

# M1 Sample Prep Cartridge Kit for RNA 2.0

---

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.

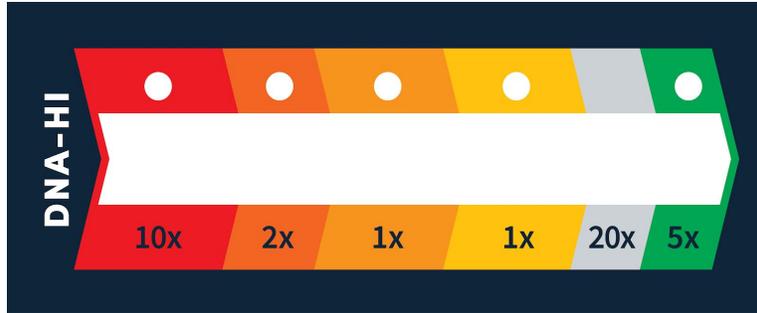
This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Last Updated: 08/24/2020

# Table of Contents

---

Brief Overview	3
Kit Contents	4
Technical Specifications	4
Sample Extraction Protocol	5
1. Sample Collection	5
2. ● Lysis & Binding (10 pumps)	6
3. ● Protein Wash (2 pumps)	6
4. ● Salt Wash (1 pump)	7
5. ● Drying Wash (1 pump)	7
6. ● Air Dry (20+ pumps)	8
7. ● Elution (5 pumps)	8
Disposal of M1 Sample Prep Cartridge	8
Storage	9
Disclaimer	10



# M1 Sample Prep Cartridge Kit for RNA 2.0

---

The Biomeme M1 Sample Prep Cartridge Kit for RNA 2.0 is a mobile solution for the extraction of purified nucleic acids from a variety of different sample types including but not limited to smaller volume liquids (e.g. whole blood) and direct swabs.

This kit requires no lab equipment, refrigeration, electricity, incubation, alcohol precipitation or phenol chloroform extraction. Instead, it utilizes a filtration-based method in which nucleic acids selectively bind to the silica membrane inside Biomeme's proprietary M1 Sample Prep Columns. Subsequent washes through a sequence of specially formulated buffers yields purified nucleic acids upon elution.

**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).

# Kit Contents

ITEM	QUANTITY
RNA Cartridge containing Biomeme Lysis Buffer (BLB), Protein Wash (BPW), Wash Buffer (BWB), Drying Wash (BDW), and Elution Buffer (BEB)	30x
Single-use 1mL syringe	30x
Biomeme Sample Prep Column	30x

# Technical Specifications

SPECIFICATION	VALUE
Sample Amount	25µL-100µL whole blood or Biomeme provided swab (adjustable by user)
Processing	Manual
Elution Volume	0.85mL
Time Per Prep	2-5 minutes

# Sample Extraction Protocol

Samples are lysed by mixing in Biomeme Lysis Buffer (BLB). The lysed sample is then passed through the M1 Sample Prep Column by use of the provided 1 mL luer lock syringe, binding RNA to the silica membrane inside of the column. Subsequent washes remove unwanted material and salts. Finally, purified nucleic acids are eluted off the column into the provided buffer.

Buffers come pre-aliquoted in the provided sample prep cartridges for ease-of-use and the extraction method is designed to be completed in a few simple steps. But, before beginning the sample extraction process, **please take a moment to read these important tips:**

- **Clean your work area between each RNA extraction** to avoid contamination between samples.
- **Puncture 2 holes in each section of the M1 Sample Prep Cartridge** as you move through each step to minimize liquid splatter (except Air Dry step).
- **Pump slowly**, except during the Air Dry step where rapid pumping is required, to not only minimize liquid splatter but to also improve binding to the sample prep column.
- **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>*

# 1. Sample Collection

1. Secure the Sample Prep Column to the 1mL syringe and puncture the first **red** hole of the Sample Prep Cartridge, labeled “START”. Set aside the syringe.
2. Protocols for various sample types are as follows:
  - **25µL-100µL whole blood:** add 25µL-100µL whole blood sample directly into the red section of the cartridge.
  - **Swabs:** immerse swab in the red section of the cartridge and twirl for 5 seconds to disperse sample.

*Note: The volume of sample required is user determined based on the relative abundance of target, sample type, and other factors.*

## ● 2. Lysis & Binding (10 pumps)

1. Place the syringe with the attached Sample Prep Column back into the **red** section of the Sample Prep Cartridge and draw Biomeme Lysis Buffer (BLB) fluid all the way up the syringe and pump all the way back out. Repeat for a total of 10 pumps.
2. Push all fluid in the syringe into the red section of the Sample Prep Cartridge prior to beginning the next step. **Do not transfer any liquid from one section of the sample prep cartridge to the next. This applies to each remaining step of the sample extraction protocol.**

*Note: If the column starts to clog, you will experience an increase in pressure. Do not press harder as this will cause additional clogging. Instead, remove the tip of the sample prep column from the red section of the sample prep cartridge and gently pull back the plunger, wait a few seconds, and slowly push the plunger back down. You should notice some of the liquid discharge at the open end of the syringe. Repeat this process until all liquid has been discharged from the column then proceed to the next step.*

### 3. Protein Wash (2 pumps)

1. Move the 1mL syringe with the attached Sample Prep Column into the **red-orange** section of the Sample Prep Cartridge (Biomeme Protein Wash - BPW) and pierce through the foil. Remember to pierce 2 holes per section of the cartridge to minimize liquid splatter, except during the Air Dry step.
2. Draw the BPW fluid all the way up the syringe and pump all the way back out. Repeat twice assuring that no buffer remains in the syringe before beginning the next step.

### 4. Salt Wash (1 pump)

1. Move the 1mL syringe with the attached Sample Prep Column to the **orange** section of the Sample Prep Cartridge (Biomeme Wash Buffer - BWB) and pierce through the foil.
2. Draw the BWB fluid all the way up the syringe and pump all the way back out once assuring that no buffer remains in the syringe before beginning the next step.

### 5. Drying Wash (1 pump)

1. Move the 1mL syringe with the attached Sample Prep Column to the **yellow** section of the Sample Prep Cartridge (Biomeme Drying Wash - BDW) and pierce through the foil.
2. Draw the BDW fluid all the way up the syringe and pump all the way back out once assuring that no buffer remains in the syringe before beginning the next step.

## ● 6. Air Dry (20+ pumps)

1. Move the 1mL syringe with the attached Sample Prep Column to the **blue** section of the Sample Prep Cartridge and pierce through the foil to remove excess buffer.
2. Draw air up through the syringe and quickly pump back out. Repeat pumping vigorously 20 or more times until the Sample Prep Column appears dry and does not spray fluid droplets.

## ● 7. Elution (5 pumps)

1. Move the 1mL syringe with the attached Sample Prep Column to the **green** section of the Sample Prep Cartridge (Biomeme Elution Buffer - BEB) and pierce through the foil.
2. Elute by drawing the BEB fluid all the way up through the syringe and **slowly** pump back out for a total of 5 pumps.
3. That's it! Transfer 20µL of elution from the green section of the Sample Prep Cartridge into each of your PCR reactions.

*Note: If you wish to store your eluted RNA for later use, transfer all of the eluate to a clean microcentrifuge tube.*

## Disposal of M1 Sample Prep Cartridge

We recommend placing the absorbent material supplied in the sample prep pouch onto the top of the used cartridge and placing everything back into the open pouch. These should then be placed into a separate larger sealed container or bag prior to disposal.

Always dispose of potentially biohazardous solutions according to your local, regional or national waste-disposal guidelines. DO NOT add bleach or acidic solutions directly to the buffers contained in Biomeme's M1 Sample Prep cartridges.

## **Storage**

All components of the Biomeme M1 Sample Prep Cartridge Kit for RNA 2.0 should be stored in a dry place, at room temperature (15-30°C).

# 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](mailto:support@biomeme.com)

[Patent Protected](#)  
(<https://biomeme.com/patents/>)