BioGX
Molecular Made Easy

Carbapenem and Vancomycin Resistance Open System Reagents for BD MAX™

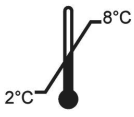
REF **450-121-C-MAX**

Σ 24 Reactions

Product Insert

For Research Use Only: Not for use in diagnostic procedures

For use with BD MAX™ System





RUO

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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 Carbapenem and Vancomycin Resistance Open System Reagents for BD MAX™ real-time PCR-based detection reagent is manufactured and packaged as an open system reagent (OSR) for use with 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 Carbapenem and Vancomycin Resistance Sample-Ready™ OSR has been formulated in lyophilized format for multiplex real-time PCR-based detection of DNA from antibiotic resistance genes vanA[1,2],vanB[1,2], bla_{GES}[3,4], bla_{KPC}[3,4,5,6], bla_{NDM}[3,4,6], bla_{OXA-48}[3,4,6,7,8], bla_{VIM}[3,4,8], and bla_{IMP}[3,4,6,8]. The lyophilized Sample-Ready OSR is available in the following format:

1. BD MAX™ System
   REF 450-121-C-MAX S2 (KPC, NDM, OXA-48, IMP, SPC)
   REF 450-121-C-MAX S4 (vanA, vanB, VIM, GES, SPC)

Note:

BD MAX™ System OSR (450-121-C-MAX S2) contains all PCR primers, probes, enzymes, dNTPs, $MgCl_2$, buffers, and other components required for PCR reaction. BD MAX extraction kits available from Becton, Dickinson and Company include a Drosophila DNA sequence which serves as a Sample Processing Control (SPC). No exogenous addition of SPC is needed.

BD MAX™ System OSR (450-121-C-MAX S4) contains all PCR primers, probes, enzymes, dNTPs, $MgCl_2$, buffers, and other components required for PCR reaction. BD MAX extraction kits available from Becton, Dickinson and Company include a Drosophila DNA sequence which serves as a Sample Processing Control (SPC). No exogenous addition of SPC is needed.

PACKAGE CONTENTS

BioGX REF: 450-121-C-MAX
Platform(s): BD MAX™ System

Each 24-reaction package contains three pouches:

1. First pouch contains 24 sealed BD MAX™ tubes of BioGX KPC, NDM, OXA-48, IMP, SPC lyophilized Sample-Ready™ OSR (450-121-C-MAX S2), each tube sufficient for a 12.5 µL PCR reaction.
2. Second pouch contains 24 sealed BD MAX™ tubes of BioGX vanA, vanB, VIM, GES, SPC lyophilized Sample-Ready™ OSR (450-121-C-MAX S4), each tube sufficient for a 12.5 µL PCR reaction.
3. Third 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 DNA Beads (10^5 copies/bead)
  - BioGX *KPC* (Part number 720-0035)
  - BioGX *NDM* (Part Number 720-0036)
  - BioGX *OXA-48* (Part Number 720-0037)
  - BioGX *IMP* (Part Number 720-0185)
  - BioGX *vanA* (Part Number 720-0018)
  - BioGX *GES* (Part Number 720-0045)
  - BioGX *vanB* (Part Number 720-0019)
  - BioGX *VIM* (Part Number 720-0044)
- BD MAX™ ExK™ DNA-2 (US BD catalog no. 442821/ International BD catalog no. 442822)
- 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

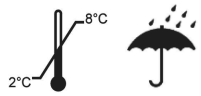
WARNINGS AND PRECAUTIONS



- For research use only. Not intended for 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 M29[9] and in Biosafety in Microbiological and Biomedical Laboratories[10].
- **BioGX REF: 450-121-C-MAX** 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 Sample-Ready™master mix if the desiccant is not present or is broken inside Sample-Ready™ 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.
- Refer to BD MAX™ ExK™ DNA-2 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.

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 ESwab™, Copan Fecal Swab ™
-Direct stool sample

REAGENT OPTICAL CONFIGURATION

Table 1a. Optical Channel Configuration for REF: 450-121-C-MAX S2

Optical Channel (Fluorophore Equivalent)	**Target**
FAM	bla_{KPC}
HEX	bla_{NDM}
Texas Red	bla_{OXA-48}
Cy5	bla_{IMP}
Cy5.5	SPC

Table 1b. Optical Channel Configuration for REF: 450-121-C-MAX S4

Optical Channel (Fluorophore Equivalent)	**Target**
FAM	vanA
HEX	bla_{GES}
Texas Red	vanB
Cy5	bla_{VIM}
Cy5.5	SPC

QUALITY CONTROL AND EXTRACTION TESTING PARAMETERS

BD MAX™ System (BioGX REF: 450-121-C-MAX)

As a starting point, users can import and install the Electronic User Defined Protocol (eUDP) that utilizes **ExK DNA-2** 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 manual[11] 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 in Copan ESwab™ or Copan FecalSwab™

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.

Direct Stool

BD MAX™ System

Collect a 10 µL loopful of direct stool and add to the Sample Buffer Tube (SBT). Do not add more than approximately 10 µL of direct stool to the Sample Buffer Tube, excessive stool matrix can introduce extraction and/or PCR inhibitors. Swirl the inoculation loop 3-4 times in the SBT to homogenize the sample. Dispose the inoculation loop. 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™ DNA Extraction tube into snap-in position 1 (Snap-1) of each extraction strip (**Figure 1**).
4. Snap one BioGX Sample-Ready™ lyophilized reagent tube 450-121-C-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 450-121-C-MAX 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.

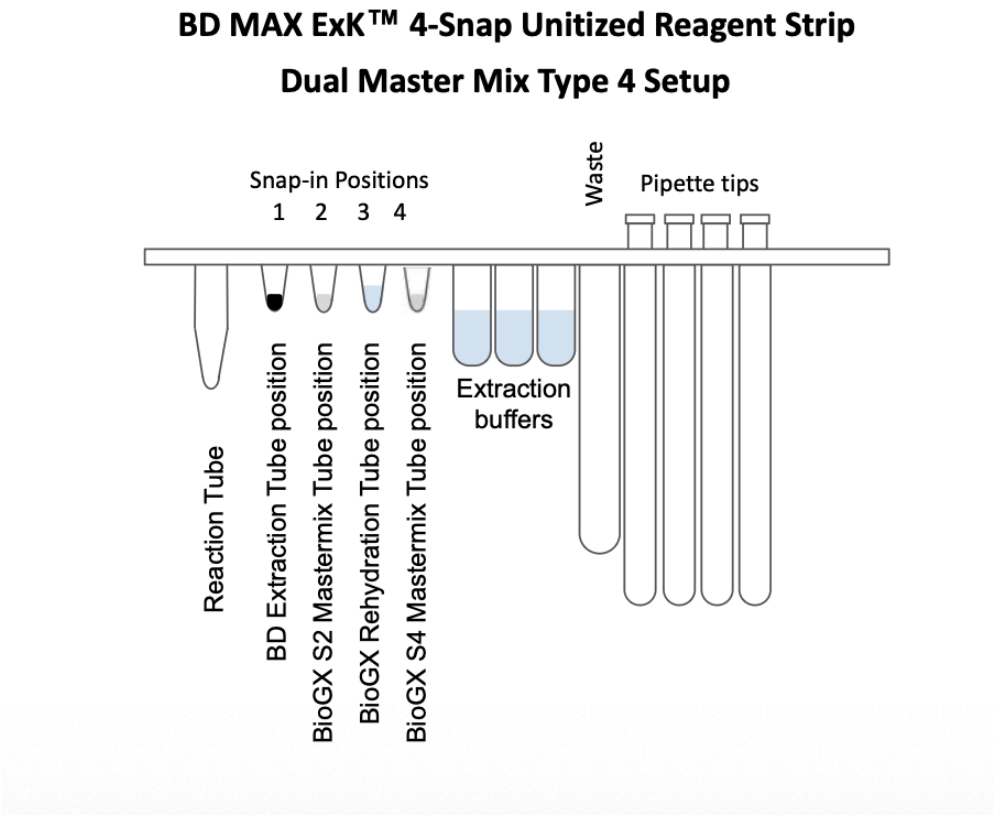


Figure 1. Diagram of BD MAX™ ExK™ 4-snap Unitized Reagent Strips

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 12.5 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.

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 2a. Multiplex PCR Results Interpretation for 450-121-C-MAX S2.

450-121-C-MAX S2					Result Interpretation
bla_{KPC}	bla_{NDM}	bla_{OXA-48}	bla_{IMP}	SPC	
+	-	-	-	+/-	bla_{KPC} POSITIVE
-	+	-	-	+/-	bla_{NDM} POSITIVE
-	-	+	-	+/-	bla_{OXA-48} POSITIVE
-	-	-	+	+/-	bla_{IMP} POSITIVE
-	-	-	-	+	bla_{KPC}, bla_{NDM}, bla_{OXA-48}, bla_{IMP} NEGATIVE
-	-	-	-	-	Unresolved*

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

Table 2b. Multiplex PCR Results Interpretation for 450-121-C-MAX S4.

450-121-C-MAX S4					Result Interpretation
vanA	vanB	bla_{VIM}	bla_{GES}	SPC	
+	-	-	-	+/-	vanA POSITIVE
-	+	-	-	+/-	vanB POSITIVE
-	-	+	-	+/-	bla_{VIM} POSITIVE
-	-	-	+	+/-	bla_{GES} POSITIVE
-	-	-	-	+	vanA, vanB, bla_{VIM}, bla_{GES} NEGATIVE
-	-	-	-	-	Unresolved*

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

REFERENCES

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11. 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	02 NOV 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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