INSTRUCTIONS FOR USE

IVD

For use under FDA Emergency Use Authorization (EUA) Only

For Prescription Use Only

REF PS-400381 Respiratory Health Control Swabs

visby medical™

INTENDED USE

The Respiratory Health Control Swabs (inactivated) are intended for use as an external positive and negative quality control to monitor the performance of the Visby Medical Respiratory Health Test. The positive control is comprised of cultured and inactivated Influenza A, Influenza B, and SARS-CoV-2 virus. The negative control is comprised of human A549 lung epithelial cells. This product has no qualitative or quantitative assigned value. This control material is nonautomated and not intended to be used for screening, monitoring, or diagnosis. This control is not intended for any specific patient population or specimen.

SUMMARY AND PRINCIPLES

The Respiratory Health Control Swabs (inactivated) can be used to monitor the Visby Medical Respiratory Health Test. Routine use of quality controls monitors test variation, lot-to-lot test kit performance, operator performance, and aid in identifying random or systemic error.

COMPOSITION

The Respiratory Health Control Swabs (inactivated) consists of 2 individually packaged positive control swabs and 2 individually packaged negative control swabs. The viral particles have been inactivated using irradiation and chemical treatments, and the human cells have been inactivated using thermal treatment. The positive control swabs contain Influenza A (H1N1) Strain California/04/09, Influenza B Virus Strain Hong Kong/5/72, and Severe Acute Respiratory Syndrome Coronavirus 2 isolate. The negative control swabs contain human A549 lung epithelial cells. The organisms are prepared in a buffered solution with materials of plant and animal origin, preservatives, and stabilizers. The solution is lyophilized into a ready-to-use swab.

WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic use. For use under emergency use authorization (EUA) only. For prescription use only.
- For professional use only. To be used by operators who have received specific training in the use of the Visby Medical Respiratory Health Test.
- Do not open foil pouch until ready to use.
- This product must be handled in accordance with Biosafety Level 1 practices as described in the United States Department of Health and Human Services Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH), Biosafety in Microbiological and Biomedical Laboratories, or other equivalent guidelines. Although this product has been inactivated; there is no known test or inactivation method that can assure that this product will not transmit infection.
- Wear proper personal protective equipment.
- Refer to the Safety Data Sheet (SDS) for more detailed information. The SDS can be located on the Visby website at **www.visbymedical.com** or by contacting Customer Support at 1-833-GoVisby (1-833-468-4729)
- This product does not contain any hazardous substances listed in 67/548/EEC or listed in1272/2008/EC.
- This product is not made with natural rubber latex.
- 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 and differentiation of nucleic acid from SARS-CoV-2, influenza A, and influenza B, not for any other viruses or pathogens; and
- 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 REQUIRED BUT NOT PROVIDED

- Visby Medical Respiratory Health Test (PS-400005)

INSTRUCTIONS FOR USE

1. Read the instructions for use and/or Quick Reference Guide for the Visby Medical Respiratory Health Test.
2. Obtain a Visby Respiratory Health Buffer Tube and Visby Respiratory Health device.
3. Tear open swab pouch at notch. Remove swab from pouch and place into the Visby Respiratory Health Buffer tube.
4. Gently tap the swab on the bottom of the tube 5 times, then discard the swab in accordance with your institution's instructions. Screw the cap back onto the tube.

5. Go to Step 2 of the Visby Medical Respiratory Health Test instructions for use or Quick Reference Guide to run the test with a Visby Respiratory Health device.
6. Interpret the results as described in the Quality Control section of the Visby Medical Respiratory Health Test instructions for use or Quick Reference Guide.
7. Note: Each swab is intended as a single use test.

EXPECTED RESULTS

- The Positive Control should yield a positive Influenza A, Influenza B, and SARS-CoV-2 result.
- The Negative Control should yield a negative result.

STORAGE AND EXPIRATION

Store the Respiratory Health Control Swabs (inactivated) at 2°C - 25°C in the original packaging up to the indicated expiration date. After opening the foil pouch, use the swab immediately.

The Respiratory Health Control Swabs (inactivated) should not be used if:

- Stored improperly.
- There is evidence of excessive exposure to heat or moisture.
- The expiration date has passed.

LIMITATIONS

For use only with the Visby Medical Respiratory Health Test.

MICROBIOLOGICAL STATE

This product was prepared using suitable inactivation methods. While the product has been tested for innocuity, universal laboratory precautions are recommended, and material should be treated as though it was a viable specimen.

KEY OF SYMBOLS

Symbol	Meaning	ISO 15223-1 Ref. Number
REF	Catalog number	5.1.6
	Do no reuse	5.4.2
LOT	Batch code	5.1.5
	Caution	5.4.4
	Consult instructions for use	5.4.3
	Manufacturer	5.1.1
	Expiration date	5.1.4
	Temperature limitation	5.3.7
	Biological risk	5.4.1
IVD	*In vitro* diagnostic medical device	5.5.1
CONTROL + / CONTROL −	Positive / negative controls	5.5.4 / 5.5.3
Σ	Contains sufficient for <n> tests	5.5.5

Visby Medical, Inc.
3010 North First Street
San Jose, CA 95134

Email: support@visby.com
Website: www.visby.com
Customer Support: 1-833-GoVisby (1-833-468-4729)