

Biomeme

SARS-CoV-2

Go-Plates

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.



Biomeme SARS-CoV-2 Go-Plates

Biomeme **SARS-CoV-2 Go-Plates** detect the RNA of severe acute respiratory syndrome coronavirus 2 that causes coronavirus disease 2019 (COVID-19), also known as “2019-nCoV” or “Wuhan coronavirus.”

The Biomeme test detects two different SARS-CoV-2 genes and is multiplexed together with Biomeme's RNA Process Control (RPC) for RNA extraction and RT-PCR (MS2 bacteriophage). Each of reaction well of the 96-well Go-Plate contains lyophilized master mix, enzymes, and multiplexed primer/probes for the following triplex reaction:

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

Each order contains one 96-well Go-Plate, which is shelf-stable if unopened. Biomeme Go-Plates are compatible for use on standard lab-bound real-time PCR thermocyclers (e.g., ABI 7500 Fast Dx, QuantStudio5 Fast, Bio-Rad CFX96). Please contact support@biomeme.com for further instruction on cutting Go-Plates for use on a Franklin three9.

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).*

Contents of Go-Plate Pouch

CONTENTS	DESCRIPTION
1x large foil pouch	The test pouch contains a 96-well PCR Go-Plate with your lyophilized assay reactions and void filling caps.
10x small clear bags	Each small clear bag includes: <ul style="list-style-type: none"> • 1x small foil pouch with a screw cap tube containing a lyophilized pellet of quantified MS2 to be used as your RNA Process Control (RPC) • 1x 2mL screw cap tube containing 200 uL of pre-aliquoted RPC Buffer used to resuspend the lyophilized RPC pellet. 1x resuspended RPC is enough positive control for 10x samples when using Biomeme M1 Prep

Technical Characteristics

SPECIFICATIONS	VALUE
PCR Tube Capacity	0.1 mL
PCR Reaction Volume	20 µL
Caps	Seal Go-Plates with adhesive thermal PCR seal (not included)
DNA-dependent DNA-polymerase	Hotstart Taq polymerase (1 min. activation @ 95°C)
Reverse transcriptase	Thermostable RNase H ⁺ recombinant MMuLV (2 min. RT step @ 55°C)
Nucleotides	Proprietary mix of dNTPs
Buffer	Tris pH 8.8 Salts and enhancers for 5' nuclease assays
Mg ⁺⁺	6 mM
Storage	15-30°C
Dissolution time	~60s

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

Multiplex Assay Characteristics

Target	WELL LOCATION	COLOR CHANNEL
SARS-CoV-2-Orf1ab gene	All	Green (FAM)
SARS-CoV-2-S gene	All	Red (ATTO647N)
RNA Process Control (Exogenous RNA Extraction and RT-PCR Process Control (MS2))	All	Amber (TexasRedX)

Example Protocol

1. Open the foil pouch, remove and unscrew the cap on one tube containing a pellet of RPC (RNA Process Control).
2. Open one screw cap tube containing 200uL RPC Buffer.
3. Drop the 1e5 pfu RPC pellet into the buffer tube to reconstitute the RPC.
4. When extracting and purifying your sample, add a portion of the resuspended RPC directly into the prep (add 20uL to the **Red** chamber of the Biomeme M1 Sample Prep cartridge, if using a Biomeme prep).
5. Close the RPC Buffer tube.
 - a. *Once resuspended, the RPC Pellet can be refrigerated at 4 °C for up to one week. It can also be frozen at -20 °C but we caution against frequent freezing and re-thawing as it will degrade the control.*
6. Continue prep as usual.
7. Transfer prepped eluate (containing extracted MS2 RNA from the RPC pellet) to the SARS-CoV-2 Go-Plate. 1 sample extraction can be used for each well of the Go-Plate (96 samples per Go-Plate, not including any wells you may reserve for additional controls or replicates).
8. Transfer Go-Plate to thermocycler.

9. Cover the wells with standard, optically clear PCR film (rather than the Biomeme void filling caps) before placing into thermocycler
 - a. If running on a QuantStudio thermocycler, please use the MicroAmp™ 96-Well Tray/ Retainer Set Capacity: 96 wells (catalogue # 4381850)

Note: For additional tips, How-To videos, and best practices for our Sample Prep system, please visit our Biomeme Sample Prep Guide, available at: <https://help.biomeme.com/sample-prep-guide>

Thermocycling Parameters

	Temperature (°C)	Duration
RT Step	55	120 secs
Initial Denature	95	60 secs
Cycling Denature	95	1 secs
Annealing	60	20 secs
Extension	N/A	N/A
Melt Curve	N/A	N/A
Number of Cycles: 45		Total Reaction Volume: 20 uL

In Silico Analysis

Inclusivity:

The SARS-CoV-2 primer and probe sets for both Orf1ab and S gene targets have 100% homology to published sequence from NCBI.

Cross-reactivity (Exclusivity):

The Orf1ab R primer returned 90% homology to SARS-CoV, however when primer BLAST was performed (which takes into account the Forward primer and the ability for PCR amplicon production) no target templates were found to SARS-CoV.

All other primers and probes had <80% homology to exclusive organisms listed below.

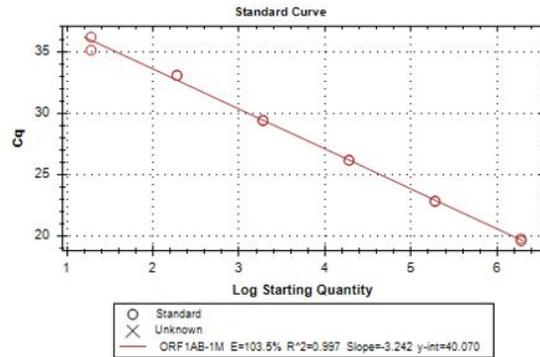
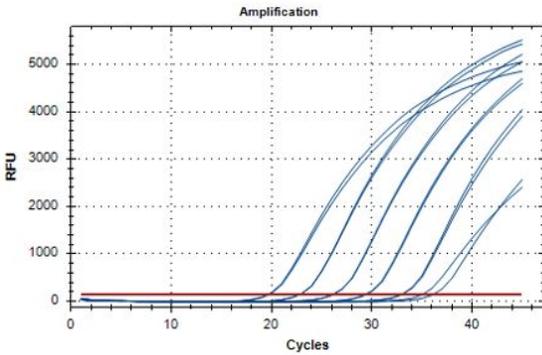
Human coronavirus 229E (taxid:11137)
Human coronavirus OC43 (taxid:31631)
Human coronavirus HKU1 (taxid:290028)
Human coronavirus NL63 (taxid:277944)
MERS coronavirus (taxid:1335626)
Human adenovirus B (taxid:108098)
Human adenovirus D (taxid:130310)
Human adenovirus C (taxid:129951)
Human adenovirus B1 (taxid:565302)
Human adenovirus 7 (taxid:10519)
Human adenovirus B7 (taxid:10519)
Human adenovirus E (taxid:130308)
Adenovirus type 8 (taxid:31545)
Human adenovirus F (taxid:130309)
Human metapneumovirus (taxid:162145)
Human parainfluenza virus 1 (taxid:12730)
Human parainfluenza virus 2 (taxid:1979160)
Human parainfluenza virus 3 (taxid:11216)
Human parainfluenza virus 4 (taxid:1979161)

Influenza A virus (taxid:11320)
Influenza B virus (taxid:11520)
Human enterovirus A (taxid:138948)
Human enterovirus B (taxid:138949)
Human enterovirus C (taxid:138950)
Human respiratory syncytial virus (taxid:11250)
Rhinovirus (taxid:12059)
Chlamydia pneumoniae (taxid:83558)
Haemophilus influenzae (taxid:727)
Legionella pneumophila (taxid:446)
Mycobacterium tuberculosis (taxid:1773)
Streptococcus pneumoniae (taxid:1313)
Streptococcus pyogenes (taxid:1314)
Bordetella pertussis (taxid:520)
Mycoplasma pneumoniae (taxid:2104)
Pneumocystis jiroveci (taxid:42068)
Candida albicans (taxid:5476)
Pseudomonas aeruginosa (taxid:287)
Staphylococcus epidermidis (taxid:1282)
Staphylococcus group (taxid:90964)

Performance Characteristics

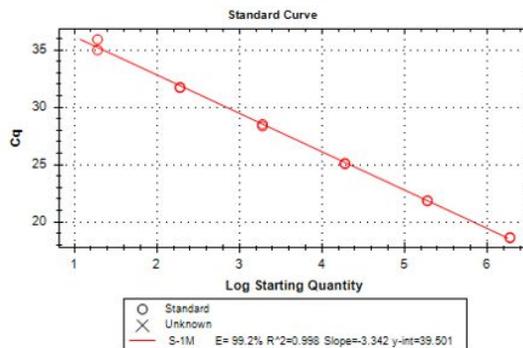
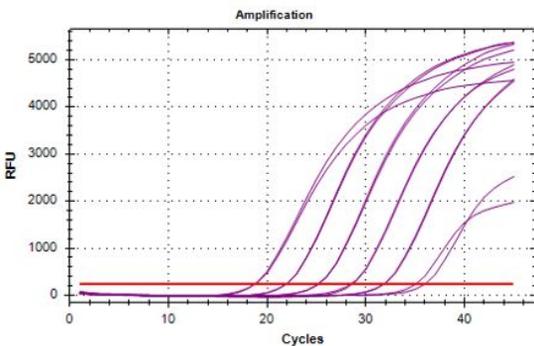
SARS-CoV-2 Orf1ab

Amplification plots of multiplexed Orf1ab ivt-RNA in serial dilution from 2×10^6 — 20 copies/reaction in lyophilized LyoRNA 2.0 Master Mix. Efficiency of 103.5%. Limit of detection not determined.



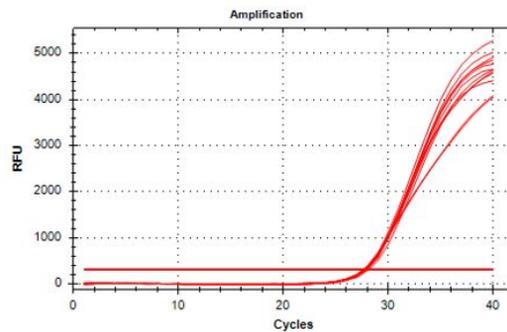
SARS-CoV-2 S

Amplification plots of multiplexed S ivt-RNA in serial dilution from 2×10^6 — 20 copies/reaction in lyophilized LyoRNA 2.0 Master Mix. Efficiency of 99.2%. Limit of detection not determined.



RNA Process Control (Exogenous RNA Extraction and RT-PCR Control - MS2)

Amplification of multiplexed MS2 RNA extraction and RT-PCR process control in lyophilized LyoRNA 2.0 Master Mix.



Storage

Go-Plate pouches should be stored in a dry place, at room temperature (15-30°C). The individual foil pouches containing a single Go-Plate are stable under these conditions if unopened. See the pouch label for expiration date.

Individual Go-Plates should be used within a reasonable period of time after removal from individual foil pouch. Once opened, the dry reagent resists high humidity for up to one hour.

Disclaimer

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/) (https://biomeme.com/privacy-policy-and-terms-of-use/).

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