



BioGX

Molecular Made Easy

Plasmodium spp., P. falciparum, P. vivax

OSR for BD MAX™

REF 350-002-A-MAX

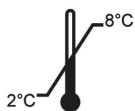


24 Reactions

Product Insert

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

For use with BD MAX™ System



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FOR LABORATORY USE ONLY

This product is manufactured and packaged as an Open System Reagent for the BD MAX™ system. It is the responsibility of the end user to determine the analytical performance of the reagents in an appropriately designed validation study. BioGX makes no claims regarding the clinical sensitivity and specificity of these reagents.

PLEASE READ ENTIRE INSERT BEFORE PROCEEDING WITH TEST SETUP.

This information is for use with BD MAX™ Windows® software release V4.72A or later.

Product Overview

This package contains one BioGX Sample-Ready™ kit for the multiplex detection of DNA from *Plasmodium* species (rRNA gene¹), *Plasmodium falciparum* (rRNA gene¹), *Plasmodium vivax* (rRNA gene¹), and human RNase P gene as the endogenous sample processing control (SPC). The SPC in the multiplex targets the human RNase P gene present in the whole blood sample, so no external addition of SPC is required. The SPC serves as both a sample extraction control and an internal amplification control (IAC). Each tube of Sample-Ready™ lyophilized reagents contains all PCR primers, probes, enzyme, dNTPs, MgCl₂, buffers, and other components required for analysis of one sample. BD MAX™ PCR Master Mix is not required.

BioGX has optimized this product for full extraction mode use on the BD MAX™ platform with BD ExK™ DNA-1 Open System extraction kits.

Extraction Kit ExK DNA-1 **REF** 442818

Basic suggested extraction processing parameters for **whole blood samples** have been provided below.

Package Contents

Each 24-reaction package contains two pouches:

The first pouch contains 24 tubes of BioGX lyophilized reagents for *Plasmodium* species, *Plasmodium falciparum*, *Plasmodium vivax* and RNase P, each sufficient for a 12.5 µL reaction, sealed in BD MAX™ 0.3 mL conical tubes.

The second pouch contains 24 tubes, each containing 25 µL of BioGX Rehydration Buffer sealed in BD MAX™ 0.3 mL conical tubes.

Not included but available through BioGX

Lyophilized Positive Control Template DNA Beads (10⁵ copies/bead).

<i>Plasmodium</i> spp.	Part number 720-0005
<i>Plasmodium falciparum</i>	Part number 720-0162
<i>Plasmodium vivax</i>	Part number 720-0166

WARNINGS AND PRECAUTIONS



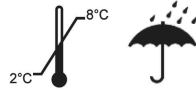
- For laboratory use only.
- Treat all biological samples, including used Extraction Kits and PCR Cartridges, as if capable of transmitting infectious agents in accordance with safe laboratory procedures such as those described in CLSI Document M29² and in Biosafety in Microbiological and Biomedical Laboratories³.
- This test has been optimized only with the BD Open System Extraction Kits and sample types listed in this procedure. The performance of this assay with other sample types or samples has not been evaluated.
- 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.
- Each Sample-Ready™ Master Mix and BioGX Rehydration Buffer tube is used to process a single sample. Do not reuse Sample-Ready™ Master Mix or BioGX Rehydration Buffer tubes.
- Refer to BD MAX™ ExK™ DNA-1 Extraction Kit 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 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 Laboratory 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. 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 months; however, the user may choose to verify an extended working time (>2 months) by performance testing with positive controls and an examination of the sample preparation control target.

Choose a BD MAX™ ExK™ Series Extraction Kit Appropriate for Your Sample Type

BioGX recommends using the BD MAX™ ExK™ DNA-1 extraction kits with this product.

Install a User Defined Protocol on the BD MAX™

Windows® Software V4.72A or later:

It will be necessary to import an Electronic User Defined Protocol (eUDP) onto the BD MAX™. The most current eUDP is available for download at www.biogx.com by using the drop down menu at the top right of the home page. Select "Education Center" then select "Int. Product Documents". Choose the appropriate product number under "Instructions for Use Manual & Product Inserts" and download the eUDP. Please refer to the BD MAX™ user manual⁴ for uploading instructions.

To manually install a protocol the basic parameters below are suggested:

Extraction Type

BioGX recommends the following extraction types for the sample types listed below:

BD MAX™ ExK™ DNA-1 (Plasma/Serum) for use with whole blood samples.

Master Mix Format

Use Type 4 workflow protocol.

Sample Extraction Parameters

It is suggested that the user set up different protocols for the various sample types to be tested. The BD MAX™ software allows one to copy an existing protocol, change specific parameters, and save a new protocol under a different name.

When programming the Sample Extraction Parameters one must allow for a 250 µL “dead volume” of liquid in the Sample Buffer Tube (SBT) that cannot be pipetted out of the tube or processed by the BD MAX™.

If the Sample Extraction Parameters differ from the default settings for the extraction kit being used, it will be necessary to program user defined parameters. The following parameters are suggested as a basic protocol for processing of the samples listed below:

BD MAX™ ExK™ DNA-1 (Plasma/Serum) - Whole Blood

Sample Lysis Time	20 minutes
Sample Lysis Temperature	37°C
Sample Volume	500 µL
Leave all other settings at default values	

Please refer to the "Sample Pretreatment and SBT Loading Volume" section below.

The end user may also define a different custom protocol by following the guidelines included in the BD ExK™ extraction kit product insert.

PCR Cycling Conditions

Cycling Stage 1: Hold 99°C for 120 sec

Cycling Stage 2: Two Temperatures x 45 Cycles of:

99°C for 12 sec, Optics Off
62°C for 36.7 sec, Optics On

Channel Settings

475/520 channel	<i>Plasmodium falciparum</i>	set Gain to 60	set Threshold to 200
530/565 channel	<i>Plasmodium vivax</i>	set Gain to 60	set Threshold to 200
585/630 channel	RNase P	set Gain to 60	set Threshold to 200
630/665 channel	<i>Plasmodium spp.</i>	set Gain to 60	set Threshold to 200
680/715 channel	Unused	set Gain to 0	

Set melt gain in all channels to 0.

BioGX suggests the minimum threshold settings listed above for each channel as a starting point for validation, but the final settings must be determined by the end user during and after laboratory validation with appropriate controls.

Ct Calculation

Select option to “Call Ct at Threshold Crossing”.

Setting the Ct min and max is optional depending upon requirements of the end user. The end user may select the valid Ct range for each target if desired.

Result Logic

To simplify reports, result logic may be used as appropriate for each target.

Color Compensation

Color compensation settings are not required.

The final settings must be determined by the end user during and after laboratory validation with appropriate controls.

BioGX suggests the minimum threshold settings listed above for each channel as a starting point for validation, but the final settings must be determined by the end user during and after laboratory validation with appropriate controls.

Melt Settings

Melt settings are not needed for BioGX reagents.

Sample Pretreatment and SBT Loading Volume

The end user may choose to validate a different pretreatment method or volume of sample to load other than the suggested sample processing outlined below. If different sample volumes are deemed appropriate for the existing workflow of the laboratory it will be necessary to modify Guardrail parameters accordingly.

Whole Blood Processing

Pipette 25-50 µL of sample, with a maximum of 100 µL into the Sample Buffer Tube (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. Thoroughly vortex the sample prior to addition to the SBT.

Other Sample Types

Please contact BioGX for processing suggestions if collecting sample types other than those described above as some sample types and/or transport media can be inhibitory to PCR or disrupt extraction without appropriate Guardrail and processing volume adjustments.

General Sample Rerun Strategy

In the unlikely event of a run failure with hard to obtain samples, the end user may desire a processing strategy that allows the remaining sample in the Sample Buffer Tube (SBT) to be rerun. If so, the Sample Volume in the Guardrail setting should be reduced accordingly. The end user should determine the appropriate strategy for available sample volume and laboratory workflow.

General Instructions for 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.

Instructions for Using BioGX Sample-Ready™ Reagents on the BD MAX™

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

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 position 1 (Snap-1) of each extraction strip (Figure 1).
4. Snap one BioGX Sample-Ready™ lyophilized reagent tube 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. Position 4 (Snap-4) will remain empty.

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

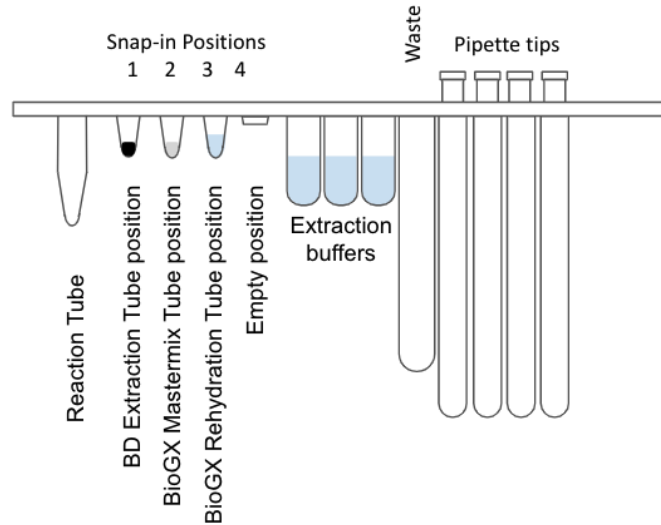


Figure 1 - Diagram of BD MAX™ ExK™ 4-snap Unitized Reagent Strips

6. Lift the tray and briefly examine the bottom of each strip to ensure all reagents are at the bottom of each tube.
7. Proceed with worklist generation and sample loading per BD MAX™ operating instructions. Select the appropriate User Defined Protocol (UDP).
8. 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.

Important Note

Always first insert all Snap-1 tubes, then all Snap-2 tubes, then all Snap-3 tubes. The Snap-4 position will remain empty unless the user has set up the reagent to run in dual Master Mix mode.

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









References

1. Kamau, Edwin, et al. "Multiplex qPCR for detection and absolute quantification of malaria." PloS one 8.8 (2013): e71539.
2. Clinical and Laboratory Standards Institute. Protection of laboratory workers from occupationally acquired infections; Approved Guideline. Document M29 (Refer to the latest edition).
3. 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.
4. BD MAX™ System User's Manual (refer to the latest revision) BD Life Sciences, Sparks, Maryland 21152 USA.

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

Rev. #	Effective Date	Summary of Changes
05	27 AUG 2021	Update branding and shipment temperature.
04	05 MAY 2021	Update Figure 1, update references, update website pathway.
03	21 MAY 2020	Update BD MAX™ software version, open pouch stability, add positive control part no., update instruction for using BioGX Sample-Ready™ Reagents on the BD MAX™, revise manufacturing designation, update UDP for compatibility with 4-Snap ExK-DNA-1.
02	29 DEC 2015	Changed product name and updated recommended whole blood sample volume.
01	15 JUN 2015	Initial Release.

SYMBOLS

Symbol	Meaning	Symbol	Meaning
	Catalog number		Contains sufficient for <n> tests
	Do not reuse		Manufacturer
	Keep dry		Temperature limitation
	Consult instructions for use		Biological Risks



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