

DASH® SARS-CoV-2 & Flu A/B Positive Control and DASH® Negative Control

Instructions for Use – IVD

REF SG-0008 | DASH® SARS-CoV-2 & Flu A/B Positive Control Swabs Kit

REF SG-0010 | DASH® Negative Control Swabs Kit

IVD **CONTROL** **Rx Only**



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INTENDED USE:

DASH® SARS-CoV-2 & Flu A/B Positive Control and **DASH Negative Control** swabs are intended for use as external assay quality controls to monitor the performance of the DASH SARS-CoV-2 & Flu A/B Test performed on the DASH Rapid PCR Instrument, and to confirm that the test cartridge and DASH Rapid PCR Instrument are functioning as intended.

PRODUCT SUMMARY

The **DASH SARS-CoV-2 & Flu A/B Positive Control** swab is comprised of cultured and inactivated influenza A, influenza B, SARS-CoV-2 virus and human A549 lung epithelial cells, whereas the **DASH Negative Control** is a blank swab, void of all media.

Viral components of the swab have been inactivated using irradiation and chemical treatments, and the human cells have been inactivated using thermal treatment. The solution is dried onto a ready-to-use swab.

Each control (positive or negative) is run as an individual sample in the exact method and process as a DASH SARS-CoV-2 & Flu A/B Test patient sample.

MATERIALS PROVIDED:

Each control kit is comprised of five (5) single-use, individually packaged, breakable swabs.

MATERIALS NOT PROVIDED but REQUIRED:

SG-0002 | DASH Rapid PCR Instrument
SG-0006 | DASH SARS-CoV-2 & Flu A/B Test Kit

STORAGE and STABILITY:

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

Controls are stable through the expiration date printed on the kit label.

DASH SARS-CoV-2 & Flu A/B Positive Control and **DASH Negative Control** swabs are for single use only. Discard after use according to your local, state, and federal regulations.

WARNINGS, LIMITATIONS, and PRECAUTIONS:

- Caution: Federal law restricts this device to sale by or on the order of a physician.
- Before performing the test, read the DASH Rapid PCR System Instrument Manual (IFU-06-023) and DASH SARS-CoV-2 & Flu A/B Test Instructions for Use (IFU-06-022) completely.
- This product is intended for *in vitro* diagnostic use only.
- Prior to use, inspect product for damage. **DO NOT** use if packaging is damaged.
- Positive control may contain biological material of human origin. Universal precautions are required when handling this product.
- **DO NOT** use product past its expiration date.
- **DO NOT** reuse control swabs.
- All components of this kit should be discarded as Biohazard waste according to local, state, and federal regulatory requirements. Observe established precautions against microbial hazards during use and disposal.
- Inadequate or inappropriate storage and transport may yield false test results.
- Keep work areas clean to prevent contamination.
- Wear appropriate personal protective equipment and gloves when running each test. Change gloves between handling each sample.

TEST PROCEDURE:

1. **DASH SARS-CoV-2 & Flu A/B Positive Control** and **DASH Negative Control swabs** are for single use only.
2. Leave control swab in individually sealed package (pouch/sleeve) until just before use. **DO NOT** use if sealed package is damaged or open.
3. 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. For complete instructions, refer to the DASH SARS-CoV-2 & Flu A/B Test IFU (IFU- 06-022) and QRG (QRG-06-002).
Note:
 - If correct control results are not obtained, repeat the test using a new control swab and a new DASH SARS-CoV-2 & Flu A/B Test cartridge.
 - If the control test fails upon repeat testing, contact customer support and do not perform additional clinical tests or report results for the DASH SARS-CoV-2 & Flu A/B Test.
4. Discard after use according to your local, state, and federal regulations.

It is recommended that external controls be tested 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 DASH SARS-CoV-2 & Flu A/B Test.
- When the DASH Rapid PCR Instrument is used for the first time.
- As deemed additionally necessary by internal quality control procedures, and in accordance with local, state, and federal regulations or accreditation requirements.

EXPECTED RESULTS:

Control	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.

If the QC result indicates “FAIL” or “Invalid”, repeat the test (returning to Step 1 for the test procedure).

If QC results do not “PASS” a second time, contact customer support at customersupport@nuclein.com or 1-888-992-DASH.

REPRODUCIBILITY:

Reproducibility of the DASH SARS-CoV-2 & Flu A/B Positive Control and DASH Negative Control was also assessed through the multi-site evaluation. The study was conducted using three (3) lots each of the **DASH SARS-CoV-2 & Flu A/B Positive Control** and **DASH Negative Control**, and evaluated by nine (9) untrained operators across three (3) sites, and performed over five (5) non-consecutive days, totaling 90 samples tested throughout the course of the study. Three (3) lots of external controls were distributed evenly across all three (3) sites. Qualitative results are summarized in the table below:

Control Type	Passing Results	% Pass (95% CI)
Negative	45/45	100.0% (92.1% -100.0%)
Positive*	45/45	100.0% (92.1% -100.0%)

*All three analytes detected in all 45 Controls

ORDERING INFORMATION:

SG-0008 | DASH SARS-CoV-2 & Flu A/B Positive Control Swabs Kit

SG-0010 | DASH Negative Control Swabs Kit

CUSTOMER SUPPORT:

Phone: 1-888-992-DASH

Email: customersupport@nuclein.com

Website: www.nuclein.com

MEDICAL DEVICE REPORTING:

MedWatch is an FDA program that supports voluntary reports of FDA-regulated products. MedWatch contact information is provided below:

Phone: 1-800-FDA-1088 **Fax:** 1-800-FDA-0178

Website: www.fda.gov/medwatch

TABLE OF SYMBOLS:

	Catalog Number		Manufacturer
	Batch Code or Lot Number		Use by or Expiration Date
	Control	Rx Only	Prescription Device
	Positive Control		Caution
	Negative Control		Do Not Re-use
	Temperature Limitations		Biological Risks
	In vitro Diagnostic medical device		Unique Device Identifier
	Consult Instructions for Use		Contains Sufficient for <n> Tests