

PRODUCT SHEET



# Biomeme

# SARS-CoV-2

# Go-Strips

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# Biomeme SARS-CoV-2 Go-Strips

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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 of 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](mailto: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 Pouch

CONTENTS	DESCRIPTION
10x small test strip pouches	Each small test pouch with a QR code contains a 3-well PCR Go-Strip with your lyophilized assay reactions and a void filling cap.
3x small clear bag	The small clear bag includes: <ul style="list-style-type: none"> <li>• 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)</li> <li>• 1x 2mL screw cap tube containing 200 <math>\mu</math>L 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</li> </ul>

## Technical Characteristics

SPECIFICATIONS	VALUE
PCR Tube Capacity	0.1 mL
PCR Reaction Volume	20 $\mu$ L
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 <sup>++</sup>	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 tube containing a pellet of RPC (RNA Process Control).
2. Open the 2mL screw cap tube of 200uL pre-aliquoted RPC Buffer.
3. Drop the RPC pellet into the buffer tube to reconstitute the RPC. 1x resuspended RPC contains enough positive control for 10x samples.
4. 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).
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 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).
8. Transfer Go-Strips to the Franklin™ thermocycler.
9. 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 (°C)	Duration
<b>RT Step</b>	55	120 secs
<b>Initial Denature</b>	95	60 secs
<b>Cycling Denature</b>	95	3 secs
<b>Annealing</b>	60	30 secs
<b>Extension</b>	N/A	N/A
<b>Melt Curve</b>	N/A	N/A
<b>Number of Cycles: 45</b>		<b>Total Reaction Volume: 20 uL</b>

## 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.

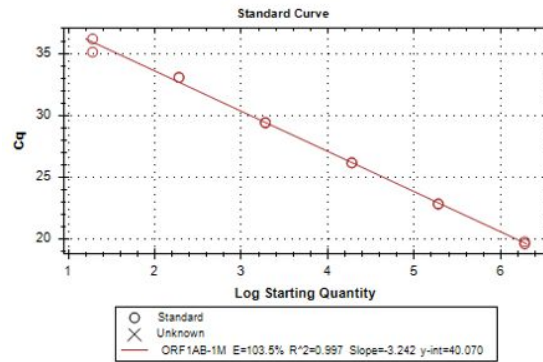
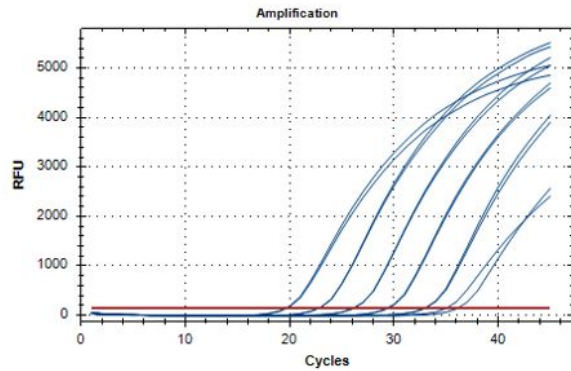
All other primers and probes had <80% homology to exclusive organisms listed below.

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

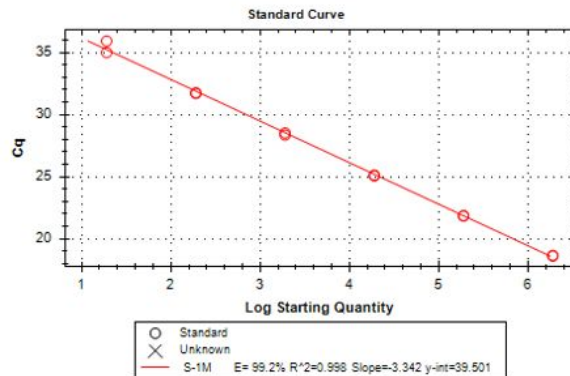
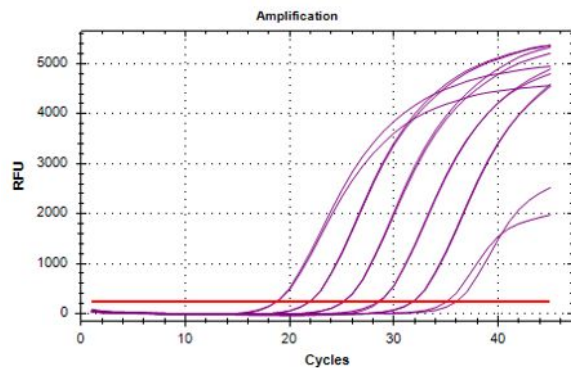
### SARS-CoV-2 Orf1ab

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



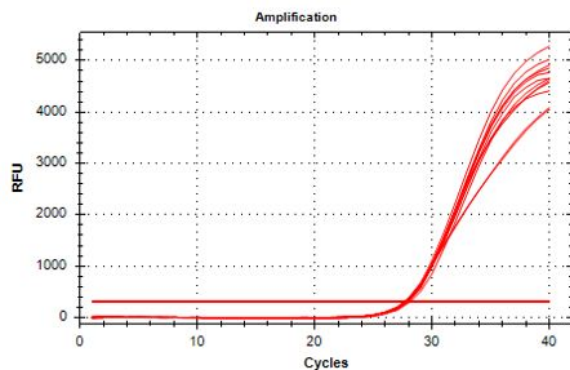
### SARS-CoV-2 S

Amplification plots of multiplexed S ivt-RNA in serial dilution from  $2 \times 10^6$  — 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-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.

**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

**For Research Use Only.** Not for use in human or veterinary diagnostics. The performance characteristics of this product have not been established.

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.

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