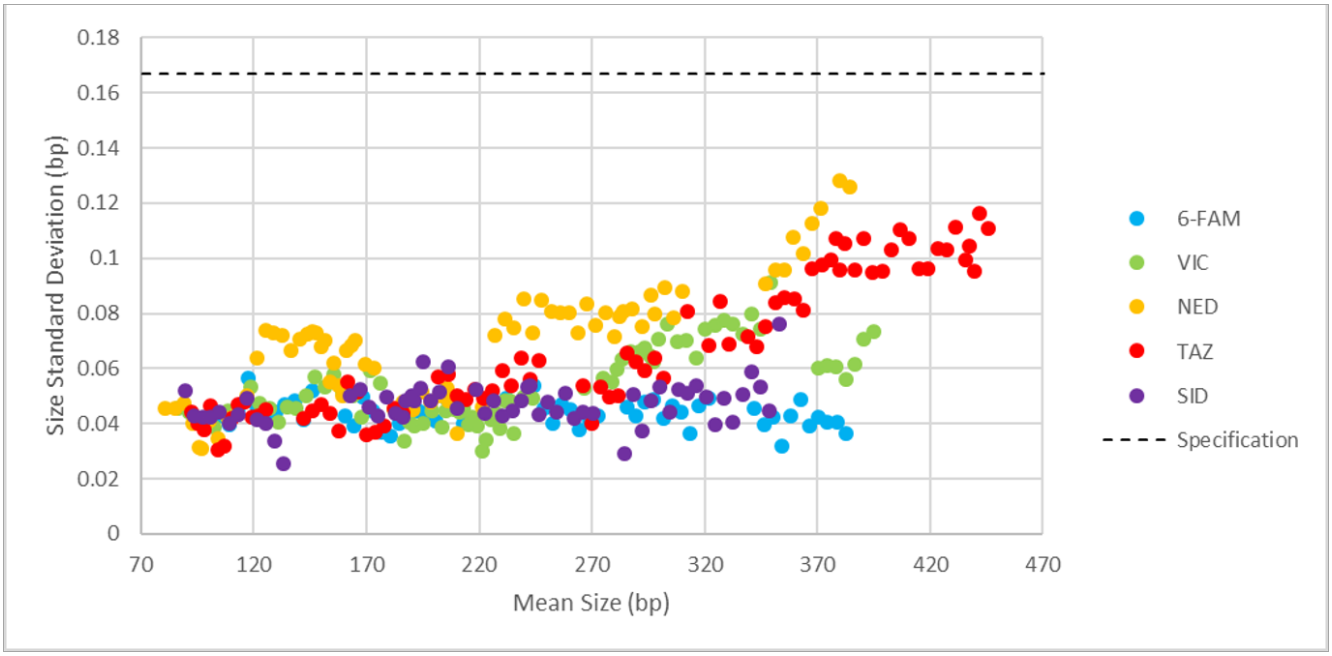


Figure 18 Precision study: Size standard deviation vs. mean size across instruments 30 GFE allelic ladder cartridges

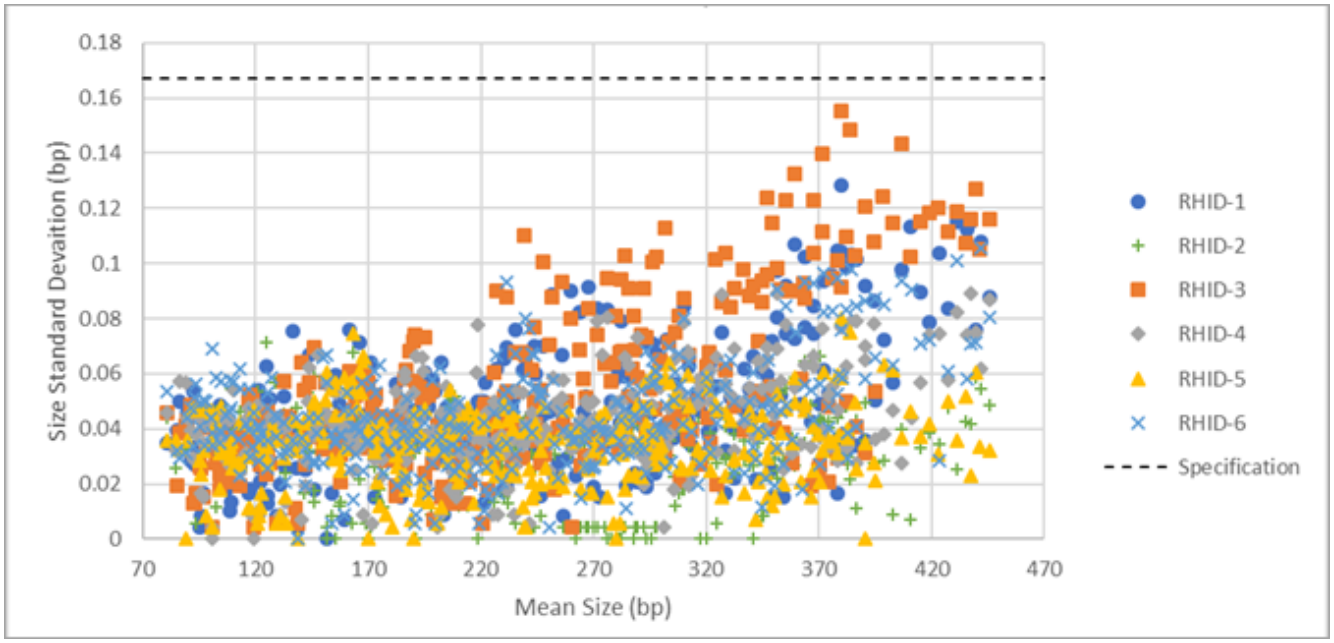


Figure 19 Precision study: Size standard deviation vs. mean size within instruments 5 GFE allelic ladder cartridges per instrument

Reproducibility and repeatability (R&R) study

Reproducibility and repeatability indicates that the same result is achieved with repeated processing of the same sample.

Cartridge and sample summary

30 ACE GFE positive control cartridges from the same lot number were run.

Note: The same instruments and primary cartridges from the precision study were used.

Run and analysis summary

6 RapidHIT™ ID instruments ran 5 GFE positive control cartridges each:

- 30 cartridges passed with no quality flags (✅).
- The mean peak heights and peak height ratios for the 30 positive controls were above the minimum specification at each locus.
- The mean peak height ratio was above 0.9 (90%) at each locus.

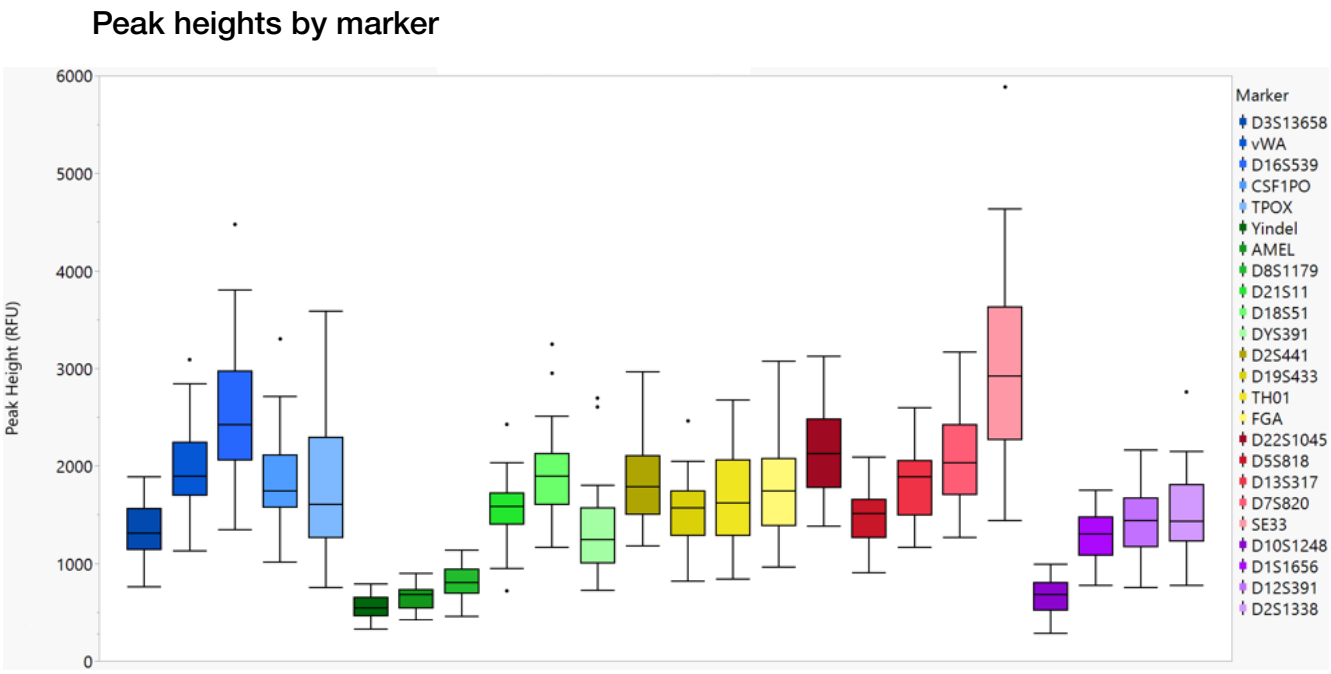


Figure 20 R&R study: Peak heights by marker 30 ACE GFE positive control cartridges.

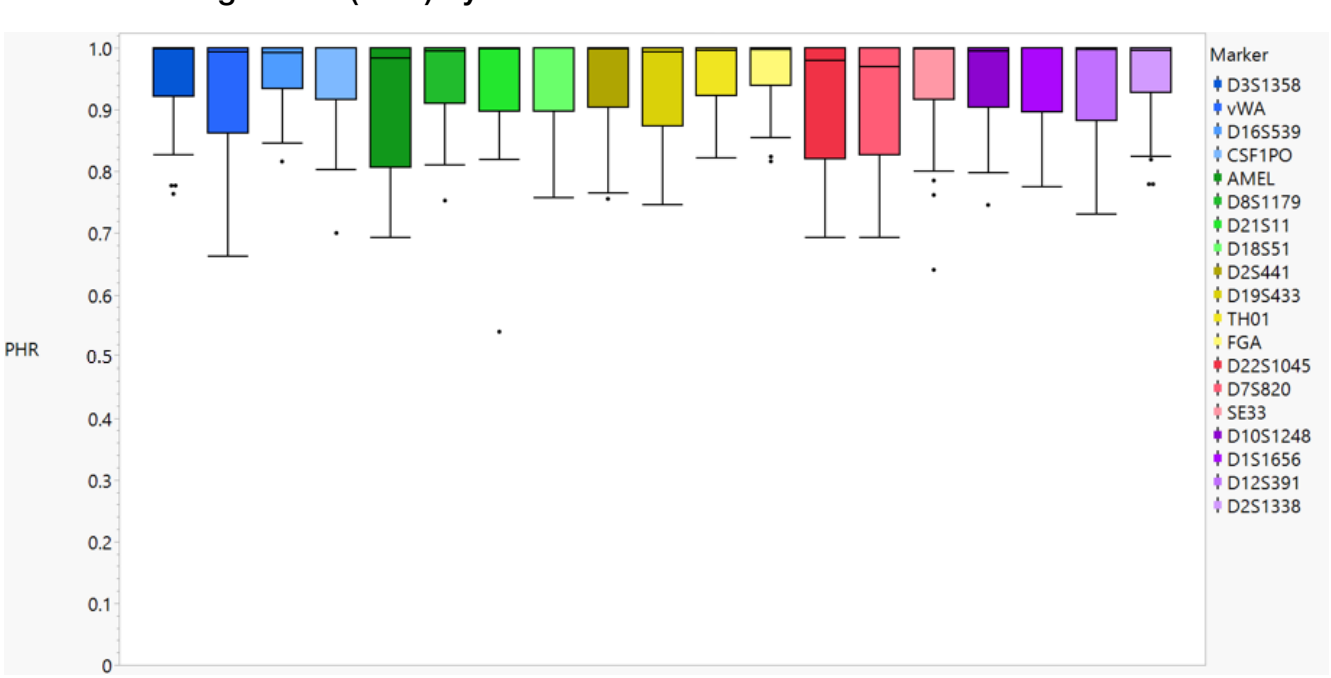


Figure 21 R&R study: PHR by marker 30 ACE GFE positive control cartridges.

Sensitivity study

Cartridge and sample summary

3 sensitivity series were run with ACE GFE sample cartridges:

- Buccal swipe series—40 cartridges
- gDNA series—50 cartridges
- Saliva series—40 cartridges

Run and analysis summary: Buccal swipe series

2 RapidHIT™ ID instruments ran 5 replicates of each "input" amount.

- Input amounts were determined by the number of swipes of the donor's cheek with the swab: 1, 5, 10 and 20 swipes were taken. This resulted in 40 total samples (2 instruments × 5 replicates × 4 inputs).
- Results showed 100% allele recovery for all inputs, with slightly declining peak heights for decreasing input amounts.

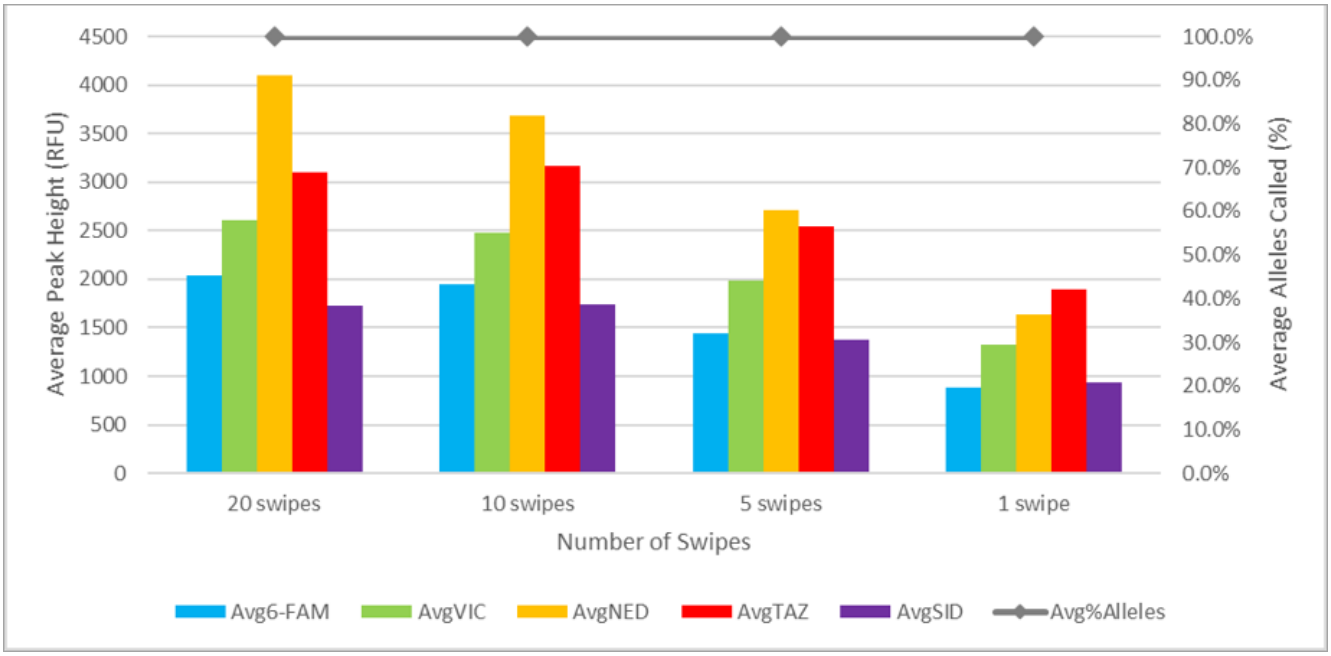


Figure 22 Sensitivity study: Buccal swipe series Male donor; 10 replicates per number of swipes

Run and analysis summary: gDNA series

2 RapidHIT™ ID instruments ran 5 replicates of each input amount.

- Input amounts were a two-fold dilution series of control DNA with total DNA amounts as follows: 500 ng, 250 ng, 125 ng, 62.5 ng, and 31.25 ng. This resulted in 50 total samples (2 instruments × 5 replicates × 5 inputs).
- Results showed 100% allele recovery for all inputs down to and including 125 ng, with declining peak heights for decreasing input amounts.

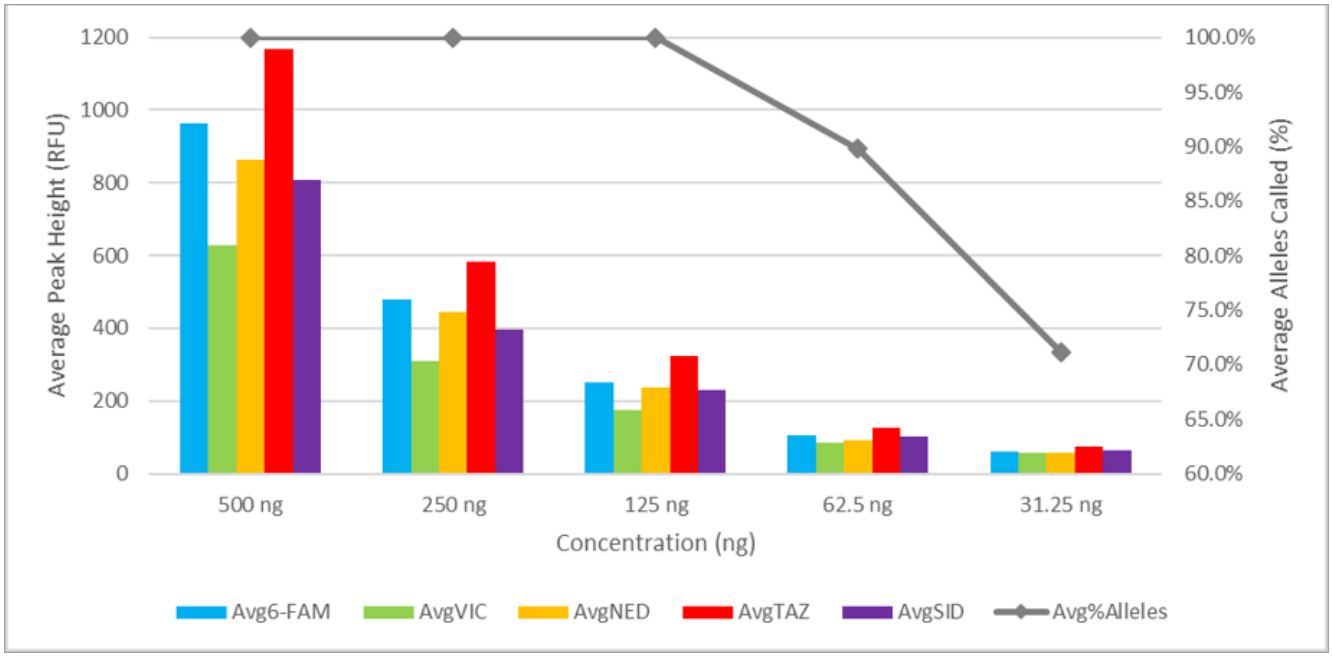


Figure 23 Sensitivity study: gDNA series DNA Control 007; 10 replicates per concentration

Run and analysis summary: Saliva series

2 RapidHIT™ ID instruments ran 5 replicates of each dilution amount.

- Input amounts were a decreasing series of saliva dilutions: starting with neat saliva, then 1:5, 1:10, and 1:20 diluted saliva, for 4 input amounts in total. This resulted in 40 total samples (2 instruments × 5 replicates × 4 inputs).
- Results showed 100% allele recovery for the neat saliva, with declining peak heights and allele recovery for the other input amounts.

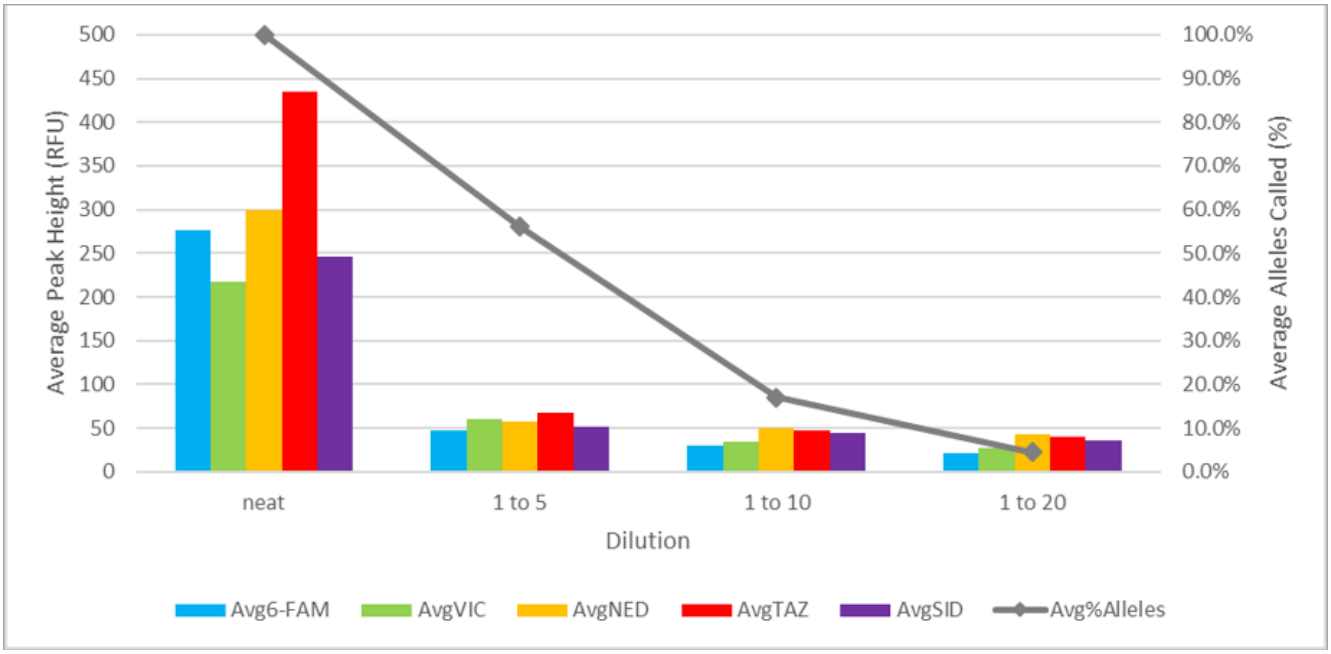


Figure 24 Sensitivity study: Saliva series Male donor; 10 replicates per dilution

Carryover study

Carryover studies indicate whether there is sample carryover from one run to the next.

Cartridge and sample summary

2 cartridge types were used:

- 10 ACE GFE sample cartridges, gDNA swabs—2,400 ng of DNA Control 007
- 10 ACE GFE negative control cartridges

Run and analysis summary

2 RapidHIT™ ID instruments ran 10 cartridges each, for a total of 20 runs:

- Each instrument ran 5 sample cartridges and 5 negative control cartridges.
- The runs were alternated as follows: A sample cartridge was run, followed by a negative control cartridge, creating a checkerboard pattern.
- All negative control cartridges passed with no quality flags (✅). A passing negative control means that no allelic peaks were detected above the analytical threshold at any locus.

Run	ACE GFE cartridge	RapidHIT™ ID instrument	
		1	2
1	Sample (2,400 ng of DNA Control 007)	—	—
2	Negative control	✔	✔
3	Sample (2,400 ng of DNA Control 007)	—	—
4	Negative control	✔	✔
5	Sample (2,400 ng of DNA Control 007)	—	—
6	Negative control	✔	✔
7	Sample (2,400 ng of DNA Control 007)	—	—
8	Negative control	✔	✔
9	Sample (2,400 ng of DNA Control 007)	—	—
10	Negative control	✔	✔

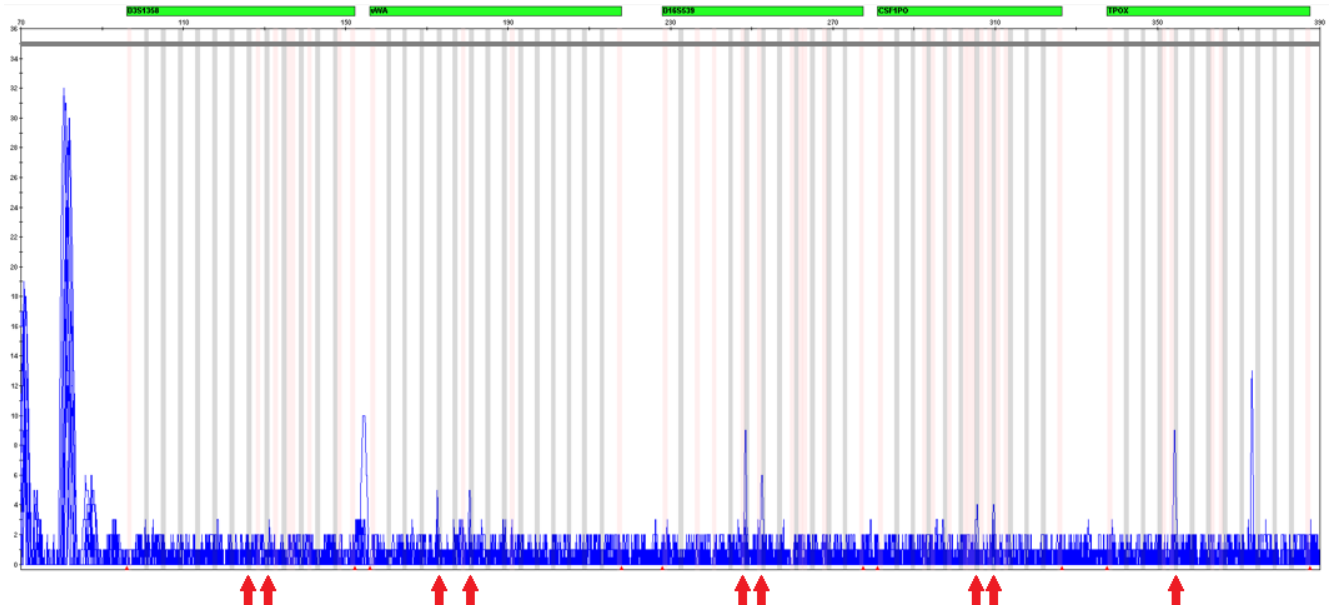


Figure 25 Carryover study: Negative controls overlaid—6-FAM™ dye 10 alternating runs. The red arrows indicate bins for the DNA Control 007 genotype. The gray line is the analytical threshold. Y-axis: RFU 0–36.

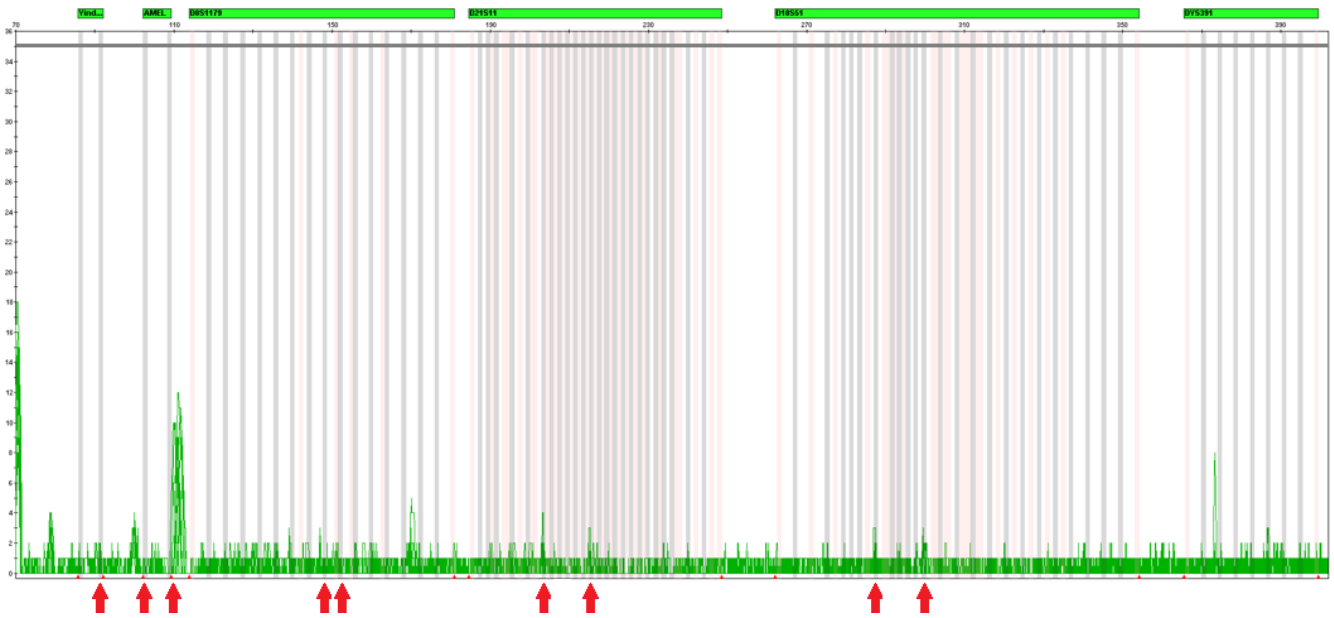


Figure 26 Carryover study: Negative controls overlaid—VIC™ dye 10 alternating runs. The red arrows indicate bins for the DNA Control 007 genotype. The gray line is the analytical threshold. Y-axis: RFU 0–36.

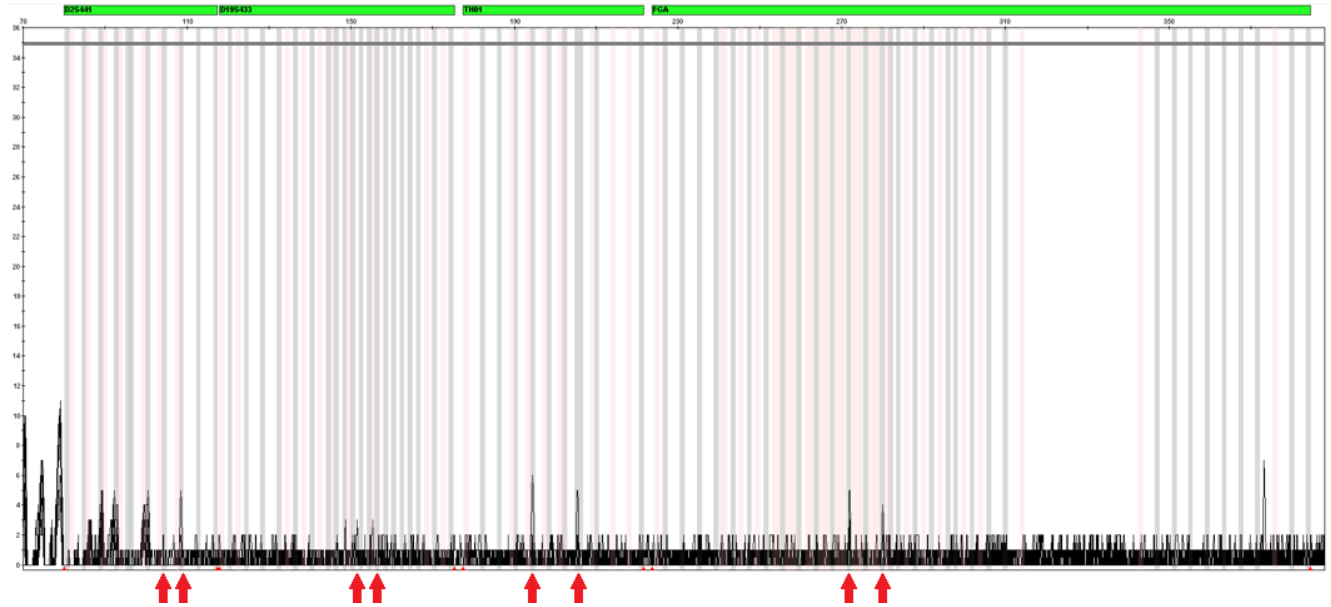


Figure 27 Carryover study: Negative controls overlaid—NED™ dye 10 alternating runs. The red arrows indicate bins for the DNA Control 007 genotype. The gray line is the analytical threshold. Y-axis: RFU 0–36.

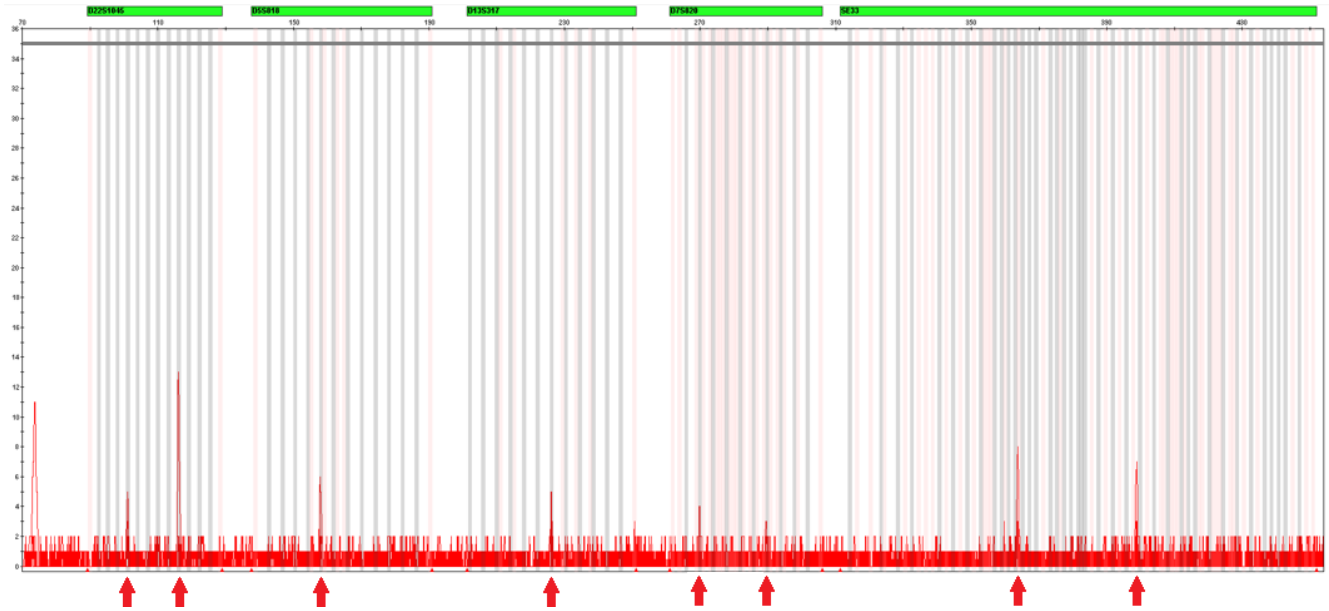


Figure 28 Carryover study: Negative controls overlaid—TAZ™ dye 10 alternating runs. The red arrows indicate bins for the DNA Control 007 genotype. The gray line is the analytical threshold. Y-axis: RFU 0–36.

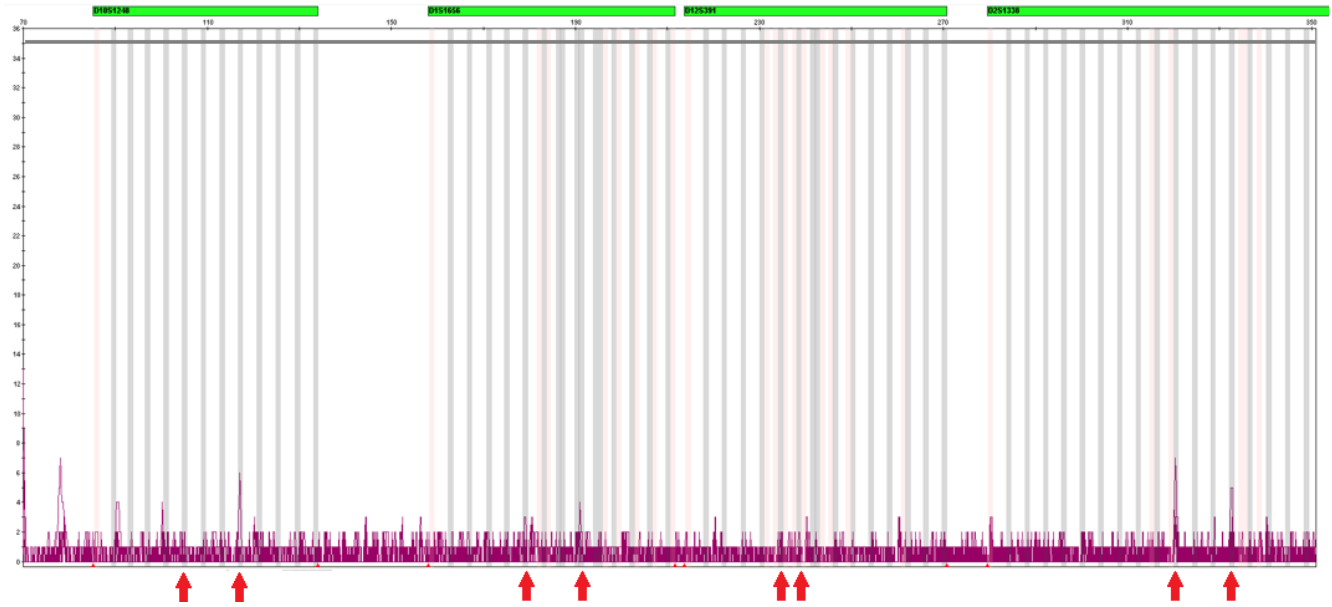


Figure 29 Carryover study: Negative controls overlaid—SID™ dye 10 alternating runs. The red arrows indicate bins for the DNA Control 007 genotype. The gray line is the analytical threshold. Y-axis: RFU 0–36.

Extra negative controls study

Cartridge and sample summary

85 ACE GFE negative control cartridges were run.

Run and analysis summary

12 RapidHIT™ ID instruments ran negative control cartridges (the number of cartridges varied per instrument):

- 77 cartridges passed with no quality flags ().
- 8 cartridges failed ():
  - 2 cartridges did not produce results because of an instrument error (DX code B2, the sample injection was delayed).
  - For the remaining 6 cartridges, the most common reasons for failure were known artifacts or spikes.
- None of the 83 runs that produced results had called carryover peaks.

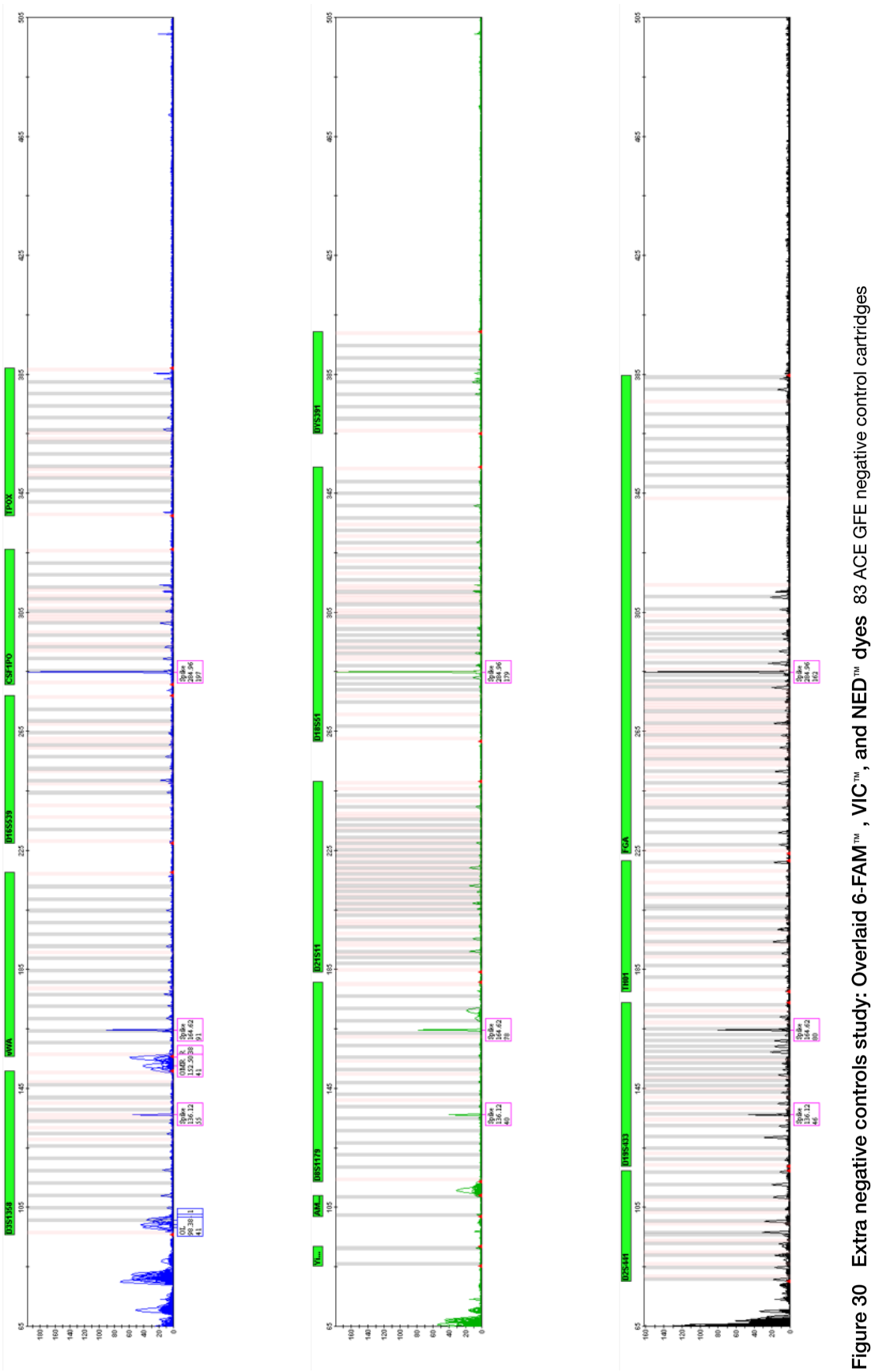


Figure 30 Extra negative controls study: Overlaid 6-FAM™, VIC™, and NED™ dyes 83 ACE GFE negative control cartridges

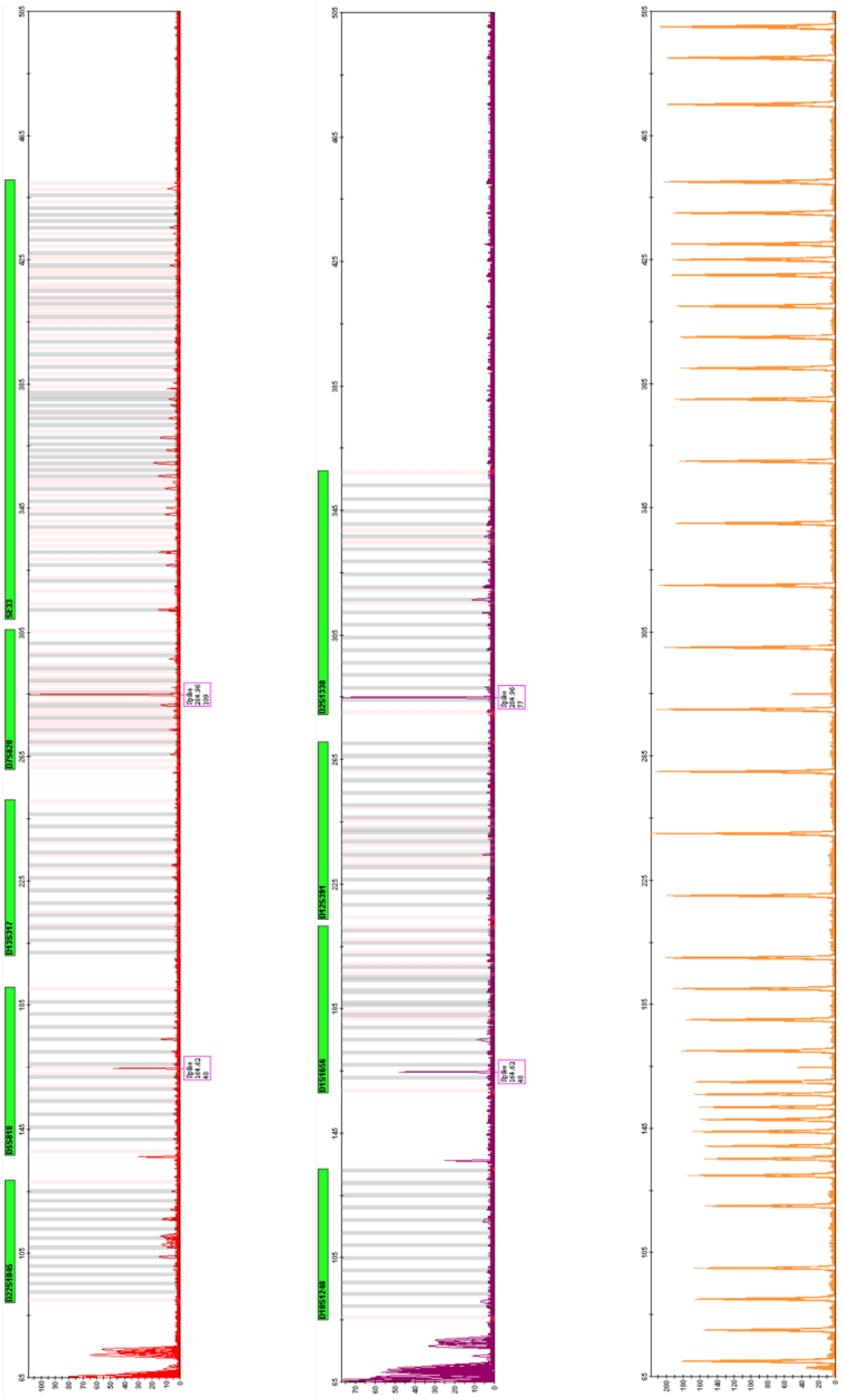


Figure 31 Extra negative controls study: Overlaid TAZ™ dye, SID™, andLIZ™ dyes 83 ACE GFE negative control cartridges

Inhibition study

Cartridge and sample summary

3 inhibition series were run with ACE GFE sample cartridges:

- Tobacco series—50 cartridges

  Note: The tobacco was prepared by grinding 2.5 g of chewing tobacco with 25 mL of nuclease-free water in a mortar. The resulting slurry was allowed to soak for 4 hours at room temperature, then the liquid was separated and stored overnight at room temperature.

- Coffee series—50 cartridges
- Mouthwash series—50 cartridges

The inhibitor was added to 750 ng of DNA Control 007 on each swab, dried overnight at room temperature, then stored at 4°C until used.

Run and analysis summary: Tobacco series

2 RapidHIT™ ID instruments ran 5 replicates of each input amount.

- Input amounts—Increasing volumes of the tobacco preparation were added to the DNA swabs for 5 input amounts in total: 0 µL (control, no inhibitor added), then 2.5 µL, 5 µL, 10 µL, and 20 µL of the tobacco preparation. This resulted in 50 total samples (2 instruments ×5 replicates × 5 inputs).
- Results showed 100% allele recovery for all samples, with declining peak heights as the amount of inhibitor increased.
- All runs passed with no quality flags (✔), regardless of inhibitor type or concentration.

A one-way ANOVA test was performed to compare the means of peak height (by dye) and PHR grouped by inhibitor volume:

- The p-values for the mean of peak height (by dye) are all <0.05, indicating that the mean of at least one volume is significantly different.
- The PHR p-value is >0.05, indicating that the means are statistically equal.
- An All Pairs Tukey-Kramer test was used to compare the peak height means. For all dyes, the 0 µL volume is significantly different from the other volumes.

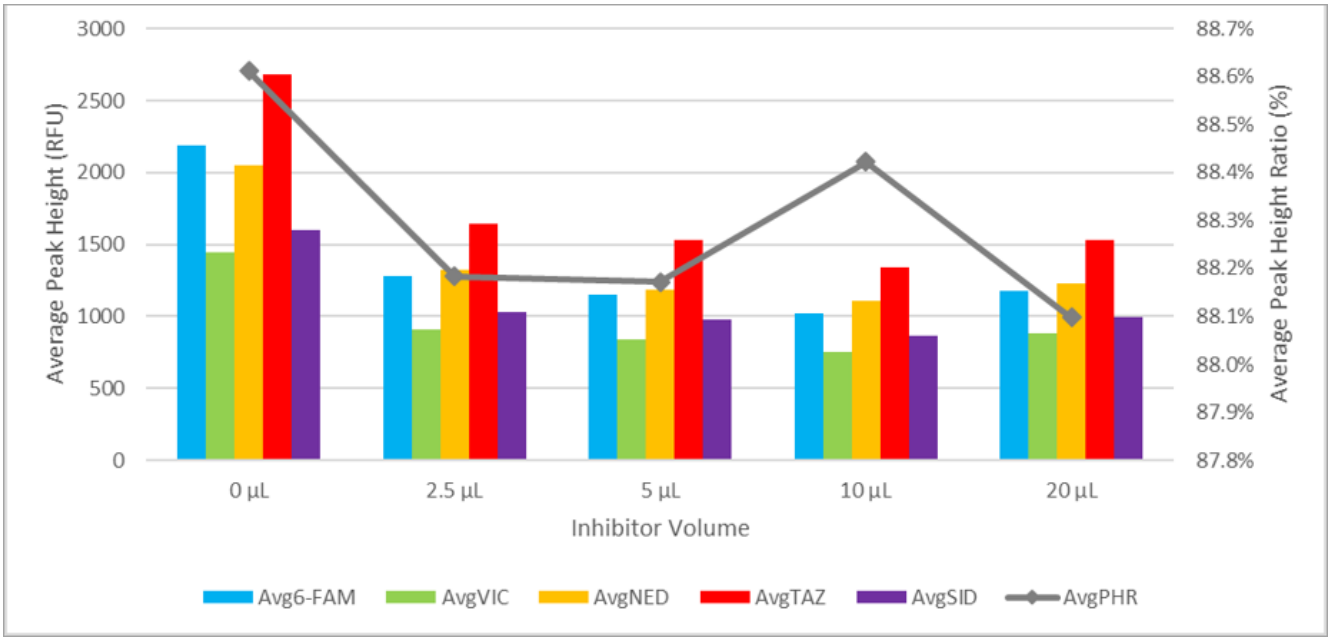


Figure 32 Inhibition study: Tobacco series 750 ng of DNA Control 007; 10 replicates per volume

By	DF	Sum of squares	Mean square	Fs	p-value
6-FAM™	4	97634659	24408665	34.1705	<0.0001
VIC™	4	31434531	7858633	23.5578	<0.0001
NED™	4	47030531	11757633	35.7961	<0.0001
TAZ™	4	143237476	35809369	31.0455	<0.0001
SID™	4	26521520	6630380	28.0765	<0.0001
PHR	4	0.0042981	0.001075	0.1833	0.9471

Run and analysis summary: Coffee series

2 RapidHIT™ ID instruments ran 5 replicates of each input amount.

- Input amounts—Increasing volumes of coffee were added to the DNA swabs for 5 input amounts in total: 0 µL (control, no inhibitor added), then 2.5 µL, 5 µL, 10 µL, and 20 µL of coffee. This resulted in 50 total samples (2 instruments ×5 replicates × 5 inputs).
- Results showed 100% allele recovery for all samples, with slightly lower peak heights for the inhibited samples compared to the control, and roughly equivalent peak heights for each of the inhibited samples.

A one-way ANOVA test was performed to compare the means of peak height (by dye) and PHR grouped by inhibitor volume.

- The p-value for the mean of peak height (by dye) are all <0.05, indicating that the mean of at least one volume is significantly different.
- The PHR p-value is >0.05, indicating that the means are statistically equal.
- An All Pairs Tukey-Kramer test was used to compare the peak height means:
  - 6-FAM™ and TAZ™ dyes: The 0 µL volume is significantly different from the 2.5 µL, 5 µL, and 20 µL volumes.
  - VIC™ dye: The 0 µL volume is significantly different from the 2.5 µL volume.
  - NED™ dye: The 0 µL volume is significantly different from the 2.5 µL, 5 µL, and 20 µL volumes. Additionally, the 2.5 µL and 10 µL volumes are significantly different from each other.
  - SID™ dye: The 0 µL volume is significantly different from the 2.5 µL and 5 µL volumes.

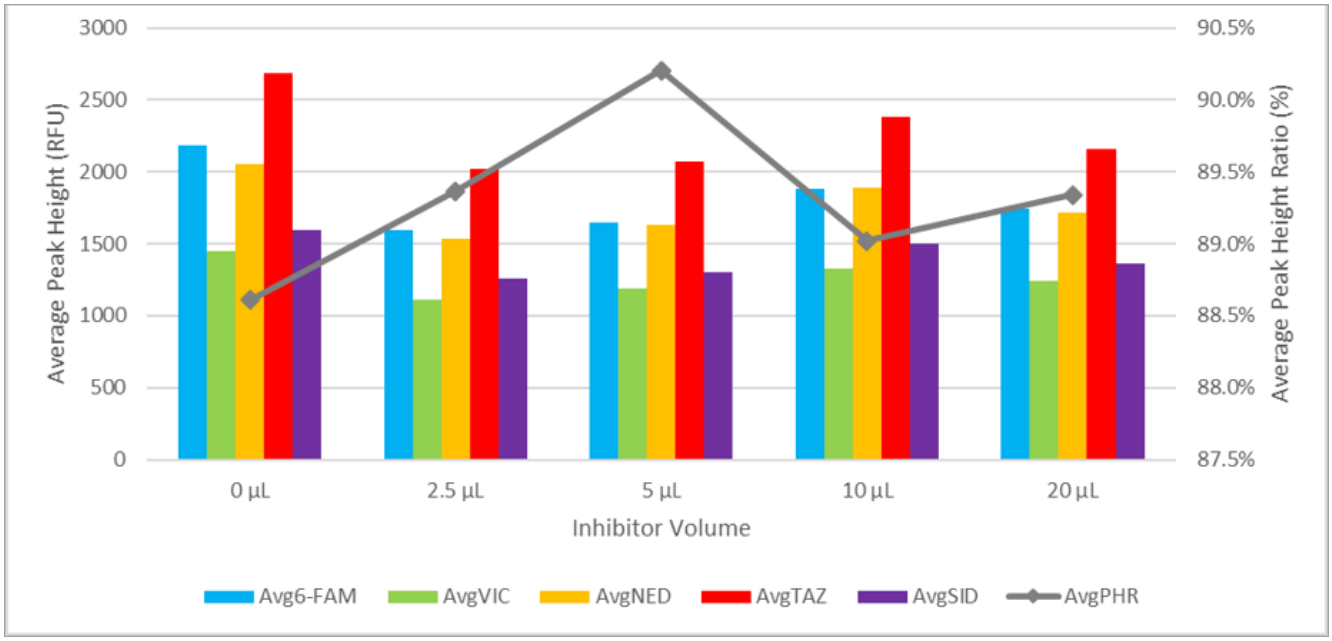


Figure 33 Inhibition study: Coffee series 750 ng of DNA Control 007; 10 replicates per volume

By	DF	Sum of squares	Mean square	Fs	p-value
6-FAM™	4	24600635	6150159	5.3205	0.0003
VIC™	4	7084567	1771142	3.3161	0.0107
NED™	4	13820069	3455017	7.4596	<0.0001
TAZ™	4	37436035	9359009	5.7121	0.0002
SID™	4	6480329	1620082	4.6081	0.0012
PHR	4	0.0267496	0.006687	1.3211	0.2602

Run and analysis summary: Mouthwash series

2 RapidHIT™ ID instruments ran 5 replicates of each dilution amount.

- Input amounts—Increasing volumes of mouthwash were added to the DNA swabs for 5 input amounts in total: 0 µL (control, no inhibitor added), then 2.5 µL, 5 µL, 10 µL, and 20 µL of mouthwash. This resulted in 50 total samples (2 instruments ×5 replicates × 5 inputs).
- Results showed 100% allele recovery for all samples, with slightly lower peak heights for the inhibited samples compared to the control, and roughly equivalent peak heights for each of the inhibited samples.

A one-way ANOVA test was performed to compare the means of peak height (by dye) and PHR grouped by inhibitor volume.

- The p-value for the mean of peak height (by dye) are all <0.05, indicating that the mean of at least one volume is significantly different.
- The PHR p-value is >0.05, indicating that the means are statistically equal.
- An All Pairs Tukey-Kramer test was used to compare the peak height means:
  - 6-FAM™, VIC™, and SID™ dyes: The 0 µL volume is significantly different from the other volumes.
  - NED™ dye: The 0 µL volume is different from the other volumes; the 2.5 µL volume is different from the 10 µL and 20 µL volumes.
  - TAZ™ dye: The 0 µL volume is different from the other volumes; the 2.5 µL volume is different from the 20 µL volume.

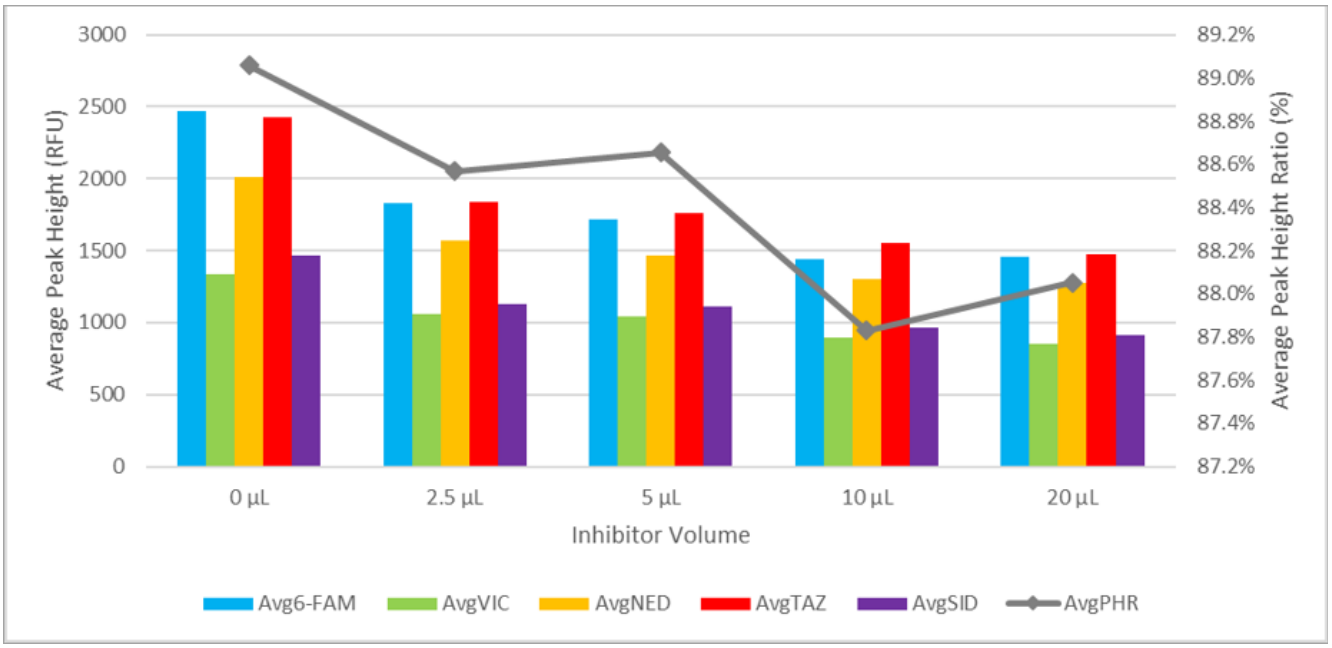


Figure 34 Inhibition study: Mouthwash series 750 ng of DNA Control 007; 10 replicates per volume

By	DF	Sum of squares	Mean square	Fs	p-value
6-FAM™	4	77720565	19430141	17.7670	<0.0001
VIC™	4	15268010	3817002	11.0805	<0.0001
NED™	4	28487583	7121896	19.3837	<0.0001
TAZ™	4	70189049	17547262	17.0636	<0.0001
SID™	4	14641108	3660277	14.4077	<0.0001
PHR	4	0.0194374	0.004859	0.8464	0.4959

Mixture study

Mixtures run on RapidHIT™ ID instruments should trigger the MIX quality flag in RapidLINK™ Software v2.0 analysis.

The MIX flag is triggered in the following scenarios:

- 2 or more markers have 3 or more called alleles
- 1 or more markers have 3 or more called alleles, and another 2 or more markers have yellow PHR

A mixture in a single-source sample or negative control can indicate contamination.

Note: For more information on the MIX quality flag, see the flag appendix in the *RapidLINK™ Software v2.0 User Guide* (Pub. No. MAN0030010).

Cartridge and sample summary

3 male-to-female mixture series were run with ACE GFE sample cartridges:

- gDNA series—54 cartridges
- Saliva series—54 cartridges

Run and analysis summary: gDNA series

2 RapidHIT™ ID instruments ran 3 replicates of each ratio.

- Input amounts were various combinations of the male and female gDNA samples used:
  - A 1:1 mixture of the two genotypes
  - 1:0, 1:2, 1:4 and 1:8 ratios of male:female DNA
  - 1:0, 1:2, 1:4 and 1:8 ratios of female:male DNA

  This resulted in 54 total samples (2 instruments × 3 replicates × 9 inputs).
- Results showed that the mixtures were detected by RapidHIT™ ID System v2.0. In RapidLINK™ Software v2.0:
  - The MIX quality flag was triggered for all mixed samples, except for 2 of the 1:8 samples.
  - The ACC quality flag was triggered for all of the 1:8 samples, indicating the presence of extra or missing peaks at the Amelogenin and/or Y-markers

Table 13 Mixture study: gDNA series results

Ratio (M:F)	MIX flag	ACC[1] flag	No. of possible minor peaks	Number of minor peaks called						
				Rep 1	Rep 2	Rep 3	Rep 4	Rep 5	Rep 6	Average[2]
1:0	0/6	0/6	0	0	0	0	0	0	0	**0**
1:1	6/6	0/6	26/20	26/20	26/20	26/20	26/20	26/20	26/20	**26/20**
1:2	6/6	5/6	26	25	25	25	25	26	25	**25**
1:4	6/6	6/6	26	18	14	13	15	15	16	**15**
1:8	4/6	6/6	26	2	3	3	5	5	4	**3**
8:1	6/6	0/6	20	2	3	4	2	3	4	**3**
4:1	6/6	0/6	20	15	12	14	13	16	11	**13**
2:1	6/6	0/6	20	20	20	20	20	20	20	**20**
0:1	0/6	0/6	0	0	0	0	0	0	0	**0**

[1] ACC = Amelogenin Crosscheck

[2] The average was rounded down to the nearest whole number.

Run and analysis summary: Saliva series

2 RapidHIT™ ID instruments ran 3 replicates of each ratio.

- Input amounts were various combinations of the male and female saliva samples used:
  - A 1:1 mixture of the two genotypes
  - 1:0, 1:2, 1:4 and 1:8 ratios of male:female DNA
  - 1:0, 1:2, 1:4 and 1:8 ratios of female:male DNA

  This resulted in 54 total samples (2 instruments × 3 replicates × 9 inputs).
- Results showed that the mixtures were detected by RapidHIT™ ID System v2.0. In RapidLINK™ Software v2.0:
  - The MIX quality flag was triggered for all 1:1 and 1:2 samples, except for one of the 1:2 replicates. This sample was a 1:2 male:female mixture.
  - The MIX quality flag was triggered for all of the mixture samples where the male DNA was present in greater quantities than the female DNA, including all six 1:8 female:male samples.
  - None of the 1:4 or 1:8 male:female samples were detected as mixtures. However, the ACC quality flag was triggered for all of these samples, due to discrepancies between Amelogenin and the Y markers.
  - As such, all samples were flagged as MIX or ACC.

Ratio (M:F)	MIX flag	ACC[1] flag	No. of possible minor peaks	Number of minor peaks called						
				Rep 1	Rep 2	Rep 3	Rep 4	Rep 5	Rep 6	Average[2]
1:0	0/6	0/6	0	0	0	0	0	0	0	**0**
1:1	6/6	5/6	28/27	23/27	28/27	19/27	19/27	26/27	21/27	**22/27**
1:2	5/6	6/6	28	5	5	4	12	3	5	**5**
1:4	0/6	6/6	28	1	1	1	2	1	1	**1**
1:8	0/6	6/6	28	1	1	1	1	2	1	**1**
8:1	6/6	0/6	27	25	24	26	24	24	24	**24**
4:1	6/6	0/6	27	27	27	27	27	27	27	**27**
2:1	6/6	4/6	27	27[3]	27[3]	27	27[3]	27[3]	27	**27**
0:1	0/6	0/6	0	0	0	0	0	0	0	**0**

[1] ACC = Amelogenin crosscheck

[2] The average was rounded down to the nearest whole number.

[3] The Y allele dropped out for the major donor.

Reliability testing results

Category	Test result
Installation	RapidHIT™ ID System v2.0 software was installed on 4 RapidHIT™ ID instruments for end-to-end verification runs.
Sign In	150 unique fingerprints were used to sign into the system. All sign-ins were successful.
Users	Functions to create, edit, and manage instrument users accounts and privileges performed as expected.
Runs	• Runs were performed with and without (standalone) connection to RapidLINK™ Software v2.0. • Sample, allelic ladder, positive control, and negative control runs generated expected results at run completion: ✅ (pass), ☑ (quality flag), or ❌ (fail) • Passing allelic ladder runs were added to the ladder library. • Confirmed that the allelic ladder selected from the library was the one that most closely matched the sample. • Confirmed that a dye matrix file was generated and applied after a positive control run. • Demo mode was used to perform mock runs and demonstrate end-to-end use of the system as intended.

(continued)

Category	Test result
Maintenance	• Maintenance scripts and on-screen indicators functioned as expected. • Users were able to follow on-screen prompts for primary cartridge replacement. • Users were prompted and able to perform steps as indicated to clear critical DX codes.
RapidLINK™ Software v2.0	• At run completion, results were transferred to RapidLINK™ Software v2.0 through a connected network or USB device. • The following instrument management operations were verified: connecting, disconnecting, authorizing, and deauthorizing. • The following run management operations were verified: reviewing samples, uploading to an external database, exporting run logs/folders, and exporting reports. • Confirmed that the workflows were correctly downloaded to the instrument.

Performance verification of RapidHIT™ ID System v2.0.1

The objective of the verification was to assess the performance of RapidHIT™ ID System v2.0.1 after the following updates were made to the analysis settings in Expert System Software v2.0.1 (Primary Analysis v1.0 and GeneMapper™ ID-XR v1.0.1):

- Virtual bins 12.1, 13.1, and 14.3 in the D19S433 bin set were removed
- Stochastic thresholds for D18S51, FGA, and D13S317 were changed to 100 RFU from 99 RFU, 93 RFU, and 97 RFU, respectively.

The 510 runs from the validation data set population study (see “Samples” on page 110) were reprocessed through the RapidHIT™ ID System v2.0.1 analysis pipeline (primary and secondary analysis). Run status results for the 500 population samples (510 total runs) resulted in 85.9% flag-free runs (), 12.2% flagged runs (), and 2% failed runs (). For all passing runs, allelic data was concordant with the known truth, all microvariants were labeled as expected, and sizing accuracy was <0.3 bp. The ten samples that generated failing results in RapidHIT™ ID System v2.0 returned the same failing results in RapidHIT™ ID System v2.0.1 (nine runs for size quality issues and one run for a current issue).

- Two samples that generated flag-free results in v2.0 were flagged in v2.0.1. In v2.0, the donors had alleles at D19S433 that fell into virtual bins. In v2.0.1, with the removal of three virtual bins at this marker, these peaks were flagged as off ladder (OL).
- Due to the change in the D19S433 bin set, two additional Expert System flags were generated in v2.0.1. In v2.0, two samples that contained a D19S433 n–3 artifact did not show flags at this marker. In v2.0.1, a BIN flag was generated in both cases.

Conclusions

- RapidHIT™ ID System v2.0 achieved a first pass success rate of 86.3% (440/510). "First pass" refers to the initial instrument results, without analyst review.
- RapidHIT™ ID System v2.0 achieved a second pass success rate of 94.9% (484/510). "Second pass" refers to the results after analyst review in RapidLINK™ Software v2.0.
- Quality flags were observed in 12% of the runs. The most common reasons for a quality flag were the D19S –3 nt artifact, pull-up in the Y markers, and the TH01 –5 nt artifact.
- During the population study, the most common cause for failed ( ) runs was a size quality failure. Size quality failures were also seen in the sensitivity study (buccal swipe series and saliva series).
- Precision and accuracy are within the requirements for the system.
- Sensitivity studies demonstrate that the system typically produces full profiles with 125 pg of purified DNA.
- No called carryover peaks were observed.
- In terms of peak height suppression, there is evidence of minor inhibition when tobacco, coffee, or mouthwash is present on the sample. However, all alleles were recovered for all inputs of each inhibitor measured.
- The system can detect a mixture down to a 1 to 8 ratio.
- For all mixture samples, the system triggered MIX or ACC quality flags, indicating that no mixtures were missed.
- The performance verification of RapidHIT™ ID System v2.0.1 demonstrated consistent results with RapidHIT™ ID System v2.0 and achieved a first pass success rate of 85.9%.

D Instrument specifications

- Dimensions, clearance, and weight 140
- Instrument layout and connections 141
- Environmental requirements 143
- Electrical requirements 144

Dimensions, clearance, and weight

Specification	Height	Length (depth)	Width	Weight
Dimension	48 cm (19 in.)	53 cm (21 in.)	27 cm (10.5 in.)	• 28.4 kg (62.6 lb.) —With primary cartridge • 25.4 kg (56.0 lb.)— Instrument only • 3.0 kg (6.6 lb.)— Primary cartridge only
Additional clearance	25 cm (10 in.)	28 cm (11 in.) Minimum rear clearance is 10 cm (4 inches). Clearance is required to allow air flow around the instrument and to allow the power cord to be easily removed without moving the instrument.	13 cm (5 in.) 64 cm (25 in.) required on one side for computer	N/A

Instrument layout and connections



Figure 35 Dimensions and clearances

① Height 48 cm (19 in.)
② Height clearance 25 cm (10 in.)
③ Length (depth) 53 cm (21 in.)
④ Length (depth) clearance 28 cm (11 in.)
Length (depth) clearance when replacing the primary cartridge114 cm (45 in.)
⑤ Width 27 cm (10.5 in.)
⑥ Width clearance 13 cm (5 in.)
64 cm (25 in.) required on one side for computer

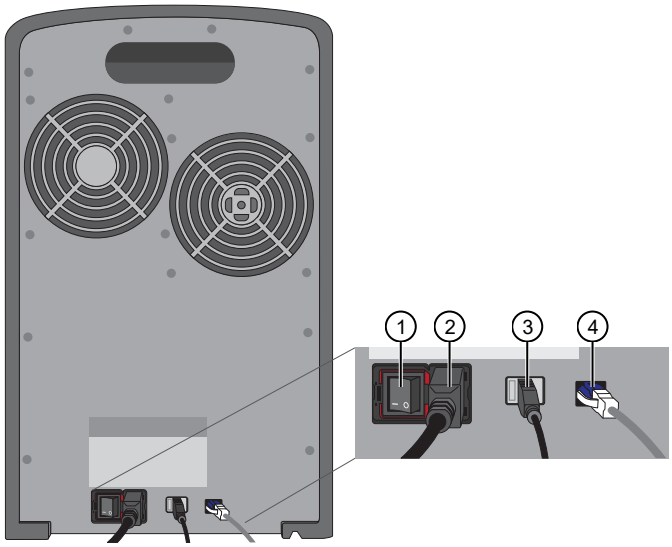


Figure 36 Rear panel

① Main power switch
② Power connection
③ USB port for optional barcode scanner connection
④ Ethernet port for computer connection

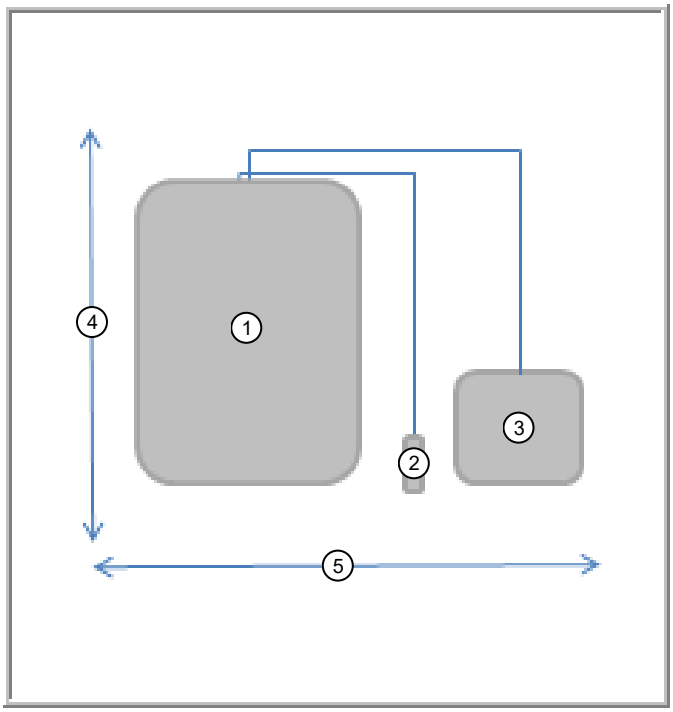


Figure 37 Component connections

① Instrument
② Optional barcode scanner
③ Computer
④ Total length (depth) space required 109 cm (43 in.)
⑤ Total width space required 116 cm (45 in.)

Environmental requirements

Condition	Requirement
Installation site	Indoor use only
Altitude	Safety tested up to 2,600 meters (8,500 feet)
Electromagnetic interference	Do not use this instrument near sources of strong electromagnetic radiation (for example, unshielded intentional RF sources). Strong electromagnetic radiation can interfere with the proper operation of the device.
Transient/overvoltage category	Installation categories II
Vibration	Do not install the instrument near strong vibration sources, such as a centrifuge, pump, or compressor. Excessive vibration affects instrument performance.

(continued)

Condition	Requirement
Pollution degree	II Do not install the instrument in an environment that has nonconductive pollutants such as dust particles or wood chips. Typical environments with a Pollution Degree II rating are laboratories and sales and commercial areas.
Operating conditions	• 15–30°C (59–86°F) (Room temperature should not fluctuate ±2°C during an instrument run) • 20–80% relative humidity, noncondensing
Storage conditions	For instrument only without primary cartridge installed: 4–40°C (39–104°F) Minimum 20% relative humidity, maximum 80% (non-condensing) **IMPORTANT!** • The primary cartridge requires storage at 15–30°C (59–86°F). • The gel cartridge requires storage at 2–8°C (36–46°F).
Transport conditions	–20°C to +60°C (–4°F to +140°F) Minimum 20% relative humidity, maximum 80% (non-condensing)
Other conditions	Ensure that the room is away from any vents that could expel particulate material on the components. Avoid placing the instrument and computer near heaters, cooling ducts, or in direct sunlight. Maintain about 10 cm (4 in.) of space around all sides of the instrument for air flow.

Electrical requirements

CAUTION! Do not unpack or plug in any components until they are configured for the proper operating voltage by the service representative.

WARNING! For safety, the power outlet for the instrument must be accessible at all times. In case of emergency, you must be able to immediately disconnect the main power supply to all the equipment. Allow sufficient space between the wall and the equipment so that the power cords can be disconnected in case of emergency.

- Dedicated line and ground between the instrument and the main electrical service
- Maximum power dissipation: 230 W, 370 VA (not including computer)
- Mains AC line voltage tolerances should not exceed ±10 percent of nominal voltage
- Maximum current: 3 A
- Fuse rating: 5 A, 250 V, Slow-blow, 5 × 20 mm

Device	Rated voltage	Circuit required	Rated frequency	Rated power
Instrument	100–240 ±10% VAC[1]	≥10 A	50/60 Hz	600 W

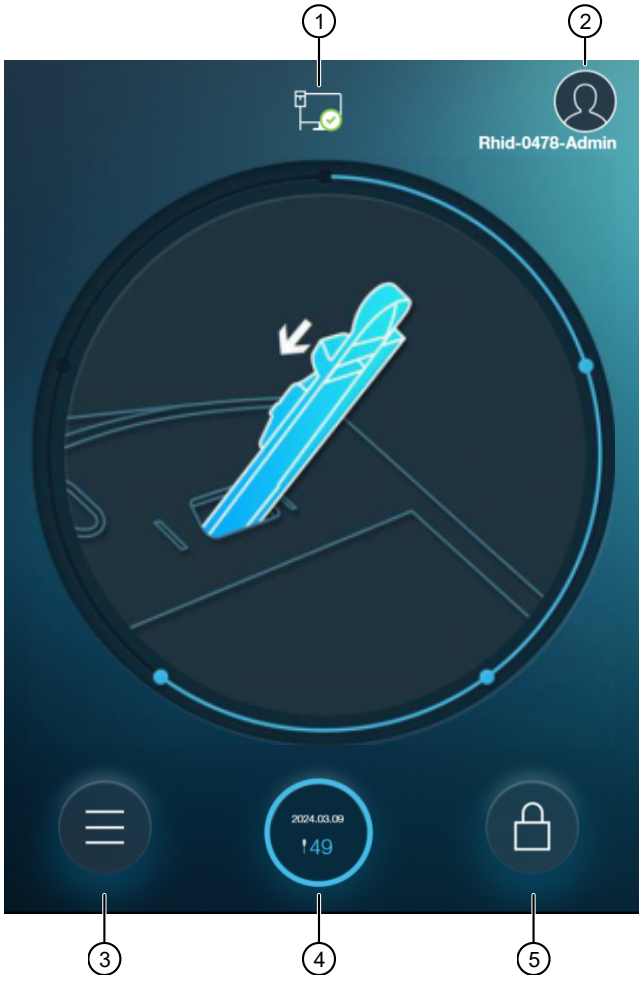
[1] If the supplied power fluctuates beyond the rated voltage, a power line regulator may be required. High or low voltages can adversely affect the electronic components of the instrument.



Touchscreen descriptions

- Insert cartridge screen 147
- Remove cartridge screen 148
- Menu screen 149

Insert cartridge screen



① Instrument connection status:

- —The instrument is connected to the RapidLINK™ Software.
- —The instrument is connected to the RapidLINK™ Software, but is currently offline.
- No icon—A connection was never initiated between the instrument and the RapidLINK™ Software.

See “Check the RapidLINK™ Software connection” on page 83.

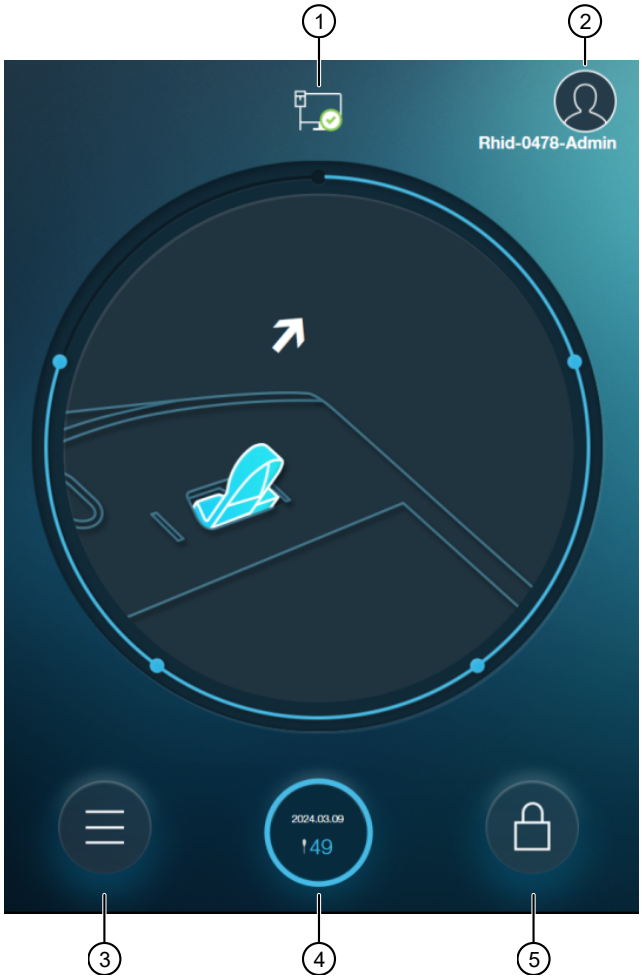
② The name of the signed in user.

③ Tap to display the menu screen. See “Menu screen” on page 149.

④ Displays the expiration date and run count for the primary (reagent) cartridge. The run count indicates the number of runs that have been performed, not the number of runs that are remaining (for example, "65" indicates that 65 runs have been performed). For more information, see “View primary cartridge information” on page 75.

⑤ Tap to sign out and lock the touchscreen (displays the lock screen).

Remove cartridge screen



① Instrument connection status:

- —The instrument is connected to the RapidLINK™ Software.
- —The instrument is connected to the RapidLINK™ Software, but is currently offline.
- No icon—A connection was never initiated between the instrument and the RapidLINK™ Software.

See “Check the RapidLINK™ Software connection” on page 83.

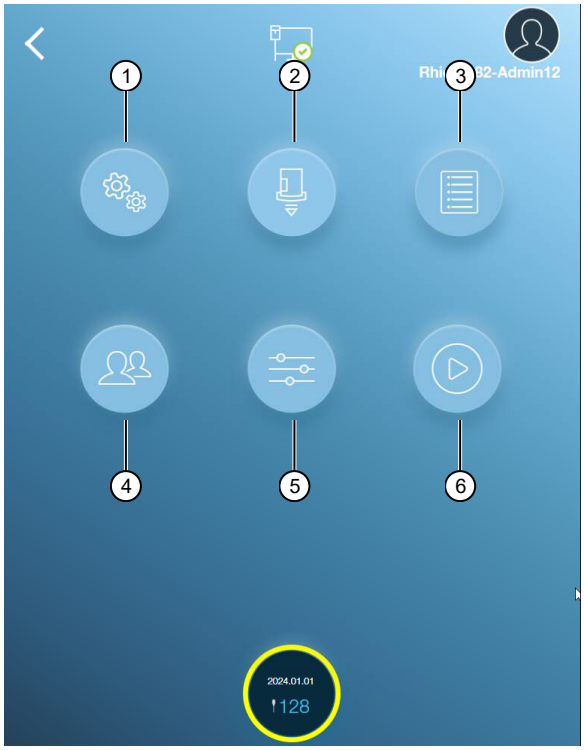
② The name of the signed in user.

③ Tap to display the menu screen. See “Menu screen” on page 149.

④ Displays the expiration date and run count for the primary (reagent) cartridge. The run count indicates the number of runs that have been performed, not the number of runs that are remaining (for example, "65" indicates that 65 runs have been performed). For more information, see “View primary cartridge information” on page 75.

⑤ Tap to sign out and lock the touchscreen (displays the lock screen).

Menu screen



① Configure the instrument settings (see page 36).
② Replace the primary cartridge (see “Replace the primary cartridge” on page 76).
③ View run logs (see page 35).
④ Manage instrument users (see page 58).
⑤ Configure the instrument options (see page 54).
⑥ View a quick video on how to collect a buccal swab sample and run the sample on the instrument.

Safety

WARNING! GENERAL SAFETY. Using this product in a manner not specified in the user documentation may result in personal injury or damage to the instrument or device. Ensure that anyone using this product has received instructions in general safety practices for laboratories and the safety information provided in this document.

- Before using an instrument or device, read and understand the safety information provided in the user documentation provided by the manufacturer of the instrument or device.
- Before handling chemicals, read and understand all applicable Safety Data Sheets (SDSs) and use appropriate personal protective equipment (gloves, gowns, eye protection, and so on). To obtain SDSs, visit **thermofisher.com/support**.

Symbols on this instrument

Symbols may be found on the instrument to warn against potential hazards or convey important safety information. In this document, the hazard symbol is used along with one of the following user attention words.

- **CAUTION!**—Indicates a potentially hazardous situation that, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices.
- **WARNING!**—Indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury.
- **DANGER!**—Indicates an imminently hazardous situation that, if not avoided, will result in death or serious injury.

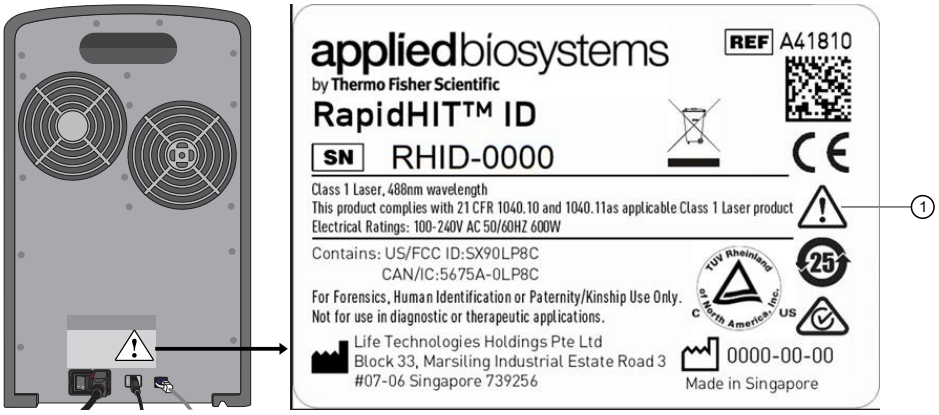
Standard safety symbols

Symbol and description
CAUTION! Risk of danger. Consult the manual for further safety information.

Symbole et description
MISE EN GARDE ! Risque de danger. Consulter le manuel pour d'autres renseignements de sécurité.

Location of safety labels

Rear panel

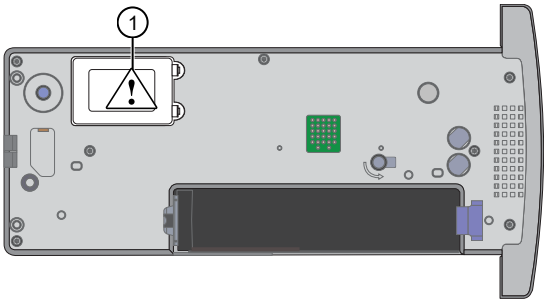


① ⚠ = Location of symbol

CAUTION! Risk of danger. Consult the manual for further safety information.

MISE EN GARDE ! Risque de danger. Consulter le manuel pour d'autres renseignements de sécurité.

Primary cartridge



① ⚠ = Location of symbol

CAUTION! The capillary is fragile. Handle the primary cartridge with care after you remove the capillary cover.

Control and connection symbols

Symbols and descriptions	
	On (Power)
	Off (Power)
	Earth (ground) terminal
	Protective conductor terminal (main ground)
	Direct current
	Alternating current
	Both direct and alternating current

Conformity symbols

Conformity mark	Description
	Indicates conformity with safety requirements for Canada and U.S.A.
	Indicates conformity with European Union requirements.
	INDICATES CONFORMITY WITH THE WEEE DIRECTIVE 2012/19/EU. **CAUTION!** To minimize negative environmental impact from disposal of electronic waste, do not dispose of electronic waste in unsorted municipal waste. Follow local municipal waste ordinances for proper disposal provision and contact customer service for information about responsible disposal options.
	Environmental protection symbol of the China RoHS directive. The number in the symbol indicates the "Environment-friendly Use Period" of the product in years. The symbol is used if a substance restricted in China is used in excess of the maximum permitted limit.
	Indicates conformity with Australian standards for electromagnetic compatibility.

(continued)

Conformity mark	Description
	DATE OF MANUFACTURE (YYYY-MM-DD)
	MANUFACTURER
	CATALOGUE NUMBER

Safety information for instruments not manufactured by Thermo Fisher Scientific

Some of the accessories provided as part of the instrument system are not designed or built by Thermo Fisher Scientific. Consult the manufacturer's documentation for the information needed for the safe use of these products.

Instrument safety

General



CAUTION! Do not remove instrument protective covers. If you remove the protective instrument panels or disable interlock devices, you may be exposed to serious hazards including, but not limited to, severe electrical shock, laser exposure, crushing, or chemical exposure.

Physical injury



CAUTION! Moving Parts. Moving parts can crush, pinch and cut. Keep hands clear of moving parts while operating the instrument. Disconnect power before servicing.

Electrical safety

WARNING! Ensure appropriate electrical supply. For safe operation of the instrument:

- Plug the system into a properly grounded receptacle with adequate current capacity.
- Ensure the electrical supply is of suitable voltage.
- Never operate the instrument with the ground disconnected. Grounding continuity is required for safe operation of the instrument.

AVERTISSEMENT ! Veiller à utiliser une alimentation électrique appropriée. Pour garantir le fonctionnement de l'instrument en toute sécurité :

- Brancher le système sur une prise électrique correctement mise à la terre et de puissance adéquate.
- S'assurer que la tension électrique est convenable.
- Ne jamais utiliser l'instrument alors que le dispositif de mise à la terre est déconnecté. La continuité de la mise à la terre est impérative pour le fonctionnement de l'instrument en toute sécurité.

WARNING! Power Supply Line Cords. Use properly configured and approved line cords for the power supply in your facility.

AVERTISSEMENT ! Cordons d'alimentation électrique. Utiliser des cordons d'alimentation adaptés et approuvés pour raccorder l'instrument au circuit électrique du site.

WARNING! Disconnecting Power. To fully disconnect power either detach or unplug the power cord, positioning the instrument such that the power cord is accessible.

AVERTISSEMENT ! Déconnecter l'alimentation. Pour déconnecter entièrement l'alimentation, détacher ou débrancher le cordon d'alimentation. Placer l'instrument de manière à ce que le cordon d'alimentation soit accessible.

Cleaning and decontamination

CAUTION! Cleaning and Decontamination. Use only the cleaning and decontamination methods that are specified in the manufacturer user documentation. It is the responsibility of the operator (or other responsible person) to ensure that the following requirements are met:

- No decontamination or cleaning agents are used that can react with parts of the equipment or with material that is contained in the equipment. Use of such agents could cause a HAZARD condition.
- The instrument is properly decontaminated a) if hazardous material is spilled onto or into the equipment, and/or b) before the instrument is serviced at your facility or is sent for repair, maintenance, trade-in, disposal, or termination of a loan. Request decontamination forms from customer service.
- Before using any cleaning or decontamination methods (except methods that are recommended by the manufacturer), confirm with the manufacturer that the proposed method will not damage the equipment.

MISE EN GARDE ! Nettoyage et décontamination. Utiliser uniquement les méthodes de nettoyage et de décontamination indiquées dans la documentation du fabricant destinée aux utilisateurs. L'opérateur (ou toute autre personne responsable) est tenu d'assurer le respect des exigences suivantes:

- Ne pas utiliser d'agents de nettoyage ou de décontamination susceptibles de réagir avec certaines parties de l'appareil ou avec les matières qu'il contient et de constituer, de ce fait, un DANGER.
- L'instrument doit être correctement décontaminé a) si des substances dangereuses sont renversées sur ou à l'intérieur de l'équipement, et/ou b) avant de le faire réviser sur site ou de l'envoyer à des fins de réparation, de maintenance, de revente, d'élimination ou à l'expiration d'une période de prêt (des informations sur les formes de décontamination peuvent être demandées auprès du Service clientèle).
- Avant d'utiliser une méthode de nettoyage ou de décontamination (autre que celles recommandées par le fabricant), les utilisateurs doivent vérifier auprès de celui-ci qu'elle ne risque pas d'endommager l'appareil.

Instrument component and accessory disposal

To minimize negative environmental impact from disposal of electronic waste, do not dispose of electronic waste in unsorted municipal waste. Follow local municipal waste ordinances for proper disposal provision and contact customer service for information about responsible disposal options.

Laser safety



WARNING! LASER HAZARD. Under normal operating conditions, the RapidHIT™ ID Instrument is categorized as a Class 1 laser product. However, removing the protective covers and (when applicable) defeating the interlocks can result in exposure to the internal Class 3Bv laser. Lasers can burn the retina, causing permanent blind spots. To ensure safe laser operation:

- Never look directly into the laser beam.
- Do not remove safety labels, instrument protective panels, or defeat safety interlocks.
- The system must be installed and maintained by a Thermo Fisher Scientific Technical Representative.
- Remove jewelry and other items that can reflect a laser beam into your eyes or the eyes of other people.
- Wear proper eye protection and post a laser warning sign at the entrance to the laboratory if the laser protection is defeated for servicing.
- DO NOT operate the laser when the laser cooling fan is off. When the laser is overheated, it can cause severe burns on contact.

The following table lists laser safety symbols and alerts that may be present on the instrument.

Alert
 **DANGER!** Class 3b (III) visible and/or invisible laser radiation present when open and interlocks defeated. Avoid exposure to beam.

Alerte
 **DANGER !** Rayonnement laser visible ou invisible de classe 3b (III) présent en position ouverte et avec les dispositifs de sécurité non enclenchés. Éviter toute exposition au faisceau.

Safety and electromagnetic compatibility (EMC) standards

The instrument design and manufacture complies with the following standards and requirements for safety and electromagnetic compatibility.

Safety standards

Reference	Description
EU Directive 2014/35/EU	European Union “Low Voltage Directive”
IEC 61010-1 EN 61010-1 UL 61010-1 CAN/CSA C22.2 No. 61010-1	*Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements*
IEC 61010-2-010 EN 61010-2-010	*Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of materials*
IEC 61010-2-081 EN 61010-2-081	*Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes*

EMC standards

Reference	Description
EU Directive 2014/30/EU	European Union "EMC Directive"
EN 61326-1 IEC 61326-1	*Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements – Part 1: General Requirements*
FCC Part 15.225 (47 CFR)	*Operation within the band 13.110-14.010 MHz.*
AS/NZS CISPR 11	*Limits and Methods of Measurement of Electromagnetic Disturbance Characteristics of Industrial, Scientific, and Medical (ISM) Radiofrequency Equipment*
ICES-001, Issue 4	*Industrial, Scientific and Medical (ISM) Radio Frequency Generators*
FCC Part 15 Subpart B (47 CFR)	*U.S. Standard Radio Frequency Devices* This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Environmental design standards

Reference	Description
Directive 2012/19/EU	European Union "WEEE Directive"—Waste electrical and electronic equipment
Directive 2011/65/EU & Commission Delegated Directive (EU) 2015/863	European Union "RoHS Directive"—Restriction of hazardous substances in electrical and electronic equipment

Radio compliance standards

Reference	Description
Directive 2014/53/EU	European Union "RE Directive"—Radio equipment
RFID	FCC Notice (for U.S. Customers): This device complies with Part 15 of the FCC Rules: Operation is subject to the following conditions: 1. This device may not cause harmful interference, and 2. This device must accept any interference received, including interference that may cause undesired operation. Changes and modifications not expressly approved by Thermo Fisher Scientific can void your authority to operate this equipment under Federal Communications Commissions rules.
RFID	Canada (English) CAN ICES-3(A) / NMB-3(A): This device complies with Industry Canada license-exempt RSS standards. Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.
RFID	Canada (Français) CAN ICES-3(A) / NMB-3(A): Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage adioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.
Radio regulatory approval information	Singapore—Complies with IMDA Standards DA105282

(continued)

Reference	Description
Radio regulatory approval information	Japan—Complies with MIC Radio Laws 本装置は、総務省指定第 AC-19117 号の型式指定を受けた誘導式読み書き通信設備を内蔵しています。 This instrument has a built-in the inductive read/write communication equipment specified by the Ministry of Internal Affairs and Communications designated number AC-19117. 

Chemical safety

WARNING! GENERAL CHEMICAL HANDLING. To minimize hazards, ensure laboratory personnel read and practice the general safety guidelines for chemical usage, storage, and waste provided below. Consult the relevant SDS for specific precautions and instructions:

- Read and understand the Safety Data Sheets (SDSs) provided by the chemical manufacturer before you store, handle, or work with any chemicals or hazardous materials. To obtain SDSs, see the "Documentation and Support" section in this document.
- Minimize contact with chemicals. Wear appropriate personal protective equipment when handling chemicals (for example, safety glasses, gloves, or protective clothing).
- Minimize the inhalation of chemicals. Do not leave chemical containers open. Use only with sufficient ventilation (for example, fume hood).
- Check regularly for chemical leaks or spills. If a leak or spill occurs, follow the manufacturer cleanup procedures as recommended in the SDS.
- Handle chemical wastes in a fume hood.
- Ensure use of primary and secondary waste containers. (A primary waste container holds the immediate waste. A secondary container contains spills or leaks from the primary container. Both containers must be compatible with the waste material and meet federal, state, and local requirements for container storage.)
- After emptying a waste container, seal it with the cap provided.
- Characterize (by analysis if needed) the waste generated by the particular applications, reagents, and substrates used in your laboratory.
- Ensure that the waste is stored, transferred, transported, and disposed of according to all local, state/provincial, and/or national regulations.
- **IMPORTANT!** Radioactive or biohazardous materials may require special handling, and disposal limitations may apply.

AVERTISSEMENT ! PRÉCAUTIONS GÉNÉRALES EN CAS DE MANIPULATION DE PRODUITS CHIMIQUES. Pour minimiser les risques, veiller à ce que le personnel du laboratoire lise attentivement et mette en œuvre les consignes de sécurité générales relatives à l'utilisation et au stockage des produits chimiques et à la gestion des déchets qui en découlent, décrites ci-dessous. Consulter également la FDS appropriée pour connaître les précautions et instructions particulières à respecter :

- Lire et comprendre les fiches de données de sécurité (FDS) fournies par le fabricant avant de stocker, de manipuler ou d'utiliser les matériaux dangereux ou les produits chimiques. Pour obtenir les FDS, se reporter à la section « Documentation et support » du présent document.
- Limiter les contacts avec les produits chimiques. Porter des équipements de protection appropriés lors de la manipulation des produits chimiques (par exemple : lunettes de sûreté, gants ou vêtements de protection).
- Limiter l'inhalation des produits chimiques. Ne pas laisser les récipients de produits chimiques ouverts. Ils ne doivent être utilisés qu'avec une ventilation adéquate (par exemple, sorbonne).
- Vérifier régulièrement l'absence de fuite ou d'écoulement des produits chimiques. En cas de fuite ou d'écoulement d'un produit, respecter les directives de nettoyage du fabricant recommandées dans la FDS.
- Manipuler les déchets chimiques dans une sorbonne.

- Veiller à utiliser des récipients à déchets primaire et secondaire. (Le récipient primaire contient les déchets immédiats, le récipient secondaire contient les fuites et les écoulements du récipient primaire. Les deux récipients doivent être compatibles avec les matériaux mis au rebut et conformes aux exigences locales, nationales et communautaires en matière de confinement des récipients.)
- Une fois le récipient à déchets vidé, il doit être refermé hermétiquement avec le couvercle fourni.
- Caractériser (par une analyse si nécessaire) les déchets générés par les applications, les réactifs et les substrats particuliers utilisés dans le laboratoire.
- Vérifier que les déchets sont convenablement stockés, transférés, transportés et éliminés en respectant toutes les réglementations locales, nationales et/ou communautaires en vigueur.
- **IMPORTANT !** Les matériaux représentant un danger biologique ou radioactif exigent parfois une manipulation spéciale, et des limitations peuvent s'appliquer à leur élimination.

Biological hazard safety



WARNING! BIOHAZARD. Biological samples such as tissues, body fluids, infectious agents, and blood of humans and other animals have the potential to transmit infectious diseases. Conduct all work in properly equipped facilities with the appropriate safety equipment (for example, physical containment devices). Safety equipment can also include items for personal protection, such as gloves, coats, gowns, shoe covers, boots, respirators, face shields, safety glasses, or goggles. Individuals should be trained according to applicable regulatory and company/ institution requirements before working with potentially biohazardous materials. Follow all applicable local, state/provincial, and/or national regulations. The following references provide general guidelines when handling biological samples in laboratory environment.

- U.S. Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, 6th Edition, HHS Publication No. (CDC) 300859, Revised June 2020
  cdc.gov/labs/bmbl
- Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs)
  who.int/publications/i/item/9789240011311

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Related documentation

Document	Publication number
RapidHIT™ ID System v2.0 User Guide	MAN0026593
RapidINTEL™ Plus Sample Cartridge User Bulletin	MAN0026595
RapidLINK™ Matching Suite Software v1.0 User Guide	MAN0030052
RapidLINK™ Software v2.0 User Guide	MAN0030010
SmallPond™ DNA Matching System Installation and Setup Guide	MAN0025091
Technical Note: Artifacts Identified Post-Developmental Validation: RapidHIT™ ID ACE GlobalFiler™ Express and RapidINTEL™ Sample Cartridges	Go to **thermofisher.com**, then search for the technical note by title, or contact your local Human Identification representative.

Customer and technical support

For support, use one of the contact methods listed below, depending on your location.

Location	Contact method
In North America	Send an email to: **HIDTechSupport@thermofisher.com**
	Call **888-821-4443**; select option **2**, then say "HID" or "Human Identification".
Outside North America	Contact your local support office.

For the latest services and support information for all locations, go to **thermofisher.com/support** to obtain the following information.

- Worldwide contact telephone numbers
- Product support
- Order and web support
- Safety Data Sheets (SDSs; also known as MSDSs)

Additional product documentation, including user guides and Certificates of Analysis, are available by contacting Customer Support.

Limited product warranty

Life Technologies Corporation and its affiliates warrant their products as set forth in the Life Technologies' General Terms and Conditions of Sale at **www.thermofisher.com/us/en/home/global/terms-and-conditions.html**. If you have questions, contact Life Technologies at **www.thermofisher.com/support**.