

ONBOARDING



New Customer Onboarding Guide

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Version 1.2



TABLE OF CONTENTS

Biomeme Onboarding Outline: ‘Biomeme 101’	3
Customer Success Team:	3
Contact:.....	3
Description:	3
General Objectives:.....	4
Expectations/Goals:.....	4
Onboarding Video Call Agenda	5
Materials Checklist.....	8
Storage Requirements	11
Cleaning and Decontamination Tips	12
Folder & Run Organization/Naming Runs	17
Glossary: Commonly Used Terms and Abbreviations.....	19

Biomeme Onboarding Outline:

'Biomeme 101'

Customer Success Team:

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Contact:

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Description:

Customer onboarding is a vital process that helps new customers learn a company's product. Here at Biomeme, we take the onboarding process to heart and strive to offer a top-tier customer experience. During the onboarding process, you will have access to over 20 How-To videos, a personalized video onboarding call with our customer success team, and much more. Our goal is to ensure that every new customer gets the chance to participate in each carefully designed part of the onboarding process to ensure success with our product.

General Objectives:

1. Become familiar with your new Biomeme products, including but not limited to Go-Strips, M1 Sample Prep, and portable Franklin thermocycler
2. Learn and utilize new or unfamiliar terms/vocabulary
3. Be comfortable navigating our Help Desk, Biomeme Go App, and the Biomeme Cloud
4. Become comfortable going through the end-to-end workflow
5. Become confident in analyzing your results

Expectations/Goals:

1. Fill out the New Customer Onboarding Form (if applicable). This will help the customer success team personalize your onboarding call. We will send this to you if we need this information.
2. Schedule and attend your onboarding call with the customer success team. We highly recommend all new customers participate in an onboarding call. We are flexible and can make almost anytime work with your schedule. Click [here](#) to schedule this call if you have not yet done so.
3. Choose a Team Name and create user accounts for all members of your team. The customer success team will create these accounts for you.

4. Watch all applicable How-To videos and explore FAQs on the Help Desk before your onboarding call. This will help give you more familiarity with our products.
5. Download, install and log into the Biomeme Go App before your onboarding call.
6. Communicate with the customer success team often, as we are here to help answer questions, troubleshoot problems, and be your number one contact after you receive your new Biomeme products. We like to hear when things are going well, too!

Onboarding Video Call Agenda

The onboarding call will be approximately 60-90 minutes long but can be shorter or longer to accommodate your needs. If there are any points that you would like to go over in more or less detail, do not hesitate to let the Customer Success team know before the onboarding call. During a typical call, expect to go over the following points/topics (for SARS-CoV-2 use cases):

1. **Welcome and Introductions** - The Biomeme Customer Success team will introduce themselves, and the trainees will have the opportunity to do so as well.

2. **Laboratory and Background Information** - If you have not yet filled out the New Customer Form (if applicable), this will be the time where the Customer Success team will ask the trainees about your lab background and experience. We will also ask about your goals with the product, i.e., runs per week, when you plan on starting, etc.
3. **Recommended Safety and Cleaning Points** - We will review our recommendations regarding PPE and cleaning/disinfection during the end-to-end workflow.
4. **Materials** - We will review the materials that you need to perform the end-to-end workflow. Make sure before the call you have the Biomeme Go App downloaded, installed, and logged in.
5. **Overview of Method** - Quick review of what we will be going over in the following few steps.
6. **Resuspending RPC buffer** - We will demonstrate how to resuspend the lyophilized RPC pellet (internal positive control).
7. **Sample Extraction using M1 Sample Prep** - We will demonstrate how to use our M1 sample prep and syringes/barbed column tips to extract the nucleic acids into a purified sample ready for PCR.
8. **Filling Go-Strips** - We will demonstrate how to fill the Go-Strips with the purified sample.

9. **Loading the Franklin Thermocycler** - We will demonstrate how to load the Franklin.
10. **Biomeme Go App** - We will show you how to Navigate the Biomeme Go App.
11. **Starting a Run** - We will demonstrate how to start a run using the Biomeme Go App.
12. **Navigating Help Desk** - If not already familiar with our Help Desk, we will show where all the useful things live.
13. **Results Interpretation** - We will walk you through results interpretation on the Biomeme Go App.
14. **Biomeme Cloud** - We will demonstrate how to navigate and see your results on the Cloud. We will show you specific examples of runs that you may encounter.
15. **Recommended Clean-up Procedure** - We will briefly go over the clean-up procedure.
16. **Questions** - This is the time where we will address any final questions that you may have.

Materials Checklist

SARS-CoV-2 Real-Time RT-PCR Test: Per one 9-well reaction

Standard Lab Equipment:

EQUIPMENT	QTY
PPE (gloves at minimum, goggles, face shield, lab coat)	As needed
Biohazard bags	1x
Ethanol (diluted to 70%) in a spray bottle for cleaning	As needed
Bleach for cleaning	As needed
Paper towels	As needed

For Collection:

EQUIPMENT	QTY
Biomeme DNA/RNA Preservation Buffer or BD Universal Viral Collection Kit (Viral Transport Media)	As needed
DNA/RNA Preservation Buffer Tubes	9x
Collection Swabs	9x
Premeditated way of labeling vials, whether it is handwritten with a marker or given a barcode/QR code	As needed

For RPC resuspension:

EQUIPMENT	QTY
RPC Kit Contents: RPC pellet, buffer, 1mL disposable pipette	1x kit

For Preparation: (get out as many as you will need before you start)

EQUIPMENT	QTY
Sample prep tray	1x
Biomeme M1 Sample Prep Cartridge Kit for RNA 2.0	9x
Syringes	9x
Barbed Column Tips	9x
Biomeme SARS-CoV-2 Go-Strips	3x
200µL Transfer Pipette	9x
Void filling cap strips	3x
Pink 20µL Fixed Volume Pipette	1x
Pipette tips	18x
2mL Self-Standing Tubes	9x

To Test and Analyze Sample:

EQUIPMENT	QTY
Smart Phone	1x
Biomeme Go app and Login info	N/A
Biomeme Franklin three9 Real-Time PCR Thermocycler	1x
Biomeme Cloud	N/A

Optional:

EQUIPMENT	QTY
Micropipette(s)	As needed
Vortex	1x
Positive Control (See IFU for our recommendations)	1x
Molecular Grade Water	As needed

Storage Requirements

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

SOURCE: REF#	COMPONENT	STORAGE REQUIREMENTS/SHELF LIFE
Biomeme: 3000567	200µL Transfer Pipette Pack	Store in a dry place at room temperature (15-30°C).
Biomeme: 3000536	Biomeme M1 Sample Prep Cartridge Kit for RNA 2.0	Store in a dry place at room temperature (15-30°C)/ 1 year.
Biomeme: 3000011	20µL Fixed Volume Pipette	Store in a dry place at room temperature (15-30°C).
Biomeme: 3000572	Pipette Tips	Store in a dry place at room temperature (15-30°C).
Biomeme: 3000150	2mL Self-Standing Tubes Pack	Store in a dry place at room temperature (15-30°C).
Biomeme: 3000555	Biomeme SARS- CoV-2 Go-Strips*	If unopened, store in a dry place at room temperature (15-30°C)/1 year. Remove as much air from the pouch as possible when re-sealing and ensure the zipper is fully closed. Always check the quality of reagents before use.
Component of 3000555	RNA Positive Control	If unopened, store in a dry place at room temperature (15-30°C)/1 year. Once resuspended, RPC can be stored at room temperature (15-30°C) for a maximum of 2 days. For

SOURCE: REF#	COMPONENT	STORAGE REQUIREMENTS/SHELF LIFE
		longer-term storage, it can be aliquoted and frozen at -20 °C for up to three months. See RPC Optimization Guide for further details.
Biomeme: 1000003	Biomeme Franklin three9 Real-Time PCR Thermocycler	Store in a dry place at room temperature (15-30°C).
Biomeme: 3000577	DNA/RNA Preservation Buffer Tubes	Store in a dry place at room temperature (15-30°C)/1 year.
N/A	DNA/RNA Preservation Buffer Tubes with sample	Store in a dry place at room temperature (15-30°C)/1 year
N/A	Purified Extracted Sample in Collection Tube	Use purified patient samples as soon as possible after extraction.

Cleaning and Decontamination Tips

The environment is full of DNases and RNases, and other enzymes that degrade genetic material. When working with DNA and RNA, it is best to try and minimize the introduction of these enzymes into our samples, especially after they are purified. Further, limiting contamination across samples, which could potentially result in false positives, is very important. Below, good cleaning practices will be outlined to help avoid sample degradation and contamination. Please also see

page 12 in the [IFU \(Instructions for Use\)](#) for more information about minimizing the risks of contamination.

During Sample Testing

Always wear PPE (personal protective equipment)

1. Gloves with adequate chemical resistance
 - a. Some components of the Biomeme SARS-CoV-2 test have irritative properties. Gloves protect your hands from such components
 - b. Gloves help prevent contamination from skin getting into your samples/RPC
 - c. Gloves should be changed or sprayed with 70% ethanol between processing each sample

2. Goggles/Face shield
 - a. Goggles help protect your eyes from exposure to hazardous or infectious materials during sample collection or processing

3. Lab coat
 - a. Lab coats help protect your skin and clothing from hazardous or infectious materials

RPC Aliquoting

1. Regardless of lab throughput, we highly recommend aliquoting and freezing RPC to prevent contamination of the entire tube

2. If there is a contamination event that may have compromised the RPC, the aliquot used that day should be disposed of, and after a deep clean, another aliquot can be thawed and used

Do Not Place Hand -- Whether Gloved or Not -- Inside of Pouches/Bags (Go-Strips, Cartridges, Pipettes, etc.)

3. It is standard practice to shake out needed contents out of a bag, opposed to putting hands inside of a bag, even with a clean glove on
4. Before doing any sample processing, take out the materials needed and place in clean sample tray

Biohazard Waste Bag/Bin

1. Always dispose of potentially biohazardous solutions according to your local, regional, or national waste disposal guidelines
2. Keep a biohazard bin/bag within reach to dispose of used pipette tips, M1 cartridges, syringes, barbed column tips, used Go-strips/void caps, etc.
3. Be mindful of your specific workplace and whether or not you need to use a sharps container

Keep Lids on Everything

1. When not in use, keep caps/lids on all vials and tubes

2. If cap/lid must be placed down, make sure to put it on a clean working surface (such as the sample prep tray cover or KimWipe) with the inside facing down on the clean working

Cleaning Workspace

1. **DO NOT** add bleach or acidic solutions directly to the liquids contained in Biomeme's M1 Sample Prep cartridges
 - a. The BLB (Biomeme Lysis Buffers) and BPW (Biomeme Protein Wash) buffers can form highly reactive compounds when combined with sodium hypochlorite (a.k.a. liquid bleach)
 - b. If a spilled liquid contains potentially infectious agents, clean the affected area multiple times with laboratory detergent and water. Then, clean the area with 1% (v/v) sodium hypochlorite
2. If liquid containing these buffers is spilled, clean with suitable laboratory detergent, like CaviCide and water, or 70% alcohol

Before and After Runs are Completed

Wash Hands

1. Wash hands thoroughly with soap and warm water before and after handling samples, prep tools, equipment, etc.

Clean All Work Surfaces Thoroughly

1. It is a good rule of thumb to always clean before and after doing molecular work to best mitigate the risks of contamination
2. Before working, spray a paper towel with freshly made 10% bleach, then wipe down the work surface, then wipe up residue with ethanol (70%)
3. After working, wipe down with ethanol, then with 10% bleach, sprayed on a paper towel first, then the work surfaces

Use Bleach to Clean (10% sodium hypochlorite)

1. Use only before or after you are done running samples, sprayed onto a paper towel first
2. Clean everything with this, aside from reusable pink fixed volume pipette, outside of the RPC vial, and scissors/blade used to cut Go-Strips/Void filling caps
3. Bleach degrades any nucleic acid that is present and is the best way to clean/decontaminate
4. Bleach can degrade RPC or kill the reaction if any residue gets into Go-Strips
5. **DO NOT** make direct contact with bleach and buffers from M1 Sample prep or preservation tubes

Ethanol (70%)

1. Always go over anything you cleaned with bleach with ethanol or to wipe up excess residue

Folder & Run Organization/Naming Runs

Folder and run organization depend on lab throughput. Below we will outline best practices for effective management of folder and run organization for each throughput level. We will also review the best methods of naming runs.

Low Throughput Lab: fewer than 250 samples per week

1. If you are performing fewer than 250 samples or ~28 runs per week, putting all runs in one folder per month will work fine
 - a. For example:
 - i. 2021 → 03 - March → *save runs here*
 - ii. 2021 → 04 - April → *save runs here*

High Throughput Lab: more than 250 samples per week

1. If you are performing more than 250 or ~28 runs per week, we recommend organizing runs by Month → Week of X-X
 - a. For example:
 - i. 2021 → 03 - March → Week of 3-1 → *save runs here*
 - ii. 2021 → 03 - March → Week of 3-8 → *save runs here*
 - iii. 2021 → 04 - April → Week of 4-5 → *save runs here*

- iv. 2021 → 04 - April → Week of 4-12 → *save runs here*

Naming Runs

1. In the Biomeme Go App, right after you choose where to save the run, the app will prompt you with “Run Setup”
 - a. This step will include “Run Name,” “Parent Folder,” and “GPS Coordinates.”
2. In this step, keep the run name exactly as it automatically generates.
 - a. The automatically generated name will be in the format of “2021-03-22-16130441”
 - b. If desired, initials of who is running the samples can be added onto the end of the automatically generated name, as this will help keep track of who runs which samples on any given day if there are multiple users.
 - c. For example:
 - i. “2021-03-22-16130441SS”

Some More Helpful Tips

1. If you plan to use “Month” as a folder, always name it by the month order and then the date,
 - a. For example:
 - i. “01 - January”, “07 - July”, “12 - December”
 - b. This will keep the folders ordered chronologically, opposed to alphabetically
2. There are many ways to name/organize folders besides the ones that we have outlined above

- a. One thing that we always recommend is to create your organization plan before you ever start to perform tests on your Franklin Thermocycler

Note: At this time, once a folder is created, it is not able to be moved or renamed. We are unable to move a run between folders.

3. Importantly, whichever naming schema you choose, try to keep everything as consistent as possible

Glossary: Commonly Used Terms and Abbreviations

ACRONYM	DEFINITION
BDW	Biomeme Drying Wash
BEB	Biomeme Elution Buffer
BLB	Biomeme Lysis Buffer
BPW	Biomeme Protein Wash
BWB	Biomeme Wash Buffer
cDNA	complementary Deoxyribonucleic Acid
CDC	Centers for Disease Control and Prevention
CLIA	Clinical Laboratory Improvement Amendments of 1998
COVID-19	Coronavirus Disease of 2019
DNA	Deoxyribonucleic Acid

ACRONYM	DEFINITION
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
IFU	Instructions For Use
IPC	Internal Positive Control
IVD	In Vitro Diagnostics
LOD	Limit Of Detection
NTC	No Template Control
Orf1ab	Open Reading Frame 1ab
PCR	Polymerase Chain Reaction
qPCR	quantitative (or semi-quantitative) Polymerase Chain Reaction
PPE	Personal Protective Equipment
RFU	Relative Fluorescence Units
RNA	Ribonucleic Acid
RPC	RNA Process Control
RT-PCR	Reverse Transcriptase Polymerase Chain Reaction
RUO	Research Use Only
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SDS	Safety Data Sheets
VTM	Viral Transport Media

PRODUCT	PURPOSE	MFG. BY BIOMEME?
200uL Transfer Pipettes	Used to transfer 200uL of patient sample into the first chamber of the M1 Sample Prep Cartridge	No

PRODUCT	PURPOSE	MFG. BY BIOMEME?
2mL Sample Collection Tubes	Screw-cap tubes with many uses; commonly used for collecting the extracted sample after performing M1 Sample Prep or holding aliquots of other solutions such as processed positive control. Preferred over tubes with flip-cap for long-term storage	No
Android Smartphone OR Rugged CAT Phone	Standard Android smartphone with the Biomeme Go app pre-installed, included as a required product in the EUA for SARS test. Rugged CAT phone also has the Biomeme Go app pre-installed and is more durable than the standard android smartphone.	No
Barb Column Tips	Tips compatible with Luer-Lock syringes sold/used with M1 Sample Prep Cartridges. These tips contain a silica membrane (called a filter) that captures the target DNA/RNA from the sample during the sample prep.	YES
Barrier Pipette Tips	Disposable pipette tips that come in varying sizes to accommodate the various sizes of pipettes and contain a filter that acts as a barrier between the part of the tip that will hold the liquid, and the pipette itself. These are preferred because they lessen the risk of pipette contamination.	No
BDW (Biomeme Drying Wash)	Biomeme Drying Wash is found in the 4 th chamber of the M1 Sample Prep cartridge. It prepares the filter for efficient drying in the Air-Dry Step that follows.	YES
BEB (Biomeme Elution Buffer)	Biomeme Elution Buffer is found in the 6 th and final chamber of the M1 Sample Prep cartridge. This solution will cause the DNA/RNA to be released from the filter, into this solution, which then becomes the extracted sample. This solution is not designed to stabilize the DNA/RNA for long, and the extracted sample must be used within 4 hours maximum since the sample preparation.	YES
BLB (Biomeme Lysis Buffer)	Biomeme Lysis Buffer is found in the 1 st chamber of the M1 Sample Prep, or in Biomeme's VTM which is called DNA/RNA Preservation Buffer. This buffer lyses cells and breaks open viral capsids to release the DNA/RNA into solution and inactivates the SARS-CoV-2 virus after 10 minutes of incubation, significantly lowering the risk of working with a potentially hazardous sample.	YES
BPW (Biomeme Protein Wash)	Biomeme Protein Wash is found in the 2 nd chamber of the M1 Sample Prep cartridge and causes unwanted proteins to unbind from the filter, increasing the purity of the extracted sample.	YES
BWB (Biomeme Washing Buffer)	Biomeme Wash Buffer is found in the 3 rd chamber of the M1 Sample Prep cartridge and causes other potential contaminants to unbind from the filter, increasing the purity of the extracted sample.	YES
Bulk Vial	These contain the same lyophilized assay that is found in the Go-Strips or Go-Plates, but in bulk. A bulk vial is one time use, because once it is	YES

PRODUCT	PURPOSE	MFG. BY BIOMEME?
	resuspended, it has a short shelf life. One bulk vial is enough for about 165 reactions, but this number may vary depending on the final concentration desired.	
Centrifuge	A machine that generates centrifugal force, which at low speeds for short amounts of time (<4 seconds), can gently pull any droplets on the inside of the tube to the bottom, without causing separation of the homogenous solution. When working with microliter volumes, a small droplet remaining separate from the rest of the sample can significantly alter the concentration of the sample and therefore impact the test result.	No
Fixed-Volume Pipette (10uL)	Reusable pipette used to transfer 10uL volumes, required for processing positive control samples.	No
Fixed-Volume Pipette (20uL)	Reusable pipette used to transfer 20uL volumes, required for transferring purified/extracted sample into Go-Strip wells.	No
Flocked Specimen Collection Swabs	Used to collect nasopharyngeal or nasal swab specimens.	No
Franklin one9 Thermocycler	Portable, hand-held, battery-operated thermocycler. The Franklin one9 has 1 active color channel (FAM probe - green) and 9 reaction wells. The other two color channels can be activated by using an upgrade code, since all Franklins are inherently capable of detecting all three color channels. The thermocycler can cycle through temperatures as low as 40°C and as high as 100°C.	YES
Franklin two9 Thermocycler	Portable, hand-held, battery-operated thermocycler. The Franklin two9 has 2 active color channels (FAM – green and ATTO647N - red) and 9 reaction wells. The third color channel can be activated by using an upgrade code, since all Franklins are inherently capable of detecting all three color channels. The thermocycler can cycle through temperatures as low as 40°C and as high as 100°C.	YES
Franklin three9 Thermocycler	Portable, hand-held, battery-operated thermocycler. The Franklin three9 has 3 active color channels (FAM – green, TexasRedX - amber, and ATTO647N - red) and 9 reaction wells. The thermocycler can cycle through temperatures as low as 40°C and as high as 100°C.	YES
Go-Plates	Pre-aliquoted 96-well PCR plate that contains the lyophilized master mix, enzymes, and multiplexed primer/probes.	YES
Go-Strips	Pre-aliquoted 3-well PCR strips that contain the lyophilized master mix, enzymes, and multiplexed primer/probes.	YES
Molecular Grade Water (a.k.a. Nuclease-Free Water)	Water that is suitable for use in molecular biology applications which requires the water to be free of DNases/RNases (nucleases) and	No

PRODUCT	PURPOSE	MFG. BY BIOMEME?
	proteases, as these enzymes inhibit PCR reactions. This is preferred sample type for NTC QC tests.	
M1 Sample Prep Cartridge	<p>An easy-to-use method of nucleic acid (sample) extraction that generates a purified sample ready for PCR. Buffers come pre-aliquoted in the provided sample prep cartridges for ease-of-use and the extraction method is designed to be completed in as little as 1 minute. Sold with the subcomponents required for use, barb column tips and syringes.</p> <p><u>Different types of M1 preps are currently mfg. By Biomeme:</u></p> <p>RNA 2.0 (soon to be renamed as “DNA/RNA”) – optimized for RNA, used for SARS and most sample types, including DNA sample types</p> <p>DNA-HI – optimized for large volume samples to provide a concentrated extracted sample</p> <p>DNA – optimized for DNA, but will no longer be manufactured since the RNA 2.0 type provides comparable performance on DNA samples</p>	YES
Preservation Buffer (DNA/RNA)	Biomeme's VTM that inactivates the virus and stabilizes the sample contents for long-term preservation at room temperature. Collected samples are stored in this buffer until molecular analysis. This buffer has almost the exact same composition as the BLB.	YES
Sample Prep Tray	A 3-D printed tray that organizes and streamlines sample preparation. It contains placeholders for the tubes, M1 cartridge, and Go-Strips, along with graphics of the steps and the order in which to complete them.	YES
Safety Data Sheet (SDS)	<p>A document for a product that details the properties of each product/chemical it contains, the physical, health, and environmental hazards of the product, the recommended protective measures, and the safety precautions for proper handling, storing, transporting, and disposal of the chemical/product.</p> <p>Previously known as MSDS (Material SDS)</p>	No
Void Filling Caps	Rubbery caps that are placed in Go-Strip wells to seal the PCR reaction to prevent evaporation and contamination.	YES
Vortex	A machine used to efficiently mix a solution with contents that may have settled. For best results, the RPC buffer and purified sample should be vortexed before use.	No

OTHER TERMS	
Aliquot	To separate a stock of solution into smaller volumes that are ideal for storage, or to

OTHER TERMS	
	minimize risk of stock contamination
Amplicon	The product of PCR which is only produced if the target is present. The presence of amplicons is a positive result, and lack of amplicon production is a negative result. The amount of amplicons at the end of the reaction are directly related to the viral load of the sample, and can be measured using qPCR methods.
Amplification	The process by which the target nucleic acid is enzymatically replicated to produce identical copies. The most widely used amplification method is Polymerase Chain Reaction (PCR).
Amplification Plot	The graph that qPCR results are displayed on, and in Real-Time qPCR, live updates are made to the amplification plot. This plot can be viewed for every run on the Biomeme Go app or the Biomeme Cloud.
Assay	In qPCR, this refers to all target-specific components of the test, such as primers and probes.
Baseline View (on Biomeme Cloud)	This view shows the amplification plot of the run data that has been processed by the algorithm designed by Biomeme specifically for that assay.
Biomeme Cloud	A data management software that allows the user to view their team's run results in an interactive graph view and provides metrics for the Cq and RFU values of the selected samples/runs.
Biomeme Go App	Smartphone app that is required to run/control the Franklin thermocycler and allows the user to view their results in real time.
cDNA	Complementary DNA is synthesized from RNA, and therefore, it is complementary in sequence to the RNA target template in the sample. cDNA is the product of the Reverse Transcriptase step that is first in RT-PCR. For RNA sample types, cDNA must be synthesized prior to the start of PCR, because PCR can only be done on double stranded nucleic acid.
Contamination	The introduction of foreign material in the sample at any step of the end-to-end workflow that may lead to false results or inhibition of the test.
COVID-19	The name of the disease caused by SARS-CoV-2.
Cq Value	The cycle at which enough amplicons have been produced to pass the limit of detection. This value directly correlates to the concentration of the target in the raw sample.
Detailed Data Function (in Biomeme Cloud)	Provides detailed information about the run, device, and protocol used such as sample names, type of protocol, run time, location of the run (if tagged), and more.
Device Log	An entire history of a device that can be used as a diagnostic tool.
DNases/RNases	Enzymes present in the environment that break down nucleic acids. Proper cleaning of lab and supplies will ensure that these enzymes do not cause inhibition of the PCR reaction and prevent unwanted degradation of target nucleic acids.

OTHER TERMS	
Error log/Info Log	A log of all device communications to the android phone, which can be sent to the Biomeme Support email from the phone for use as a diagnostic tool, if the file size of this log is under 25MB.
Exponential Growth	Growth that occurs at an increasing rate, instead of a set rate. In PCR, after every cycle, the number of amplicons doubles if the target nucleic acid was present.
External Positive Control	A control sample that is expected to produce a positive result, used to confirm the capability and validity of the testing performed on the validated system. The external PC is run separately from the test samples but goes through the same methods as regular samples to ensure that <i>all</i> components of the test are functioning as expected, and inhibitory contamination is not present. Biomeme recommends using the Exact Diagnostics brand SARS-CoV-2 Standard as the external PC when validating with the Biomeme SARS assay.
False Negative	When a sample is truly positive, but the result suggests it is negative.
False Positive	When a sample is truly negative, but the result suggests it is positive.
Filter Function (in Biomeme Cloud)	This analysis function allows the user to select and deselect wells and color channels independently of one another and apply the selections to the runs desired.
Fluorescent/Color Channels	Probes contain fluorophores that can be excited and emit fluorescent signals at specific wavelengths, which are then detected by the Franklin and shown as a curve on the amplification plot. Color channels are differentiated from one another by using different fluorophores for the probes, because different fluorophores emit at different wavelengths. The Franklin thermocycler can detect up to three different wavelengths, allowing three different color channels (green, amber, and red) per reaction. Each color channel of an assay represents one specific gene target.
IFU	A document containing comprehensive directions on every aspect of using the product(s) of a system. The most up to date version of Biomeme's SARS IFU can be found HERE .
Internal Positive Control	A type of control commonly incorporated into human diagnostic testing designs to allow for greater confidence in the result because it confirms the validity of each individual patient sample. In Biomeme's SARS-CoV-2 test, intact MS2 bacteriophage is added to each patient sample, prior to sample extraction, to act as an internal positive control, ensuring the process is working as expected and highlights sample-specific inhibition, if present.
Invalid Result	As stated in the Biomeme SARS IFU, this is a result where no targets amplify. No amplification in the RPC target, with negative S and Orf1ab targets, suggests method failure. This sample must be re-run.
IVD	Human diagnostics performed outside of the body. Products authorized for use under this specification means they can be used to diagnose humans.

OTHER TERMS	
Linear Drift	A curve generating due a linear increase detected, which is not representative of target amplification because target amplification is exponential and generates a sigmoidal curve.
LOD	The minimum copies of target nucleic acid that must be present in the sample to be detected by the device. This value is specific to the assay.
Lyophilization	The process of dehydration, which is used to preserve biological material and reagents, without the need to store at cold temperatures and significantly extending the shelf life of the product. Commonly known as freeze-drying.
Lysis	Breaking down the external layer of the target (cell membrane/wall or viral capsid) to release the contents, such as nucleic acids, into the solution prior to sample extraction. This is the main purpose of the BLB in the first chamber of any type of M1 cartridge.
Master Mix	Basic components needed for any PCR reaction to occur, such as enzymes, ions, and free nucleotides. This mix does not contain target-specific components.
Negative Control	These are implemented in PCR to verify that no component of the test (such as RPC buffer, M1 Sample Prep, or Go-Strips) or lab equipment (pipette tips, etc.) has been contaminated with target nucleic acids, or inhibitory contaminants. These controls ensure that the positive results generated are in fact positive and not due to contamination. The specific type of negative control most used in PCR is an NTC (No Template Control).
Negative Result	<p>A result where amplification did not occur in the target channel(s), meaning the target(s) were not present in the raw sample, and therefore not detected.</p> <p>As stated in the Biomeme SARS test IFU, when the RPC (amber channel – internal positive control) amplifies but the S target (red channel – SARS gene) and Orf1ab target (green channel – SARS gene) do not.</p>
No Template Control	This is the type of negative control used specifically in PCR. A solution free of any nucleic acids is processed as a normal sample, run as a normal sample, and is expected to give a negative result in all channels. This controls for reagent and/or environmental contamination and good lab practices, and ensures the positive results generated with real samples are in fact positive.
Orf1ab (gene target)	1 of 2 SARS genes in the Biomeme SARS assay, represented by the green channel. This gene is specific to the coronavirus family of viruses.
PCR	A method of synthesizing duplicate copies of the target genetic material if present, which can be applied to diagnostics testing.
Positive Control	Used to verify that the diagnostic methods are capable of adequately recovering, extracting, amplifying, and detecting the targets. This is done by using a sample that is known to contain the target genetic material, and processing and running it as a normal sample. This control ensures that the testing methods can identify a positive sample.

OTHER TERMS	
Positive Result	A result that shows both a sigmoidal curve AND have a Cq < 40. Please refer to the Biomeme SARS IFU for specific types of positive results.
PPE	Equipment such as a lab coat, goggles, gloves, etc. that is used to protect the technician from potential biological hazards in the lab.
Presumptive Positive	These are results that seem positive but are unlikely to be true positives and may be due to other reasons, but to err on the side of caution, the result is presumed as positive until the result is confirmed with a second test. Please refer to the Biomeme SARS IFU for more details and next steps.
Protocol	This is the set of directions for the thermocycler that is optimized for the specific assay. This defines the temperatures for each step, the length of time per step, and the number of total cycles for the entire PCR reaction.
Purified Sample	Often called an “extracted sample” or an “extract”, this is what the raw sample is called after it has gone through sample extraction and has been purified. Nucleic acids are highly unstable in this form, and this solution must be used within 4 hours from the time of extraction.
QR Code	A matrix bar code found on the pouch of Go-Strips or Go-Plates that is linked to the PCR protocol specific to that assay type.
Raw Sample	The collected sample before it has been extracted/purified using sample extraction methods.
Raw View (on Biomeme Cloud)	This view plots the raw, unprocessed data that the device has detected throughout the reaction.
Real-Time PCR	Quantitative PCR where results are available live, after every cycle during the reaction.
Room Temperature	At Biomeme, defined as 15°C – 30°C, as is the storage recommendation for majority of products. In a biology lab, typically defined as 20°C – 25°C.
RPC (MS2 gene target)	In the Biomeme SARS assay, the amber channel represents the internal positive control which is called this. The target is a MS2 bacteriophage.
RT-PCR	The type of PCR for all RNA sample types, where cDNA must be synthesized prior to the start of PCR, because PCR can only be done on double stranded nucleic acids. It is named Reverse Transcriptase PCR due to the name of the enzyme that synthesizes cDNA from RNA, called reverse transcriptase.
S (gene target)	1 of 2 SARS genes in the Biomeme SARS assay, represented by the red channel. This gene is specific to SARS-CoV-2.
SARS-CoV-2	The name of the virus that is detected using the Biomeme SARS assay, that causes the disease COVID-19.

OTHER TERMS	
Sigmoidal Curve	A curve that is indicative of amplification (target presence) in PCR tests. In PCR, the amount of product doubles from each cycle to the next if the target is present, which is exponential growth, and when plotted, shows as an S-shaped curve. A sigmoidal curve shows a section of truly exponential growth, but soon starts to look linear and then plateaus when the finite resources in the reaction are used up.
Threshold	In PCR, this represents the point at when the amount of product that has amplified is enough to confidently be detected and distinguished from noise. In the Biomeme Cloud on the amplification plot, this is depicted as dashed line.
Variant	A subtype of the virus that has small difference in its sequence, such as mutations, deletions, or insertions. These mutations may or may not impact the PCR test's ability to accurately detect it. The ability to detect a variant depends on the design of the test, which varies between manufacturers. Biomeme analyzes all variants of concern to confirm compatibility with our test. To date, Biomeme's SARS assay detects all SARS-CoV-2 variants of concern.
Viral Load	The number of copies of the virus's genome in the raw sample. This can provide insight to the severity of the infection or potential for transmission. One benefit to qPCR is that it can indicate the viral load of the starting sample either quantitatively, or semi-quantitatively.
VTM Viral Transport Media	A formulation of buffers, proteins, and more that stabilize the raw sample until it can be analyzed and prevent early degradation of the sample. Biomeme's DNA/RNA Preservation Buffer is the VTM used for SARS-CoV-2 testing, which has the added benefit of inactivating the virus to lower the potential risks of working with the virus.

Technical Support

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

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