



BioGX

Molecular Made Easy

Measles Virus

Open System PCR Reagents

REF 450-114-Series



24 Reactions 450-114-C-MAX

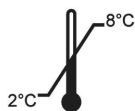


64 Reactions 450-114-LMP

Product Insert

For Research Use Only: Not for use in diagnostic procedures

For use with BD MAX™ System, ABI QuantStudio™ 5, ABI 7500 Fast Dx, Bio-Rad CFX96 Touch™, Bio-Rad CFX384 Touch™, BioGX pixl.16 real-time PCR platform



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 BioGX Measles Virus 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 (WindowsR Software V4.72A or later), 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), Bio-Rad CFX96 Touch™, CFX384 Touch™ (Maestro software version 1.1 or later) or BioGX pixl.16 (For Android® based software version 1.6.9 or later) real-time PCR platforms.

PLEASE READ ENTIRE PACKAGE INSERT BEFORE PROCEEDING TO USE THE OSR.

PRODUCT OVERVIEW

The BioGX Measles Virus Sample-Ready™ OSR has been formulated in lyophilized format for the multiplex real-time PCR-based detection of RNA from Measles Virus (N gene¹), RNase P, and Internal Amplification Control (IAC). Two different formats for the lyophilized Sample-Ready OSR kits are available:

1. BD MAX™ System
REF 450-114-C-MAX
2. ABI QuantStudio™ 5, ABI 7500 Fast Dx, Bio-Rad CFX96 Touch™, Bio-Rad CFX384 Touch™, and BioGX pixl.16 Platforms
REF 450-114-LMP

Note:

BD MAX™ System OSR (450-114-C-MAX) contains all PCR primers, probes, enzymes, dNTPs, MgCl₂, buffers, and other components required for the PCR reaction. BD MAX extraction kits available from Becton, Dickinson and Company include synthetic single-stranded RNA sequence which serves as a Sample

Processing Control (SPC). No exogenous addition of Sample Processing Control (SPC) is needed.

OSR for ABI, Bio-Rad, and BioGX pixl.16 Platforms (450-114-LMP) contain all PCR primers, probes, enzymes, dNTPs, MgCl₂, buffers, and other components required for the PCR reaction. No exogenous addition of SPC is needed.

PACKAGE CONTENTS

BioGX REF: 450-114-C-MAX

Platform(s): BD MAX™ System

Each 24-reaction package contains two pouches:

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

BioGX REF: 450-114-LMP

Platform(s): ABI QuantStudio™ 5, ABI 7500 Fast Dx, Bio-Rad CFX96 Touch™, Bio-Rad CFX384 Touch™ and BioGX pixl.16

Each 64-reaction package consists of one pouch:

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, ABI 7500 Fast Dx, Bio-Rad CFX96 Touch™, Bio-Rad CFX384 Touch™ and BioGX pixl.16 instruments.

EQUIPMENT AND MATERIALS REQUIRED BUT NOT PROVIDED

- BioGX Lyophilized Positive Control Template Beads (10⁵ copies/bead)
 - BioGX RNaseP (DNA) (Part number 720-0009)
- Measles Virus Genotype B3 2006 Isolate (Zeptometrix catalog no.0810542CFHI)
- Measles virus Quantitative Genomic RNA (ATCC catalog no. VR-24DQ)
- BioGX Molecular Grade Water or equivalent
 - BioGX Rehydration Water Part number: 800-0035-12
- Vortex Genie 2 Vortexer (VWR catalog no. 58815-234) or equivalent
- Disposable nitrile gloves
- 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)
- Calibrated micropipettes
- 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)
- 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)
- Bio-Rad CFX384 Touch consumables.
 - Bio-Rad 384-well plates (catalog no. HSP3905)
 - Bio-Rad 384-well plate sealing film, optical (catalog no. MSB1001)
- BioGX pixl.16 real-time PCR instrument (BioGX catalog no. 650-016-PXL-R)
- BioGX pixl.16 consumables.
 - TempAssure® PCR 8-Tube Strips, Att. Optical Caps (BioGX catalog no. 010-280-ETS) or
 - EasyStrip™ Plus Tube Strip with Attached Ultra Clear Caps (Thermo Fisher catalog no. AB2005) or
 - Axygen® 0.2 mL Polypropylene PCR Tube Strips and attached Flat Cap Strips, 8 Tubes/Strip (Corning catalog no.: PCR-0208-AF-C)

WARNINGS AND PRECAUTIONS

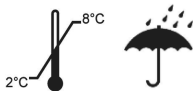


- For research use only. Not intended for use in diagnostic procedures.
- If handling biological samples, including used Extraction Kits and PCR Cartridges, treat as if capable of transmitting infectious agents in accordance with safe laboratory procedures such as those described in CLSI Document M29² and in Biosafety in Microbiological and Biomedical Laboratories³.
- BioGX REF: 450-114-C-MAX has been quality control tested only with the BD MAXTM System (using BD Open System Extraction Kits) platform.
- BioGX REF: 450-114-LMP has been quality control tested only with the ABI QuantStudioTM 5, ABI 7500 Fast Dx, Bio-Rad CFX96 TouchTM, Bio-Rad CFX384 TouchTM and BioGX pixl.16 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-ReadyTM master mix if the desiccant is not present or is broken inside the Sample-ReadyTM master mix pouches.
- Do not use reagent tubes if the cap 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 MAXTM ExKTM 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 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 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

-Oropharyngeal Swab collections transported in Copan Universal Transport Media (UTM®)

-Urine (neat)

REAGENT OPTICAL CONFIGURATION

Table 1. Optical Channel Configuration for REF 450-114-C-MAX

Optical Channel (Fluorophore Equivalent)	Target
FAM	Measles
HEX	Unused
Texas Red	RNase P
Cy5	Internal Amplification Control
Cy5.5	Unused

Table 2. Optical Channel Configuration for REF 450-114-LMP

Optical Channel (Fluorophore Equivalent)	Target
FAM	Measles
HEX	Unused
Texas Red	RNase P
Cy5	Internal Amplification Control
Cy5.5	Unused

QUALITY CONTROL AND TESTING PARAMETERS

BD MAX™ System

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 manual⁴ for uploading instructions.

ABI, Bio-Rad and BioGX pixl.16 Platforms

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)
3. BioGX pixl.16 real-time PCR platform (For Android® based software version 1.6.9 or later)

BioGX's most current ABI QuantStudio™ 5, Bio-Rad CFX96 Touch™ and BioGX pixl.16 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 manual⁵ for uploading instructions. Please refer to the Bio-Rad CFX96 Touch™ user manual⁶ for uploading instructions. Please refer to the BioGX pixl.16 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 (1 mL Copan UTM®)

BD MAX™ System

Thoroughly vortex the sample prior to addition to the Sample Buffer Tube (SBT). Pipette up to 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 as described in Section: *PCR SET-UP FOR SAMPLES TESTED ON BD MAX™ System*.

ABI, Bio-Rad and BioGX pixl.16 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 µL of purified nucleic acid to master mix as described in Section: *PCR SET-UP FOR SAMPLES TESTED ON ABI QuantStudio™ 5, Bio-Rad CFX96 Touch™ or pixl.16*

Urine sample (neat)

BD MAX™ System

Thoroughly vortex the sample prior to addition to the Sample Buffer Tube (SBT). Pipette 200 µL of neat urine 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, Bio-Rad and BioGX pixl.16 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 µL of purified nucleic acid to master mix as described in Section: *PCR SET-UP FOR SAMPLES TESTED ON ABI QuantStudio™ 5, Bio-Rad CFX96 Touch™ or pixl.16*

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

PCR SET-UP FOR TESTING USING: BD MAX™ System

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.

Assembly of BD MAX Extraction Strips and BioGX Reagents

1. Load the selected extraction cartridges into the extraction tray, 1 per sample to be tested.
2. Snap one BD MAX™ ExK™ TNA Extraction tube into snap-in position 1 (Snap-1) of each extraction strip (**Figure 1**).
3. 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, >, ^, <).
4. 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.
5. 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.
6. 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.”
7. Analyze the results by opening the completed run file in the “Results” tab.

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

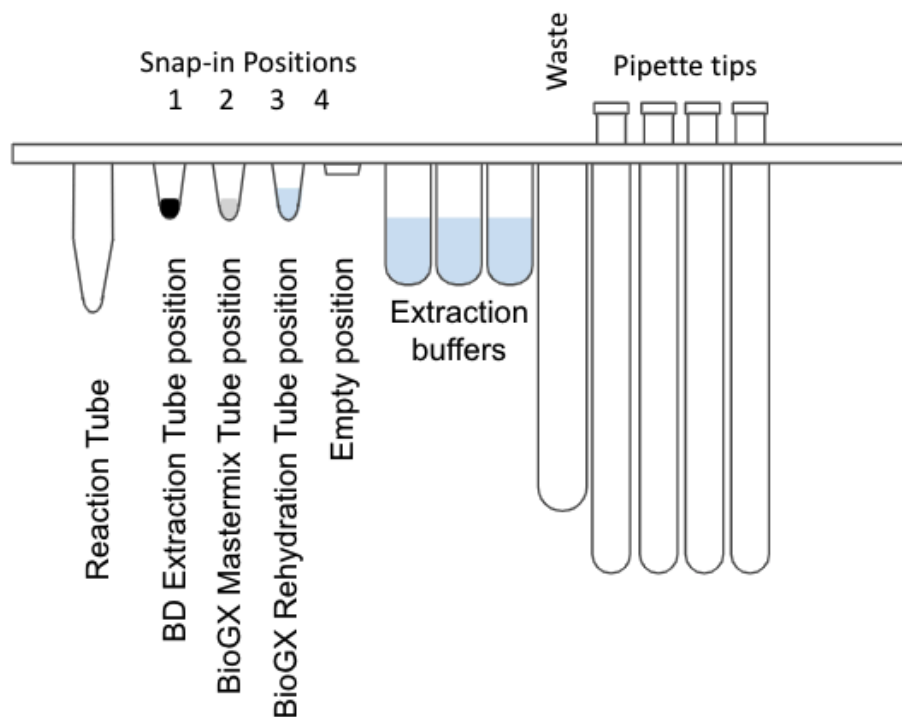


Figure 1. Diagram of BD MAX™ ExK™ 4-snap Unitized Reagent Strips.

Important Note

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

Note: The Snap-2 and Snap-4 positions will remain empty.

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

PCR SET-UP FOR TESTING USING: ABI QuantStudio™ 5, Bio-Rad CFX96 Touch™, BioGX pixl.16

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 tube of lyophilized BioGX reagents. The rehydrated master mix is more than sufficient for 4 samples to be tested.

Note: Rehydrated master mix must be transferred to clean 8-tube PCR strips or 96-well PCR plates compatible with appropriate Applied Biosystems, Bio-Rad and BioGX pixl.16 platform.

3. Mix by gently pipetting up and down.
(IMPORTANT: Keep rehydrated master mix in a cold block or on ice if setup 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).
4. Transfer **10 µL** of rehydrated master mix to the bottom of **4 clean, 8-tube PCR strips or 96-well PCR plates compatible with appropriate Applied Biosystems, Bio-Rad and BioGX pixl.16 platform.**
5. To each tube containing **10 µL** of rehydrated master mix, add **5 µL** of extracted sample.
5. Affix the optical caps/seals to the PCR tube strips/plates.
6. Pulse spin the sealed PCR tube strips/plates.
7. Load PCR tube strips/plates into the real-time PCR platform and start the run. Avoid unnecessary delay once samples 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 3. Multiplex PCR Results Interpretation for 450-114-C-MAX.

Measles Virus	RNase P	IAC	Interpretation
+	+/-	+/-	Measles virus POSITIVE
-	+	+	Measles virus NEGATIVE
-	+	-	Unresolved*
-	-	+	Unresolved*
-	-	-	Unresolved*

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

Table 4. Multiplex PCR Results Interpretation for 450-114-LMP.

Measles Virus	RNase P	IAC	Interpretation
+	+/-	+/-	Measles virus POSITIVE
-	+	+	Measles virus NEGATIVE
-	+	-	Unresolved*
-	-	+	Unresolved*
-	-	-	Unresolved*

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

REFERENCES

1. Hummel, Kimberly B., et al. "Development of quantitative gene-specific real-time RT-PCR assays for the detection of measles virus in clinical specimens." *Journal of virological methods* 132.1-2 (2006): 166-173.
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 info@biogx.com with any questions you may have regarding this product.

Rev. #	Effective Date	Summary of Changes
01	03 SEP 2026	Initial Release.

SYMBOLS

Symbol	Meaning	Symbol	Meaning
	Catalog number		Contains sufficient for <n> tests
	Research Use Only		Manufacturer
	Keep dry		Temperature limitation
	Biological Risks		



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