

## ***Package Insert***

# **SARS-CoV-2 N1, N2, E-gene, RNase P, Flu A, Flu B, RSV A/B Open System PCR Reagents**

**REF** 450-060-Series

### **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, N2, E-gene, RNase P, Flu A, Flu B, RSV A/B 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 BD MAX™ System (Windows® Software V4.72A or later), Applied Biosystems QuantStudio™ 5 (Design & Analysis software version 1.5.1 or later), and Bio-Rad CFX96 Touch™ (Maestro software version 1.1 or later) real-time PCR platforms.

**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 (Nucleocapsid phosphoprotein gene region (N1), Nucleocapsid gene region (N2), Envelope gene (E-gene), RNase P gene<sup>1,2,3,4</sup>), Influenza A (matrix gene<sup>5</sup>), Influenza B (nonstructural gene<sup>5</sup>), RSV A and RSV B (nucleoprotein gene<sup>5</sup>) and an Internal Amplification Control (IAC)/Sample Processing Control (SPC) (synthetic single stranded RNA). The synthetic single stranded RNA serves as both a sample extraction control and an internal amplification control. Two different formats for the lyophilized Sample-Ready OSR kits are available:

1. BD MAX™ System  
**REF 450-060-F-MAX S2 (SARS-CoV-2 N1, N2, E-gene, RNase P)**  
**REF 450-060-F-MAX S4 (Flu A, Flu B, RSV A/B)**
2. ABI QuantStudio™ 5 and Bio-Rad CFX96 Touch™ Platforms  
**REF 450-060-LMP MM1 (SARS-CoV-2 N1, N2, E-gene, RNase P)**  
**REF 450-060-LMP MM2 (Flu A, Flu B, RSV A/B)**

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# **SARS-CoV-2 N1, N2, E-gene, RNase P, Flu A, Flu B, RSV A/B Open System PCR Reagents**

**REF** 450-060-Series

### **Note:**

**BD MAX™ System OSR (450-060-F-MAX S2 (SARS-CoV-2 N1, N2, E-gene, RNase P))** contains all PCR primers, probes, enzymes, dNTPs, MgCl<sub>2</sub>, buffers, and other components required for PCR reaction. BD MAX extraction kits available from Becton, Dickinson and Company include a synthetic single stranded RNA sequence which serves as a Sample Processing Control (SPC). No exogenous addition of SPC is needed.

**BD MAX™ System OSR (450-060-F-MAX S4 (Flu A, Flu B, RSV A/B))** contains all PCR primers, probes, enzymes, dNTPs, MgCl<sub>2</sub>, buffers, and other components required for PCR reaction. BD MAX extraction kits available from Becton, Dickinson and Company include a synthetic single stranded RNA sequence which serves as a Sample Processing Control (SPC). No exogenous addition of SPC is needed.

**OSR for ABI and Bio-Rad Platforms (450-060-LMP MM1 (SARS-CoV-2 N1, N2, E-gene, RNase P))** contain all PCR primers, probes, enzymes, dNTPs, MgCl<sub>2</sub>, 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 SPC is needed.

**OSR for ABI and Bio-Rad Platforms (450-060-LMP MM2 (Flu A, Flu B, RSV A/B))** contain all PCR primers, probes, enzymes, dNTPs, MgCl<sub>2</sub>, 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 SPC is needed.

### **PACKAGE CONTENTS**

**BioGX REF:** 450-060-F-MAX S2

**Platform(s):** BD MAX™ System

Each 24-reaction package contains two pouches:

1. First pouch contains 24 sealed BD MAX™ tubes of BioGX lyophilized Sample-Ready™ OSR, each tube sufficient for a 12.5 µL PCR reaction.
2. Second pouch contains 24 sealed BD MAX™ tubes, each containing 25 µL of OSR-specific BioGX Rehydration Buffer.

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# **SARS-CoV-2 N1, N2, E-gene, RNase P, Flu A, Flu B, RSV A/B Open System PCR Reagents**

**REF** 450-060-Series

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**BioGX REF:** 450-060-F-MAX S4

**Platform(s):** BD MAX™ System

Each 24-reaction package contains two pouches:

3. First pouch contains 24 sealed BD MAX™ tubes of BioGX lyophilized Sample-Ready™ OSR, each tube sufficient for a 12.5 µL PCR reaction.
4. Second pouch contains 24 sealed BD MAX™ tubes, each containing 25 µL of OSR-specific BioGX Rehydration Buffer.

**BioGX REF:** 450-060-LMP MM1

**Platform(s):** ABI QuantStudio™ 5 and Bio-Rad CFX96 Touch™

Each 64-reaction package consists of one pouch:

1. The pouch contains 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 ABI QuantStudio™ 5 and Bio-Rad CFX96 Touch™ instruments.

**BioGX REF:** 450-060-LMP MM2

**Platform(s):** ABI QuantStudio™ 5 and Bio-Rad CFX96 Touch™

Each 64-reaction package consists of one pouch:

2. The pouch contains 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 ABI QuantStudio™ 5 and Bio-Rad CFX96 Touch™ instruments.

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# **SARS-CoV-2 N1, N2, E-gene, RNase P, Flu A, Flu B, RSV A/B Open System PCR Reagents**

**REF** 450-060-Series

### **EQUIPMENT AND MATERIALS REQUIRED BUT NOT PROVIDED**

- Lyophilized Positive Control Template DNA Beads (10<sup>5</sup> copies/bead)
  - BioGX SARS-CoV-2 Nucleocapsid phosphoprotein gene (N1) (Part number 720-0206)
  - BioGX SARS-CoV-2 Nucleocapsid phosphoprotein gene (N2) (Part number 720-0207)
  - BioGX SARS-CoV-2 Nucleocapsid phosphoprotein gene (E gene) (Part number 720-0215)
  - 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)
- BioGX Molecular Grade Water or equivalent
  - BioGX Rehydration Water (Part number: 800-0035-12)
- BD MAX™ ExK™ TNA-3 (US BD catalog no. 442827/ International BD catalog no. 442828)
- BD MAX™ PCR Cartridges (US and International BD catalog no. 437519)
- 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)
- 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)

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# **SARS-CoV-2 N1, N2, E-gene, RNase P, Flu A, Flu B, RSV A/B Open System PCR Reagents**

**REF** 450-060-Series

### **WARNINGS AND PRECAUTIONS**



- For research use only. Not intended for human or animal diagnostics use.
- 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 M29<sup>6</sup> and in Biosafety in Microbiological and Biomedical Laboratories<sup>7</sup>.
- BioGX REF: 450-060-F-MAX has been quality control tested only with the BD Open System Extraction Kits on the BD MAX<sup>TM</sup> System.
- BioGX REF: 450-060-LMP has been quality control tested only with the Applied Biosystems QuantStudio<sup>TM</sup> 5 and Bio-Rad CFX96 Touch<sup>TM</sup> 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<sup>TM</sup> master mix if the desiccant is not present or is broken inside the Sample-Ready<sup>TM</sup> 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.
- Refer to BD MAX<sup>TM</sup> ExK<sup>TM</sup> TNA-3 Extraction Kit Instructions or to other respective nucleic acid extraction kits manufacturers' instructions for information about proper handling, cautions, and proper waste disposal.
- Do not mix septum caps between Sample Buffer Tubes or re-use septum caps as contamination may occur and compromise test results.
- Check BD Unitized Reagent Strips for proper liquid fills (ensure that the liquids are at the bottom of the tubes).
- 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.

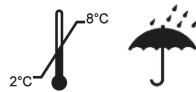


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# **SARS-CoV-2 N1, N2, E-gene, RNase P, Flu A, Flu B, RSV A/B Open System PCR Reagents**

**REF** 450-060-Series

### **STORAGE REQUIREMENTS AND RECOMMENDATIONS**



Product ships at ambient temperature, 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 2 weeks; however, the user may choose to verify an extended working time > 2 weeks 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<sup>®</sup>), Copan ESwab<sup>™</sup>, BD<sup>™</sup> UVT or saline
- Nasal wash

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**SARS-CoV-2 N1, N2, E-gene, RNase P, Flu A, Flu B, RSV  
A/B Open System PCR Reagents**

**REF** 450-060-Series

**REAGENT OPTICAL CONFIGURATION**

**Table 1a.** Optical Channel Configuration for REF 450-060-Series  
(BioGX REF: 450-060-F-MAX S2, 450-060-LMP MM1).

Optical Channel (Fluorophore Equivalent)	Target
FAM	SARS-CoV 2 (N2 gene)
HEX	SARS-CoV 2 (E gene)
Texas Red	SARS-CoV 2 (N1 gene)
Cy5	SPC/IAC
Cy5.5	RNase P

**Table 1b.** Optical Channel Configuration for REF 450-060-Series  
(BioGX REF: 450-060-F-MAX S4, 450-060-LMP MM2).

Optical Channel (Fluorophore Equivalent)	Target
FAM	Unused
HEX	Influenza A
Texas Red	RSV A/B
Cy5	Influenza B
Cy5.5	SPC/IAC



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# SARS-CoV-2 N1, N2, E-gene, RNase P, Flu A, Flu B, RSV A/B Open System PCR Reagents

**REF** 450-060-Series

### QUALITY CONTROL AND EXTRACTION TESTING PARAMETERS

#### **BD MAX™ System (BioGX REF: 450-060-F-MAX S2, 450-060-F-MAX S4)**

As a starting point, users can import and install the Electronic User Defined Protocol (eUDP) that utilizes **ExK TNA-3** extraction kits onto the BD MAX™. BioGX's most current eUDP utilized for quality control of this product can be obtained by sending an email to [TS@biogx.com](mailto:TS@biogx.com). Please refer to the BD MAX™ user manual<sup>8</sup> for uploading instructions.

#### **ABI and Bio-Rad Platforms (BioGX REF: 450-060-LMP MM1, 450-060-LMP MM2)**

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

BioGX's most current ABI QuantStudio™ 5 and Bio-Rad CFX96 Touch™ PCR run files utilized for quality control of this product can be obtained by sending an email to [TS@biogx.com](mailto:TS@biogx.com). Please refer to the Applied Biosystems QuantStudio™5 user manual<sup>9</sup> for uploading instructions. Please refer to the Bio-Rad CFX96 Touch™ user manual<sup>10</sup> 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)**

##### **BD MAX™ System**

Thoroughly vortex the sample prior to addition to the Sample Buffer Tube (SBT). Pipette 100 µL of sample into the SBT, aseptically place the BD™ septum cap on each SBT. Pulse vortex the SBT for 1-3 seconds, and load the SBT into the extraction tray.



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# SARS-CoV-2 N1, N2, E-gene, RNase P, Flu A, Flu B, RSV A/B Open System PCR Reagents

**REF** 450-060-Series

**ABI QuantStudio™ 5 and Bio-Rad CFX96 Touch™ (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 for ABI QuantStudio™ 5 and Bio-Rad CFX96 Touch™*.

**Swab sample (1 mL Copan Universal Transport Media (UTM®), Copan ESwab™, BD™ UVT or saline)**

### **BD MAX™ System**

Thoroughly vortex the sample prior to addition to the Sample Buffer Tube (SBT). Pipette 50 µL of sample into the SBT, aseptically place the BD™ septum cap on each SBT. Pulse vortex the SBT for 1-3 seconds, and load the SBT into the extraction tray.

**ABI QuantStudio™ 5 and Bio-Rad CFX96 Touch™ (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 for ABI QuantStudio™ 5 and Bio-Rad CFX96 Touch™*.

## Nasal Wash

**Pretreatment:** Freeze-thaw of nasal wash samples can provide better extraction results and reduce inhibitory effects.

### **BD MAX™ System**

Thoroughly vortex the sample prior to addition to the Sample Buffer Tube (SBT). Pipette **700 µL** of Viral Transport Medium (eg. BD™ Universal Viral Transport or Copan Universal Transport Medium) and **50 µL** of pretreated nasal wash sample into the SBT, aseptically place the BD™ septum cap on each SBT. Pulse vortex the SBT for 1-3 seconds, and load the SBT into the extraction tray.

**Note:** Copan UTM® or BD™ UVT viral transport media support the necessary dilution of nasal wash samples to achieve optimal extraction.

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# SARS-CoV-2 N1, N2, E-gene, RNase P, Flu A, Flu B, RSV A/B Open System PCR Reagents

**REF** 450-060-Series

**ABI QuantStudio™ 5 and Bio-Rad CFX96 Touch™ (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 for ABI QuantStudio™ 5 and Bio-Rad CFX96 Touch™*.

### **BioGX QUALITY CONTROL TEST SETUP PROCEDURE**

#### **BD MAX™ System Quality Control Test Setup**

##### **Loading a Sample Buffer Tube (SBT)**

1. Add the appropriate sample volume to each SBT.
2. Aseptically place BD™ septum cap on each SBT.
3. Vortex the SBT for 1-3 seconds.
4. Load the SBT into the extraction tray.

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

##### **Assembly of BD MAX Extraction Strips and BioGX Reagents**

1. Choose the appropriate BD MAX™ extraction kit (see above). **DO NOT** use BD MAX™ master mix or the blank 0.3 mL conical tubes that come with the extraction kit.
2. Load the selected extraction cartridges into the extraction tray, 1 per sample to be tested.
3. Snap one BD MAX™ ExK™ TNA Extraction tube into snap-in position 1 (Snap-1) of each extraction strip (**Figure 1**).
4. Snap one BioGX Sample-Ready™ lyophilized reagent tube 450-6-F-MAX S2 into position 2 (Snap-2) of each extraction strip. Check to make sure the lyophilized cake is at the bottom of the tube prior to inserting into the strip. The funnel-shaped cake may be in any orientation (v, >, ^, <).
5. Snap one BioGX Rehydration Buffer tube into position 3 (Snap-3) of each extraction strip. Check to make sure the buffer is at the bottom of the tube prior to inserting into the strip.
6. Snap one BioGX Sample-Ready™ lyophilized reagent tube 450-6-F-MAX S4 into position 4 (Snap-4) of each extraction strip. Check to make sure the lyophilized cake is at the bottom of

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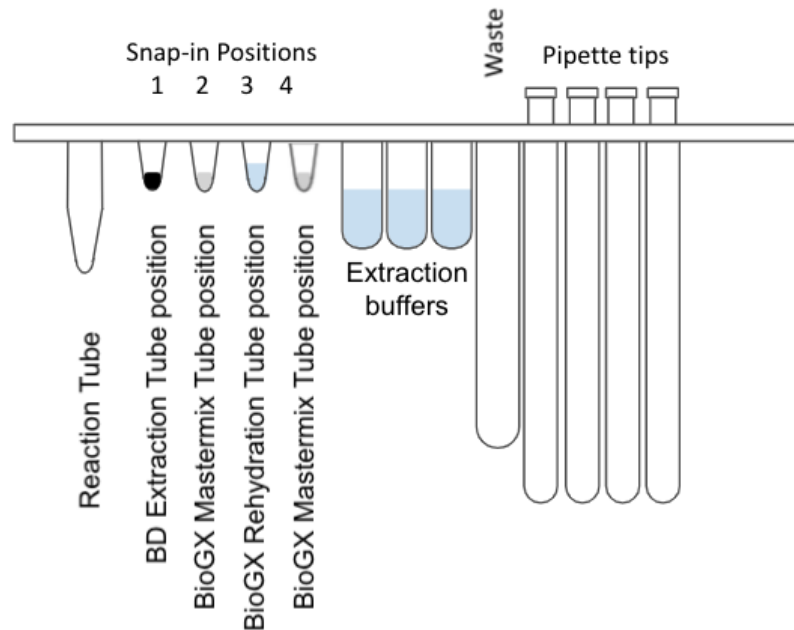
# SARS-CoV-2 N1, N2, E-gene, RNase P, Flu A, Flu B, RSV A/B Open System PCR Reagents

**REF** 450-060-Series

the tube prior to inserting into the strip. The funnel-shaped cake may be in any orientation (v, >, ^, <).

7. Lift the tray and briefly examine the bottom of each strip to ensure all reagents are at the bottom of each tube and bubbles are not present in Extraction buffer reservoirs.
8. Proceed with worklist generation and sample loading per BD MAX™ operating instructions. Select the appropriate User Defined Protocol (UDP). Load the extraction tray and, if necessary, a new PCR card into the instrument, close the door, and click “Start Run.”
9. Analyze the results by opening the completed run file in the “Results” tab.

### BD MAX ExK™ 4-Snap Unitized Reagent Strip Dual Master Mix Type 4 Setup



**Figure 1.** Diagram of BD MAX™ ExK™ 4-snap Unitized Reagent Strips

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# **SARS-CoV-2 N1, N2, E-gene, RNase P, Flu A, Flu B, RSV A/B Open System PCR Reagents**

**REF** 450-060-Series

### **Important Note**

Always first insert all Snap-1 tubes, then all Snap-2 tubes, then all Snap-3 tubes and then all Snap-4 tubes.

Approximately 25 µL of extracted nucleic acid remains in the position 3 tube after extraction. This may be removed and saved for further analyses after the run has been completed.

**ABI QuantStudio™ 5 and Bio-Rad CFX96 Touch™ Quality Control Test Setup (450-060-LMP MM1 and 450-060-LMP MM2)**

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

**NOTE: IF 450-060-LMP MM1 AND 450-060-LMP MM2 ASSEMBLY IS PERFORMED IN PARALLEL, ENSURE SEPARATION OF BioGX REAGENTS TO PREVENT SET UP ERRORS. THE SAME EXTRACTED PATIENT SAMPLE IS USED FOR 450-060-LMP MM1 AND 450-060-LMP MM2.**

### **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 ABI QuantStudio™ 5 and Bio-Rad CFX96 Touch™ instruments. Rehydrated master mix must be transferred to 8-tube PCR strips or 96-well PCR plates compatible with appropriate instruments.
3. Mix by gently pipetting up and down. (IMPORTANT: Keep rehydrated master mix in a cold block or on ice if setup cannot not 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 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.

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**SARS-CoV-2 N1, N2, E-gene, RNase P, Flu A, Flu B, RSV  
A/B Open System PCR Reagents**

**REF** 450-060-Series

**INTERPRETATION OF RESULTS**

**Table 2a.** Multiplex PCR Results Interpretation for 450-060-Series  
(REF: 450-060-F-MAX S2, 450-060-LMP MM1)

SARS CoV-2 (N1)	SARS CoV-2 (N2)	SARS CoV-2 (E gene)	RNase P	IAC or SPC	Result Interpretation
+	+	+	+/-	+/-	SARS CoV-2 POSITIVE
+	+	-	+/-	+/-	SARS CoV-2 POSITIVE
+	-	+	+/-	+/-	SARS CoV-2 POSITIVE
-	+	+	+/-	+/-	SARS CoV-2 POSITIVE
+	-	-	+/-	+/-	SARS CoV-2 POSITIVE
-	+	-	+/-	+/-	SARS CoV-2 POSITIVE
-	-	+	+/-	+/-	SARS CoV-2 POSITIVE
-	-	-	+	+	SARS-CoV-2 NEGATIVE
-	-	-	+/-	-	UNRESOLVED*

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

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**SARS-CoV-2 N1, N2, E-gene, RNase P, Flu A, Flu B, RSV  
A/B Open System PCR Reagents**

**REF** 450-060-Series

**Table 2b.** Multiplex PCR Results Interpretation for 450-060-Series  
(REF: 450-060-F-MAX S2, 450-060-LMP MM1)

Influenza A	RSV A/B	Influenza B	IAC or SPC	Interpretation
+	-	-	+/-	Influenza A POSITIVE
-	+	-	+/-	RSV A/B POSITIVE
-	-	+	+/-	Influenza B POSITIVE
-	-	-	+	Influenza A, RSV A/B, Influenza B NEGATIVE
-	-	-	-	Unresolved*

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

**ASSAY PERFORMANCE**

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

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# SARS-CoV-2 N1, N2, E-gene, RNase P, Flu A, Flu B, RSV A/B Open System PCR Reagents

**REF** 450-060-Series

### 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_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: 06. <https://www.fda.gov/media/134922/download>
4. Corman, Victor M., et al. "Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR." *Eurosurveillance* 25.3 (2020): 2000045.
5. 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.
6. Clinical and Laboratory Standards Institute. Protection of laboratory workers from occupationally acquired infections; Approved Guideline. Document M29 (Refer to the latest edition).
7. 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.
8. BD MAX™ System User's Manual (refer to the latest revision) BD Life Sciences, Sparks, Maryland 21152 USA.
9. QuantStudio™ Design and Analysis software User Guide, ThermoFisher Scientific, Waltham, Massachusetts, USA (Refer to the latest version).
10. 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](mailto:info@biogx.com) with any questions you may have regarding this product.**











Rev. #	Effective Date	Summary of Changes
01	28 MAY 2021	Initial Release.

**Package Insert**

**SARS-CoV-2 N1, N2, E-gene, RNase P, Flu A, Flu B, RSV  
A/B Open System PCR Reagents**

**REF** 450-060-Series

**SYMBOLS**

Symbol	Meaning
	For Research Use Only
	Batch code
	Caution
	Manufacturer
	Contains sufficient for <n> tests
	Temperature limitation
	Keep dry
	Keep away from sunlight
	Expiration date
	Biological Risks



**BioGX**

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