

# FLashDx-1000-E/Cartridge Test Quick Guide

## WARNINGS

- **DO NOT** open a cartridge pouch until you are ready to perform testing.
- **DO NOT** use a cartridge that appears wet or damaged.
- **DO NOT** use a cartridge that has been dropped.
- **DO NOT** shake, lay flat or invert the cartridge after adding the sample.
- **DO NOT** reuse disposable pipettes or cartridges.
- **DO NOT** turn off or unplug the instrument during a test as this will stop and fail the test.

## Instrument preparation/Cartridge Storage

### • Powering Instrument

1. Make sure the power switch at the back of the instrument is at OFF position. Plug the instrument into a 110V/220V wall outlet.
2. (Optional): Plug in USB barcode scanner.
3. Switch on the power switch at the back of the instrument.
4. Wait for the instrument to boot up and complete self-calibration.
5. Log in and system is now ready to go.

**Note: Default “admin” password: 123456**

If the software keyboard is set to Chinese input by default, press the globe button on soft keyboard to switch to English input.

- **Cartridge Storage** Cartridges should be stored at 2-8 °C.

## Run Sample or External Control Test

### • Load Sample or External Control

#### Step 1: Open Pouch

1. Choose the correct cartridge type to match the sample to be tested.
2. Tear open the aluminum foil pouch of the cartridge, then take out the cartridge and set it upright on the table.



#### Step 2: Prepare cartridge

Check whether the lyophilized reagent (a white pellet) is at the bottom of the sample chamber (indicated by arrow). If not, gently tap the cartridge on the table to make the lyo pellet drop to the bottom.







#### Step 3: Open Sample Chamber

Peel off the foil covering the sample loading port top surface. Make sure that no foil is left around the sample port (indicated by arrow).





<p><b>Step 4: Load Sample</b></p> <p>Use a pipette or an enclosed disposable transfer pipette to load sample or external control into the sample chamber. When using a pipette, please check the cartridge manual for the correct loading sample volume.</p> <p>Note that inactivating VTM/UTM containing guanidine is not compatible. Always use the suggested VTM/UTM for best results.</p> 	<p><b>Step 5: Close Lid</b></p> <p>Close the sample lid.</p> <p>NOTE: Press down the lid hard until a click is felt. When the lid is fully closed, it is flush with the rest of the cartridge top. Fail to fully close the lid may jam the system and cause contamination!</p> 	<p><b>Step 6: Load Cartridge</b></p> <p>Take off the chip cover (clear plastic) to expose black chip, so the cartridge is ready to load into the instrument.</p> 
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## • Load Cartridge

1. Click  button or use the barcode scanner to input the required sample ID and other optional sample information. This can be done after Step 5 as well, but it is highly recommended that you enter the sample ID before loading the cartridge to avoid mixing up the cartridges if you are loading multiple instruments at a time.
2. Press  button to open the door.
3. Insert cartridge into loading bay. Point the chip side to the left and push the cartridge all the way down until a click is felt. The system should tell you that cartridge is ready.
4. Press  button again to close the door. Flashing button means system is still working on closing door.
5. Wait until the instrument finishes reading the barcode and prompt the running interface. You have to enter the sample ID by either manual input or scanning a 1-D sample barcode. A run cannot be started until a sample ID has been entered.
6. Press  button to start the run.
7. The instrument will run the cartridge (the indicator light will be green) and report the result in about 50 minutes.

## • Unload Cartridge

1. View the result.
2. (Optional) Press “Approval” button to approve the result as needed.
3. Press “Home” button to return to the homepage.
4. Press  button to open the door.
5. Unload the cartridge and dispose it per user’s organization and local regulatory policies and procedures.
6. Press  button to close the door. The instrument will be in Standby mode (the indicator light will be blue).

## Results Interpretation

<b>+</b>	The target is detected (any of the assays related to the target reports positive).
<b>-</b>	The target is NOT detected (all assays related to the target report negative).
<b>Undetermined</b>	Suggest to re-test if no other targets test positive.
<b>Invalid</b>	No target is detected AND IC is invalid. Suggest to re-test.
<b>Error</b>	Test error has been reported during a test. Suggest to re-test if it is a cartridge error. Contact technical support if it is an instrument error. Please refer to instrument IFU for error code.

## Power Off

1. Press “Home” button to return to the homepage.
2. Press “Off” button and wait till the system shuts down and the screen is turned off. The fan will still be on.
3. Switch off the power switch at the back of the instrument.