

DASH® SARS-CoV-2 & Flu A/B Test
Quick Reference Guide

IVD

Rx Only

- For use with direct anterior nasal swab specimens.
- For laboratories with a CLIA Certificate of Waiver.
- Laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test.
- Store DASH® Rapid PCR Instrument and cartridge at room temperature (between 15°C and 30°C).

Warnings and Precautions

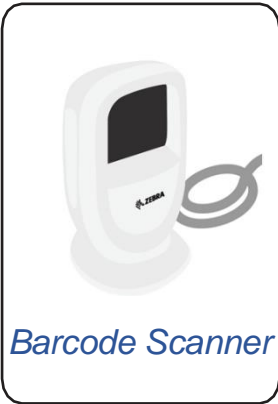
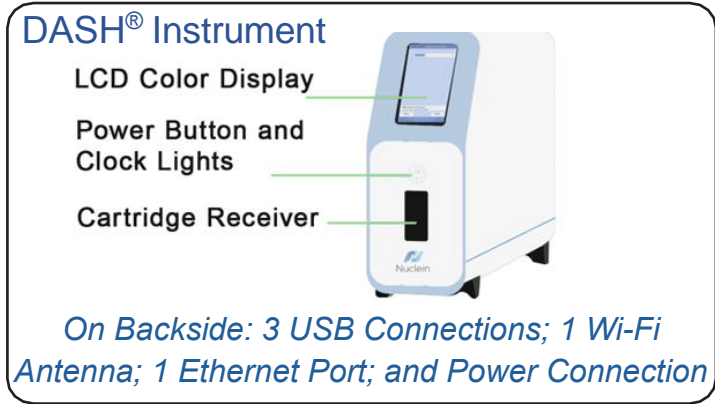
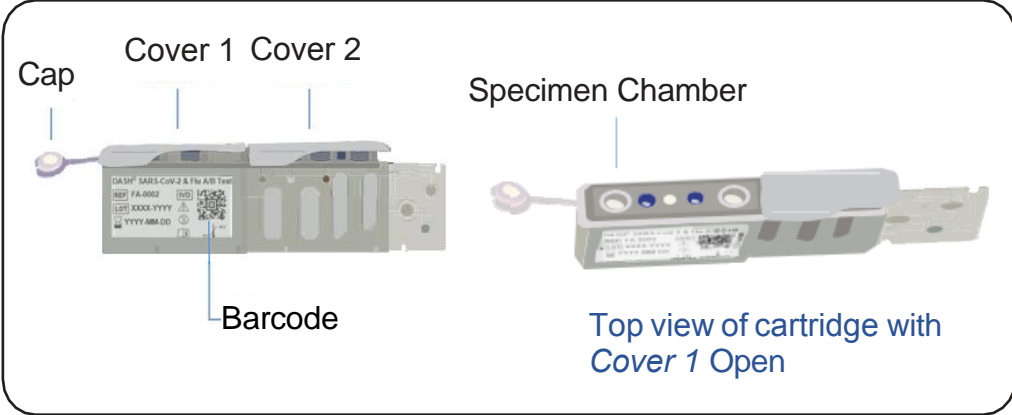
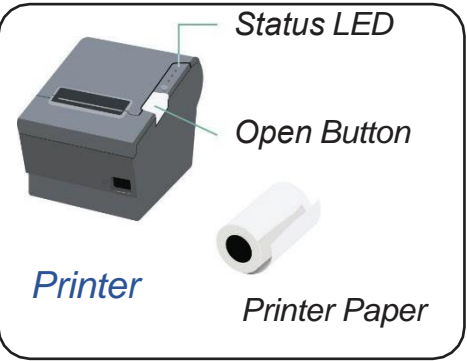
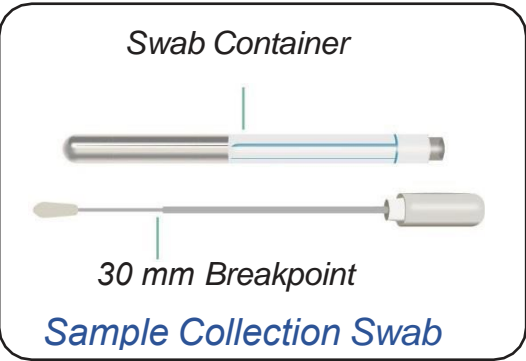
- **Before performing a test**, read the complete procedure outlined in this document. Quality Control procedures (IFU-06-021) must be followed before performing a test. Please refer to the assay Instructions for Use (IFU-06-022) and Instrument manual (IFU-06-023) for more information. These can be found at www.nuclein.com/Product-Documents.
- Conduct all testing on a level surface.
- **DO NOT** freeze the cartridge.
- **DO NOT** use a cartridge or swab if the package is damaged or open.
- **DO NOT** use a cartridge that is wet or has leaked.
- **DO NOT** use a cartridge if foil seals are broken.
- **DO NOT** use a test cartridge past its expiration date.
- **DO NOT** use a cartridge that has been dropped.
- **DO NOT** handle cartridge by the thin films or the *Cap*. Only handle by the labeled end, under *Cover 1*.
- **DO NOT** open cartridge *Cover 1* until you are ready to insert sample into *Specimen Chamber*.

Before You Begin

- Samples must be inserted into cartridge without delay after sample collection.
- Sample collection must be performed as per CDC guidance (cdc.gov/coronavirus)
- Cartridge must be kept at room temperature (15°C to 30°C) and run within one hour of sample insertion. Otherwise, the cartridge should be discarded and a new sample collected for testing.
- Environmental conditions for operating the DASH SARS-CoV-2 & Flu A/B Test are 15°C to 30°C; 20% - 80% RH; Altitude up to 1,676 meters (5,500 feet). Operating the test system outside of specifications may cause incorrect results.
- Keep work area clean to prevent contamination. Instrument exterior surface should be cleaned with 10% bleach (expressed as 0.6% sodium hypochlorite) followed by water, then 70% ethanol or 70% isopropyl.

DASH Rapid PCR System Materials (only use materials listed below)

- SG-0002 | DASH Instrument
- SG-0004 | DASH Accessories Kit
 - Barcode Scanner, Power Adaptor, Power Cord, Printer and Paper, Printer Cable
- SG-0006 | DASH SARS-CoV-2 & Flu A/B Test Kit
- SG-0008 | DASH SARS-CoV-2 & Flu A/B Positive Control Swabs Kit
- SG-0010 | DASH Negative Control Swabs Kit
- SG-0012 (Puritan 25-3606-U BT) | Sample Collection Swabs
- Powder Free Gloves



Quality Controls: External Positive and Negative Controls

Quality controls must be used to show that the test is working properly. The DASH® SARS-CoV-2 & Flu A/B Positive Control (SG-0008) and DASH Negative Control (SG-0010) are available separately.

Environmental Conditions: External Controls

DASH SARS-CoV-2 & Flu A/B Positive Control and DASH Negative Control swabs must be stored at room temperature (15°C to 30°C).

Instructions for Use for Running External Controls

Controls are tested using the same procedure as for a patient sample, but instead of scanning the patient sample barcode, scan the barcode on the control swab packaging. See IFU-06-021 for additional instructions.

Test external controls at the times noted below:

- Each time a new lot of DASH® SARS-CoV-2 & Flu A/B Test cartridges is received.
- Each time a new operator performs the test.
- When the instrument is used for the first time for a specific test.
- As deemed additionally necessary by internal quality control procedures, and in accordance with local, state and federal regulations or accreditation requirements.

External Controls: Expected Results

CONRTOL	EXPECTED RESULT	INTERPRETATION
Positive	Flu A: PASS	Flu A target RNA is detected.
	Flu B: PASS	Flu B target RNA is detected.
	SARS-CoV-2: PASS	SARS-CoV-2 target RNA is detected.
	Procedural Control: Valid	Amplification meets acceptance criteria.
Negative	Flu A: PASS	Flu A target RNA is not detected.
	Flu B: PASS	Flu B target RNA is not detected.
	SARS-CoV-2: PASS	SARS-CoV-2 target RNA is not detected.
	Procedural Control: Valid	Amplification meets acceptance criteria.

Test Result Interpretation

TARGET	RESULT	INTERPRETATION
SARS-CoV-2	POSITIVE	The target nucleic acids of SARS-CoV-2 are detected.
	NEGATIVE	The target nucleic acids of SARS-CoV-2 are not detected.
Flu A	POSITIVE	The target nucleic acids of Flu A are detected.
	NEGATIVE	The target nucleic acids of Flu A are not detected.
Flu B	POSITIVE	The target nucleic acids of Flu B are detected.
	NEGATIVE	The target nucleic acids of Flu B are not detected.
Procedural Control	VALID	Amplification meets acceptance criteria.
	INVALID	Presence or absence of the target nucleic acids cannot be determined. Repeat test with a new cartridge.*
ERROR		Presence or absence of the target nucleic acids cannot be determined. DASH Instrument detected an error and aborted the current test. Repeat test with a new cartridge.*

* If repeat test also results in an error or invalid, please contact Nuclein Customer Support at customersupport@nuclein.com or 1-888-992-DASH.

Nuclein Customer Support:

Phone: 1-888-992-DASH | Email: customersupport@nuclein.com
Nuclein, LLC, 8305 Cross Park Drive, Austin, Texas 78754
www.nuclein.com

1. Initialize DASH® Instrument:

- a) Press the power button to turn on the DASH Instrument.
- b) Wait for instrument to initialize and complete the warm-up process.
- c) Select username from the drop-down menu.
- d) Enter your 5-digit PIN. Touch “Enter.”
- e) The instrument is now ready to run a test.

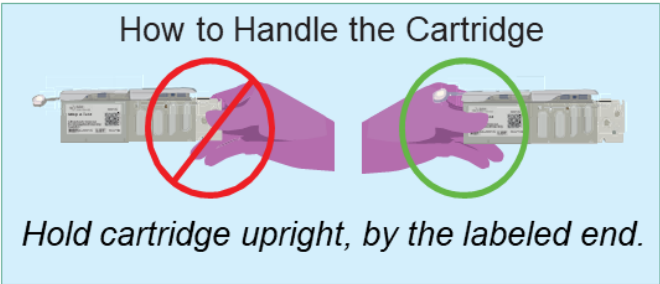


2. **Collect Patient Sample:** Insert the entire collection tip of the swab (usually ½ to ¾ of an inch, or 1 to 1.5 cm) inside the nostril. Gently rotate swab in a circular motion against the nasal wall at least 4 times. Using the same swab, repeat collection with the other nostril. Once complete, immediately prepare cartridge and add sample to cartridge without delay.

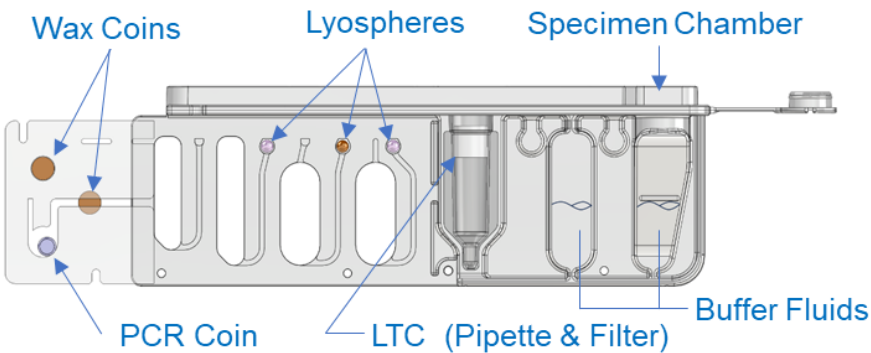


3. Prepare Cartridge:

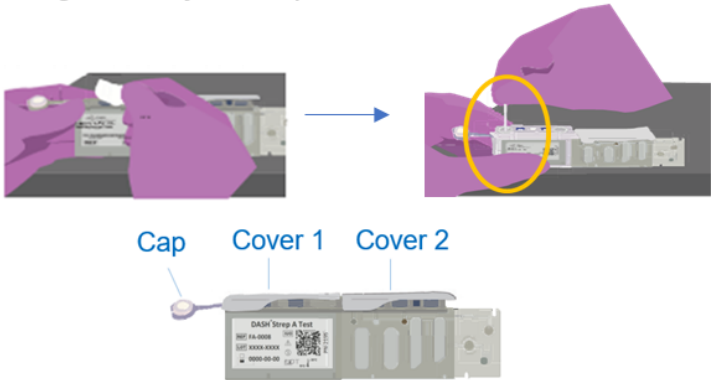
- a) Remove cartridge from packaging.



- b) Inspect cartridge prior to use. Make sure it appears to be intact.



- c) Hold cartridge upright on flat surface (as shown below). Peel off *Cover 1* and immediately insert sample swab into *Specimen Chamber*. **DO NOT** open *Cover 1* until testing is ready to be performed.

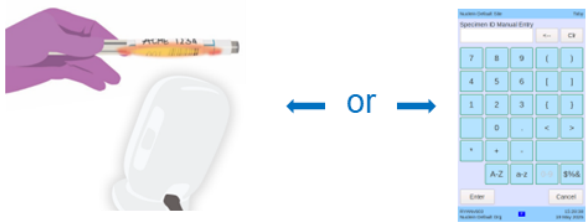


- d) Break off the swab stem at 30 mm breakpoint, then close the cartridge *Cap* by snapping it into place.



4. Scan Barcodes:

- a) Scan the patient sample barcode, or enter the specimen ID on the keypad and touch “Enter”.



- b) Scan the cartridge barcode.



5. Sample and Cartridge Confirmation:

- a) Confirm *Specimen Chamber* contains the swab tip and cartridge *Cap* is closed.
- b) Hold cartridge upright on flat surface (as shown below).
- c) Peel off *Cover 2*. Touch the “Open” button on the instrument screen, then touch the “Seal Removed” button. **DO NOT** remove *Cover 2* until the cartridge is ready to be inserted into the DASH Instrument.



6. Run Test:

- a) Insert the cartridge.



- b) Test will run automatically. Blue lights on the front of the instrument indicate progress.

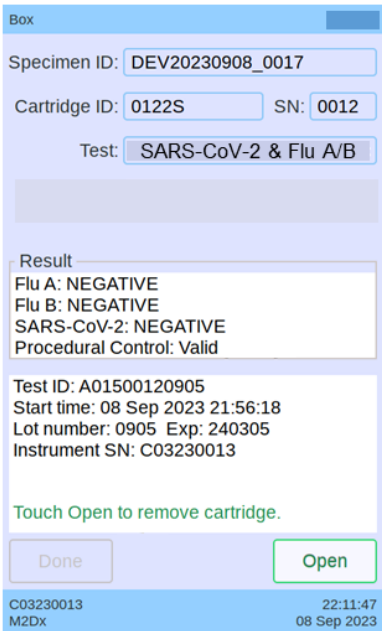


7. Complete Test:

- a) After test is complete, results are displayed on the screen and will print automatically.



- b) Touch “Open” to remove the cartridge.



- c) Discard the used cartridge in biohazard waste as per site procedures.