

DASH SARS-CoV-2/S Test Quick Reference Guide

Please refer to the Instructions for Use (IFU) for more detailed information.
Please refer the Package Insert for Specimen Collection and Handling.

- IVD** For use under Emergency Use Authorization (EUA) Only
- For Direct Anterior Nasal Swab Specimens
- For *in vitro* Diagnostic Use
- For Rx Use Only

 Store DASH Analyzer and Cartridges at room temperature (between 15°C and 30°C).

- DO NOT** use a Cartridge that is wet or has leaked.
- DO NOT** use a Cartridge whose top Covers are not intact.
- DO NOT** use a Cartridge that has been dropped.
- DO NOT** open Cartridge Cover #1, until you are ready to perform testing.

- DO NOT** open Cartridge Cover #2, until you are ready to insert Cartridge into the machine.
- DO NOT** flip Cartridge over after peeling off Cover.
- DO NOT** hold the Cartridge with the back end next to the Cover #2.

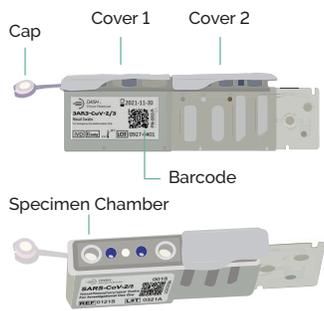
This product has not been FDA cleared or approved; but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.

This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3 (b)(1), unless the declaration is terminated, or authorization is revoked sooner.

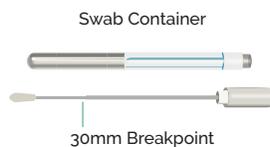
Materials Provided

DASH SARS-CoV-2/S Cartridge

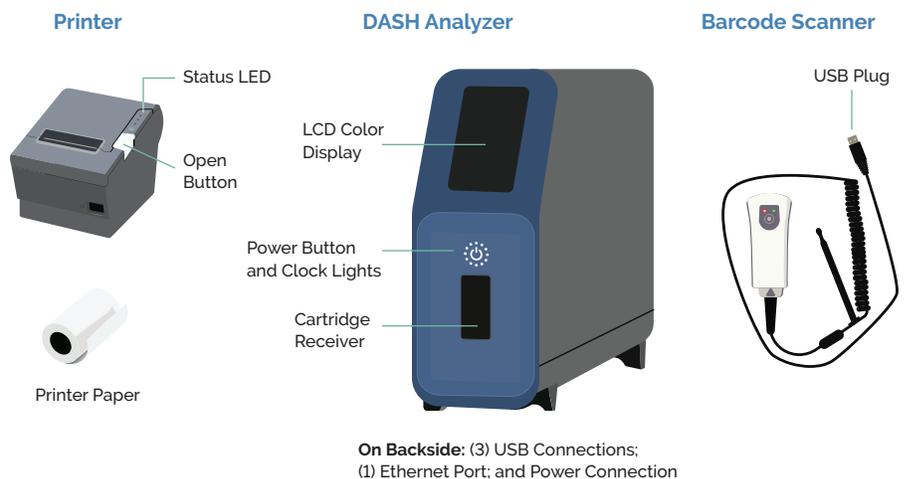


(Top View of Cartridge With Cover 1 Open)

Patient Swab



Required But Not Provided



Before You Begin

- Direct anterior nasal swabs can be stored at room temperature (15-30°) for up to 48 hours until testing is performed on the DASH analyzer.
- The environmental conditions for operating DASH SARS-CoV-2/S test are 15-30°C, 20%-80% relative humidity.
- Follow the step-by-step instructions on the DASH Analyzer screen.

Video Tutorials



Unpacking



Setup



Running a Quality Control Sample



Running Patient Samples

TEST PROCEDURES begin on back

Test Procedure: How to Test a Patient Specimen

1. Turn DASH Analyzer on and Login

When the DASH Analyzer is switched on, by pressing the Power Button, or after another User has logged out, the drop down list of usernames will be displayed.

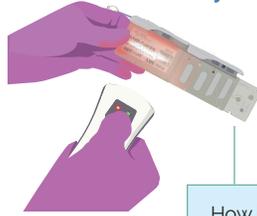


Select your username, and enter your 4-digit PIN and touch "Enter."

2a. Scan specimen barcode



2b. Scan Cartridge barcode. Run test immediately.

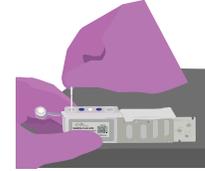


3. Follow instructions on the screen to prepare the specimen and Cartridge

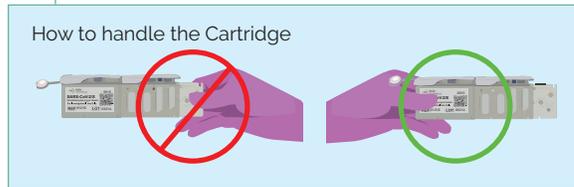
3a. Peel off Cover #1



3b. Insert Swab into Specimen Chamber.

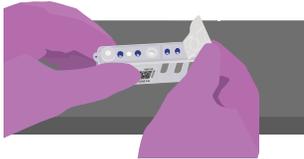


3c. Break off Swab stem and discard, and close Cartridge cap

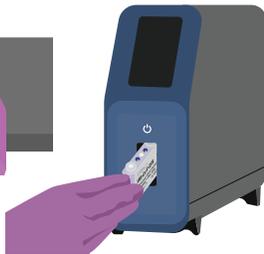


How to handle the Cartridge

4. Peel off Cover #2. Run test immediately.



5. Insert the Cartridge



6. Test will run automatically. Light will indicate progress.



Power button with clock lights

7a. After test is completed; the results will also print automatically.



7b. Touch "Open" to remove Cartridge.



Result Interpretation

RESULT	INTERPRETATION
SARS-CoV-2 NEGATIVE	The 2019 novel coronavirus (SARS-CoV-2) target nucleic acids are not detected.
SARS-CoV-2 POSITIVE	The 2019 novel coronavirus (SARS-CoV-2) target nucleic acids are detected.
INVALID	Presence or absence of the 2019 novel coronavirus (SARS-CoV-2) target nucleic acids cannot be determined. Repeat test with a new nasal specimen and new cartridge.
ERROR	Presence or absence of the 2019 novel coronavirus (SARS-CoV-2) target nucleic acids cannot be determined. Repeat test with a new nasal specimen and new cartridge. Analyzer detected an error and aborted the current test.

Quality Controls: Positive and Negative Controls

Controls must be used to show that the Test is working properly. The DASH SARS-CoV-2/S Test Positive Control Swab (REF 0314P) and DASH SARS-CoV-2/S Test Negative Control Swab (REF 0315N) are available separately.

The DASH SARS-CoV-2/S Test Positive and Negative Control Swabs must be stored at room temperature. Controls are tested using the same procedure as for a patient sample, but instead of scanning the patient specimen barcode, scan the barcode on the Control Swab packaging.

It is recommended that external controls be tested at the frequency noted below.

- Each time a new lot or a new shipment of DASH SARS-CoV-2/S Test is received.
- Each time a new operator is performing the test.
- When the Analyzer is used for the first time.
- When the software is upgraded.
- When problems are suspected or identified.
- As deemed additionally necessary by internal quality control procedures, and in accordance with Local, State and Federal regulations or accreditation requirements.

If correct control results are not obtained, repeat the test using a new Control Swab, and a new test Cartridge.

If the control testing continues to fail, do not perform additional clinical specimen tests or report results.

If the positive or negative external controls fail, repeat with new external control and a new DASH SARS-CoV-2/S Test.

If the repeat test fails, please contact Minute Molecular Technical Support at 1-888-992-DASH or techservice@m2dx.com.