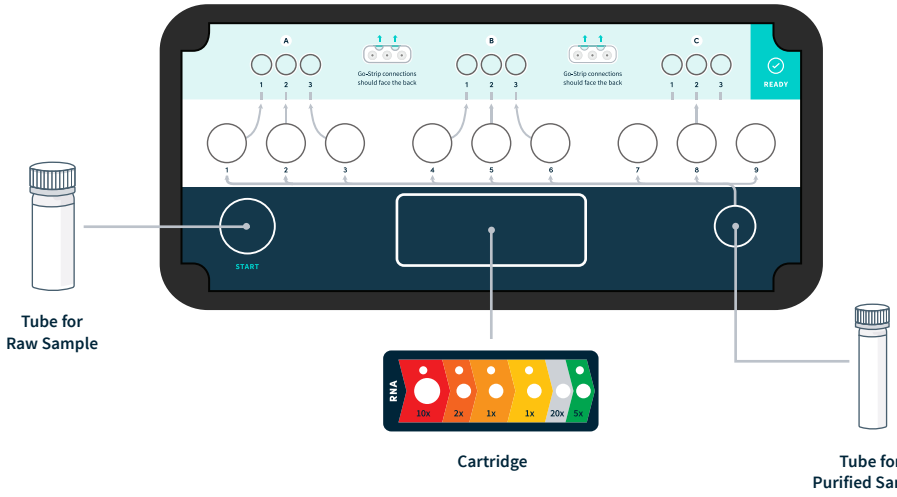
QUICK START GUIDE

Biomeme

SARS-CoV-2 Go-Strips

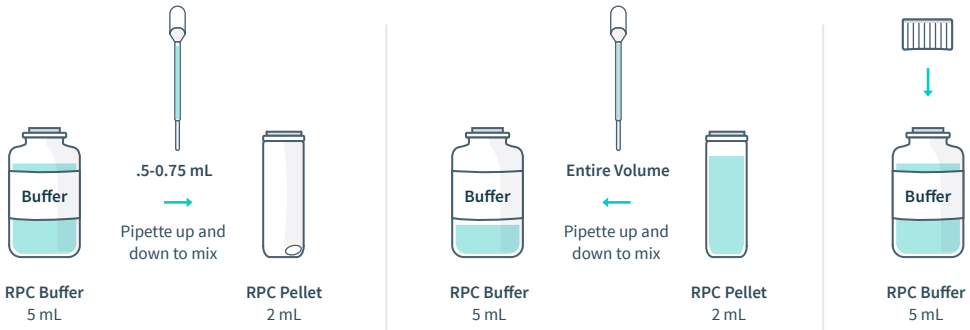
1 Setup Sample Prep Tray



NOTE

You can store your clean accessories in the upside down tray lid.

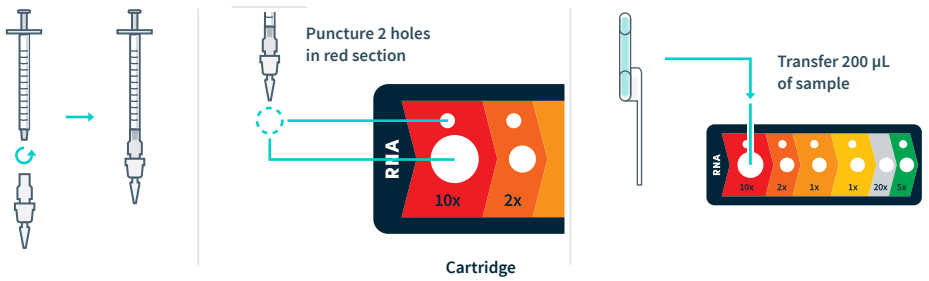
2 Prepare RNA Process Control (MS2)



Your RPC is now ready. Cap the 5 mL tube.

To extend shelf-life, keep resuspended RPC refrigerated for up to 1 week or aliquot and freeze.

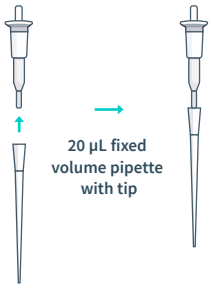
3 Add Sample to Cartridge

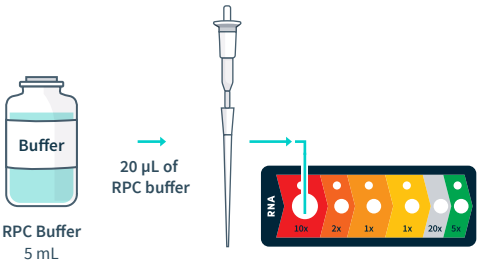


10 mins

Incubate at room temperature for at least 10 minutes

4 Add RPC to Cartridge





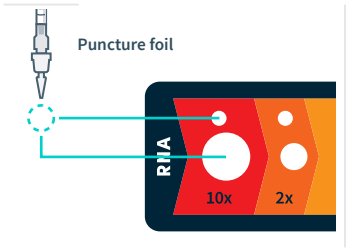
NOTE

With this step, there is no need to wait 10 minutes before adding RPC.

You can incubate multiple cartridges at once, set aside, and then extract samples one at a time.

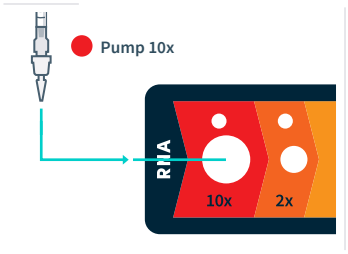
5 Sample Extraction

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



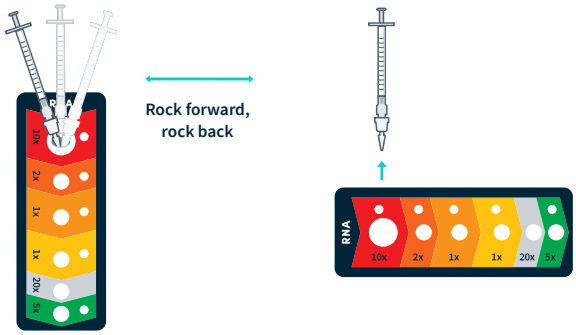
2) Insert the syringe tip into the big hole and pump the No. of times indicated to bind DNA/RNA to the inside of the syringe tip and wash away debris.

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



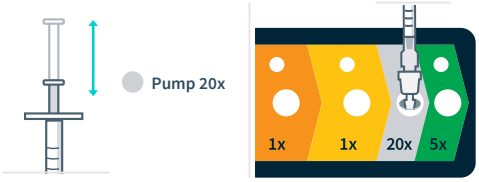
3) Fully expel the liquid from the syringe.

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



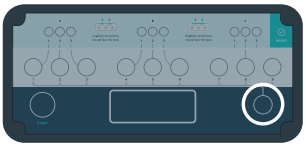
5) Move to the next step to pump the indicated times and continue washing the DNA/RNA bound inside the column tip.

6) When doing the 20x Air Dry step, **vigorously pump** the syringe to dry the tip as much as possible.

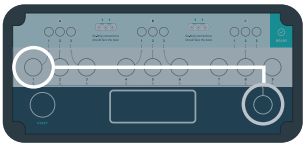


7) Move to the final step to unbind and wash the DNA/RNA off the syringe tip and into the Green chamber.

8) 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.

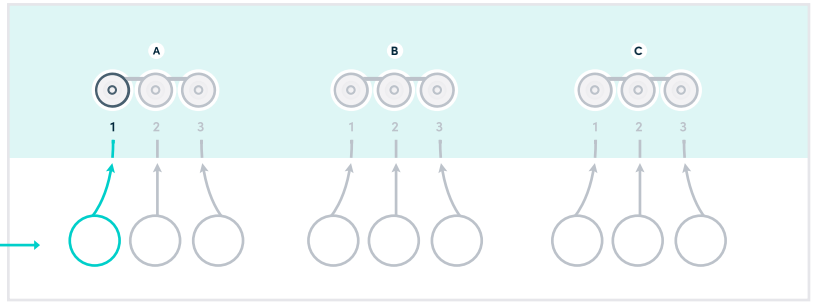
Reload the lower row of your tray with new materials for your next sample extraction.

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.

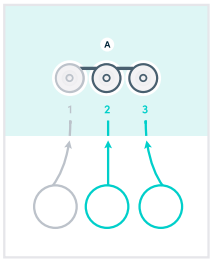
Transfer 20 µL from first Pure Sample to Go-Strip A1

Mix by pipetting up and down 5x

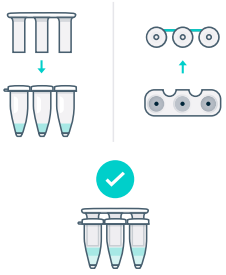


Discard pipette tip

Screw cap back on purified sample tube in slot 1

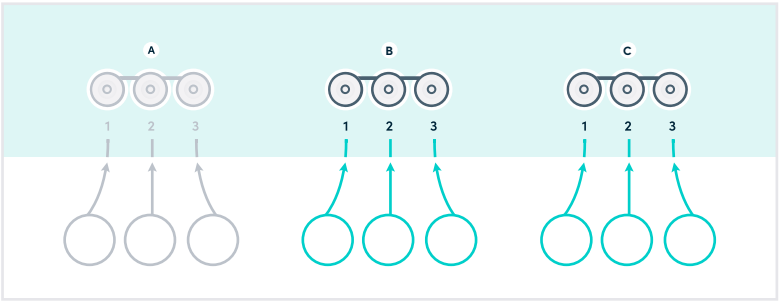


Repeat this process for the remaining 2 reaction wells in Strip A.



Once each well is filled, place a void filling cap into the Go-Strip. Don't press the cap down *(it will be secured by the thermocycler lid)*.

Align the Go-Strip and void filling cap so that the strip connections are visible through the void filling cap cutouts.



Once Strip A is capped, repeat the above process for loading the samples into Strip B and C.

NOTE

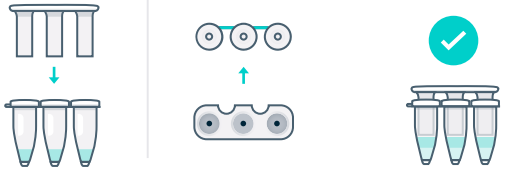
External controls are not provided with the Biomeme SARS-CoV-2 test.

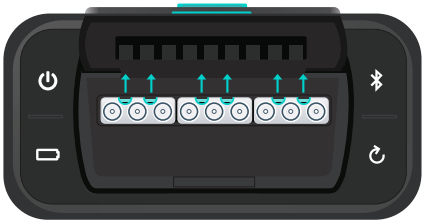
Quality control requirements should be performed in conformance with local, state, and/or federal regulations or accreditation requirements and your laboratory's standard quality control procedures.

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.

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

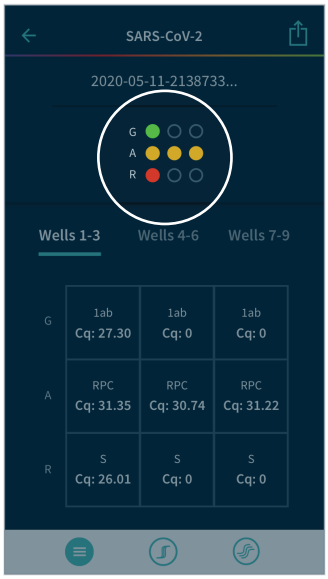
Scan QR code on test pouch.

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

10 Interpreting Results

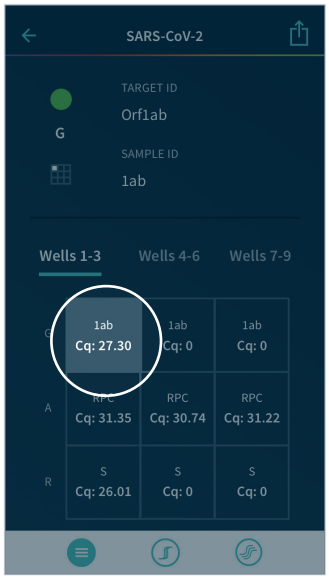
SARS-CoV-2 Orf1ab Target	SARS-CoV-2 S Target	RPC (MS2)	Result	Actions
⊕	⊕	⊕ ⊖	**Positive**	Report results to the sender and appropriate public health authorities.
⊖	⊕	⊕ ⊖	**Positive**	Report results to the sender and appropriate public health authorities.
⊕	⊖	⊕ ⊖	**Presumptive Positive**	Re-extract the sample and run the rRT-PCR again. Report presumptive positive results to sender and appropriate 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.
⊖	⊖	⊖	**Invalid**	Re-extract the sample and run the rRT-PCR again. If the same result is obtained as the first run, report as Invalid.
⊖	⊖	⊕	**Negative**	Report results to sender.

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



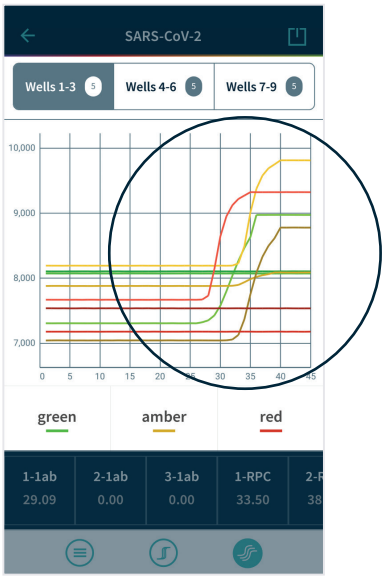
Dot Matrix

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.