appliedbiosystems

RapidHIT™ ID System v1.3.1

USER GUIDE

for use with:

RapidLINK™ Software v1.1.5

Publication Number MAN0018938

Revision A.0

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

ThermoFisher SCIENTIFIC

Life Technologies Corporation | 6055 Sunol Blvd | Pleasanton, CA 94566 USA
For descriptions of symbols on product labels or product documents, go to thermofisher.com/symbols-definition.

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

Revision history: Pub. No. MAN0018938

Revision	Date	Description
A.0	05 January 2021	New document for RapidHIT™ ID System v1.3.1.

Contents

1 Product information

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

Product description

The Applied Biosystems™ RapidHIT™ ID System v1.3.1 system uses the following components.

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

  You add a sample to the cartridge, then insert the sample cartridge into the instrument.

- **RapidHIT™ ID System v1.3.1**—The instrument provides an intuitive user interface that guides you through routine use.

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

- **RapidLINK™ Software v1.1.5**—When an instrument run is complete, the DNA profile is sent to the RapidLINK™ Software. You can review DNA profiles, view electropherograms, and update DNA profiles. With the activation of RapidLINK™ applications (apps), you can perform sample matching, kinship analysis, and familial searching. You can also compare profiles that are generated to the optional Staff Elimination Database.

  Additionally, you can monitor all instruments that contribute DNA profiles to the RapidLINK™ Software.

  For information on the RapidLINK™ Software v1.1.5, see the *RapidLINK™ Software v1.1.5 User Guide* (Pub. No. MAN0018939).

Sample cartridge types

Abbreviation on labels / in software	Sample type	STR chemistry	Features	For more information see
RapidHIT™ ID ACE GlobalFiler™ Express Sample Cartridge				
ACE GFE / GFE	Single-source, buccal swab	GlobalFiler™ Express	Optimized data analysis thresholds (based on v 1.3)	Appendix E, "Software verification RapidHIT™ ID System v1.3.1"
RapidINTEL™ Sample Cartridge				
AB RI	Casework, single-source, blood and saliva samples	GlobalFiler™ Express	Increased sensitivity for investigative leads samples	*RapidINTEL™ Sample Cartridge for Blood and Saliva Samples Validation User Bulletin* (Pub. No. MAN0018979)
RapidHIT™ ID ACE NGM SElect™ *Express* Sample Cartridge				
ACE NGM / NGM	Single-source, buccal swab	NGM SElect™ Express	Systematic allelic ladder library	• Appendix D, "Validation of the Systematic Allelic Ladder Library (ACE NGM sample cartridges only)" • *RapidHIT™ ID ACE NGM SElect™ Express Sample Cartridge for RapidHIT™ ID System v1.2 Validation User Bulletin* (Pub. No. MAN0018973)

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.

Table 1 RapidHIT™ ID Primary Cartridge GlobalFiler™ Express 100 Kit (Cat. No. A41841)[1]

Contents	Amount	Storage
Box 1		
Primary cartridge—GlobalFiler™ Express 100	1 primary cartridge for 100 runs[2]	Room temperature (15–30°C)
Utility cartridge (for primary cartridge replacement)	2 utility cartridges	
Box 2		
Gel cartridge (for primary cartridge replacement)	1 gel cartridge	4–10°C
ACE GlobalFiler™ Express control cartridge (allelic ladder, for installation)	1 control cartridge	
RapidHIT™ ID ACE GlobalFiler™ Express positive control cartridge (for installation)	1 positive control cartridge	

[1] The primary, utility, gel, and allelic ladder cartridges are also used for the RapidINTEL™ Sample Cartridge Kit (Cat. No. A43942).
[2] Primary cartridges can be ordered separately (Cat. No. A41841, includes gel, utility, and ACE GFE Control Cartridge [allelic ladder] cartridges).

Table 2 RapidHIT™ ID Primary Cartridge NGM SElect™ 100 Kit (Cat. No. A41847)

Contents	Amount	Storage
Box 1		
Primary cartridge—NGM SElect™ Express 100	1 primary cartridge for 100 runs[1]	Room temperature (15–30°C)
Utility cartridge (for primary cartridge replacement)	2 utility cartridges	
Box 2		
Gel cartridge (for primary cartridge replacement)	1 gel cartridge	4–10°C
NGM control cartridge (allelic ladder, for installation)	1 control cartridge	
NGM positive control cartridge (for installation)	1 positive control cartridge	

[1] Primary cartridges can be ordered separately (Cat. No. A43409, includes gel, utility, and ACE NGM Control Cartridge [allelic ladder] cartridges).

Table 3 Sample cartridges

Component	Cat. No.
RapidHIT™ ID ACE GlobalFiler™ Express 50 Sample Kit 50 sample cartridges, 2 positive control cartridges, 2 negative control cartridges	A41831
RapidHIT™ ID ACE NGM SElect™ Express 50 Sample Kit 50 sample cartridges, 2 positive control cartridges, 2 negative control cartridges	A41838
RapidINTEL™ Sample Cartridge Kit 50 sample cartridges, 2 positive control cartridges, 2 negative control cartridges	A43942

Table 4 Accessories

Component	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 to request an update to your configuration.	MLS
Whatman™ OmniSwab	09-923-376 (WB100035)
Puritan 3" Sterile Standard Cotton Swab w/Semi-Flexible Polystyrene Handle	25-8032 PC

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

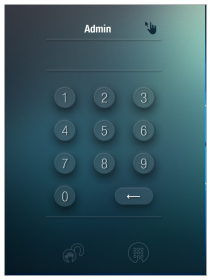
Thermo Fisher Scientific strongly recommends that you maintain unique passwords for all accounts in use on this product. All passwords should be reset upon first sign in to the product. Change passwords according to your organization's password policy.

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

Workflow

Obtain swab or substrate samples according to your standard operating procedure.

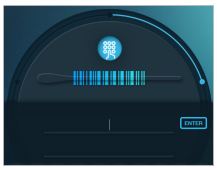
▼



Sign in.

▼

Scan the sample cartridge barcode or enter the sample identification number.

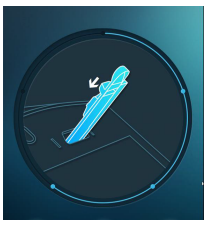


IMPORTANT! Do not include the following in sample IDs: "ladder", "posctrl", or "negctrl" (case does not matter). The software processes any sample IDs that contain these names as allelic ladders or controls.

▼

Insert the swab or substrate sample into a sample cartridge.

▼



Insert the sample cartridge into the instrument.

The run starts automatically.

▼

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

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 22.

▼

Remove the sample cartridge from the instrument, then view the result.

▼

RapidLINK™

Review results and run applications in the RapidLINK™ Software.

2 Collect and prepare the sample

Sample collection: GlobalFiler™ Express and NGM SElect™ Express sample cartridges

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 w/Semi-Flexible Polystyrene Handle (Puritan Cat. No. 25-8032 PC)
- **NGM SElect™ Express**—Whatman™ OmniSwab, (Fisher Scientific™ Cat. No. 09-923-376 [WB100035])

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).

Sample collection: RapidINTEL™ sample cartridges

Blood and saliva samples have been validated for use with RapidINTEL™ sample cartridges. Samples were processed for validation as described in *RapidINTEL™ Sample Cartridge for Blood and Saliva Samples Validation User Bulletin* (Pub. No. MAN0018979).

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

3 Run the instrument to generate a DNA profile

Power on the internal computer

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.

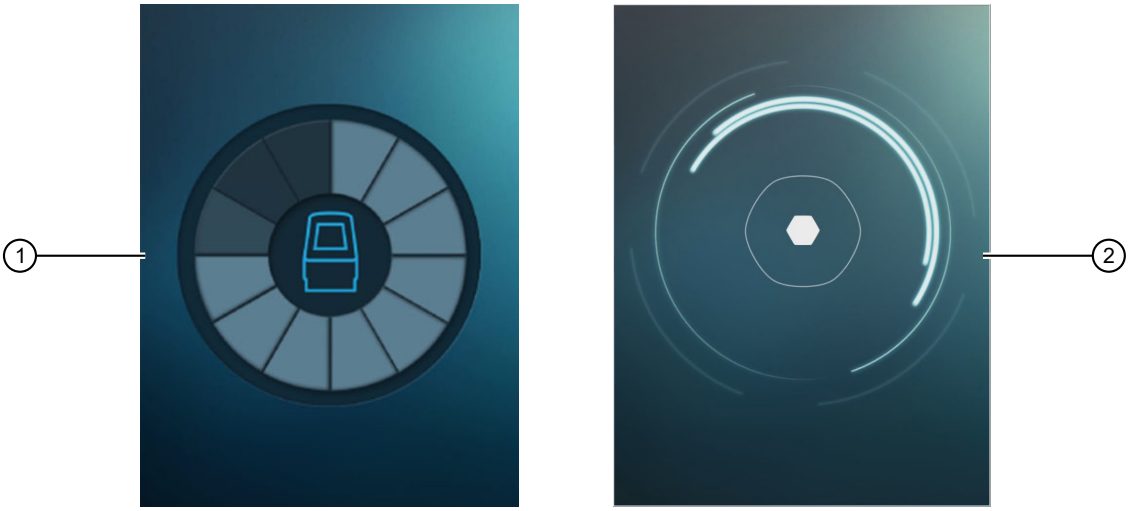


Figure 1 Startup and lock screens

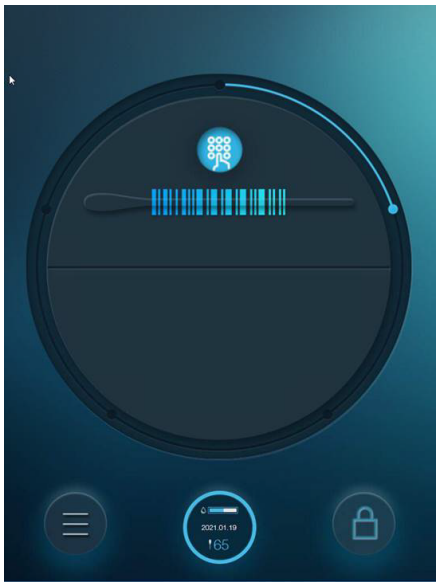
① Startup screen
② Lock screen

Sign in to the instrument

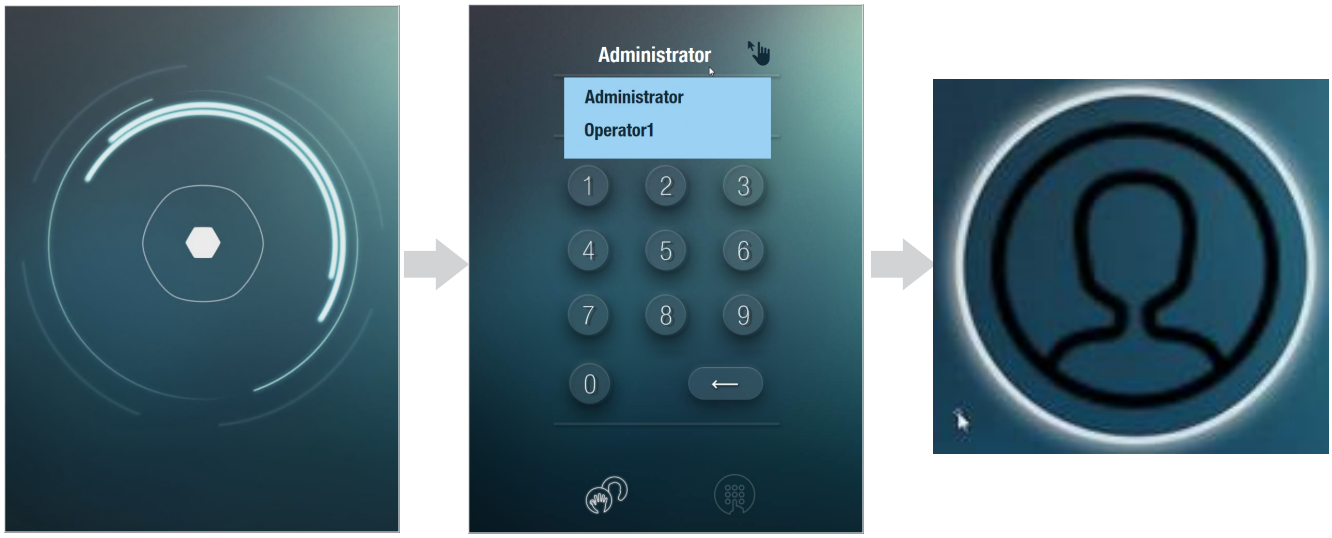
You can sign in using any of the authentication methods that are configured for your profile.

- To use facial recognition or fingerprint methods, position your face in front of the camera or touch the fingerprint reader.

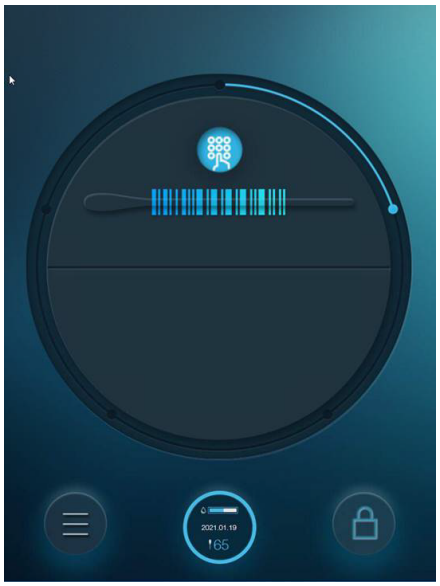
The sample identification screen is displayed.



- To use a PIN, perform the following steps.
  a. Touch the lock screen.
  b. Touch .
  c. Touch , then select your user name.

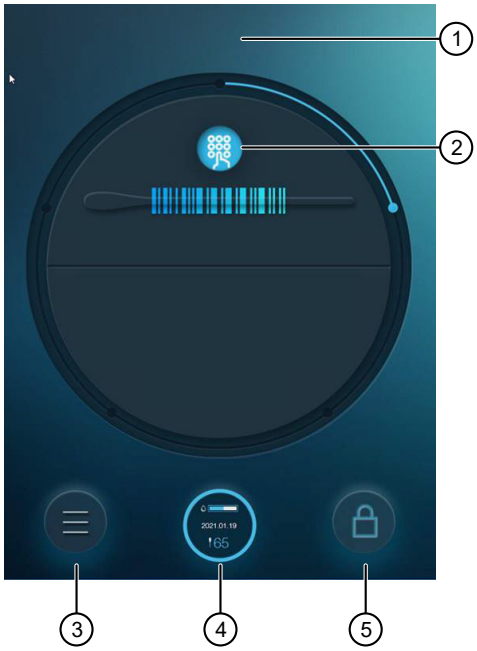


  d. Enter your PIN with the keypad.
  The sample identification screen is displayed.



If an error code is displayed when you sign in, see “An error code is displayed when you sign in” on page 47.

Parts of the sample identification screen



1. No icon is displayed if the instrument is connected to the RapidLINK™ Software.
   Indicates that the instrument is not connected to the RapidLINK™ Software
   See “Check the RapidLINK™ Software connection” on page 46.
2. Touch to display the keyboard to enter a sample identification number.
3. Touch to display the menu screen.
4. Displays the 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 36.
5. Touch to sign out and lock the touchscreen (displays the lock screen).

Enter the sample identification number

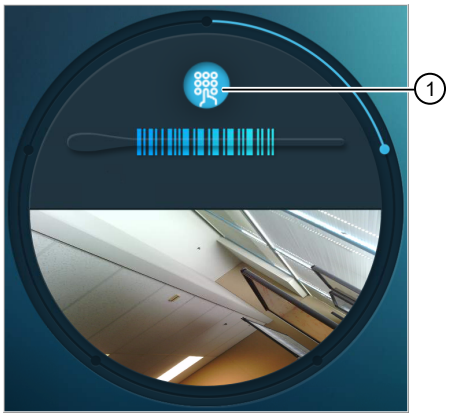
Scan a barcode with the camera

Note: You can also use a compatible handheld barcode scanner. For information on the compatible scanner, see “Required materials not supplied” on page 10.

1. If the sample identification screen is not displayed, touch until it is displayed.
2. Hold the barcode in front of the camera at the top left of the instrument.
   When the camera reads the barcode, the sample identification number is displayed.

Enter a sample ID or barcode

1. If the sample identification screen is not displayed, touch ← until it is displayed.
2. Touch the sample identification screen.
3. Touch ⁞⁞⁞ to display the keypad.



① Keypad

Note: The software allows you to enter the following characters for sample ID: /\?%*:|'.<> space. However, it changes these characters to underscore(_) when it creates the data file for the sample. The sample ID with underscores is displayed in the RapidLINK™ Software.

4. Enter the sample ID or barcode, then touch **Enter**.

IMPORTANT! Do not include the following in sample IDs: "ladder", "posctrl", or "negctrl" (case does not matter). The software processes any sample IDs that contain these names as allelic ladders or controls.

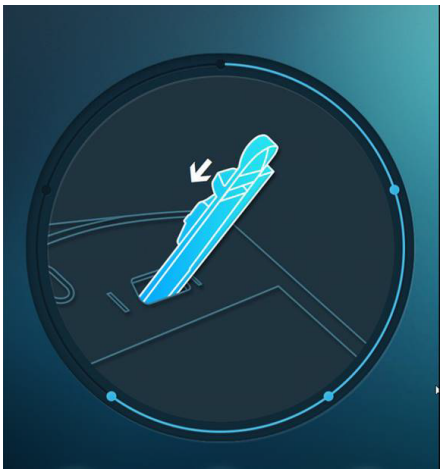
The sample identification number is displayed.

Insert the sample cartridge into the instrument (automatically starts the run)

A sample cartridge run takes ~90–110 minutes to complete.

1. Insert the sample swab into the sample cartridge.

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



The run starts automatically after you insert the sample cartridge. For more information, see “Run times for different sample cartridges” on page 22.

IMPORTANT! Do not remove the sample cartridge until you are prompted to do so (see “Remove the sample cartridge from the instrument” on page 23).

When the run is complete, the remove sample cartridge screen is displayed for ~30 seconds, then the currently signed-in user is automatically signed out.

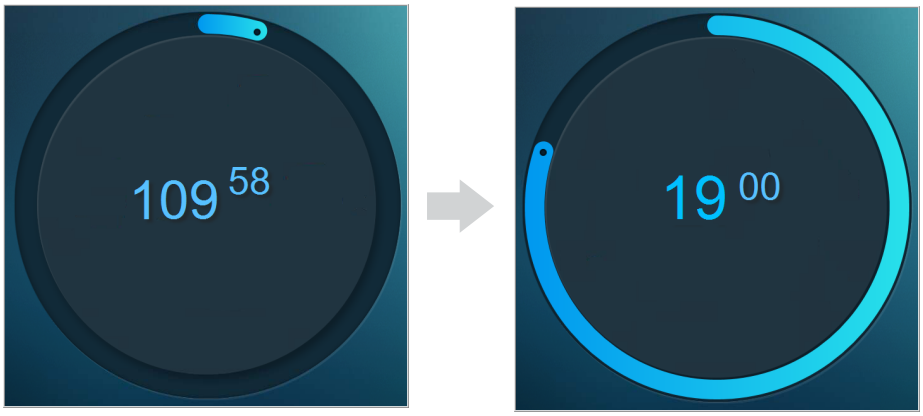
Run times for different sample cartridges

- 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
RapidHIT™ ID ACE NGM SElect™ *Express* Sample Cartridge	~19 minutes
RapidINTEL™ Sample Cartridge	~14 minutes

- If the instrument requires priming, the run time can extend up to 110 minutes.

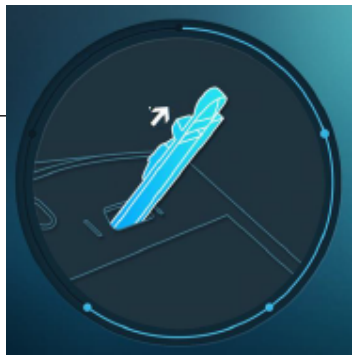
The figure below shows a countdown timer example for an NGM SElect™ Express sample cartridge.



Remove the sample cartridge from the instrument

1. If the lock screen is displayed, touch the lock screen, then sign in.

2. When the remove sample cartridge screen is displayed, remove the sample cartridge from the instrument.



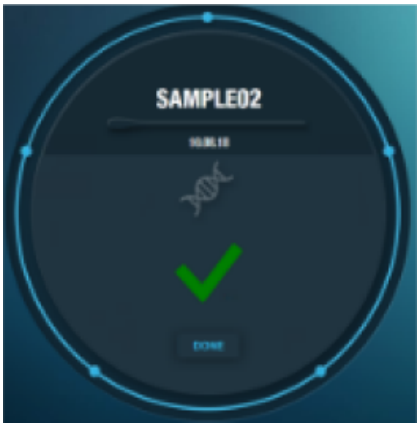
IMPORTANT! Do not remove the cartridge until you are prompted to do so.

If you remove the cartridge before you are prompted to do so, the results screen is not displayed. To display the results screen, insert the cartridge again, wait until you are prompted to remove the cartridge, then remove the cartridge again.

If you cannot easily remove the sample cartridge, see “You cannot easily remove the sample cartridge from the instrument” on page 47.

The result is displayed.

3. Tap **Done** to dismiss the result screen.

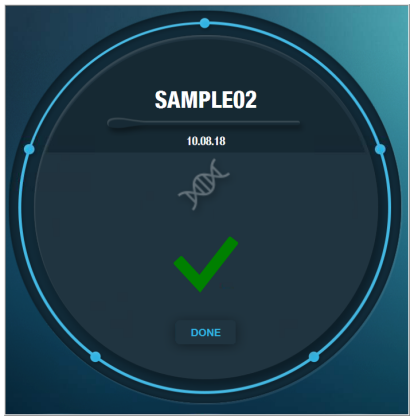


4. Discard the sample cartridge.

   Use proper precautions for disposal. Follow local, state, provincial and federal regulations for disposal.

Proceed immediately to “Check the run result” on page 24.

Check the run result



1. Review the status.

Status	DNA profile is generated	Meaning	Action
Green 	Yes	The DNA profile does not contain quality score flags.	The DNA profile is ready for analysis by the RapidLINK™ Software. No further action is needed on the instrument.
Yellow 	Yes	• The DNA profile contains quality score flags, or • The run result contains only size standard peaks. It does not contain sample peaks.	The DNA profile is available for review in the RapidLINK™ Software. Proceed according to your standard operating protocol.
Red 	No	The DNA profile was not generated.	A DNA profile is *not* available for review in the RapidLINK™ Software. Proceed according to your standard operating protocol.

2. Click **Done** to dismiss the status.
   The instrument automatically signs out the user and displays the lock screen.

View and export the run results

This function lists the results for the runs performed by the signed-in user.

1. Touch **(Menu)**.
2. Touch **(Run Data)**.
   The screen displays the status from the results screen: Green, Yellow, Red.
   The following figure is an example of the run log for one user that shows each status.

3. *(Optional)* To export, insert a USB device into the front USB port on the instrument. Touch **Export**.

Note: The **Export** button is not displayed if:

- The RapidHIT™ ID Instrument is configured to delete the run data after it is transferred to the RapidLINK™ Software.
- There is no USB device inserted into a USB port.

The run data is copied to the USB device and is also retained on the instrument.

Sign out

IMPORTANT! Leave the main power switch (on the back panel) set to On at all times.

Power is necessary to maintain the gel temperature.

The signed-in user is automatically signed out when a run is complete.

You can also sign out manually.

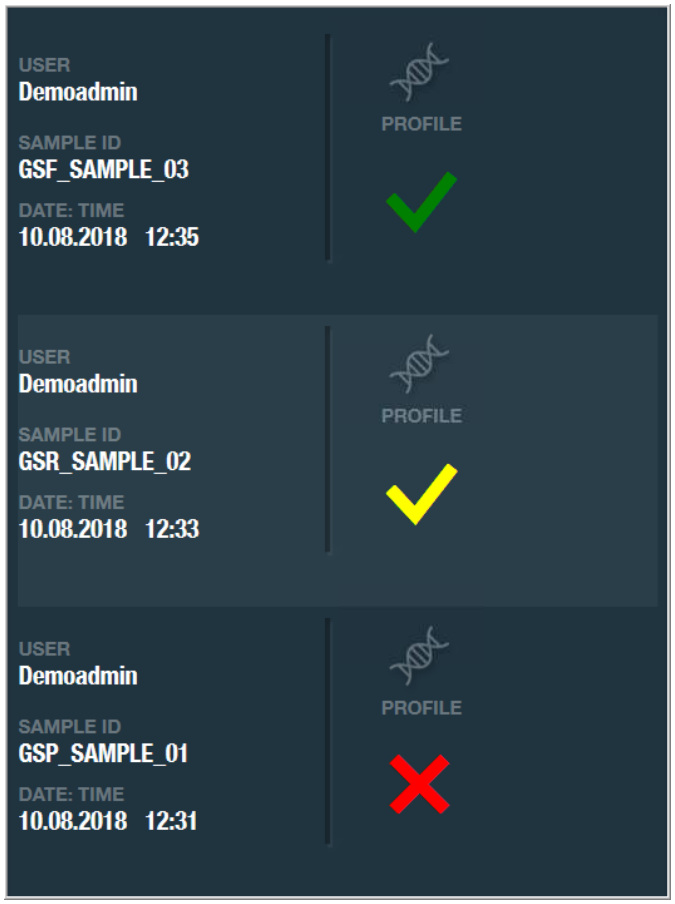
1. If the sample identification screen is not displayed, touch ← until it is displayed.
2. Touch 🔒.

The lock screen is displayed.

4 Manage the instrument and software

View and export the run results for all runs (administrator or supervisor only)

1. Sign in as an administrator or a supervisor.
2. Touch **(Menu)**.
3. Touch **(Run Data)**.
   The screen displays the status from the results screen: Green, Yellow, Red.
   The following figure is an example of the run log for one user that shows each status.



4. *(Optional)* To export, insert a USB device into the front USB port on the instrument. Touch **Export**.

Note: The **Export** button is not displayed if:

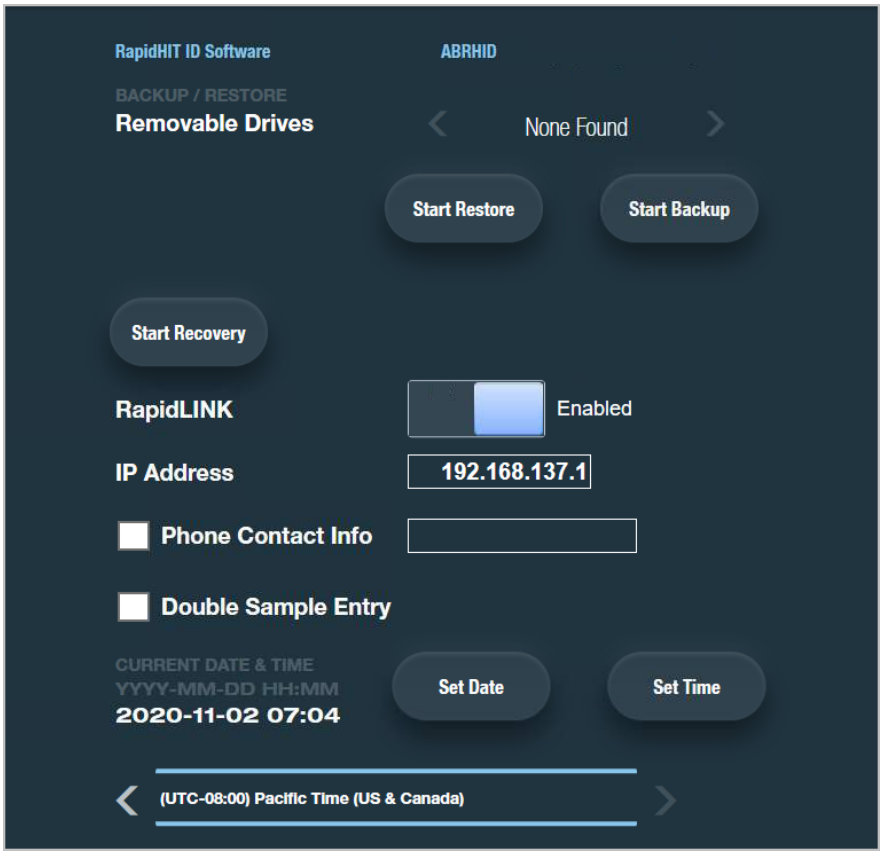
- The RapidHIT™ ID Instrument is configured to delete the run data after it is transferred to the RapidLINK™ Software.
- There is no USB device inserted into a USB port.

The run data is copied to the USB device and is also retained on the instrument.

Configure instrument settings (administrator or supervisor only)

1. Sign in as an administrator or a supervisor.
2. Touch **(Menu)**.
3. Touch **(Settings)**.

4. In the settings screen, configure the instrument settings as needed.



Setting	Description	User access
Start Backup and **Start Restore**	See "Back up and restore data (administrator only)" on page 45.	Administrator
Start Recovery	Reset the instrument hardware. See "Recover the instrument (administrator or supervisor only)" on page 45.	Administrator or supervisor
RapidLINK	Make the instrument available for selection in the RapidLINK™ Software.	Administrator
IP Address	The IP address of the RapidLINK™ Software. The address is displayed after the RapidLINK™ Software connects to the instrument.	Read-only, can be seen by anyone
Phone Contact Info	The phone number of the primary contact for the instrument. This number is displayed in diagnostic code screens.	Administrator
Double Sample Entry	This function cannot be disabled in this version of the software.	Administrator or supervisor
Set Date and **Set Time**	Sets the instrument date and time.	Administrator

Manage users (administrator only)

User roles and permissions

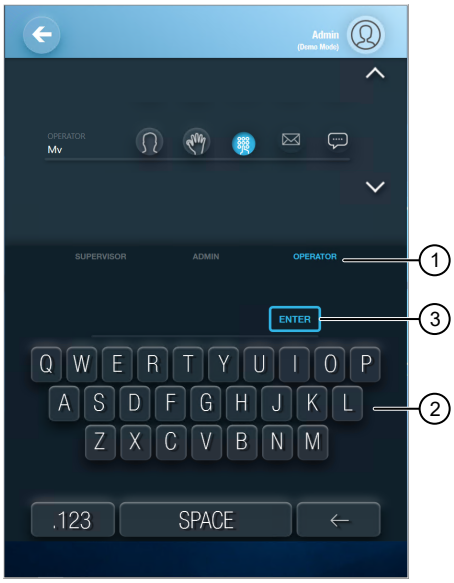
User role	Permission to perform the following tasks
Operator	• Perform a run • View the run log for the signed-in user
Supervisor	Operator tasks, plus: • Replace a primary cartridge • View the run log for all users • Recover (reset) the instrument • Export run data to a USB device
Admin (administrator)	Operator and supervisor tasks, plus: • Create a user • Back up and restore • Enable/disable RapidLINK™ connection • Change the date, time, and time zone

Add a user

Note: By default, when a user account is created on one RapidHIT™ ID Instrument, that same user account is authorized for all instruments on the same network. If needed, an administrator can remove the authorization for individual instruments (see “Remove authorization for an instrument” on page 34).

1. Sign in as an administrator.
2. Touch **(Menu)**.
3. Touch **(Manage users)**.

4. Touch **(Add user)**.

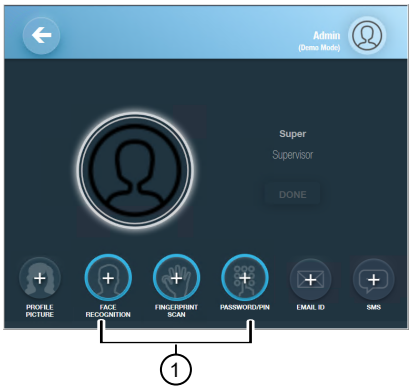


① Select a user role
② Enter a user name
③ Touch **Enter**

5. To assign a role to the user, touch **Supervisor**, **Admin**, or **Operator**.
   For a description of user roles, see “User roles and permissions” on page 31.

6. Enter a user name, then touch **Enter**.

7. Touch a user authentication method.



① User authentication methods

Option	Procedure
Face Recognition 	1. Adjust the user position so that the face is centered in the live camera view. 2. Touch **Start Face Scan**.
Fingerprint Scan 	1. Place any of the user's fingers on the fingerprint pad on the front of the instrument. 2. Remove and touch as instructed by the software. **Note:** The Fingerprint Scan function may be disabled for your laboratory.
Password/PIN 	Enter a **PIN** (6 characters) two times.

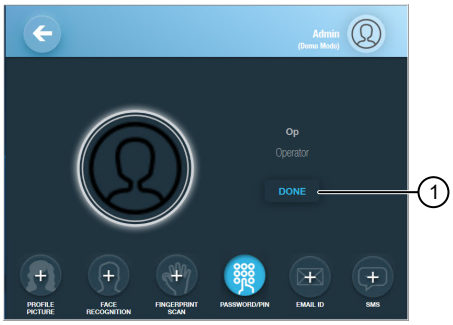
8. *(Optional)* Add an email address or SMS mobile phone number.

   Note: The profile picture function is not supported in this version of software.

9. Touch .

   A success message screen is displayed.

10. Touch the success message screen to close it, then touch **Done** to close the add user screen.



1 Touch **Done**

Remove authorization for an instrument

When you remove authorization, you prevent the user from signing in to an instrument.

In the RapidLINK™ Software, remove the instrument from the **Authorized Instruments** list for the user. For a detailed procedure, see the *RapidLINK™ Software v1.1.5 User Guide*.

Note: Removing authorization applies only to a single instrument. If you want to remove authorization for multiple instruments, repeat this procedure for each instrument.

Note: If an instrument is disconnected from the network during this process, the user authorization will not be removed for that instrument when the instrument is reconnected.

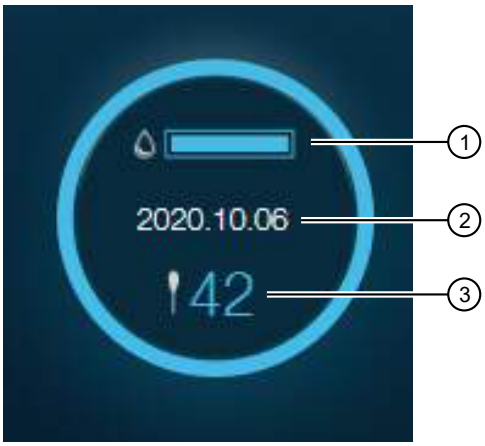
5 Maintain the instrument

Routine maintenance

Task	Frequency
Run a sample cartridge if the instrument is not in use daily	At minimum, once every 7 days
Clean the touchscreen. **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, touch ← until it is displayed. The screen displays the gel volume, expiration date, and number of runs performed for the primary cartridge.



① Gel volume—Indicates the amount of gel remaining in the primary cartridge. When the amount of gel remaining is 30–16%, the outer ring turns yellow. When the amount of gel remaining is ≤15%, the outer ring turns red. The primary cartridge, including gel, must be changed when the outer ring is red.

② 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. Buffer expiration is considered in the primary cartridge expiration date.

③ 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, "42" indicates that 42 runs have been performed).

Replace the primary cartridge (administrator or supervisor only)

This procedure requires ~2 hours to complete.

Note: For RapidINTEL™ Sample Cartridge applications, use a GFE primary cartridge.

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.

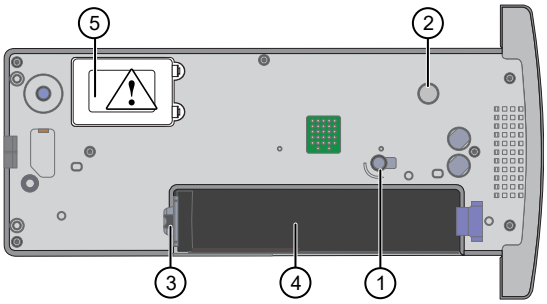


Figure 2 Parts of the primary cartridge before preparation

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.

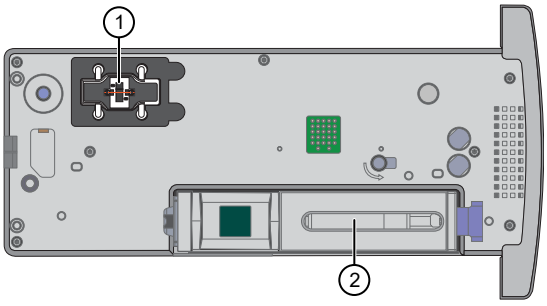


Figure 3 Primary cartridge after preparation

1. Capillary
2. Gel cartridge

Prepare a new primary cartridge

You need the following components for this procedure:

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

See Figure 2 on page 37 for the location of the parts of the primary cartridge.

1. Sign in as an administrator or a supervisor.
2. Touch **(Menu)**.
3. Touch **(Primary cartridge)**.

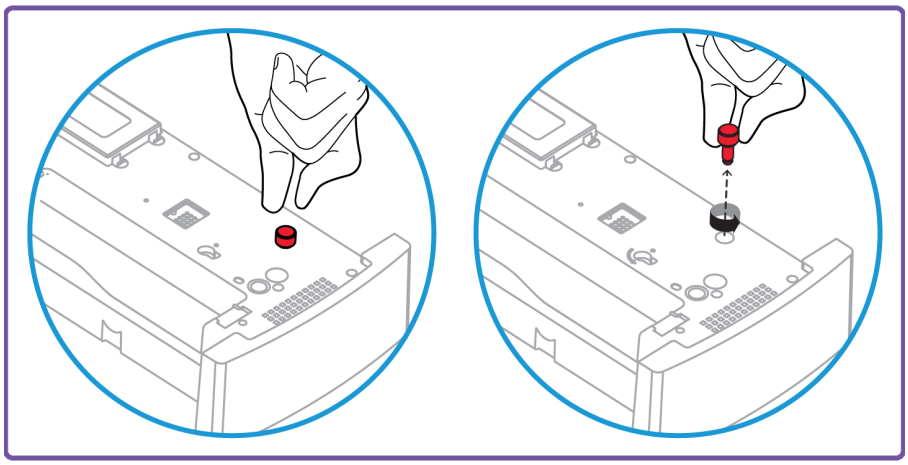
① Primary cartridge icon

4. Touch **Yes** to confirm that you want to remove the primary cartridge.

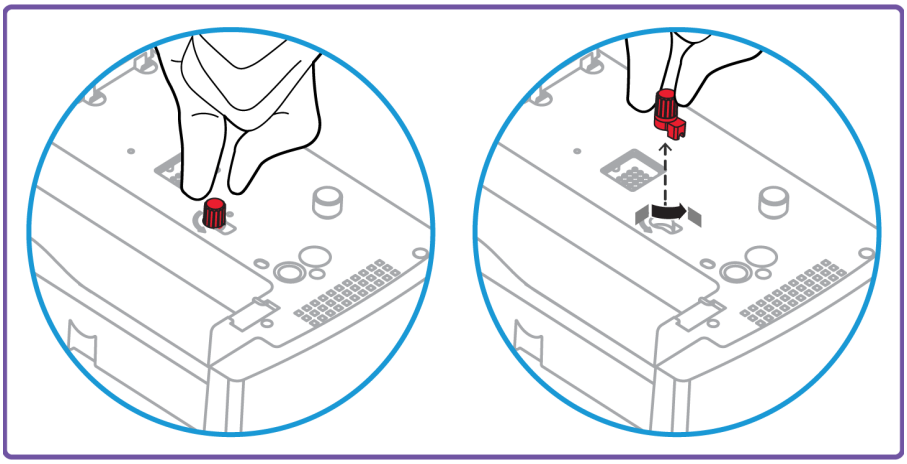
The first primary cartridge screen is displayed.

Note: You can touch the numbered buttons to display illustrations for the following steps.

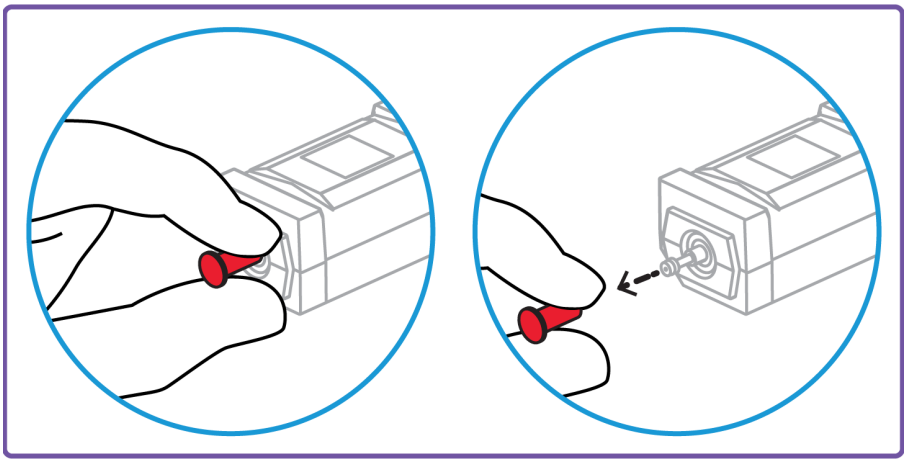
5. Unscrew the shipping plug in the cathode block.



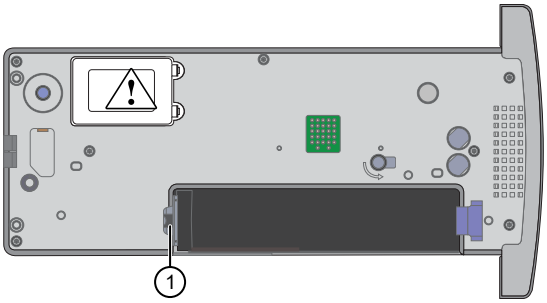
6. Turn the shipping plug in the check valve 90° counterclockwise, then remove it.



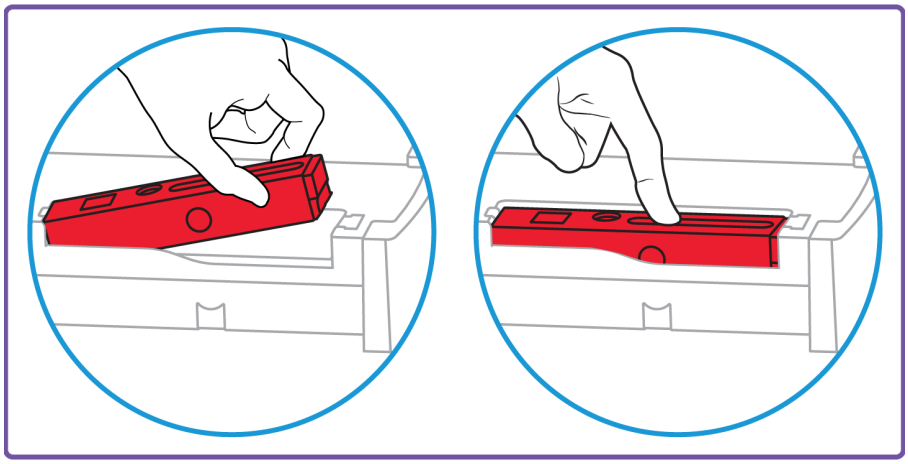
7. Gel cartridge: Remove the shipping plug from the gel cartridge inlet by pulling the plug straight out of the inlet. Do not twist the plug when removing.



8. Insert the gel cartridge into the primary cartridge with the tip of the gel cartridge facing the gel cartridge inlet and the square marker on the top.



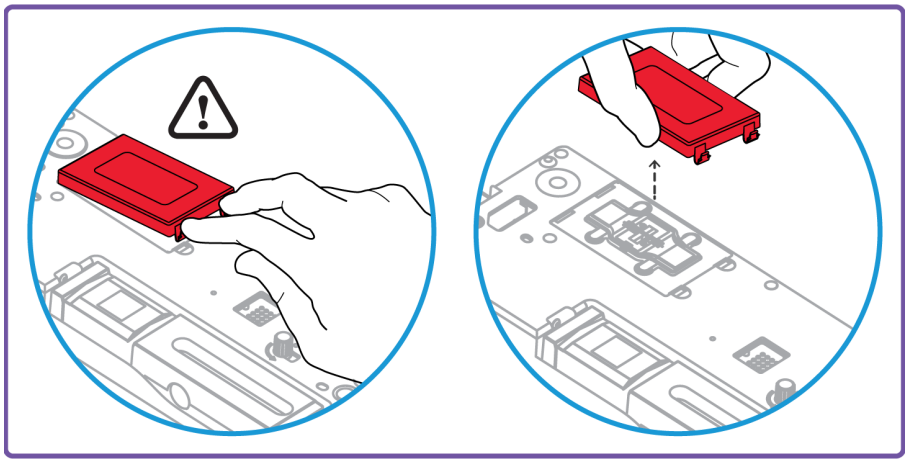
① Gel cartridge inlet



The gel cartridge clicks when it is fully inserted into the primary cartridge.

9. Remove the shipping cover from the capillary by pressing the brackets toward the cover, then swinging the cover up and away from the capillary.

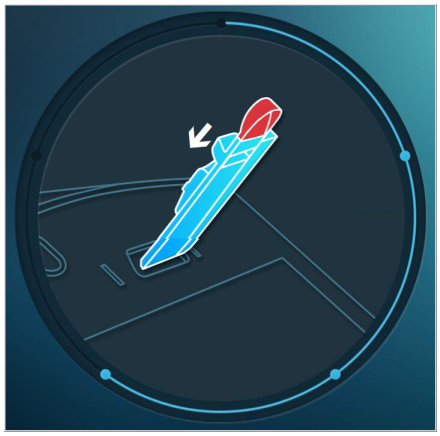
CAUTION! The capillary is fragile. Handle the primary cartridge with care after you remove the capillary cover.



10. Touch **Done** at the bottom of the primary cartridge screen.

11. 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 9 minutes while the instrument disengages the primary cartridge. After ~3 minutes, the remove primary cartridge screen is displayed (see step 1 on page 43.



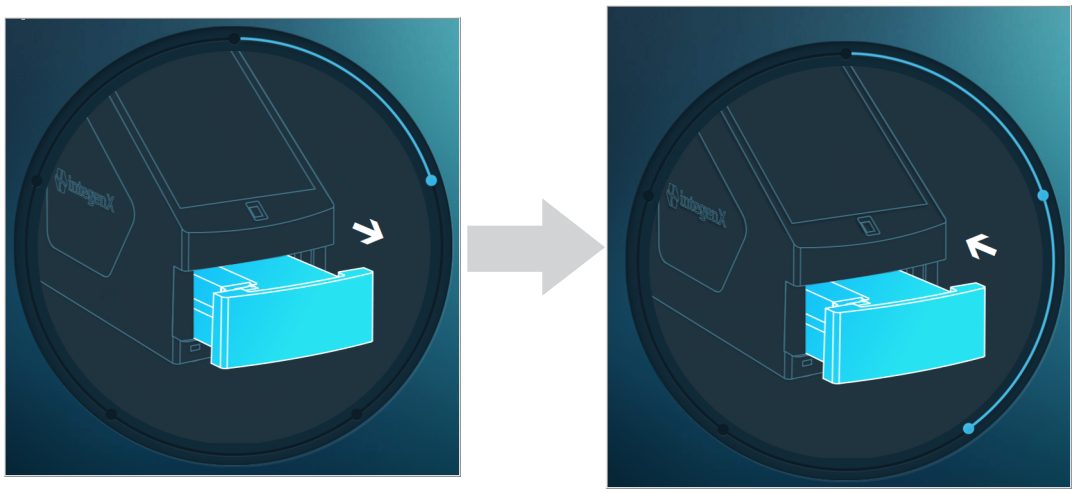
Insert the prepared primary cartridge (administrator or supervisor only)

You need the following components for this procedure:

- Prepared primary cartridge
- Allelic ladder cartridge that is provided with the new primary cartridge
- Positive and negative control cartridges that are provided with the new primary cartridge

Note: The software does not prompt you to run the control cartridges after you insert a new primary cartridge. Run the control cartridges according to your standard operating protocol.

1. When the remove primary cartridge screen is displayed (~3 minutes after you insert the utility cartridge in the instrument in step 11 in the previous procedure), pull the used primary cartridge out of the instrument.



2. When the insert primary cartridge screen is displayed, insert the new 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.

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

4. Run the allelic ladder cartridge: Insert and remove the allelic ladder cartridge when the associated screen is displayed.
   The software displays a Green ✓ for a ladder profile that contains the expected number of alleles and a Red ✗ for a ladder profile that does not contain the expected number of alleles. Follow your standard operating protocol for how to proceed.

5. Run the positive and/or negative control cartridge according to your standard operating procedure. See “Check the run result” on page 24.

Discard the used primary and allelic ladder cartridges.

Use proper precautions for disposal. Follow local, state, provincial and federal regulations for disposal.

Run a control cartridge

Note: For RapidINTEL™ Sample Cartridge applications, use a GFE control (allelic ladder) cartridge.

1. If the sample identification screen is not displayed, touch ← until it is displayed.
2. Insert the control cartridge in the instrument.

   The instrument reads the label on the cartridge and automatically assigns the sample identification as "POSCTRL", "NEGCTRL", or "LADDER".

   Note: If you enter names other than the names listed above, the names are overwritten in the RapidLINK™ Software with the names listed above.
3. When the run is complete, remove the cartridge from the instrument.
4. Review the status and take the appropriate action. See Table 5.
5. Touch **Done**. The instrument automatically signs out the user and displays the lock screen.

Table 5 Control cartridge results

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

Status	DNA profile was generated	Meaning	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.	No further action is needed on the instrument.
Red 	No	• The DNA profile was not generated, or 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.	Follow your standard operating protocol for how to proceed.

Back up and restore data (administrator only)

The backup function copies run data from the instrument to a USB device. It does not copy user profiles or instrument settings.

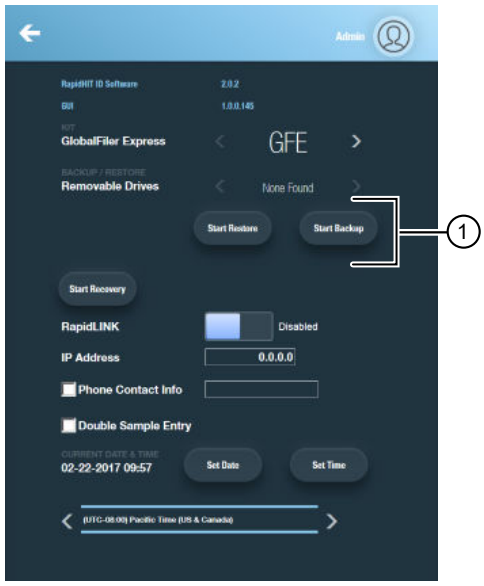
The restore function overwrites the run data on the instrument with the run data from the USB device.

1. Insert a USB device into the USB port on the front of the instrument.

   The **Removable Drives** field displays the name of the USB device.

2. In the settings screen, touch **Start Backup** or **Start Restore**.

   The **Start Backup** button or **Start Restore** buttons change to **Abort** and a progress bar is displayed. When the procedure is complete, a message is displayed.



① Backup and restore functions

Recover the instrument (administrator or supervisor only)

The recovery function resets the sample cartridge hardware in the instrument.

This function does not affect run data, user profiles, or settings.

1. In any screen, touch ☰.
2. In the settings screen, touch **Start Recovery**.
3. Follow the prompts that are displayed on the screen.

Prepare the instrument for shipping

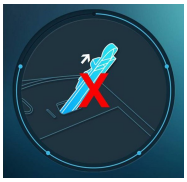
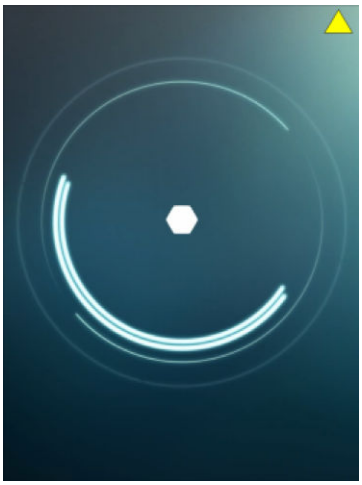
Contact Thermo Fisher Scientific Support for requirements.

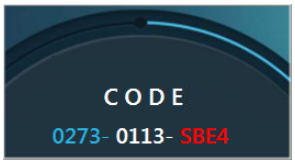
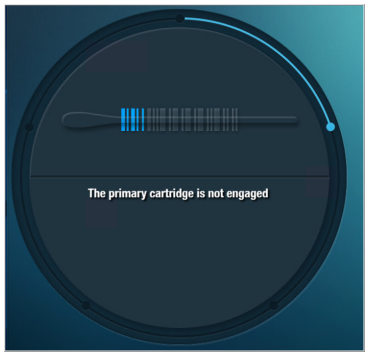
A Troubleshooting

Check the RapidLINK™ Software connection

1. In the sample identification screen, check the top of the screen.
   If is displayed, the instrument is not connected to the software.
2. Ensure that the **RapidLINK** setting is enabled. See “Configure instrument settings (administrator or supervisor only)” on page 29.

Troubleshooting: Symptoms, causes, and actions

Observation	Possible cause	Recommended action
Red X on cartridge screen 	Sample cartridge is expired.	Obtain a new swab and prepare a new cartridge.
	Sample cartridge is inserted improperly in instrument.	Remove the sample cartridge from the instrument and re-insert.
A yellow triangle is displayed on the lock screen 	An error code has been generated.	Touch the lock screen to obtain the error code. Contact Thermo Fisher Scientific Support.

Observation	Possible cause	Recommended action
An error code is displayed when you sign in 	There is a problem with the instrument.	Record the error code. Contact Thermo Fisher Scientific Support.
is displayed on the sample identification screen	Indicates that the instrument is not connected to the RapidLINK™ Software.	See "Check the RapidLINK™ Software connection" on page 46.
You cannot easily remove the sample cartridge from the instrument	The sample cartridge is locked in the sample cartridge port.	RapidHIT™ ID system administrator or supervisor: Run the recover function (see "Recover the instrument (administrator or supervisor only)" on page 45).
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 a green ✓ if it passes or a red ✗ if it fails.
"The primary cartridge is not engaged" message is displayed on the sample identification screen 	There is a problem with the instrument or the primary cartridge.	Contact Thermo Fisher Scientific Support.

Observation	Possible cause	Recommended action
RapidINTEL™ run is listed as a GFE run in RapidLINK™ Software	A RapidINTEL™ cartridge run failed on the instrument and the correct cartridge information is not sent to the RapidLINK™ Software.	No action.

B

Instrument specifications

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 4 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

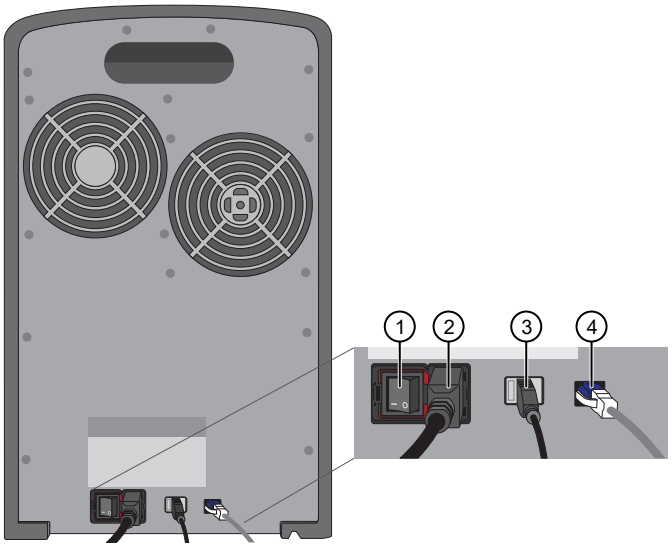


Figure 5 Rear panel

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

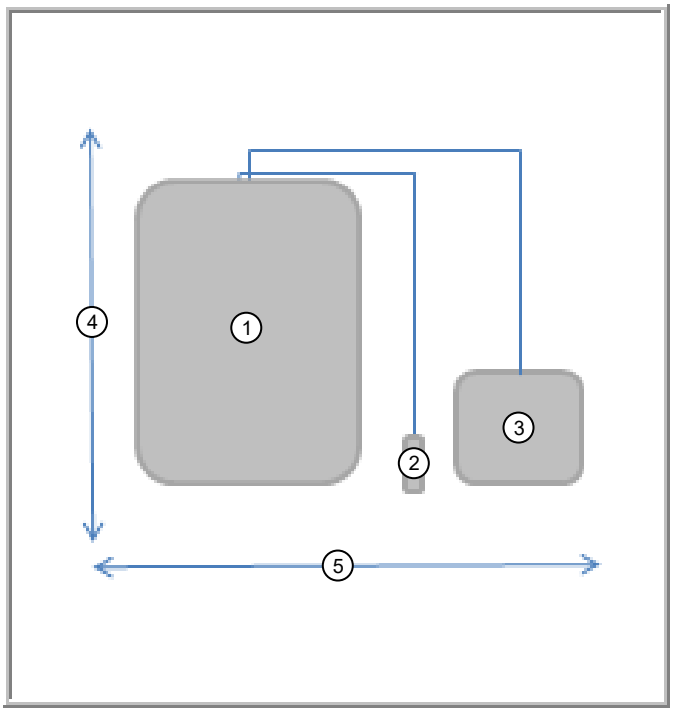


Figure 6 Component connections

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.
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°C–30°C (59°F–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°C to 40°C (39°F to +104°F) Minimum 20% relative humidity, maximum 80% (non-condensing) **IMPORTANT!** • The primary cartridge requires storage at 15°C to 30°C (59°F to +86°F). • The gel cartridge requires storage at 4°C to 10°C (39°F to +50°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.

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.

C

Analysis settings

Threshold settings

Table 6 Threshold settings (contained in panel)

System Threshold	RapidHIT™ ID ACE GlobalFiler™ Express Sample Cartridge	RapidINTEL™ Sample Cartridge	RapidHIT™ ID ACE NGM SElect™ *Express* Sample Cartridge
Analytical threshold	35 RFU	50 RFU	All loci 50, except: SE33 = 35
Stochastic threshold (inconclusive Homozygous (IHO flag) threshold)	All loci 91 RFU, except: • TPOX = 105 • Y indel = 35 • DYS391 = 35 • TH01 = 140 • SE33 = 105 • D12S391 = 105 • D2S1338 = 105	1,600 RFU 50 RFU for Y indel and DYS391	All loci 150, except: • D22S1045 = 200 • TH01 = 200 • D2S441 = 100 • D1S1658 = 100 • SE33 = 105
Minimum peak height ratio threshold (Heterozygote Imbalance (IMB flag) threshold)	40%	40% 99% for Y indel and DYS391	40%
Minimum heterozygous peak intensity threshold (inconclusive Heterozygous (IHE flag) threshold)	—	640 RFU	—
Stutter filters	20%	Locus-specific[1]	20%

Table 6 Threshold settings (contained in panel) *(continued)*

System Threshold	RapidHIT™ ID ACE GlobalFiler™ Express Sample Cartridge	RapidINTEL™ Sample Cartridge	RapidHIT™ ID ACE NGM SElect™ *Express* Sample Cartridge
Locus-specific filter	20%	21%	20%
		30% for the positive control	
Ploidy (PL flag) threshold (maximum number of expected peaks)	2	2	2
Global filter (between loci)	20%	21%	20%
		30% for the positive control	
Minimum off-ladder (OL) intensity	30 RFU	30 RFU	30 RFU

[1] See Table 7.

Table 7 RapidINTEL™ Sample Cartridge Stutter thresholds. When not indicated, the stutter threshold is –4 nucleotides from the allele peak.

Dye	Marker	Avg Stutter + 4SD (%)
6-FAM™	D3S1358	27
	vWA	25
	D16S539	25
	CSF1PO	22
	TPOX	16
VIC™	Y indel (stutter –2)[1]	21
	AMEL (stutter –9)[1]	21
	D8S1179	20
	D21S11	25
	D18S51	28
	DYS391	18
NED™	D2S441	16
	D19S433	29
	TH01	18
	FGA	27

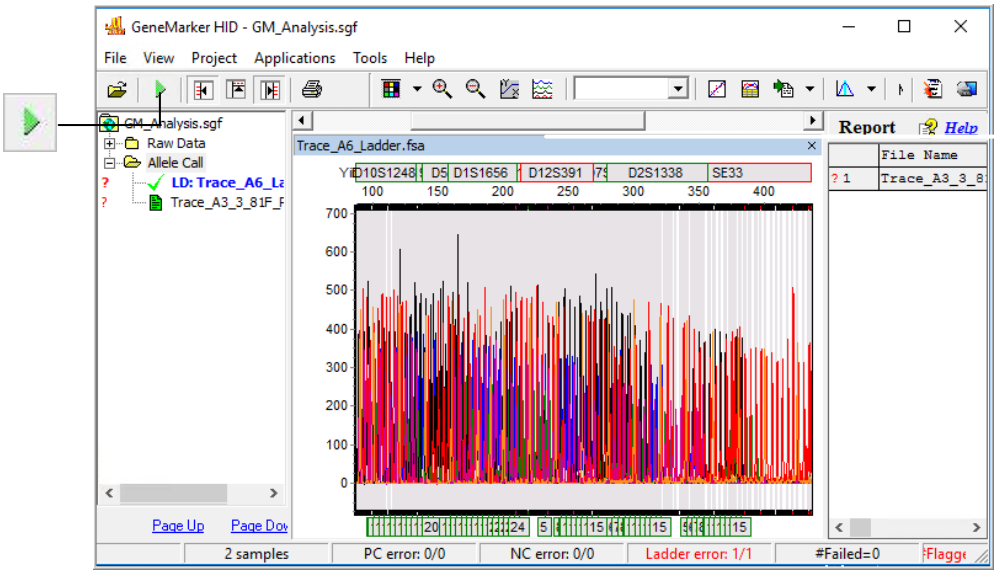
Table 7 RapidINTEL Sample Cartridge Stutter thresholds. When not indicated, the stutter threshold is –4 nucleotides from the allele peak. *(continued)*

Dye	Marker	Avg Stutter + 4SD (%)
TAZ™	D22S1045 (stutter –3)	34
	D5S818	26
	D13S317	18
	D7S820	18
	SE33	30
SID™	D10S1248	29
	D1S1656	26
	D12S391	30
	D2S1338	31

[1] Stutter threshold is set to the same value as the locus-specific filter values and will have no effect on filtering.

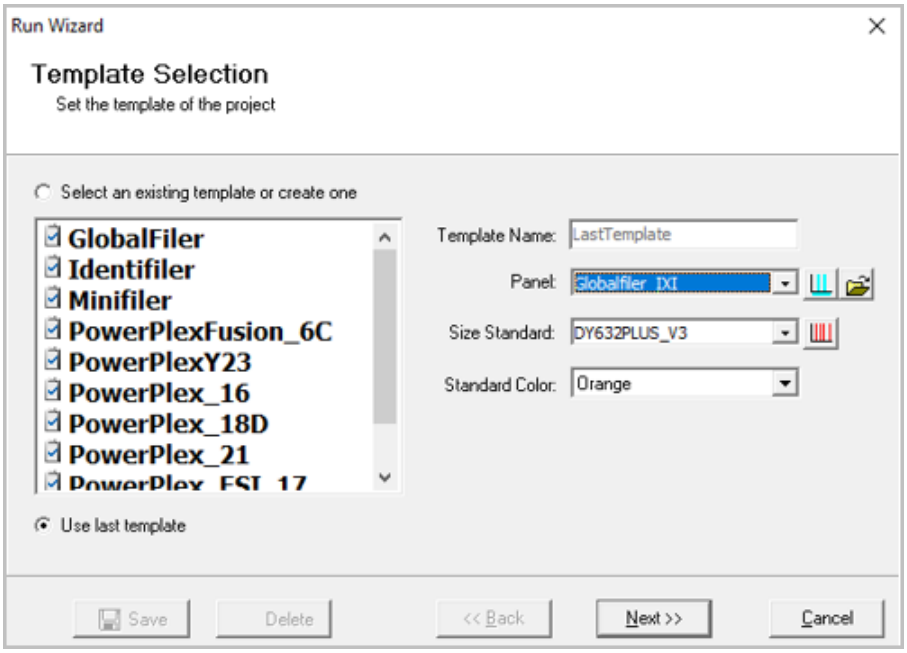
Display analysis settings in the GeneMarker™ HID STR Human Identity Software

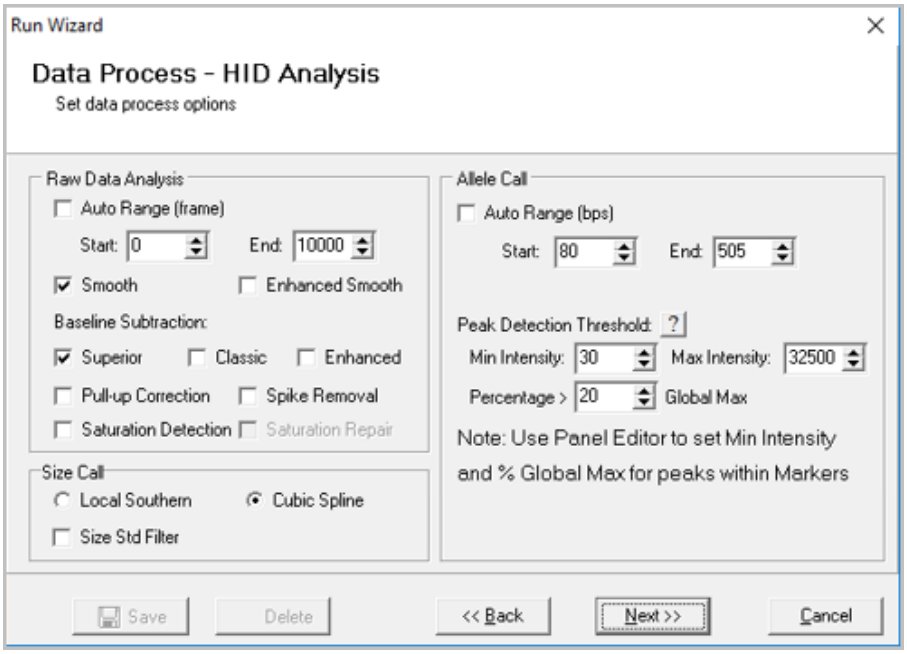
1. Open a sample in the RapidLINK™ Software.
2. Double-click the sample to open the GeneMarker™ HID Software.
3. Click .

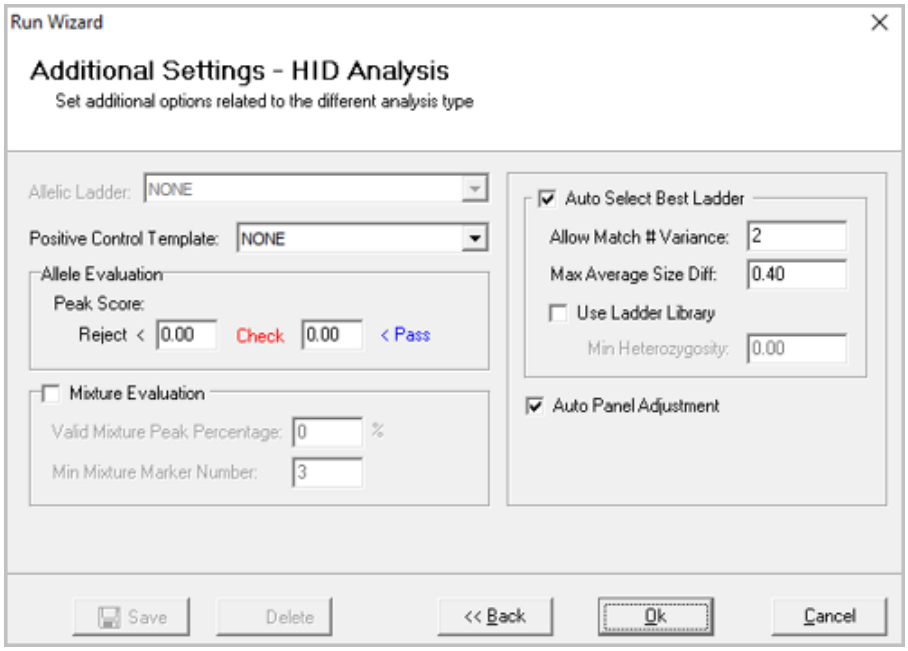


The **Run Wizard** screens are displayed with analysis settings. Click **Next** to display additional settings screens.

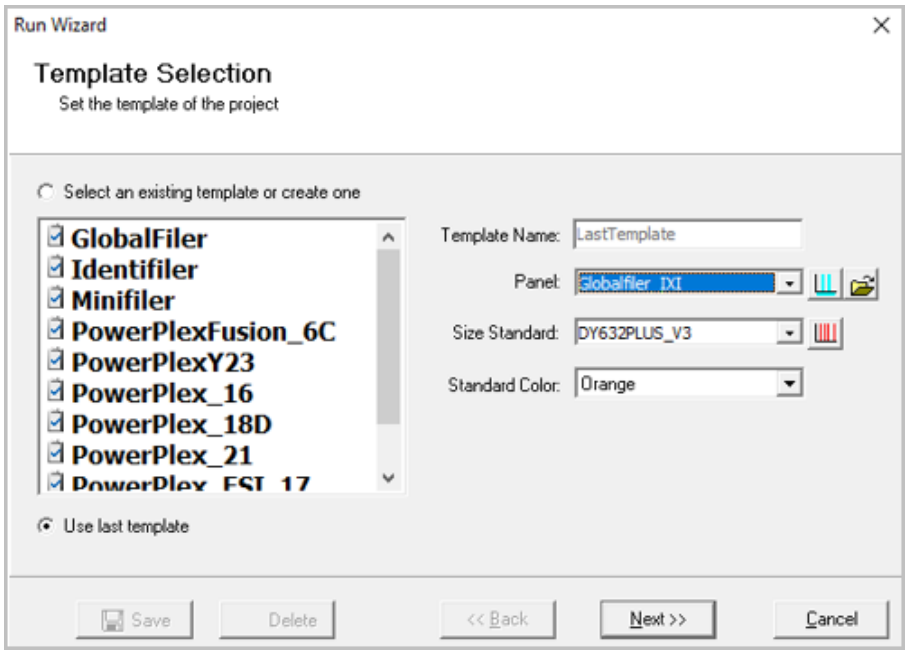
Analysis settings: GlobalFiler™ Express sample cartridges

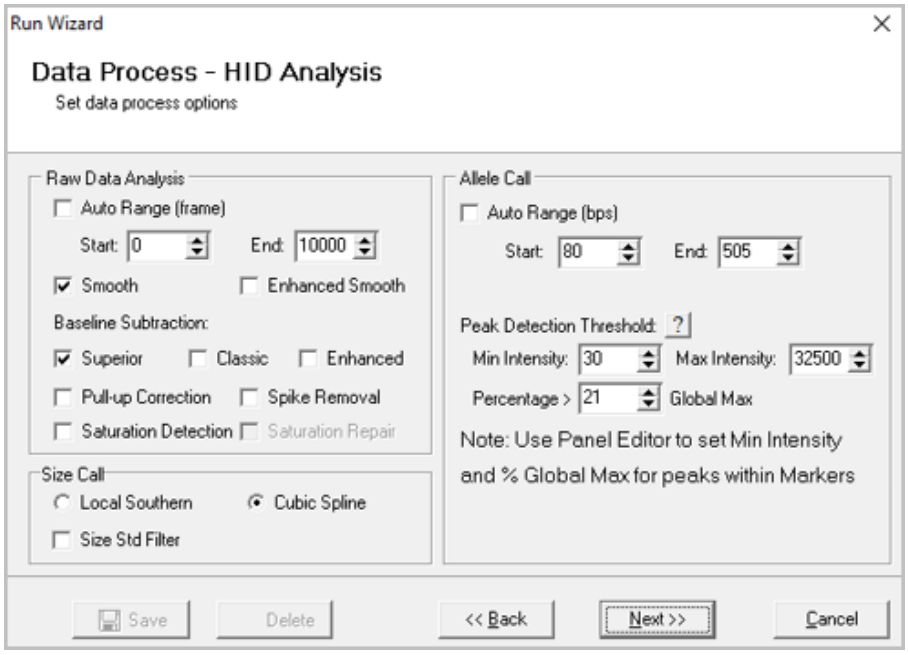




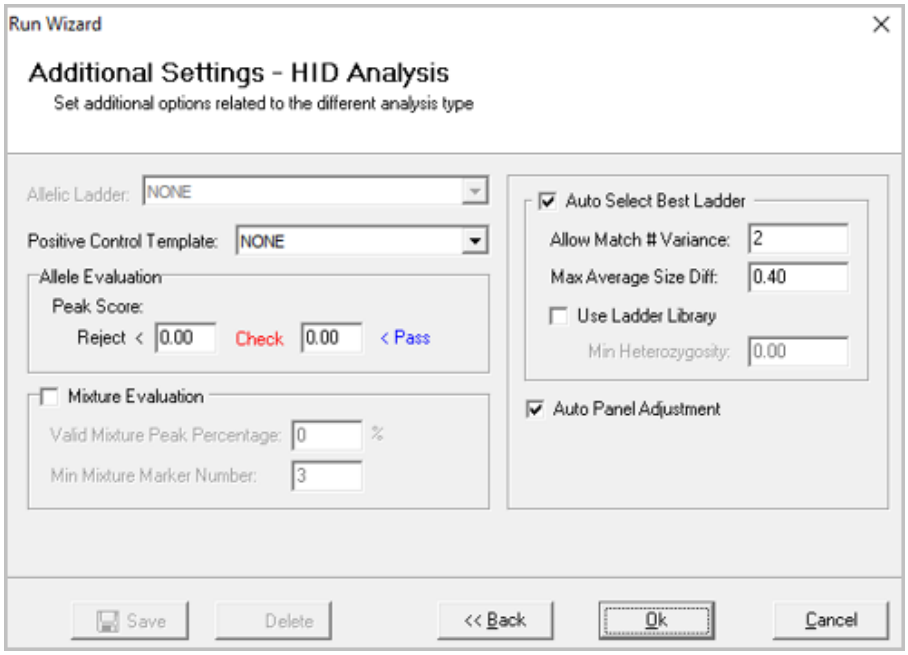


Analysis settings: RapidINTEL™ sample cartridges

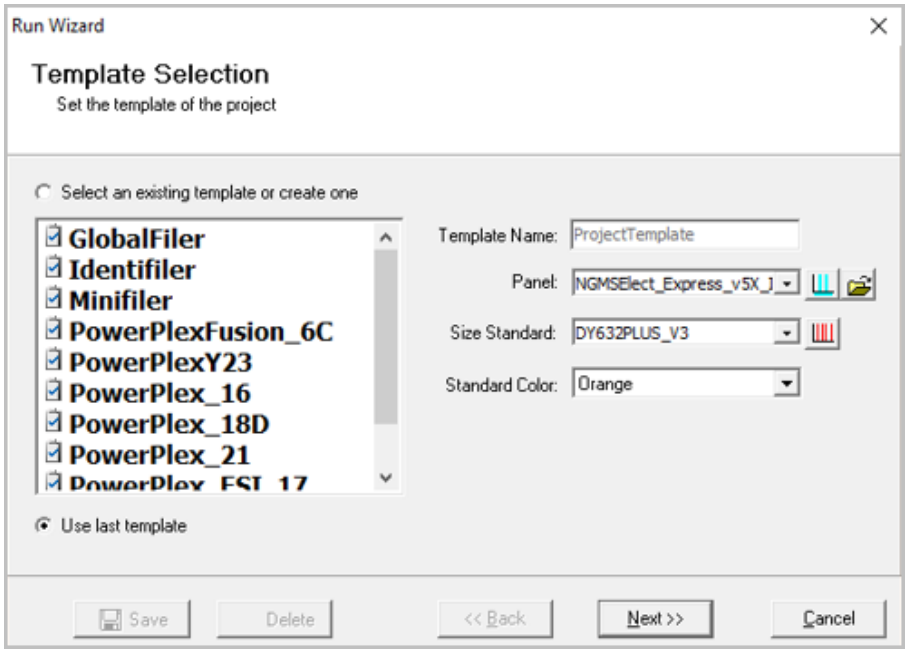


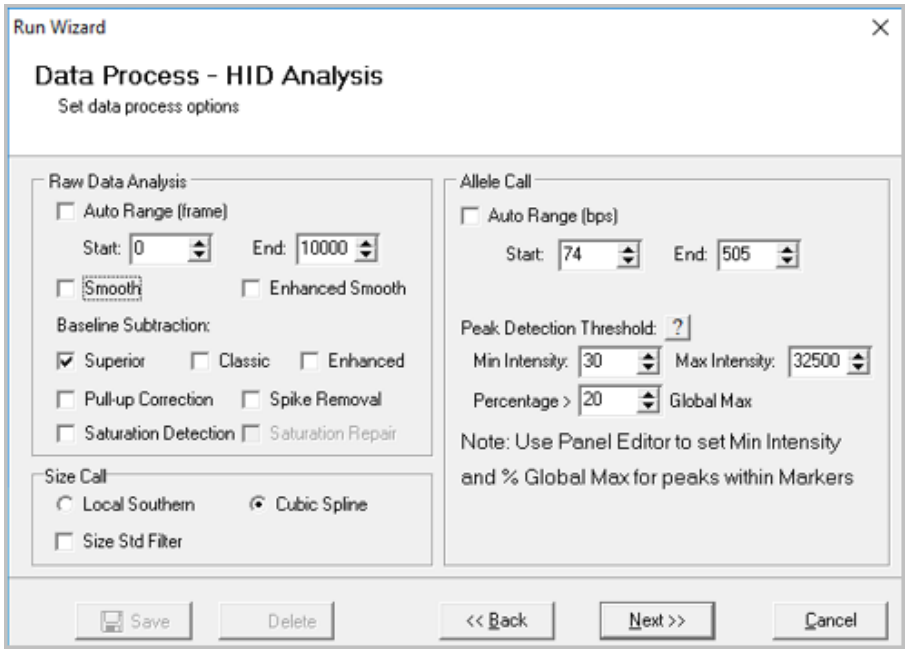


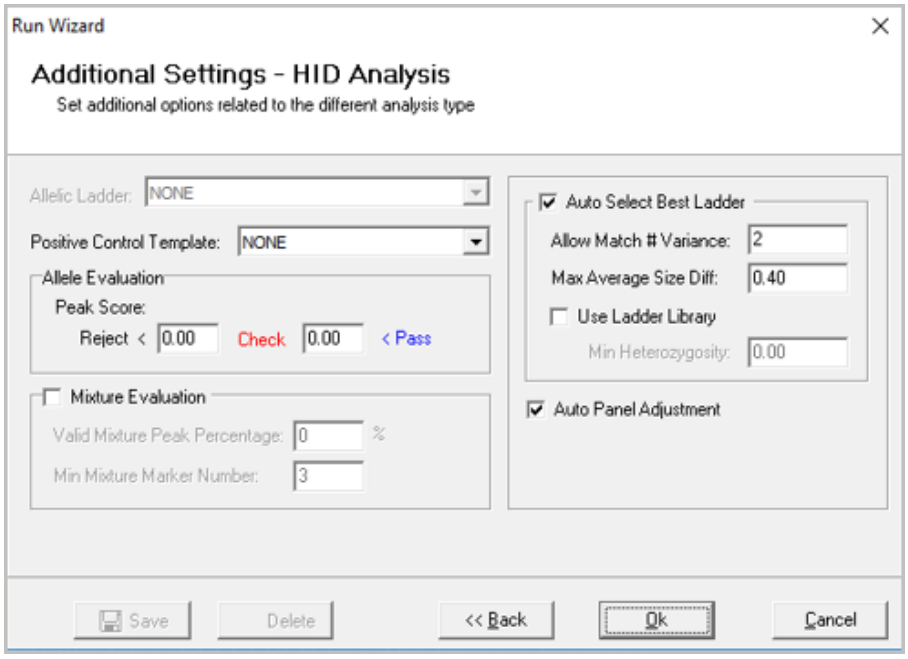
Note: The screen above shows the **Global Max Percentage** for samples. For the RapidINTEL™ positive control, the setting is <30% .



Analysis settings: NGM SElect™ *Express* sample cartridges






Run Wizard
Additional Settings - HID Analysis
Set additional options related to the different analysis type
Allelic Ladder:
NONE
Positive Control Template:
NONE
Allele Evaluation
Peak Score:
Reject <
0.00
Check
0.00
< Pass
Mixture Evaluation
Valid Mixture Peak Percentage:
0
%
Min Mixture Marker Number:
3
Auto Select Best Ladder
Allow Match # Variance:
2
Max Average Size Diff:
0.40
Use Ladder Library
Min Heterozygosity:
0.00
Auto Panel Adjustment
Save
Delete
<< Back
Ok
Cancel

D Validation of the Systematic Allelic Ladder Library (ACE NGM sample cartridges only)

Background

The size of a sample peak is calculated based on its relation to peaks in a co-migrating size standard. After sizing, the sample peak is assigned an allelic designation by matching the sample peak to a similarly sized allelic-ladder-derived bin. The migration of sample and allelic ladder peaks depends on electrophoresis conditions such as run temperature and gel polymer age, which can result in peak migration differences from run-to-run. If the migration difference between sample peaks and corresponding allelic ladder peaks is too large, allele matching can result in off-ladder (OL) or out-of-bin (OB) calls.

When using a multi-capillary system, it is possible to run allelic ladder and samples simultaneously to reduce run-to-run migration variation for proper sample genotyping. The RapidHIT™ ID System, a single-capillary system, cannot run an allelic ladder alongside the sample in an injection. Therefore, the use of an Empirical Allelic Ladder Library that contains various ladders run under different migration conditions was applied to address variation.

About the Systematic Allelic Ladder Library

The Systematic Allelic Ladder Library model was introduced for the RapidHIT™ ACE NGM SElect™ Express Sample Cartridge to improve genotyping accuracy and reproducibility (RapidHIT™ ID System v1.2.1). The model predicts the behavior of allelic ladders run under various electrophoretic conditions and is based on characterized differences for each ladder allele as a function of temperature and gel age. The Systematic Allelic Ladder Library enables the instrument software to predict the sizing of a ladder at any combination of the two run conditions.

We evaluated an expansive dataset to validate the Systematic Allelic Ladder Library model. The dataset consisted of the following:

- >2,000 RapidHIT™ ACE NGM SElect™ Express Sample Cartridge runs
- >3,500 RapidHIT™ ACE GlobalFiler™ Express Sample Cartridge runs (data not shown)
- Allelic ladders and samples run across the recommended temperature range and gel lifespan

---

Note: Although the RapidHIT™ ACE GlobalFiler™ Express Sample Cartridge was used for validation of the function, the Systematic Allelic Ladder Library is supported for the RapidHIT™ ACE NGM SElect™ Express Sample Cartridge only.

Our evaluation of the model confirmed that environmental temperature and gel age were the two variables that most significantly affect sizing on the RapidHIT™ ID System. From the model, the Systematic Allelic Ladder Library was developed to represent prescribed combinations of temperature and gel age, resulting in a more robust genotyping solution, as shown in Figure 7.

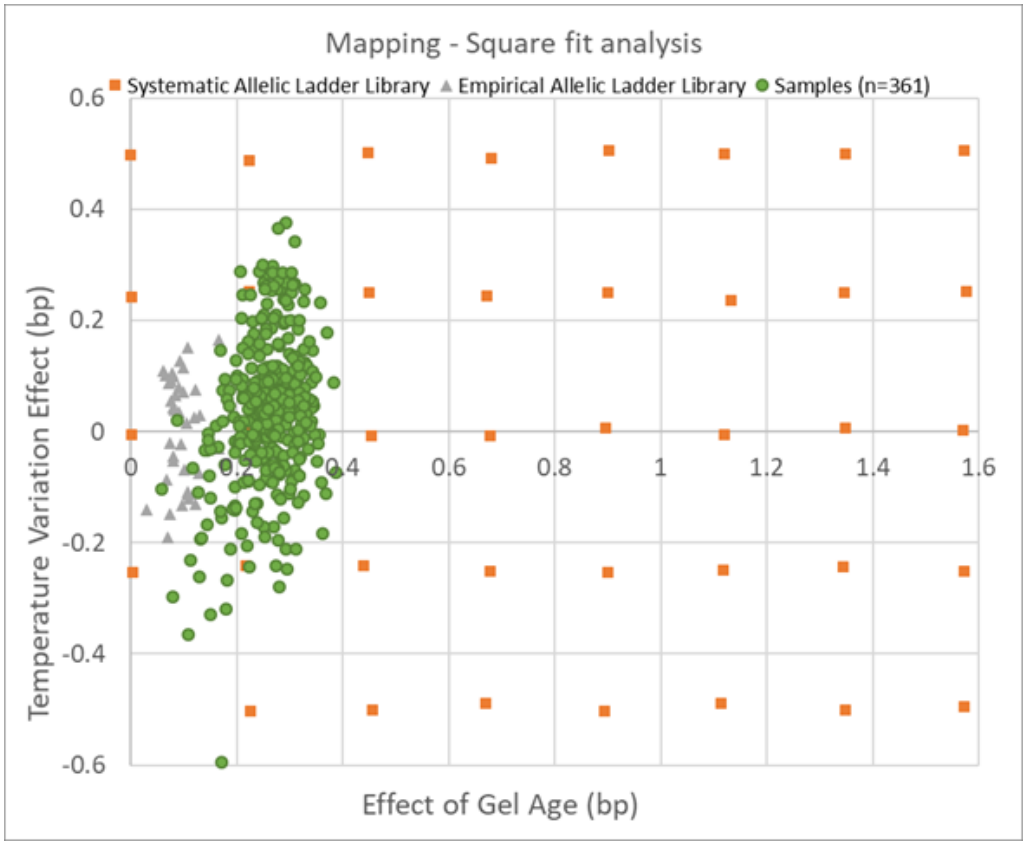


Figure 7 Square fit analysis

The square fit analysis shows the position of the allelic ladder library and samples from the RapidHIT™ ID System v1.2 RapidHIT™ ACE NGM SElect™ Express validation, relative to the empirical and systematic allelic ladder libraries.

Study overview

The performance of the Systematic Allelic Ladder Library was assessed for concordance and accuracy by re-analyzing the 361 runs from the original RapidHIT™ ACE NGM SElect™ Express Sample Cartridge validation for the RapidHIT™ ID System v1.2, without changing any other analysis parameters. See Table 8.

Table 8 Samples and positive controls re-analyzed during the Systematic Allelic Ladder Library validation

Study name	Number of RapidHIT™ ID ACE NGM SElect™ *Express* cartridges	
	Sample cartridges	Positive control cartridges
Accuracy	—	25
Sample Concordance	246	—
Sensitivity	43[1]	—
Inhibition	30	—
Mixtures	18	—

[1] One sample failed, resulting in 42 profiles generated for the sensitivity study.

Concordance

Concordance was evaluated using expected sample genotypes from previous 3130*xl* Genetic Analyzer or 3500xL Genetic Analyzer runs. These genotypes were compared to the data obtained using the original (RapidHIT™ ID System v1.2) and re-analyzed (RapidHIT™ ID System v1.2.1) NGM SElect™ *Express* data set.

Analysis using the Systematic Allelic Ladder Library resulted in 100% concordance for the expected genotypes. Additionally, the sample profile shown in Figure 8 genotyped correctly without the need for manual ladder substitution. In the initial RapidHIT™ ID ACE NGM SElect™ *Express* Sample Cartridge validation for RapidHIT™ ID System v1.2, this sample required manual allelic ladder selection to resolve an out-of-bin (OB) allele designation (Figure 8, pane A). The ladder selection process in RapidHIT™ ID System v1.2.1, using the Systematic Allelic Ladder Library, resulted in the previous OB allele designation being assigned the concordant allele call (Figure 8, pane B).

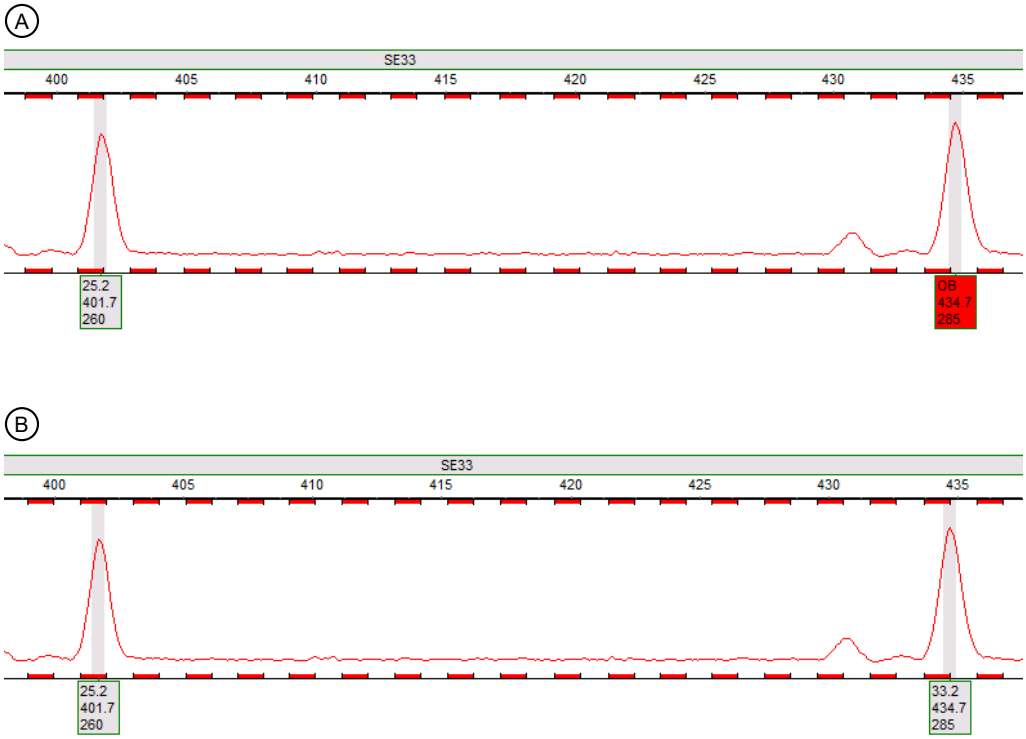


Figure 8 Concordance

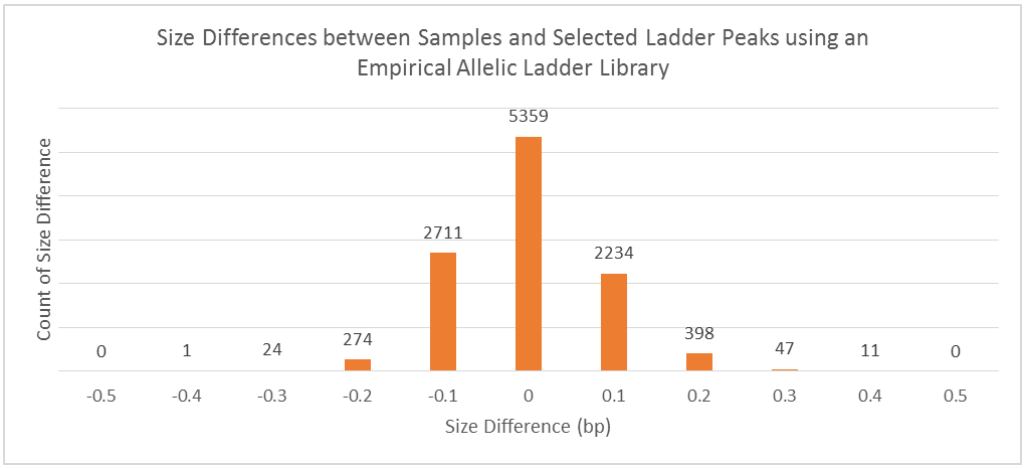
The sample profile analyzed with the existing Allelic Ladder Library (pane A) indicated the presence of an OB allele at the SE33 locus. When the profile was reanalyzed using the Systematic Allelic Ladder Library (pane B), the OB resolved to the concordant allele designation.

Accuracy

To evaluate for accuracy, the performance of the Systematic Allelic Ladder Library in RapidHIT™ ID System v1.2.1 was compared to the performance of the Empirical Allelic Ladder Library in RapidHIT™ ID System v1.2. For the comparison, each allele designation in the 361 validation samples was evaluated. The alleles were measured for size differences between the sample and allelic ladders from the libraries. The smaller the difference between the observed allele size in the sample and the allele from the selected ladder indicates a closer match.

Figure 9 shows that the Systematic Allelic Ladder Library analysis (pane B) resulted in a tighter match between the sample and selected ladder peaks when compared to the Empirical Allelic Ladder Library (pane A). A normal distribution of the data points was observed. The size differences observed between the libraries is statistically significant, showing a relevant improvement in sizing when using the Systematic Allelic Ladder Library.

Ⓐ



Ⓑ

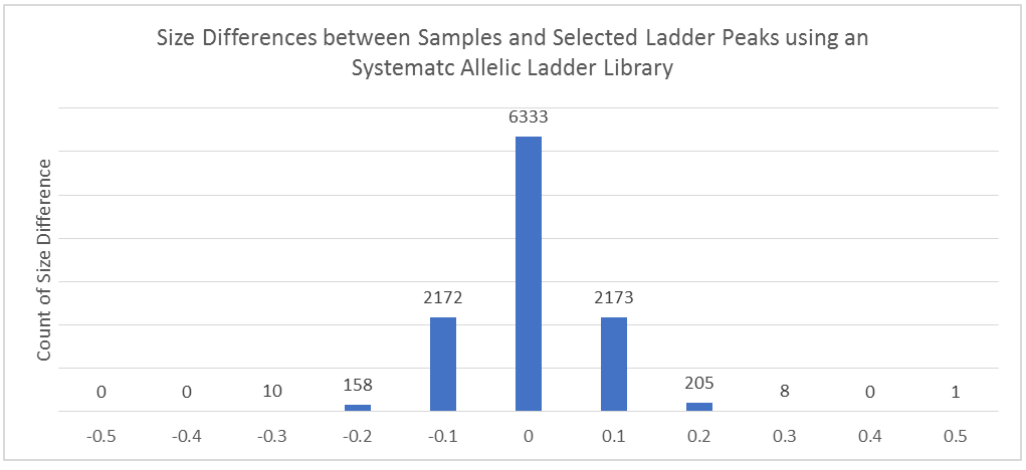


Figure 9 Accuracy

Histograms of size differences observed between the samples and ladder peaks for an empirical allelic ladder library (pane A) and the systematic allelic ladder library (pane B) from RapidHIT™ ACE NGM SElect™ Express validation.

Absolute size difference

Because allelic ladder selection is performed on a per-sample basis, the aggregate size difference between sample peaks and selected allelic ladder peaks was another method used to compare performance. For each ladder library, the total size difference between sample peaks and selected allelic ladder peaks was calculated on a per-sample basis. Because concordance was already assessed, and a normal distribution was confirmed, absolute values of the observed size differences were used for this comparison.

Figure 10 shows the overall trend that allelic ladders selected from the Systematic Allelic Ladder Library in RapidHIT™ ID System v1.2.1 are closer in size to sample allele designations than those ladders selected from the Empirical Allelic Ladder Library in RapidHIT™ ID System v1.2. The smaller the size differences observed, the more robust the genotyping. In all cases, implementing the Systematic Allelic Ladder Library in RapidHIT™ ID System v1.2.1 showed smaller size differences, resulting in more accurate sample genotyping.

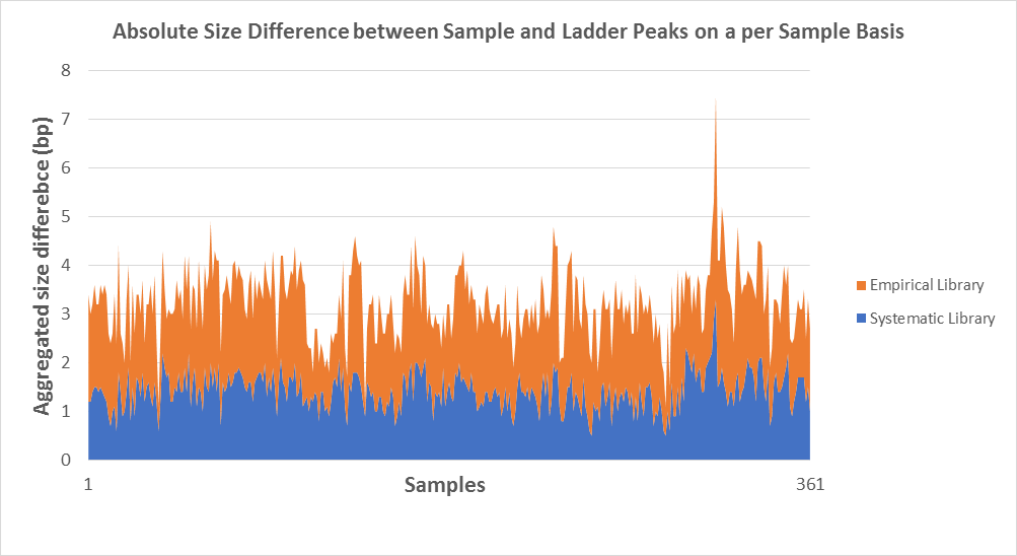


Figure 10 Absolute size difference

Calculated absolute size difference between sample and selected allelic ladder peaks on a per-sample basis for the Empirical Allelic Ladder Library and Systematic Allelic Ladder Library.

Conclusion

The Systematic Allelic Ladder Library for the ACE NGM SElect™ Express Sample Cartridge successfully demonstrated sample genotype concordance. The performance of the Systematic Allelic Ladder Library improved genotyping accuracy without requiring any changes to other sample analysis parameters.

E Software verification RapidHIT™ ID System v1.3.1

Objective of the software verification

The objective of this verification is to ensure that software modifications made in earlier versions of the RapidHIT™ ID System v1.3.1 and RapidLINK™ Software v1.1.5 do not adversely affect performance when using GlobalFiler™ Express, NGM SElect™ Express, and RapidINTEL™ sample cartridges.

Testing was performed according to Quality Assurance Standards (QAS) for DNA Databasing Laboratories (July 1, 2020). Functionality, regression, accuracy, and reliability testing was performed.

Cartridge types are abbreviated as listed below throughout this section.

Type	Abbreviation used in this appendix
RapidHIT™ ID ACE GlobalFiler™ Express	ACE GFE sample, allelic ladder, or control cartridge
RapidINTEL™	AB RI sample or control cartridge (uses ACE GFE allelic ladder)
RapidHIT™ ID ACE NGM SElect™ *Express*	ACE NGM sample, allelic ladder, or control cartridge

Studies, standards, and samples

Test Parameter	QAS Reference	Samples
Functionality	8.9.3.1 8.9.3.2	Control, allelic ladder, and sample runs were performed on RapidHIT™ ID v1.3.1 across 2 instruments: • 6 ACE GFE, 6 AB RI, and 6 ACE NGM control cartridges – 3 positive control cartridges (2 passing, 1 failing) – 3 negative control cartridges (2 passing, 1 failing) • 2 ACE GFE and 2 ACE NGM allelic ladder cartridges • 10 samples for each sample cartridge type: – ACE GFE and ACE NGM sample cartridges: Buccal samples – AB RI sample cartridges: Saliva diluted 1:1 with PBS. 4 µL of the 1:1 dilution was pipetted directly onto the swab and dried before processing.
Regression	8.9.3.1 8.9.3.2	20 samples for each sample cartridge type were processed with the RapidHIT™ ID v1.3.1 and earlier versions of the software: • ACE GFE sample cartridges: 20 buccal reference samples • AB RI sample cartridges: 10 blood and 10 saliva samples of varying sample input volumes • ACE NGM sample cartridges: 20 buccal reference samples
Accuracy	8.9.3.2	Control, allelic ladder, and sample runs were performed on RapidHIT™ ID v1.3.1 across 2 instruments: • 2 ACE GFE and 2 ACE NGM positive control cartridges • 10 samples for each sample cartridge type: – ACE GFE and ACE NGM sample cartridges: Buccal samples – AB RI sample cartridges: Saliva diluted 1:1 with PBS. 4 µL of the 1:1 dilution was pipetted directly onto the swab and dried before processing.
		20 samples for each sample cartridge type were processed with the RapidHIT™ ID v1.3.1 and previous versions of the software: • ACE GFE sample cartridges: 20 buccal reference samples • AB RI sample cartridges: 10 blood and 10 saliva samples of varying sample input volumes • ACE NGM sample cartridges: 20 buccal reference samples
		All samples from functionality, regression, and reliability studies were evaluated.

(continued)

Test Parameter	QAS Reference	Samples
Reliability	8.9.3.1 8.9.3.2	Sample runs: • 8 controls from the functionality study • 10 samples from the functionality study Data reprocessing runs: • 20 passing samples for each sample cartridge type
Precision	8.9.3.2	Sensitivity and precision studies were not performed during software verification because the changes made to the software do not impact sensitivity and precision of results. Specificity studies were performed during developmental validation of the STR kits. For information see the *GlobalFiler™ Express PCR Amplification Kit User Guide* (Pub. No. 4477672) and the *AmpFℓSTR™ NGM SElect™ Express PCR Amplification Kit User Guide* (Pub. No. 4474109).
Sensitivity	8.9.3.2	
Specificity	8.9.3.2	

Functionality testing results

To confirm that the software performed sample processing and analysis as expected, 104 samples, allelic ladder, and control cartridges were processed with ACE GFE and AB RI consumables and processed on 2 instruments as shown in Table 9.

The RapidLINK™ Software v1.1.5 was used to confirm that each cartridge type was correctly identified, the appropriate run protocol was used, and the applicable data analysis thresholds were applied.

For a description of the flags listed in this section, see the *RapidLINK™ Software v1.1.5 User Guide* (Pub. No. MAN0018939).

Controls and allelic ladders

To verify that the software correctly identifies a discordant profile for positive controls, 1 ACE GFE, 1AB RI, and 1 ACE NGM positive control swab was replaced with a sample swab to generate an incorrect profile for the positive control. The software reported a failing result ❌ for these three positive controls. One AB RI positive control also generated a failing result ❌ due to allele imbalance (IHE) at the D10S1248 marker. Remaining positive control cartridges reported passing results ✅. One ACE NGM negative control generated a failing result ❌ due to a dye artifact that exceeded the detection threshold.

For negative control testing, a positive control swab was inserted into a negative control cartridge of each cartridge type and processed through at least one instrument. The altered negative controls reported a failing result ❌ due to the presence of DNA. One AB RI negative control also generated an (OB) peak at the D2S441 marker. Remaining negative control cartridges reported passing results ✅.

The four allelic ladder cartridges ran appropriately and reported passing results ✅ on two different instruments.

Note: The ACE GFE allelic ladder is used to genotype ACE GFE and AB RI samples.

Samples

The 10 ACE GFE sample cartridges met the defined thresholds and produced ✅ results. Some AB RI sample cartridges produced ✅ results. These samples were evaluated in the RapidLINK™ Software v1.1.5. The following flags were observed and were appropriately triggered based on the data and analysis parameters: IHE, OB, IMB and IHO. All samples resulted in concordant genotype results as compared to known reference data.

Table 9 Runs performed to evaluate the functionality of the RapidHIT ID v1.3.1 system with samples and controls using ACE GlobalFiler Express and RapidINTEL sample and control cartridges.

Sample number	Cartridge type	RHID-1 result	RHID-2 result	Details If flag(s) are present, indicated by instrument: Marker (Flag)
1	ACE GFE sample	✅	✅	—
2		✅	✅	—
3		✅	✅	—
4		✅	✅	—
5		✅	✅	—
6		✅	✅	—
7		✅	✅	—
8		✅	✅	—
9		✅	✅	—
10		✅	✅	—
11	ACE GFE positive control	✅	✅	—
12		✅	✅	—
13		❌	❌	RHID-1 & RHID-2: Control swab was removed and replaced with sample swab
14	ACE GFE negative control	✅	✅	—
15		✅	✅	—
16		❌	❌	RHID-1 & RHID-2: Positive control swab processed in cartridge
17	ACE GFE allelic ladder	✅	✅	—
18		✅	✅	—
19	AB RI positive control	✅	❌	RHID-2: D10S1248 (IHE)
20		✅	✅	—

Table 9 Runs performed to evaluate the functionality of the RapidHIT ID v1.3.1 system with samples and controls using ACE GlobalFiler Express and RapidINTEL sample and control cartridges. *(continued)*

Sample number	Cartridge type	RHID-1 result	RHID-2 result	Details If flag(s) are present, indicated by instrument: Marker (Flag)
21	AB RI positive control	✗	✓	RHID-1: Control swab was removed and replaced with sample swab
22	AB RI negative control	✓	✓	—
23		✗	✓	RHID-1: D2S441 (OB) peak called at 97.5 bp
24		✓	✗	RHID-2: Positive control swab processed in cartridge
25	AB RI saliva sample	✓	✓	RHID-2: D10S1248 (IHE)
26		✓	✓	RHID-1: Female sample, Y indel (OB) pull-up called
27		✓	✓	RHID-1: Female sample, Y indel (OB) pull-up called RHID-2: D10S1248 (IHE)
28		✓	✓	RHID-1: AMEL (IHO), D8S1179 (IMB/IHE), D10S1248 (IHE)
29		✓	✓	RHID-1: D3S1358 (IHO), TPOX (IHE), AMEL (IHO), D8S1179 (IHE), D19S433 (IHE), D5S818 (IHE/IMB), D7S820 (IMB), D10S1248 (IHE/IMB), D1S1656 (IHE), D12S391 (IHE), D2S1338 (IMB/IHE)
30		✓	✓	RHID-1: Female sample, Y-indel 89.2 bp peak
31		✓	✓	RHID-1: Female sample, Y-indel 89.2 bp peak
32		✓	✓	RHID-1: AMEL (IHO), D10S1248 (IHE) RHID-2: Female sample, Y-indel (OB) pull up, D8S1179 (IMB), D12S391 (IMB)
33		✓	✓	RHID-2: Female sample, DYS391 (OB) pull-up
34		✓	✓	RHID-1: Female sample, Y-indel 89.2 bp peak
35	ACE NGM allelic ladder	✓	✓	—
36		✓	✓	—
37	ACE NGM positive control	✓	✓	—
38		✓	✓	—

Table 9 Runs performed to evaluate the functionality of the RapidHIT ID v1.3.1 system with samples and controls using ACE GlobalFiler Express and RapidINTEL sample and control cartridges. *(continued)*

Sample number	Cartridge type	RHID-1 result	RHID-2 result	Details If flag(s) are present, indicated by instrument: Marker (Flag)
39	ACE NGM positive control	✗	✗	RHID-1 and RHID-2: Control swab was removed and replaced with sample swab
40	ACE NGM negative control	✓	✓	—
41		✓	✓	—
42		✗	✗	RHID-1: Positive control swab processed in cartridge RHID-2: D10S1248 80 bp dye artifact peak
43	ACE NGM sample	✓	✓	—
44		✓	✓	—
45		✓	✓	RHID-1: D22S1045 (OB) pull up
46		✓	✓	RHID-1 and RHID-2: FGA (OB) microvariant concordant with known reference
47		✓	✓	—
48		✓	✓	RHID-1 and RHID-2: AMEL 99.9 bp peak
49		✓	✓	—
50		✓	✓	—
51		✓	✓	RHID-2: SE33 (OB) 322.1 bp spike
52		✓	✓	—

Regression testing results

Regression testing was performed to confirm that the software changes made in RapidHIT™ ID System v1.3.1 do not impact the software functionality. Twenty passing samples were selected to evaluate performance. The samples were processed with the original version of software with which the cartridges were released (v1.3 for ACE GFE, v1.1.3 for AB RI, and v1.2 for ACE NGM) and the same data set was re-processed in RapidHIT™ ID System v1.3.1.

The results from all samples were concordant for allele call, peak height, and bp size between the software versions (Table 10).

Table 10 Allele call, peak height, and bp size concordance evaluated for 20 samples per sample cartridge type in previous and updated software versions.

Sample cartridge type	Previous software version	Allele call, peak height, and size concordance to v1.3.1
ACE GFE	v1.3	100%
AB RI	v1.1.3	100%
ACE NGM	v1.2	100%

Accuracy testing results

Sizing accuracy was measured by calculating the difference, in base pair, of each sample allele as compared to the equivalent allelic ladder allele.

Sample runs

Each allele in the samples were evaluated for precision. Samples that did not generate data, such as negative controls and modified (swab removed) positive controls, were not included.

The size difference between a sample allele and associated ladder allele were evaluated as shown in Figure 11 for ACE GFE and Figure 12 for AB RI. As shown, the maximum difference for each allele as compared to the allelic ladder is at or below 0.3 bp for all samples and controls tested with RapidHIT™ ID System v1.3.1. (Size differences less than 0.4 bp promote accurate genotyping.)

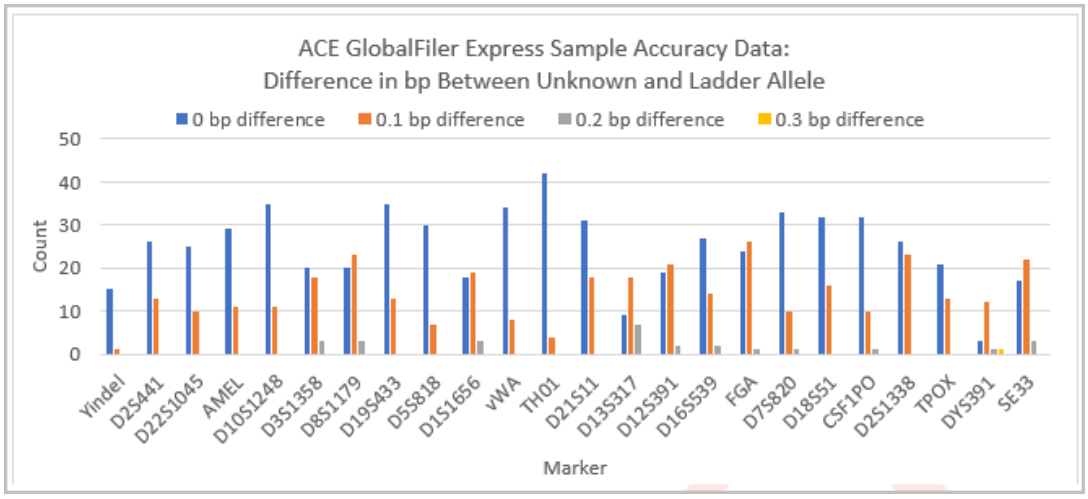


Figure 11 Samples and positive controls processed with ACE GFE cartridges across two RapidHIT ID instruments. The size difference in bp is shown per marker running from the smallest to largest markers (bp).

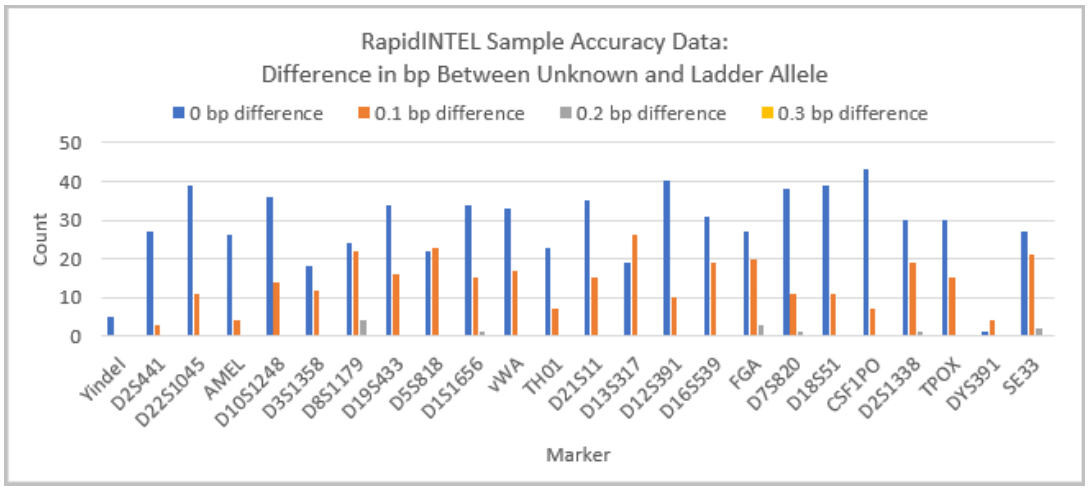


Figure 12 Samples and positive controls processed with AB RI cartridges across two RapidHIT ID instruments. The size difference in bp is shown per marker running from the smallest to largest markers (bp).

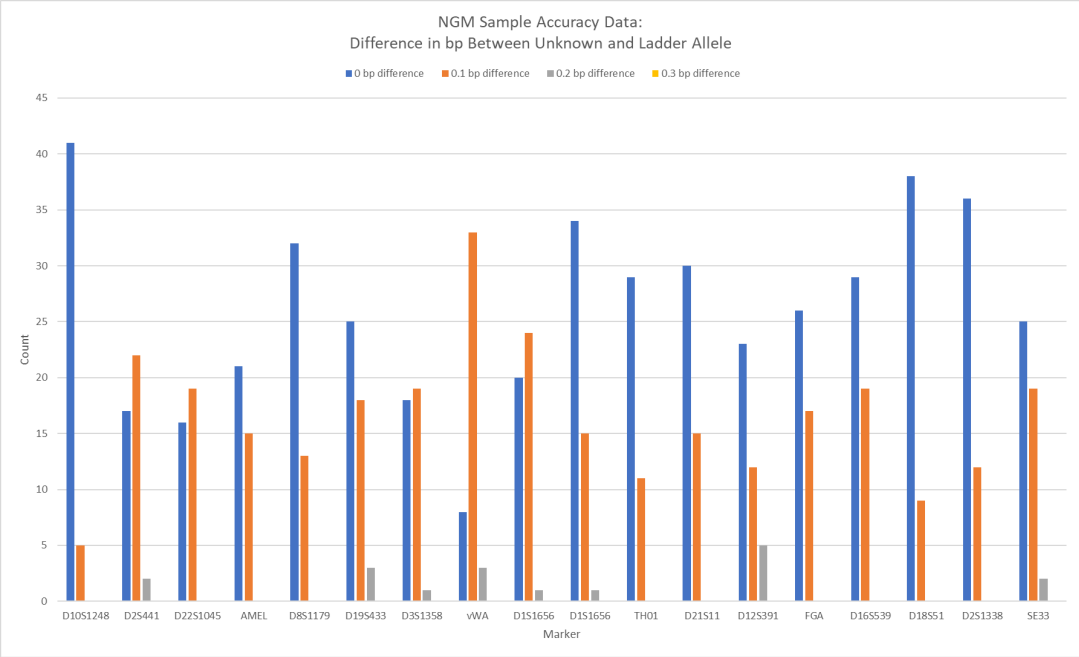


Figure 13 Samples and allelic ladders processed with NGM cartridges across two RapidHIT ID instruments. The size difference in bp is shown per marker running from the smallest to largest markers (bp).

Data reprocessing

The regression test data was evaluated for accuracy. The results show that the sizing accuracy was not impacted by the software modification.

Reliability testing results

To evaluate the software performance within and beyond functional aspects, a variety of user scenarios were tested as presented in Table 11. Functional and non-functional tasks from instrument login through secondary software integration performed as expected.

Table 11 Test cases to evaluate the reliability of the RapidHIT ID v1.3.1 system. Functional and non-functional testing evaluated critical aspects of software performance.

Category	Test	Performed as Expected (Y/N)
Installation	User can install and/or upgrade: • RapidHIT™ ID System v1.3.1 • RapidLINK™ Software v1.1.5	Y
Instrument sign in	• Fingerprint authentication works properly. • A user cannot access the instrument without at least one form of authentication.	Y

Table 11 Test cases to evaluate the reliability of the RapidHIT ID v1.3.1 system. Functional and non-functional testing evaluated critical aspects of software performance. *(continued)*

Category	Test	Performed as Expected (Y/N)
Run	• If disk space is not available on the instrument to store data from the run, an error message is displayed. • Samples generate ✓, ✓, or ✗ result as expected when a run is complete. • A sample ID must be scanned or entered before a sample cartridge run can be started (not applicable for allelic ladder and control cartridges).	Y
Functional testing (2 RapidHIT ID instruments)	The following functions were evaluated to ensure that software changes did not affect functionality: • Instrument settings • Operator, Supervisor, and Admin roles allow access to the expected functions	Y
Functional testing RapidLINK™ Software testing (1 per RapidHIT ID instrument)	The following functions were evaluated to ensure that software changes did not affect functionality: • Authorization of a user to access an instrument • Consumables chart • Run reports • Reports to PDF or CSV format • Table and button functionalities are consistent across the software • Allele edits made in the GeneMarker™ HID STR Human Identity Software are saved and reflected in the RapidLINK™ Software	Y

Conclusion

Software modifications made in earlier versions of the RapidHIT™ ID System v1.3.1 and RapidLINK™ Software v1.1.5 do not adversely affect performance when using GlobalFiler™ Express, NGM SElect™ Express, and RapidINTEL™ sample cartridges. The new versions of software maintain the functionality, accuracy, and reliability of previous versions.

F

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, see the "Documentation and Support" section in this document.

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.

Location of safety labels

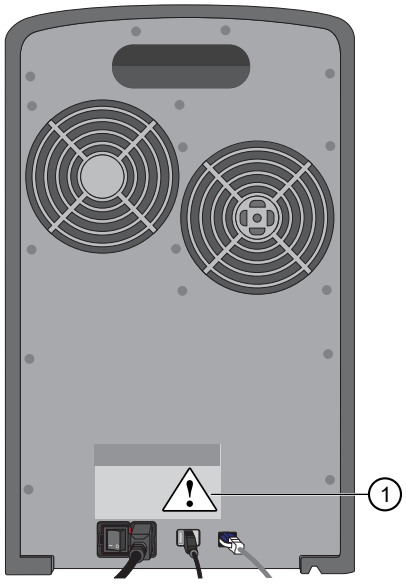


Figure 14 Rear panel

⚠ ① **CAUTION!** Risk of danger. Consult the manual for further safety information.

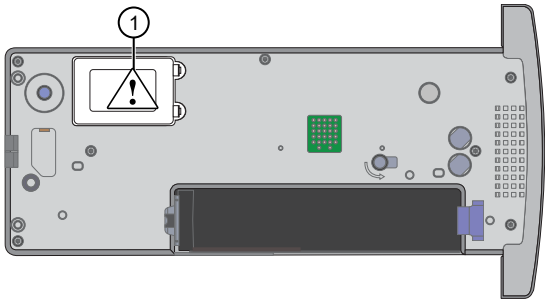


Figure 15 Primary cartridge

⚠ ① **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

(continued)

Symbols and descriptions	
	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.

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.

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

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

Cleaning and decontamination

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

- No decontamination or cleaning agents are used that could cause a HAZARD as a result of a reaction with parts of the equipment or with material contained in the equipment.
- The instrument is properly decontaminated a) if hazardous material is spilled onto or into the equipment, and/or b) prior to having the instrument serviced at your facility or sending the instrument for repair, maintenance, trade-in, disposal, or termination of a loan (decontamination forms may be requested from customer service).
- Before using any cleaning or decontamination methods (except those recommended by the manufacturer), users should confirm with the manufacturer that the proposed method will not damage the equipment.

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.

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*

(continued)

Reference	Description
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	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.

(continued)

Reference	Description
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
	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 adequate ventilation (for example, fume hood).
- Check regularly for chemical leaks or spills. If a leak or spill occurs, follow the manufacturer's 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 necessary) 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.

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)*, 5th Edition, HHS Publication No. (CDC) 21-1112, Revised December 2009; found at:
  https://www.cdc.gov/labs/pdf/CDC-BiosafetymicrobiologicalBiomedicalLaboratories-2009-P.pdf
- World Health Organization, *Laboratory Biosafety Manual*, 3rd Edition, WHO/CDS/CSR/LYO/2004.11; found at:
  www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf

Documentation and support

Related documentation

Document	Publication number
RapidHIT™ ID System v1.3.1 User Guide	MAN0018938
RapidLINK™ Software v1.1.5 User Guide	MAN0018939
RapidINTEL™ Sample Cartridge for Blood and Saliva Samples Validation User Bulletin	MAN0018979
RapidHIT™ ID ACE NGM SElect™ Express Sample Cartridge for RapidHIT™ ID System v1.2 Validation User Bulletin	MAN0018973
Application Note: Bone sample processing on the RapidHIT™ ID system with RapidINTEL™ cartridges	COL33625 0620

Customer and technical support

For support:

- **In North America**—Send an email to **HIDTechSupport@thermofisher.com**, or call **888-821-4443 option 1**.
- **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/or its affiliate(s) 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 any questions, please contact Life Technologies at **www.thermofisher.com/support**.

Bibliography

Hennessy LK *et al*. (2014). *Developmental validation of the GlobalFiler® express kit, a 24-marker STR assay, on the RapidHIT™ System*. *Forensic Science International: Genetics* (13): 247-258.

Buscaino J *et al*. (2018) *Evaluation of a rapid DNA process with the RapidHIT™ ID system using a specialized cartridge for extracted and quantified human DNA*. *Forensic Science International: Genetics* (34): 116-127.

Salceda S *et al*. (2017) *Validation of a rapid DNA process with the RapidHIT™ ID system using GlobalFiler™ Express chemistry, a platform optimized for decentralized testing environments. Forensic Science International: Genetics* (28): 21-34.

Index

T

U

V

W