Biomeme

SARS-CoV-2 Real-Time RT-PCR Test

Instructions for Use, v1.6

For Use Under an Emergency Use Authorization (EUA) Only

Rx Only | For *In Vitro* Diagnostic Use

Note: The Biomeme SARS-CoV-2 test has been validated but FDA's independent review of this validation is pending.

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Brief Overview

The Biomeme SARS-CoV-2 Real-Time RT-PCR Test is a qualitative multiplex assay for *in vitro* diagnostic (IVD) use on Biomeme's Franklin™ Real-Time PCR System. It is only for use under the **Emergency Use Authorization (EUA)** and is intended for the detection of RNA from SARS-CoV-2.

SAFETY WARNING

When working with our products, always wear appropriate personal protective equipment (PPE) (e.g. lab coat, disposable gloves with adequate chemical resistance, mouth/face protection, goggles, etc.) For more information, please review the product's safety data sheet(s) (SDS).

Intended Use

The Biomeme SARS-CoV-2 test for use on the Biomeme Franklin Real-Time PCR System is a real-time RT-PCR test intended for qualitative detection of RNA from SARS-CoV-2 in nasopharyngeal and oropharyngeal (throat) swab samples* from patients who meet COVID-19 clinical and/or epidemiological criteria. Testing is limited to Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a certified laboratories performing SARS-CoV-2 testing. Other Authorized Testing Locations - Patient care settings. The Biomeme SARS-CoV-2 test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Results are for the identification of SARS-CoV-2 RNA in nasopharyngeal and oropharyngeal (throat) swab samples during 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 target detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive 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 Biomeme SARS-CoV-2 Real-Time RT-PCR Test is intended for use by trained personnel specifically instructed and trained in the techniques of real-time PCR and *in vitro* diagnostic procedures. The Biomeme SARS-CoV-2 Real-Time RT-PCR Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

***Note**: Nasal swabs and mid-turbinate swabs are considered acceptable specimen types for use with Biomeme's SARS-CoV-2 Real Time RT-PCR test, but performance with these specimen types has not been established. Testing of nasal and mid-turbinate nasal swabs (self-collected under supervision of or collected by a healthcare provider) is limited to patients with symptoms of COVID-19. Please refer to FDA's FAQs on Diagnostic Testing for SARS-CoV-2 for additional information.*

Summary and Explanation

An outbreak of respiratory illness of unknown etiology in Wuhan City, Hubei Province, China was initially reported to the World Health Organization (WHO) on December 31, 2019.[1] Chinese authorities identified a novel coronavirus (2019-nCoV), which has resulted in thousands of confirmed human infections in multiple provinces throughout China and exported cases in several Southeast Asian countries and more recently the United States. Cases of severe illness and some deaths have been reported. The International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2.[2]

The Biomeme SARS-CoV-2 Real-Time RT-PCR Test is a molecular *in vitro* diagnostic test that aids in the detection and diagnosis of SARS-CoV-2 and is based on widely used nucleic acid amplification technology. The Biomeme SARS-CoV-2 Real-Time RT-PCR Test contains primers and probes and internal controls used in RT-PCR for the *in vitro* qualitative detection of SARS-CoV-2 RNA.

[1] Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/index.html.
[2] bioRxiv. https://www.biorxiv.org/content/10.1101/2020.02.07.937862v1.

Principle of the Procedure

The Biomeme SARS-CoV-2 Real-Time RT-PCR Test utilizes Biomeme's M1 Sample Prep Cartridge for RNA extraction, Biomeme's SARS-CoV-2 Go-Strips assay, and Biomeme's portable Franklin™ Real-Time qCPR Thermocycler. Franklin's companion mobile app, Biomeme Go, scans tests, runs PCR experiments online or offline, and is used to quickly interpret your test results while conveniently syncing data to the Biomeme Cloud.

Biomeme's M1 Sample Prep Cartridges require no lab equipment, refrigeration, electricity, incubation, alcohol precipitation or phenol chloroform extraction. Instead, they utilize a filtration-based method in which nucleic acids selectively bind to the silica membrane inside Biomeme's proprietary M1 Sample Prep columns. Subsequent washes through a sequence of specially formulated buffers yields purified nucleic acids upon elution in minutes.

The Biomeme SARS-CoV-2 Real-Time RT-PCR Test detects two different SARS-CoV-2 genes and is multiplexed together with Biomeme's RNA Process Control (RPC) for RNA extraction and RT-PCR (MS2 bacteriophage) in 0.1 mL low-profile, thin-walled, optically clear 3-well strips (Go-Strips). Each reaction well of the 3-well Go-Strip already contains lyophilized master mix, enzymes, and multiplexed primer/probes for the following triplex reaction:

- **Orf1ab** - Open reading frame 1ab gene
- **S** - Spike gene
- **RPC** - RNA Process Control (MS2 bacteriophage)

Go-Strips are designed for the Biomeme Franklin™ mobile handheld qPCR thermocycler. Please contact support@biomeme.com for further instruction on running Go-Strips on the Bio-Rad CFX96, ABI 7500, or QuantStudio5 using the "fast" block. The Biomeme SARS-CoV-2 assay is also available in a 96-well Go-Plate format for direct use onBio-Rad CFX96, ABI 7500, or QuantStudio5 using the "fast" block.

Contents

The materials provided for the Biomeme SARS-CoV-2 Real-Time RT-PCR Test can be found in Table 1 below. Equipment, software and other materials that are required to run and analyze test results but not provided can be found in Table 2.

Table 1: Biomeme SARS-CoV-2 Real-Time RT-PCR Test - Consumables

Source: REF#	Component	Description
Biomeme: 3000567	200µL Transfer Pipette Pack	Pack of disposable transfer pipettes to transfer VTM into Extraction Kit
Biomeme: 3000536	Biomeme M1 Sample Prep Cartridge Kit for RNA 2.0	RNA Extraction Kit containing cartridges, syringes, and binding column tips
Biomeme: 3000011	20µL Fixed Volume Pipette	20µL pipette to transfer purified RNA into Biomeme Go-Strips
Biomeme: 3000572	Pipette Tips	Boxes of 96 pipette tips to transfer purified RNA into Biomeme Go-Strips
Biomeme: 3000150	2mL Self-Standing Tubes Pack	Pack of tubes for storing purified samples
Biomeme: 3000555	Biomeme SARS-CoV-2 Go-Strips*	Pre-aliquoted 3-well PCR strips. Each well contains a 20µL lyophilized triplex reaction. Also includes RNA Process Control.

***Note**: Contains Bovine Serum Albumin of USA origin. Certified BSE free.*

Additional Form Factors

SARS-CoV-2 Assays also come in two additional form factors:

- 3000562: Biomeme SARS-CoV-2 Go-Plates (96 rxns at 20 uL)
- 3000564: Biomeme SARS-CoV-2 Bulk Vials (65 rxns at 20 uL)

Table 2: Biomeme SARS-CoV-2 Real-Time RT-PCR Test - Equipment, Software & Other Materials

The following equipment and software is required to run the test and analyze results.

Source: REF#	Component	Description
Biomeme: 1000003	Biomeme Franklin three9 Real-Time PCR Thermocycler	Real-Time PCR Thermocycler
Biomeme: 1000013 or Biomeme: 1000012	Android Smartphone w/ Biomeme Go Mobile App or Rugged Android Smartphone w/ Biomeme Go Mobile App	Controller for Biomeme Franklin Thermocycler
Biomeme: 2000006	Biomeme Cloud	PCR Data Management Software
Biomeme: 3000563	Biomeme Sample Prep Tray	Tray to streamline preparation and extraction of DNA or RNA from your samples
Suitable Sample Collection		
Provided by User	BD: 220531: BD Viral Transport Media (VTM) or Thermo Scientific™: R12515: MicroTest™ M5™ Viral Transport Media (VTM-M5)	Collect and maintain samples during transport and before molecular analysis
External Controls*		
No Template Control (NTC)	Molecular Grade Water	Monitors contamination that could produce false positive results
Positive Control (PC)	BEI NR-52285: Viral Genomic RNA (from SARS-Related Coronavirus 2, Isolate USA-WSA1/2020 or Exact Diagnostics COV019: SARS-CoV-2 Standard	Control that is not exposed to the experimental treatment and is known to produce a positive result

***Note:** External controls are not provided with the Biomeme SARS-CoV-2 test. Quality control requirements should be performed in conformance with local, state, and/or federal regulations or accreditation requirements and your laboratory's standard quality control procedures.*

***Note**: Biomeme's Safety Data Sheets (SDS) are available at help.biomeme.com under 'Product Document Library'.*

Warnings & Precautions

As with any test procedure, good laboratory practice is essential to the proper performance of this assay. Due to the high sensitivity of this test, care should be taken to keep reagents and amplification mixtures free of contamination. The Biomeme SARS-CoV-2 Real-Time RT-PCR Test workflow should be performed by qualified and trained staff to avoid the risk of erroneous results.

- The assay is for *in vitro* diagnostic use under the FDA Emergency Use Authorization Only.
- Specimens should always be treated as if infectious and/or biohazardous in accordance with safe laboratory procedures. Refer to Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with SARS-CoV-2.
- Follow necessary precautions when handling specimens. Use personal protective equipment (PPE) consistent with current guidelines for the handling of potentially infectious samples. Refer to Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition - CDC.
- Always use pipette tips with aerosol barriers. Tips that are used must be sterile and free from DNases and RNases.
- Do not eat, drink, smoke, apply cosmetics or handle contact lenses in areas where reagents and human specimens are handled.
- Modifications to assay reagents, assay protocol, or instrumentation are not permitted, and are in violation of the product Emergency Use Authorization.
- Do not use the kit after the indicated expiry date.
- Dispose of waste in compliance with the local, state, and federal regulations.

- Safety Data Sheets are available upon request.
- Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.
- Positive results are indicative of the presence of SARS-CoV-2 RNA.
- Handle all samples and controls as if they are capable of transmitting infectious agents.
- Reagents must be stored and handled as specified in Tables 1 and 2.

Sample Collection, Handling, and Storage

Proper specimen collection, storage, and transport are critical to the performance of this test. Inadequate specimen collection, improper specimen handling and/or transport may yield a false result. See the Swab Collection section below for collection procedure. Nasopharyngeal specimens can be stored at room temperature (15–30 °C) for up to 8 hours and refrigerated (2–8 °C) up to seven days until sample extraction is performed using Biomeme's M1 Sample Prep Cartridges.

SAFETY WARNING

Handle all samples and controls as if they are capable of transmitting infectious agents. Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19).

Instructions for Use

Minimize the Risk of Contamination

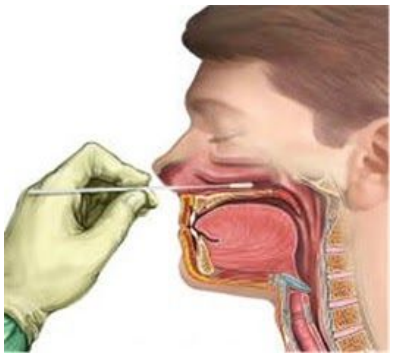
- For components that are bulk packaged, such as empty tubes or void filling caps for the Go-Strips, always pour out onto a clean surface a few from the bag rather than reaching your fingers into the bag.

- Do not reuse consumables. They are for one-time use only.
- Always use caution when transferring specimens from primary containers to secondary tube(s).
- Always use a new pipette tip for each specimen.
- All procedures should be performed in a BSL2 laboratory, and specimens handled within a Biological Safety Cabinet.
- Precautions must be taken to prevent cross contamination of samples.

Nasopharyngeal (NP) Swab Collection

Describe to the patient what they can expect during the NP collection and the importance of staying still to allow for the least discomfort and accurate collection. Additionally, encourage the patient to blow his or her noses to clear nasal passage.

1. Put on a mask, eye protection, gloves and any other necessary PPE.
2. With the person's head in a neutral position, insert the swab into either nostril straight back (not upwards), along the floor of the nasal passage until you reach the posterior wall of the nasopharynx (generally half of the distance from the base of the nose to the front of the ear).

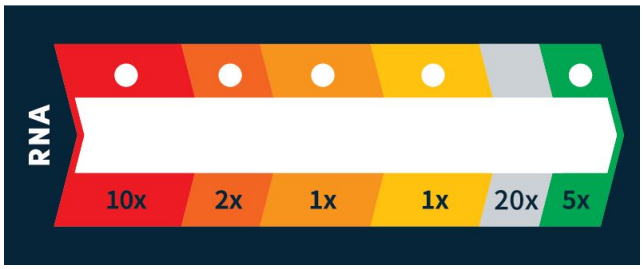


3. Rotate the swab gently then leave in place for a few seconds.
4. Carefully remove the swab without touching the sides of the nostril.

5. Open a viral transport tube (e.g. BD Viral Transport Media or MicroTest™ M5™ Viral Transport Media) and place the swab inside.
6. Break the swab at the indicated break line and cap the sample collection tube tightly. Shake the tube after capping.
7. Proceed to Sample Extraction.

***Note**: Nasal swabs and mid-turbinate swabs are considered acceptable specimen types for use with Biomeme's SARS-CoV-2 Real Time RT-PCR test, but performance with these specimen types has not been established. Testing of nasal and mid-turbinate nasal swabs (self-collected under supervision of or collected by a healthcare provider) is limited to patients with symptoms of COVID-19. Please refer to FDA's FAQs on Diagnostic Testing for SARS-CoV-2 for additional information.*

RNA Extraction Using M1 Sample Prep Cartridge



After collecting your sample, use Biomemes's M1 Sample Prep Cartridge (REF# 3000536) to purify your RNA. Samples are lysed by mixing into Biomeme's Lysis Buffer (BLB). The lysed sample is then passed through the M1 Sample Prep column by use of the provided 1mL luer lock syringe, binding RNA to the silica membrane inside of the column. Subsequent washes remove unwanted material and salts. As a result, purified nucleic acids are eluted off the column into the provided buffer.

Buffers come pre-aliquoted in the provided sample prep cartridges for ease-of-use and the extraction method is designed to be completed in 6 simple steps. But, before beginning the sample extraction process, please take a moment to read these important tips:

- **Clean your work area between each RNA extraction** to avoid contamination between samples.
- **The extraction cartridge can be labeled** on the side with the sample ID using a Sharpie® or similar style marker.
- **Puncture 2 holes in each section of the M1 Sample Prep Cartridge** as you move through each step to minimize liquid splatter (except Air Dry step).
- **Pump slowly**, except during the Air Dry step where rapid pumping is required, to not only minimize liquid splatter but to also improve binding to the sample prep column.
- **Additional pumps in each cartridge section** beyond the specified number will not adversely affect extraction performance.
- **Prior to removing the syringe barb tip from each cartridge section** rock the syringe completely forward and backward to enlarge the holes in the foil covering.

Prepare RNA Process Control

The Biomeme SARS-CoV-2 Real-Time RT-PCR Test includes RNA Process Control (RPC) and RPC Pellets. Extractions should be performed in batches of 9 total reactions, to include: one (1) negative control (NTC), one (1) positive control (PC), and seven (7) patient samples.

1. Remove the 2mL screw cap tube containing your RPC pellet to open the tube.
2. Open the 5mL screw cap tube containing your RPC buffer.
3. Using a 1mL transfer pipette, pull 0.5 - 0.75mL of RPC buffer and add to the RPC pellet in the 2mL tube.
4. Pipette up and down with the transfer pipette to mix.
5. Transfer the entire volume back into the 5mL RPC buffer tube, again pipetting up and down to mix.

   ***Note**: Check the box on the tube to indicate the RPC Buffer now contains the RPC material.*
6. Your RPC is now ready to add to your upcoming sample extractions (this will equal ~400 pfu per 20µL PCR reaction).

The resuspended RPC has a maximum shelf life of **1 week** when stored at room temperature. For longer term storage, aliquot out and freeze at -20°C to 80°C.

Add Your Sample

1. Vortex or shake your viral transport tube containing your swab sample for 10 seconds.
2. Open your M1 Sample Prep Cartridge pouch and remove the contents.
3. Secure the sample prep column to the syringe and puncture the red section of your sample prep cartridge twice. Temporarily set aside the syringe - place the 1mL luerlock syringe with column attached on a tube rack such that the tip of the column is not touching any surface.
4. Using a 200µL transfer pipette (REF# 3000567), or your own 200µL pipette, transfer 200µL of media from the transport tube containing your sample and add it into the red section of your sample prep cartridge.
5. Discard your transfer pipette and incubate at room temperature (15–25°C) for at least 10 minutes. You can move to adding your RNA Process Control (RPC) while you wait.

Add RNA Process Control (RPC)

1. Attach a pipette tip to your 20µL fixed volume pipette and transfer 20µL of RPC buffer containing the RPC into the punctured red section of your sample prep cartridge.
2. After the sample has finished incubating for at least 10 minutes at room temperature (15–25°C) inside the red section of the cartridge, proceed to Lysis & Binding.

***Note**: If you intend to extract and test multiple samples (e.g., 7 samples + NTC, PC) you can label and line up 7 of the M1 Sample Prep cartridges. Then for each cartridge: use a clean pipette tip to puncture the red section of a cartridge, add your sample to the cartridge, add your RPC to the cartridge, and then set the cartridge aside to incubate. As each cartridge is finished incubating, you can proceed to Lysis & Binding below.*

Lysis & Binding (10 Pumps)

1. Place the syringe with the attached sample prep column back into the **red** section of the sample prep cartridge and draw Biomeme Lysis Buffer (BLB) fluid all the way up the syringe and pump all the way back out. Repeat for a total of **10 pumps**.
2. Push all fluid in the syringe into the red section of the sample prep cartridge prior to beginning the next step. **Do not transfer any liquid from one section of the sample prep cartridge to the next. This applies to each remaining step of the sample extraction protocol**.

   ***Note**: If the column starts to clog, you will experience an increase in pressure. Do not press harder as this will cause additional clogging. Instead, pull up the syringe slightly (but not all the way out of the cartridge) to reduce the pressure and gently pull back the plunger, wait a few seconds, and slowly push the plunger back down. Some of the liquid should discharge at the open end of the syringe. Repeat this process until all liquid has been discharged from the column then proceed to the next step.*

Protein Wash (2 Pumps)

1. Move the 1mL syringe with the attached sample prep column into the **red-orange** section of the sample prep cartridge (Biomeme Protein Wash - BPW) and pierce through the foil. Remember to pierce 2 holes per section of the cartridge to minimize liquid splatter, except during the Air Dry step.
2. Draw the BPW fluid all the way up the syringe and pump all the way back out. Repeat for a total of **2 pumps** assuring that no buffer remains in the syringe before beginning the next step.

Salt Wash (1 Pump)

1. Move the 1mL syringe with the attached sample prep column to the **orange** section of the sample prep cartridge (Biomeme Wash Buffer - BWB) and pierce through the foil twice.
2. Draw the BWB fluid all the way up the syringe and pump all the way back out **once** assuring that no buffer remains in the syringe before beginning the next step.

Drying Wash (1 Pump)

1. Move the 1mL syringe with the attached sample prep column to the **yellow** section of the Sample Prep Cartridge (Biomeme Drying Wash - BDW) and pierce through the foil twice.
2. Draw the BDW fluid all the way up the syringe and pump all the way back out **once** assuring that no buffer remains in the syringe before beginning the next step.

Air Dry (20+ Pumps)

1. Move the 1mL syringe with the attached sample prep column to the **blue** section of the Sample Prep Cartridge and pierce through the foil once to remove excess buffer.
2. Draw air up through the syringe and quickly pump back out. Repeat pumping vigorously **20 or more times** until the sample prep column appears dry and does not spray fluid droplets.

Elution (5 Pumps)

1. Move the 1mL syringe with the attached sample prep column to the **green** section of the Sample Prep Cartridge (Biomeme Elution Buffer - BEB) and pierce through the foil twice.
2. Elute by drawing the BEB fluid all the way up through the syringe and slowly pump back out for a total of **5 pumps**.

Transfer Extracted RNA to Storage Tube

1. After completing the 5th pump, draw up the entire fluid into the syringe from the green section and transfer it to a 2mL self-standing tube (REF# 3000150).
2. Cap the tube and dispose of the M1 Sample Prep Cartridge and syringe with binding column.

SAFETY WARNING

Always dispose of potentially biohazardous solutions according to your local, regional or national waste-disposal guidelines. DO NOT add bleach or acidic solutions directly to the liquids contained in Biomeme's M1 Sample Prep cartridges. The BLB and BPW buffers contain guanidine salts, which can form highly reactive compounds when combined with bleach. If liquid containing these buffers is spilt, clean with a suitable laboratory detergent and water. If the spilt liquid contains potentially infectious agents, clean the affected area first with laboratory detergent and water, and then with 1% (v/v) sodium hypochlorite.

Repeat Extractions and Transfer Extracted RNA to Storage Tubes

1. Repeat these Sample Collection & Extraction steps with a new set of materials for up to 7 total samples (+1 NTC and 1 PC) to optimize throughput of the Biomeme Franklin™ thermocycler.
2. Proceed to Loading Pure Sample into Go-Strips.

Loading Pure Sample into Go-Strips

ATTENTION

Contents of the Go-Strip may shift during transport. When starting to work with any Go-Strip, make sure the cake of the lyophilized reagent rests at the bottom of the Go-Strip wells. Tap the bottom of the sealed Go-Strip gently but firmly against a solid surface before removing the foil seal and adding your sample.

1. Open the contents of a Biomeme SARS-CoV-2 Go-Strips (REF# 3000555). Do not immediately discard the Go-Strips pouch as you'll need to scan the QR code in a later step.
2. Start with a single Go-Strip and remove the foil covering.

3. Attach a pipette tip to a 20µL fixed volume pipette (REF# 3000011) or prepare your own 20µL pipette.

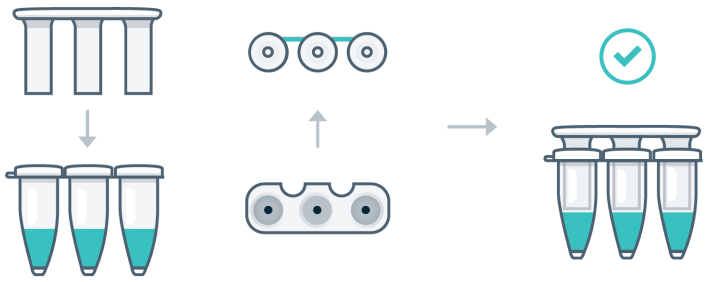
   ***Note**: The strip connections between the tubes of your Go-Strip will face the back of the thermocycler once inserted. When resuspending your reactions and transferring your extracted RNA into the different reaction wells, replicate this orientation to ensure accurate result interpretation (e.g. transfer sample 1 into the far left reaction well of your first Go-Strip, sample 2 into the middle reaction well of your first Go-Strip, and sample 3 into the far right reaction well of your first Go-Strip).*

4. Additionally, when mixing your samples try to avoid introducing bubbles.

***Note**: If bubbles have been introduced, remove them from the lower portion of the PCR tubes by gently tapping the Go-Strips against your work surface before capping. Bubbles may remain at the top of the tube, but bubbles at the bottom are not acceptable.*

5. Unscrew the cap of your first purified sample in the 2mL tube and transfer 20µL of the extracted RNA into the **first** reaction well of your Go-Strip. Pipette up and down 3-5 times to mix your PCR reaction.

6. Discard your pipette tip and repeat the process of transferring your samples only for the remaining 2 reaction wells. Once all wells of a single Go-Strip are filled, make sure to place a void filling cap into the Go-Strip to minimize any risk of contamination. Align the Go-Strip and void filling cap so that the strip connections are visible through the cap cutouts as shown in the illustration below:



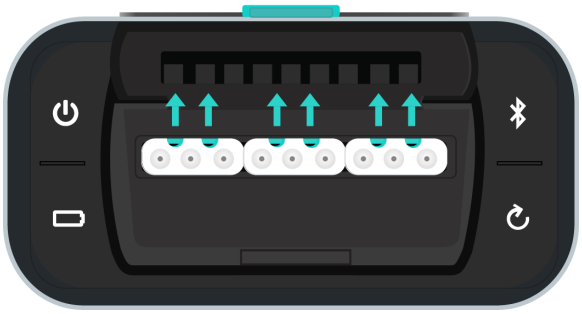
Profile View **Top View**

7. The void filling caps may feel slightly loose, this is normal. The thermocycler lid will secure the caps into place when closed, sealing each PCR reaction. **DO NOT** attempt to push the cap down.

***Note**: If utilizing a No Template Control (NTC) and/or external Positive Control (PC), add in a similar manner to other samples. It is recommended that the NTC be added first (Well 1) and the PC last (Well 9) after the addition of samples.*

Placing Go-Strips into Franklin™ Thermocycler

1. Open the lid of the thermocycler (REF# 1000003) by pressing the latch on top of the unit.
2. Place Go-Strips, with caps inserted, into each 3-well slot. Once again, make sure the strip connections are visible through the void filling cap cutouts and are facing the back of the thermocycler as shown in the illustration below.



PCR Layout Example (for one full Franklin™ run) - without External Controls

	Go-Strip 1 (left)			Go-Strip 2 (middle)			Go-Strip 3 (right)		
Well	1	2	3	4	5	6	7	8	9
	S1	S2	S3	S4	S5	S6	S7	S8	S9

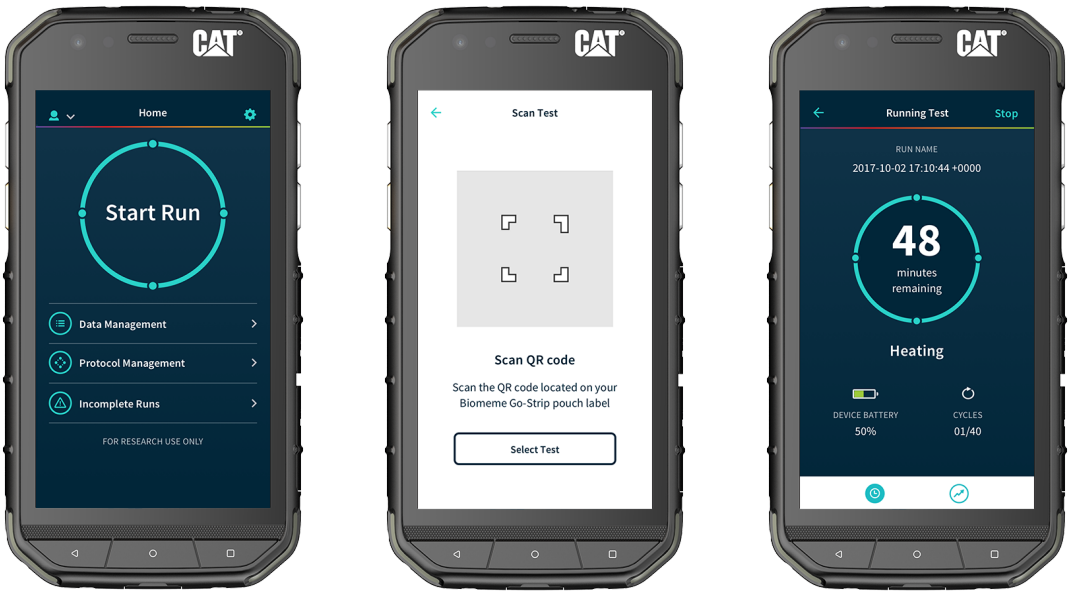
PCR Layout Example (for one full Franklin™ run) – with External Controls

	Go-Strip 1 (left)			Go-Strip 2 (middle)			Go-Strip 3 (right)		
Well	1	2	3	4	5	6	7	8	9
	NTC	S1	S2	S3	S4	S5	S6	S7	PC

3. Close the thermocycler lid securely.

Note: *After your run has completed, be careful when removing your Go-Strips and void filling caps.* ***DO NOT*** *remove only the void filling cap to avoid liquid splatter and PCR amplicon contamination.*

Launch Biomeme Go App on Smartphone



Biomeme Go (REF# 1000013 or REF# 1000012) is an intuitive smartphone app that pairs wirelessly with it's real-time PCR thermocycler. It is compatible with Android 6.0.0+ and iOS 13+.

The easy-to-use interface allows you to run, monitor, and analyze your tests online or offline and quickly interpret your results. Follow the simple steps outlined below to begin your test.

1. Launch the Biomeme Go app on your smartphone by tapping the icon on your phone's home screen if you haven't already and log in.
2. From the main dashboard of Biomeme Go, tap **Start Run**.
3. Use the camera on your smartphone to scan the **QR code** printed on the Go-Strips pouch you opened earlier.

   Note: *The first time you launch the QR code scanner, you may be asked to give permission to access the camera on your device. You will only have to grant permission once.*

4. **Confirm** you have scanned the correct test.
5. **Confirm** the test protocol is as follows:

Name	SARS-CoV-2
RT	55°C 120 sec
Initial Denature	95°C 60 sec
Cycles	45
Cycling Denature	95°C 3 sec
Anneal	60°C 30 sec
Extension	No Extension

6. Select the quantity of 3-well Go-Strips to run simultaneously in your thermocycler by adjusting the **+ (Add)** and **- (Subtract)** buttons, then tap **Confirm**. The maximum number of Go-Strips per test run is 3 (9 reactions).
7. Choose to **Scan** or **Generate** your Sample ID. You can change the sample ID on the next screen if you'd like.
8. Review your Sample IDs and tap **Continue** once you're ready to proceed.

9. Select which folder you'd like to save your run into. If you haven't created a folder, click **Add Folder** located towards the top right corner and create one.
10. Once you've selected the folder to save your run into, you can optionally change the **Run Name**, update your **GPS Coordinates** and/or add **Location** tags. If you wish, you can also add a note to the run by selecting the **Note** icon in the upper right corner.
11. Tap **Confirm** to proceed to **Run Setup**.
12. If you haven't done so already, power on your thermocycler by pressing and holding the **Power** button on the top of your device and tap **Continue** back in the Biomeme Go app.
13. Select your preferred connection method:
    a. Connect via **Bluetooth**:
        i. Press the Bluetooth button on top of your device and tap **Confirm**.
        ii. Tap **Scan** and wait a few seconds for your thermocycler to be found.

            ***Note**: the first time you try to scan for devices, you may be asked to give the Biomeme Go app permission to turn on Bluetooth. Please make sure that the "Location" service is enabled in your phone settings. The latest version of Bluetooth requires that location discovery is enabled to properly pair devices.*

        iii. Once the thermocycler is found, select it and tap **Confirm** to pair your devices.

    b. Connect via **USB**:
        i. Insert the long USB cable into the back of the thermocycler (note the correct orientation of the cable plug shown in the app).
        ii. Insert the short USB cable into the phone. Then connect the two cables together (note the correct orientation of the cable plug shown in the app).
        iii. Tap **OK** in the pop-up screen.
        iv. Wait for confirmation in the app that your connection was successful.
14. Confirm the subsequent tutorial screens to ensure your Go-Strips are loaded properly and close the lid on your thermocycler before starting your run.

15. Tap the **Start Test** button to begin your test!

Monitor Your PCR Run in Real Time

1. During the PCR run you can monitor the progress of your PCR, including the real-time PCR amplification plots by swiping left.
2. Once the PCR run is completed the thermocycler will download the run results to the smartphone controller.

***Note**: You don't need to worry about your smartphone screen turning off or going to sleep. The experiment will continue to run. If the app freezes or crashes, the experiment will also continue to run and your data can be found in the Incomplete Runs section of the app once you've reloaded the Biomeme Go app and reconnected to the thermocycler. For more information on recovering and reattaching test data, please see help.biomeme.com.*

Interpreting Results

Recommended cycle cut-off is 40 cycles. Any amplification after cycle 40 should be considered negative, however as this is not a quantitative assay, positivity must not be solely based on the Cq cutoff of a single target gene but should be an amalgam of Cq cutoff, visual analysis of amplification curve, and comparison of all targets. The user should repeat testing on any sample with questionable interpretation, as suggested in the results interpretation table.

QC Material Pass/Fail Criteria

Control Type	Control Name	Used to Monitor	SARS-CoV-2 Orf1ab	SARS-CoV-2 S	RPC	Expected Cq values
Negative	NTC	Reagent and/or environmental contamination	-	-	-	None detected

Positive	PC	Substantial reagent failure including primer and probe integrity	+	+	+	< 40
Extraction	RPC	Failure in lysis and extraction procedure, potential contamination during extraction	-	-	+	< 40

- If the PC is negative for any of the assay targets, repeat the PCR. If the PC remains negative, re-extract the entire batch of samples. If the newly extracted PC is still negative, suspect system failure and discontinue testing until the source of failure is found and eliminated. Patient testing should not resume until the PC is performing as expected.
- If the NTC is positive for any of the assay targets, first repeat PCR. If the NTC remains positive, that batch of extracted samples are invalid and the user must repeat the extraction for the entire bath. If the newly extracted NTC is still positive, suspect contamination of the test system and discontinue testing until the source of contamination is found and eliminated. Patient testing should not resume until NTC is performing as expected.

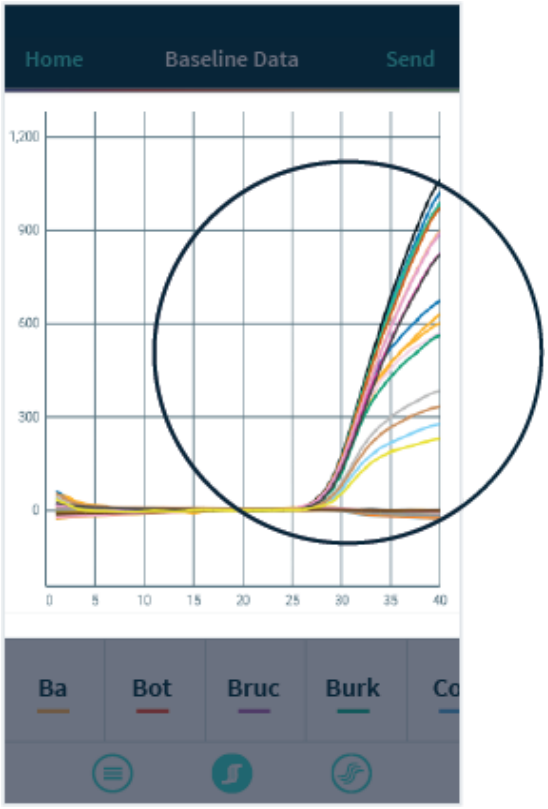
Patient Sample Pass/Fail Criteria

SARS-CoV-2 orf1ab target	SARS-CoV-2 S target	RPC	Result	Actions
+	+	±	Positive	N/A
If only one target is positive		±	Positive	N/A
-	-	-	Invalid	Re-extract the sample and run the rRT-PCR again. If the same result is

				obtained as the first run, report as Invalid.
-	-	+	Negative	N/A

This algorithm should be used in conjunction with recommended Cq cutoff value and visual analysis of amplification curves.

Columns 1, 2 and 3 are your reaction wells (e.g. 1-3, 4-6, and 7-9). The letters indicate the channel (Green, Amber, Red). Solid dots indicate your target was detected while empty dots indicate the opposite.



View the fluorescent signal for each channel plotted against the cycle number over the duration of your PCR experiment.

Look at your Go-Strips after your run has completed to check for any abnormalities such as bubbles or loss of sample. If this happens, we recommend re-running your sample.

***Note**: Remember that after your run has completed, be careful when removing your Go-Strips and void filling caps. DO NOT remove only the void filling cap to avoid liquid splatter and PCR amplicon contamination.*

Examples

The first screenshot below guides you through key components of the qualitative result screen followed by examples of the possible Biomeme SARS-CoV-2 Real-Time RT-PCR Test results as outlined in the Interpretation Table above.

Qualitative Result Screen Components

1. **Export Your Results**
   Share your results via email or download to a shared drive (e.g. Google Drive).

2. **Fluorescent Channels**
   See which fluorescent channels were detected during your run (e.g. Green, Amber, Red).

3. **Well Selection**
   Toggle tabs to see your results per Go-Strip, per channel (e.g. Wells 1 - 3, 4 - 6, 7 - 9).

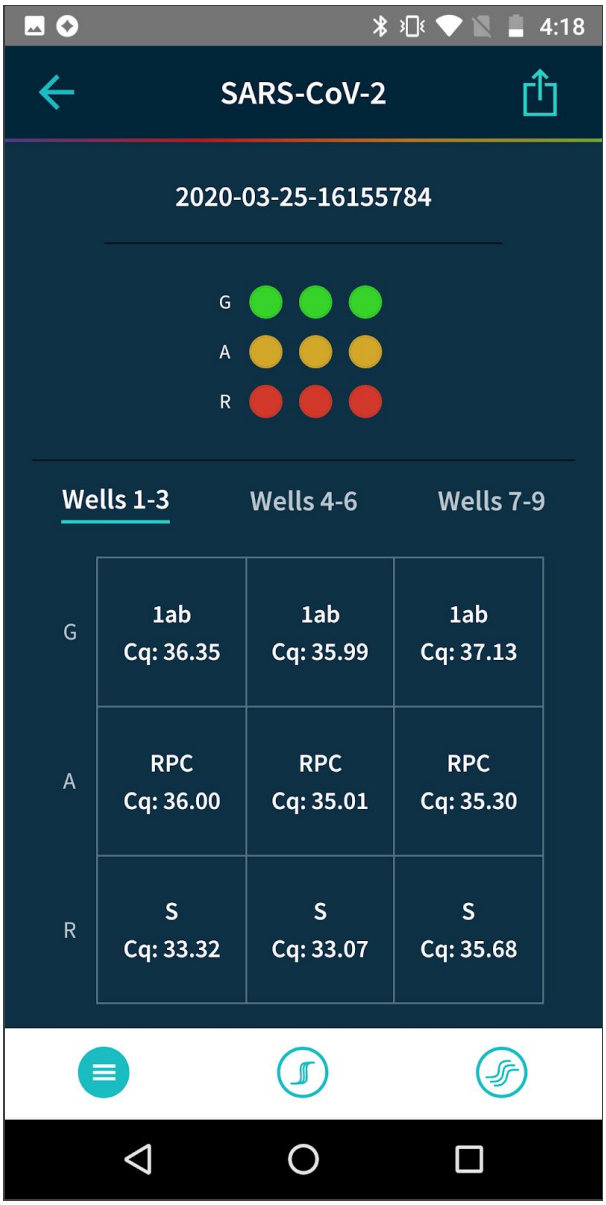
4. **Cq Values per Target/Sample**
   View Cq values for each of your targets per sample.

5. **Baselined Data**
   View amplification plots for your baselined data.

6. **Raw Data**
   View amplification plots for your raw data.

Positive Result

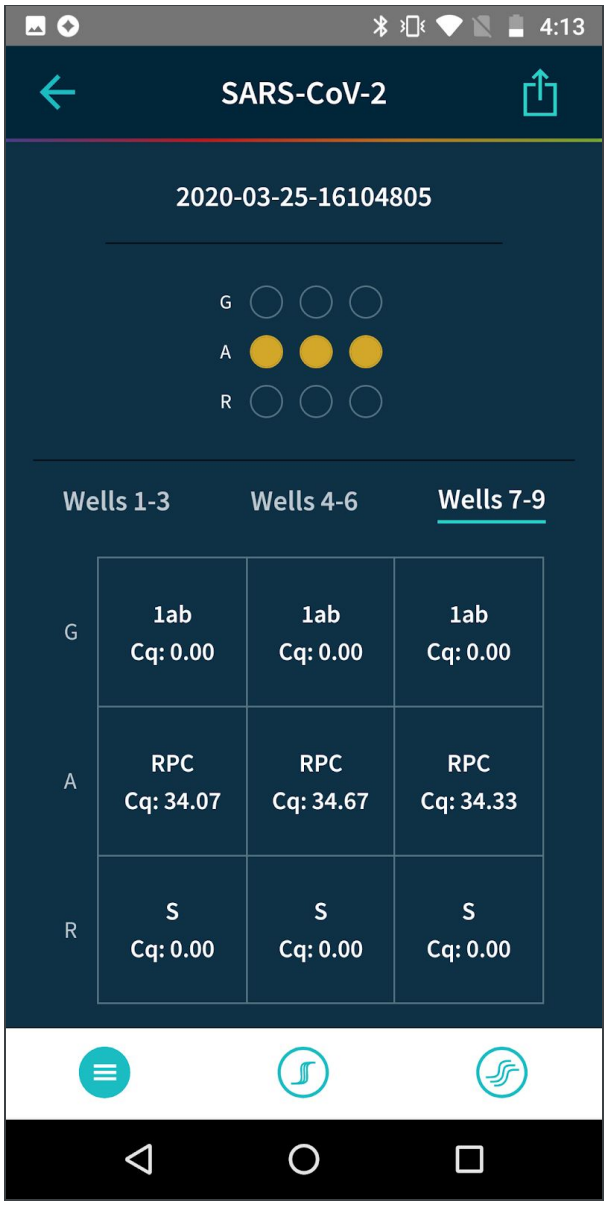
All targets detected



No additional action required other than reporting.

Negative Result

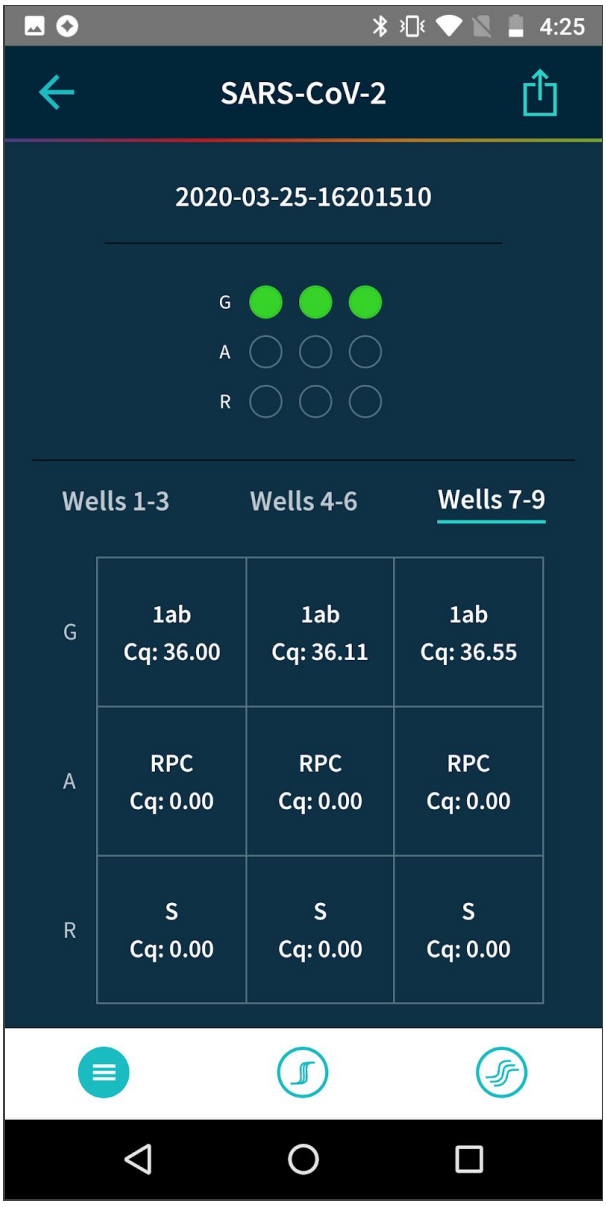
Only RPC detected



No additional action required other than reporting.

Positive Result

Only Orf1ab target detected



No additional action required other than reporting.

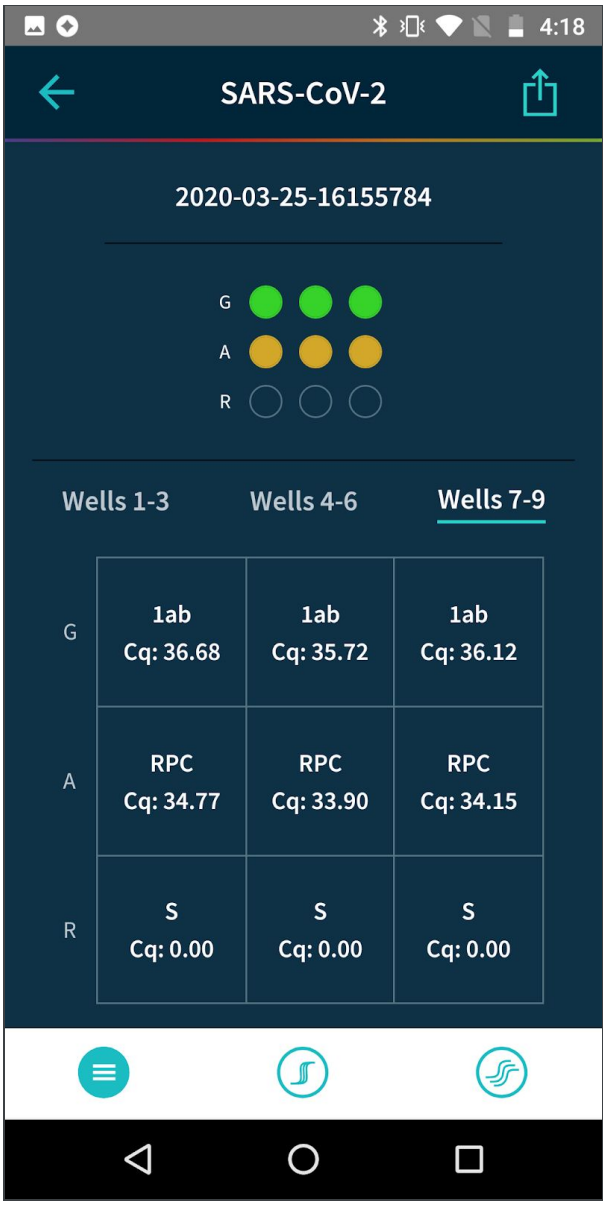
Positive Result

Only S target detected

No additional action required other than reporting.

Positive Result

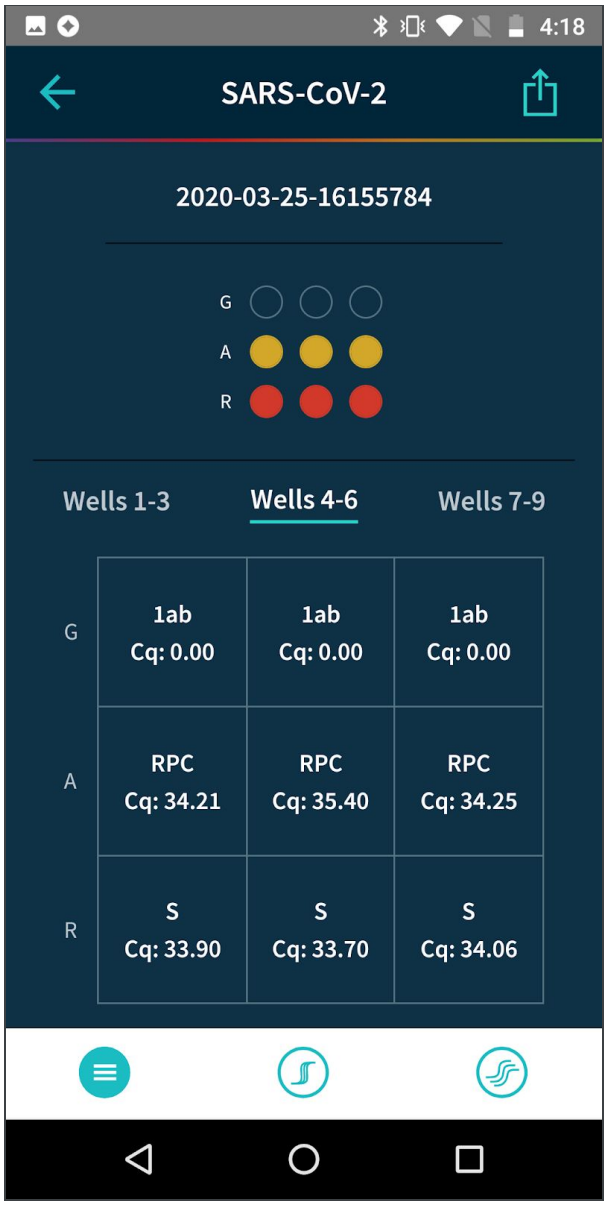
Orf1ab target & RPC detected
S target not detected



No additional action required other than reporting.

Positive Result

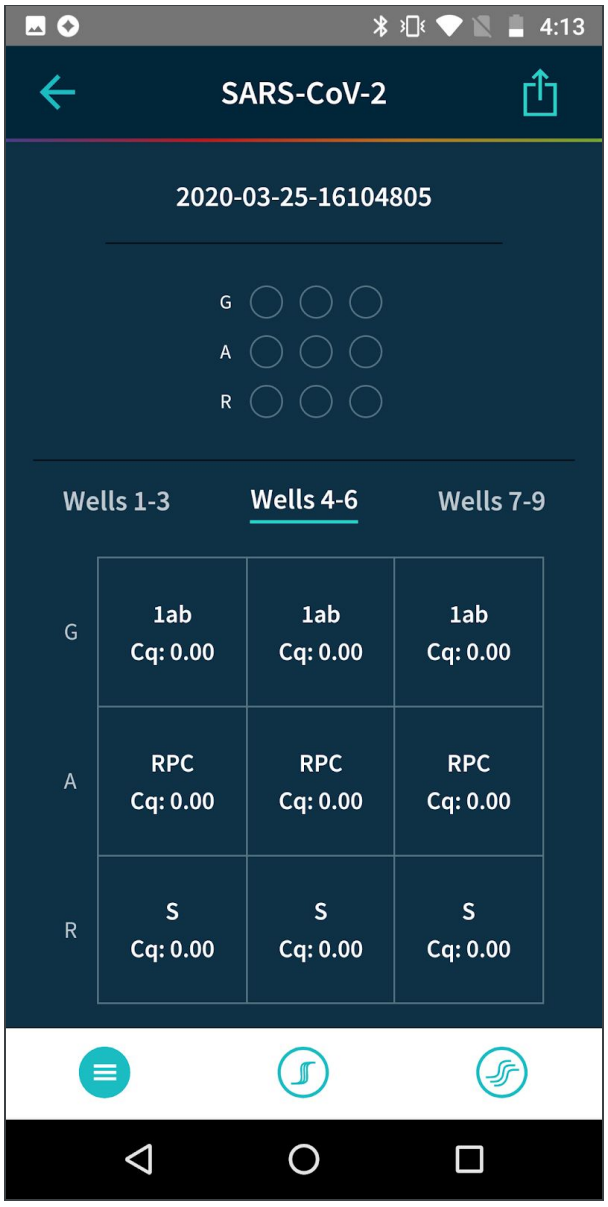
S target & RPC detected
Orf1ab target not detected



No additional action required other than reporting.

Invalid

Nothing detected



Re-extract the sample and run the rRT-PCR again.
If the same result is obtained as the first run, report as Invalid.

Assay Limitations

- The use of this assay as an *in vitro* diagnostic under the FDA Emergency Use Authorization (EUA) is limited to laboratories that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a. Other Authorized Testing Locations - Patient care settings. The Biomeme SARS-CoV-2 test is only for use under the Food and Drug Administration's Emergency Use Authorization.
- Biomeme SARS-CoV-2 Real-Time RT-PCR Test performance was established using nasopharyngeal swab specimens.

  ***Note**: Oropharyngeal swabs, nasal swabs and mid-turbinate swabs are considered acceptable specimen types for use with Biomeme's SARS-CoV-2 Real Time RT-PCR test, but performance with these specimen types has not been established. Testing of nasal and mid-turbinate nasal swabs (self-collected under supervision of or collected by a healthcare provider) is limited to patients with symptoms of COVID-19. Please refer to FDA's FAQs on Diagnostic Testing for SARS-CoV-2 for additional information.*

- Samples must be collected, transported, and stored using appropriate procedures and conditions. Improper collection, transport, or storage of specimens may hinder the ability of the assay to detect the target sequences.
- Extraction and amplification of nucleic acid from clinical samples must be performed according to the specified methods listed in this procedure. Other extraction approaches and processing systems have not been evaluated.
- False-negative results may arise from:
    - Improper sample collection
    - Degradation of the viral RNA during shipping/storage
    - Specimen collection after nucleic acid can no longer be found in the specimen matrix
    - Using unauthorized extraction or assay reagents
    - The presence of RT-PCR inhibitors
    - Mutation in the SARS-CoV-2 virus

  - Failure to follow instructions for use

- False-positive results may arise from:
  - Cross contamination during specimen handling or preparation
  - Cross contamination between patient samples
  - Specimen mix-up
  - RNA contamination during product handling
- The impacts of vaccines, antiviral therapeutics, antibiotics, chemotherapeutic or immunosuppressant drugs have not been evaluated. The Biomeme SARS-CoV-2 Real-Time RT-PCR Test cannot rule out diseases caused by other bacterial or viral pathogens.
- Negative results do not preclude infection with SARS-CoV-2 virus, and should not be the sole basis of a patient management decision.
- Laboratories are required to report all positive results to the appropriate public health authorities.

Conditions of Authorization for Labs

The Biomeme SARS-CoV-2 Real-Time RT-PCR 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/emergency-situations-medical-devices/emergency-use-authorizations

To assist clinical laboratories running the Biomeme SARS-CoV-2 Real-Time RT-PCR Test, the relevant Conditions of Authorization are listed verbatim below, and are required to be met by laboratories performing the EUA test.

- Authorized laboratories[1] using the Biomeme SARS-CoV-2 Real-Time RT-PCR Test will include with result reports of the Biomeme SARS-CoV-2 Real-Time RT-PCR Test, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

- Authorized laboratories using the Biomeme SARS-CoV-2 Real-Time RT-PCR Test will perform the Biomeme SARS-CoV-2 Real-Time RT-PCR Test as outlined in the Instructions for Use. 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 perform the Biomeme SARS-CoV-2 Real-Time RT-PCR Test are not permitted.
- Authorized laboratories that receive the Biomeme SARS-CoV-2 Real-Time RT-PCR Test must notify relevant public health authorities of their intent to run the test prior to initiating testing.
- Authorized laboratories using the Biomeme SARS-CoV-2 Real-Time RT-PCR Test will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories will collect information on the performance of the test and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Biomeme (biomeme@biomeme.com, 267-930-7707) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which they become aware.
- All laboratory personnel using the test must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the test in accordance with the authorized labeling.
- Biomeme, it's authorized distributor(s) and authorized laboratories using the Biomeme SARS-CoV-2 Real-Time RT-PCR 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] For ease of reference, this will refer to, "Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a certified laboratories with FDA Emergency Use Authorization FDA for performing SARS-CoV-2 testing. Other Authorized Testing Locations - Patient care settings" as "authorized laboratories."

Performance Characteristics

Clinical Evaluation

1. A master list of Sample IDs were generated, and labels made for synthetic specimens to be made for the Clinical Evaluation.
2. A technician not performing the Clinical Evaluation scrambled the cohort to eliminate bias.
3. A technician not performing the Clinical Evaluation:
    1. Created 30 "negative" specimens using 30 individual clinical negative specimens.
    2. Created 20 "positive specimens", 10 at a concentration @ 2x LoD and the remaining 10 @ 3x LoD (5 specimens), 4x LoD (3 specimens) and 5x LoD (2 specimens).

       ***Note**: 10 of the samples at 1x LoD in the LoD Study were counted as the 1x LoD "positives" towards the Clinical Evaluation.*
4. Acceptance Criteria:
    1. ≥ 95% agreement for the positive specimens @ 2x LoD.
    2. 100% agreement for all other specimens, including negative specimens.

As of March 24th, 2020, Biomeme has tested 30 "positive" and 30 "negative" specimens. Specimen type is NP swab. "Positive" specimens were created with varying concentrations, 10 @ 2x LoD, 10 @ 1x LoD and remaining 10 between 3x-5x LoD. "Negative" specimens were created using individual clinical negative matrix (NP swabs) specimens.

The Clinical Evaluation study was done by spiking in known concentration of Genomic RNA from SARS-Related Coronavirus 2, Isolate USA-WSA1/2020 (BEI NR-522285, Lot: 70033320, Mftg Date: 11FEB2020) into individual clinical negative matrix (NP swab), for "positive" samples. Individual negative matrix (NP swab) specimens were used as is for "negative" samples. The clinical negative matrix was mixed with BLB in the red section of the Biomeme M1 sample prep cartridge for RNA 2.0 prior to addition of viral genomic RNA and RNA Process Control. Real-Time RT-PCR assays were performed using Biomeme's SARS-CoV-2 Go-Strips, (REF 3000555) on the Biomeme

Franklin three9 Real-Time PCR Thermocycler (REF 000003) and Android Smartphone W/Biomeme Go Mobile App (REF 1000013).

Table 3: Summary of Biomeme SARS-CoV-2 Real-Time RT-PCR Assay Generated By Testing Human Respiratory Specimens Collected From Individual NP Swabs

Specimen Type	Number of Specimens	Biomeme SARS-CoV-2 Assay Positive	Biomeme SARS-CoV-2 Assay Negative	Biomeme SARS-CoV-2 Assay Inconclusive
NP Swab	60	30	30	0

Positive percent agreement= 30/30= 100%
Negative Percent Agreement=30/30= 100%

Table 4: Detailed List of 50 samples run in the Clinical Evaluation

			Targets				
#	Description	Expected Result	orf1ab	RPC	S	Final Result	PASS/ FAIL
1	NEG	NEG	NEG	POS	NEG	NEG	PASS
2	NEG	NEG	NEG	POS	NEG	NEG	PASS
3	3.6 genome equivalent per uL	POS	POS	POS	POS	POS	PASS
4	NEG	NEG	NEG	POS	NEG	NEG	PASS
5	5.4 genome equivalent per uL	POS	POS	POS	POS	POS	PASS
6	3.6 genome equivalent per uL	POS	POS	POS	POS	POS	PASS

7	7.2 genome equivalent per uL	POS	POS	POS	POS	POS	PASS
8	NEG	NEG	NEG	POS	NEG	NEG	PASS
9	NEG	NEG	NEG	POS	NEG	NEG	PASS
10	NEG	NEG	NEG	POS	NEG	NEG	PASS
11	NEG	NEG	NEG	POS	NEG	NEG	PASS
12	NEG	NEG	NEG	POS	NEG	NEG	PASS
13	5.4 genome equivalent per uL	POS	POS	POS	POS	POS	PASS
14	NEG	NEG	NEG	POS	NEG	NEG	PASS
15	7.2 genome equivalent per uL	POS	POS	POS	POS	POS	PASS
16	NEG	NEG	NEG	POS	NEG	NEG	PASS
17	NEG	NEG	NEG	POS	NEG	NEG	PASS
18	NEG	NEG	NEG	POS	NEG	NEG	PASS
19	5.4 genome equivalent per uL	POS	POS	POS	POS	POS	PASS
20	5.4 genome equivalent per uL	POS	POS	POS	POS	POS	PASS
21	5.4 genome equivalent per uL	POS	POS	POS	POS	POS	PASS
22	NEG	NEG	NEG	POS	NEG	NEG	PASS
23	NEG	NEG	NEG	POS	NEG	NEG	PASS
24	NEG	NEG	NEG	POS	NEG	NEG	PASS
25	NEG	NEG	NEG	POS	NEG	NEG	PASS
26	NEG	NEG	NEG	POS	NEG	NEG	PASS
27	NEG	NEG	NEG	POS	NEG	NEG	PASS

28	NEG	NEG	NEG	POS	NEG	NEG	PASS
29	9 genome equivalent per uL	POS	POS	POS	POS	POS	PASS
30	NEG	NEG	NEG	POS	NEG	NEG	PASS
31	NEG	NEG	NEG	POS	NEG	NEG	PASS
32	NEG	NEG	NEG	POS	NEG	NEG	PASS
33	NEG	NEG	NEG	POS	NEG	NEG	PASS
34	3.6 genome equivalent per uL	POS	POS	POS	POS	POS	PASS
35	3.6 genome equivalent per uL	POS	POS	POS	POS	POS	PASS
36	3.6 genome equivalent per uL	POS	POS	POS	POS	POS	PASS
37	NEG	NEG	NEG	POS	NEG	NEG	PASS
38	7.2 genome equivalent per uL	POS	POS	POS	POS	POS	PASS
39	3.6 genome equivalent per uL	POS	POS	POS	POS	POS	PASS
40	3.6 genome equivalent per uL	POS	POS	POS	POS	POS	PASS
41	3.6 genome equivalent per uL	POS	POS	POS	POS	POS	PASS
42	NEG	NEG	NEG	POS	NEG	NEG	PASS
43	NEG	NEG	NEG	POS	NEG	NEG	PASS
44	NEG	NEG	NEG	POS	NEG	NEG	PASS
45	3.6 genome equivalent per uL	POS	POS	POS	POS	POS	PASS
46	9 genome equivalent per uL	POS	POS	POS	POS	POS	PASS
47	3.6 genome equivalent per uL	POS	POS	POS	POS	POS	PASS

48	NEG	NEG	NEG	POS	NEG	NEG	PASS
49	NEG	NEG	NEG	POS	NEG	NEG	PASS
50	NEG	NEG	NEG	POS	NEG	NEG	PASS
NSC	No Sample Control (NSC)	NEG	NEG	NEG	NEG	NEG	PASS
NSC	No Sample Control (NSC)	NEG	NEG	NEG	NEG	NEG	PASS
NSC	No Sample Control (NSC)	NEG	NEG	NEG	NEG	NEG	PASS
NSC	No Sample Control (NSC)	NEG	NEG	NEG	NEG	NEG	PASS
	NTC	NEG	NEG	NEG	NEG	NEG	PASS
	NTC	NEG	NEG	NEG	NEG	NEG	PASS
	NTC	NEG	NEG	NEG	NEG	NEG	PASS
	NTC	NEG	NEG	NEG	NEG	NEG	PASS
	NTC	NEG	NEG	NEG	NEG	NEG	PASS
	NTC	NEG	NEG	NEG	NEG	NEG	PASS
	NTC	NEG	NEG	NEG	NEG	NEG	PASS
	NTC	NEG	NEG	NEG	NEG	NEG	PASS
	NTC	NEG	NEG	NEG	NEG	NEG	PASS
	NTC	NEG	NEG	NEG	NEG	NEG	PASS
	NTC	NEG	NEG	NEG	NEG	NEG	PASS

Analytical Performance

Analytical Sensitivity (Limit of Detection)

LoD studies determine the lowest detectable concentration of viral genomic RNA for both Orf1ab and S targets. The LoD study was done by spiking in known concentration of Genomic RNA from SARS-Related Coronavirus 2, Isolate USA-WSA1/2020 (BEI NR-522285, Lot: 70033320, Mftg Date: 11FEB2020) into individual clinical negative matrix (NP swab). The clinical negative matrix was

mixed with BLB in red section of Biomeme M1 sample prep cartridge for RNA 2.0 prior to addition of viral genomic RNA and for RNA control, MS2 bacteriophage pellet was resuspended by provided resuspension buffer from Biomeme M1 sample prep cartridge for RNA 2.0 kit and added into the mix. Samples were extracted via Biomeme M1 sample prep cartridge for RNA 2.0 (REF 3000536). Real-Time RT-PCR assays were performed using Biomeme's SARS-CoV-2 Go Strips, (REF 3000555) on Biomeme Franklin three9 Real-Time PCR Thermocycler (REF 000003) and Android Smartphone W/Biomeme Go Mobile App (REF 1000013).

A approximate LoD for each target of the Biomeme's SARS-CoV-2 Go Strips was determined by using the Genomic RNA from SARS-Related Coronavirus 2, Isolate USA-WSA1/2020 (BEI NR-522285, Lot: 70033320, Mftg Date: 11FEB2020) and testing 3, 3-fold serial dilutions and triplicate PCR reactions. A confirmation of the LoD was determined using 2, 3-fold serial dilutions of 20 extracted RNA samples for each target. The lowest concentration with 19/20 detected was the LoD.

Table 5: Limit of Detection Confirmation of SARS-CoV-2 Go-Strips for Orf1ab and S Targets

Targets	Orf1ab		S	
RNA concentration[1]	1.8	0.6	1.8	0.6
Positives/Total	20/20	18/20	20/20	19/20
Mean Cq[2]	34.23	35.90	32.40	34.52
Standard Deviation (Cq)	0.82	0.66	0.61	0.77

[1]Concentration is presented in genome equivalent per uL
[2]Mean Cq reported for positive results only

Table 6: Final Limit of Detection

Virus	Material	Limit of Detection (genome equivalent per uL)

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)	Genomic RNA	1.8

Analytical Reactivity (Inclusivity)

- Orf1ab and S - BLASTn analysis queries alignments were performed with the oligonucleotide primer and probe sequences of the Biomeme SARS-CoV-2 multiplex assay with publicly available nucleic acid sequences for SARS-CoV-2 in the Betacoronavirus nucleotide sequence database as of March 2, 2020 to demonstrate the predicted inclusivity of the Biomeme SARS-CoV-2 multiplex assay. All the alignments show 100% identity of the Biomeme SARS-CoV-2 multiplex to the publicly available SARS-CoV-2 sequences in the betacoronavirus nucleotide sequence database.

Analytical Specificity (Exclusivity)

- Biomeme Orf1ab Assay - The forward primer and probe sequences showed high sequence homology to Bat SARS-like coronaviruses. The reverse primer sequence showed high sequence homology to Bat SARS-like and human SARS coronavirus. Combining primers and probe, no significant homologies with the human genome, other coronaviruses, common respiratory flora, human microflora and other viral pathogens that would predict potential false positives rRT-PCR results.
- Biomeme S Assay - The forward primer sequence showed high sequence homology to Bat SARS-like coronavirus. The reverse primer and probe sequence showed no significant homologies with the human genome, other coronaviruses, common respiratory flora, human microflora and other viral pathogens that would predict potential false positives rRT-PCR results.
- In summary, the Biomeme SARS-CoV-2 multiplex assay (Orf1ab and S), designed for the specific detection of SARS-CoV-2, showed no significant combined homologies with human genome, other coronaviruses, or human microflora that would predict potential false positive rRT-PCR results.

Table 7: List of Organisms To Be Analyzed *In Silico* or By Direct Testing

Other high priority pathogens from the same genetic family	High priority organisms likely in circulating areas
Human coronavirus 229E	Adenovirus (e.g. C1 Ad. 71)
Human coronavirus OC43	Human Metapneumovirus (hMPV)
Human coronavirus HKU1	Parainfluenza virus 1-4
Human coronavirus NL63	Influenza A & B
SARS-coronavirus	Human Enterovirus A, B, C
MERS-coronavirus	Respiratory syncytial virus
	Rhinovirus
	Chlamydia pneumoniae
	Haemophilus influenzae
	Legionella pneumophila
	Mycobacterium tuberculosis
	Streptococcus pneumoniae
	Streptococcus pyogenes
	Bordetella pertussis
	Mycoplasma pneumoniae
	Pneumocystis jiroveci (PJP)
	Candida albicans
	Pseudomonas aeruginosa
	Staphylococcus epidermis
	Staphylococcus salivarius

Technical Support

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The customer is responsible for compliance with regulatory requirements that pertain to their procedures and uses of the instrument. The information in this guide is subject to change without notice.

DISCLAIMER: TO THE EXTENT ALLOWED BY LAW, BIOMEME INC. AND/OR ITS AFFILIATE(S) WILL NOT BE LIABLE FOR SPECIAL, INCIDENTAL, INDIRECT, PUNITIVE, MULTIPLE, OR CONSEQUENTIAL DAMAGES IN CONNECTION WITH OR ARISING FROM THIS DOCUMENT, INCLUDING YOUR USE OF IT.

Revision	Date	Description
1.0	April 3, 2020	New document
1.1	April 8, 2020	Updated Table 4 LOD, NTC and PC instructions
1.2	April 9, 2020	Updated NTC and PC instructions
1.3	April 13, 2020	Added Biomeme Go OS compatibility statement (Android 6.0.0+ and iOS 13+)
1.4	April 15, 2020	Changed 'General Guidelines' section to be more specific: 'Minimize the Risk of Contamination'
1.5	April 20, 2020	Added note to 'Add RNA Process Control (RPC)' section for incubating cartridges in bulk
1.6	May 1, 2020	• Grammatical updates • Updated Contents tables • Updated 'RNA Extraction Using M1 Sample Prep Cartridge' section • Added statement regarding FDAs independent review of validation • Added storage recommendation to 'Prepare RNA Process Control' section • Updated 'Positive Control Material' section • Added footnotes to Table 5 • In 'Placing Go-Strips into Franklin™ Thermocycler' section, split tables into 2 for running PCR w/ and w/o External Controls • Added additional screenshots to 'Patient Sample Pass/Fail Criteria' section

		• Introduced ‘Final Limit of Detection’ table