Laboratory Name:
Laboratory Address:
Date:

Visby Respiratory Health Test

Clinical and Laboratory Standards Institute Procedure

This CLSI test procedure template is intended to provide an outline reference for the procedure and performance of the Visby Respiratory Health Test. This document is not intended to replace the complete Instructions for Use. Any modifications to this document are the sole responsibility of the Institution.

1. Intended Use

The Visby Medical Respiratory Health Test is a single-use (disposable), fully integrated, rapid, automated RT-PCR in vitro diagnostic test intended for the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B viral RNA in healthcare provider-collected nasopharyngeal and anterior nasal swab specimens, and healthcare provider-instructed self-collected anterior nasal swab specimens (collected on site) from individuals with signs and symptoms of respiratory tract infection consistent with COVID-19. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high, moderate, or waived complexity tests. The Visby Medical Respiratory Health Test is authorized for use at the Point of Care (POC), i.e., inpatient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the simultaneous detection and differentiation of SARS-CoV-2, influenza A, and influenza B viral RNA in clinical specimens and are not intended to detect influenza C virus. SARS-CoV-2, influenza A, and influenza B viral RNA are generally detectable in nasopharyngeal and anterior nasal swab specimens during the acute phase of infection.

Positive results are indicative of the presence of SARS-CoV-2, influenza A, and/or influenza B nucleic acid, but do not rule out bacterial infection or co-infection with other pathogens not detected by the test. Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. The agent detected may not be the definitive cause of disease. Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities. Negative results for SARS-CoV-2, influenza A, and influenza B are presumptive and should be confirmed with an alternative molecular FDA-cleared or authorized assay, if necessary, for patient management. Negative results do not preclude SARS-CoV-2, influenza A, and/or influenza B infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and/or epidemiological information.

The Visby Medical Respiratory Health Test is intended for use by operators who have received specific training in the use of the Visby Medical Respiratory Health Test. The Visby Medical Respiratory Health Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

2. Principles of the Procedure

The Visby Medical Respiratory Health Test is a single-use (disposable), fully integrated, fast, compact device containing a reverse transcription polymerase chain reaction (RT-PCR) based assay for qualitative detection of influenza A, influenza B, and/or SARS-CoV-2 viral RNA in upper respiratory tract specimens. The device automatically performs all steps required to complete lysis, reverse transcription (RT), PCR amplification, and detection.

Specimens collected using nasopharyngeal (NP) or anterior nasal (AN) swabs (without transport media) are placed in the Visby Medical Respiratory Health Buffer and then transferred into the sample port of the device using the provided fixed volume pipette. The sample enters a lysis module and rehydrates the RT enzyme and RT primers. The mixture then moves through a sample preparation module where viruses and human cells are simultaneously lysed, and RNA is reverse transcribed. The resulting fluid (containing cDNA) is then mixed with lyophilized PCR reagents containing the DNA polymerase enzyme and PCR primers. The PCR mixture (containing cDNA template and reagents) is then thermal cycled to amplify the targets, including human beta-2 microglobulin (B2M) RNA, which serves as a process control. After PCR, the biotinylated product is hybridized to covalently bound capture probes at specific locations along a flow channel. The flow channel is configured to facilitate an enzymatic reaction that uses streptavidin bound horseradish peroxidase (HRP) and a colorimetric substrate that forms a purple precipitate. The operator observes a color change at the specific locations indicating the presence of an amplified target. Test results can be expected in approximately 30 minutes: illumination of a “DONE” status light on the front of the device and a purple color in the “RESULTS VALID” 4 spot, indicate a successful test. A purple spot adjacent to “Flu A”, “Flu B”, and/or “COVID-19” signifies the presence of, influenza A, influenza B, and/or SARS-CoV-2 viral RNA

3. Specimen Collection and Handling

Specimen Types	Nasopharyngeal swab-collected by a Health Care Provider (HCP) Anterior Nasal swab-collected by patient or HCP
Patient Sample Storage Specifications	For best results, patient collected samples should be tested as soon as possible. If storage is required, specimens can be held: 2 hours at room temperature 59°F - 86°F (15°C-30°C) or 48 hours refrigerated temperature 36-46°F (2°C-8°C)

4. Materials

Materials Provided in 10 pack Test Kit	10 Visby Medical Respiratory Health Devices 12 Pipettes 12 Visby Respiratory Health Buffer Tubes 12 Disposal Bags 1 Quick Reference Guide
Materials Required and Available as Accessories	Visby Power Adapter External Controls
Required but Not Supplied	Gloves Disposal Bin Swabs
External Controls	Respiratory Health Control Swab Kit: • 2 Positive Swabs • 2 Negative Swabs

5. Test Kit Storage

Store the Visby Medical Respiratory Health Test kit between 36°F and 86°F (2°C and 30°C), and 5% and 80% humidity. Do not freeze. If exposed to cold temperatures, ensure that the Visby Medical Respiratory Health Test device is allowed to come to room temperature (at least 55°F [13°C]) prior to use.

6. Quality Control

Internal Procedural Controls

The Visby Medical Respiratory Health device contains an internal process control assay that targets human beta-2 microglobulin (B2M) RNA. The internal process control monitors lysis, reverse transcription, PCR amplification, and detection. If these steps are completed successfully, then a purple spot will develop next to “Results Valid” in the results window. If the purple spot does not appear, the test result is Invalid, and the test must be repeated with a new Visby Medical Respiratory Health device.

Electronic Control

The electronic controls monitor the device to ensure proper operation. If the electronic control passes, a green *done* status light appears. If this control fails, the white status light will fail to illuminate or will flash.

If the power light is blinking:

• The device is outside operating temperature (55ºF–88ºF or 13ºC–31ºC).

• If the room is in the right temperature range, wait for the device to reach operating temperature. The power light will become stable when that happens.

• If the room is too cold or too hot, move to a different location within the operating

temperature range. • Wait until the power light is stable before loading the sample.

If the power light and progress lights are blinking together:

• The device has encountered an error and is no longer functional.

• Refer to the Retesting Instructions.

External Positive and Negative Controls

External Controls must be run once with each new shipment and once for each new operator. Further controls may be tested in order to conform with local, state and/or federal regulations, accrediting groups, or your lab’s standard Quality Control procedures.

7. Test Procedure

Please follow instructions carefully. This test is designed for use by Health Care Professionals.

Operating Conditions

TEMPERATURE **55°F - 88°F** (13° - 31°C)	HUMIDITY **5%-80%**	Run the test on a clean, level surface. Test samples within 2 hours of collection (at room temperature) or 48 hours (at refrigerated temperatures)

Step 1 | Add Patient Swab to Visby Respiratory Health Buffer Tube

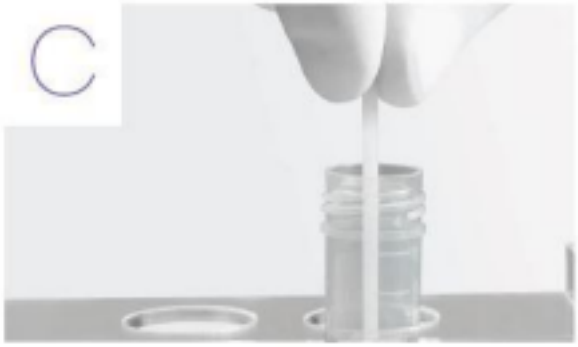
A

Open the Visby Respiratory Health Buffer Tube and **place it** in tube holder.

B

Take the patient swab.

C



Place the patient swab into Visby Respiratory Health Buffer Tube. Note: **Break the handle** of the swab.

D

With the swab in the tube, screw cap back onto the Visby Respiratory Health Buffer Tube. Label the tube. **Note the time.**

Step 2 | Mix and Add Patient Sample

A

Mix the sample by **gently inverting** the tube **5 times**. Note: Failure to invert may lead to inaccurate results.

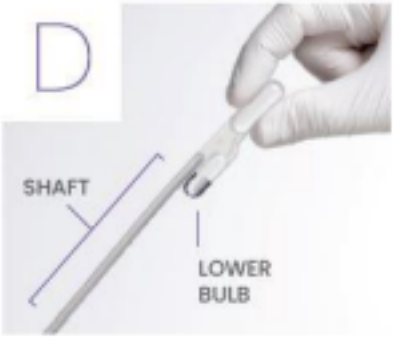
B

Squeeze the **upper bulb** of the provided pipette and submerge the tip to the **bottom** of the sample tube.

C

Release the upper bulb **slowly** to fill the shaft. **Keep pipette tip submerged** until shaft is full. Extra fluid should enter the lower bulb.

D

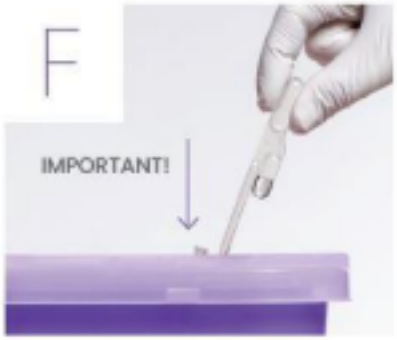


Ensure the **shaft** is filled with liquid sample. Note: Do not squeeze lower bulb or invert the pipette.

E

Place the tip at the **bottom** of the sample port and then squeeze the **upper bulb** of the pipette to release **all** of the sample.

F



Some fluid will remain in the lower bulb. Discard the pipette according to your institution's guidelines immediately. **Do not set down.**

Step 3 | Run the Test

⚠ Do not move test while running.

⚠ Run the test immediately after adding patient sample.

A

Slide the **switch upwards** in a firm, swift motion to close the sample port to start the test. **Do not move test while running.** Note: Make sure the switch is pushed all the way up.

B

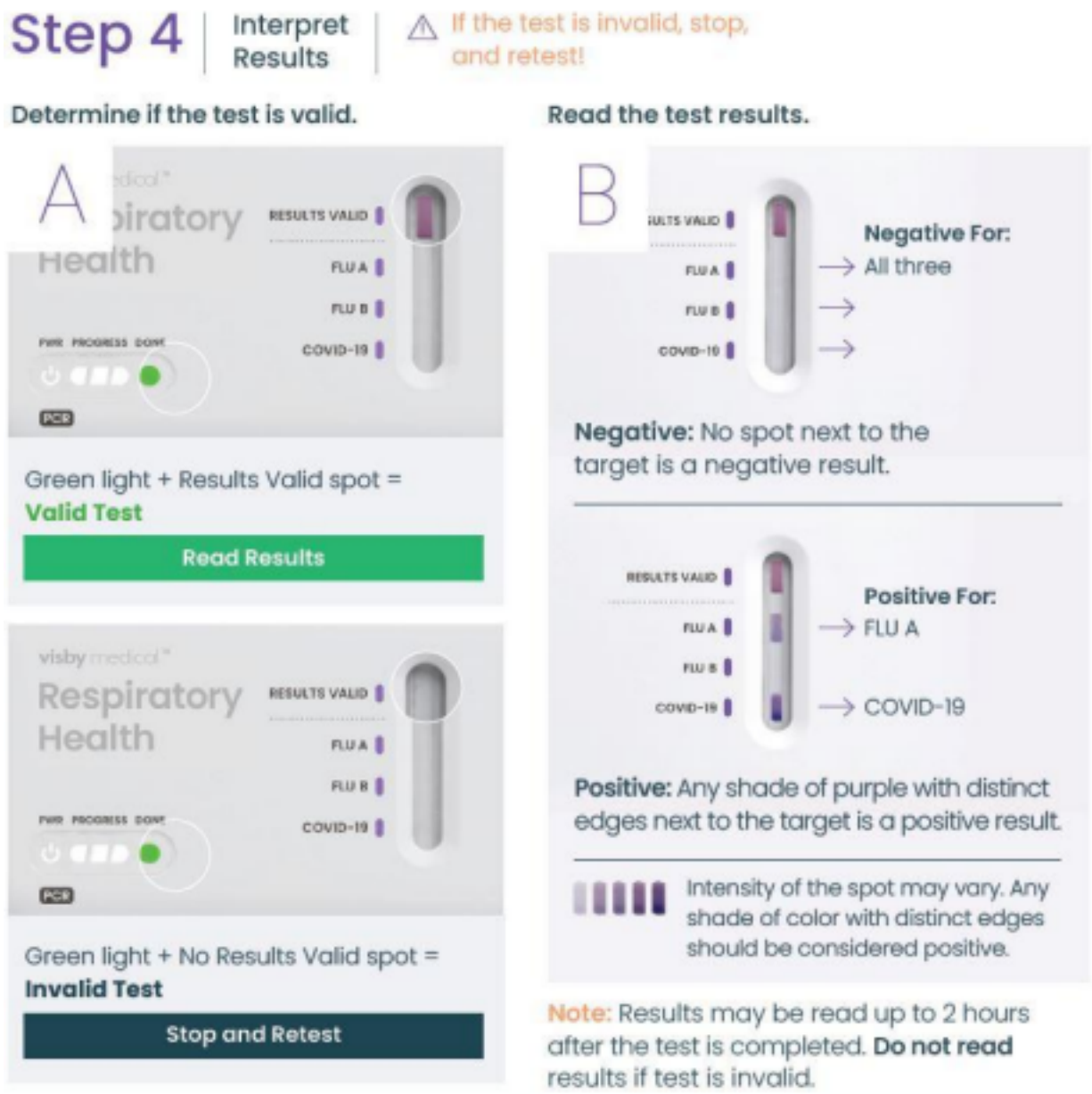
Check that the first **progress indicator light is blinking**. Lights will initially blink and then become stable as the test progresses. Note: If something different happens to the lights, please refer to the Troubleshooting Section.

C

The second progress indicator light should become stable within **20 minutes**.

D

Wait approximately **30 minutes** for a green light to appear indicating the test is finished running.



The Visby Respiratory Health device, pipette, and Specimen should be disposed of in accordance with local regulations.

8. Retest Procedure

If a retest is required, obtain the leftover sample from the Visby Respiratory Health Buffer tube. If the leftover sample has been stored for ≤ 120 minutes at room temperature or for ≤ 48 hours at refrigerated temperature, then it is stable and can be re-tested with a new device. If the leftover sample has exceeded the storage recommendations, and/or if the sample volume is insufficient, collect a new sample and repeat the test with a new Visby Medical Respiratory Health Test.

If a repeat test with a patient sample fails, collect a new sample for testing or contact Visby Medical Customer Support at 1-833-468-4729 (1-833-GoVisby).

9. References/Related Documents

Visby Medical Respiratory Health Instructions for Use, DR-400003
Visby Medical Respiratory Health Quick Reference Guide, DR-400004