



BioGX

Molecular Made Easy

SARS-CoV-2 (N1), Flu A, Flu B, RSV Open System PCR Reagents

REF 450-066-H-HMP

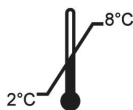


150 Reactions

Product Insert

For Research Use Only: Not intended for In Vitro Diagnostic Use

For use with ABI QuantStudio™ 5, ABI 7500 Fast Dx



RUO



BioGX
1500 First Avenue, North, L136, Birmingham, AL 35203, USA
Phone: +1.205.250.8055
Fax: +1.205.449.8055

For Research Use Only

Research use only reagents are not intended for human or animal diagnostic use. It is the responsibility of the end user to determine the performance of the reagents in an appropriately designed validation study for their intended use.

The SARS-CoV-2 (N1), 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 Applied Biosystems QuantStudio™ 5 (Design & Analysis software version 1.5.1 or later) Applied Biosystems 7500 Fast Dx (SDS software version 1.4 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 a synthetic single stranded RNA that serves as an Internal Amplification Control (IAC). One format for the lyophilized Sample-Ready OSR kit is available:

1. ABI QuantStudio™ 5 and ABI 7500 Fast Dx Platforms
REF 450-066-H-HMP

Note:

OSR for ABI Platforms (450-066-H-HMP) contains 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). No exogenous addition of sample processing control is needed.

PACKAGE CONTENTS

BioGX REF: 450-066-H-HMP

Platform(s): ABI QuantStudio™ 5 and ABI 7500 Fast Dx

Each 150-reaction package contains two pouches:

1. First pouch contains 3 vials of BioGX lyophilized Sample-Ready™ OSR, each tube sufficient for 50 x 15 µL PCR reactions.
2. Second pouch contains 1 vial of BioGX Rehydration Buffer, containing 1600 µL of OSR-specific BioGX Rehydration Buffer H.

EQUIPMENT AND MATERIALS REQUIRED BUT NOT PROVIDED

- Lyophilized Positive Control Template RNA Beads (10⁵ 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
- Disposable nitrile gloves
- Applied Biosystems QuantStudio 5 (0.2 mL) consumables
 - Thermo Fisher optical 8-tube strip (catalog no. 4316567)
 - Thermo Fisher ultra-clear optical caps, strips of 8 (catalog no. AB-0866)
 - Thermo Fisher 96-well optical clear reaction plates (catalog no. A36924)
 - Thermo Fisher 96-well qPCR plate seals (catalog no. AB-1170)
- Applied Biosystems 7500 Fast Dx (0.1 mL) consumables.
 - Thermo Fisher optical 8-tube strip (catalog no. 4358293)
 - Thermo Fisher ultra-clear optical caps, strips of 8 (catalog no. 4323032)
 - Thermo Fisher 96-well optical reaction plates (catalog no. 4346906)
 - Thermo Fisher 96-well qPCR plate seals (catalog no. 4311971)

WARNINGS AND PRECAUTIONS

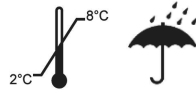


- For research use only. Not intended for human or animal diagnostics use.
- If handling biological samples, treat as if capable of transmitting infectious agents in accordance with safe laboratory procedures such as those described in CLSI Document M29⁵ and in Biosafety in Microbiological and Biomedical Laboratories⁶.
- This test has been optimized only with the Applied Biosystems QuantStudio™ 5 and ABI 7500 Fast Dx 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 master mix if the desiccant is not present or is broken inside the pouches. Do not use reagent vials if they are 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.



- Clean and disinfect all surfaces with a 10% bleach solution followed by molecular grade water.
- Use clean gloves when handling PCR reagents.

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 performance validations. BioGX's guarantee of reagent integrity does not extend beyond the Manufacturer Recommended Use By Date. Avoid exposing the reagents (lyophilized or rehydrated) to direct sunlight or long-term ambient lighting. Store unused rehydrated master mix up to 24 hours at 2-8°C, protected from light. Tightly reseal the pouch with unused vials 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 450-066-H-HMP.

Optical Channel (Fluorophore Equivalent)	Target
FAM	RSV A/B
VIC	SARS-CoV-2 (N1)
TAMRA	Flu B
ROX	Flu A
Cy5	IAC

QUALITY CONTROL AND EXTRACTION TESTING PARAMETERS

ABI Platforms (BioGX REF: 450-066-H-HMP)

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

1. Applied Biosystems QuantStudio™ 5 (Design & Analysis software version 1.5.1 or later)
2. ABI 7500 Fast Dx (SDS software version 1.4 or later)

BioGX's most current ABI QuantStudio™ 5 and ABI 7500 Fast Dx PCR run files utilized for quality control of this product can be obtained by sending an email to TS@biogx.com. Please refer to the Applied Biosystems QuantStudio™5 user manual⁷ for uploading instructions. Please refer to the ABI 7500 Fast Dx user manual⁸ 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[®]), BD[™] UVT or saline collections)

ABI 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 μ L to purified nucleic acid to master mix as described in Section: *BioGX Quality Control Test Setup Procedure for ABI Platforms*.

Swab sample (1 mL Copan Universal Transport Media (UTM[®]), BD[™] UVT or saline collections)

ABI 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 μ L to purified nucleic acid to master mix as described in Section: *BioGX Quality Control Test Setup Procedure for ABI Platforms*.

BioGX QUALITY CONTROL TEST SETUP PROCEDURE

ABI Platforms Quality Control Test Setup

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

BioGX Product 450-066-H-HMP is recommended for use with swab samples collected in 1 or 3 mL collection media (i.e. Copan UTM[®], BD[™] UVT or saline). For validated magnetic bead or silica column nucleic acid extraction method, pipette appropriate volume of sample into the extraction tube/plate and proceed with protocol as per manufacturer's instructions for use.

1. Transfer **500 μ L** of **BioGX Rehydration Buffer H** to one vial of lyophilized BioGX SARS-CoV-2 (N1), Flu A, Flu B, RSV reagents. Mix by gently pipetting up and down with 1000 μ L pipet tip. (IMPORTANT: Keep rehydrated master mix in a cold block or on ice if set-up 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).
2. Transfer **10 μ L** of **rehydrated master mix** to the bottom of **50 empty wells** (8-tube PCR strips or 96-well PCR plate).
3. To each well containing **10 μ L** of **rehydrated master mix**, add **5 μ L** of **extracted sample**.
4. Affix the appropriate optical caps or optical plate seals.
5. Pulse spin the sealed PCR plate or tube to mix and bring liquid to the bottom.
6. Load 8-tube PCR strips or 96-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 450-066-H-HMP.

SARS-CoV-2 (N1)	RSV A/B	Flu B	Flu A	IAC	Interpretation
+	-	-	-	+/-	SARS-CoV-2 POSITIVE
-	+	-	-	+/-	RSV A/B POSITIVE
-	-	+	-	+/-	Flu B POSITIVE
-	-	-	+	+/-	Flu A POSITIVE
-	-	-	-	+	SARS-CoV-2, Flu A, Flu B, RSV A/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
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. QuantStudio™ Design and Analysis software User Guide, ThermoFisher Scientific, Waltham, Massachusetts, USA (Refer to the latest version).
8. Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument Instructions for Use (2012). Life Technologies Holdings Pte Ltd, Singapore. Publication Part Number 4406991 [Rev. E].

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

Rev. #	Effective Date	Summary of Changes
01	29 OCT 2021	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



bioGX
1500 First Avenue, North, L136, Birmingham, AL 35203, USA
Phone: +1.205.250.8055
Fax: +1.205.449.8055