



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

Biomeme, Inc.
1015 Chestnut Street, Suite 1401
Philadelphia, PA19107

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Brief Overview

The Biomeme SARS-CoV-2 Real-Time RT-PCR Test for use on the Biomeme Franklin™Real-Time PCR System is a qualitative multiplex, in vitro diagnostic (IVD) assay. 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 Real-Time RT-PCR Test is a real-time RT-PCR test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal, nasal, and oropharyngeal swab specimens, and nasopharyngeal wash/aspirate or nasal aspirate specimens collected from individuals 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 complexity tests.

Results are for the identification of SARS-CoV-2 RNA which is generally detected 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 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 qualified clinical laboratory 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.

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 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 in upper respiratory specimens.

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 [ML Sample Prep Cartridge](#) for RNA extraction, Biomeme's [SARS-CoV-2 Go-Strips](#) assay, and Biomeme's portable [Franklin™](#)

[Real-Time qPCR 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 MI 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 MI 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 RNAProcess Control (RPC) for RNA extraction and RT-PCR (**M_S2** 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 - RNAProcess Control (**M_S2** bacteriophage)

Go-Strips are designed for the Biomeme Franklin™ mobile handheld qPCR thermocycler. The Biomeme SARS-CoV-2 Real-Time RT-PCR Test is also available in a 96-well [Go-Plate](#) format for direct use on the Bio-Rad CFX96 or QuantStudio5 using the "fast" block (see Appendix 1 &2).

Contents

The materials available 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 VT Minto Extraction Kit
Biomeme: 3000536 or Biomeme: 3000574	Biomeme MI Sample Prep Cartridge Kit for RNA2.0 or Biomeme MI Sample Prep Cartridge Kit for RNA2.0 NC	RNAExtraction Kit containing cartridges, syringes, and binding column tips.
Biomeme: 3000011	20µL Fixed Volume Pipette Kit	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* Kit	Pre-aliquoted 3-well PCR strips. Each well contains a 20µL lyophilized triplex reaction. The kit also includes Biomeme's lyophilized RNAExtraction and RT-PCR Process Control pellets ('RPC' - MS2 bacteriophage).

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

Each item above can be purchased individually.

Additional Form Factors

SARS-CoV-2 Assays also come in one additional form factor:

- [3000562](#): Biomeme SARS-CoV-2 Go-Plates (96 rxns at 20 uL)

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

The following equipment and software are required to run the test and analyze results. While Go-Strips are designed for the Biomeme Franklin™mobile handheld qPCR thermocycler, the Biomeme SARS-CoV-2 Real-Time RT-PCR Test is also available in a 96-well [Go-Plate](#) format for direct use on the Bio-Rad CFX96 or QuantStudio 5 using the “fast” block (see Appendix 1 &2). Both the Go-Strip and Go-Plate form factors are validated for use on these alternative instruments.

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
Biomeme: 3000577	Biomeme DNA/RNA Preservation Buffer	Used to 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)	BEINR-52285 : Viral Genomic RNA (from SARS-Related Coronavirus 2, Isolate USA-WSAI/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 other than Biomeme's exogenous RNAProcess Control (MS2 Bacteriophage) are not provided with the Biomeme SARS-CoV-2 Real-Time RT-PCR 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'.

Note: Samples should be collected in accordance with CDC Guidelines.

Note: The Biomeme SARS-CoV-2 Real-Time RT-PCR Test can also be used with the Bio-Rad CFXMaestro 1.1 version 4.1.2433.1219 (REF 1855195) and the Applied Biosystems Quant Studio 5 Design and Analysis Software v1.4.3 (REF A84322).

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.

- For in vitro diagnostic use only.
- For Emergency Use Authorization only.
- For Prescription Use only.
- The Biomeme SARS-CoV-2 Real-Time RT-PCR Test has not been FDAcleared or approved; the test has been authorized by FDAunder an Emergency Use Authorization (EUA) for use by laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- The Biomeme SARS-CoV-2 Real-Time RT-PCR Test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- The Biomeme SARS-CoV-2 Real-Time RT-PCR 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.

- Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.
- 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 local, state, and federal regulations.
- Safety Data Sheets (SDS) 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.

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. Sample handling and storage should be consistent with CDC guidelines. The Biomeme SARS-CoV-2 Real-Time RT-PCR Test has been validated for use with BD Universal Viral Collection Kit and the Biomeme DNA/RNA Preservation Buffer. Samples collected in the BD Universal Viral

Collection Kit should be handled and stored according to the manufacturer's instructions. Samples collected in Biomeme DNA/RNA Preservation Buffer can be stored at room temperature (15–30 °C) for up to 14 days until sample extraction is performed using Biomeme's MI Sample Prep Cartridges.

SAFETY WARNING

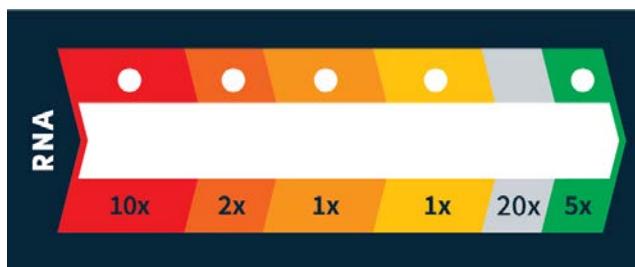
Handle all samples and controls as if they are capable of transmitting infectious agents. Refer to the [CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation \(PUIs\) for Coronavirus Disease 2019 \(COVID-19\)](#).

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.
- Precautions must be taken to prevent cross contamination of samples.

RNA Extraction Using M1 Sample Prep Cartridge



After collecting your sample, use Biomeme's M1 Sample Prep Cartridge (REF# [3000536](#)) to purify your RNA Samples. Samples are lysed by mixing in 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. It is recommended that you utilize separate work areas for sample preparation, nucleic acid extraction, and PCR amplification.
- 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 an RNA Process Control (RPC) detection assay and lyophilized RPC Pellets (MS2 bacteriophage).

1. Remove and open the 2mL screw cap tube containing your RPC pellet.
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 it 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. Open your M1 Sample Prep Cartridge pouch and remove the contents.
2. 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.
3. Using a 200µL transfer pipette (REF# [3000567](#)), or your own 200µL pipette, transfer 200µL of media from the collection tube containing your sample and add it into the red section of your sample prep cartridge.
4. Discard your transfer pipette and incubate at room temperature (15–25°C) for 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 20 μ L fixed volume pipette and transfer 20 μ L 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 MI 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 the syringe up 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 BPWfluid 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 1mLsyringe 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 1mLsyringe 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 BDWfluid 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 1mLsyringe with the attached sample prep column to the blue section of the Sample Prep Cartridge and pierce through the foil once.
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 1mLsyringe 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 (about 850 μ L) into the syringe from the green section and transfer it to a 2mLself-standing tube (REF# [3000150](#)).
2. Cap the tube and dispose of the M1 Sample Prep Cartridge and syringe with binding column.

SAFETYWARNING

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 BPWbuffers 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 new clinical specimens to optimize throughput of the Biomeme Franklin™thermocycler (e.g., for up to 7 total samples plus 1 NTCand 1 PC).
2. Proceed to [Loading Pure Sample into Go-Strips](#).

Preparation of Positive Control Samples

The Biomeme SARS-CoV-2 Real-Time RT-PCR Test has been validated with two external positive controls that are to be prepared as described below. Only one positive control is needed for each assay.

Viral Genomic RNA (from SARS-Related Coronavirus 2, Isolate USA-WSAI/2020 (BEI REF NR-52285)

1. Resuspend the RPC included in the SARS-CoV-2 Go-Strip Kit according to Biomeme's instructions
2. Dilute the stock of BEI viral genomic RNA down to 1000 genome equivalent per μL (GE/ μL)
 - a. For example: Stock concentration at 4.8E4 GE/ μL
 - i. Add 2.08 μL of stock into 97.91 μL of TE = 1000 GE/ μL
 3. Add 20 μL of resuspended RPC into Biomeme M1 RNA sample prep kit for cartridges
 4. Add 200 μL of negative NP swab into prep
 5. Add 7.65 μL of viral genomic RNA at 1000 GE/ μL into prep
 6. Follow Biomeme's assay instructions and isolate total RNA
 7. Transfer the elution into a 1.75 mL Eppendorf tube. This will be the positive control.
 8. Aliquot out into 20 μL volume
 9. Add 20 μL of positive control into one well of the SARS-CoV-2 Go-Strip

Exact Diagnostics SARS-CoV-2 (REF COV019)

1. Resuspend the RPC included in the SARS-CoV-2 Go-Strip Kit according to Biomeme's instructions
2. Add 20 μL of resuspended RPC into Biomeme M1 RNA sample prep kit for cartridges
3. Add 200 μL of negative NP swab into prep
4. Add 10 μL of EXACT diagnostic standard at 200 copies per μL into prep
5. Follow Biomeme's assay instructions and isolate total RNA
6. Transfer the elution into a 1.75 mL Eppendorf tube. This will be the positive control.
7. Aliquot out into 20 μL volume
8. Add 20 μL of positive control into one well of the SARS-CoV-2 Go-Strip

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 20 μ L fixed volume pipette (REF# [3000011](#)) or prepare your own 20 μ L 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).

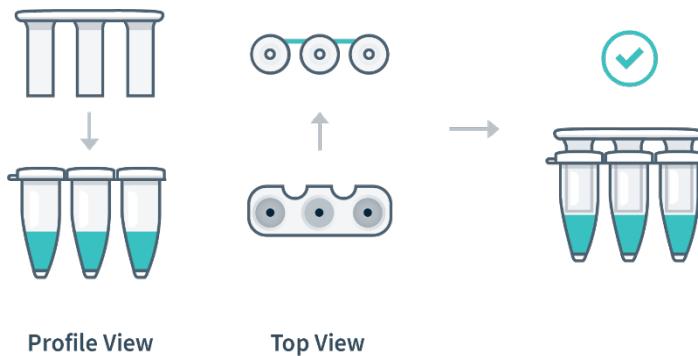
4. Additionally, when mixing your samples try to avoid introducing bubbles.



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 20 μ L 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:

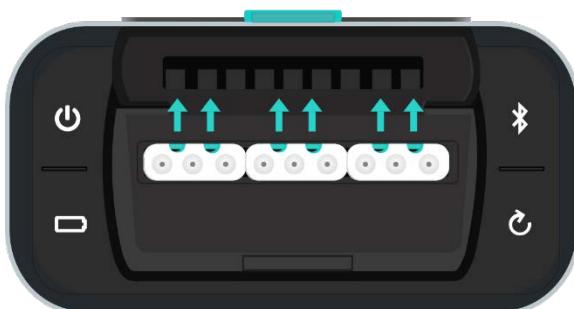


7. The void filling caps may feel slightly loose, this is normal. The thermocycler lid will secure the caps into place when closed, sealing each PCR reaction. DO NOT attempt to push the cap down.

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 the 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

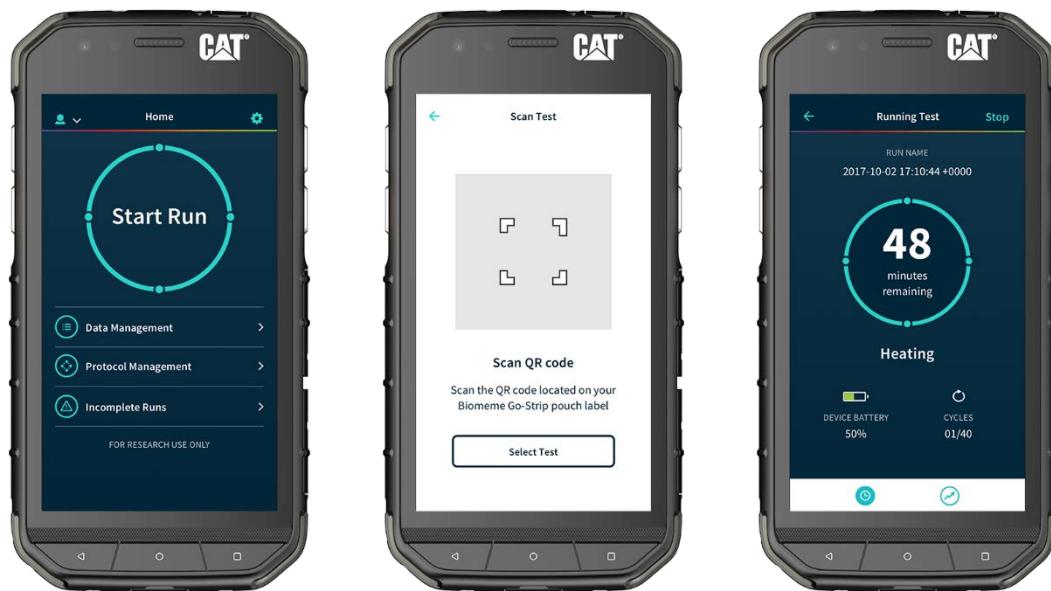
PCR Layout Example (for one full Franklin™ run) - with External Controls

	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

- 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 the Franklin™ real-time PCR thermocycler. It is compatible with Android 6.0.0+. 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 QRcode 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

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 would 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

The recommended cycle cut-off is 40 cycles. Any amplification after cycle 40 should be considered negative. 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.

Table 3: 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, failure in extraction procedure	+	+	+	<40
Extraction	RPC	Failure in lysis and extraction procedure, potential contamination during extraction, RT-PCR failure	-	-	+	<40

Table 4: Patient Specimen Results Interpretation

SARS-CoV-2 Orf1ab target	SARS-CoV-2 S target	RPC	Result	Actions
+	+	±	Positive	Report results to the sender and appropriate public health authorities.
-	+	±	Positive	Report results to sender and appropriate public health authorities.
+	-	±	Presumptive Positive	<p>Re-extract the sample and run the rRT-PCR again. Report presumptive positive results to sender and appropriate public health authorities.</p> <p>For samples with a repeated presumptive positive result, additional confirmatory testing may be conducted, if it is necessary to differentiate between SARS-CoV-2 and other SARS-like viruses for epidemiological purposes or clinical management.</p>
-	-	-	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	Report results to sender.

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.

- When all SARS-CoV-2 targets are negative but the RPC is positive, the result should be considered as valid and negative.
- When all SARS-CoV-2 targets are positive but the RPC is positive or negative, the results should be considered as valid and positive.
- When all SARS-CoV-2 targets and the RPC is negative, the result is invalid. Re-extract the sample and run the rRT-PCR again. If the same result is obtained as the first run, a new specimen should be obtained.
- If only the SARS-CoV-2 S target is positive, and the RPC target is positive or negative, the result for SARS-CoV-2 is positive.
- If only the SARS-CoV-2 Orflab target is positive, and the RPC target is positive or negative, the result for SARS-CoV-2 is presumptive positive. A negative SARS-CoV-2 S (Target 1) result and a positive SARS-CoV-2 Orflab (Target 2) result is suggestive of:
 - 1) a sample at concentrations near or below the limit of detection of the test,
 - 2) a mutation in the Target 1 target region in the oligo binding sites,
 - 3) infection with some other Sarbecovirus (e.g., SARS-CoV or some other Sarbecovirus previously unknown to infect humans), or
 - 4) other factors.

The sample should be retested. For samples with a repeated presumptive positive result, additional confirmatory testing may be conducted if it is necessary to differentiate between SARS-CoV-2 and other SARS-like viruses for epidemiological purposes or clinical management.

- If an NTC is run and the result is positive, then contamination may have occurred. Re-extract all samples within the extraction batch and re-test.

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. For use of the SARS-CoV-2 test with alternative thermocyclers, please refer to Appendix 1 and Appendix 2.

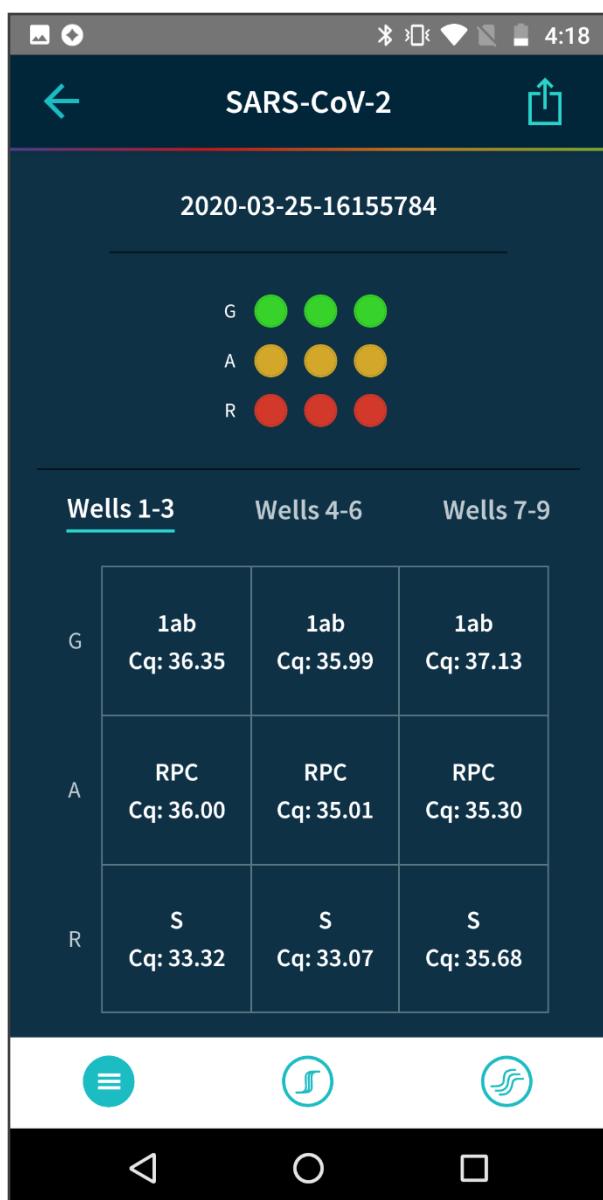
Qualitative Result Screen Components



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. Baseline Data
View amplification plots for your baselined data.
6. Raw Data
View amplification plots for your raw data.

Positive Results

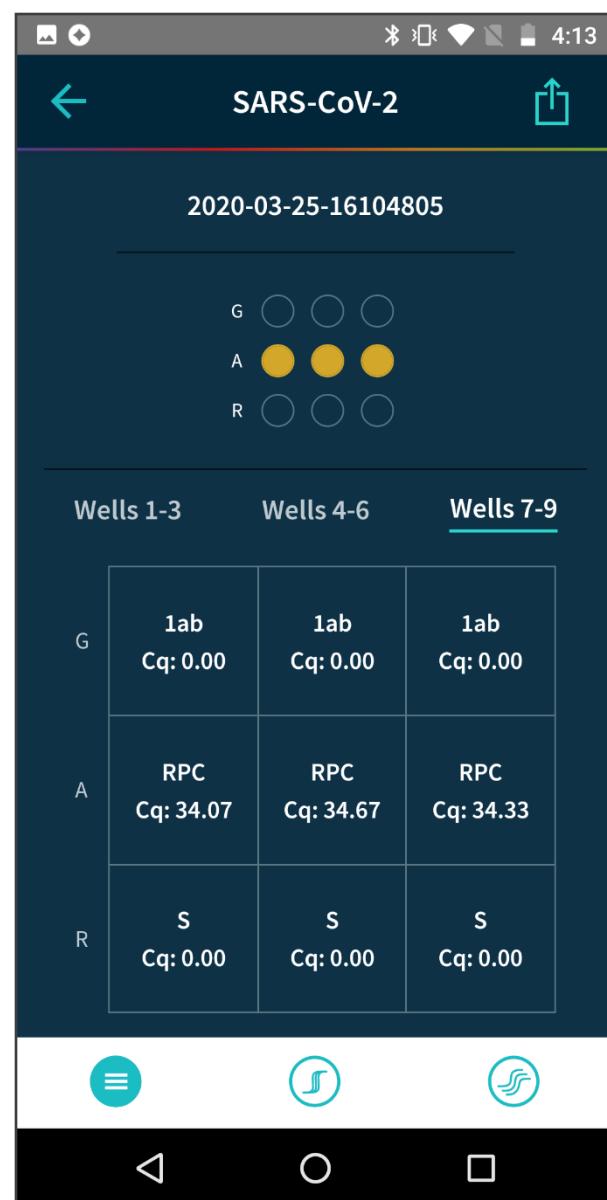
All targets detected



Report results to the sender and appropriate public health authorities.

Negative Results

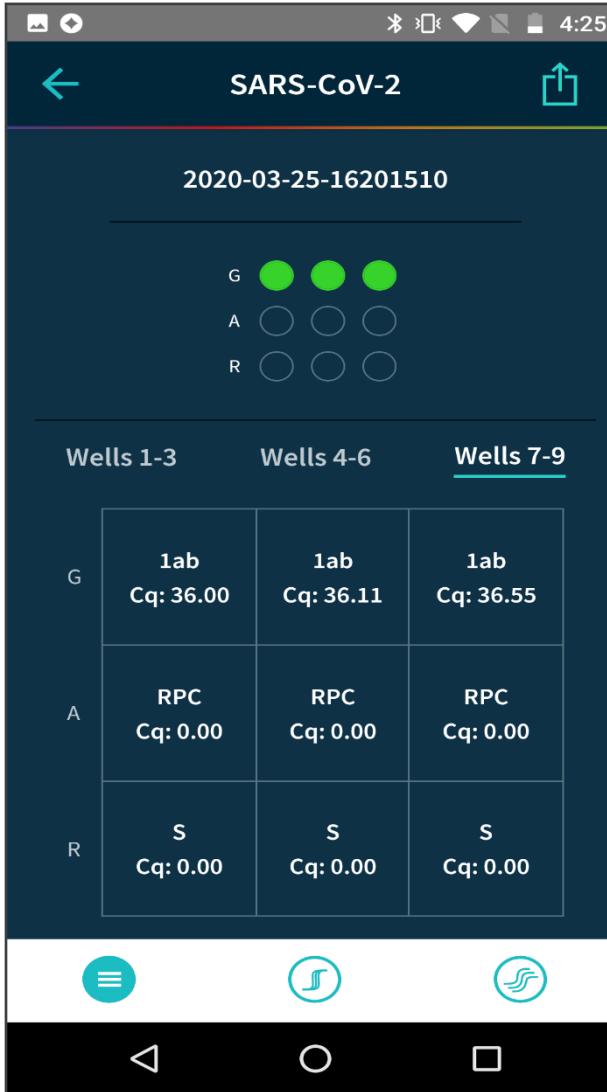
Only RPC detected



Report results to sender.

Presumptive Positive Results

Only Orf1ab target detected

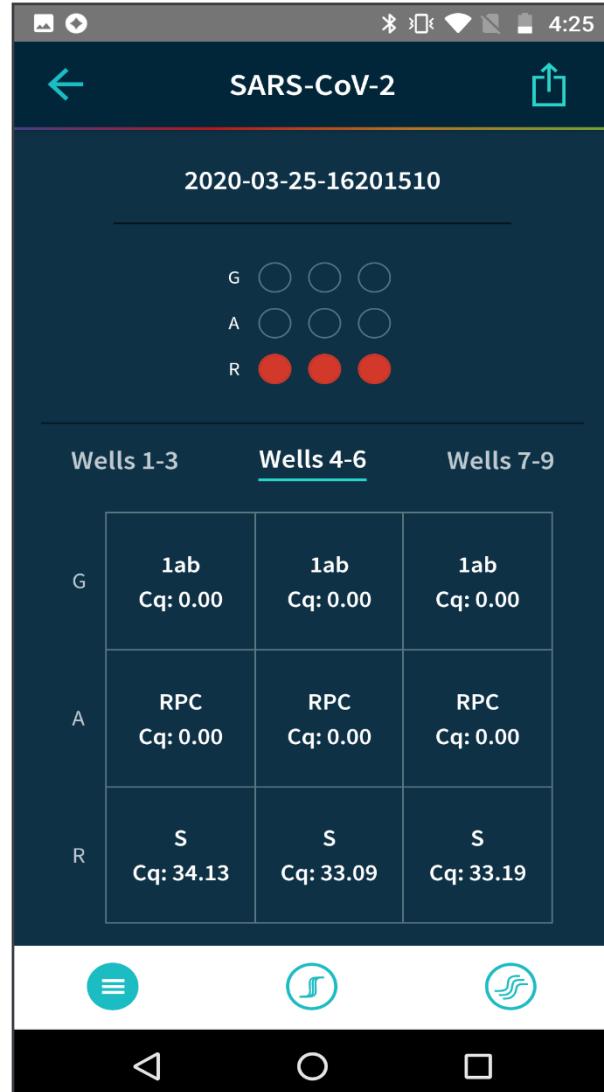


Re-extract the sample and run the rRT-PCR again.
Report presumptive positive results to sender and appropriate public health authorities.

For samples with a repeated presumptive positive result, additional confirmatory testing may be conducted, if it is necessary to differentiate between SARS-CoV2 and other SARS-like viruses for epidemiological purposes or clinical management.

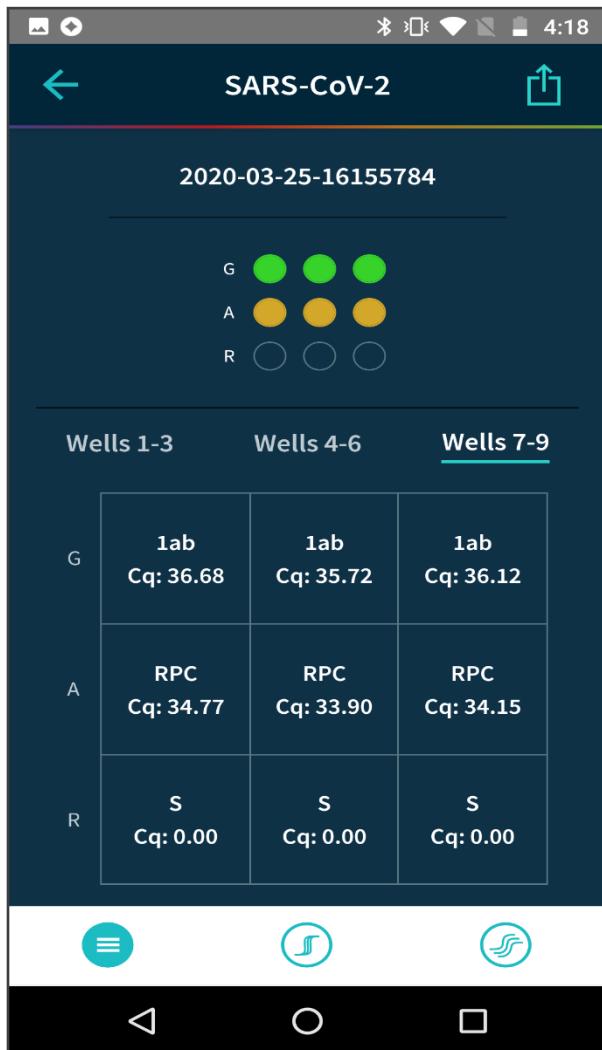
Positive Results

Only S target detected



Report results to the sender and appropriate public health authorities.

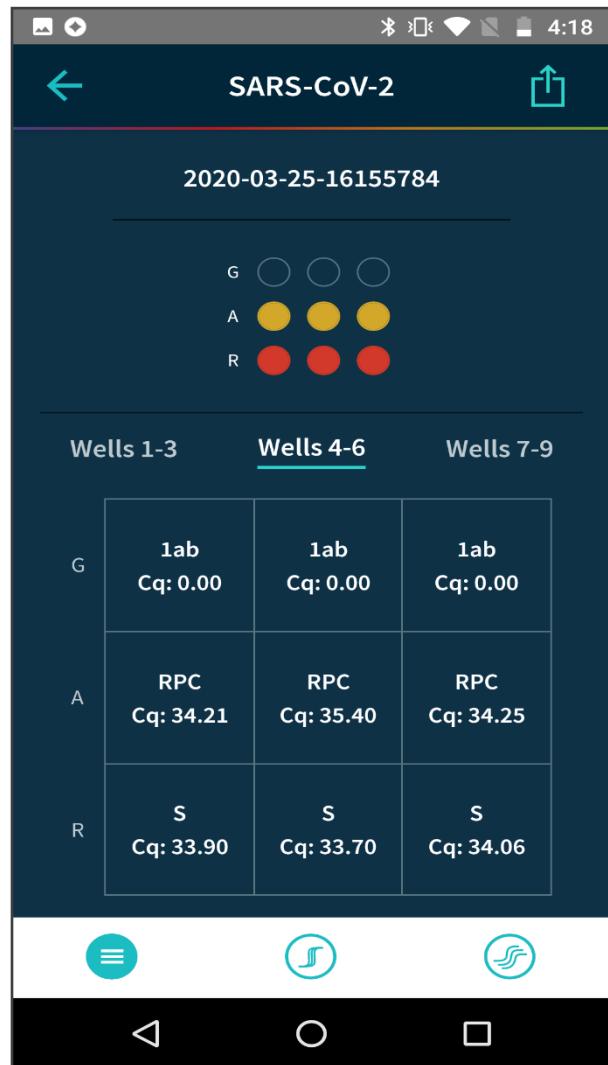
Presumptive Positive Results
Orflab target & RPCdetected
S target not detected



Re-extract the sample and run the rRT-PCR again.
Report presumptive positive results to sender and appropriate public health authorities.

For samples with a repeated presumptive positive result, additional confirmatory testing may be conducted, if it is necessary to differentiate between SARS-CoV-2 and other SARS-like viruses for epidemiological purposes or clinical management.

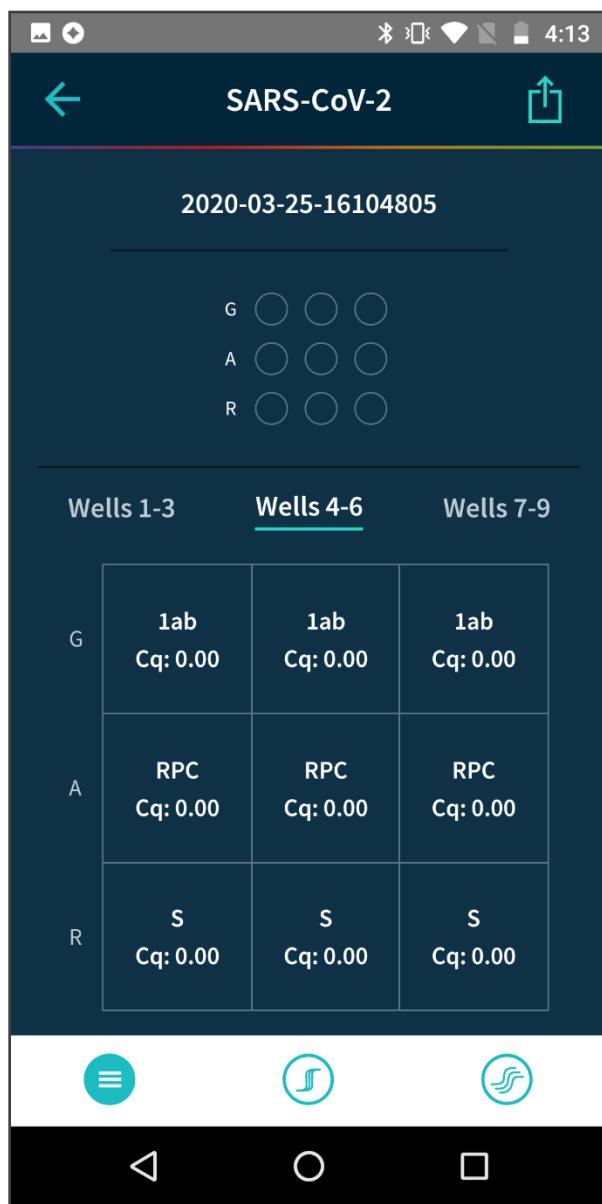
Positive Results
S target & RPCdetected
Orflab target not detected



Report results to the sender and appropriate public health authorities.

Invalid Results

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 Biomeme SARS-CoV-2 Real-Time RT-PCR Test is for in vitro diagnostic use under FDA Emergency Use Authorization only. 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 complexity tests.

- Biomeme SARS-CoV-2 Real-Time RT-PCR Test performance was established using nasopharyngeal swab.

Note: Nasal and oropharyngeal swab specimens, as well as nasopharyngeal wash/aspirate or nasal aspirate specimens are considered acceptable specimen types for use with Biomeme SARS-CoV-2 Real Time RT-PCR test.

- 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. Negative results must be combined with clinical observations, patient history, and epidemiological information.
 - Based on the in silico analysis, SARS-CoV and other SARS-like coronaviruses in the same subgenus (Sarbecovirus) as SARS-CoV-2 may cross-react with the Biomeme Orflab target. SARS-CoV is not known to be currently circulating in the human population, and therefore is highly unlikely to be present in patient specimens.
 - Results from this test should be used in conjunction with clinical correlation with patient history and other diagnostic information available to the physician.
 - 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 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>

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

- Authorized laboratories¹ using the Biomeme SARS-CoV-2 Real-Time RT-PCR 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.

- Authorized laboratories using the Biomeme SARS-CoV-2 Real-Time RT-PCR Test will use the Biomeme SARS-CoV-2 Real-Time RT-PCR 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 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/OHT-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Biomeme (support@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, its 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 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 high complexity tests” as “authorized laboratories.”

Performance Characteristics

Analytical Performance

Analytical Sensitivity (Limit of Detection)

LoD studies determine the lowest detectable concentration of viral genomic RNA for both Orflab and S targets that consistently yields a 95% positivity. The LoD study was done by spiking in known concentrations of Genomic RNA from SARS-Related Coronavirus 2, Isolate USA-WSA1/2020 (BEI NR-52285, Lot: 70033320, Mfg Date: 11FEB2020) into individual clinical negative matrix (NP swab). The clinical negative matrix was mixed with BLB in the red section of Biomeme MI sample prep cartridge for RNA2.0 prior to addition of viral genomic RNA. The RNAcontrol MS2 bacteriophage pellet was resuspended by provided resuspension buffer from Biomeme MI sample prep cartridge for RNA2.0 kit and added into the mix. Samples were extracted via Biomeme MI sample prep cartridge for RNA2.0 (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 preliminary LoD was determined by extracting and testing three 3-fold serial dilutions of the viral genomic RNA in negative NP swab matrix. A confirmation of LoD was determined by extracting and testing 20 replicates of two 3-fold serial dilutions of viral genomic RNA in negative NP swab matrix.

The preliminary LoD was then confirmed by testing 40 individual nasopharyngeal swab specimens spiked with 1.8 genomic copies/ μ L of SARS CoV-2 RNA (BEI Resources). The observed positivity rate among the 40 samples was 95% and 97.5% for the Orflab and S targets, respectively.

Table 5: Preliminary LoD Study Data with Biomeme Franklin Thermocycler

Sample Concentration	% Reactivity		
	Orflab Target	S Target	RPC Target
0.9 GE/ μ L	80% (4/5)	100% (5/5)	100% (5/5)
1.8 GE/ μ L	100% (5/5)	100% (5/5)	100% (5/5)
2.7 GE/ μ L	100% (5/5)	100% (5/5)	100% (5/5)
3.6 GE/ μ L	100% (5/5)	100% (5/5)	100% (5/5)

Table 6: LoD Confirmation Data with Biomeme Franklin Thermocycler

Sample Concentration	% Reactivity		
	Orflab Target	S Target	RPC Target
1.8 GE/ μ L	95% (38/40)	97.5% (39/40)	100% (20/20)
0.6 GE/ μ L	90% (18/20)	95% (19/20)	100% (20/20)

Table 7: Final Limit of Detection

Virus	Material	Limit of Detection (genome equivalent per μ L)
Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)	Genomic RNA	1.8

An adaptive LoD Study was performed to establish equivalent assay performance to the Biomeme Franklin™ on the Bio-Rad CFX and the Applied Biosystems QuantStudio 5 thermocycler. 5 replicates each at 0.5x LoD, 1x LoD, 1.5x LoD, and 2x LoD were run on the alternative thermocyclers. Dilutions were made by spiking SARS-Related Coronavirus 2, Isolate USA-WSA1/2020 (BEINR-52285, Lot: 70033320, Mtg Date: 11FEB2020) into negative clinical NP matrix. 4/5 replicates were positive at 0.5xLoD, while 5/5 replicates were positive at 1x LoD, for each alternative instrument being tested (see Table 8 and Table 9).

A confirmatory LoD study was performed at 1x LoD by spiking SARS-Related Coronavirus 2, Isolate USA-WSA1/2020 (BEINR-52285, Lot: 70033320, Mtg Date: 11FEB2020) into 20 individual clinical negative NP matrices. All 20 replicates, or 100%, were positive across all instruments at this concentration (1.8 GE/uL) (see Table 10 and Table 11).

Table 8: Bio-Rad CFX96 LoD

Sample Dilution	% Reactivity		
	Orflab Target	S Target	MS2 Target
0.5x LoD	100% (5/5)	80% (4/5)	100% (5/5)
1x LoD	100% (5/5)	100% (5/5)	100% (5/5)
1.5x LoD	100% (5/5)	100% (5/5)	100% (5/5)
2x LoD	100% (5/5)	100% (5/5)	100% (5/5)

Table 9: Applied Biosystems QuantStudio 5 LoD

Sample Dilution	% Reactivity		
	Orf1ab Target	S Target	MS2 Target
0.5x LoD	80% (4/5)	100% (5/5)	100% (5/5)
1x LoD	100% (5/5)	100% (5/5)	100% (5/5)
1.5x LoD	100% (5/5)	100% (5/5)	100% (5/5)
2x LoD	100% (5/5)	100% (5/5)	100% (5/5)

Table 10: Bio-Rad CFX96 LoD Confirmation

Sample Dilution	% Reactivity		
	Orf1ab Target	S Target	MS2 Target
1.8 GE/ μ L	100% (20/20)	100% (20/20)	100% (20/20)

Table 11: Applied Biosystems QuantStudio 5 LoD Confirmation

	% Reactivity		
	Orf1ab Target	S Target	MS2 Target
1.8 GE/ μ L	100% (20/20)	100% (20/20)	100% (20/20)

Table 12: Equivalence Between Carrier/No Carrier Sample Prep

Sample Dilution		% Reactivity		
		Orf1ab target	S target	MS2 target
0.6 GE/ μ L	Carrier RNA	100% (5/5)	100% (5/5)	100% (5/5)
	No Carrier RNA	100% (5/5)	100% (5/5)	100% (5/5)
1.8 GE/ μ L	Carrier RNA	100% (5/5)	100% (5/5)	100% (5/5)
	No Carrier RNA	100% (5/5)	100% (5/5)	100% (5/5)
5.4 GE/ μ L	Carrier RNA	100% (5/5)	100% (5/5)	100% (5/5)
	No Carrier RNA	100% (5/5)	100% (5/5)	100% (5/5)

Table 13: Equivalence Between BD VTM and Biomeme Preservation Buffer

		% Reactivity		
		Orf1ab target	S target	MS2 target
1x LoD	Biomeme Preservation buffer	100% (5/5)	100% (5/5)	100% (5/5)
	BD VTM	100% (5/5)	100% (5/5)	100% (5/5)

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 Real-Time RT-PCR Test with publicly available nucleic acid sequences for SARS-CoV-2 in the betacoronavirus nucleotide sequence database as of July 1, 2020 to demonstrate the predicted inclusivity of the Biomeme SARS-CoV-2 Real-Time RT-PCR Test. The Orf1ab primers and probe show 100% homology to greater than or

equal to 99.96% of significant sequences returned. The S primers and probe show 100% homology to greater than or equal to 99.87% of significant sequences returned. A small number of significant sequence alignments showed a single mismatch in the primer or probe regions. No sequence was found to contain more than a single mismatch in each primer and probe in the assay. No sequence was found to contain more than a single mismatch in more than one of the primers and probe in either the Orflab or S assays.

Analytical Specificity (Exclusivity and Cross-reactivity)

- Cross-reactivity of the Biomeme SARS-CoV-2 Real-Time RT-PCR Test was evaluated in an in silico analysis against normal and pathogenic organisms associated with the respiratory tract.
- Biomeme Orflab 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 as well as *Candida albicans*. 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 positive rRT-PCR results.
- Biomeme S Assay - Only the forward primer sequence showed high sequence homology to Bat SARS-like coronavirus. No other high sequence homology was observed for the forward primer sequence. 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 Real-Time RT-PCR Test, a multiplex assay (Orflab and S), designed for the specific detection of SARS-CoV-2, showed no significant combined homologies with human genome or human microflora that would predict potential false positive rRT-PCR results. Only the Orflab assay demonstrated significant homology among all assay components for bat SARS-like coronaviruses. However, the risk of false positive results due to potential reactivity with bat SARS coronaviruses not known to currently infect humans is low.

Endogenous and Exogenous Interference Studies

The following substances were tested for inhibitory effects on RT-PCR using respiratory specimens positive for RNA viruses processed with the Biomeme M1 Sample Prep for RNA2.0. No interference with any of the substances was observed.

Table 14: List of Endogenous/Exogenous Substances Tested

Interfering Substance	Active Ingredient	Concentration Tested
Blood	Human blood	2% (v/v)
Throat lozenges	Benzocaine, menthol	0.15 mg/mL
Saline Nasal Spray	Sodium chloride	0.026 mg/mL
No Drip Nasal Mist	Oxymetazoline hydrochloride (0.05%)	10% (v/v)
Extra Strength Nose Drops	Phenylephrine hydrochloride (1%)	10% (v/v)
Saline Nasal Spray with Aloe	Sodium chloride (0.65%)	10% (v/v)
Zicam, Nasal Swab Gel	Luffa operculata, Galphimia glauca, histaminum hydrochloricum, sulfur	10% (w/v)
Flonase/Nasal corticosteroid	Fluticasone propionate (50mcg/ spray)	10% (v/v)

A separate study was conducted to test the effect of mucin on the SARS-CoV-2 Real-Time RT-PCR Test. In this study, three replicates of VTM containing SARS-CoV-2 RNA at 3X the LoD with or without 2% mucin were extracted using the Biomeme M1 Sample Prep Cartridge for RNA2.0. All replicates were positive for SARS-CoV-2 with the Biomeme SARS-CoV-2 Real-Time RT-PCR Test.

Clinical Evaluation

A total of 98 positive and 57 negative nasopharyngeal swab samples previously tested with an FDA EUA RT-PCR assay were tested with the Biomeme SARS-CoV-2 Real-Time RT-PCR Test. The results are presented in Table 15 below.

Table 15: Overall Performance Estimate Based On Single Positive Target Algorithm

		EUAAuthorized Comparator Method	
		Positive	Negative
Biomeme	Positive	95	1†
	Negative	3*	56

†Sample was retested by another comparator with results negative

*One sample was retested by another comparator with results positive

PPA: 96.9% (95% CI: 91.3% to 99.4%)

NPA: 98.3% (95% CI: 90.6% to 100%)

Contrived Clinical Samples:

The performance of the Biomeme SARS-CoV-2 Real-Time RT-PCR Test was evaluated using contrived clinical samples. A total of 60 contrived positive samples were prepared for testing by spiking individual negative clinical nasopharyngeal swab (NP) specimen matrix with known concentrations of genomic RNA from SARS-Related Coronavirus 2, Isolate USA-WSA1/2020 (BEI NR-52285, Lot: 70033320, Mfg Date: 11FEB2020). Prior to the addition of SARS-CoV-2 RNA, sample matrix was pre-mixed with Biomeme Lysis Buffer (BLB) from the Biomeme MI Sample Prep Cartridge for RNA2.0 nucleic acid extraction kit and the RPC (see Table 16).

Of the 60 contrived positive samples, 40 contained SARS-CoV-2 RNA at 1x the LoD (same samples as those in the LoD confirmation study), 10 contained SARS-CoV-2 RNA at 2x the LoD, and the remaining 10 contained SARS-CoV-2 RNA between 3x and 5x the LoD. An additional 30 individual negative nasopharyngeal swab specimens were also included in the study. RNA from each sample was manually extracted using the Biomeme MI Sample Prep Cartridge for RNA2.0 with a total elution volume of 850 µL. The results of the Biomeme SARS-CoV-2 Real-Time RT-PCR Test are shown in Table 16 below.

Table 16: Clinical Evaluation with Contrived Nasopharyngeal Swab Specimens

RNA Concentration (relative to LoD)	RNA Concentration (GE/µl)	Number of Positives	Mean Ct	
			Orflab	S
1x	1.8	39/40 ^a	34.75	33.51
2x	3.6	10/10	33.19	31.14
3x	5.4	5/5	33.46	32.36
4x	7.2	3/3	30.96	29.71
5x	9	2/2	31.24	30.05
Negative	0	0/30	NA	NA

^aSamples prepared at 1XLoD are the same as those tested in the LoD confirmation study.

PPA at 1-2x LoD = 98.0% (95% CI: 89.4% to 100%)

PPA at 3-5x LoD = 100% (95% CI: 69.2 to 100%)

NPA = 100% (95% CI: 88.4 to 100%)

Appendix 1: Loading SARS-CoV-2 Go-Plates for Bio-Rad CFX Maestro 96-well plate instruments

1. Open the contents of a Biomeme SARS-CoV-2 Go-Plate (REF#[3000562](#)).
 - If not loading the entire 96-well Go-Plate, cut the desired number of wells away from the Go-Plate using sterile scissors.
 - Insert the unused portion of the Go-Plate back into the foil pouch.
 - Remove any excess air from the pouch and reseal the ziplock.
 - Ensure the ziplock is fully sealed to maximize shelf-life of the unused reactions.
2. Place the wells you into to use into a 96-well plate tray for setup of your PCR run.
3. Working on one row at a time, carefully peel away the foil from the wells.
4. Attach a pipette tip to a 20µLfixed volume pipette (REF# [3000011](#)) or use your own 20µL pipette.
5. Unscrew the cap of your first purified sample and transfer 20µLof the extracted RNAinto the first reaction well.

Note: The strip connections between the tubes of your Go-Plate will face the back of the thermocycler once inserted. When transferring your extracted RNAinto 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-Plate Well, moving from a left to right orientation.

6. Pipette up and down 3-5 times to mix your PCRreaction. When mixing your samples try to avoid introducing bubbles.

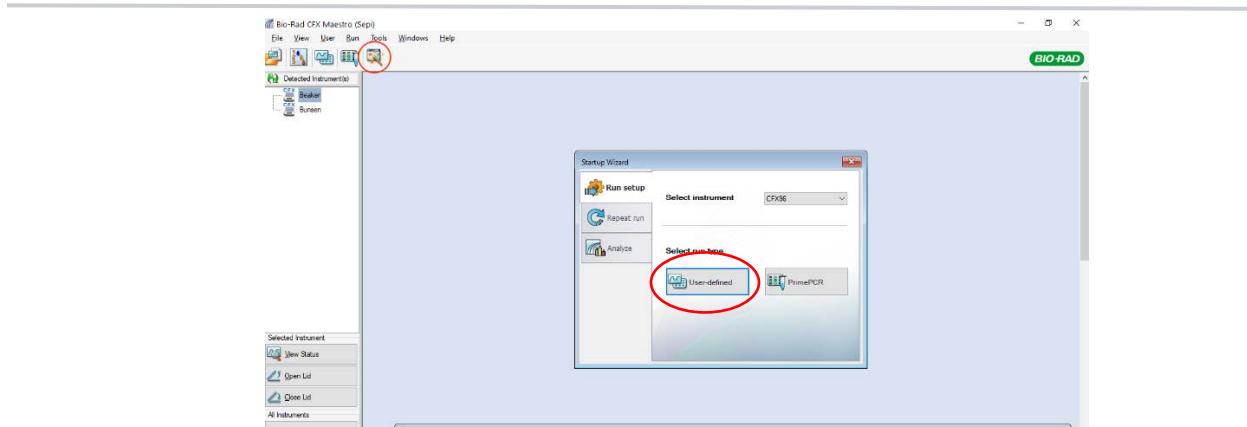
Note: If bubbles have been introduced, remove them from the lower portion of the PCR tubes by gently tapping them against your work surface before sealing. Bubbles may remain at the top of the tube, but bubbles at the bottom are not acceptable.

7. Discard your pipette tip and repeat this process for the remaining reaction wells. Once all reaction wells are filled, apply an optical adhesive sealer. Firmly press down with a plastic sealer while moving around the outer edges of the top of the to ensure a good seal. Cut away any excess adhesive when less than 96 wells are used.

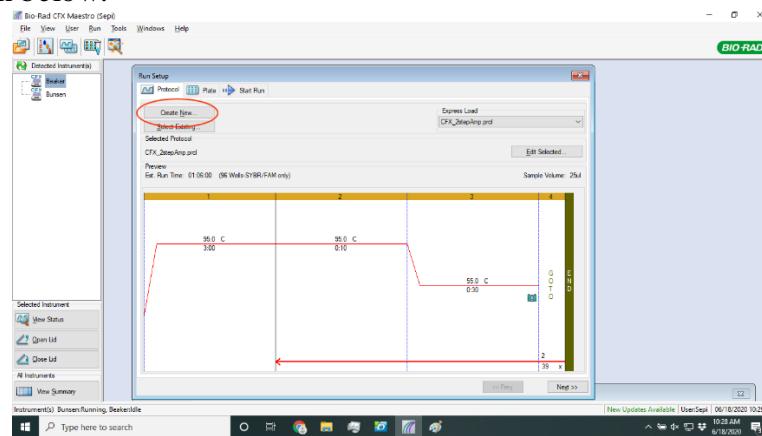
Note: You can use a plate spinner to make sure your PCRreactions are at the bottom of the plate.

Loading the Bio-Rad CFX96:

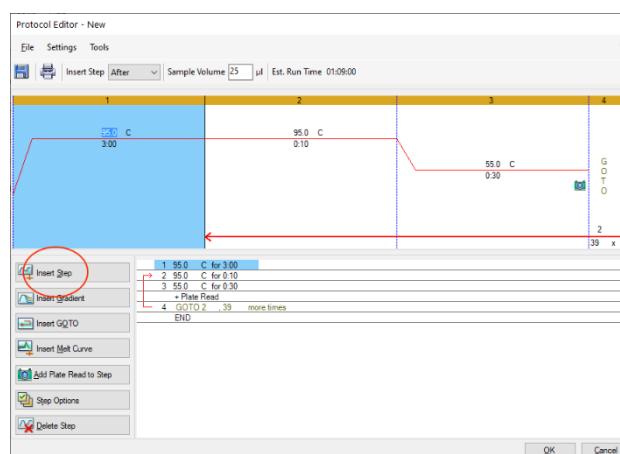
1. Turn on Bio-Rad CFX96 instrument
2. Open the Bio-Rad CFXMaestro 1.1 version 4.1.2433.1219 (REF 1855195)
3. Select “Start Up Wizard” shown below:



4. Select “User-defined” tab. This will take you to Run set up page. Then click on “Create New” as shown below:

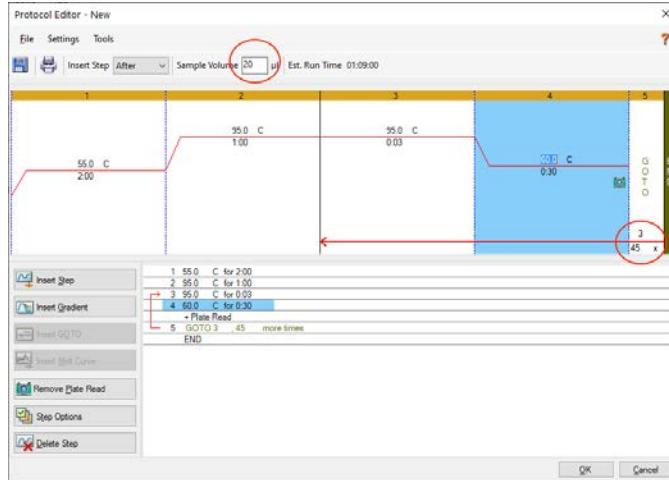


5. On the protocol editor page, click on “Insert Step” to add the RT step to the protocol

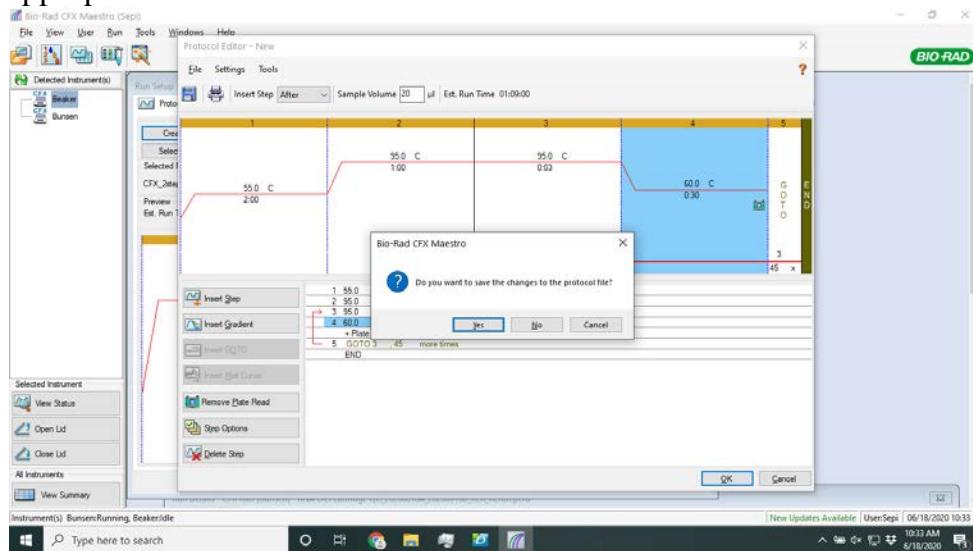


6. Set up your PCR thermocycling parameters as follows:
 - a. Step 1 (RT): 55 C for 2 minutes

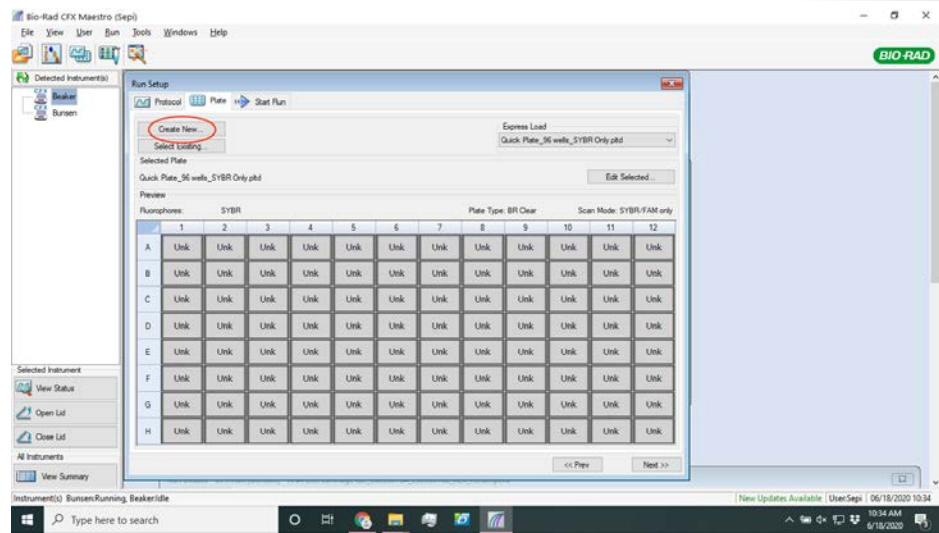
- b. Step 2 (Initial Denature): 95°C for 1 minute
 - c. Step 3 (Denature): 95°C for 3 seconds
 - d. Step 4 (Anneal): 60°C for 30 seconds
7. Change the cycles from a default of 39X to 45X
8. Change the reaction volume shown below from default 25 uL to 20 uL



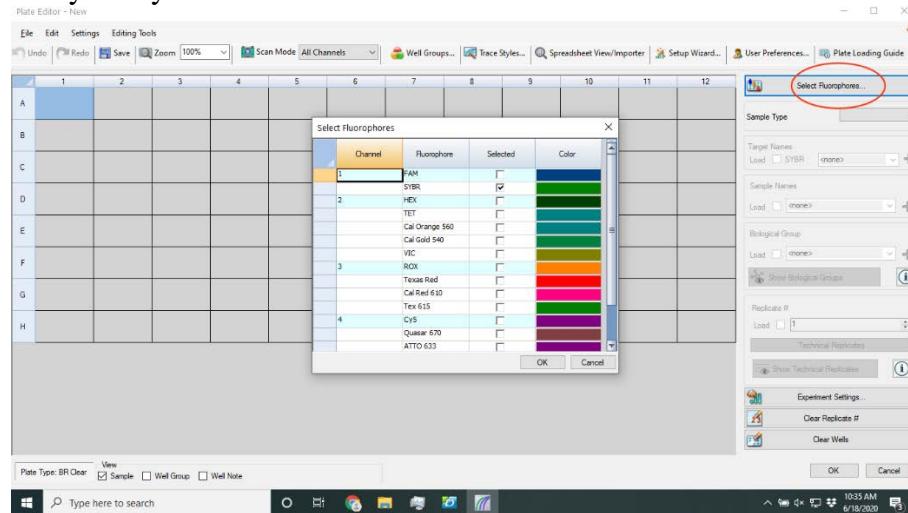
9. Press “Ok” once you are finished setting up the thermocycling parameters. The program will now ask whether you want to save your protocol file. Click on “Yes” and save your file where appropriate.



10. Once finished press “Next”. This will take you plate set up screen. Click on “Create New”. Now you will set up your plate layout.

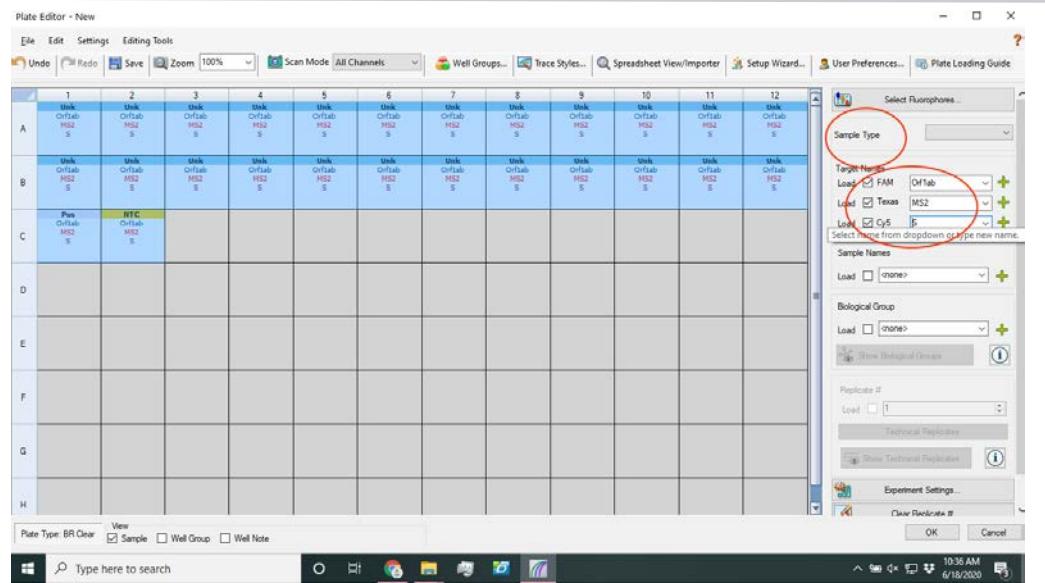


11. To start click on “Select Fluorophores”. From the list you want to select ‘FAM, Texas Red, and Cy5’ as your dyes.

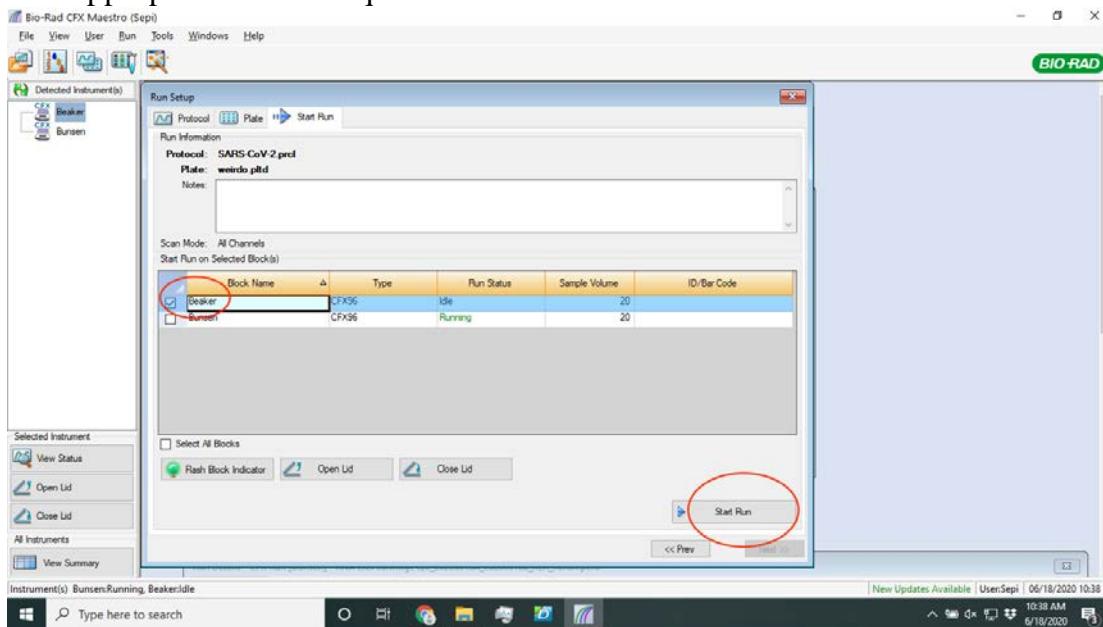


12. Depending on how you have loaded your plate, you can select “Sample Type” and give either “Unknown”, “Positive control”, or “NTC” tags to each well. For example, in the image below, 24 unknown samples were selected with one positive control and one NTC.
13. Name each target by typing the target name into each of the appropriate dyes:

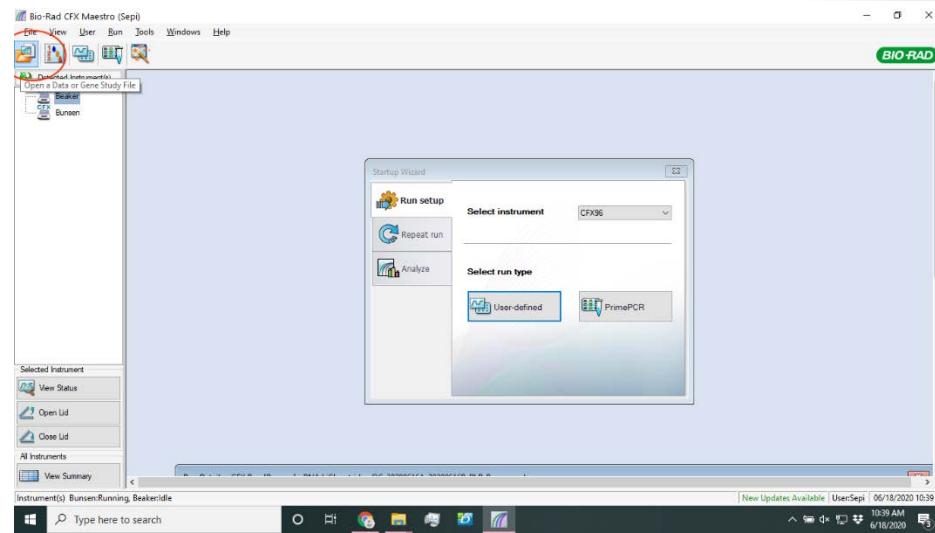
- FAM: “Orflab”
- Texas Red: “MS2” or “RPC”
- Cy5: “S”



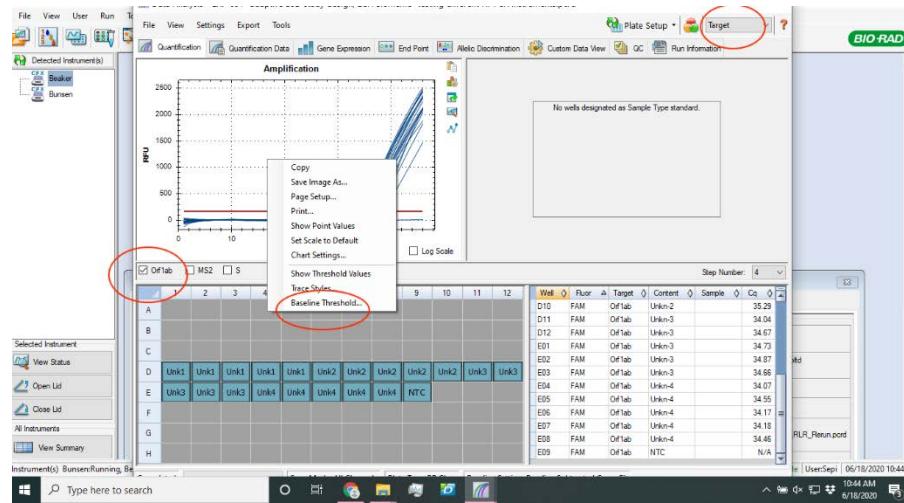
14. The software will ask you whether you want to save the plate setup. Click on “Yes” and save your plate file where appropriate.
15. Press on next to go to the “Start Run” page. If multiple Bio-Rad CFX96 instruments are connected to the computer, select the appropriate one. Click on “Start Run”. The software will ask you again to save your data file. Click on “Yes” and save your data file where appropriate with a unique name.



16. Once the run is finished, the result will pop up automatically on the screen. If it does not, then you can click on the “Open a Data or Gene Study File” icon shown below and open up your data file with the unique ID to view the results.

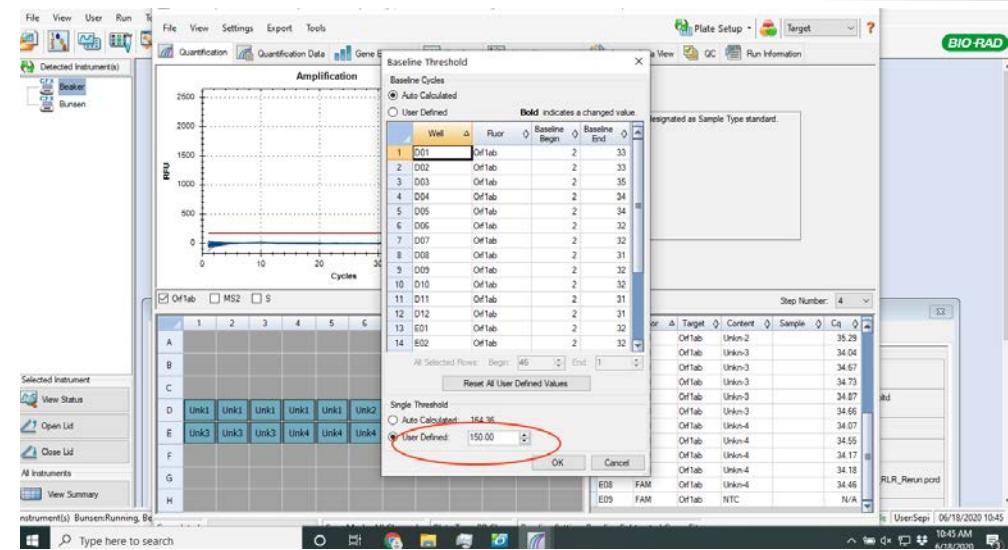


17. From the results screen, pick “Target” from the tab on the right-hand corner of the screen shown below. Select only one target, for example Orflab as shown. Right click on the screen and select “Baseline Threshold”.

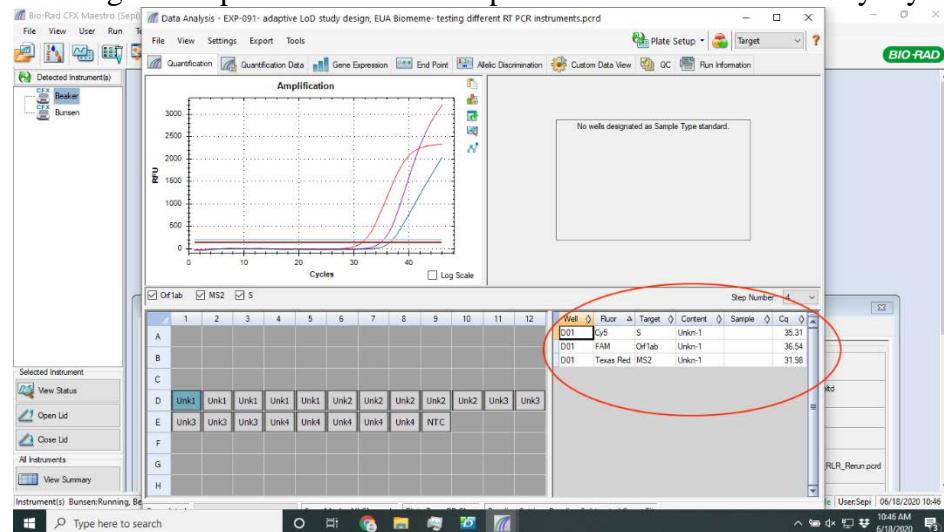


18. On the baseline threshold page, click on “User Defined” and change the value to a specific number for each target:

- Orflab = 150
- S= 200
- RPC or MS2 = 200



19. Once the thresholds are set for each target, you can begin analyzing your sample by clicking on each well. On the right side of the page (shown below), you can see the Cq values for each give sample. Refer to the interpretation result table to analyze your data.



Appendix 2: Loading SARS-CoV-2 Go-Plates for Applied Biosystems Quant Studio 5 96-well plate instruments

1. Open the contents of a Biomeme SARS-CoV-2 Go-Plate (REF#[3000562](#)).
 - If not loading the entire 96-well Go-Plate, cut the desired number of wells away from the Go-Plate using sterile scissors.
 - Insert the unused portion of the Go-Plate back into the foil pouch.
 - Remove any excess air from the pouch and reseal the ziplock.
 - Ensure the ziplock is fully sealed to maximize shelf-life of the unused reactions.
2. Place the wells you want to use into a 96-well plate tray for setup of your PCR run.
3. Working on one row at a time, carefully peel away the foil from the wells.
4. Attach a pipette tip to a 20µL fixed volume pipette (REF# 3000011) or use your own 20 uL pipette
5. Unscrew the cap of your first purified sample and transfer 20µL of the extracted RNA into the first reaction well.

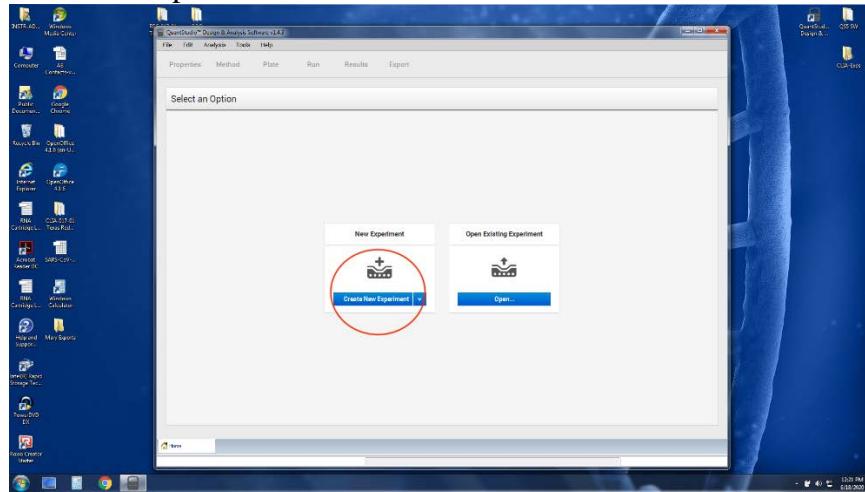
Note: The strip connections between the tubes of your Go-Plate will face the back of the thermocycler once inserted. When transferring your extracted RNA into the different reaction wells, replicate this orientation to ensure accurate result interpretation (e.g. transfer sample 1 into the far-left reaction well of your first Go-Plate Well, moving from a left to right orientation).

6. Pipette up and down 3-5 times to mix your PCR reaction. 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 them against your work surface before sealing. Bubbles may remain at the top of the tube, but bubbles at the bottom are not acceptable.
7. Discard your pipette tip and repeat this process for the remaining reaction wells. Once all reaction wells are filled, apply an optical adhesive sealer. Firmly press down with a plastic sealer while moving around the outer edges of the top of the to ensure a good seal. Cut away any excess adhesive when less than 96 wells are used.
8. Turn on the QuantStudio5. Once the instrument is booted up, press the “open drawer” button on the touch screen of the instrument
9. Carefully load your reaction wells into the blue plate adapter provided with the QuantStudio5. Close the adapter.
10. Load the adapter containing your reaction wells into the 96 well block of the QuantStudio5.
11. Close the drawer by pressing on the “open drawer” button.

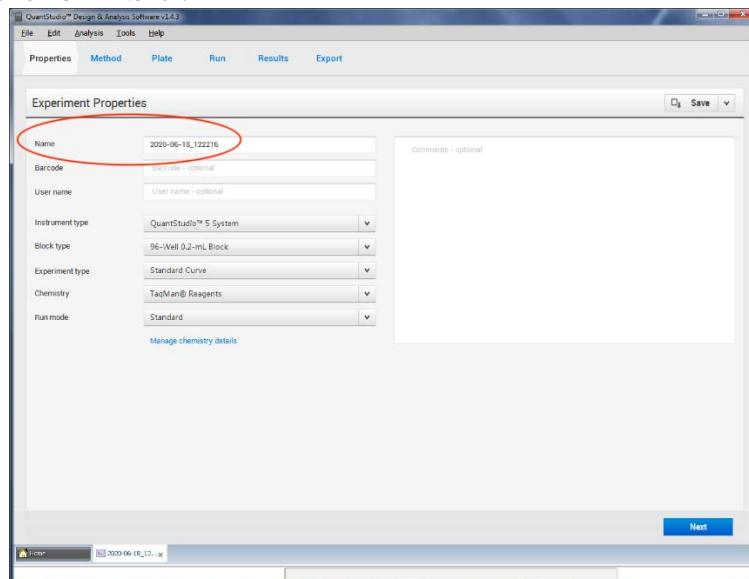
Note: You can use a plate spinner to make sure your PCR reactions are at the bottom of the plate.

Loading the QuantStudio5:

1. Open the QuantStudio™ Design and Analysis Software
2. Select “Create New Experiment” shown below:

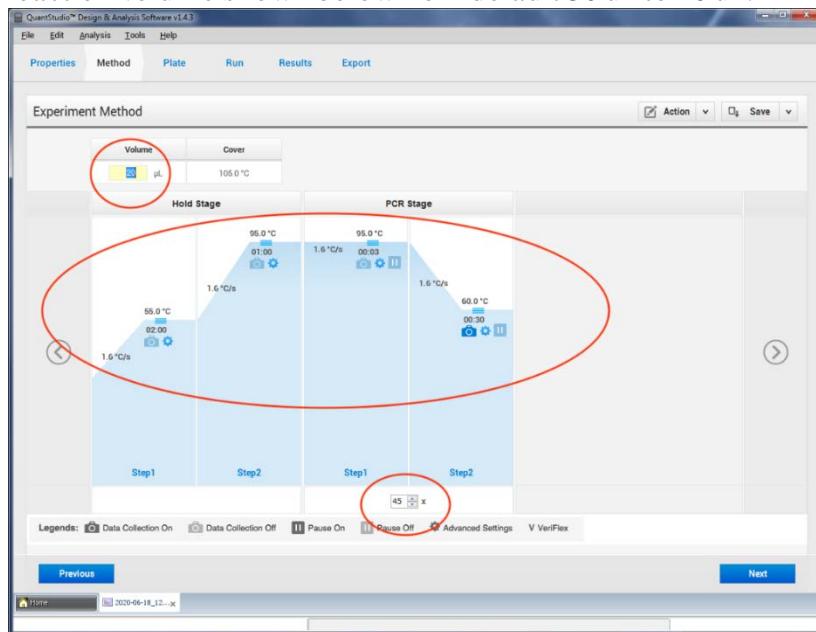


3. Change the run name if needed as shown in the image below. Once you have entered a unique name, click on “Next”.

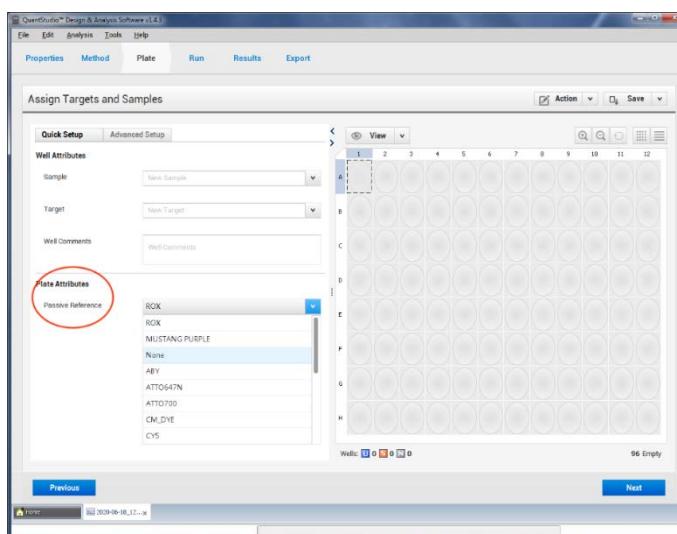


4. On the “method” tab make sure that PCR thermocycling parameters are set as follows:
 - a. Step 1 (RT): 55 C for 2 minutes

- b. Step 2 (Initial Denature): 95 C for 1 minute
 - c. Step 3 (Denature): 95 C for 3 seconds
 - d. Step 4 (Anneal): 60 C for 30 seconds
5. Change the cycles to 45Xcycles
6. Change the reaction volume shown below from default 50 uLto 20 uL



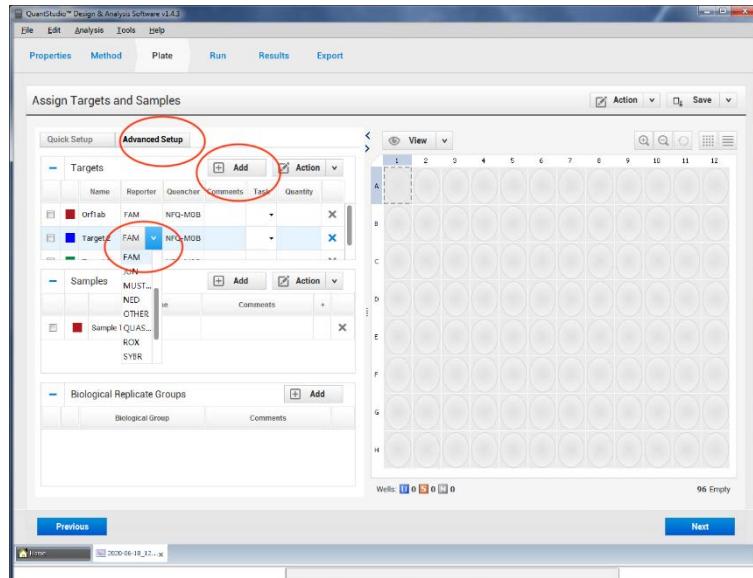
7. Press next once you are finished setting up the thermocycling parameters. In the “Plate” tab, click on the drop down on “Passive reference” and change the default from “ROX” to “None”.



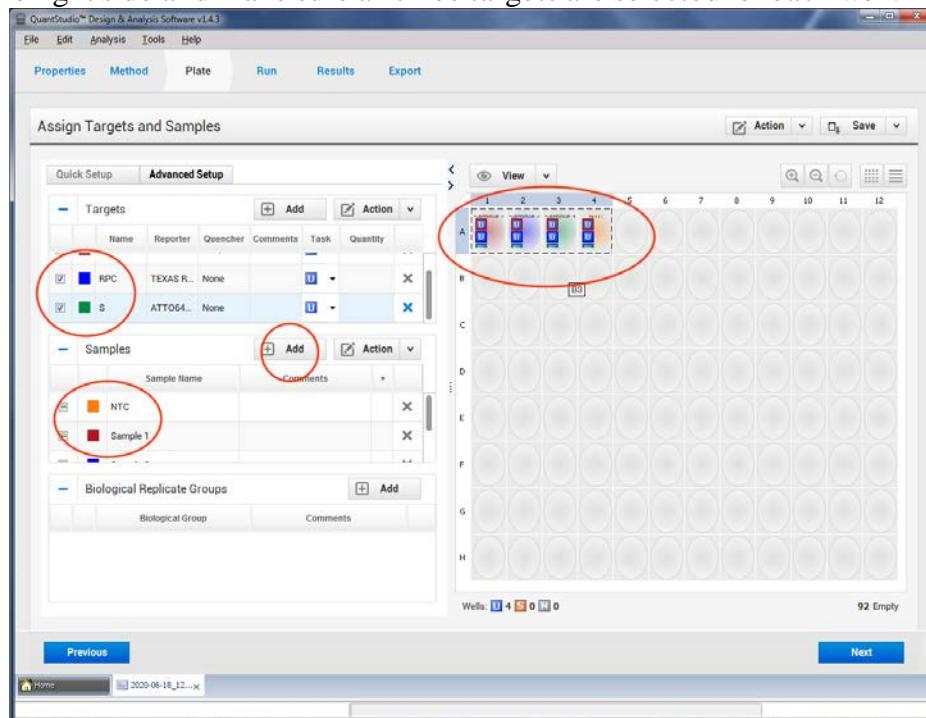
8. In the plate tab, click on “Advanced setup”. In that page, click on the “Add” button as shown below and add 2 other targets (total of 3 targets). Change the name of the target and pick appropriate reporter dye for each target:
- FAM: Orflab

- b. Texas RedX RPC
- c. ATTO647N: S

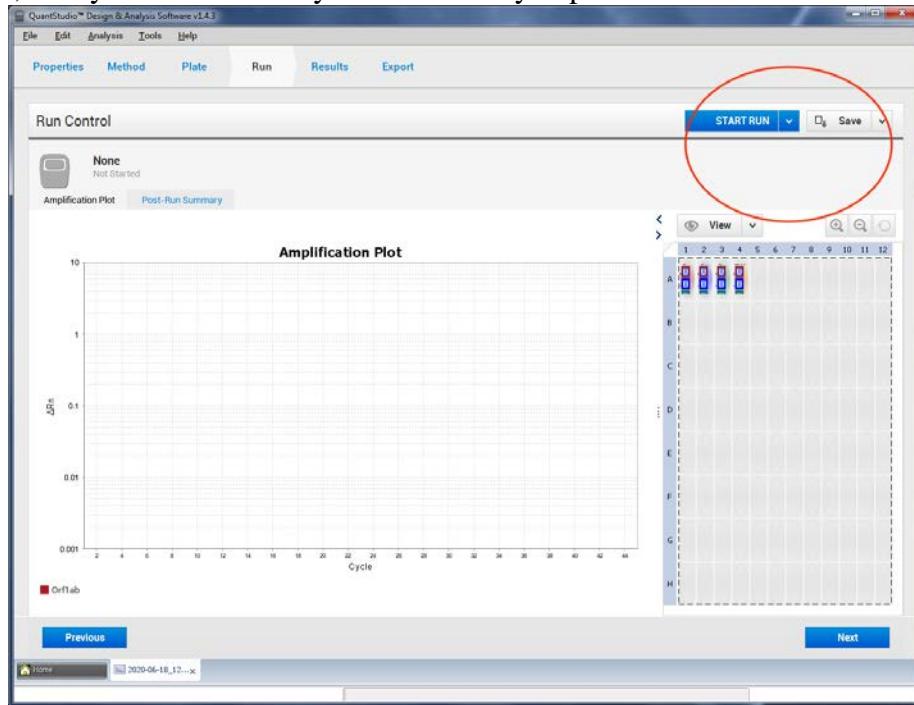
Note: Make sure that your instrument is calibrated with specified dyes (FAM, ATTO647N and TexasRedX) before use.



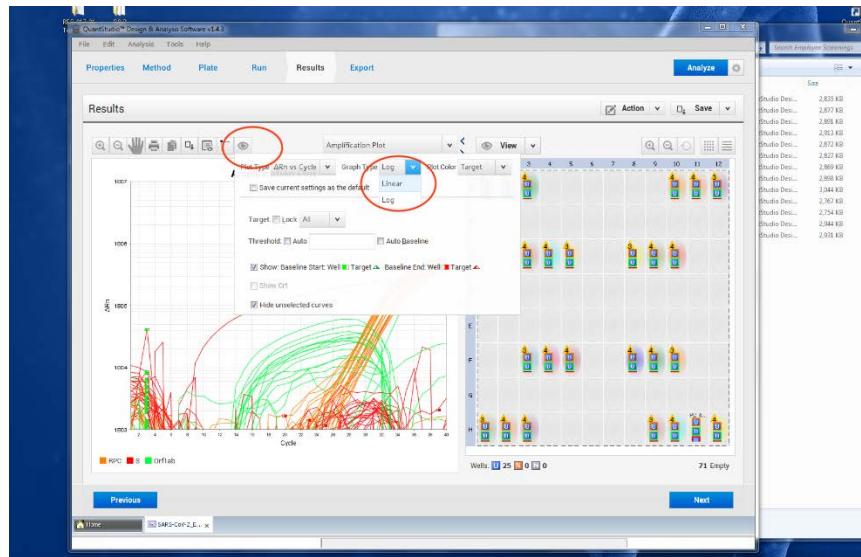
9. Click on the “Add button” shown below to add number of samples you are running based on your plate layout. You can change the sample name as preferred. Click on each well on the right side and make sure all three targets are selected for each well.



10. Click next, now you want to save your run where you prefer and then click on “Start Run”.

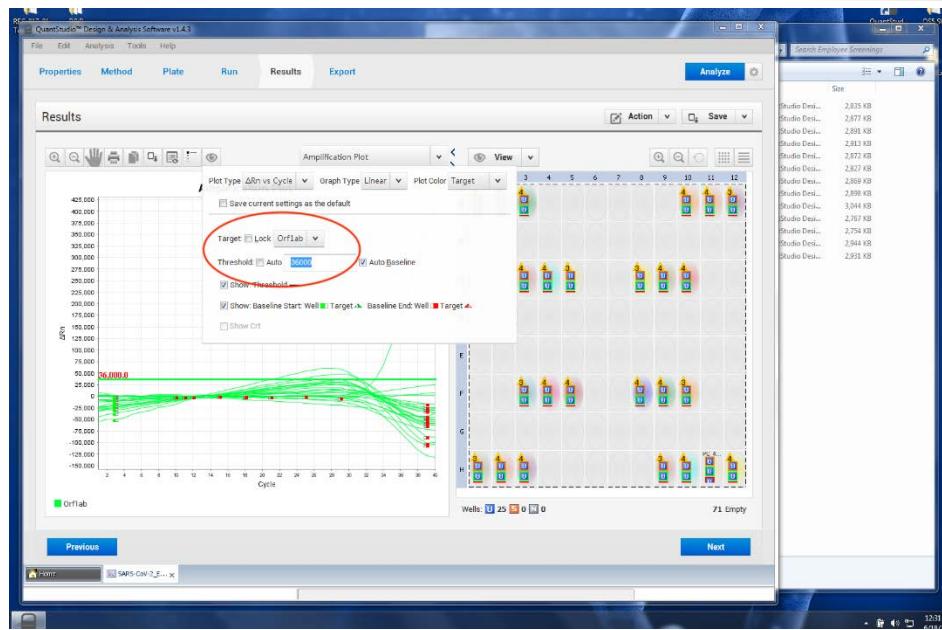


11. Once your run is finished and on “Results” tab, click on the “eye” icon and from the drop-down show in the image, change the graph type from “Log” to “Linear”.

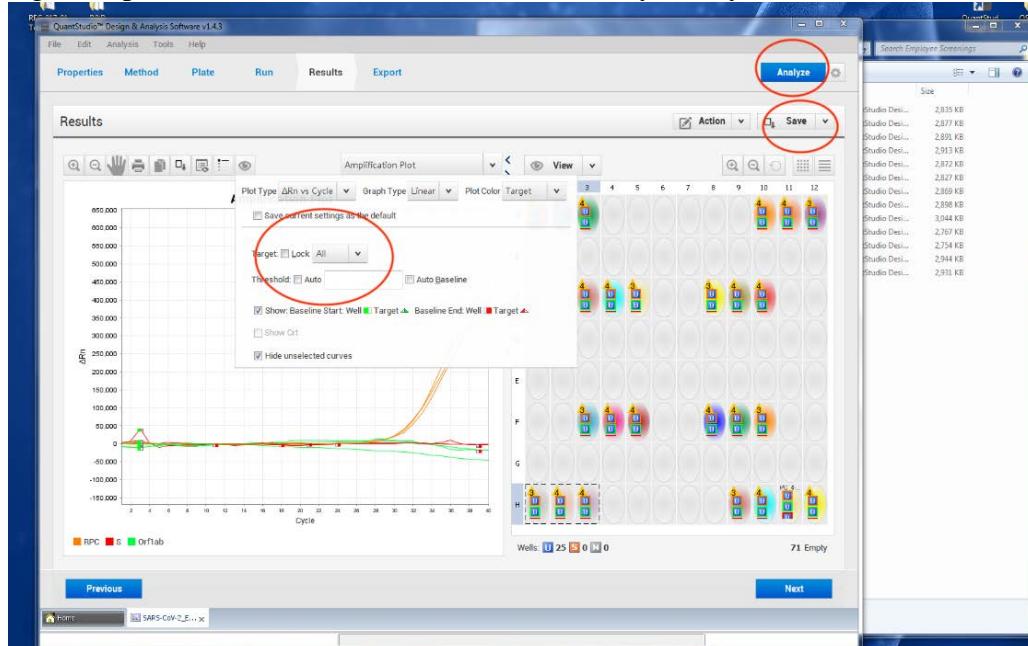


12. Next, from the “Target” drop down, pick each target one by one and change the threshold from auto to the following:

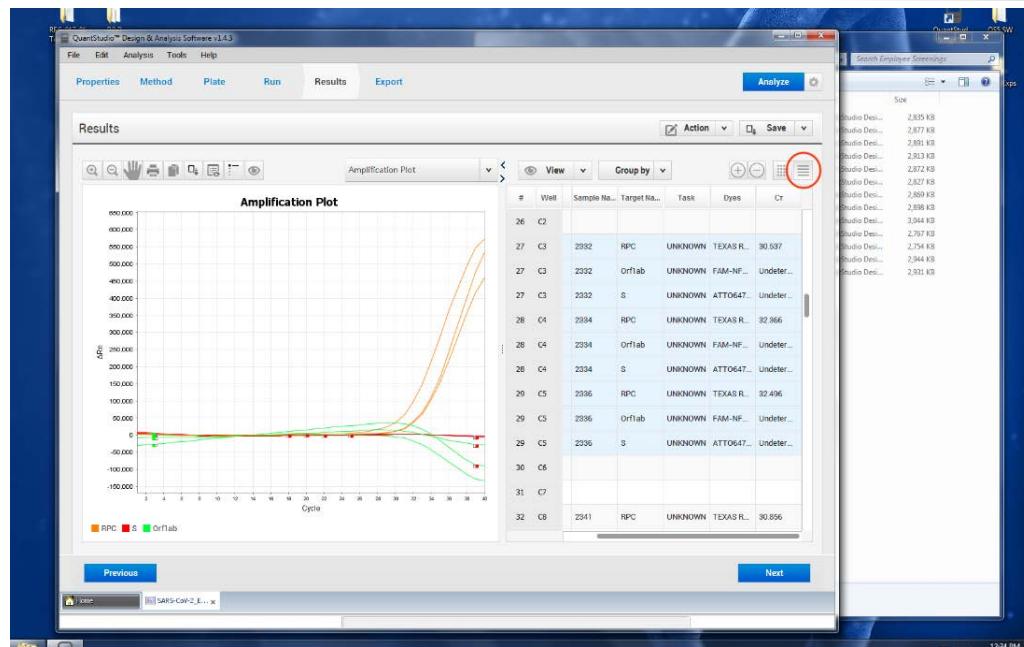
- a. Orflab: 36000
- b. S: 38000
- c. RPC: 56000



- Once you have set the threshold for all the targets individually, click on “All” from the target drop down. Then click on “Save” followed by “Analyze” as shown below.



- As shown in the image below, click on the tab and you can see the CT values given for each sample and target. Refer to interpretation result table to analyze your data.



Technical Support

Biomeme, Inc.
1015 Chestnut Street, Suite 1401
Philadelphia, PA19107

Phone: 267-930-7707
FAX: 855-940-0157
Email: support@biomeme.com

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.

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Revision	Date	Description
1.0	April 7, 2020	New document
1.1	May 15, 2020	<p>Updated Intended Use.</p> <p>Updated Tables 1, 2, 3, 4, 6.</p> <p>Added Tables 7, 8, 10.</p> <p>Updated Interpreting Results section.</p> <p>Updated NTC and PC instructions.</p> <p>Added Biomeme Go OS compatibility statement.</p> <p>Changed 'General Guidelines' section to be more specific.</p> <p>Added note to 'Add RNAProcess Control (RPC)' section for incubating cartridges in bulk.</p> <p>Updated 'RNAExtraction Using MI Sample Prep Cartridge' section.</p> <p>Added statement regarding FDA's independent review of validation.</p> <p>Added storage recommendation to 'Prepare RNAProcess Control' section.</p> <p>Updated 'Positive Control Material' section.</p> <p>Added Additional Clinical Performance Data.</p> <p>In 'Placing Go-Strips into Franklin™Thermocycler' section, split tables into 2 for running PCR w/ and w/o External Controls.</p> <p>Added additional screenshots to 'Patient Sample Pass/Fail Criteria' section.</p> <p>Grammatical/clarity updates.</p> <p>Updated Contents tables.</p>
1.2	June 10, 2020	<p>Updated reference to BEI genomic material.</p> <p>Updated LoD section</p> <p>Removed limitations from Intended Use</p> <p>Removed Bulk Vials alternative form factor</p> <p>Summarized Table 7</p> <p>Included Comparator Method information</p> <p>Updated Table 4, Table 1, Table 2</p>
1.3	June 19, 2020	<p>Removed Table 7 as it was a duplicate of Table 5</p> <p>Removed Sample Collection Materials and added note</p> <p>Added note about use of alternative thermocyclers</p> <p>Clarified Clinical and LoD Studies tables</p> <p>Added Appendix 1 and Appendix 2</p> <p>Cleaned up text for clarity</p>
1.4	June 19, 2020	<p>Updated Sample Storage information</p> <p>Removed requirement for procedures to be performed in BSL2 laboratory</p> <p>Reorganized placement of Table 6, Table 12, Table 13, and Table 14</p> <p>Added description of Adaptive LoD Study of alternative thermocyclers</p> <p>Corrected positivity rate of LoD study</p>

1.5	July 20, 2020	<p>Removed Swab Collection section</p> <p>Removed shaking VTMstep prior to adding sample as it is only required for NP swab sample types</p> <p>Removed limitations statement mentioning use in CLIA labs as it is a duplicate</p> <p>Reorganized Clinical Evaluation section to lead with Clinical Data and follow with Contrived Specimen data</p> <p>Combined Clinical Evaluation data into one table (Table 5)</p> <p>Added detail about use of NP swabs for clinical samples</p> <p>Updated LoD procedure for clarity</p> <p>Added summary of equivalence between carrier/no carrier and BD/Biomeme VTM</p>
1.6	July 21, 2020	Updated Table 5

Franklin™ Real-Time PCR Thermocycler w/ Biomeme Go App (EUA)

For IVD Use ONLY. For Emergency Use Authorization ONLY.

This product has not been FDA cleared or approved; the product has been authorized by FDA for use with the Biomeme SARS-CoV-2 Real-Time RT-PCR Test under an Emergency Use Authorization (EUA) for use by laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

This product has been authorized only for use with the Biomeme SARS-CoV-2 Real-Time RT-PCR Test for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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Brief Overview

Biomeme Franklin™ is a portable thermocycler for real-time PCR analysis with producing results in under an hour. The mobile thermocycler enables multiplex real-time detection of up to 27 targets from 1 sample or test 9 samples for up to 3 targets each. Each unit is just under 3 lbs, hand-held, and battery-operated for maximum portability enabling a full day's work out in the field on a single charge.

Biomeme Go is a free and intuitive smartphone mobile app that pairs wirelessly with Franklin™ to easily run, monitor, and analyze your PCR experiments.

Thermocycler Technical Specifications

SPECIFICATION	VALUE
Sample Capacity	9 Wells
Reaction Volume per Well	20µL
Total Channels	3
Franklin™ three9 Fluorophores	FAM / SYBR (Green), TexasRedX (Amber), ATTO647N (Red)
System Control & Data Transfer	Wireless (BLE)
Integrated Barcode Scanner	Yes
Max Samples per Run	9
Max PCR Targets per Run	27
Weight	1.20 kg / 2.65 lb
Operating Ambient Temperature	4 - 40°C / 39 - 104°F

Operating Humidity Limit	0 - 99%
Operating Altitude Limit	3,048 m / 10,000 ft
Wall Power (VAC)	100 - 240V
Voltage	19V
Full Load Current	3.3A
Internal Battery	5 hrs
Quantitative	Yes
IP Rating	IP30
Indoor/Outdoor?	Indoor or Outdoor in a Covered Area
Pollution Degree	2
Degree of Ingress Protection	Keep 5 cm Clearance Around the Thermocycler for Proper Performance

Thermocycler Button Layout

There are a total of 4 buttons located on the top of your Franklin™ thermocycler:



Logging In and Out of Biomeme Go

To Log In (requires internet connection)

1. Open the Biomeme Go mobile app on your smartphone by tapping the app icon on your phone's home screen.
2. Enter your email address and password (both are case sensitive).
3. Tap the Login button.
4. If you're part of multiple teams (Enterprise Users Only), select which team to log in under (you can toggle between teams once logged in).

Note: If you have forgotten your password, click "Forgot Password" or email support@biomeme.com. If you are traveling to a remote location to perform PCR and will not have internet access while there, you must log in before your connection is lost.

To Log Out

1. Open the User menu by clicking the user icon  in the top left corner.
2. Select Logout.

Loading Pure Sample into Go-Strips

Attention: Contents of the Go-Strip may shift during transport. When starting to work with your test, 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 pouch. 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 or prepare your own 20µL pipette.

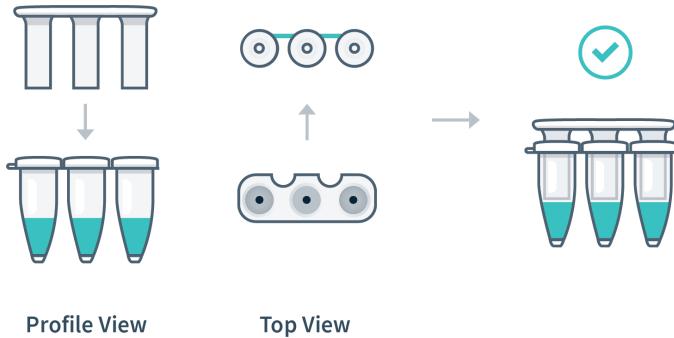
Note: The strip connections between the tubes of your Go-Strip will face the back of the thermocycler once inserted. When resuspending your reactions and transferring your extracted RNA into the different reaction wells, replicate this orientation to ensure accurate result interpretation (e.g. transfer 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:

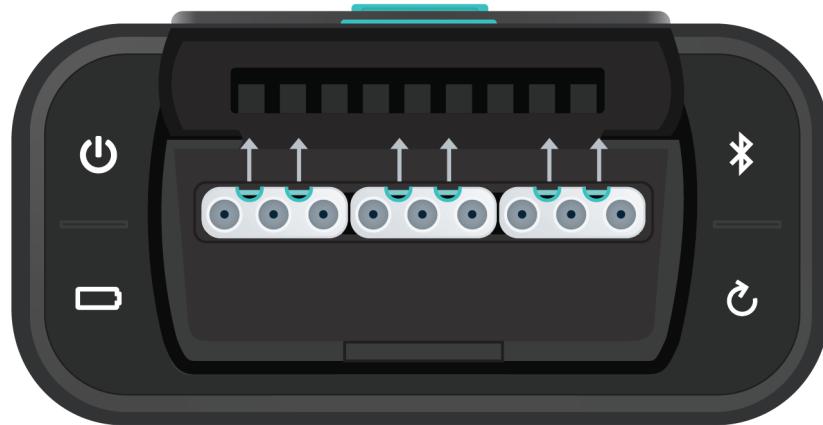


7. The void filling caps may feel slightly loose, this is normal. The thermocycler lid will secure the caps into place when closed, sealing each PCR reaction.
DO NOT attempt to push the cap down.

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 your thermocycler by pressing the latch on top of the unit.
2. Place your Go-Strips, with the void filling 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.



- Close the thermocycler lid securely and navigate to the Biomeme Go mobile application on your smartphone to begin your testing protocol. For further instructional information, please contact support@biomeme.com.

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

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

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

Go-Strip	Go-Strip 1 (left)			Go-Strip 2 (middle)			Go-Strip 3 (right)		
Well	1	2	3	4	5	6	7	8	9
Samples & Controls	NTC	S2	S3	S4	S5	S6	S7	S8	PC

Note: Transport your Franklin™ thermocycler in its carrying case. Additionally, moving your thermocycler while thermocycling could result in errors. We highly recommend not moving or opening the device while thermocycling to avoid losing your PCR run. After your run has completed, be careful when removing your Go-Strips and void filling caps to avoid liquid splatter and PCR amplicon contamination.

How To Start Your First Run

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. (see "[Logging In and Out](#)").
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.

Note: The first time you scan a QR code, you may be asked to give your QR scanner 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

6. Select the quantity of 3-well Go-Strips to run simultaneously in your thermocycler by adjusting the **+** (add) and **-** (subtract) icons, 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 would like to save your run into. If you haven't yet created a folder, click Add Folder located towards the top right corner to create one.
10. Once you have selected the folder to save your run into, you can optionally change your Run Name, update your GPS Coordinates, and/or add Location tags. If you wish, you can add a note to the run file by selecting the Note icon  in the upper right corner.
11. Tap Confirm to proceed to Run Setup.
12. If you haven't already, **power on your thermocycler** by pressing the Power  button on top of your device and tap Continue back in the Biomeme Go app.
13. If your smartphone is not already connected to your thermocycler via Bluetooth (BLE) or serial, the app will prompt you to connect. **Enable Bluetooth on your thermocycler** by pressing the  Bluetooth button on top of the device.
14. Tap Scan in the app and wait a few seconds for your device to be found.
15. Once the thermocycler is found, select it in order to pair your devices.

Note: The first time you try to scan for devices, you'll 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.

16. You are almost ready to start your run. If you would like to, select [View Load Strips Tutorial](#) located below the [Confirm](#) button to learn more about properly loading your Go-Strips into your thermocycler. If not, tap [Confirm](#) to proceed.
17. Confirm the subsequent tutorial screens to ensure your Go-Strips are loaded properly and close the lid on your thermocycler before starting your run.
18. Tap the [Start Run](#) button to begin your test!

Monitor Your PCR Run in Real Time

- The Biomeme Go app will remain in live view while the test runs. The app will display how many minutes remain in your run, the thermocycler battery percentage, and the cycle number.
- By swiping to the left, you will be able to view real-time data as the test proceeds. You can toggle between Go-Strips by touching the wells you wish to view using the tabs at the top of the screen. You can always swipe to the right to return to the previous screen.
- You can manually stop the run at any time by tapping the [Stop](#) button in the upper right corner. Do note that this will end the run and you will not be able to restart the test. The run data up to that point will then be available in the [Data Management](#) section of the app. Runs intentionally stopped by the user are not considered incomplete runs.

Note: You do not 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 Incomplete Runs, please refer to the "[Recovering & Reattaching Test Data](#)" section.

How To Create a New Project Folder

1. Log into the Biomeme Go app if you haven't done so already (see "[Logging In and Out](#)").
2. Select Data Management from the main dashboard of Biomeme Go.
3. Tap Add Folder.
4. Enter a name for your new folder.
5. Tap the Add Folder button to create and save.

Interpreting Results

For our SARS-CoV-2 test, the recommended cycle cut-off is 40 cycles. Any amplification after cycle 40 should be considered negative. 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.

Interpretation Table

SARS CoV 2 Orf1ab target	SARS CoV 2 S target	RPC	Result	Actions
+ (Cq ≤ 40)	+ (Cq ≤ 40)	±	Positive	Report results to the sender and appropriate public health authorities.
- (Cq > 40)	+ (Cq ≤ 40)	±	Positive	Report results to sender and appropriate public health authorities.
+ (Cq ≤ 40)	- (Cq > 40)	±	Presumptive Positive	<p>Re-extract the sample and run the rRT-PCR again. Report presumptive positive results to sender and appropriate public health authorities.</p> <p>For samples with a repeated presumptive positive result, additional confirmatory testing may be conducted, if it is necessary to differentiate between SARS-CoV-2 and other SARS-like viruses for epidemiological purposes or clinical management.</p>
- (Cq > 40)	- (Cq > 40)	-	Invalid	Re-extract the sample and run the rRT-PCR again. If the same result is obtained as the first run, report as Invalid.
- (Cq > 40)	- (Cq > 40)	+	Negative	Report results to sender.

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.

- When all SARS-CoV-2 targets are negative but the RPC is positive, the result should be considered as valid and negative.

- When all SARS-CoV-2 targets are positive but the RPC is positive or negative, the results should be considered as valid and positive.
- When all SARS-CoV-2 targets and the RPC is negative, the result is invalid. Re-extract the sample and run the rRT-PCR again. If the same result is obtained as the first run, a new specimen should be obtained.
- If only the SARS-CoV-2 S target is positive, and the RPC target is positive or negative, the result for SARS-CoV-2 is positive.
- If only the SARS-CoV-2 Orf1ab target is positive, and the RPC target is positive or negative, the result for SARS-CoV-2 is presumptive positive. A negative SARS-CoV-2 S (Target 1) result and a positive SARS-CoV-2 Orf1ab (Target 2) result is suggestive of:
 - a sample at concentrations near or below the limit of detection of the test,
 - a mutation in the Target 1 target region in the oligo binding sites,
 - infection with some other Sarbecovirus (e.g., SARS-CoV or some other Sarbecovirus previously unknown to infect humans), or
 - other factors.

The sample should be retested. For samples with a repeated presumptive positive result, additional confirmatory testing may be conducted if it is necessary to differentiate between SARS-CoV-2 and other SARS-like viruses for epidemiological purposes or clinical management.

If an NTC is run and the result is positive, then contamination may have occurred. Re-extract all samples within the extraction batch and re-test.

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. Baseline Data

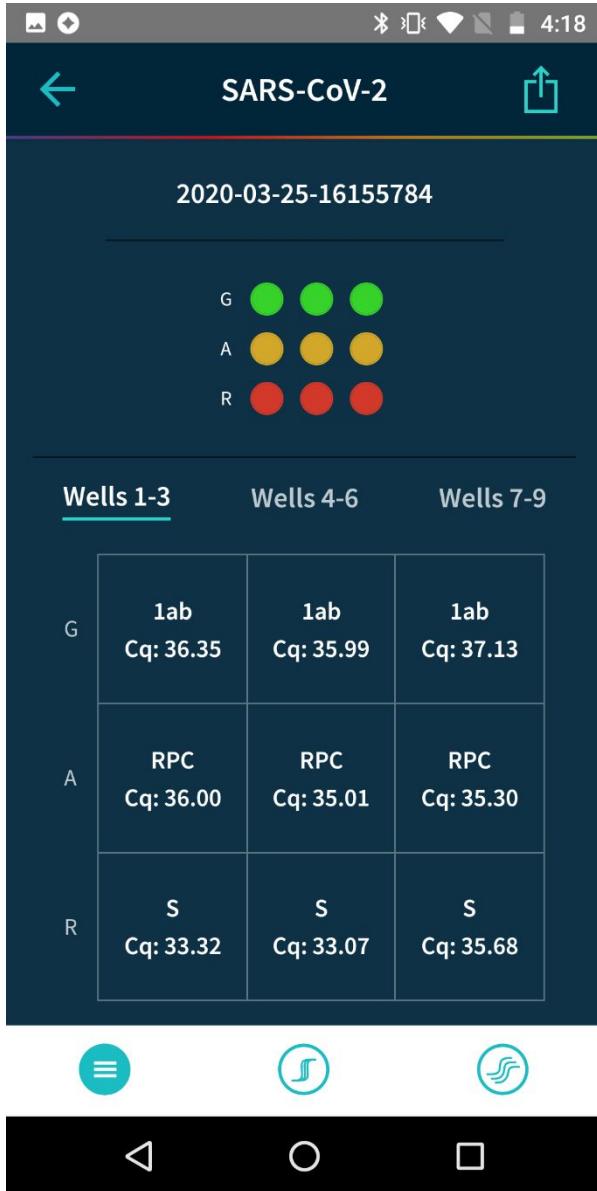
View amplification plots for your baselined data.

6. Raw Data

View amplification plots for your raw data.

Positive Results

All targets detected



Report results to the sender and appropriate public health authorities.

Negative Results

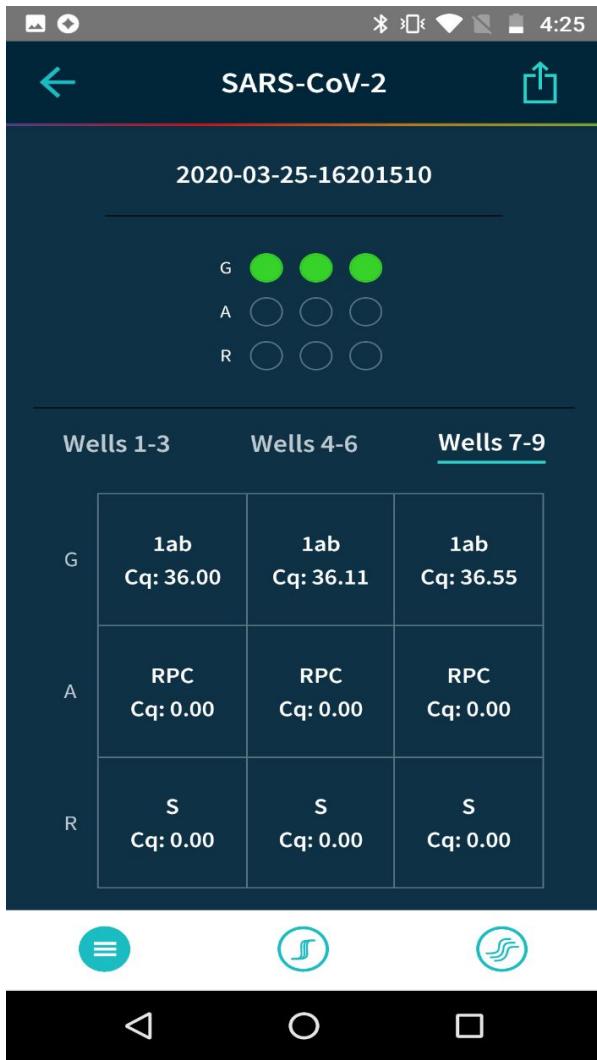
Only RPC detected



Report results to sender.

Presumptive Positive Results

Only Orf1ab target detected

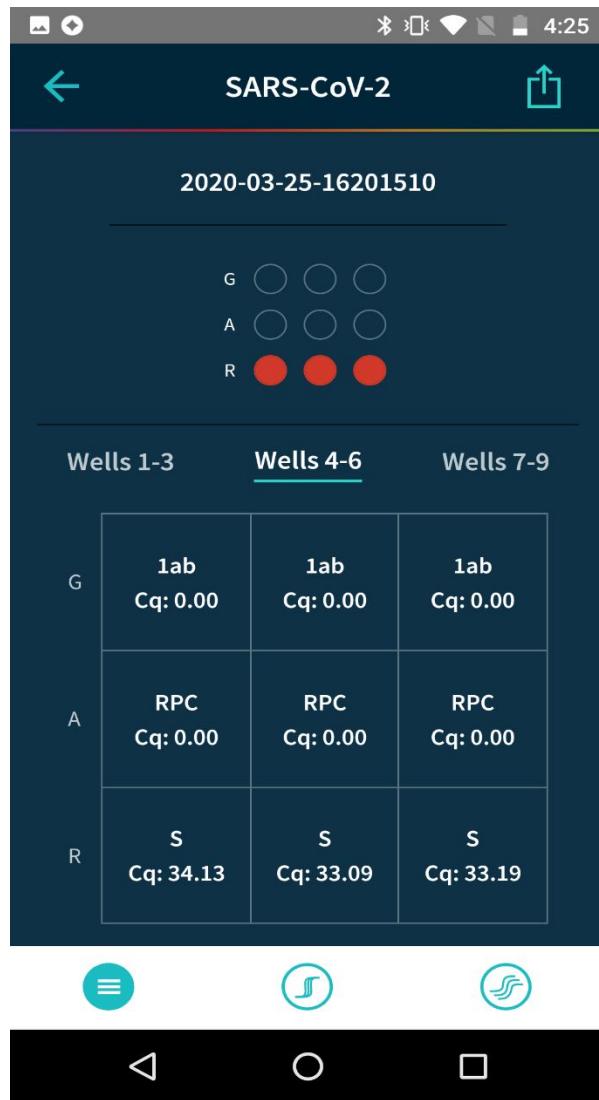


Re-extract the sample and run the rRT-PCR again.
Report presumptive positive results to sender and appropriate public health authorities.

For samples with a repeated presumptive positive result, additional confirmatory testing may be conducted, if it is necessary to differentiate between SARS-CoV-2 and other SARS-like viruses for epidemiological purposes or clinical management.

Positive Results

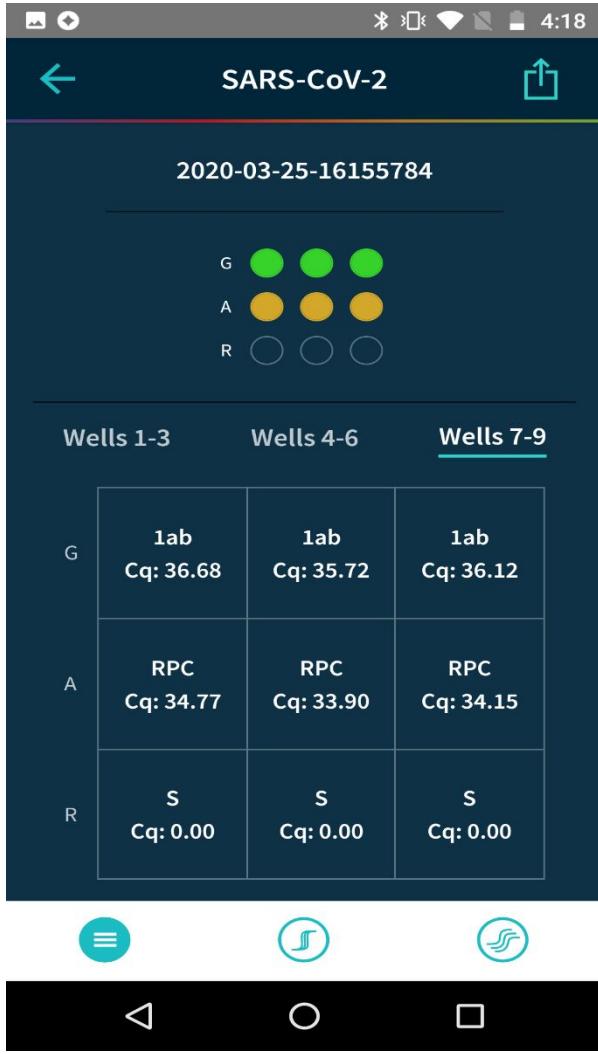
Only S target detected



Report results to the sender and appropriate public health authorities.

Presumptive Positive Results

Orf1ab target & RPC detected
S target not detected

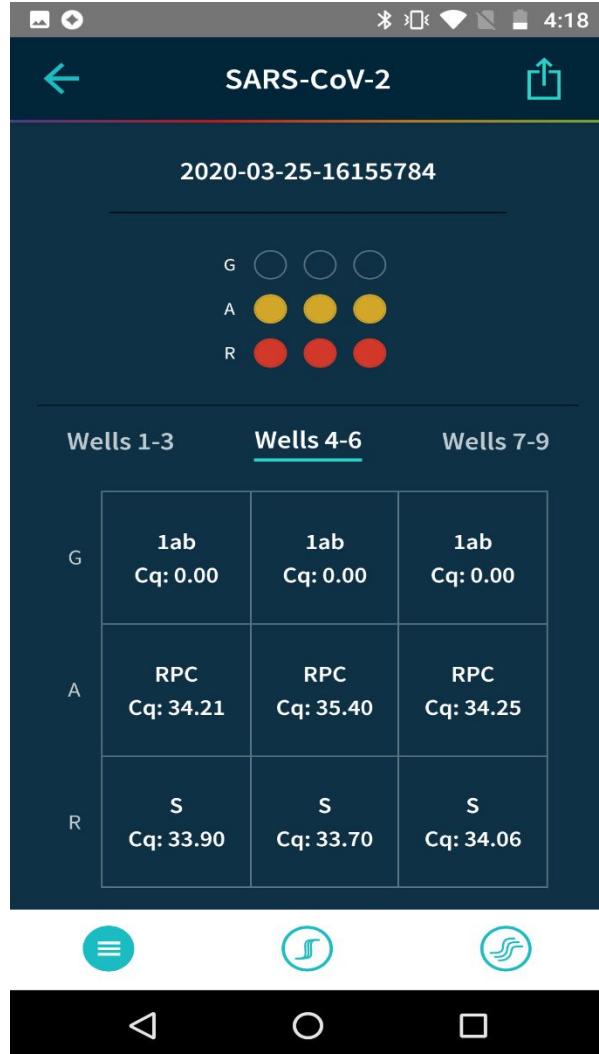


Re-extract the sample and run the rRT-PCR again.
Report presumptive positive results to sender and appropriate public health authorities.

For samples with a repeated presumptive positive result, additional confirmatory testing may be conducted, if it is necessary to differentiate between SARS-CoV-2 and other SARS-like viruses for epidemiological purposes or clinical management.

Positive Results

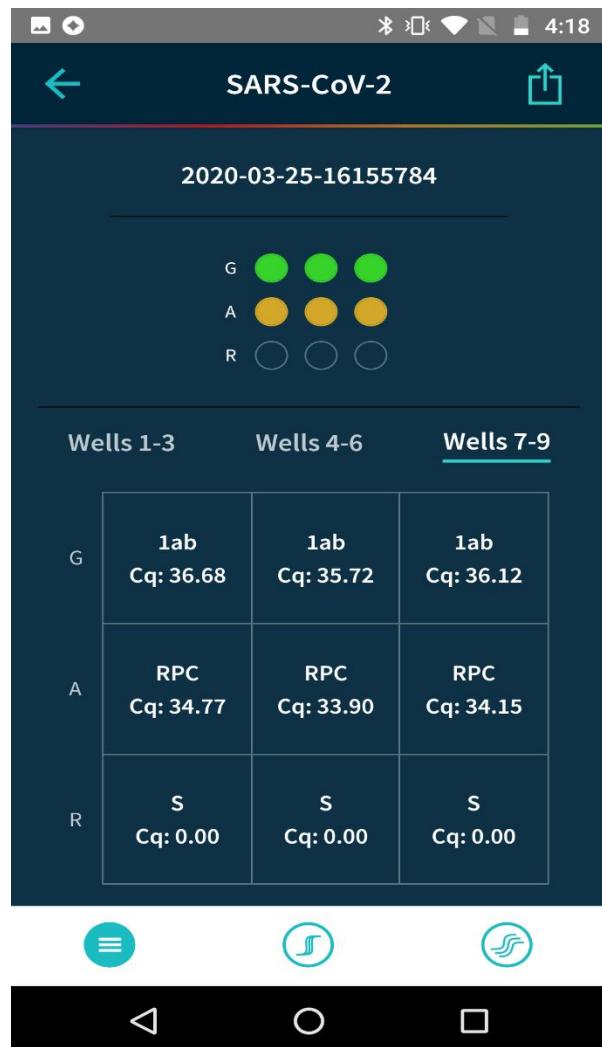
S target & RPC detected
Orf1ab target not detected



Report results to the sender and appropriate public health authorities.

Invalid Results

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.

Viewing Completed Run Data

Run data for completed and intentionally stopped runs is available in the Data Management section of Biomeme Go.

1. Log into the Biomeme Go app if you haven't done so already (see "[Logging In and Out](#)").
2. Select Data Management from the main dashboard of Biomeme Go.
3. Choose the folder in which your run data is saved.
4. Tap the name of the run you wish to view.

Viewing Incomplete Runs

Incomplete Runs can occur for a variety of reasons (see "[Common Scenarios](#)" for examples). If this happens, you can still view the incomplete run data:

1. Log into the Biomeme Go app if you haven't done so already (see "[Logging In and Out](#)").
2. Select Incomplete Runs from the main dashboard of Biomeme Go to view a list of all runs classified as incomplete.

Note: After selecting your incomplete run, please wait roughly 30 seconds before your run data begins to populate. Be sure to connect to your thermocycler via wire or Bluetooth so your app can automatically transfer data off the thermocycler once available. Runs that are intentionally stopped by the user are not considered incomplete runs and the run data will not be available in this section of the Biomeme Go app.

Thermocycler LED Status Indicators

Vertical LED on the front of your thermocycler.

Franklin™ has 5 LEDs on the front of the unit. The LEDs are used to convey various states of the thermocycler as outlined in the table below.

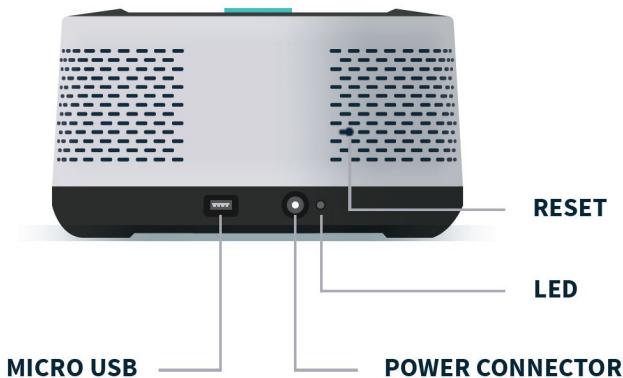
COLOR	INTERPRETATION
WHITE	5 solid indicates your thermocycler is on 5 blinking indicates Bluetooth (BLE) is pairing
GREEN	2 solid indicates remaining battery is between 21 and 40% 3 solid indicates remaining battery is between 41 and 60% 4 solid indicates remaining battery is between 61 and 80% 5 solid indicates remaining battery is between 81 and 100% 1 blinking indicates charging
YELLOW	1 solid indicates run start to 9% complete 2 solid indicates run is between 10 and 31% complete 3 solid indicates run is between 32 and 53% complete 4 solid indicates run is between 54 and 75% complete 5 solid indicates run is between 76 and 99% complete
RED	1 solid indicates remaining battery is between 0 and 20% 5 blinking indicates thermocycler lid is open or an error <i>Note: If the battery is in the red, you shouldn't start your run until you plug your thermocycler into power.</i>
BLUE	5 blinking indicates your test is complete and data is ready to be synced to your smartphone

Turning Your Thermocycler On and Off

To power on your thermocycler, press and hold the power button  (located on the top of the unit) for roughly half a second. The status LED on the front of your thermocycler will illuminate white to indicate it has successfully turned on.

To turn the unit off, press and hold the power button for 1.5 seconds and the status LED will turn off upon release of the button. The unit will also turn itself off after 15 minutes of inactivity.

Charging & Checking Thermocycler Battery Status



Note: To preserve your smartphone's battery life, disconnect from the thermocycler when it's not in use.

If your battery is running low, simply plug the AC power adapter into an outlet and insert the power connector into the back of your thermocycler. The LED on the back of the thermocycler will illuminate blue.

If you're unable to turn your thermocycler off using the power button on top, you may press the reset button to force it off (all test data on the unit will be lost).

Lastly, when the battery  button is held, the LED on the front of your thermocycler indicates the battery charge status as follows:

LED STATUS	BATTERY PERCENTAGE
5 solid	
4 solid	
3 solid	
2 solid	
1 solid	

A single green LED will blink while charging. If your battery charge is between 0 and 20%, the bottom most LED will blink green while charging.

If your battery charge is greater than 20%, the top most LED will blink green while charging.

For proper battery maintenance and performance, please fully charge the thermocycler battery at least once every six months. The thermocycler should not be left without charging for extended periods of time. If your device has not been charged in more than six months and you cannot get the thermocycler to turn back on, please contact support@biomeme.com.

Enabling & Disabling Bluetooth (BLE *) on Your Thermocycler

Bluetooth can be turned on or off at any time by pressing and holding the Bluetooth button on the top of your thermocycler for roughly half a second. By default, Bluetooth is disabled. A blue LED will light up next to the BLE button indicating it is enabled.

Once enabled, tap Connect via BLE when prompted in the smartphone app. If working with multiple Franklin™ thermocyclers, select the appropriate unit and tap Confirm. The LED on the front of your thermocycler will flash white indicating it's connected.

How To Update the Biomeme Go App

1. Navigate to the Google Play Store on your smartphone by tapping the Play Store  icon on your phone's home screen.
2. Tap the hamburger menu icon  in the top left corner.
3. Select My Apps & Games.
4. Choose Update next to Biomeme Go.

Note: If your app is already up-to-date, you will not see the app icon appear in the updates section. This is perfectly normal and no further action is required at this time.

Transferring Data



Wireless (Bluetooth)

On your computer, make sure your Bluetooth is set to Receive a File. This will prepare your computer to accept the data transfer from your smartphone.

- In the mobile app, navigate through View Results and select a test.
- Once on the test result screen, tap Send in the top right corner.
- A menu will slide in with sharing options. Select Bluetooth and transition to the Choose Bluetooth Device screen.

Note: Instructions could vary depending on your computer and/or smartphone Operating System. If you require further assistance, please contact support@biomeme.com.

Reporting a Problem or Error

1. Log into the Biomeme Go app if you haven't done so already (see "[Logging In and Out](#)").
2. Tap the Gear icon  in the top right corner to open the Settings menu.

3. Click the Settings sub-menu item.
4. Under Contact Us, click Report Error.
5. Select your email client (e.g. Gmail) and add support@biomeme.com to the “To” field if it’s not already there. An email will automatically be drafted on your behalf with all the necessary device information for us to better help resolve your issue(s).

Note: Do not remove the body or the attachment that was automatically added to your email. This information helps our engineering teams troubleshoot.

Viewing Thermocycler Device Information in Biomeme Go

1. Log into the Biomeme Go app if you haven’t done so already (see “[Logging In and Out](#)”).
2. Tap the Gear icon  in the top right corner to open the Settings menu.
3. Select the Settings sub-menu item and from there you’ll see thermocycler-specific information (e.g. Software Version, Serial Number, MAC Address, etc.).

Switching Teams (Enterprise Plan Only)

1. Log into the Biomeme Go app if you haven’t done so already (see “[Logging In and Out](#)”).

2. Tap the Gear icon  in the top right corner to open the Settings menu.
3. Click the Switch Team sub-menu item.
4. Select from the list of available teams.
5. Alternatively, tap the User icon  in the top left corner and choose Selected Team to make a switch.

Maintenance & Cleaning

The Biomeme Franklin™ thermocycler is maintenance-free and has no serviceable parts. In the case of thermocycler failure or damage, please contact support@biomeme.com.

The outside of the Franklin™ thermocycler can be cleaned using a 70% ethanol solution which must be sprayed on a cloth rather than directly on the Franklin thermocycler. Lysol wipes or Micro-Chem Plus wet paper towels are acceptable as well. Do not spray or pour solution directly onto the thermocycler when cleaning.

- Do not disassemble the thermocycler for cleaning
- Do not immerse in water or cleaning solutions
- Do not clean with soap or other solutions
- Avoid cleaning the heating wells (silver)

If you do need to clean your heating wells because it's impacting performance, please contact support@biomeme.com for specific instructions.

Safety Notice

The instrument can pose electrical hazards to the operator if used inappropriately and hence it is important to understand, familiarize and implement the safety notices given below to ensure safety of the operator.

The instrument and its equipment should be operated, maintained, stored and as directed in this document. Failure to comply may impair the protection provided by the instrument and its ancillary equipment.

General Safety Warnings



Do not modify the instrument hardware. The system is not user serviceable by the user in any circumstances.



Do not place the instrument near liquid filled containers or areas where the instrument and its equipment may be subjected to dripping or splashing liquids.



Do not use the instrument in extreme heat, humidity, dust and vibration conditions Electrical Safety Notice.



CAUTION - Heating wells may be hot. Care must be taken when inserting or removing cuvettes.

Electrical Safety Warnings



Unplug AC power cord from the wall outlet in case of an emergency.

	Caution, possibility of electric shock
	Caution, hot surface
	Caution
	Keep Dry
	<p>No Waste</p> <p><i>This symbol on the product or on its packaging indicates that this product must not be disposed of with your other household waste. Instead, it is your responsibility to dispose of your waste equipment by handing it over to a designated collection point for the recycling of waste electrical and electronic equipment. The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about where you can drop off your waste equipment for recycling, please contact your local city office, your household waste disposal service or the shop where you purchased the product.</i></p>

Declaration of Conformity

This declaration of conformity is issued for:

Product: Biomeme Franklin™ qPCR Thermocycler
Model Number: Franklin™

The object of this declaration is in conformity with European Union directives 2014/35/EU, 2014/30/EU and 2011/65/EU.

The following harmonized standards were applied:

	IEC 61010-1:2010, AMD1:2016
Safety	IEC 61010-2-010:2014
	IEC 61010-2-081:2015
	IEC 62133-2:2017
	IEC 62479:2010
EMC	IEC 61326-1:2013
	ETSI EN 301 489-1 V2.1.1
	ETSI EN 301 489-17 V3.1.1
Hazardous Substances	EN 50581:2012

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Troubleshooting

Reattach & Recover Common Scenarios

Did you start your run and return to your thermocycler later in the day only to realize it's now off? Maybe your app crashed or your phone died and you're wondering how to retrieve your test results? Below are some common scenarios and the steps to take to get your results.

	Biomeme Go App		
	Open	Closed	
Franklin Thermocycler	On	A	B
	Off	C	D

Note: **DO NOT** push Stop Run in the app. This will lose any run data that has not successfully synced from the device to the app. For security reasons the same smartphone used to initiate the test must be used to download the test results.

“My test has been running for a while but the number of cycles isn’t decreasing on the app. What should I do?

This means that the Bluetooth connection between the device and the app has been interrupted. **DO NOT** press Stop Run. Instead you just need to reset the Bluetooth connection. Follow the steps in Scenario A below.

“My run has completed and I’ve pressed a bunch of buttons. I’m feeling flustered, confused, and frustrated; what should I do?”

1. Turn off the thermocycler and close the Biomeme smartphone app.
2. Follow the steps described in section **D** below.

If you’re still having problems recovering and/or reattaching your test data, please contact support@biomeme.com.

“My Biomeme Go app is returning a WRONG THERMOCYCLER error.”

1. Turn off the thermocycler and close the Biomeme smartphone app.
2. Follow the steps described in section **D** below.

A: “My thermocycler is **ON**, my test is currently running or has completed, and my Biomeme Go app is still **OPEN**. ”

1. Power cycle the Bluetooth. Press the Bluetooth  button on top of the thermocycler to turn **OFF** the Bluetooth Pairing.
2. Press the Bluetooth  button on top of the thermocycler to turn the Bluetooth connection back on.
3. Press Scan in the Biomeme smartphone app.
4. Select your thermocycler from the list in the app.
5. Tap Confirm in the app.

Note: If your test is currently running, the LED on the front of your thermocycler will be blinking amber. If your test has completed, the front LED will be blinking blue.

B: “My thermocycler is **ON**, my test is currently running or has completed, and my Biomeme Go app has **CLOSED**.”

1. Relaunch the Biomeme smartphone app by selecting the icon on your smartphone’s home screen.
2. Press the Bluetooth  button on top of the thermocycler to turn it **OFF** the bluetooth.
3. Press the Bluetooth  button on the top of the thermocycler to turn Bluetooth back **ON**.
4. From the app’s home screen, tap Incomplete Runs.
5. Select your test from the list of incomplete runs.
6. Press the Scan button in the app and select your thermocycler.
7. Tap Connect via BLE in the app.
8. Tap the Reattach Test button in the app.
9. Please wait while your run data is transferred.

C: “My thermocycler is **OFF** and my Biomeme Go app is **OPEN**.”

1. Press the Power  button on top of your Franklin™ three9 thermocycler to turn it back on. If your thermocycler doesn’t turn back on, make sure it’s connected to a power source as your battery may have died.
2. Press the Recovery  button on top of your thermocycler.
3. The thermocycler will quickly blink blue, white, red, then green indicating it has successfully recovered the previously completed or failed run.
4. Press the Bluetooth  button on top of your thermocycler.
5. Press Scan in the Biomeme smartphone app.

6. Select your thermocycler from the list in the app and tap Confirm.
7. Please wait while your run data is transferred.

Note: This assumes your test was completed before the thermocycler powered off. It is usually not possible to reattach and recover the run data if the thermocycler shuts off during the run. Please always ensure your device has at least 30% battery power before starting your run.

D: “My thermocycler is **OFF** and my Biomeme Go app is **CLOSED**. ”

1. Press the Power  button on top of your Franklin™ three9 thermocycler to turn it back **ON**. If your thermocycler doesn’t turn back on, make sure it’s connected to a power source as your battery may have died.
2. Press the Recovery  button on top of your thermocycler.
3. The thermocycler will quickly blink blue, white, red, then green indicating it has successfully recovered the previously completed or failed run.
4. Press the Bluetooth  button on top of your thermocycler.
5. Relaunch the Biomeme smartphone app by selecting the icon on your smartphone’s home screen.
6. From the Biomeme app’s home screen, tap Incomplete Runs.
7. Select your test from the list of incomplete runs.
8. Press Scan in the Biomeme smartphone app.
9. Select your thermocycler from the list in the app and tap Confirm.
10. Tap Connect via BLE in the app.
11. Tap the Reattach Test button in the app.
12. Please wait while your run data is transferred.

Note: This assumes your test was completed before the thermocycler powered off. It is usually not possible to reattach and recover the run data if the thermocycler shuts off during the run. Please always ensure your device has at least 30% battery power before starting your run.

Bluetooth

Why is my Bluetooth (BLE) not connecting?

If you are having trouble connecting, ensure that you enabled Bluetooth on both your smartphone and thermocycler.

Why is my thermocycler not showing up in the connection list in my app?

Ensure that Bluetooth is turned **ON**. The LED next to the thermocycler's Bluetooth  button should be illuminating blue. If your thermocycler is still not showing in the list of the app, try tapping Scan in the app multiple times to allow for discovery.

My Bluetooth connection was lost during a test run...

If you lose your Bluetooth connection, the smartphone app will notify you that the connection has been lost. It will prompt you to reconnect to the thermocycler if you are able to. Upon reconnecting, the test data will update on the smartphone after a short delay (1-2 seconds).

How do I change the Bluetooth name of my thermocycler?

You must first pair your thermocycler and smartphone. Then...

1. From the Biomeme Go main dashboard, tap the gear icon in the upper right corner.

2. Select Settings.
3. Tap the text field with the existing Bluetooth name and override it with a name of your choice (no spaces, 18 characters max).
4. Tap Rename.

General

What happens if my test stops prematurely?

If your test fails, the smartphone will notify you of the error returned from the thermocycler. Your last run will be saved in the Biomeme mobile app up to the point of failure, but the data will not be processed resulting in no Cq values, baseline, or graph of smooth data. The raw data and information about your run is still exportable through the xlsx spreadsheet, however.

My thermocycler turned off during a test run...

If your thermocycler turns off during a test, then the thermocycler battery may be dead and the unit should be plugged into power. Your connection to the smartphone will also be lost. If this happens, we recommend you to stop the run in the smartphone mobile app. See Recovering & Reattaching Test Data for more details.

I have a low battery warning at test start...

You are able to start a test, but ensure that you are plugged into a charger before the thermocycler runs out of power.

How do I stop a test?

While the test is running, you have the ability to press the stop run button. Doing so will prompt the mobile app to ask you to confirm that you would like to stop the test in progress. Upon stopping, your run will be saved to the current point, and available in the test results section of the mobile app.

The thermocycler failed to start test...

If your run fails to start, the app will return to the home screen and have you restart the setup of your test. Restart the thermocycler then reconnect the smartphone. If starting still fails after many retries, please contact support@biomeme.com.

What should I do if I receive a heater error message?

Retry running your test, but if the error persists please contact support@biomeme.com.

Disclaimer

This product has not been FDA cleared or approved; the product has been authorized by FDA for use with the Biomeme SARS-CoV-2 Real-Time RT-PCR Test under an Emergency Use Authorization (EUA) for use by laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

This product has been authorized only for use with the Biomeme SARS-CoV-2 Real-Time RT-PCR Test for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Biomeme products may not be transferred to third parties, resold, modified for resale or used to manufacture commercial products or to provide a service to third parties without written approval of Biomeme, Inc.

Biomeme warrants every thermocycler to be free of defects in material and workmanship for one year from the date of shipment to buyer. All warranties are subject to our [Terms and Conditions and Privacy Policy](#).
(<https://biomeme.com/privacy-policy-and-terms-of-use/>).

Biomeme, Inc.
1015 Chestnut Street, Suite 1401
Philadelphia, PA, USA 19107
support@biomeme.com

[Patent Protected](#)
(<https://biomeme.com/patents/>)

This equipment 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. This 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 own expense.

This device contains:

FCC ID: XPYNINAB1

IC: 8595A-NINAB1

Warning: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

This device may not cause interference.

This device must accept any interference, including interference that may cause undesired operation of the device.