

SARS-CoV-2 Go-Strips

Setup Sample Prep Tray 1 000 000 io-Strip connections Go-Strip connections (i) NOTE You can store your clean accessories in the upside down tray lid. Tube for Raw Sample Cartridge Tube for **Purified Sample** Prepare RNA Process Control (MS2) 2 Your RPC is now ready. Cap the 5 mL tube. .5-0.75 mL Entire Volume The resuspended RPC has a Buffer Buffer Buffer

Pipette up and

down to mix

RPC Pellet

2 ml

RPC Buffer

5 ml

maximum shelf life of 2 days when stored at room temperature. For longer term storage, aliquot out and freeze at -20°C for up to three months.

3 Add Sample to Cartridge

Pipette up and

down to mix

RPC Pellet

2 mL

RPC Buffer

5 mL



RPC Buffer

5 mL



Incubate at room temperature for at least 10 minutes

4 Add RPC to Cartridge



5 Sample Extraction

1) At the start of each step, pierce foil twice in the indicated circles.



2) Insert the syringe tip into the big hole and pump the No. of times indicated to bind DNA/RNA to the inside of the syringe tip and wash away debris.

Additional pumps in each cartridge section beyond the specified number will not adversely affect extraction performance.



3) Fully expel the liquid from the syringe.

4) Rock the syringe far forward and far back to increase the foil opening and be able to easily remove the syringe.



- 5) Move to the next step to pump the indicated times and continue washing the DNA/RNA bound inside the column tip.
- 6) When doing the 20x Air Dry step, **vigorously pump** the syringe to dry the tip as much as possible.



- Visually inspect the barbed column tip for liquid before entering the last chamber. If there is liquid present, perform the air-dry step again.
- 7) Move to the final step to unbind and wash the DNA/RNA off the syringe tip and into the Green chamber.
- Transfer all of your elution liquid from the green section of the cartridge into the empty Transfer Tube located in the lower right corner of your tray.



Cap and move the filled Transfer Tube to slot 1 of the Pure Samples row of your tray.



6 Decontaminate & Reload

Store or dispose of your sample collection tube, dispose of your syringe and sample prep cartridge, and clean your work surface and the lower prep area of your tray.

Reload the lower row of your tray with new materials for your next sample extraction.

7 Load Samples into Go-Strips

Place Go-Strips into tray, remove foil seal from Go-Strip in slot A. Ensure connections between the tubes face the back of test tray.









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.

8 Place Go-Strips into Franklin[™] Thermocycler

Once all Go-Strip wells are filled with void filling caps set, begin placing them into the Franklin from Left to Right

Make sure the strip connections are visible through the void filling cap cutouts and facing the back of the thermocycler.









Make sure the strip connections are visible through the void filling cap cutouts and facing the back of the thermocycler.

9 Start Run



Scan QR code on test pouch.

Proceed to follow the step-by-step tutorials to begin your PCR test.



10 Interpreting Results

SARS-CoV-2 Orf1ab Target	SARS-CoV-2 S Target	RPC (MS2)	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 the sender and appropriate public health authorities.
(Cq ≤ 40)	(Cq > 40)	(+	Presumptive Positive	Re-extract the sample and run the rRT-PCR again. Report presumptive positive results to sender and appropri- ate 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 SARS-CoV-1 or other Sarbecovirus currently unknown to infect humans, for epidemiological purposes or clinical management.
(Cq>40)	(Cq > 40)	Θ	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.

See comprehensive IFU or help.biomeme.com for QC Material Pass/Fail Criteria.



Dot Matrix

Columns 1, 2 and 3 are your reaction wells (e.g. 1-3, 4-6, and 7-9). The letters indicate the channel (*Green, Amber, Red*). Solid dots indicate your target was detected while empty dots indicate the opposite.



Cq Values A Cq value greater than 0 indicates your target was detected.



Amp Plot

View the fluorescent signal for each channel plotted against the cycle number over the duration of your PCR experiment.

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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USA Only:

- This test has not been FDA cleared or approved;

This test has been authorized by FDA under an EUA for use by authorized laboratories;
This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and

- This test 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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