

SARS-CoV-2, Flu A, Flu B, RSV Open System PCR Reagents

REF 450-118-LMP

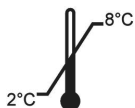


64 Reactions

Product Insert

For Research Use Only: Not for use in diagnostic procedures

For use with Bio-Rad CFX96 Touch™, Bio-Rad CFX384 Touch™



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For Research Use Only

Research use only reagents are not for use in diagnostic procedures. It is the responsibility of the end user to implement for the intended use.

The SARS-CoV-2, Flu A, Flu B, RSV real-time PCR-based detection reagent is manufactured and packaged as an open system reagent (OSR) for use with open system platforms and has to be validated by the user. Examples of open system platforms are the Bio-Rad CFX96 Touch™ and CFX384 Touch™ (Maestro software version 1.1 or later).

PLEASE READ ENTIRE PACKAGE INSERT BEFORE PROCEEDING TO USE THE OSR.

PRODUCT OVERVIEW

The BioGX Sample-Ready™ OSR has been formulated in lyophilized format for the multiplex real-time PCR-based detection of RNA from SARS-CoV-2 (N1; nucleocapsid phosphoprotein gene^{1,2,3}), Influenza A (matrix gene⁴), Influenza B (nonstructural gene⁴), RSV A and RSV B (nucleoprotein gene⁴) and an integrated synthetic single stranded RNA that serves as an Internal Amplification Control (IAC). The assay format for the lyophilized Sample-Ready OSR kit is available for:

1. Bio-Rad CFX96 Touch™ and Bio-Rad CFX96 Touch™ Platforms **REF 450-118-LMP**

Note:

OSR for Bio-Rad CFX96 Touch™ and Bio-Rad CFX96 Touch™ Platforms (450-118-LMP) contain all PCR primers, probes, enzymes, dNTPs, MgCl₂, buffers, and other components required for the PCR reaction. Synthetic single stranded RNA sequence is included in the OSR master mix and serves as Internal Amplification Control (IAC).

PACKAGE CONTENTS

BioGX REF: 450-118-LMP

Platform(s): Bio-Rad CFX96 Touch™ and Bio-Rad CFX96 Touch™

Each 64-reaction package contains:

1. One pouch of 2 x 8-tube strips. Each tube contains BioGX lyophilized Sample-Ready™ OSR sufficient for 4 x 15 µL PCR reactions.

Note: 8-tube strips containing reagents **ARE NOT** compatible with the Bio-Rad CFX platforms.

EQUIPMENT AND MATERIALS REQUIRED BUT NOT PROVIDED

- Lyophilized Positive Control Template RNA Beads (10^5 copies/bead)
 - BioGX SARS-CoV-2 Nucleocapsid phosphoprotein gene (N1) (Part number 720-0206)
 - BioGX Flu A (Part number 720-0002)
 - BioGX Flu B (Part number 720-0003)
 - BioGX RSV A (Part number 720-0181)
 - BioGX RSV B (Part number 720-0182)
- Vortex Genie 2 Vortexer (VWR catalog no. 58815-234) or equivalent
- BioGX Molecular Grade Water or equivalent
 - BioGX Rehydration Water (Part number: 800-0035-12)
- Disposable nitrile gloves
- Bio-Rad CFX96 Touch consumables.
 - Bio-Rad 8-tube PCR strips without caps (catalog no. TLS0851)
 - Bio-Rad Optical flat 8-cap strips for PCR tubes (catalog no. TCS0803)
 - Bio-Rad 96-well plates (catalog no. HSP9655)
 - Bio-Rad 96-well plate sealing film, optical (catalog no. MSB1001)
- Bio-Rad CFX384 Touch consumables.
 - Bio-Rad 384-well plates (catalog no. HSP3905)
 - Bio-Rad 384-well plate sealing film, optical (catalog no. MSB1001)

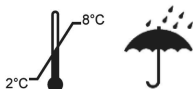
WARNINGS AND PRECAUTIONS



- For research use only. Not intended for use in diagnostic procedures.
- If handling biological samples, including used Extraction Kits and PCR Cartridges, treat as if capable of transmitting infectious agents in accordance with safe laboratory procedures such as those described in CLSI Document M29⁵ and in Biosafety in Microbiological and Biomedical Laboratories⁶.
- BioGX REF: 450-118-LMP has been quality control tested only with the Bio-Rad CFX96 Touch™ and Bio-Rad CFX96 Touch™ real-time PCR platforms.
- Do not use the reagents if the protective pouches are open or torn upon arrival.
- Close reagent protective pouches promptly with the zip seal after each use. Remove any excess air in the pouches prior to sealing and store at 2-8 °C.
- Do not remove desiccant from the PCR master mix pouches.
- Do not use Sample-Ready™ master mix if the desiccant is not present or is broken inside the Sample-Ready™ master mix pouches.
- Do not use reagent tubes if the foil seal has been opened or damaged.

- Do not mix reagents from different pouches and/or kits and/or lots.
- Do not use expired reagents and/or materials.
- Do not pipette by mouth.
- Do not smoke, drink, or eat in areas where samples or kits are being handled.
- Dispose of unused reagents and waste in accordance with country, federal, provincial, state, and local regulations.
- Use clean gloves when handling extraction kit components and PCR reagents and buffer tubes.

STORAGE REQUIREMENTS AND RECOMMENDATIONS



Reagents are stable at a temperature range of 2-30°C during shipment for 5 days, but BioGX recommends long-term storage at 2-8°C. Reagents have been tested to demonstrate optimal performance when stored properly and consumed by the Manufacturer Recommended Use By Date. The end user may opt to extend the useful life for Research Use Only reagents upon completing their own performance validations. BioGX's guarantee of reagent integrity does not extend beyond the Manufacturer Recommended Use By Date when stored properly. Avoid exposing the reagents (lyophilized or rehydrated) to direct sunlight or long-term ambient lighting. Tightly reseal the pouch with unused reactions and immediately return to a refrigerator after opening. To mitigate reagent performance degradation from exposure to moisture, BioGX suggests using the entire contents of the opened pouch within 1 month; however, the user may choose to verify an extended working time > 1 month by performance testing with positive controls and an examination of the sample preparation control target.

SAMPLE TYPES UTILIZED FOR QUALITY CONTROL TESTING

-Swab samples collected in Copan Universal Transport Media (UTM[®]), BD[™] UVT or saline collections

REAGENT OPTICAL CONFIGURATION

Table 1. Optical Channel Configuration for REF 450-118-LMP.

Optical Channel (Fluorophore Equivalent)	Target
FAM	SARS-CoV-2 (N1)
CFO	Flu A
CFR	RSV A/B
Q670	Flu B
Q705	IAC

QUALITY CONTROL AND EXTRACTION TESTING PARAMETERS

Bio-Rad Platforms

As a starting point, users can import and install a PCR run file onto:

1. Bio-Rad CFX96 Touch™ (Maestro software version 1.1 or later)
2. Bio-Rad CFX384 Touch™ (Maestro software version 1.1 or later)

BioGX's most current Bio-Rad CFX96 Touch™ and Bio-Rad CFX384 Touch™ run files utilized for quality control of this product can be obtained by sending an email to TS@biogx.com. Please refer to the Bio-Rad CFX96 Touch™ user manual⁷ for uploading instructions. Please refer to the Bio-Rad CFX384 Touch™ user manual⁷ for uploading instructions.

SAMPLE VOLUMES UTILIZED DURING QUALITY CONTROL TESTING

The end user may choose to validate a different pretreatment method or volume of sample to load other than the sample processing used by BioGX for QC testing as outlined below.

Swab sample (3 mL Copan Universal Transport Media (UTM®))

Bio-Rad Platforms Platforms (validated magnetic bead or silica column extraction kits)

Thoroughly vortex the sample prior to processing. Follow manufacturer recommendations for extraction of appropriate sample volume. Transfer 5 µL to purified nucleic acid to master mix as described in Section: *BioGX Quality Control Test Setup Procedure*.

Swab sample (1 mL Copan Universal Transport Media (UTM[®]))

BioRad Platforms (validated magnetic bead or silica column extraction kits)

Thoroughly vortex the sample prior to processing. Follow manufacturer recommendations for extraction of appropriate sample volume. Transfer 5 µL to purified nucleic acid to master mix as described in Section: *BioGX Quality Control Test Setup Procedure*.

BioGX QUALITY CONTROL TEST SETUP PROCEDURE

Bio-Rad Platforms Quality Control Test Setup

WEAR NITRILE GLOVES WHEN HANDLING LYOPHILIZED REAGENTS TO REDUCE THE GENERATION OF STATIC CHARGES. DO NOT USE LATEX GLOVES.

Assembly of BioGX Reagents

1. Prepare the appropriate number of 8-tube PCR strips or 96-well PCR plates.
2. Transfer 40 µL of molecular grade water to one vial of lyophilized BioGX reagents. The rehydrated master mix is more than sufficient for 4 samples to be tested.

Note: 8-tube strips containing reagents **ARE NOT** compatible with Bio-Rad CFX96 Touch[™] or Bio-Rad CFX96 Touch[™] instruments. Rehydrated master mix must be transferred to 8-tube PCR strips, 96-well or 384-well PCR plates compatible with the instrument.

3. Mix by gently pipetting up and down. (IMPORTANT: Keep rehydrated master mix in a cold block or on ice if setup cannot be completed within 20 minutes. If the rehydrated master mix cannot be used immediately, it can be capped and stored up to 24 hours at 2-8°C, protected from light).
4. Transfer 10 µL of rehydrated master mix to the bottom of 4 empty wells.
5. To each well containing 10 µL of rehydrated master mix, add 5 µL of extracted sample.
6. Affix the appropriate optical caps or optical plate seals.
7. Pulse spin the sealed PCR plate or tube to mix and bring liquid to the bottom.
8. Load 8-tube PCR strips or 96-well or 384-well PCR plates into the real-time PCR platform and start the run. Avoid unnecessary delay once tubes/plates are loaded into the real-time PCR instrument.

ASSAY PERFORMANCE

All BioGX Research Use Only products are designed to detect 20 copies or less of the target nucleic acid per reaction.

INTERPRETATION OF RESULTS

Table 2. Multiplex PCR Results Interpretation for 450-118-LMP.

SARS-CoV-2	Flu A	RSV A/B	Flu B	IAC	Interpretation
+	-	-	-	+/-	SARS-CoV-2 POSITIVE
-	+	-	-	+/-	Flu A POSITIVE
-	-	+	-	+/-	RSV A/B POSITIVE
-	-	-	+	+/-	Flu B POSITIVE
-	-	-	-	+	SARS-CoV-2, Flu A, RSV A/B, Flu B NEGATIVE
-	-	-	-	-	Unresolved*

*Failed PCR due to inhibition, reagent failure or incorrect assembly of PCR reaction.









REFERENCES

1. US Centers for Disease Control and Prevention. 2020. 2019-Novel coronavirus (2019-nCoV) real-time rRT-PCR panel primers and probes.
<https://www.cdc.gov/coronavirus/2019-ncov/downloads/rt-pcr-panel-primer-probes.pdf>
2. US Centers for Disease Control and Prevention. 2020. Revision to Test Instructions CDC 2019 Novel Coronavirus (nCoV) Real-Time RT-PCR Diagnostic Panel (EUA200001).
[https://www.aphl.org/Materials/Signed CDC Letter to PHLs-N3 Removal Instructions 26Feb2020.pdf](https://www.aphl.org/Materials/Signed%20CDC%20Letter%20to%20PHLs-N3%20Removal%20Instructions%2026Feb2020.pdf)
3. US Centers for Disease Control and Prevention. 2020. 2019-Novel coronavirus (2019-nCoV) real-time rRT-PCR panel primers and probes. CDC-006-00019, Revision: 02.
<https://www.fda.gov/media/134922/download>
4. Chen, Yu, et al. "Simultaneous detection of influenza A, influenza B, and respiratory syncytial viruses and subtyping of influenza A H3N2 virus and H1N1 (2009) virus by multiplex real-time PCR." *Journal of clinical microbiology* 49.4 (2011): 1653-1656.
5. Clinical and Laboratory Standards Institute. Protection of laboratory workers from occupationally acquired infections; Approved Guideline. Document M29 (Refer to the latest edition).
6. Centers for Disease Control and Prevention and National Institutes of Health. Biosafety in Microbiological and Biomedical Laboratories. Choosewood L.C. and Wilson D.E. (eds) (2009). HHS Publication No. (CDC) 21-1112.
7. CFX96 Touch, CFX96 Touch Deep Well, CFX Connect, and CFX384 Touch Systems Instruction Manual (refer to the latest version), Bio-Rad Laboratories, Inc., Hercules, California, USA (Refer to the latest version).

Please call BioGX or email info@biogx.com with any questions you may have regarding this product.

Rev. #	Effective Date	Summary of Changes
01	19 JAN 2026	Initial Release.

SYMBOLS

Symbol	Meaning	Symbol	Meaning
	Catalog number		Contains sufficient for <n> tests
	Research Use Only		Manufacturer
	Keep dry		Temperature limitation
	Consult instructions for use		Biological Risks



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