COVID-19

Package Insert

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

MODEL: 001260

PS-001315 Rev B 12/20

Device Name

Visby Medical COVID-19 Test

Common or Usual Name

Visby COVID-19 Test

Intended Use

The Visby COVID-19 Test is a single-use (disposable), fully-integrated, rapid, automated RT-PCR in vitro diagnostic test intended for the qualitative detection of SARS-CoV-2 RNA 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. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high or moderate 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. 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. 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.

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 COVID-19 Test is a rapid, 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 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 COVID-19 Test is a single-use (disposable), fully-integrated, rapid, 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 COVID-19 Test device are functioning properly, then the Results Valid spot will produce color.

The Visby test uses commercially available Universal Transport Media manufactured by Copan Diagnostics or Universal Viral Transport System supplied by BD. See Material Required but Not Supplied for part number information. After collection with Copan's collection kit, specimens are transferred with a pastette into the COVID-19 dilution tube. The pastette is then discarded and the diluted sample is ready for processing with the Visby COVID-19 Test.

Materials

Materials Provided in Test Kit

- Visby 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 COVID-19 Dilution Kit††
  - Dilution tube
  - Visby Pastette 1 (650 µL)
- Visby Pastette 2 (650 µl)
- Package Insert
- Quick Reference Guide
- 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

Ancillary Dilution Kit:
The Visby Medical COVID-19 Dilution Kit is designed to dilute nasopharyngeal, nasal, or mid-turbinate samples collected in Copan Diagnostics' Universal Transport Medium (UTM) for viruses or BD Universal Viral Transport (UVT) system prior to analysis with the Visby COVID-19 Test.

			Distributors or Private Label Names for the Same Copan Swab				
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 puch)	Copan	56380CS01	N/A	23600966	N/A	N/A
Flocked Swab	Mid-Turbinate Flocked Swab (Contoured pediattic flocked swab with 80mm break point in peel pouch)	Copan	56780CS01	N/A	23600967	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		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 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 Medical COVID-19 Dilution Kit is designed to dilute nasopharyngeal, nasal, or mid-turbinate samples collected in Copan Diagnostics' Universal Transport Medium (UTM) for viruses or BD Universal Viral Transport (UVT) system prior to analysis with the Visby 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 1-833-GoVisby (1-833-468-4729) or help@visbymedical.com.

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

Storage and Stability

Storage

Test Unit

Store the Visby 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 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 COVID-19 Test, the Visby COVID-19 Dilution Kit should be disposed of in the Biohazard Bag according to the Institution's standard practices. DO NOT STORE DILUTED SAMPLE.

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

Warnings and Precautions

General

1. For in vitro diagnostic use.
2. This test has not been FDA cleared or Approved.
3. This test has been authorized by FDA under an EUA for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate complexity/high complexity tests.
4. This test has been authorized only for the detection of nucleic acid from SARS CoV-2, not for any other viruses or pathogens.
5. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests 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 authorization is terminated or revoked sooner.
6. This product is for single use only; do not reuse the Visby COVID-19 Test.
7. Caution: Federal Law restricts this device for sale by or on the order of a licensed practitioner (US only).
8. Follow the Institution's safety procedures for working with chemicals and handling biological samples.
9. 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.
10. The Visby COVID-19 Test's control panel and results must be interpreted as per the instructions provided on this guide.
11. Leave the Visby COVID-19 Test sealed in the foil pouch until just before use.
12. Do not use the Visby COVID-19 Test past its expiration date.
13. Do not use the Visby COVID-19 Test if it appears broken.
14. Do not use the Visby COVID-19 Test if it has been dropped.
15. Do not shake or tilt the Visby COVID-19 Test after adding a sample.
16. Do not add excessive sample into the test as this may result in an error.
17. Run the test on a clean, level surface.
18. Do not move the Visby COVID-19 Test while it is running the sample.
19. Do not touch or move charging cable, adapter or device while the test is running.
20. Do not unplug the Visby COVID-19 Test during operation.
21. At a low frequency, clinical samples can contain inhibitors that may generate invalid results. Site to site invalid rates may vary.
22. 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.
23. Keep the work area clean to prevent contamination.
24. Do not try to disassemble the Visby COVID-19 Test. In the case of a positive sample, this could lead to sample leakage and potential contamination.
25. If a spill occurs with the Visby COVID-19 Test and/or dilution kit, 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 COVID-19 Test, and/or the COVID-19 Dilution Kit. Discard affected single use materials according to the Institution's standard practices.
26. 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.

Visby 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 COVID-19 Test. Using other power adapters to operate the Visby 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 Universal Viral Transport System (UVT). 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 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 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 COVID-19 Test should be placed in the provided Biohazard Bag prior to disposal.
9. The Visby 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 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 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 COVID-19 Dilution Kit

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 COVID-19 Tests and specimens diluted in Visby Medical COVID-19 Dilution kits 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 Medical COVID-19 dilution tube, ensure the tip of the pastette touches the inner wall of the dilution tube above the fluid.
4. The Visby Medical COVID-19 Dilution Kit should only be used to dilute swab specimens.
5. The Visby Medical COVID-19 Dilution Kit is for single use only. Do not re-use the Visby Medical COVID-19 Dilution Kit to elute more than one sample. Do not use the Visby Medical Dilution Kit to load more than one Visby COVID-19 Test.
6. Use the Visby Medical COVID-19 Dilution Kit only as directed.
7. Ensure tube caps are tightened prior to inverting specimen.
8. Always dilute patient samples with the Visby Medical COVID-19 Dilution Kit in accordance with the dilution instructions.
9. Do not apply the dilution buffer directly onto the skin or mucous membranes or ingest.
10. Do not use the Visby COVID-19 Dilution Kit if it appears to be damaged or opened.
11. The Visby COVID-19 Dilution Kit 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 COVID-19 Dilution Kit past its expiration date.
13. Visby Medical COVID-19 Dilution Kit 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 Medical COVID-19 Dilution Kit.
15. The Visby COVID-19 Test requires a sample input of a specified volume from a fixed-volume pastette that is provided. If no sample is added into the Visby COVID-19 Test, the Results Valid spot will not be displayed.

Visby COVID-19 Test Instructions for Use

Please follow these instructions carefully.

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

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

The Visby COVID-19 Test, pastettes, and COVID-19 Dilution Kit 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.

Visby COVID-19 Test Procedure

Step 1 Set Up the Workstation

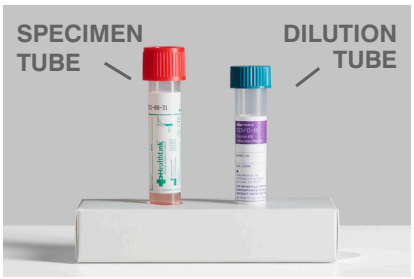
Operating Conditions: Ensure the test is run at room temperature 66.2°F to 82.4°F in a cool, dry environment. Read all the instructions including the Package Insert.

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 Sample

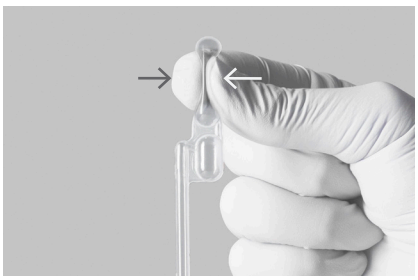
Use this procedure to dilute the patient sample.

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.

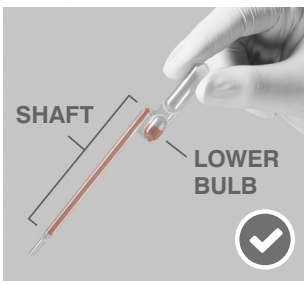
C **Uncap** both tubes. Place caps wet side up.



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.

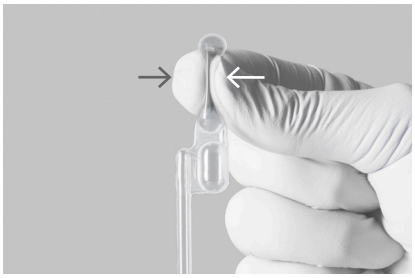
Step 3 Load the Sample into the Device

⚠ 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**.

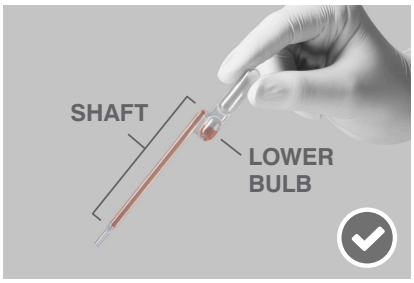
C Open the cap of the Dilution tube. Place cap wet side up. Take the **second** Visby pastette.



D Squeeze the **upper bulb**.

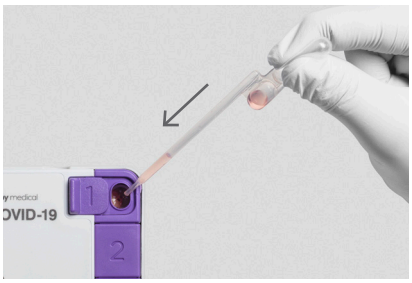
E **Keeping the bulb squeezed**, lower the pastette tip to the bottom of the Dilution tube.

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.

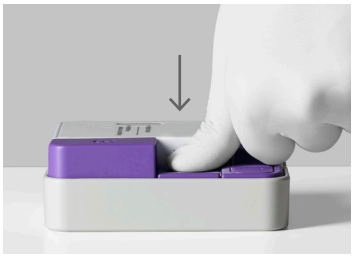
I **Discard** the pastette according to your institution's standard practices. **Do not set it down**. Recap the Dilution tube.

Step 4 Run the Test

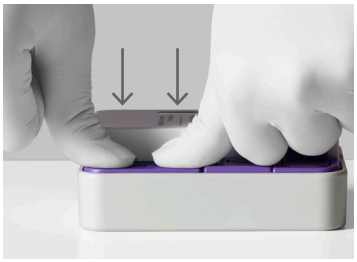
⚠ IMPORTANT! Each button will have a different feel as it “clicks” into place.
Push firmly to make sure **all buttons are completely down** or the test may not work.

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

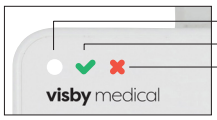
AFTER 30 MINUTES

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 new 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".

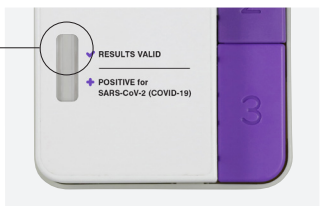
VALID
A purple spot indicates a valid test.

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

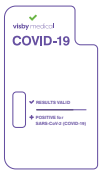
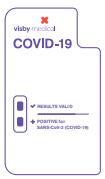
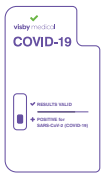
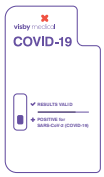
No purple spot in this location indicates a negative result.

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.

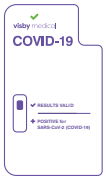
Please refer to the Package Insert for additional details.

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

Interpretation of Sample Results

Result	Interpretation	Recommendation
	• Valid test (✔, RESULTS VALID) • Negative for SARS-CoV-2 (COVID-19)	• Report results of patient sample
	• Valid test (✔, RESULTS VALID) • Positive for SARS-CoV-2 (COVID-19)	• Report results of patient sample
	• Invalid test; control fail (✔, RESULTS VALID)	• Discard test • Repeat test using a new Visby COVID-19 Test and new Dilution Kit • 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 • Repeat test using a new Visby COVID-19 Test and new Dilution Kit • 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 • Repeat test using a new Visby COVID-19 Test and new Dilution Kit • If repeat fails, contact Visby Medical Customer Support
	• Invalid test; control fail (✔, RESULTS VALID)	• Discard test • Repeat test using a new Visby COVID-19 Test and new Dilution Kit • If repeat fails, contact Visby Medical Customer Support
	✖ Error: Invalid	• Discard test • Repeat test using a new Visby COVID-19 Test and new Dilution Kit • If repeat fails, contact Visby Medical Customer Support

Interpretation of External Control Results

Result	Interpretation	Recommendation
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 COVID-19 Test, a new negative control vial, and a new Dilution Kit • 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 COVID-19 Test, a new positive control vial, and a new Dilution Kit • 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 the Universal transport media (UTM) or Universal Viral Transport System (UVT). Repeat the test with a new Visby Medical COVID-19 Dilution Kit and Visby COVID-19 Test. If the leftover 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 Medical COVID-19 Dilution Kit and Visby COVID-19 Test.

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

Limitations

1. The performance of the Visby 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 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. Performance has not been established in asymptomatic individuals.
13. 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.

MedWatch report can be generated using Food and Drug Administration (FDA)’s FORM 3500B and submitted online at www.fda.gov/medwatch or returned by mail to the address on the pre-addressed form, or submitted by fax to 1-800-FDA-0178 (1-800-332-0178). The FDA also has a dedicated toll-free number for those who want to submit a report by phone at 1-800-FDA-1088 (1-800-332-1088).

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 will 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 the Visby Medical COVID-19 Test will 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.

C. Authorized laboratories that receive the Visby Medical COVID-19 Test will notify the relevant public health authorities of their intent to run the Visby Medical COVID-19 Test prior to initiating testing.

D. Authorized laboratories using the Visby Medical COVID-19 Test will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

E. Authorized laboratories will 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@visbymedical.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.

F. 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.

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

[1] The letter of authorization refers 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" as "authorized laboratories."

Quality Control

The Visby 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 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.

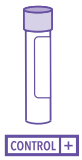
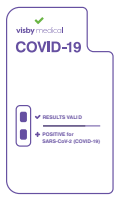
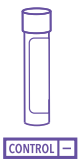
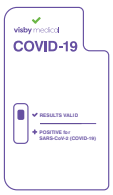
At a low frequency, patient samples can contain inhibitors that may generate invalid results.

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 Medical COVID-19 Dilution Kit, and Visby COVID-19 Test. If the repeat test fails, please contact Visby Medical Customer Support at 1-833-GoVisby (1-833-468-4729) or help@visbymedical.com.

Important Information

The Visby COVID-19 Test is an in vitro diagnostic for the qualitative detection of viral RNA from the SARS-CoV-2. 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 COVID-19 Dilution Kit. 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 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.

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.

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 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)

An *in silico* study was executed to analyze the primer and capture probe binding sequences of in the SARS-Cov-2 genome to demonstrate that the primers and capture probe will detect all variants of the SARS-CoV-2 virus identified to date (August 2020) and predict inclusivity of the Visby COVID-19 test. A total of 13,898 sequences from the NCBI database, and 25,724 sequences from the GISAID database were evaluated in this study. The forward primer was a perfect match to 99.76% of all sequences across both databases. The reverse primer was a perfect match to 99.76% of all sequences across both databases. The probe was a perfect match to 99.65% of all sequences across both databases. Greater than 99% of sequences analyzed exhibited no mismatches to the primers and probe.

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 x 10^5	genomic copies/mL	8/9 (1)	3/3
Human Coronavirus OC43	1.1 x 10^5	genomic copies/mL	3/3	3/3
Human Coronavirus HKU1	1.1 x 10^5	genomic copies/mL	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 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
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 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 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 COVID-19 test demonstrated both PPA and NPA for detection of SARS-CoV-2 RNA of 100% (95% CI: 88.6%-100.0%).

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Table 04: Visby 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 COVID-19 Test in accordance with the Instructions for Use. 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

Index of Symbols

Symbol	Meaning	Symbol	Meaning
	Power supply		Temperature limitation
REF	Catalog number		Humidity limitation
	Do not reuse		Biological risks
	Handle with care	IVD	In vitro diagnostic medical device
LOT	Batch code		Do not use if package is damaged
	Caution	c N us 61010	Nemko 61010
	Consult instructions for use		Waste container
	Manufacturer	CONTROL + CONTROL −	Positive/negative controls
	Expiration date		

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