PRODUCT SHEET

Biomeme

Biomeme SARS-CoV-2 Go-Strips

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.

Last Updated: 08/24/2020

Biomeme SARS-CoV-2 Go-Strips

Biomeme **SARS-CoV-2 Go-Strips** 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 reaction well of the 3-well Go-Strip 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)

Go-Strips are designed for the Biomeme Franklin™ mobile handheld qPCR device. Please contact support@biomeme.com for further instruction on running Go-Strips on the Bio-Rad CFX96 and ABI 7500 and QuantStudio5 using the “fast” block.

***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-Strips

CONTENTS	DESCRIPTION
1x pre-cut tray of 32 Go-Strips	Each tray includes 32 Go-Strips, each with three reaction wells (96 rxns). These strips contain the lyophilized Biomeme SARS-CoV-2 assay.
1x small clear bag	Each clear bag contains: • 1x small foil pouch with a 2mL screw cap tube containing a lyophilized pellet of quantified MS2 to be used as your RNA Process Control (RPC). • 1x screw cap tube containing 5mL of pre-aliquoted RPC Buffer used to resuspend the lyophilized RPC pellet. 1x resuspended RPC is enough positive control for 250 sample extractions when adding 20 uL to each extraction. • 1x transfer pipette (1mL)

Technical Characteristics

SPECIFICATIONS	VALUE
PCR Tube Capacity	0.1 mL
PCR Reaction Volume	20 µL
Caps	Biomeme Void Filling Cap (required for correct operation on Franklin thermocycler)
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	1, 2, 3	Green (FAM)
SARS-CoV-2-S gene	1, 2, 3	Red (ATTO647N)
RNA Process Control (Exogenous RNA Extraction and RT-PCR Process Control (MS2))	1, 2, 3	Amber (TexasRedX)

Example Protocol

1. Unscrew the 2mL tube containing a pellet of RPC (RNA Process Control).
2. Open the screw cap tube of 5mL pre-aliquoted RPC Buffer.
3. Use the 1mL transfer pipette to transfer approximately 0.5-0.75mL of the RPC buffer to the 2 mL tube containing the RPC pellet.
4. Pipette up and down to thoroughly mix.
5. Using the same transfer pipette, transfer the entire contents of the 2mL tube to the 5mL tube of RPC buffer. Shake thoroughly to ensure proper mixing.
6. When extracting and purifying your sample, add a portion of the resuspended RPC directly to the crude sample (add 20uL directly into the **Red** chamber of the Biomeme M1 Sample Prep cartridge, if using a Biomeme prep).
7. Close the RPC Buffer tube.
    a. *Once resuspended, the RPC Pellet can be refrigerated at 4 ℃ for up to one week. It can also be frozen at -20 ℃ but we caution against frequent freezing and re-thawing as it will degrade the control.*
8. Continue prep as usual.

9. Transfer prepped eluate (containing extracted MS2 RNA from RPC pellet) to the SARS-CoV-2 Go-Strips. 1 sample extraction for each well (not including any wells you may reserve for additional controls or replicates).
10. Transfer Go-Strips to the Franklin™ thermocycler.
11. Use the app to set-up and begin your run.

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 for Use on Franklin

	Temperature (℃)	Duration
RT Step	55	120 secs
Initial Denature	95	60 secs
Cycling Denature	95	3 secs
Annealing	60	30 secs
Extension	N/A	N/A
Melt Curve	N/A	N/A
Number of Cycles: 45		**Total Reaction Volume:** 20 uL

In Silico Analysis

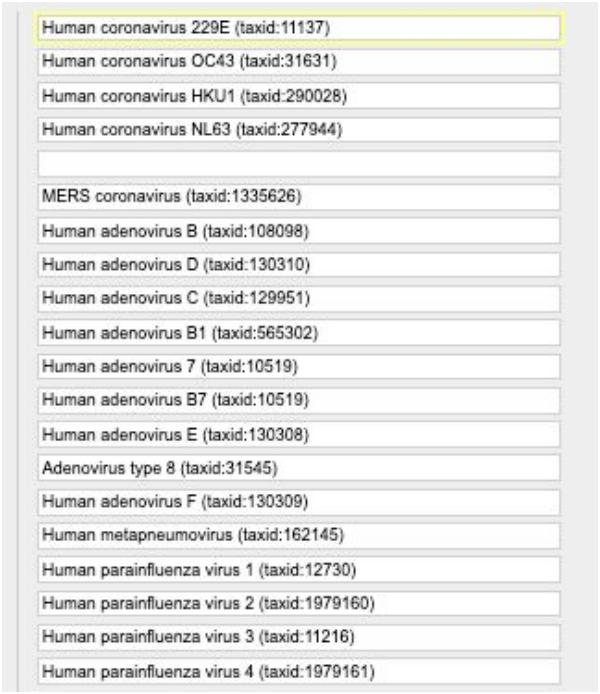
Inclusivity:

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.

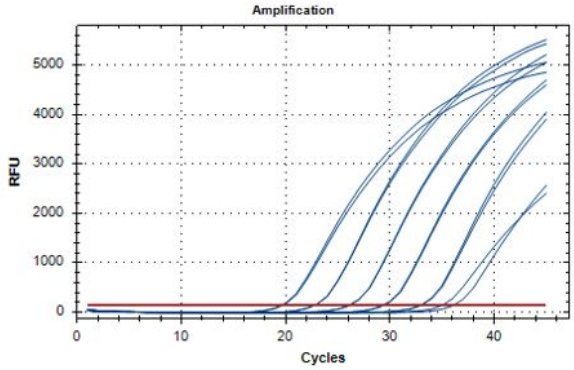
All other primers and probes had <80% homology to exclusive organisms listed below.

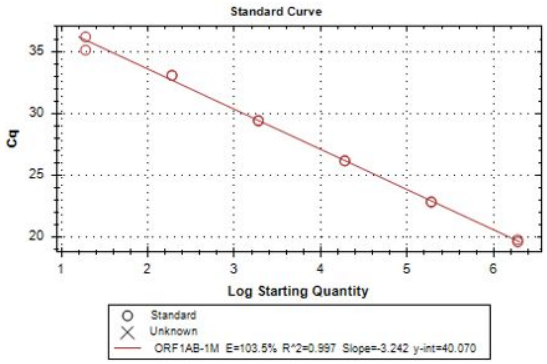


Performance Characteristics

SARS-CoV-2 Orf1ab

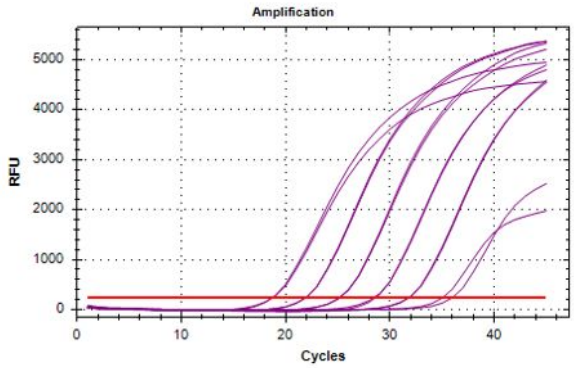
Amplification plots of multiplexed Orf1ab ivt-RNA in serial dilution from 2e6 — 20 copies/reaction in lyophilized LyoRNA 2.0 Master Mix. Efficiency of 103.5%. Limit of detection not determined.

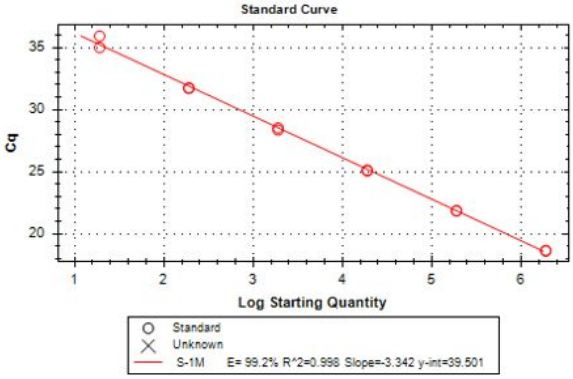




SARS-CoV-2 S

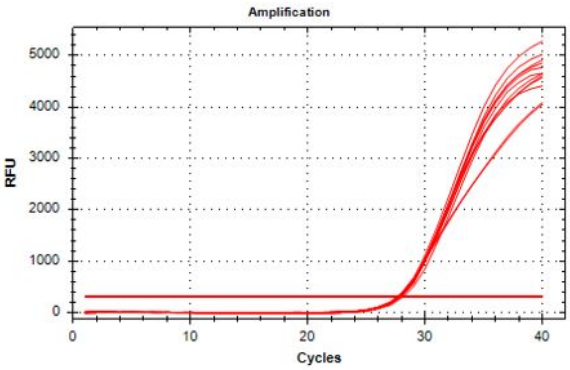
Amplification plots of multiplexed S ivt-RNA in serial dilution from 2e6 —20 copies/reaction in lyophilized LyoRNA 2.0 Master Mix. Efficiency of 99.2%. Limit of detection not determined.





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

Individual test strips 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.

Once resuspended, the RPC Pellet can be refrigerated at 4 ℃ for up to one week. It can also be frozen at -20 ℃ but we caution against frequent freezing and re-thawing as it will degrade the control.

NOTE: *Once the large pouch has been opened, ensure that it is closed completely between use to provide additional protection for the small pouches inside.*

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

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