visby medical™

COVID-19
Point of Care

Package Insert

For the qualitative detection of SARS-CoV-2 nucleic acid. For IVD Use. For Rx only. For Emergency Use Authorization Only.

IVD Rx ONLY

REF PS-001541

PS-001418 Rev C07/22

visby medical™

COVID-19

Point of Care

Name

Visby Medical COVID-19 Point of Care Test

Common or Usual Name

Visby COVID-19 Point of Care Test

Intended Use

The Visby Medical COVID-19 Point of Care Test is a single-use (disposable), fully-integrated, fast, automated RT-PCR in vitro diagnostic test intended for the qualitative detection of SARS-CoV-2nucleic acid in nasopharyngeal, anterior nasal (nasal), or mid-turbinate swabs, collected by a health care provider (HCP) or anterior nasal or mid-turbinate swabs self-collected (by individuals 18 years of age or older, under the supervision of an HCP) from individuals suspected of COVID-19 by their HCP. 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 COVID-19 Point
of Care Test is authorized for use at the Point of Care (POC) i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the identification of SARS-CoV-2 RNA. The SARS- CoV-2 R is generally detectable in respiratory specimens during the acute ph of infection. Positive results are indicative of the presence of SARS-Co 2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection stat Posit results do not rule out bacterial infection or co-infection with her viruses. The agent detected may not be the definitive cause of ease. Laboratories within the United States and its terr ies are requ d to report all results to the appropriate public he th auth s. Neg ive results do not preclude SARS-CoV-2 infecti and should not s the sole basis for patient management isions. Negative results must be combined with clinical observations, ient hist , and epidemiological information.

The Visby Medical COVID-19 Care T is inten d for use by laboratory personnel wh ave rece ed speci ng on the use of the Visby Medical CO -19 Point Care Test. Th Visby COVID-19 Point of Care Test is only for u unde e F rug Administration's Emergency Use Authorizat

Summary and Explanation of the Procedure

The Visby COVID-19 Point of Care Test is a fast, instrument-free, single-use (disposable) molecular in vitro diagnostic testfor the qualitative detection of ribonucleic acid from the SARS-CoV-2 virus. The Visby COVID-19 Point of Care Test contains allcomponents required to carry out an assay for SARS-CoV-2 in nasopharyngeal, anterior nasal, or mid-turbinate swabs.

Principles of the Procedure

The Visby COVID-19 Device is a single-use (disposable), fully- integrated, fast, compact device containing a reverse transcriptionpolymerase chain reaction (RT-PCR) based assay for qualitative polymerase detection of viral RNA from the SARS-CoV-2 virus. The device automatically performs all steps required to complete lysis, reverse transcription, polymerase chain reaction, and amplicon detection.

Nasopharyngeal, dual nostril mid-turbinate or dual nostril anterior nasal swabs are placed in Visby Buffer and then transferred into the sample port of the device. The sample enters a lysis module and then rehydrates the RT enzyme and RT primers. The mixture then moves through a fixed temperature module where virus is simultaneously lysed and the viral RNA reverse transcribed. The resulting fluid (containing cDNA) is then mixed with lyophilized PCR reagents containing biotinylated primers specific to the N1 gene of the SARS-COV-2 virus and to 18S ribosomal RNA, which serves as a process control. The PCR mixture (containing cDNA template and reagents) is then thermocycled to amplify the SARS- CoV-2 (if present) and 18S targets.

After PCR, the biotinylated p duct is moved t he detection module, which contains covalently bo capture probe mmobilized in the shape of two distinct tangular ots along a w channel. Detection of the target-spec PCR product is comp ed using an enzyme-linked colorim assay usi strepta ound horseradish peroxidase (H and a c rimetric substrate that forms a purple precipita . The o observes color change at the specific locations dicating t presenc an amplified target. A purple color in the "R ults Valid" sp ates a successful internal control, and a rple c in the "Positive or SARS-CoV-2 (COVID-19)" spot indicates de tio the V-2 virus.

Materials

Provided in Test

- Visby COVID-19 Device
- Visby Test Tube Holder
- Visby Buffer Tube
- Visby Pastette
- Package Insert
- Quick Reference Guide
- Recommended Collection Instructions
- Biohazard Bag

Required Accessories

- Visby Power Adapter

Required but Not Supplied

- Absorbent Pads
- Hazardous Waste Disposal Bin
- Gloves
- Nasopharyngeal, Mid-turbinate or Anterior nasal swabs. Use sterile rayon, foam, polyester or flocked flexible shaft swabs

Available but not Provided

- SARS-CoV-2 Positive and A549 Cells Negative External Control (Swabs) by Microbiologics®
- 15 mL screw top tube, Falcon 14-959-70C, or equivalent

Note: This device complies with Part 15 of the FCC Rules. Operation is subject to the following conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that maycause undesired operation.

The Visby COVID-19 Point of Care Test has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. The equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential areais likely to cause harmful interference in which case the user will be required to correct the interference at his/her own expense.

Warnings and Precautions

General

1. For in vitro diagnostic use.
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 laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate, or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
3. This product has been authorized only for the detection of nucleic acid from SARS CoV-2, not for any other viruses or pathogens.
4. 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.
5. This product is for single use only; do not reuse the Visby COVID-19 Point of Care Test.
6. Federal Law restricts this device for sale by or on the order of a licensed practitioner (US only).
7. While color-blind users may be unable to differentiate red, green, and white status lights, they can consult the light location and shape of the light to determine test status. When interpreting results, the purple shade may appear as a dark shade for some users.

Visby Medical COVID-19 Testing

1. Follow your institution's and the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) or refer tothe Recommended Collection Instructions included with theVisby COVID-19 Point of Care Test.
2. The Visby COVID-19 Point of Care Test's control and results mustbe interpreted as per the instructions provided on this guide.
3. Leave the Visby COVID-19 Device sealed in the foil pouchuntil just before use.
4. Do not use the Visby COVID-19 Point of Care Test past its expiration date.
5. Do not use the Visby COVID-19 Device if it appears broken orhas been dropped.
6. Do not shake or tilt the Visby COVID-19 Device after adding a sample.
7. Do not add excessive sample into the Device as this mayresult in an error.
8. Run the Device on a clean, level surface.
9. Do not touch, move, or unplug charging cable, adapter, or Device while the test is running.
10. At a low frequency, clinical samples can contain inhibitorsthat may generate invalid results.
11. Keep the work area clean to prevent contamination.
12. Wear gloves while handling samples and change gloves between testing each specimen. If the gloves come in contact with specimen or appear to be wet, change gloves to avoid contamination. Change gloves before leaving work area andupon entry into work areas.
13. Do not try to disassemble the Visby COVID-19 Device. In thecase of a positive sample, this could lead to sample leakageand potential contamination.
14. The Visby COVID-19 Device should be placed in the biohazardbag and disposed of in the appropriate specimen waste containers according to your institution's standard practices.
15. The results of the Visby COVID-19 Device must be read within2 hours after the green check mark light appears. Failure to do so may yield invalid results. After 2 hours or after the Device is unplugged the green check mark will turn off indicating that the read window has expired.
8. Each button will have a different feel as it clicks into place. Push firmly to make sure all buttons are completely down or the test may yield invalid results.
9. The Visby COVID-19 Device requires a sample input of a specified volume from a fixed-volume pastette that is provided. If no sample is added into the Visby COVID-19 Device, the Results Valid spot will not be displayed.

Visby Power Adapter

1. Use only the supplied Visby power adapter to power theVisby COVID-19 Device. Using other power adapters tooperate the Visby COVID-19 Device will void the safetyprotection of the Device.
2. The Visby power adapter should be replaced if an increased number of RED X errors are observed.
3. Dispose of the power adapter as per local, federal, and institutional guidelines.

Specimen and Visby Buffer

1. Follow the CDC's guidelines and your institution's safety procedures for working with chemicals and handling biological samples.
2. Treat all biological specimens in the Visby Buffer tube as capable of transmitting infectious agents.
3. The Visby Buffer is used to process a single specimen only.If retest is required, refer to the retesting procedure section inthe Package Insert.
4. Storing the Visby Buffer above 40°C after the addition of the patient sample can lead to false negative results.
5. Mix the specimen in the Visby Buffer Tube by inverting thetube 5 times. Reducing the number of inversions may resultin invalid or inaccurate results.
6. Failure to use the Visby Buffer as directed can result in inaccurate test results.
7. Do not place the swab in viral transport media, saline, water or other buffers prior to testing.
8. Do not use the Visby Buffer Tube if it appears to be leaking, damaged, or opened.
9. The Visby Buffer is a clear, colorless, and odorless solution.Do not use if the solution appears discolored, has a strong odor or has any particles in it.
10. Do not use the Visby Buffer past its expiration date.

Spills

1. If a spill occurs with the Visby COVID-19 Point of Care Test, soak up the spillage with a disposable absorbent pad. Spray the contaminated area and materials with 10% bleach. Wipe down the surface so that it is saturated with bleach and let it sit at least 5 minutes. Once a minimum of 5 minutes has passed, spray the area with 70% ethyl or isopropyl alcohol and wipe down the surface. Dispose of affected single-use materials such as the absorbent pad, test tube holder, the Visby COVID-19 Device, and/or the COVID-19 Visby Buffer tube as biohazard. Affected single-use materials according to your institution's standard practices.
2. If a spill occurs on the Visby Adapter, unplug the unit and wipe it down vigorously with 70% ethyl or isopropyl alcohol. Allow the power adapter to completely dry before using it again.

Safety

1. Visby Buffer may contain irritants. Do not ingest the contents of the tube. If the contents of the tube are splashed in your eyes, flush your eyes with water. If the contents splash onto your skin, wash with soap and water. If irritation persists, notify a health care provider.
2. Follow your institution's safety procedures for working with chemicals and handling biological samples.

Temperature Definitions

Room Temperature: 66°F to 82°F (19°C to 28°C) **Refrigerated Temperature:** 35°F to 46°F (2°C to 8°C)

Frozen Temperature: 5°F to -74°F (-15°C to -59°C)

Storage, Stability and Specimen Collection

Storage

Store the Visby COVID-19 Point of Care Test in a cool and dry environment (36°F-86°F). Do not freeze. In case of refrigeration or other exposure to cold temperatures, ensure that the Visby COVID-19 Device is allowed to come to its minimum operating temperature prior to use.

Specimen Collection

The Visby COVID-19 Point of Care Test is intended for testing nasopharyngeal, anterior nasal, or mid-turbinate swabs collected without transport media. Use sterile rayon, foam, polyester or flocked flexible shaft swabs. Collect samples in accordance CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) or the Recommended Collection Instructions provided with the Visby COVID-19 Point of Care Test.

WARNING: Testing samples if stored for more than one hour at room temperature can result in inaccurate test results.

Specimen

Anterior nasal, mid-turbinate, or nasopharyngeal swabs should be tested as soon as possible after collection. If immediate testing is not possible, place patient swab in a dry tube labeled with patient information, and capped tightly at room temperature for up to one (1) hour prior to testing. Ensure the swab fits securely within the tube and the cap is tightly closed.

WARNING: Testing samples if stored for more than one hour at room temperature can result in inaccurate test results.

Specimen Stability in Visby Buffer

Specimen is stable in Visby Buffer in the following conditions:

- 45 minutes at room temperature.
- 24 hours at refrigerated temperature.

WARNING: Testing sample that have exceeded these storage conditions can result in inaccurate results. Do not store above 40°C.

Visby COVID-19 Point of Care Test Instructions for Use

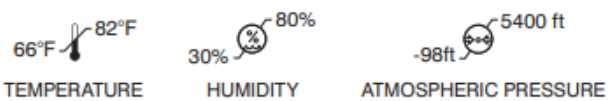
Please follow these instructions carefully.

Do not remove the Visby COVID-19 Device from the foil pouch until the workspace is prepared and you are ready to run the test.

Run the Visby COVID-19 Device at room temperature on a clean,level surface.

The Visby COVID-19 Device, pastettes, and Visby Buffer shouldbe disposed of in accordance with local regulations.

Operating Conditions



Visby COVID-19 Point of Care Test Procedure

Step 1 Set Up the Workspace

Operating Conditions: Ensure the test is run at room temperature in a cool, dry environment. Set up a new workspace for each Visby COVID-19 Point of Care Test. Clean the workspace and use a new absorbent pad after each test. Change gloves between handling samples and setting up a new test. Place the VisbyCOVID-19 Device on a level surface.

Note: Leave the Visby COVID-19 Device sealed in the foil pouch until just before use. Proceed to Step 2 only when ready to run the test. Do not use the Visby COVID-19 Device if it appears broken or has been dropped. Do not use the VisbyCOVID-19 Point of Care Test past its expiration date.

Patient swab samples are stable at room temperature for 1 hour at room temperature. Patient sample must be added to Visby Bufferwithin one hour of collection. Failure to add the sample within the allotted time or the use of alternate media may result ininvalid or inaccurate test results.

Step 2 Add Sample to the Visby Buffer Tube

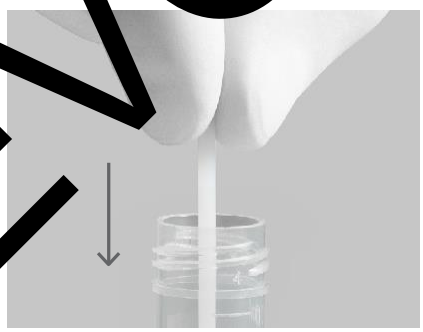
Patient sample must be used with Visby Buffer only. Place the device on a level surface.

A Open the Visby Buffer Tube.

Note: Do not use the Visby Buffer Tube past its expiration date.

B Place the Visby Buffer Tube in the tube holder.

C Take the collected patient sample.



D Place the patient swab into the Visby Buffer.

Note: If your swab still has a breakpoint - break the handle of the swab.

E Screw cap back on the Visby Buffer Tube.

Patient sample is stable in Visby Buffer at room temperature for 45 minutes and 24 hours at refrigeration.

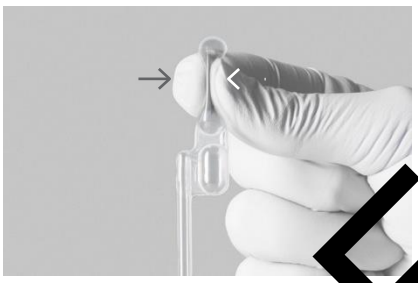
Step 3 Load the Sample into the Device

STOP! DO NOT plug in the test until Step 4E.

A Pick up the **Visby Buffer Tube**.

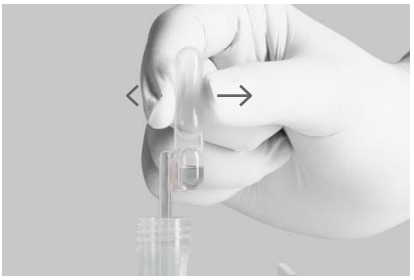
B Mix the specimen in the Visby Buffer Tube by inverting the tube **5 times**.

C Open the cap of the Visby Buffer Tube. Place cap wet side up. Take the Visby pastette.

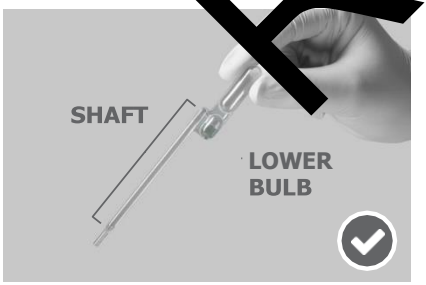


D Squeeze the **upper bulb**.

E **Keeping the bulb squeezed**, lower the pastette tip to the bottom of the Visby Buffer Tube.

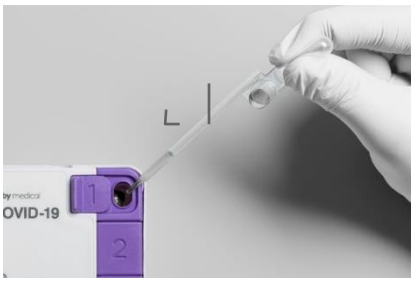


F Keep the tip fully under the fluid. Release the upper bulb.



G Fill the **entire shaft** with fluid. Some fluid should enter the lower bulb.

Note: Do not squeeze lower bulb or invert the pastette.



H Place the tip of the pastette into **Sample Port (Button 1)**. Squeeze the bulb to dispense the liquid. Some fluid will remain in the lower bulb.

Note: Do not overfill.

I Discard the pastette.

Note: Store the remaining Visby Buffer for retesting if needed.

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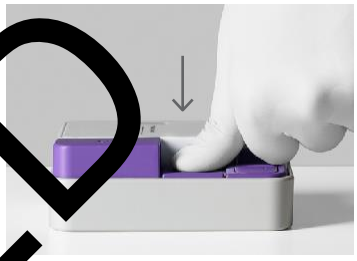
Step 4 Run the Test

IMPORTANT! Each button will have a different feel as it "clicks" into place.
Push firmly to make sure **all buttons are completely down** or the test may not work.

A After loading sample into devic[illegible] Button 1[illegible] **sliding** the cap to th[illegible]

B Push Button 1 **[illegible]ll the w[illegible] down** to ad[illegible]he sample.



C Push Button 2 **all the way down** to unlock button 3.

D Push Button 3 **all the way down**. Use two thumbs, push firmly.

Note: All buttons should be **all the way down**.

E Plug in the device until it clicks into place. A stable white light indicates the testis running.

Ensure that there is no gap between the power adapter plug and device.

WAIT 30 MINUTES! DO NOT touch or move the charging adapter, cable or device.
DO NOT shake or tilt the Visby COVID-19 Device after adding a sample.

Step 5 Get the Results

AFTER 30 MINUTES

A Check if the results are ready.
Look to the top left corner of the device.

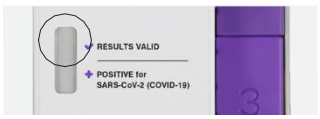
READY
A green check indicates the results are ready to be read. If present, proceed to Step 5B.

ERROR
A red indicates that an electronic failure occurred. Repeat the test.

B If a green check appears, confirm the results are valid. Look at the results window for a purple spot near "RESULTS VALID".

VALID
This is the control spot.
A purple spot indicates a valid test.
If present, proceed to Step 5C.

INVALID
No purple spot indicates an invalid test.
Repeat the test.



Instructions to repeat the test: Sample in Visby Buffer is stable for 45 minutes at room temperature and 24 hours at refrigeration. If storage conditions are exceeded, obtain new sample and repeat test with a new pastette, a new Visby Buffer Tube, and a new Visby COVID-19 Device.

C Read and record the results. Look at the results window for a purple spot near "POSITIVE for SARS-CoV-2 (COVID-19)".
Results may be read from 30 to 2[illegible] hours after the test is completed.
The intensity of the spot in the results window may vary. **Any shade of color should be considered a spot.**

Positive Result

A purple spot in this location indicates a positive result.

Negative Result

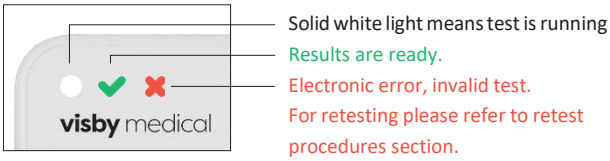
No purple spot in this location indicates a negative result.

After use, the Visby COVID-19 Device should be placed in a Biohazard Bag prior to disposal. The used Device, pastette, Visby Buffer, and specimen collection kit should be disposed of in the appropriate specimen waste containers according to your institution's standard practices.

Need Help? Call 1-833-GoVisby (1-833-468-4729)

Color Blindness Precaution

⚠ While color-blind users may be unable to differentiate red, green, and white status lights, they may observe the light location and shape of the light to determine test status.



Quality Control

Internal Controls:

Each Visby Medical COVID-19 Device includes internal electronicand process controls.

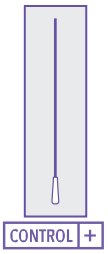
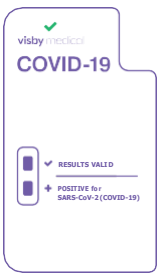
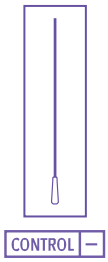
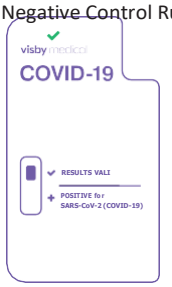
1. Electronic Controls – The Visby COVID-19 Device will automatically detect various issues including hardware failures, invalid operating temperatures and other conditions that can lead to inaccurate test results. If one of these issues is detected, the device will display a 'Red X' status light and the test must be repeated. A green check mark indicates thatthe test was successful.
2. Process Control – The Visby COVID-19 Device includes an assay that targets 18S ribosomal RNA. This process control is carried through all stages of the testing process, including lysis, reverse transcription, PCR amplification, and colorimetric detection. Development of a purple spot in the "Results Valid" window indicates that all testing processes were successful. If a purple spot does not appear in the "Results Valid" window, the test is invalid and should be repeated.

External Positive and Negative Controls:

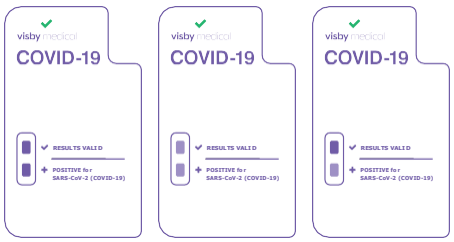
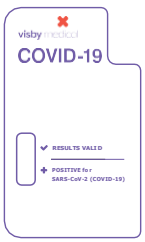
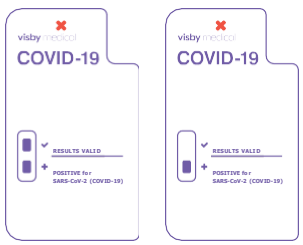
External controls should be used in accordance with local, state, and federal accrediting organizations as applicable. Testing of external control materials may be appropriate to train new operators or when receiving new device shipments. Visby Medical suggests the use of the Microbiologics control materials described in the figure below. Use of other commercial external control materials may be appropriate.

To run external control swabs, unwrap the swab, and gently tap the swab against the bottom of the Visby Buffer Tube 15 times. Discard the swab according to your institutions guidelines and screw the cap back on the buffer tube. Proceed to Step 3.

Each positive or negative external control is for single use only. External control stability in the Visby Buffer has not been established.

Product	Unit	Control Key
SARS-CoV-2 Positive and A549 Cells Negative External Control (Swabs) by Microbiologics®	SARS-CoV-2 Positive External Control Swab 	Valid Positive Control Run 
	A549 Cells Negative External Control Swab 	Valid Negative Control Run 

Interpretation of Results

Result	Interpretation	Next Steps
 **Note:** Any shade of color with defined edges, as illustrated above, should be considered a spot.	• Valid test (, RESULTS VALID) • Negative for SARS-CoV-2 (COVID-19) (POSITIVE for SARS-CoV-2 (COVID-19))	• Report results of patient sample
 **Note:** Any shade of color with defined edges, as illustrated above, should be considered a spot.	• Valid test (, RESULTS VALID) • Positive for SARS-CoV-2 (COVID-19) (POSITIVE for SARS-CoV-2)	Report results of patient sample
	• Invalid test; control fail (RESULTS VALID)	• Discard test • Refer to the retest procedure section below • If repeat test fails, contact Visby Medical Customer Support
	☼ Blinking white light for 2-3 minutes, then turns to Red ✖ ✖ Error: Invalid	• Discard test • Refer to the retest procedure section below • Repeat the test - Do not plug in the power source before Step 4E. Push the adapter jack into the device's chargingport until you feel it click in place. Ensure that there is no gap between the adapter jack & device charging port. A stable white light will appear indicating the test is running • If repeat test fails, contact Visby Medical Customer Support
	✖ Error: Invalid	• Discard test • Refer to the retest procedure section below • If repeat test fails, contact Visby Medical Customer Support

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Under Rare Circumstances

The following are occasionally observed and should not be confused with a positive result.

Background Staining
The background color in the results window may turn a lightshade of blue or purple over time. This is a normal feature ofthe chemistry. This should not be considered a positive result.

Speckling and Bubbles
Samples containing blood or mucus may result in nonspecific small flakes in the results window. These are normal conditions and should not impact the interpretationof results. It is also normal for bubbles to appear in the results window during test processing.

Spot Shadow
An extremely faint spot without distinct edges may be seenin the results window. This may be a result of non-specificbinding. Repeat the test with a new Visby Buffer tube and Visby COVID-19 Device.

If you are unsure how to interpret a result, please contact Visby Medical Customer Support at 1-833-GoVisby (1-833-468-4729) or support@visbymedical.com.

Retest Procedure

Samples stored in Visby Buffer

Obtain the leftover sample from the Visby Buffer tube. Repeat the test with a new Visby COVID-19 Device.

Note: Patient sample in Visby Buffer is stable for 45 minutesat room temperature and 24 hours at refrigeration. If storage conditions are exceeded, obtain new sample and repeat test with new Visby COVID-19 Point of Care Test.

External Controls

If the positive or negative external control fail, repeat with a new external control and a new Visby COVID-19 Point of Care Test. If the repeat test fails, please contact Visby Medical Customer Support at 1-833-468-4729 (1-833-GoVisby).

Limitations

1. The performance of the Visby COVID-19 Point of Care Test was established using nasopharyngeal swab specimens. Mid-turbinate and anterior nasal swabs (collected by an HCP or self-collected under the supervision of an HCP) are considered acceptable specimen types for use with the Visby COVID-19 Point of Care Test but performance with these specimen types has not been established.
2. Erroneous results may occur from improper specimen collection, sample dilution, technical error, sample mix-up,or if the viral load in the patient sample is below the limit of detection of the Visby COVID-19 Point of Care Test.
3. Careful compliance with the instructions in this insert and Quick Reference Guide Instructions are necessary to avoid erroneous results.
4. Because the detection of SARS-CoV-2 is dependent on the viralload present in the sample, reliable results are dependent on proper sample collection, sample processing, handling, and storage.
5. Built-in procedural controls of the Visby COVID-19 Point ofCare Test cannot identify false positive results.
6. This test has been evaluated with human specimen material only.
7. The effect of interfering substances has been evaluated onlyfor those listed within the labeling.
8. Mutations within the target region of SARS-CoV-2 could affect primer and/or probe binding, resulting in failure to detect the presence of virus.
9. This Test cannot rule out diseases caused by other bacterialor viral pathogens.
10. Performance has not been established in asymptomatic individuals.
11. Viral nucleic acid may persist independent of virus viability. Detection of SARS-CoV2 nucleic acid does not implythat the corresponding virus is infectious or are the causativeagents for clinical symptoms.
12. The performance of this test was established based on the evaluation of a limited number of clinical specimens. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over

Conditions of Authorization for Laboratories

The Visby COVID-19 Point of Care Test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labelingare available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas.

However, to assist clinical laboratories and/or Point of Care Settings using the Visby COVID-19 Point of Care Test (referred to in the Letter of Authorization as “Your Product”), the relevant Conditions of Authorization are listed below:

1. Authorized laboratories* using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
2. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materialsrequired to use your product are not permitted.
3. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
4. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
5. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/ OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs. gov) and you (support@visbymedical.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product

of which they become aware.

6. All laboratory personnel using your product must be appropriately trained in the use of the Visby Medical COVID-19Point of Care Test and use appropriate laboratory and personal protective equipment when handling this kit, and useyour product in accordance with the authorized labeling.
7. Visby Medical, Inc., authorized distributor(s), and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

* The letter of authorization refers to "authorized laboratories" as "laboratories certified under CLIA that meet requirements to perform high, moderate, or waived complexity tests. The Visby Medical COVID-19 Point of Care test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation."

Analytical Performance

Analytical Sensitivity (Limit of Detection)

The limit of detection (LoD) is the lowest concentration of viral nucleic acid that is reliably detected by the Visby COVID-19 Point of Care Test. The LoD was first estimated by preparing 3-fold serial dilutions of inactivated SARS-CoV-2 virus (USA WA1/2020 strain) into negative clinical matrix. The dilutions were then transferred onto nasopharyngeal swabs and four replicates of five different concentrations were tested. The lowest concentration that had 100% detection was estimated to be the LoD. The LoD was then confirmed by preparing and testing 40 replicates at the concentration (435 copies/swab). The LoD was confirmed when 39/40 replicates gave positive test results (Table 01). One sample was excluded due to an invalid test result.

Analytical Reactivity (Inclusivity)

Visby Medical follows FDA policy[4] to routinely monitor SARS-CoV-2 sequences to determine if there is any impact to the Visby Medical COVID-19 test performance. As of June 2022, 11,322,345 SARS-CoV-2 sequences submitted to the GISAID database5 have been analyzed, including sequences from Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1), Delta (B.1.617.2) and Omicron (B.1.1.529 and BA) variants. To date, this period process has identified one mismatch that occurred in >5% of sequences, however, in-silico assessment indicates that this variant has no impact on the performance of the Visby test.

Analytical Specificity/Exclusivity (Cross-Reactivity and Microbial Interference)

An *in silico* study was performed to assess for potential cross- reactivity with related pathogens and normal or pathogenic flora that are reasonably likely to be encountered in clinical specimens. This assessment showed no sequence homology with SARS coronavirus and Bat SARS-like coronavirus genome for the forward and reverse primers; high sequence homology with SARS coronavirus and Bat SARS-like coronavirus genome was identified with the probe sequence. However, there are no significant homologies with the human genome, other coronaviruses, other normal or pathogenic flora that would predict potential false positive results when combining primers and probes. In addition, wet testing was also performed to evaluate the Visby COVID-19 Test performance when in the presence of 31 viral and bacterial organisms. Each organism was individually seeded into an artificial nasal matrix and tested on three devices with both COVID-19 negative samples and COVID-19 positive samples at 2x the LoD. The expected results were achieved 100% of the time. The organisms, concentrations and results are listed below. None of the 31 organisms demonstrated cross-reactivity with the Visby COVID-19 Test at the concentrations in Table 02. Testing was repeated with the Visby COVID-19 Point of Care test using a direct swab specimen for influenza A, influenza B and RSV using clinical matrix. Assessments with the other organisms were not repeated with the Visby COVID-19 Point of Care Test as the device including primer and probe sequences is unchanged and testingwith the Visby COVID-19 Test was performed at high organism concentrations.

Table 01: LoD Determination using inactivated SARS-CoV-2 (USA_WA1/2020 strain)

	Concentration (genomic copies/swab)	Detection Rate (# positive for SARS-Cov-2 / # total tests)
LoD Serial Dilution	145	1/4
	435	4/4
	1305	4/4
	3915	4/4
	11745	4/4
LoD confirmation	**435**	**39/39***

*One result was excluded due to an invalid result

Table 02: Summary of performance for organisms tested on the Visby COVID-19 Test (Cross-Reactivity and Microbial Interference)

Organism	Concentration Tested	Units	Negative Samples (# of Valid Devices Negative for SARS-CoV-2)	Positive Samples (# of Valid Devices Positive for SARS-CoV-2)
Human Coronavirus 229E	1.1×10^5	genomic copies/mL	8/9 (1)	3/3
Human Coronavirus OC43	1.1×10^5	genomic copies/mL	3/3	3/3
Human Coronavirus HKU1	1.1×10^5	genomic copies/mL	3/3	3/3
Human Coronavirus NL63	1.1×10^5	genomic copies/mL	3/3	3/3
SARS-Coronavirus (2003)	1.1×10^5	genomic copies/mL	3/3	3/3
MERS-Coronavirus	1.1×10^5	genomic copies/mL	/3	3/3
Adenovirus, C1 Ad 71	2.5×10^{-3}	ng/ µ L	3/3	3/3
Human metapneumovirus (hMPV)	1.1×10^5	genomic copies/mL	3/	3/3
Human parainfluenza virus 1	2.5×10^{-3}	ng/ µ L	/3	3/3
Human parainfluenza virus 2	2.5×10^{-3}	ng/ µ L	/3	3/3
Human parainfluenza virus 3	2.5×10^{-3}	ng/ µ L	3/3	8/9 (2)
Human parainfluenza virus 4b	2.5×10^{-3}	ng/ µ L	3/3	3/3
Influenza A	1.1×10^6	$CEID_{50}$/m	3/3	6/6 (3)
Influenza B	1.1×10^6	$CEID_{50}$/mL	3/3	6/6 (3)
Enterovirus 68	1.1×10^5	nomic copies/mL	3/3	3/3
Respiratory syncytial virus	1.1×10^5	nic copies/m	3/3	6/6 (3)
Human rhinovirus 17 (strain 33342)	1.1×10^5	genomic /mL	3/3	3/3
Chlamydia pneumoniae	10^6	IFU/mL	3/3	3/3
Haemophilus influenzae	1.1×10^6	nomic copies/mL	3/3	3/3
Legionella pneumophila	1.1×10^6	genomic copies/mL	3/3	3/3
Mycobacterium tuberculosis	1.1×10^6	genomic copies/mL	3/3	3/3
Streptococcus pneumoniae	1.1×10^6	genomic copies/mL	3/3	3/3
Streptococcus pyogenes	$1.1 \times$	genomic copies/mL	3/3	3/3
Bordetella parapertu	1.1×10^6	genomic copies/mL	3/3	3/3
Mycoplasma pneumon	1.1×10^6	genomic copies/mL	3/3	3/3
Pneumocystis jirovecii (PJP) also called: *Pneumocystis carin Delanoe and Delanoe*	1.1×10^6	nuclei/mL	3/3	3/3
Candida albicans	1.1×10^6	genomic copies/mL	3/3	3/3
Pseudomonas aeruginosa	1.1×10^6	genomic copies/mL	3/3	3/3
Staphylococcus epidermis	1.1×10^6	genomic copies/mL	3/3	3/3
Streptococcus salivarius	1.1×10^6	genomic copies/mL	3/3	3/3
Pooled human nasal wash	10%	percent of total volume	3/3	3/3

(1) A fresh sample was retested for the potential cross-reactive organism and tested with twice the number of devices; the expected results were achieved in all cases. As the contrived positive SARS-CoV-2 samples were prepared in the same lab space as the negative samples, this is the suspected root cause for the observed false positive result.
(2) A fresh sample was retested for potential microbial interference with twice the number of devices, and expected results were achieved in all cases.
(3) Testing was performed with the Visby COVID-19 Test and the Visby COVID-19 Point of Care Test.

Analytical Specificity (Interfering Substances)

A study was executed to determine the effect of potentially interfering endogenous and exogenous substances that may be present in a clinical sample on the performance of the Visby COVID-19 Point of Care Test. Each potential interfering substance was seeded into negative clinical matrix and then transferred to a nasopharyngeal swab. For each substance, additional negative matrix was transferred to three swabs to create a negative sample, and matrix with inactivated SARS-CoV-2 virus (USA WA1/2020 strain) was transferred to three swabs to create a positive (2X LoD) sample. Both the negative and positive samples were tested in triplicate. The substances, concentrations, and results are listed below (Table 03). None of the substances tested for interference impacted the performance or results of the Visby COVID-19 Point of Care Test.

Table 03: Summary of valid device performance for each interfering substance

Interfering Substance	**Assay Interference Limit**	**Negative Samples** (# of Valid Devices Negative for SARS-CoV-2)	**Positive Samples (2X LoD)** (# of Valid Devices Positivefor SARS-CoV-2)
Afrin	25% (v/v)	3/3	3/3
Biotin	3.5 µg/mL	3/3	3/3
Fresh Whole Blood Pooled Human Donors	5% (v/v)	3/3	3/3
Flonase	25% (v/v)	3/3	3/3
Mucin	1% (w/v)	3/3	3/3
Mupirocin	12 g/mL	3/3	3/3
Nasacort	25 v/v)	3/3	3/3
NeoSynephrine Cold & Sinus Extra Strength Spray	25% (v/v)	3/3	3/3
Nasal Saline Spray	2 % (v/v)	3/3	3/3
Tobramycin	2 g/mL	3/3	3/3
Zanamivir (Relenza)	500 ng/mL 5 mg/mL	3/3	3/3
Zicam Allergy Relief	25% (v/v)	3/3	3/3

Clinical Performance – Point of Care

Clinical Study Performance

The clinical performance of the Visby Medical COVID-19 Point of Care Test was established in a single center prospective clinical study conducted in a typical point of care (POC) setting. Five operators representing typical POC users tested specimens from96 study participants over a 4-week period.

Study participants were consented, and two nasopharyngeal swab (NPS) samples were collected. One NPS was placed in universal transport media (UTM) and sent to a reference laboratory for comparator testing using a EUA COVID-19 Test. The other NPS sample was not placed in any transport media and was tested on-site using the Visby COVID-19 Point of Care Test.
All study participants were symptomatic with the exception of two. The average age among study subjects was 31 with a rangebetween 9 and 72. Of the 96 specimens tested, 11 yielded initial invalid results (initial invalid rate 11.5% (11/96)). For one subject, the Visby COVID-19 Point of Care Test didn't yield a valid result during retest. The overall valid rate of the Visby COVID-19 Point ofCare Test was 99.0% (95/96).

Positive percent agreement (PPA) was calculated as 100% x (TP / TP + FN). True positive (TP) indicates that both the Visby and comparator method had a positive result for SARS-CoV-2, and false negative (FN) indicates that the Visby result was negative while the comparator result was positive. Negative percent agreement (NPA) was calculated as 100% x (TN / TN+ FP). True negative (TN) indicates that both the Visby and the comparator method had negative results, and a false positive (FP) indicates that the Visby result was positive, but the comparator result was negative. The exact binomial two-sided 95% confidence interval was calculated. The results are summarized in Table 04.

Table 04: Visby COVID-19 Point of Care Test vs EUA Comparator Assay

		EUA COVID-19 Test		
		Positive	**Negative**	**Totals**
Visby COVID-19 Point of Care Test	**Positive**	31	3[a]	34
	Negative	0	61	61
	Totals	31	64	95
[a] One of three false positive results was positive when tested with another EUA COVID-19 assay.				
PPA	**100.0% (95% CI: 89.0%-100.0%)**			
NPA	**95.3% (95% CI: 87.1%-98.4%)**			

Second Prospective Clinical Study

A second two-armed prospective study was performed in a typical POC setting using a different molecular EUA COVID-19 test as the comparator assay. As in the previous study, subjects were consented and two NPS samples were collected. One swab was placed in UTM and tested at a reference laboratory using a molecular EUA COVID-19 test while a second swab was placed directly into Visby Buffer and tested on-site with the Visby Medical COVID-19 Point of Care Test.

In the first arm of the study, subjects suspected of COVID-19 by their HCP were enrolled without regard to the results of standard of care test results and the Visby testing was performed by 2 typical POC personnel. A total of 95 subjects were enrolled over 12 non-consecutive days. Eight (8) tests (8%, 8/95) had an initial invalid test result, of which all provided valid results upon retesting. Of the 95 subjects with valid test result, 85 were symptomatic and 10 were asymptomatic. The PPA and NPA for the Visby Medical COVID-19 Test for the first arm of the study is shown in Table 05.

Table 05: Visby COVID-19 Point of Care Test vs EUA Comparator Assay

		EUA COVID-19 Test		
		Positive	**Negative**	**Totals**
Visby COVID-19 Point of Care Test	**Positive**	40	3[b]	43
	Negative	2[a]	50	52
	Totals	42	53	95
PPA	**95.2% (95% CI: 84.2%-99%)**			
NPA	**94.3% (95% CI: 84.6%-98.1%)**			
a. Retesting of one specimen with the Visby test gave a positive result. b. One of the three false positive sample were positive when tested with an alternate EUA molecular assay.				

In the second arm of study, subjects with positive results by standard of care testing were selectively enrolled and tested. Testing was performed by one typical POC personnel. A total of 17 subjects were enrolled over 13 non-consecutive days. Three (3) tests (16.7%, 3/18) had an initial invalid test result, of which one was valid upon retesting and was excluded from data analysis. Of the 16 subjects with valid test results, all were symptomatic. The PPA and NPA for the Visby Medical COVID-19 POC Test, for this arm of the study, is shown in Table 06.

Between the two study arms, the Visby test detected 100% (12/12) samples with low viral loads (as determined by the Ct value of the comparator assay).

Table 06: Visby COVID-19 Point of Care Test vs EUA Comparator Assay with standard of care positive samples

		EUA COVID-19 Test		
		Positive	**Negative**	**Totals**
Visby COVID-19 Point of Care Test	**Positive**	13	1[a]	14
	Negative	0	2	2
	Totals	13	3	16
PPA	**100% (95% CI: 77.2%-100%)**			
NPA	**66.7% (95% CI: 20.8%-93.9%)**			
a. The false positive sample was positive when tested with an alternate EUA molecular assay.				

Contrived Specimen Performance

Contrived direct swab samples were used to evaluate performanceof the test near the assay LoD in a POC setting. Testing was integrated into the workflow of the prospective study over a 2-day period. Each operator tested 3 low positive (<2xLoD) and 3 negative specimens. Results are summarized in Table 07 by operator,by sample type, and overall. Of the 30 tested specimens, 3 (10%) yielded invalid results during the initial test. Study operators were able to perform the test correctly with an overall agreement rate of 100.0%.

Table 07: Contrived Specimen Results

						Overall Agreement	
Operator	**1**	**2**	**3**	**4**	**5**	**Total**	**95% CI**
Positive (2x LOD)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (15/15)	79.6%-100.0%
Negative	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (2/2)*	100.0% (3/3)	[illegible]0% (14/[illegible])	78.5%-100.0%
*Initial and retest yielded invalid results							

References

1. Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/index.html. Accessed February 9, 2020.
2. bioRxiv. (https://www.biorxiv.org/content/10.1101/2020.02.07.937862v1). Accessed March 3, 2020.
3. Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease2019 (COVID-19). https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html
4. FDA Policy for Evaluating Impact of Viral Mutations on COVID-19 Tests: https://www.fda.gov/regulatory-information/ search-fda-guidance-documents/policy-evaluating-impact-viral-mutations-covid-19-tests
5. FDA The GISAID Initiative, which promotes the rapid sharing of data from all influenza viruses and the coronavirus causing COVID-19: https://www.gisaid.org/

Note: Safety Data Sheets (SDS) are available at Visby Medical Customer Support 1-833-GoVisby (1-833-468-4729) or support@visbymedical.com.

Note: For information on how to obtain additional materials, contact Visby Medical Customer Support at 1-833-GoVisby(1-833-468-4729) or support@visbymedical.com.

Index of Symbols

ISO 15223-1
Symbols to be used with Medical device labels, labeling and information to be supplied

Symbol/ Reference number	Title	Symbol/ Reference number	Title
5.1.6	Catalog number	5.3.7	Temperature limit
5.4.2 REF	Do not re-use	5.3.8	Humidity limitation
5.3.1	Fragile, handlewith care	5.4.1	Biological risks
5.1.5 LOT	Batch code	IVD	In vitro diagnostic medical device
5.4.4	Caution	5.2.8	Do not use if package is damaged
5.4.3	Co t instructio f se	5.5.3 CO OL –	Negative control
5.1.1	Manufactu	CONTROL +	Positive control
5.5.5	ns sufficient for tests	21 CFR 801.109 Rx ONLY	For prescription use only
5.1.4	Use-by	c N us 6100	Nemko 61010
	supply		Waste container

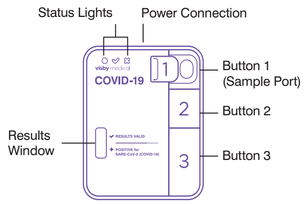
Visby Medical, Inc. 3010 North First StreetSan Jose, CA 95134

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

PS-001418 Rev C 07/22

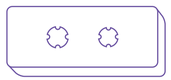
Materials Provided and Required

Visby COVID-19 Device

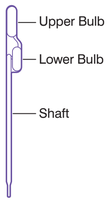


Visby Buffer Tube

Test Tube Holder



Visby Pastette

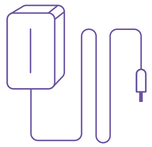


Biohazard Bag

After use, the Visby COVID-19 Device should be placed in a Biohazard Bag prior to disposal.

Required Accessories

Visby Power Adapter



Materials Required but not Supplied

Gloves

Nasopharyngeal, Mid-turbinate or Anterior Nasal Specimen Collection Swab

Disposal Bin

Absorbent Pads

Warnings

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate, or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- 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.

Caution

⚠ Keep the work area clean to prevent contamination. Wear gloves while handling samples and change gloves between testing each specimen.

Storage Specifications

Store the Visby COVID-19 Point of Care Test in a cool and dry environment (36°F-86°F). Do not freeze.

Ensure Visby COVID-19 Device comes to minimum operating temperature before use.

Patient swab sample is stable in dry tube for 1 hour at room temperature.

Patient sample is stable in Visby Buffer for 24 hours at refrigerated temperature and 45 minutes at room temperature. Ensure the sample comes to minimum operating temperature before adding to the Visby COVID-19 Device.

Operating Conditions

66°F – 82°F
TEMPERATURE

30% – 80%
HUMIDITY

Temperature Definitions

ROOM TEMPERATURE	REFRIGERATED TEMPERATURE
66°F - 82°F	35°F - 46°F

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Quality Control

External controls should be used in accordance with local, state, and federal accrediting organizations as applicable. Visby Medical suggests the use of the following control materials, however other commercial external control materials may be appropriate.

External Positive and Negative Controls

SARS-CoV-2 Positive and HeLa Cells Negative External Control (Swabs) by Microbiologics®

To run external control swabs, unwrap the swab, and gently tap the swab against the bottom of the Visby Buffer Tube 15 times. Discard the swab according to your institutions guidelines and screw the cap back onto the Visby Buffer Tube. Proceed to Step 3.

External control stability with Visby Buffer has not been established. Each positive or negative external control is for single use only.

If the positive external controls fail, repeat with new external control and a new Visby COVID-19 Point of Care Test. If the repeat test fails, please contact Visby Medical Customer Support at 1-833-468-4729 (1-833-GoVisby).

Sample Collection

Collect patient samples using NP (Nasopharyngeal), dual nostril MT (Mid-turbinate), or dual nostril Anterior nasal swab. Use recommended sample collection instructions included in the Visby COVID-19 Point of Care Test.

Color Blindness Precaution

⚠ While color-blind users may be unable to differentiate red, green, and white status lights, they may observe the light location and shape of the light to determine test status.

Solid white light means test is running
Results are ready.
Electronic error, invalid test. Refer to instructions to repeat a test.

COVID-19
Point of Care

visby medical™

Quick Reference Guide

For the qualitative detection of SARS-CoV-2 nucleic acid. For IVD Use. For Rx only. For Emergency Use Authorization Only.

IVD Rx ONLY

REF PS-001541

Need Help?

Email Us
support@visbymedical.com

Call Us
1-833-GoVisby
(1-833-468-4729)

www.visbymedical.com

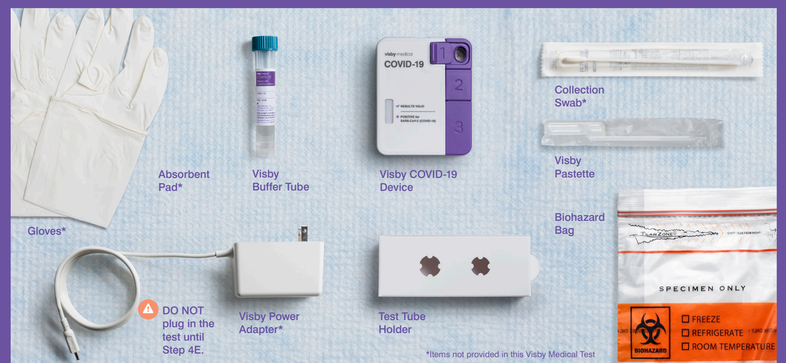
⚠ WAIT! DO NOT PLUG IN THE TEST UNTIL STEP 4E

visby medical™

www.visbymedical.com

Step 1 Set Up the Workspace

Operating Conditions: Ensure the test is run at room temperature in a cool, dry environment. Set up a new workspace for each Visby COVID-19 Point of Care Test. Clean the workspace and use a new absorbent pad after each test. Change gloves between handling samples and setting up a new test. Place the Visby COVID-19 Device on a level surface.



Note: Leave the Visby COVID-19 Device sealed in the foil pouch until just before use. Please proceed to Step 2 only when ready to run the test. Do not use the Visby COVID-19 Device if it appears broken or has been dropped. Do not use the Visby COVID-19 Point of Care Test past its expiration date.

Patient swab sample is stable in a dry tube for 1 hour at room temperature. Patient sample must be added to Visby Buffer within one hour of collection. Failure to add the sample within the allotted time or the use of alternate media may result in invalid or inaccurate test results.

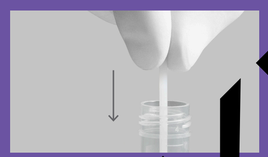
Step 2 Add Sample to the Visby Buffer Tube

Patient sample must be used with Visby Buffer only. Place the device on a level surface.

A Open the Visby Buffer Tube.

Note: Do not use the Visby Buffer Tube past its expiration date.

B Place the Visby Buffer Tube in a tube holder.



D Place the patient s into th Visby Buffer.

Note: If your swab still breakpoint, the ha of the

C Take the co d patient sample.

E Screw cap ck on the Visby Buffer Tube.

Patient sample is stable in Visby Buffer at room temperature for 45 minutes and 24 hours at refrigeration.

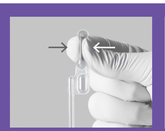
Step 3 Load the Sample into the Device

⚠ STOP! DO NOT plug in the test until Step 4E.

A Pick up the **Visby Buffer Tube.**

B Mix the specimen in the Visby Buffer Tube by inverting the tube **5 times**.

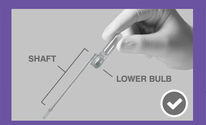
C Open the cap of the Visby Buffer Tube. Place cap wet-side up. Take the Visby pastette.



D Squeeze the **upper bulb.**

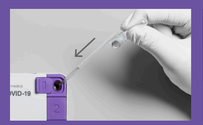
E **Keeping the bulb squeezed**, lower the pastette tip to the bottom of the Visby Buffer Tube.

F Keep the tip fully under the fluid. Release the upper bulb.



G Fill the **entire shaft** with fluid. Some fluid should enter the lower bulb.

Note: Do not squeeze lower bulb or invert the pastette.



H Place the tip of the pastette into **Sample Port (Button 1)**. Squeeze the bulb to dispense all the liquid. Some fluid will remain in the lower bulb.

Note: Do not overfill.

I Discard the pastette.

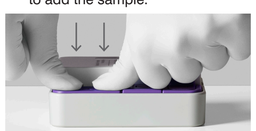
Note: Store the remaining Visby Buffer for retesting if needed.

Step 4 Run the Test

⚠ IMPORTANT! Each button will have a different feel as it "clicks" into place.
Push firmly to make sure **all buttons are completely down** or the test may not work.

A After loading sample into device, close Button 1 by **sliding** the cap to the right.

B Push Button 1 **all the way down** to add the sample.



D Push Button 3 **all the way down**. Use two thumbs, push firmly.

Note: All buttons should be **all the way down**.

C Push Button 2 **all the way down** to unlock button 3.

E Plug in the device until it clicks into place. A stable white light indicates the test is running.

Ensure that there is no gap between the power adapter plug and device.

WAIT 30 MINUTES! DO NOT touch or move the charging adapter, cable or device. **DO NOT** shake or tilt the Visby COVID-19 Device after adding a sample.

Step 5 Get the Results

AFTER 30 MI ES

A Chec he results ready. Look to top le corner of the device.

READY
A green c k indicates results are re t, proceed p 5B.

ERRO
A red ✖ indicates that an electronic failure occurred. Repeat the test.

B If a green check ✔ appears, confirm the results are valid. Look at the results window for a purple spot near "RESULTS VALID".

VALID
This is the control spot.
A purple spot indicates a valid test.
If present, proceed to Step 5C.

INVALID
No purple spot indicates an invalid test.
Repeat the test.

Instructions to repeat the test: Sample in Visby Buffer is stable for 45 minutes at room temperature and 24 hours at refrigeration. If storage conditions are exceeded, obtain new sample and repeat test with a new pastette, a new Visby Buffer Tube, and a new Visby COVID-19 Device.

C Read and record the results. Look at the results window for a purple spot near "POSITIVE for SARS-CoV-2 (COVID-19)". Results may be read for up to 2 hours after the test is completed.
The intensity of the spot in the results window may vary. **Any shade of color should be considered a spot.**

Positive Result

A purple spot in this location indicates a positive result.

Negative Result

No purple spot in this location indicates a negative result.

After use, the Visby COVID-19 Device should be placed in a Biohazard Bag prior to disposal. The used Device, pastette, Visby Buffer, and specimen collection kit should be disposed of in the appropriate specimen waste containers according to your institution's standard practices.

Refer to Package Insert for more guidance on reading the results.

Need Help? Call 1-833-GoVisby (1-833-468-4729)