visby medical™

COVID-19

Package Insert

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

MODEL: 001260

PS-001315 Rev D 08/21

COVID-19

Device Name

Visby Medical COVID-19 Test

Common or Usual Name

Visby COVID-19 Test

Intended Use

The Visby Medical COVID-19 Test is a single-use (disposable), fully-integrated, fast, automated RT-PCR in vitro diagnostic test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal, anterior nasal, or dual nostril mid-turbinate (mid-turbinate) nasal swabs collected by a health care provider (HCP), or anterior nasal or mid-turbinate nasal swabs self-collected (in a healthcare setting), from individuals suspected of COVID-19 by their healthcare provider. Testing of non-pooled specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate or high complexity tests.

This test is also for the qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to 5 individual samples from nasopharyngeal, anterior nasal, or midturbinate nasal swabs collected by a HCP, or anterior nasal or mid-turbinate nasal swabs self-collected (in a healthcare setting) using individual vials containing transport media. Negative results from pooled testing should not be treated as definitive. If a patient's clinical signs and symptoms are inconsistent with a negative result or if results are necessary for patient management, then the patient should be considered for individual testing. Specimens included in pools with a positive or invalid result must be tested individually prior to reporting a result. Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing. For specific patients, whose specimen(s) were the subject of pooling, a notice that pooling was used during testing must be included when reporting the result to the clinician or healthcare provider. Testing of pooled specimens is limited to laboratories certified under CLIA, 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection.[1] Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status.[2] Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities. Negative results do not preclude SARS-CoV-2 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 epidemiological information.[2]

The Visby Medical COVID-19 Test is intended for use by laboratory personnel who have received specific training on the use of the Visby Medical COVID-19 Test. The Visby Medical COVID-19 Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Summary and Explanation of the Procedure

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

Principles of the Procedure

The Visby Medical COVID-19 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 viral RNA from the SARS-CoV-2.

The SARS-CoV-2 primer and probe sets are designed to detect the nucleocapsid (N) region of SARS-CoV-2 in nasopharyngeal, nasal, or mid-turbinate swabs collected by a health care provider (HCP), or nasal or mid- turbinate swabs self-collected (in a healthcare setting) from individuals who are suspected of COVID-19 by their healthcare provider.

The test automatically performs all steps required to complete sample preparation, complementary DNA production, amplification, and detection. The sample mixes with lyophilized RT-PCR reagents and is then thermocycled such that the cDNA molecules present are amplified enough to be detectable by a colorimetric system. Amplified target (if present) is hybridized to specific locations along a flow channel. This flow channel is configured to facilitate an enzymatic reaction that utilizes horseradish peroxidase (HRP) and a color producing substrate. This will result in an observable color change for a positive reaction.

The control strategy relies on a positive spot on the flow cell. If all elements in the Visby Medical COVID-19 Test device are functioning properly, then the Results Valid spot will produce color.

The Visby test uses commercially available Universal Transport Media (UTM) or Viral Transport Media (VTM) as shown in the table below. See Material Required but Not Supplied for part number information. After collection specimens are transferred with a Visby Pipette into the Visby Buffer Tube. The Visby Pipette is then discarded and the diluted sample is ready for processing with the Visby Medical COVID-19 Test.

Materials

Materials Provided in Test Kit

- Visby Medical COVID-19 Test*†
  (The following components are enclosed in the device)
  - Wash Reagent
  - HRP Enzyme Reagent
  - Substrate Reagent
  - Pellet 1, Pellet 2, Pellet 3, Pellet 4 (Freeze-dried)
- Visby Test Tube Holder
- Visby Buffer Tube††
- Visby Pipette (650 µl)
- Package Insert
- Quick Reference Guide
- Quick Reference Guide (Pooling)
- Biohazard Bag

Materials Required and Available as Accessories

- Visby Power Adapter*†

Materials Required but Not Supplied

- NATtrol™ SARS-CoV-2 External Run Controls by ZeptoMetrix
- Absorbent Pads
- Hazardous Waste Disposal Bin
- Medical Gloves
- Commercially available transport media
- Nasopharyngeal, Nasal, or Mid-Turbinate Swabs
- Standard adjustable volume pipette

COVID-19

			Distributors or Private Label Names				
Product Line/Type	**Description**	**Manufacturer**	**Part Number**	**BD**	**Fisher Healthcare**	**Hardy/ Healthlink**	**DHI/ Quidel**
UTM/Nasopharyngeal Sample Collection Kit	Flexible Minitip Flocked Swab + 3mL UTM Viral Transport Media in 100 mm Tube	Copan	305C	220531	23001720	3C036NHL	403C
UTM/Nasopharyngeal Sample Collection Kit	Minitip Flocked Swab + 3mL UTM Viral Transport	Copan	307C	220529	23001721	3C037NHL	401C
UTM/Nasopharyngeal Sample Collection Kit	UTM with Adult Contoured FLOQSwab Set	Copan	N/A	N/A	N/A	N/A	407C
UTM/Nasopharyngeal Sample Collection Kit	UTM with Pediatric Contoured FLOQSwab	Copan	N/A	N/A	N/A	N/A	408C
Flocked Swab	Mid-Turbinate Flocked Swab (Contoured adult flocked swab with 80mm break point in peel pouch)	Copan	56380CS01	N/A	23600966	N/A	N/A
Flocked Swab	Mid-Turbinate Flocked Swab (Contoured pediatric flocked swab with 80mm break point in peel pouch)	Copan	56780CS01	N/A	23600967	N/A	N/A
VTM	MicroTest M4RT Transport	Remel	R12587	N/A	R12587 R12705 (with swab)	N/A	N/A
VTM	UniTranz-RT Transport System	Puritan	UT300	N/A	22027112	N/A	N/A
UTM	Transport media only (no swab included)	Copan	330C	220220	23001718	330CHL	330C.DHI
Flocked Swab	Nasopharyngeal Flocked swab (Flexible minitip flocked swab with 100mm breakpoint in peel pouch)	Copan	503CS01	220252	23600952	N/A	503CS01
Flocked Swab	Nasopharyngeal Flocked swab (Flexible minitip flocked swab with 100mm breakpoint in dry tube)	Copan	N/A	553C	N/A	23600961	N/A
Flocked Swab	Nasopharyngeal Flocked swab (Minitip flocked swab with 100mm breakpoint in peel pouch)	Copan	518CS01	220251	23600956	518CS01	N/A
Flocked Swab	Nasopharyngeal Flocked swab (Minitip flocked swab with 100mm breakpoint in dry tube)	Copan	518C	N/A	23600953	N/A	N/A

Product Line	**ZeptoMetrix Catalog #**	**Virus/Cell Line**	**Description**
NATtrol™ SARS-CoV-2	NATSARS(COV2)-ERC1 (6 x 1 mL)	Inactivated SARS-CoV-2	Positive Control
NATtrol™ SARS-CoV-2	NATSARS(COV2)-NEG1 (6 x 1 mL)	A-549	Negative Control

***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 may cause undesired operation.

†Note: The Visby Medical COVID-19 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 area is likely to cause harmful interference in which case the user will be required to correct the interference at his/her own expense.

††Note: The Visby Buffer Tube is designed to dilute nasopharyngeal, nasal, or mid-turbinate samples collected in commercially available transport medias prior to analysis with the Visby Medical COVID-19 Test. See Materials Required but Not Supplied for part number information.

Note: Safety Data Sheets (SDS) are available at Visby Medical Customer Support at 1-883-GoVisby (1-833-468-4729) or support@visby.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@visby.com.

Storage and Stability

Storage

Test Unit

Store the Visby Medical COVID-19 Test between 36°F and 86°F (2°C and 30°C), 30% and 80% humidity. Do not freeze. In case of refrigeration or other exposure to cold temperatures, ensure that the Visby Medical COVID-19 Test is allowed to fully come to at least its minimum operating temperature of 66°F (19°C) prior to use.

Specimen and Diluted Specimen

SARS-CoV-2 is stable in UTM for 5 hours at 86°F (30°C), 48 hours at 39°F (4°C) and 7 days at -4°F (-20°C) when tested on the Visby Medical COVID-19 Test.

After loading the Visby Medical COVID-19 Test, the Visby Buffer Tube should be disposed of in the Biohazard Bag according to the Institution's standard practices. DO NOT STORE DILUTED SAMPLE.

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

Specimen Collection

Use freshly collected specimens for optimal test performance. Inadequate specimen collection or improper sample handling/ storage/transport/dilution may yield erroneous results. Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19).

The Visby Medical COVID-19 Test is intended for testing nasopharyngeal, nasal, or mid-turbinate swabs eluted in viral transport media and then diluted in the Visby Buffer Tube.

Warnings and Precautions

General

1. For *in vitro* diagnostic use.
2. For prescription use only.
3. For use under an Emergency Use Authorization only.
4. This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories.
5. This product has been authorized only for the detection of nucleic acid from SARS CoV-2, not for any other viruses or pathogens.
6. 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.
7. This product is for single use only; do not reuse the Visby Medical COVID-19 Test.
8. Caution: Federal Law restricts this device for sale by or on the order of a licensed practitioner (US only).
9. Follow the Institution's safety procedures for working with chemicals and handling biological samples.
10. 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.
11. The Visby Medical COVID-19 Test's control panel and results must be interpreted as per the instructions provided on this guide.
12. Leave the Visby Medical COVID-19 Test sealed in the foil pouch until just before use.
13. Do not use the Visby Medical COVID-19 Test past its expiration date.
14. Do not use the Visby Medical COVID-19 Test if it appears broken.
15. Do not use the Visby Medical COVID-19 Test if it has been dropped.
16. Do not shake or tilt the Visby Medical COVID-19 Test after adding a sample.
17. Do not add excessive sample into the test as this may result in an error.
18. Run the test on a clean, level surface.
19. Do not move the Visby Medical COVID-19 Test while it is running the sample.
20. Do not touch or move charging cable, adapter or device while the test is running.
21. Do not unplug the Visby Medical COVID-19 Test during operation.
22. At a low frequency, clinical samples can contain inhibitors that may generate invalid results. Site to site invalid rates may vary.
23. Wear gloves while handling samples. If they come in contact with specimen or appear to be wet, change gloves to avoid contaminating other specimens. Change gloves before leaving work area and upon entry into work areas.
24. Keep the work area clean to prevent contamination.
25. Do not try to disassemble the Visby Medical COVID-19 Test. In the case of a positive sample, this could lead to sample leakage and potential contamination.
26. If a spill occurs with the Visby Medical COVID-19 Test and/ or Visby Buffer Tube, soak up material 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 rest for 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 Medical COVID-19 Test, and/or the Visby Buffer Tube. Discard affected single use materials according to the Institution's standard practices.
27. If a spill occurs on the Visby power 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.

Specimen Pooling (For High Complexity Laboratories)

1. Contamination may occur if carryover of samples is not adequately controlled during sample pool preparation, handling, and processing.
2. Testing of pooled specimens may impact the detection capability of the Visby Medical COVID-19 Test.
3. Some positive samples may not be detected when diluted and tested in pools. SARS-CoV-2 RNA concentration is reduced when a positive sample is pooled with other samples, and the reduction corresponds inversely to the pool size.

Visby Medical COVID-19 Test and Accessories

1. The Visby power adapter should be replaced after 1000 uses. Failure to do so may result in faulty electronic connections and invalid results.
2. Use only the supplied Visby power adapter to power the Visby Medical COVID-19 Test. Using other power adapters to operate the Visby Medical COVID-19 Test will void the safety protection of the device.
3. Dispose of the power adapter per local, federal, and institutional guidelines.
4. Collect samples in Universal Transport Media (UTM), or Viral Transport Media (VTM). Use collection instructions included in the Visby Medical Kit. Please do not use nasal sprays, gels, or creams prior to collecting specimen.
5. Operating Conditions: The Visby Medical COVID-19 Test should be used between 66°F and 82°F (19°C and 28°C), 30% to 80% humidity, and -98ft to 5400ft elevation (101700 Pa to 84300 Pa). Failure to do so may yield invalid results.
6. Follow manufacturer's transport media instructions for specimen storage.
7. The Visby Medical COVID-19 Test is best used in a room with adequate lighting and away from glare. Failure to do so may result in an inability to see the results on the test.
8. After use, the Visby Medical COVID-19 Test should be placed in the provided Biohazard Bag prior to disposal.
9. The Visby Medical COVID-19 Test should be disposed of in the appropriate specimen waste containers according to the Institution's standard practices.
10. The results of the Visby Medical COVID-19 Test must be read within 120 minutes after the green check mark light appears. Failure to do so may yield invalid results. After 120 minutes or the test is unplugged the green check mark will turn off indicating that the read window has expired.
11. The Visby Medical COVID-19 Test must be run on a level surface and should not be moved during operation. Failure to do so may yield invalid or inaccurate results.
12. 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.

Specimen and Visby Buffer Tube

1. Follow the CDC's guidelines and the Institution's safety procedures for working with chemicals and handling biological samples[3].
2. Treat all biological specimens, including used Visby Medical COVID-19 Tests and specimens diluted in Visby Buffer Tubes as capable of transmitting infectious agents. Because it is often impossible to know which may be infectious, all biological specimens should be treated with standard precautions. Follow the guidelines for specimen handling from the Centers for Disease Control and Prevention and the Clinical Laboratory Standards Institute[3].
3. When dispensing sample into the Visby Buffer Tube, ensure the tip of the Visby Pipette touches the inner wall of the Visby Buffer Tube above the fluid.
4. The Visby Buffer Tube should only be used to dilute swab specimens.
5. The Visby Medical Buffer Tube is for single use only. Do not re-use the Visby Buffer Tube to elute more than one sample. Do not use the Visby Buffer Tube to load more than one Visby Medical COVID-19 Test.
6. Use the Visby Buffer Tube only as directed.
7. Ensure tube caps are tightened prior to inverting specimen.
8. Always dilute patient samples with the Visby Buffer Tube in accordance with the dilution instructions.
9. Do not apply the Visby Buffer directly onto the skin or mucous membranes or ingest.
10. Do not use the Visby Buffer Tube if it appears to be damaged or opened.
11. The Visby Buffer is a clear, colorless, and odorless solution. Do not use if the solution appears discolored or has a strong odor.
12. Do not use the Visby Buffer Tube past its expiration date.
13. Visby Buffer Tube 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.
14. If the contents of the tube are spilled at any time during the dilution procedure, use a new Visby Buffer Tube.
15. The Visby Medical COVID-19 Test requires a sample input of a specified volume from a fixed-volume Visby Pipette that is provided. If no sample is added into the Visby Medical COVID-19 Test, the Results Valid spot will not be displayed.

Visby Medical COVID-19 Test Instructions for Testing Individual Samples

Please follow these instructions carefully.

Immediately load the Visby Medical COVID-19 Test after performing the dilution step.

Run the Visby Medical COVID-19 Test at room temperature between 66°F to 82°F (19°C to 28°C) on a clean, level surface.

The Visby Medical COVID-19 Test, Visby Pipettes, and Visby Buffer Tube should be disposed of in accordance with local regulations.

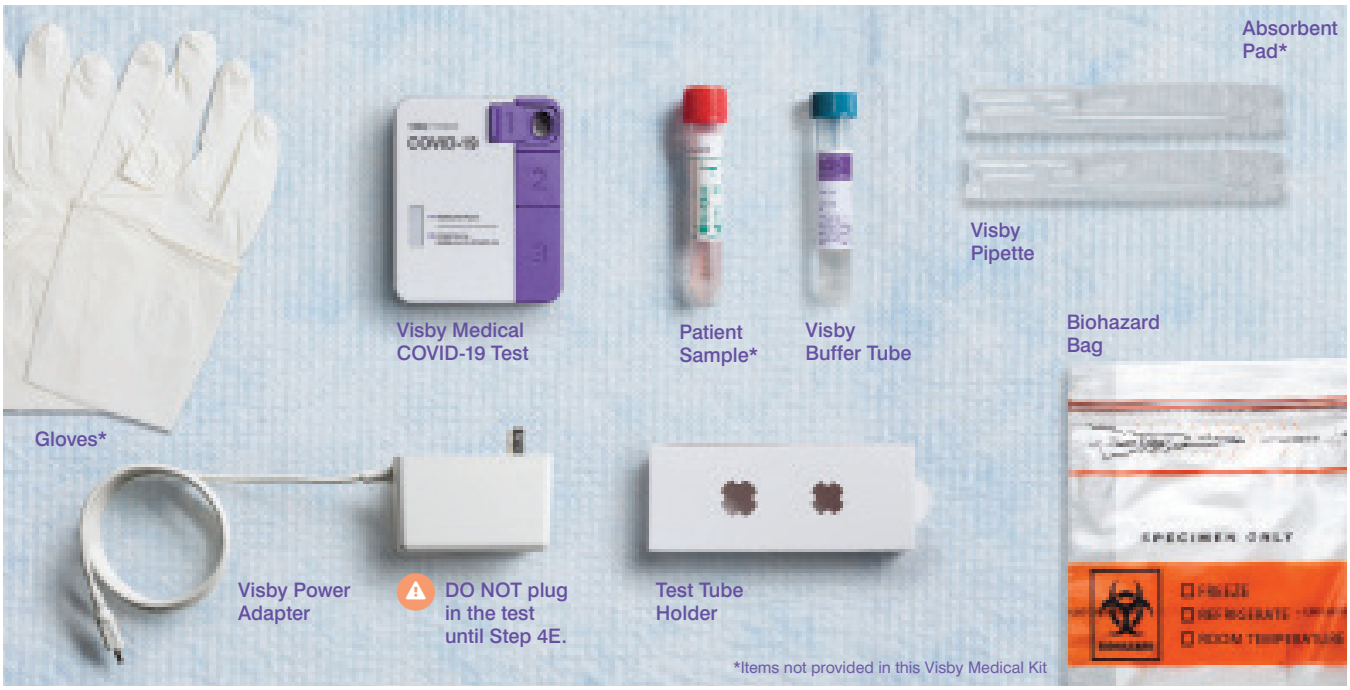
Operating Conditions

TEMPERATURE	HUMIDITY	PRESSURE
66°F - 82°F	**30% - 80%**	**-98ft - 5400ft**
(19° - 28°C)		(101700 Pa - 84300 Pa)

Run the test on a clean, level surface. If held at room temperature, test samples within five hours of collection.

Step 1 Set Up the Workstation

Operating Conditions: Ensure the test is run at room temperature 66.2°F to 82.4°F in a cool, dry environment. Read all the instructions including the Package Insert.



Run on a clean, level surface. It is important to change gloves and absorbent pads after every test to avoid contamination.

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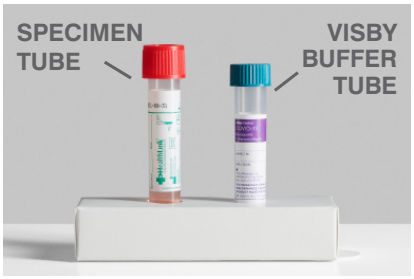
COVID-19

Step 2 Dilute Sample

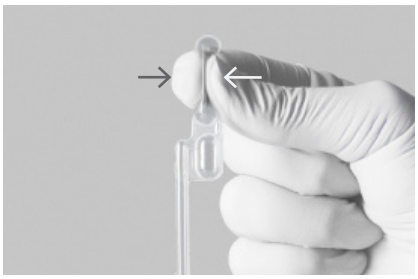
Use this procedure to dilute the patient sample.

A Invert patient specimen tube **5 times**. Place it in the tube holder.



B Place **Visby Buffer Tube** in the tube holder.

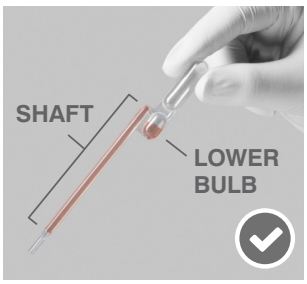
C **Uncap** both tubes. Place caps wet side up.



D Take Visby Pipette and squeeze the **upper bulb**.

E **Keeping the bulb squeezed**, lower the pipette tip to the bottom of the specimen collection 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 Visby Pipette.

H Squeeze the upper bulb to **dispense all the fluid** in the shaft into the Visby Buffer Tube. Some fluid will remain in the lower bulb.

I **Discard** the Visby Pipette as per your institution's practices. **Do not set it down.**

J Screw the cap back on both tubes. Make sure they are on **tight**. Put aside patient specimen.

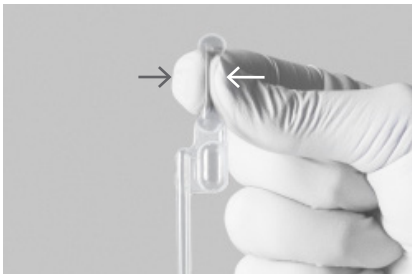
Step 3 Load the Sample into the Device

⚠ 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**.

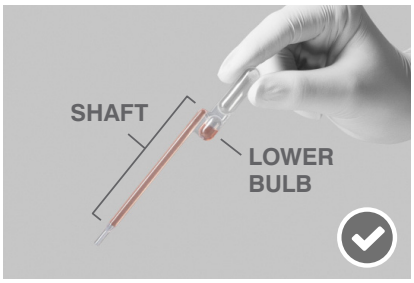
C Open the cap of the Visby Buffer Tube. Place cap wet side up. Take a **second** Visby Pipette.



D Squeeze the **upper bulb**.

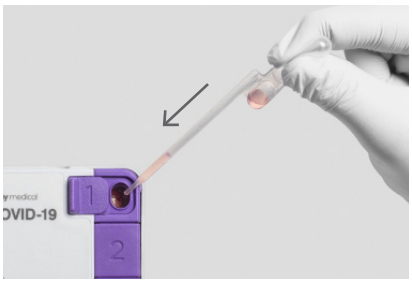
E **Keeping the bulb squeezed**, lower the Visby Pipette tip to the bottom of the Visby Buffer Tube.

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 Visby Pipette.



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

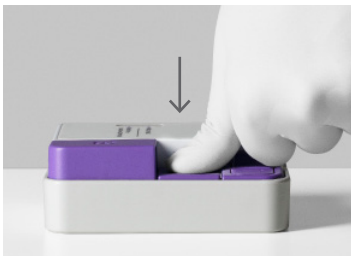
I **Discard** the Visby Pipette according to your institution's standard practices. **Do not set it down**. Recap the Visby Buffer Tube.

Step 4 Run the Test

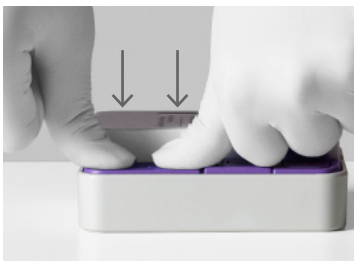
⚠ IMPORTANT! Each button will have a different feel as it “clicks” into place.
Push firmly to make sure **all buttons are completely down** or the test may not work.

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.



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 test is running.
Ensure that there is no gap between the adapter jack and the device.

WAIT 30 MINUTES!
DO NOT touch or move the charging adapter, cable or device.

Step 5 Get the Results

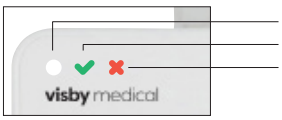
AFTER 30 MINUTES

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 using a new test and new Visby Buffer Tube.

Color Blindness Precaution
While color-blind users may be unable to differentiate red, green, and white status lights, they may consult 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.
Start again with a new test and new Visby Buffer Tube.

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

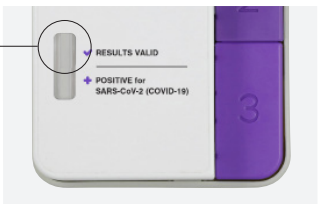
VALID
A purple spot indicates a valid test.

This is the control spot.

If present, proceed to Step 5C.

INVALID
No purple spot indicates an invalid test.

Repeat using a new test and new Visby Buffer Tube.



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 Medical COVID-19 Test should be placed in a Biohazard Bag prior to disposal. The used test, Visby Pipette, Visby Buffer Tube, and specimen collection kit should be disposed of in the appropriate specimen waste containers according to the Institution's standard practices.

Please refer to the Package Insert for additional details.

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

Visby Medical COVID-19 Instructions for Testing Pooled Samples

(For High Complexity Laboratories Only)

Specimen Pooling

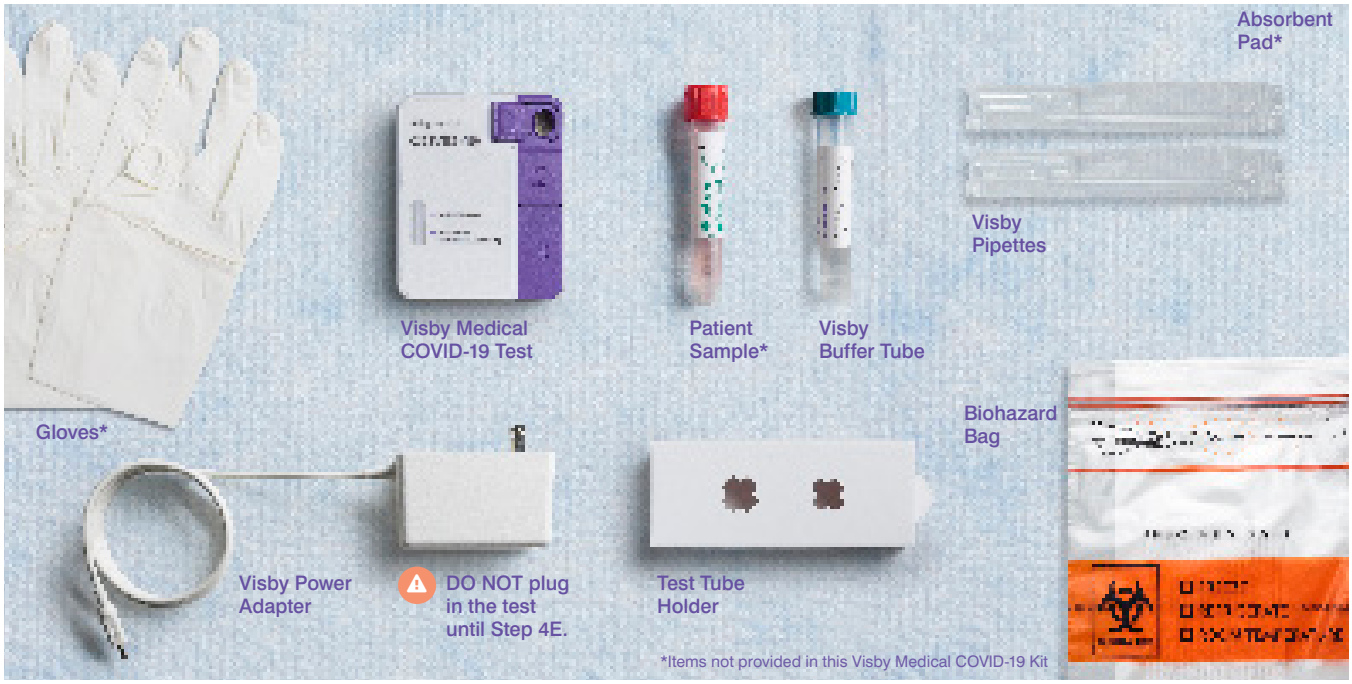
Determining the Appropriate Strategy for Implementation and Monitoring: When considering specimen pooling, laboratories should evaluate the appropriateness of a pooling strategy based on the positivity rate in the testing population and the efficiency of the pooling workflow. Refer to Appendix A of this Package Insert for additional information prior to implementation of specimen pooling.

Preparing Samples for Pooling: Nasopharyngeal, mid-turbinate, and anterior nasal swab specimens collected into VTM/UTM can be used. When pooling samples, use a standard adjustable volume pipette and reference the table below to determine how much sample to transfer into the pool (e.g., 130 uL for each sample in pools of 5). Ensure that each sample has sufficient volume for pool construction and any possible deconvolution testing that may be required.

Number of Samples Pooled	Amount of Sample Added to Visby Buffer
2	325 µL
3	217 µL
4	163 µL
5	130 µL

Step 1 Set Up the Workstation

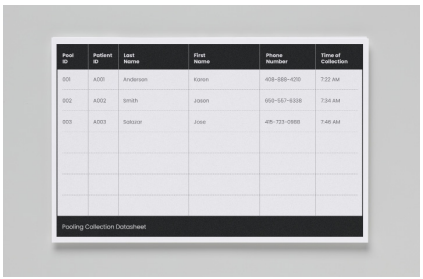
Operating Conditions: Ensure the test is run at room temperature 66.2°F to 82.4°F in a cool, dry environment. Read all the instructions including the Package Insert.



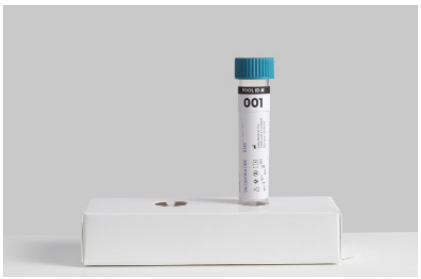
Run on a clean, level surface. It is important to change gloves and absorbent pads after every test to avoid contamination. Note: A standard adjustable volume pipette is also required when running pooled samples.

Step 2 Combine all samples in the pool to the Visby Buffer Tube

Use this procedure to transfer the appropriate amount of patient sample to the Visby Buffer for pooling.



A Gather patient samples for pooling. Record patient information and assign a **pool ID**.



B Place a label with the **pool ID** on the **Visby Buffer Tube**.

Number of Samples	Volume of Sample to Add
2	325 µL
3	217 µL
4	163 µL
5	130 µL

C Set the standard adjustable volume pipette to the appropriate volume based on the number of samples to be pooled.

D Invert patient specimen tubes **5 times**.

E Using a standard adjustable volume pipette, transfer the appropriate sample volume to the Visby Buffer Tube.

F Repeat steps D and E for **all patient samples** in the same pool.

Note: Replace the pipette tip before transferring each sample. Add all samples to the same Visby Buffer Tube.

G After adding all samples into the Visby Buffer Tube, place the cap back on.

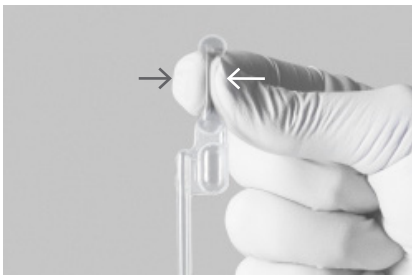
Step 3 Load the Sample into the Device

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

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

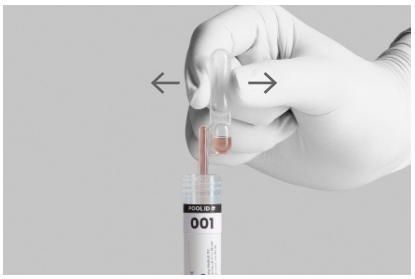
B Mix the specimen in the Visby Buffer Tube by inverting the tube **5 times**.

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

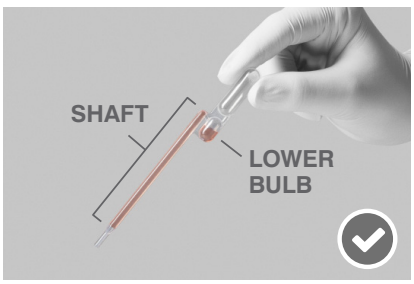


D Squeeze the **upper bulb**.

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

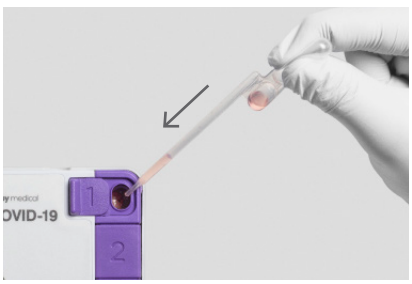


F Keep the tip fully under the fluid. Release the upper bulb.



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

Note: Do not squeeze lower bulb or invert the Visby Pipette.



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

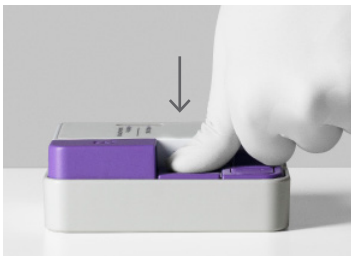
I **Discard** the Visby Pipette according to your institution's standard practices. **Do not set it down**. Recap the Visby Buffer Tube.

Step 4 Run the Test

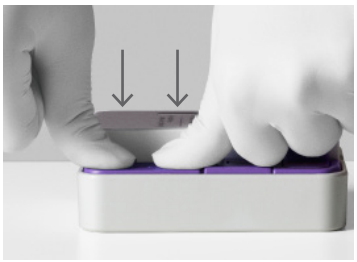
⚠ IMPORTANT! Each button will have a different feel as it “clicks” into place.
Push firmly to make sure **all buttons are completely down** or the test may not work.

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.



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 test is running.
Ensure that there is no gap between the adapter jack and the device.

WAIT 30 MINUTES!
DO NOT touch or move the charging adapter, cable or device.

visby medical

COVID-19

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 using a new test and new Visby Buffer Tube.

Color Blindness Precaution
While color-blind users may be unable to differentiate red, green, and white status lights, they may consult 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.
Start again with a new test and new Visby Buffer Tube.

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

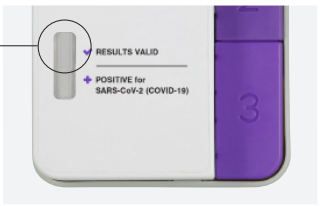
VALID
A purple spot indicates a valid test.

This is the control spot.

If present, proceed to Step 5C.

INVALID
No purple spot indicates an invalid test.

Generate a new pool or test the samples individually using a new test and new Visby Buffer Tube.



*Note: Step 5C continues on next page

Step 5 Get the Results (Continued)

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.

Examination and Interpretation of Pooled Patient Specimen Results

Negative - Negative results should be reported for each patient in the pool. The test results should indicate that sample pooling was used. Negative results from pooled sample testing should not be treated as definitive. If the patient's clinical signs and symptoms are inconsistent with a negative result and if results are necessary for patient management, then the patient should be considered for individual testing.

Positive - Specimens with a positive sample pool result must be tested individually prior to reporting a result. Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing.

Invalid - Pools with invalid results can be retested using a new Visby Medical COVID-19 Test and new Visby Buffer Tube by generating a new pool using stored UTM samples or by testing the samples individually.

After use, the Visby Medical COVID-19 Test should be placed in a Biohazard Bag prior to disposal. The used test, Visby Pipette, Visby Buffer Tube, and specimen collection kit should be disposed of in the appropriate specimen waste containers according to the Institution's standard practices.

Please refer to this Package Insert for additional details.

Need Help? Call 1-833-GoVisby (1-833-468-4729) or e-mail support@visby.com

visby medical

COVID-19

Interpretation of Sample Results

Note: Further guidance around pooling results interpretation available in Appendix A.

Result	Interpretation	Recommendation
	• Valid test (✔, RESULTS VALID) • Negative for SARS-CoV-2 (COVID-19)	• Report results of patient sample • For pooled samples, indicate use of pooling in report
	• Valid test (✔, RESULTS VALID) • Positive for SARS-CoV-2 (COVID-19)	• Report results of patient sample • For pooled samples, repeat testing with individual samples prior to reporting the results
	• Invalid test; control fail (✔, RESULTS VALID)	• Discard test • When testing individual samples, repeat test using a new Visby Medical COVID-19 Test and new Visby Buffer Tube • Pools with invalid results can be retested by using the stored UTM/VTM samples and generating a new pool or by testing the samples individually • If repeat fails, contact Visby Medical Customer Support
	☼ Blinking white light for 2-3 minutes, then turns to Red ✖ ✖ Error: Power interrupt failure. The device was plugged in before Step 4E	• Discard test • When testing individual samples, repeat test using a new Visby Medical COVID-19 Test and new Visby Buffer Tube • Pools with invalid results can be retested by using the stored UTM/VTM samples and generating a new pool or by testing the samples individually • Push the adapter jack into the device's charging port 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 fails, contact Visby Medical Customer Support
	✖ Error: Invalid	• Discard test • When testing individual samples, repeat test using a new Visby Medical COVID-19 Test and new Visby Buffer Tube • Pools with invalid results can be retested by using stored UTM/VTM samples and generating a new pool or by testing the samples individually • If repeat fails, contact Visby Medical Customer Support

Interpretation of External Control Results

Result	Interpretation	Recommendation
	• Invalid test; control fail (✔, ▯ RESULTS VALID)	• Discard test • When testing individual samples, repeat test using a new Visby Medical COVID-19 Test and new Visby Buffer Tube • Pools with invalid results can be retested by using stored UTM/VTM samples and generating a new pool or by testing the samples individually • If repeat fails, contact Visby Medical Customer Support
	✖ Error: Invalid	• Discard test • When testing individual samples, repeat test using a new Visby Medical COVID-19 Test and new Visby Buffer Tube • Pools with invalid results can be retested by using stored UTM/VTM samples and generating a new pool or by testing the samples individually • If repeat fails, contact Visby Medical Customer Support
Result for Negative Control 	• Valid test (✔, ▮ RESULTS VALID) • External negative control passed	• Any other combination - discard test and repeat negative external control using a new Visby Medical COVID-19 Test, a new negative control vial, and a new Visby Buffer Tube • If repeat fails, contact Visby Medical Customer Support
Result for Positive Control 	• Valid test (✔, ▮ RESULTS VALID) • External positive control passed	• Any other combination - discard test and repeat positive external control using a new Visby Medical COVID-19 Test, a new positive control vial, and a new Visby Buffer Tube • If repeat fails, contact Visby Medical Customer Support

Under Rare Circumstances

The following are occasionally observed but should not be confused with a positive signal:

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

Speckling and Bubbles
In certain cases, samples heavy in blood or mucus may result in nonspecific small flakes in the results window. These are normal conditions and should not impact interpretation of results. It is also normal for bubbles to appear in the results window during test processing.

Spot Variance
The color of the spot may vary in color hue and intensity depending on the nature of the infection. As long as the shape is filled with color and the spot has distinct edges, any colored spot should be considered a real spot.

Retest Procedure

Obtain the leftover sample from the Universal Transport Media (UTM) or Viral Transport Media (VTM). Repeat the test with a new Visby Buffer Tube and Visby Medical COVID-19 Test. If the sample volume is insufficient, or the retest continues to return an invalid or red “X” result, collect a new sample and repeat the test with a new Visby Buffer Tube and Visby Medical COVID-19 Test.

If the positive or negative external controls fail, repeat the test with a new external control, Visby Buffer Tube, and Visby Medical COVID-19 Test. If the repeat test fails, please contact Visby Medical Customer Support at 1-833-GoVisby (1-833-468-4729) or support@visby.com

COVID-19

Limitations

1. The performance of the Visby Medical COVID-19 Test was established using nasopharyngeal swab specimens. Mid-turbinate and nasal swabs are considered acceptable specimen types for use with the Visby Medical COVID-19 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 Medical 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 viral load present in the sample, reliable results are dependent on proper sample collection, sample dilution, handling, and storage.
5. Built-in procedural controls of the Visby Medical COVID-19 Test do not indicate false positive results.
6. As with other assays of this type, there is a risk of false negative. A false negative result may occur if a specimen is improperly collected, transported or handled. False negative results may also occur if inadequate numbers of organisms are present in the specimen.
7. Additional follow-up testing is recommended if the result is negative and clinical symptoms persist.
8. This test has been evaluated with human specimen material only.
9. The effect of interfering substances has been evaluated only for those listed within the labeling.
10. 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.
11. This test cannot rule out diseases caused by other bacterial or viral pathogens.
12. Sample pooling has only been validated using nasopharyngeal swab specimens.
13. Samples should only be pooled when testing demand exceeds laboratory capacity and/or when testing reagents are in short supply.
14. Performance has not been established in asymptomatic individuals.
15. Viral nucleic acid may persist in vivo, independent of virus viability. Detection of analyte target does not imply that the corresponding viruses are infectious or are the causative agents for clinical symptoms.
16. 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 time.

Conditions of Authorization for the Laboratory

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

However, to assist clinical laboratories using the Visby Medical COVID-19 Test, the relevant Conditions of Authorization are listed below:

A. Authorized laboratories[1] using the Visby Medical COVID-19 Test 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.
B. Authorized laboratories using specimen pooling strategies when testing patient specimens with the Visby Medical COVID Test must include with test result reports for specific patients whose specimen(s) were the subject of pooling, a notice that pooling was used during testing and that "Patient specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing."
C. Authorized laboratories using the Visby Medical COVID-19 Test must use the Visby Medical COVID-19 Test 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 materials required to use the Visby Medical COVID-19 Test are not permitted.
D. Authorized laboratories implementing pooling strategies for testing patient specimens must use the "Specimen Pooling Guidelines" provided in the Appendix to evaluate the appropriateness of continuing to use such strategies based on the recommendations in the protocol.
E. Authorized laboratories that receive the Visby Medical COVID-19 Test must notify the relevant public health authorities of their intent to run the Visby Medical COVID-19 Test prior to initiating testing.
F. Authorized laboratories using the Visby Medical COVID-19 Test must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
G. Authorized laboratories must keep records of specimen pooling strategies implemented including type of strategy, date implemented, and quantities tested, and test result data generated as part of the Specimen Pooling Implementation and Monitoring Guidelines. For the first 12 months from the date of their creation, such records must be made available to FDA within 48 business hours for inspection upon request and must be made available within a reasonable time after 12 months from the date of their creation.
H. Authorized laboratories must collect information on the performance of the Visby Medical COVID-19 Test and report to DMD/OHT7-OIR/ OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Visby Medical, Inc (support@visby.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the Visby Medical COVID-19 Test of which they become aware.
I. All laboratory personnel using the Visby Medical COVID-19 Test must be appropriately trained on the use of the Visby Medical COVID-19 test and use appropriate laboratory and personal protective equipment when handling this kit, and use the Visby Medical COVID-19 Test in accordance with the authorized labeling.

J. Visby Medical, Inc., authorized distributors, and authorized laboratories using the Visby Medical COVID-19 Test must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

[1] "Authorized laboratories" are laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high or moderate complexity tests, except testing of pooled samples is limited to laboratories certified under CLIA, 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

Quality Control

The Visby Medical COVID-19 Test has built-in procedural controls. The results of the procedural controls are displayed in the results window and status areas with each test result.

Procedural Controls:

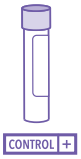
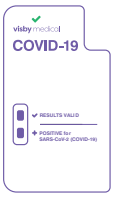
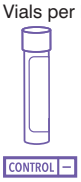
The control strategy relies on a positive spot on the flow cell. If all elements in the Visby Medical COVID-19 Test device are functioning properly, then the Results Valid spot will produce color. There is an electronic control mechanism that detects hardware, software, and various user error failures. If this control passes, a green check mark appears in the status area. If this control fails, a red "X" appears in the status area.

At a low frequency, patient samples can contain inhibitors that may generate invalid results.

External Positive and Negative Controls:

Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working and that the test is correctly performed. Test these controls once with each new shipment, new operator, and in accordance with guidelines or requirements of local, state and/or federal regulations or accrediting organizations on a regular interval as dictated by the laboratory or clinic. 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.

EXTERNAL POSITIVE AND NEGATIVE CONTROLS
NATtrol™ SARS-CoV-2 External Run Controls by ZeptoMetrix

Product Code	Unit	Control Key
ZeptoMetrix Positive Control: NATSARS(COV2)-ERC1 (6 x 1 mL)	Six (6) x 1 mL Vials per Kit 	Valid Positive Control Run 
ZeptoMetrix Negative Control: NATSARS(COV2)-NEG1 (6 x 1 mL)	Six (6) x 1 mL Vials per Kit 	Valid Negative Control Run 

If the positive or negative external controls fail, repeat with a new external control, Visby Buffer Tube, and Visby Medical COVID-19 Test. If the repeat test fails, please contact Visby Medical Customer Support at 1-833-GoVisby (1-833-468-4729) or support@visby.com.

Important Information

Use this test with nasopharyngeal, nasal, or mid-turbinate swabs collected by a health care provider (HCP), or nasal or mid-turbinate swabs self-collected (in a healthcare setting) eluted in viral transport medium and diluted with the Visby Buffer Tube. Please refer to the collection instructions for more information.

Laboratories must follow the instructions for performing the test.

⚠ Follow your institution's and CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19).

⚠ In cases where prolonged testing is conducted in enclosed environments, follow appropriate safety procedures for airborne respiratory pathogens. Users should read the complete test procedure and recommended quality control procedures before performing the test. Please refer to the package insert for more information.

🗑 After use, the Visby Medical COVID-19 Test should be placed in a Biohazard Bag prior to disposal. The used test, Visby Pipette, Visby Buffer Tube, and specimen collection kit should be disposed of in the appropriate specimen waste containers according to the Institution's standard practices.

CONTROL + / CONTROL − Controls should be run with each shipment, lot, new operator, and on a regular interval in accordance with guidelines or requirements of local, state and/or federal regulations or accrediting organizations.

COVID-19

Analytical Performance

Analytical Sensitivity (Limit of Detection)

Limit of Detection (LoD) studies were performed to determine the analytical LoD of the Visby Medical COVID-19 test. Dilutions of inactivated SARS-CoV-2 (USA_WA1/2020 strain) in negative nasopharyngeal clinical matrix were tested in replicates of 20. The LoD value was estimated by a probit analysis of the results from the range-finding study. Verification of the estimated LoD was performed by testing 20 replicates at the estimated concentration and confirming the Visby Medical COVID-19 test detected the inactivated SARS-CoV-2 virus ≥ 95% of the time. The claimed LoD of the Visby Medical COVID-19 Test for SARS-CoV-2 virus is 1,112 genomic copies/mL (Table 01).

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

Inactivated SARS-CoV-2 Virus (USA_WA1/2020)	Concentration (genomic copies/mL)	Visby Medical COVID-19 (Detected/Tested)	Visby Medical COVID-19 % Detected
Range Finding	125	9/20	45%
	250	11/20	55%
	500	15/20	75%
	750	18/20	90%
	1000	20/20	100%
Verification	1112	19/20	95%

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 July 2021, 612,687 SARS-CoV-2 sequences submitted to the GISAID database[5] in 2021 have been analyzed, including 3 sequence submissions from all common spike gene variants in circulation in the US and the WHO designated Variants of Concern. This periodic process has not identified variants of sufficient frequency (<5%) to affect the performance of the Visby test, including the Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1) and Delta (B.1.617.2) variants.

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 human genome, other coronaviruses or 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 Medical 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, allowing for a re-test of one sample. The organisms, concentrations and results are listed below. None of the 31 organisms caused cross-reactivity on the Visby Medical COVID-19 test at the concentrations in Table 02.

Table 02: Summary of performance for organisms tested on the Visby Medical 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	3/3
Adenovirus, C1 Ad 71	2.5×10^{-3}	ng/µL	3/3	3/3
Human metapneumovirus (hMPV)	1.1×10^5	genomic copies/mL	3/3	3/3
Human parainfluenza virus 1	2.5×10^{-3}	ng/µL	3/3	3/3
Human parainfluenza virus 2	2.5×10^{-3}	ng/µL	3/3	3/3

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 parainfluenza virus 3	2.5×10^{-3}	ng/µL	3/3	8/9 (2)
Human parainfluenza virus 4b	2.5×10^{-3}	ng/µL	3/3	3/3
Influenza A	1.1×10^{6}	$CEID_{50}$/mL	3/3	3/3
Influenza B	1.1×10^{6}	$CEID_{50}$/mL	3/3	3/3
Enterovirus 68	1.1×10^{5}	genomic copies/mL	3/3	3/3
Respiratory syncytial virus	1.1×10^{5}	genomic copies/mL	3/3	3/3
Human rhinovirus 17 (strain 33342)	1.1×10^{5}	genomic copies/mL	3/3	3/3
Chlamydia pneumoniae	1.1×10^{6}	IFU/mL	3/3	3/3
Haemophilus influenzae	1.1×10^{6}	genomic 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	1.1×10^{6}	genomic copies/mL	3/3	3/3
Bordetella parapertussis	1.1×10^{6}	genomic copies/mL	3/3	3/3
Mycoplasma pneumoniae	1.1×10^{6}	genomic copies/mL	3/3	3/3
Pneumocystis jirovecii (PJP), also called: *Pneumocystis carinii 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.

Analytical Specificity (Interfering Substances)

A study was executed to determine the effect of endogenous and exogenous potentially interfering substances that may be present in a clinical sample on the performance of the Visby Medical COVID-19 test. Each potential interfering substance was seeded into negative nasopharyngeal clinical matrix and tested in triplicate. Each potential interfering substance was also seeded into the negative nasopharyngeal clinical matrix spiked with inactivated SARS-CoV-2 virus at 2X LoD and tested in triplicate. The substances, concentrations and results are listed below. It was determined that the worst case was represented by a mid-turbinate swab saturated with the interferent. The swab is capable of holding a maximum of 75 µL resulting in a final maximum concentration post-elution of 2.5% (v/v). None of the substances tested for interference impacted the performance or results of the Visby Medical COVID-19 test at the concentrations in Table 03 (Table 3 shown in following page).

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

Interfering Substance	Concentration	Negative Samples # Negative for SARS-CoV-2 / # Tested	Positive Samples # Positive for SARS-CoV-2 / # Tested
Mucin	1% (w/v)	3/3	3/3
Zanamivir (Relenza)	282 ng/mL	3/3	3/3
Biotin	3.5 µg/mL	3/3	3/3
Mupirocin	12 mg/mL	3/3	3/3
Tobramycin	2.43 mg/mL	3/3	3/3
Afrin	2.5% (v/v)	3/3	3/3
Fresh Whole Blood Pooled Human Donors	5% (v/v)	3/3	3/3
Flumist [3]	2.5% (v/v)	3/3	3/3
Flonase	2.5% (v/v)	3/3	3/3
Nasacort	2.5% (v/v)	3/3	3/3
Nasal Saline Spray	2.5% (v/v)	3/3	3/3
NeoSynephrine Cold & Sinus Extra Strength Spray	2.5% (v/v)	3/3	3/3
Zicam Allergy Relief	2.5% (v/v)	3/3	3/3
(3) Potential interference from non-expired Flumist was not evaluated due to the lack of availability of non-expired Flumist for testing.			

Clinical Evaluation

The objective of this study was to establish the performance characteristics of the Visby Medical COVID-19 Test as compared to an EUA-authorized test in clinical specimens. A total of sixty-three (63) samples were tested in the study. Of these, three (3) yielded invalid results during the initial test and sufficient volume in the original sample was not available for a retest. Thus, sixty (60) samples were included in the final dataset for the analysis. Specimens were randomized and blinded to the study operators.

Performance estimates for Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) are shown in Table 04. Relative to the EUA-authorized comparator test, the Visby Medical COVID-19 Test demonstrated both PPA and NPA for detection of SARS-CoV-2 RNA of 100% (95% CI: 88.6%-100.0%).

Table 04: Visby Medical COVID-19 Test vs EUA-authorized Comparator Assay

	EUA-authorized Test			
Visby COVID-19 Test		POS	NEG	TOTAL
	POS	30	0	30
	NEG	0	30	30
	TOTAL	30	30	60
PPA	100% (95% CI: 88.6%-100.0%)			
NPA	100% (95% CI: 88.6%-100.0%)			

Summary of LoD Confirmation Result using the FDA SARS-CoV-2 Reference Panel

The evaluation of sensitivity and MERS-CoV cross-reactivity was performed using reference material (T1), blinded samples and a standard protocol provided by the FDA. The study included a range finding study and a confirmatory study for LoD. Blinded sample testing was used to establish specificity and to confirm the LoD. The samples were tested with the Visby Medical COVID-19 Test in accordance with the Package Insert. The results are summarized in Table 05.

Table 05: Summary of LoD Confirmation Result using the FDA SARS-CoV-2 Reference Panel

Reference Materials Provided by FDA	Specimen Type	Product LoD	Cross-Reactivity
SARS-CoV-2	Nasopharyngeal Swab	$5.4x10^4$ NDU/mL	N/A
MERS-CoV		N/A	ND

NDU/mL = RNA NAAT detectable units/mL
N/A: Not applicable
ND: Not detected

Clinical Performance with 5-Sample Pools

The performance of the Visby Medical COVID-19 Test was first evaluated with 20 positive pools consisting of 5 samples (1 positive sample and 4 negative samples) and 20 negative pools. A total of 103 unique negative NPS samples and 20 unique positive NPS samples collected in transport media (UTM) were tested. Each positive was used in a single pool. Some negatives were pooled twice, once in a negative pool and once in a positive pool. 25% (5/20) of positive pools were composed of 1 unique weak positive sample (determined by testing with an FDA EUA RT-PCR assay) and 4 negative samples. As shown in Table 06, relative to the Visby Medical COVID-19 Test with individual samples, the Visby Medical COVID-19 Test with 5-Sample pools demonstrated a PPA of 100.0% (95% CI: 83.9%-100.0%) and a NPA of 95.0% (95% CI: 76.4%-99.1%).

Table 06: Visby Medical COVID-19 Test with Pooled Samples vs Visby Medical COVID-19 Test with Individual Samples

	Visby Medical COVID-19 Test with Individual (non-pooled) Samples			
Visby Medical COVID-19 Test with Pooled Samples (Pool Size: N=5)		POS	NEG	TOTAL
	POS	20	1	21
	NEG	0	19	19
	TOTAL	20	20	40
PPA	100.0% (95% CI: 83.9%-100.0%)			
NPA	95.0% (95% CI: 76.4%-99.1%)			

A second clincial study was performed at three geographically diverse study sites. At each site, remnant de-identified positive and negative NPS samples collected in transport media were tested with the Visby Medical COVID-19 Test individually and then in pools of 5. Each site tested 15 positive pools comprised of 1 positive and 4 negative samples and 5 negative pools, comprised of 5 negative samples. At two of the sites, the known positive and negative samples were collected at the respective study site over a specific period of time. At the third site, known positive and negative samples were provided from a biorespository with no additional pre-selection. Samples obtained from this biorepository represented a range of viral loads, including low positives.

As shown in Table 07, relative to the Visby Medical COVID-19 Test with individual samples, the Visby Medical COVID-19 Test with 5-sample pools demonstrated a PPA of 95.6% (95% CI:85.2%-98.8%) and a NPA of 100.0% (95% CI:79.6%-100.0%).

Table 07: Visby Medical COVID-19 Test with Pooled Samples vs Visby Medical COVID-19 Test with Individual Samples at Three Geographically Diverse Sites

	Visby Medical COVID-19 Test with Individual (non-pooled) Samples			
		POS	NEG	TOTAL
Visby Medical COVID-19 Test with Pooled Samples (Pool Size: N=5)	POS	43	0	43
	NEG	2*	15	17
	TOTAL	45	15	60
PPA	95.6% (95% CI: 85.2%-98.8%)			
NPA	100.0% (95% CI: 79.6%-100.0%)			

*The 2 false negatives were from two study sites.

Index of Symbols

Ref / Symbol	Meaning	Ref / Symbol	Meaning
	Power Supply	5.3.7	Temperature limitation
5.1.6 REF	Catalog number	5.3.8	Humidity limitation
5.4.2	Do not reuse	5.4.1	Biological risks
	Handle with care	5.5.1 IVD	In vitro diagnostic medical device
5.1.5 LOT	Batch code	5.2.8	Do not use if package is damaged
5.4.4	Caution	c N us 61010	Nemko 61010
5.4.3	Consult instructions for use		Waste container
5.1.1	Manufacturer	5.3.7 CONTROL −	Negative control
5.1.4	Expiration date	5.3.8 CONTROL +	Positive control

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 Disease 2019 (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/

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PS-001315 Rev D 08/21

APPENDIX A : SPECIMEN POOLING GUIDELINES

Before Implementation of Pooling: Determine Appropriate Pool Size

Pooling may increase throughput in laboratories testing samples from populations with low prevalence of SARS-CoV-2. In populations with higher prevalence, smaller pool sizes or individual sample testing may be indicated. Before a pooling strategy is implemented, laboratories should consider the appropriateness of the pooling strategy based on the positivity rate in the testing population, efficiency of the pooling workflow, and Positive Percent Agreement (PPA) for the desired pool size (where applicable). Laboratories should retain the generated test results data for inspection by the FDA upon request.

If historical laboratory data for individual specimens is available:

- To maximize pooling efficiency, if the laboratory has historical data from the previous 7-10* days generated in the laboratory testing of individual samples, we recommend estimating the positivity rate ($P_{individual}$) based on individual testing results.
  - ($P_{individual}$) = (Number of positive specimen over chosen date range ÷ Total number of specimen tested over chosen date range)*100.
- By using the calculated $P_{individual}$ and the below table (Table 08), identify the appropriate n number of samples to pool.
  - If $P_{individual}$ is less than 5%, the maximum pool size validated (n=5), should be selected to maximize the efficiency of specimen pooling. Pooling with greater than 5 samples has not been validated and should not be performed.
  - If $P_{individual}$ is greater than 25%, Dorfman pooling of patient specimens is not efficient and should not be implemented

Table 08: Result Interpretation

***P*, percent of positive subjects in tested population**	***n*** $_{maxefficiency}$ *(n corresponding to maximal efficiency)*	***Efficiency of n-sample pooling*** *(a maximum increase in the number of tested patients when Dorfman n-pooling strategy used)*
5%-6%	5	2.15-2.35
7%-12%	4	1.54-1.99
13%-25%	3	1.10-1.48

Because a positive pool requires individual retesting of each sample in the pool, the efficiency of any pooling strategy depends on the positivity rate. The efficiency (F) of n-sample pooling for positivity rate (P) can be calculated with the following formula $F=1/(1+1/n-(1-P)^n)$. The efficiency (F) indicates how many more patients can be tested with n-sample pools compared to individual testing. For example, a 5-sample pooling strategy increases number of tested patients by 2.15 times for positivity rate P of 6% (F=2.15). At F=2.15, 1000 tests can on average cover testing for 2150 patients.

If historical laboratory data for individual specimens is unavailable

- If historical data from the previous 7-10* days is unavailable, 5, 4 or 3-specimen pooling may still be implemented as Visby Medical COVID-19 Test has been validated for 5-specimen pooling.
- Note: Without calculating $P_{individual}$ the implemented pooling size may not maximize pooling efficiency.

Implementation of Pooling

When pooling samples, use a standard adjustable volume pipette and reference the table below to determine how much sample to transfer into the pool (e.g., 130 µL for each sample in the pools of 5).

Number of Samples Pooled	Amount of Sample Added to Visby Buffer Tube
2	325 µL
3	217 µL
4	163 µL
5	130 µL

Monitoring plan for use of pooling

Laboratories should evaluate the appropriateness of the pooling and pool size using the FDA recommended monitoring procedure described below.

Ongoing Monitoring of Pooling Strategy

If historical laboratory data for individual specimens is available

- After implementing a pooling strategy, evaluate the performance of pooled testing by comparing the percent positivity rate of pooled testing to that of individual testing. Calculate the percent positivity rate among patient specimens during specimen pooling (P_{pools}) on a daily basis using a moving average of the data from the previous 7-10* days of testing.
    - P_{pools} = (Number of patient specimens with a positive result as determined by individual specimen reflex testing of positive pools over chosen date range ÷ Total number of patient specimens tested in pools over chosen date range)*100
- Compare P_{pools} to $P_{individual}$. If P_{pools} is less than 85% of $P_{individual}$ ($P_{pools} < 0.85 \times P_{individual}$), it is recommended that the pool size be reassessed and adjusted to maximize pooling efficiency (if necessary), according to the criteria in the above table (Table 08).
- To ensure maximum pooling efficiency, it is recommended that $n_{maxeffiency}$ be reassessed periodically while sample pooling is implemented by the laboratory.

If historical laboratory data for individual specimens is unavailable

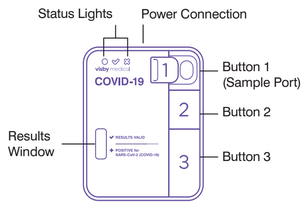
- After initiating a pooling strategy, evaluate the performance of pooled testing by calculating the initial percent positivity rate for pooled specimens ($P_{pools\text{-}initial}$). $P_{pools\text{-}initial}$ is the percent positivity rate for pooled specimens for the first 7-10* days of pooled testing.
- Calculate the initial percent positivity rate for individual specimens from pool testing ($P_{pools\text{-}initial}$) from the first 7-10* days of testing.
    - $P_{pools\text{-}initial}$ = (Number of patient specimens with a positive result as determined by individual specimen reflex testing of positive pools in first 7-10* days ÷ Total number of patient specimens tested in pools in the first 7-10* days)*100
        - If $P_{pools\text{-}initial}$ is greater than 25%, pooling of patient specimens is not efficient and should be discontinued until the percent positivity rate decreases.
        - If $P_{pools\text{-}initial}$ is less than or equal to 25%, pooling of patient specimens can be continued.
- Continue to monitor pooling strategy by calculating the percent positivity rate among patient specimens during specimen pooling ($P_{pools\text{-}x}$) for subsequent 7-10* day periods. ($P_{pools\text{-}x}$) should be updated daily using a moving average.
- Compare $P_{pools\text{-}x}$ to $P_{pools\text{-}initial}$. If $P_{pools\text{-}x}$ is less than 90% of $P_{pools\text{-}initial}$ ($P_{pools\text{-}x} < 0.90 \times P_{pools\text{-}initial}$), it is recommended that the pool size be reassessed and potentially adjusted to maximize pooling efficiency.

*7-10 days is recommended for calculating $P_{individual}$, P_{pools}, $P_{pools\text{-}initial}$, and $P_{pools\text{-}x}$. Laboratories should determine if 7-10 days is appropriate by taking into consideration laboratory testing volume and percent positivity. If the number of individual or pooled positive results collected during a given time frame is less than 10, $P_{individual}$, P_{pools}, $P_{pools\text{-}initial}$, and $P_{pools\text{-}x}$ may not be representative of the percent positivity in the testing population. Consider extending the data collection time period to increase the number of positives evaluated.

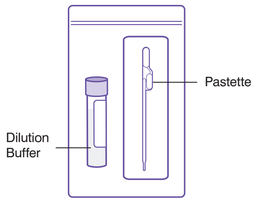
visby medical™

Materials Provided and Required

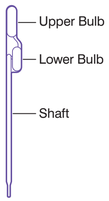
Visby COVID-19 Test



Dilution Kit



Visby Pastette

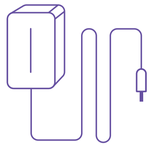


Biohazard Bag

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

Materials Required and Available as Accessories

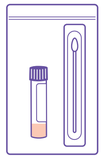
Visby Power Adapter



Materials Not Provided but Required

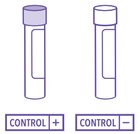
Gloves

Nasopharyngeal, Mid-turbinate or Nasal Specimen Collection Kit



Disposal Bin

External Controls



Absorbent Pads

Warnings

1. 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.
2. This product has been authorized only for the detection of nucleic acid from SARS CoV-2, not for any other viruses or pathogens.
3. 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.

Sample Collection

Collect samples in Universal Transport Media (UTM) or Universal Viral Transport System (UVT).

Use collection instructions included in the Visby Medical Kit.

Storage Specifications

Patient samples collected in UTM are stable for up to 5 hours at room temperature, or for up to 2 days in the refrigerator.

Store Visby Medical Kit in a cool and dry environment. Do not freeze.

Quality Control

External controls are run in the same manner as the patient sample. Please refer to the Visby COVID-19 Test Package Insert for more information on running external quality controls. Run external controls with every new shipment and new operator. Test in the same manner as the patient sample. For more information look at package insert.

External Positive and Negative Controls

ZeptoMetrix® NATrol™ SARS-CoV-2 positive and negative controls by ZeptoMetrix® Corporation.

Product Code	Unit	Control Key
ZeptoMetrix® NATrol™ Positive Control: NATSARS(COV2)-ERC1 (6 x 1 mL)	6 x 1 mL Vials per Kit 	Valid Positive Control Run 
ZeptoMetrix® NATrol™ Negative Control: NATSARS(COV2)-NEG1 (6 x 1 mL)	6 x 1 mL Vials per Kit 	Valid Negative Control Run 

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

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COVID-19

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Quick Reference Guide

Need More Help?

Email Us
help@visbymedical.com

Call Us
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(1-833-468-4729)

www.visbymedical.com

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

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

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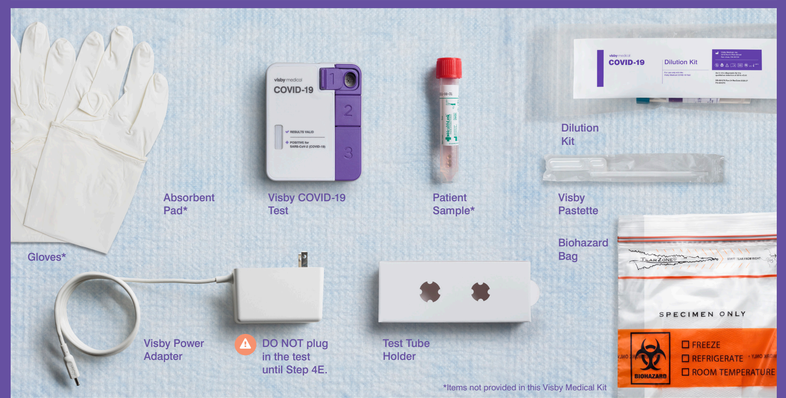
Step 1 Set Up the Workstation

Operating Conditions: Ensure the test is run at room temperature 66.2°F to 82.4°F in a cool, dry environment. Read all the instructions including the Package Insert.

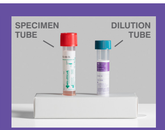


Run it on a clean, level surface. It is important to change gloves and absorbent pads after every test to avoid contamination.

Step 2 Dilute the Sample

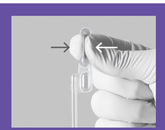
Use this procedure to dilute the patient sample.

A Invert patient specimen tube **5 times**. Place it in the tube holder.



B Place **Dilution tube** from the Visby Medical Dilution Kit in the tube holder.

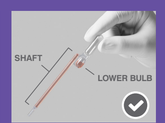
C **Uncap** both tubes. Place caps wet side up.



D Take pastette from the Dilution Kit. Squeeze the **upper bulb**.

E **Keeping the bulb squeezed,** lower the pastette tip to the bottom of the specimen collection 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 Squeeze the upper bulb to **dispense all the fluid** in the shaft into the Dilution tube. Some fluid will remain in the lower bulb.

I **Discard** the pastette as per your institution's practices. **Do not set it down.**

J Screw the cap back on both tubes. Make sure they are on **tight** Put aside patient specimen.

Step 3 Load the Sample into the Device

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

A Pick up the **Dilution tube.**

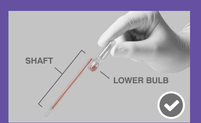
B Mix the specimen in the Dilution tube by inverting the tube **5 times**.

C Open the cap of the Dilution tube. Place cap wet-side up. Take the **second** Visby pastette.

D Squeeze the **upper bulb**.

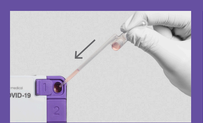
E **Keeping the bulb squeezed**, lower the pastette tip to the bottom of the Dilution tube.

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.

I **Discard** the pastette according to your institution's standard practices. **Do not set it down**. Recap the Dilution tube.

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.

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 test is running.
Ensure that there is no gap between the adapter jack and the device.

WAIT 30 MINUTES!
DO NOT touch or move the charging adapter, cable or device.

Step 5 Get the Results

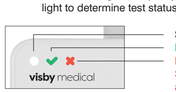
AFTER 30 MINUTES

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 using a new test and Dilution Kit.

Color Blindness Precaution
While color-blind users may be unable to differentiate red, green, and white status lights, they may consult 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.
Start again with a new test and new Dilution Kit.

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

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

INVALID
No purple spot indicates an invalid test.
Repeat using a new test and new Dilution Kit.

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.

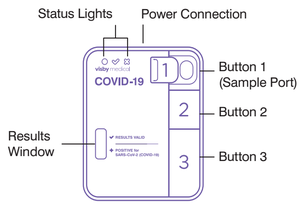
After use, the Visby COVID-19 Test should be placed in a Biohazard Bag prior to disposal. The used test, pastette, Dilution Kit, and specimen collection kit should be disposed of in the appropriate specimen waste containers according to the Institution's standard practices.

Please refer to the Package Insert for additional details.

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

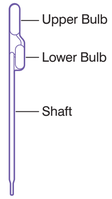
Materials Provided and Required

Visby Medical COVID-19 Test



Visby Buffer Tube

Visby Pipette

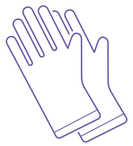


Biohazard Bag

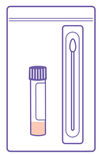
After use, the Visby Medical COVID-19 Test should be placed in a Biohazard Bag prior to disposal.

Materials Not Provided but Required

Gloves



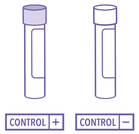
Nasopharyngeal, Mid-turbinate or Nasal Specimen Collection Kit



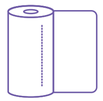
Standard Adjustable Volume Pipette

Disposal Bin

External Controls



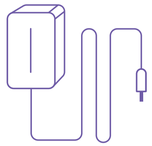
Absorbent Pads



PS-300559 Rev A 7/21

Materials Required and Available as Accessories

Visby Power Adapter



Warnings

1. 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.
2. This product has been authorized only for the detection of nucleic acid from SARS CoV-2, not for any other viruses or pathogens.
3. 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.

Sample Collection

Collect samples in Universal Transport Media (UTM), or Viral Transport Media (VTM).

Storage Specifications

Patient samples collected in UTM or VTM are stable for up to 5 hours at room temperature, or for up to 2 days in the refrigerator.

Store Visby Medical COVID-19 Kit in a cool and dry environment. Do not freeze.

Quality Control

External controls are run in the same manner as individually tested patient sample in UTM or VTM. Please refer to the Visby COVID-19 Test Package Insert for more information on running external quality controls. Run external controls with every new shipment and new operator.

External Positive and Negative Controls

ZeptoMetrix® NATrol™ SARS-CoV-2 positive and negative controls by ZeptoMetrix® Corporation.

Product Code	Unit	Control Key
ZeptoMetrix® NATrol™ Positive Control: NATSARS(COV2)-ERC1 (6 x 1 mL)	6 x 1 mL Vials per Kit 	Valid Positive Control Run 
ZeptoMetrix® NATrol™ Negative Control: NATSARS(COV2)-NEG1 (6 x 1 mL)	6 x 1 mL Vials per Kit 	Valid Negative Control Run 

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

COVID-19
Pooling

visby medical™

Quick Reference Guide

Need More Help?

Email Us
support@visby.com

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

www.visbymedical.com

For additional information, refer to the Visby Medical COVID-19 Package Insert.

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

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

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

visby medical™

www.visbymedical.com

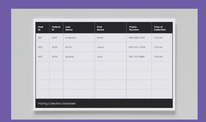
Step 1 Set Up the Workstation

Operating Conditions: Ensure the test is run at room temperature 66.2°F to 82.4°F in a cool, dry environment. Read all the instructions including the Package Insert.

Run on a clean, level surface. It is important to change gloves and absorbent pads after every test to avoid contamination.
Note: A standard adjustable volume pipette is also required when running pooled samples.

Step 2 Combine all samples in the pool to the Visby Buffer Tube

Use this procedure to transfer the appropriate amount of patient sample to the Visby Buffer for pooling.



A Gather patient samples for pooling. Record patient information and assign a **pool ID**.

B Place a label with the **pool ID** on the **Visby Buffer Tube**.

Number of Samples	Volume of Sample to Add
2	325 µL
3	217 µL
4	163 µL
5	130 µL

C Set the standard adjustable volume pipette to the appropriate volume based on the number of samples to be pooled.

D Invert patient specimen tube **5 times**.

E Using a standard adjustable volume pipette, transfer the appropriate sample volume to the Visby Buffer Tube.

F Repeat steps D and E for **all patient samples** in the same pool.
Note: Replace the pipette tip before transferring each sample. Add all samples to the same Visby Buffer Tube.

G After adding all samples into the Visby Buffer Tube, place the cap back on.

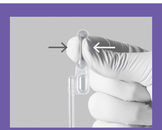
Step 3 Load the Sample into the Device

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**.

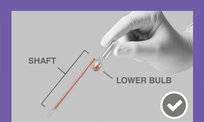
C Open the cap of the Visby Buffer Tube. Place cap wet-side up. Take a Visby Pipette.



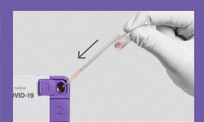
D Squeeze the **upper bulb**.

E **Keeping the bulb squeezed**, lower the Visby Pipette 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 Visby Pipette.



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

I **Discard** the Visby Pipette according to your institution's standard practices. **Do not set it down**. Recap the Visby Buffer Tube.

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.

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 test is running.
Ensure that there is no gap between the adapter jack and the device.

WAIT 30 MINUTES!
DO NOT touch or move the charging adapter, cable or device.

Step 5 Get the Results

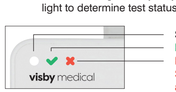
AFTER 30 MINUTES

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 using a new test and new Visby Buffer Tube.

Color Blindness Precaution
While color-blind users may be unable to differentiate red, green, and white status lights, they may consult 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.
Start again with a new test and new Visby Buffer Tube.

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

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

INVALID
No purple spot indicates an invalid test.
Generate a new pool or test the samples individually using a new test and new Visby Buffer Tube.

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.

Examination and Interpretation of Pooled Patient Specimen Results

Negative - Negative results should be reported for each patient in the pool. The test results should indicate that sample pooling was used. Negative results from pooled sample testing should not be treated as definitive. If the patient's clinical signs and symptoms are inconsistent with a negative result and if results are necessary for patient management, then the patient should be considered for individual testing.

Positive - Specimens with a positive sample pool result must be tested individually prior to reporting a result. Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing.

Invalid - Pools with invalid results can be retested using a new Visby Medical COVID-19 Test and new Visby Buffer Tube by generating a new pool using stored UTM samples or by testing the samples individually.

After use, the Visby Medical COVID-19 Test should be placed in a Biohazard Bag prior to disposal. The used test, Visby Pipette, Visby Buffer Tube, and specimen collection kit should be disposed of in the appropriate specimen waste containers according to the Institution's standard practices.

Please refer to the Package Insert for additional details.

Need Help? Call 1-833-GoVisby (1-833-468-4729) or e-mail support@visby.com