



BioGX

Molecular Made Easy

SARS-CoV-2 N1, RNase P and SARS-CoV-2 N2, RNase P Open System Reagents for BD MAX™

REF 500-001-C-MAX-R

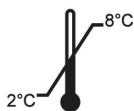


24 Reactions

Product Insert

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

For use with BD MAX™ System



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, RNase P and SARS-CoV-2 N2, RNase P 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. An example of an open system platform is the BD MAX™ System (Windows® Software V4.72A 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 (Nucleocapsid phosphoprotein gene region (N1) and Nucleocapsid phosphoprotein gene region (N2)) and human RNase P gene^{1,2,3,4}.

1. BD MAX™ System
REF 500-001-C-MAX-R S2 (SARS-CoV-2 N1, RNase P)
REF 500-001-C-MAX-R S4 (SARS-CoV-2 N2, RNase P)

Note:

BD MAX™ System OSR (500-001-C-MAX-R S2 (SARS-CoV-2 N1, RNase P)) contains all PCR primers, probes, enzymes, dNTPs, MgCl₂, buffers, and other components required for PCR reaction. No exogenous addition of SPC is needed.

BD MAX™ System OSR (500-001-C-MAX-R S4 (SARS-CoV-2 N2, RNase P)) contains all PCR primers, probes, enzymes, dNTPs, MgCl₂, buffers, and other components required for PCR reaction. No exogenous addition of SPC is needed.

PACKAGE CONTENTS

BioGX REF: 500-001-C-MAX-R 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.

BioGX REF: 500-001-C-MAX-R 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.

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 SARS-CoV-2 Nucleocapsid phosphoprotein gene (N2)
(Part number 720-0207)
 - BioGX RNaseP (RNA) (Part number 720-0208)
- 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

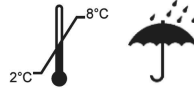
WARNINGS AND PRECAUTIONS



- 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.
- BioGX REF: 500-001-C-MAX-R has been quality control tested only with the BD Open System Extraction Kits on the BD MAX™ System.
- 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 ambient temperature (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[®]), Copan ESwab[™], BD[™] UVT or saline

REAGENT OPTICAL CONFIGURATION

Table 1a. Optical Channel Configuration for REF: 500-001-C-MAX-R S2

Optical Channel (Fluorophore Equivalent)	Target
FAM	SARS-CoV 2 (N1 gene)
HEX	Unused
Texas Red	Unused
Cy5	Unused
Cy5.5	RNase P

Table 1b. Optical Channel Configuration for REF: 500-001-C-MAX-R S4

Optical Channel (Fluorophore Equivalent)	Target
FAM	SARS-CoV 2 (N2 gene)
HEX	Unused
Texas Red	Unused
Cy5	Unused
Cy5.5	RNase P

QUALITY CONTROL AND EXTRACTION TESTING PARAMETERS

BD MAX™ System (BioGX REF: 500-001-C-MAX R S2, 500-001-C-MAX R 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. Please refer to the BD MAX™ 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[®]), 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.

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.

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 500-001-C-MAX-R 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 500-001-C-MAX-R S4 into position 4 (Snap-4) 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, >, ^, <).
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**

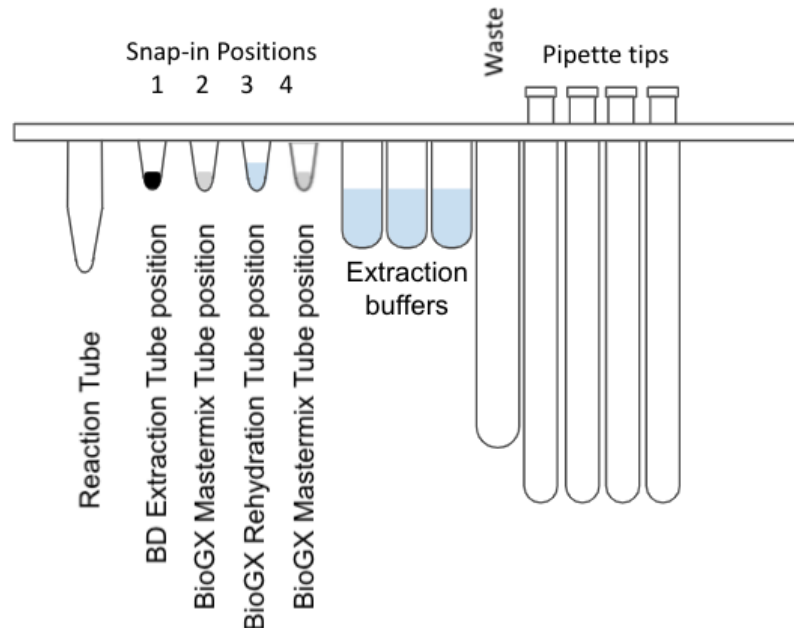


Figure 1. Diagram of BD MAX™ ExK™ 4-snap Unitized Reagent Strips

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.

INTERPRETATION OF RESULTS

Table 2. Multiplex PCR Results Interpretation for 500-001-C-MAX-R S2/S4.

500-001-C-MAX-R S2		500-001-C-MAX-R S4		Result Interpretation
SARS-CoV-2 N1	RNase P	SARS-CoV-2 N2	RNase P	
+	+/-	+	+/-	POSITIVE
+	+/-	-	+	POSITIVE
+	+/-	-	-	POSITIVE
-	+	+	+/-	POSITIVE
-	-	+	+/-	POSITIVE
-	-	-	+	Unresolved
-	+	-	-	Unresolved
-	-	-	-	Unresolved
-	+	-	+	NEGATIVE

ASSAY PERFORMANCE

All BioGX Research Use Only products are designed to detect 20 copies or less of the target nucleic acid per 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: 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. 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. BD MAX™ System User's Manual (refer to the latest revision) BD Life Sciences, Sparks, Maryland 21152 USA.

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

Rev. #	Effective Date	Summary of Changes
01	11 AUG 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