BioGX
Molecular Made Easy

Measles Virus
Open System PCR Reagents

REF **450-114-LMP**

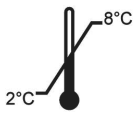
Σ 16 Reactions for use with BD MAX™ System

Σ 64 Reactions for use with ABI QuantStudio™ 5, Bio-Rad CFX96 Touch™ and BioGX pixl.16 real-time PCR platform

Product Insert

For Research Use Only: Not for use in diagnostic procedures

For use with BD MAX™ System, ABI QuantStudio™ 5, Bio-Rad CFX96 Touch™ or 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 (Windows® Software V4.72A or later), the Applied Biosystems QuantStudio™ 5 (Design & Analysis software version 1.5.1 or later), Bio-Rad CFX96 Touch™, 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 gene[1]), RNase P and Internal Amplification Control (IAC).

Note:

OSR 450-114-LMP contains all PCR primers, probes, enzymes, dNTPs, $MgCl_2$, buffers, and other components required for the PCR reaction. No exogenous addition of Sample Processing Control (SPC) is needed.

PACKAGE CONTENTS

BioGX REF: 450-114-LMP
Platform(s): BD MAX™ System, ABI QuantStudio™ 5, Bio-Rad CFX96 Touch™, BioGX pixl.16

Each 16-reaction/64-reaction package consists of one pouch that contains 2 x 8-tube PCR strips. Each tube contains BioGX lyophilized Sample-Ready™ reagents sufficient for:

a. 16 PCR reactions for use with the BD MAX™ System

OR

b. 64 PCR reactions for use with ABI QuantStudio™ 5, Bio-Rad CFX96 Touch™, BioGX pixl.16 platforms

Note: 8-tube strips containing reagents **ARE NOT** compatible with ABI QuantStudio™ 5, Bio-Rad CFX96 Touch™ and BioGX pixl.16 platforms.

EQUIPMENT AND MATERIALS REQUIRED BUT NOT PROVIDED

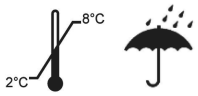
- BioGX Lyophilized Positive Control Template Beads (10^5 copies/bead)
  - BioGX Measles Virus (Part number 720-0245)
  - BioGX RNaseP (DNA) (Part number 720-0009)
- BioGX Molecular Grade Water or equivalent
  - BioGX Rehydration Water Part number: 800-0035-12
- Vortex Genie 2 Vortexer (VWR catalog no. 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)
- 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)
- BioGX pixl.16 real-time PCR instrument (BioGX catalog no. 650-016-PXL)
- 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)

  - Optional: BioGX pixl Barcode Scanner with Stand (BioGX catalog no. 650-726-SC-PXL)
- **Optional:**
  - BioGX pixl Barcode Scanner with Stand (BioGX catalog no. 650-726-SC-PXL)
- Calibrated micropipettes

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[2] and in Biosafety in Microbiological and Biomedical Laboratories[3].
- BioGX REF: 450-114-LMP has been quality control tested only with the BD MAX™ System (using BD Open System Extraction Kits), ABI QuantStudio™ 5, Bio-Rad CFX96 Touch™ 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-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 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 MAX™ ExK™ 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

-Oropharyngheal Swab collections Copan Universal Transport Media (UTM®), Copan ESwab™, Viral Transport Media (VTM)[a], saline (0.85% NaCl), Phosphate Buffer Saline (PBS)[b]

REAGENT OPTICAL CONFIGURATION

Table 1. 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

[a] *Centers for Disease Control. Preparation of Viral Transport Media (SOP#: DSR-052-05)*
[b] *PBS formulation: 137 mM NaCl, 2.7 mM KCl, 10 mM Na_2HPO_4, 1.8 mM KH_2PO_4, pH 7.2-7.4*

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 manual[4] 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 manual[5] for uploading instructions. Please refer to the Bio-Rad CFX96 Touch™ user manual[6] for uploading instructions. Please refer to the BioGX pixl.16 user manual[7] 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 UTM®, VTM, saline (0.85% NaCl) or PBS)

BD MAX™ System

Thoroughly vortex the sample prior to addition to the Sample Buffer Tube (SBT). Pipette up to 200 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*

Swab sample (1 mL Copan UTM®, Copan ESwab™, VTM, saline (0.85% NaCl) or PBS)

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*

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 one extraction cartridge into the extraction tray per specimen to be tested.
2. Snap one BD MAX™ Extraction Tube into position 1 (Snap-1) of each Unitized Reagent Strip (Figure 1).
3. Snap one BD MAX™ empty 0.3 mL conical tube into position 3 (Snap-3) of each Unitized Reagent Strip (See Figure 1).
   Note: Each BD MAX™ ExK™ TNA-3 extraction kit contains 24 empty 0.3 mL conical tubes for use in step 3.
4. Proceed with worklist generation and sample loading per BD MAX™ operating instructions. Select the appropriate User Defined Protocol (eUDP) provided by BioGX.
5. **Preparation of BioGX Measles Virus master mix**: Transfer 40 µL of BioGX molecular grade water to one tube of lyophilized 450-114-LMP reagents. Mix by gently pipetting up and down.
   IMPORTANT: Keep the rehydrated Master Mix in a cold block or on ice until dispensed into the position 3-Snap BD MAX conical tube. Rehydrated Master Mix that is not used immediately can be stored up to 24 hours at 2-8°C, protected from light.
6. Transfer 40 µL of rehydrated Master Mix to the bottom of each empty 0.3 mL conical tube into position 3 (Snap-3) of each Unitized Reagent Strip (Figure 1).
7. Lift the tray and briefly examine the bottom of each Unitized Reagent Strip to ensure all reagents are at the bottom of each tube and bubbles are not present in Extraction buffer reservoirs.
8. Load the extraction tray and, if necessary, a new PCR card into the instrument, close the door, and click “Start Run”. Avoid unnecessary delay once racks are loaded.

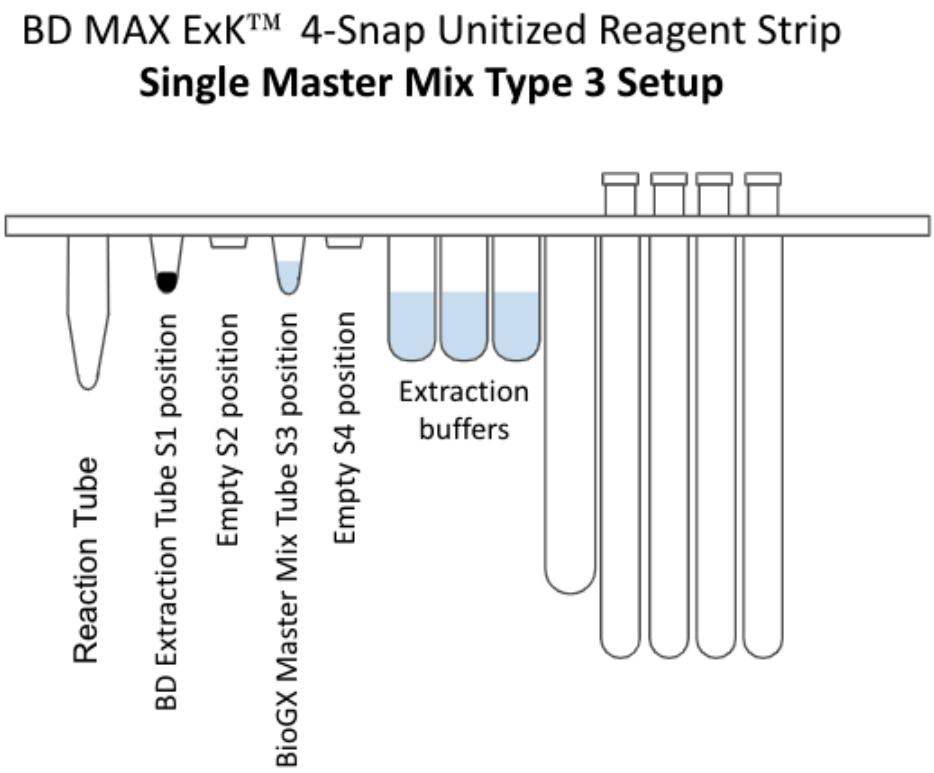


Figure 1. Diagram of BD MAX™ ExK™ 4-snap Unitized Reagent Strips.

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 2. 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.
5. QuantStudio™ Design and Analysis software User Guide, ThermoFisher Scientific, Waltham, Massachusetts, USA (Refer to the latest version).
6. 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).
7. pixl™ Real-Time PCR Platform Instructions for Use Manual (refer to the latest version)

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

Rev. #	Effective Date	Summary of Changes
01	24 SEP 2025	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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