

Biomeme RNA Process Control (RPC)

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: 12/13/2021

RNA Process Control (RPC)

Biomeme RNA Process Control (RPC) is a quantified RNA extraction and RT-PCR control (MS2 bacteriophage) in a lyophilized pellet format. It is designed to be resuspended and then added directly to the crude sample and undergo normal sample preparation and extraction. Each order contains 1 pellet which contains enough control for 250 sample extractions once resuspended.

RPC is supplied as a dry reagent to be reconstituted in our RPC Resuspension Buffer (included with every order). A proprietary freeze-drying process ensures the RPC pellet remains stable at ambient temperatures and does not require refrigeration for transport or storage. A single Biomeme RPC pellet resuspended with 5mL RPC Buffer contains MS2 bacteriophage at a concentration of 1e3 PFU.

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

CONTENTS	DESCRIPTION
1x small clear bag	<p>Each clear bag contains:</p> <ul style="list-style-type: none">• 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 20uL to each extraction.• 1x transfer pipette (1mL)

RNA Process Control Preparation

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 2mL 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, again pipetting up and down to mix.
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).
7. Close the RPC Buffer tube.
 - a. *Once resuspended, the RPC pellet can be stored at room temperature for a maximum of 2 days. For longer term storage, aliquot out and freeze at -20 °C to -80 °C for up to three months.*
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>

Storage

Biomeme RNA Process Control (RPC) should be stored in its original packaging at 15-30°C. Once resuspended in the RNA Process Control Buffer, the suspension can be stored at room temperature for a maximum of 2 days. For longer term storage, aliquot out and freeze at -20°C to -80°C for up to three months.

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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