BioGX
Molecular Made Easy

Xfree™ hMPXV Open System PCR Reagents

REF 450-086-E-PXL

Σ 16 Reactions Extraction-Free Direct Sample Tests
(ABI QuantStudio™ 5 and BioGX pixl.16 real-time PCR platform)

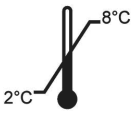
Σ 64 Reactions Extracted Sample Tests
(ABI QuantStudio™ 5 and BioGX pixl.16 real-time PCR platform)

Σ 16 Reactions Extracted Sample Tests (BD MAX™ System)

Product Insert

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

For use with BD MAX™ System, ABI QuantStudio™ 5 or BioGX pixl.16 real-time PCR platform



RUO

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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 BioGX *Xfree*™ human Monkeypox Virus (hMPXV) 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 Applied Biosystems QuantStudio™ 5 (Design & Analysis software version 1.5.1 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 *Xfree*™ Sample-Ready™ OSR has been formulated in lyophilized format for the multiplex real-time PCR-based detection of DNA from human Monkeypox virus (G2R_G gene[1,2]), human Orthopox virus (E9L NVAR gene[3]) and human RNase P gene to serve as an endogenous extraction control.

Note:

OSR 450-086-E-PXL contains all PCR primers, probes, enzymes, dNTPs, $MgCl_2$, buffers, and other components required for the PCR reaction. No exogenous addition of SPC is needed.

PACKAGE CONTENTS

BioGX REF: 450-086-E-PXL
Platform(s): BD MAX™ System, ABI QuantStudio™ 5, BioGX pixl.16

Each 16-reaction/64-reaction package consists of two pouches:

1. The first pouch contains 2 x 8-tube PCR strips. Each tube contains BioGX lyophilized Sample-Ready™ reagents sufficient for:
    a. 16 PCR reactions when used in extraction-free direct sample format on the ABI QuantStudio™ 5, BioGX pixl.16 platforms **OR**
    b. 64 PCR reactions when used in extracted sample format on the ABI QuantStudio™ 5, BioGX pixl.16 platforms **OR**
    c. 16 PCR reactions when used in extracted sample format on the BD MAX™ System

2. The second pouch contains 1 tube of Rehydration Buffer E (BioGX catalog no. 800-0031-E-L), each containing 650µL of Rehydration Buffer E.

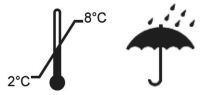
EQUIPMENT AND MATERIALS REQUIRED BUT NOT PROVIDED

- External Positive Control[s] available from BioGX or Microbix
  - BioGX Lyophilized Positive Control Template DNA Beads (10^5 copies/bead)
    - BioGX Monkeypox (Part number 720-0232)
    - BioGX Orthopox (Part number 720-0233)
    - BioGX RNaseP (DNA) (Part number 720-0009)
  - Microbix PROCEEDx™FLOQ® Monkeypox West African Positive Swab (Microbix catalog no. VP-S-81-02)
- Vortex Genie 2 Vortexer (VWR catalog no. 58815-234) or equivalent
- Disposable nitrile gloves
- BD MAX™ ExK™ DNA-3 (US BD catalog no. 442821/ International BD catalog no. 442822)
- 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)
- 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 human or animal diagnostics use.
- 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[4] and in Biosafety in Microbiological and Biomedical Laboratories[5].
- BioGX REF: 450-086-E-PXL has been quality control tested only with the BD MAX™ System (using BD Open System Extraction Kits), ABI QuantStudio™ 5 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 seal/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™ DNA-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

-Lesion swab samples collected in 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 450-086-E-PXL

Optical Channel (Fluorophore Equivalent)	**Target**
FAM	Monkeypox virus
HEX	Orthopox virus
Texas Red	Unused
Cy5	RNase P
Cy5.5	N/A

[a]Centers for Disease Control. Preparation of Viral Transport Media (SOP#: DSR-052-05)
[b]Phosphate Buffered Saline 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 (BioGX REF: 450-086-E-PXL)

As a starting point, users can import and install the Electronic User Defined Protocol (eUDP) that utilizes **ExK DNA-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[6] for uploading instructions**.**

ABI and BioGX pixl.16 Platforms (BioGX REF: 450-086-E-PXL)

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

BioGX's most current ABI QuantStudio™ 5 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[7] for uploading instructions. Please refer to the BioGX pixl.16 user manual[8] for uploading instructions.

PREPARATION OF MICROBIX EXTERNAL CONTROL

Positive Control Microbix PROCEEDx™ FLOQ® Monkeypox West African Positive Swab (Microbix catalog no. VP-S-81-02) is added into Copan Universal Transport Media (UTM®), Copan ESwab™, Viral Transport Media (VTM), saline (0.85% NaCl) or Phosphate Buffer Saline (PBS) and incubated at room temperature for 1-2 min. After the incubation, swirl the swab 5-10 times in the vial, express the swab on the inside of the vial and discard into designated biohazard waste.

Direct Sample Processing of Microbix External Control tested on ABI QuantStudio™ 5, BioGX pixl.16

Transfer **20 µL** of direct positive control sample to the rehydrated BioGX master mix as described in Section: *PCR SET-UP FOR EXTRACTION-FREE DIRECT SAMPLES TESTED ON ABI QuantStudio™ 5, BioGX pixl.16*

Extracted Sample Processing of Microbix External Control tested on BD MAX™ System

Thoroughly vortex the sample prior to processing.
For Copan Universal Transport Media (UTM®), Copan ESwab™, Viral Transport Media (VTM), saline (0.85% NaCl) or Phosphate Buffer Saline (PBS) filled with 3 mL transport media, transfer up to 400 µL of prepared Positive Control to the Sample Buffer Tube as described in: *PCR SET-UP FOR EXTRACTED SAMPLES TESTED ON BD MAX™ System.*
For Copan Universal Transport Media (UTM®), Copan ESwab™, Viral Transport Media (VTM), saline (0.85% NaCl) or Phosphate Buffer Saline (PBS) filled with 1 mL transport media, transfer up to 100 µL of prepared Positive Control to the Sample Buffer Tube as described in: *PCR SET-UP FOR EXTRACTED SAMPLES TESTED ON BD MAX™ System.*

Extracted Sample Processing of Microbix External Control tested on ABI QuantStudio™ 5, BioGX pixl.16

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 EXTRACTED SAMPLES TESTED ON ABI QuantStudio™ 5, BioGX pixl.16*

The External Control available from Microbix (Microbix PROCEEDx™ FLOQ® Monkeypox West African Positive Swab (Microbix catalog no. VP-S-81-02)) is treated as if it was a patient sample. Refer to **Table 2** in the "Results Interpretation" section for the interpretation of External Control assay results. It is recommended that one (1) External Positive Control and one (1) External Negative Control be included with each run of patient samples. BioGX recommends that the External Negative Control be prepared prior to the External Positive Control in order to reduce the potential for cross contamination as a result of control preparation.

For further reference, please refer to the product information sheet for Microbix PROCEEDx™ FLOQ® Monkeypox West African Positive Swab (Microbix catalog no. VP-S-81-02)[9].

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.

PCR SET-UP FOR EXTRACTION-FREE DIRECT SAMPLES TESTED ON ABI QuantStudio™ 5, BioGX pixl.16

Swab sample (3 mL Copan UTM®, VTM, saline (0.85% NaCl) or PBS)

Thoroughly vortex the sample prior to processing. Transfer **20 µL** of direct sample to the rehydrated BioGX master mix as described in Section: *PCR SET-UP FOR EXTRACTION-FREE DIRECT SAMPLES TESTED ON ABI QuantStudio™ 5, BioGX pixl.16*

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

Thoroughly vortex the sample prior to processing. Transfer **20 µL** of direct sample to the rehydrated BioGX master mix as described in Section: *PCR SET-UP FOR EXTRACTION-FREE DIRECT SAMPLES TESTED ON ABI QuantStudio™ 5, BioGX 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 EXTRACTION-FREE DIRECT SAMPLES TESTED ON ABI QuantStudio™ 5, BioGX pixl.16

1. Prepare the appropriate number of 8-tube PCR strips or 96-well PCR plates.
2. Transfer **30 µL** of Rehydration Buffer E to one tube of lyophilized BioGX reagents. The rehydrated master mix is sufficient for 1 sample to be tested.
Note: 8-tube strips containing reagents are only compatible with the BioGX pixl.16 platform. 8-tube strips containing reagents ARE NOT compatible with Applied Biosystems Platforms. Rehydrated master mix must be transferred to 8-tube PCR tube strips or 96-well PCR plates compatible with appropriate instruments.
3. Mix by gently tapping the tube with your fingers until the lyophilized pellet has been dissolved.
(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. To each PCR tube containing **30 µL** of rehydrated master mix, add **20 µL** of direct sample.
5. Affix the optical caps/seals to the PCR tube strips/plates.
6. Pulse spin the sealed PCR tube strips/plates.
7a. **For BioGX pixl.16 Platform:** Load PCR tube strips into the real-time PCR platform and start the run. Avoid unnecessary delay once samples are loaded into the real-time PCR instrument.
7b. **For Applied Biosystems Platform:** Transfer rehydrated master mix to 8-tube PCR tube strips or 96-well PCR plates compatible with the appropriate instrument and start the run. Avoid unnecessary delay once samples are loaded into the real-time PCR instrument.

PCR SET-UP FOR EXTRACTED SAMPLES TESTED ON ABI QuantStudio™ 5, BioGX pixl.16 or BD MAX™ System

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 400 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 EXTRACTED SAMPLES TESTED ON BD MAX™ System.*

ABI 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 EXTRACTED SAMPLES TESTED ON ABI QuantStudio™ 5, BioGX 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 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 as described in Section: *PCR SET-UP FOR EXTRACTED SAMPLES TESTED ON BD MAX™ System.*

ABI 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 EXTRACTED SAMPLES TESTED ON ABI QuantStudio™ 5, BioGX 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 ON 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™ DNA-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 hMPXV master mix**: Transfer 40 µL of BioGX Rehydration Buffer E to one tube of lyophilized 450-086-E-PXL 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.

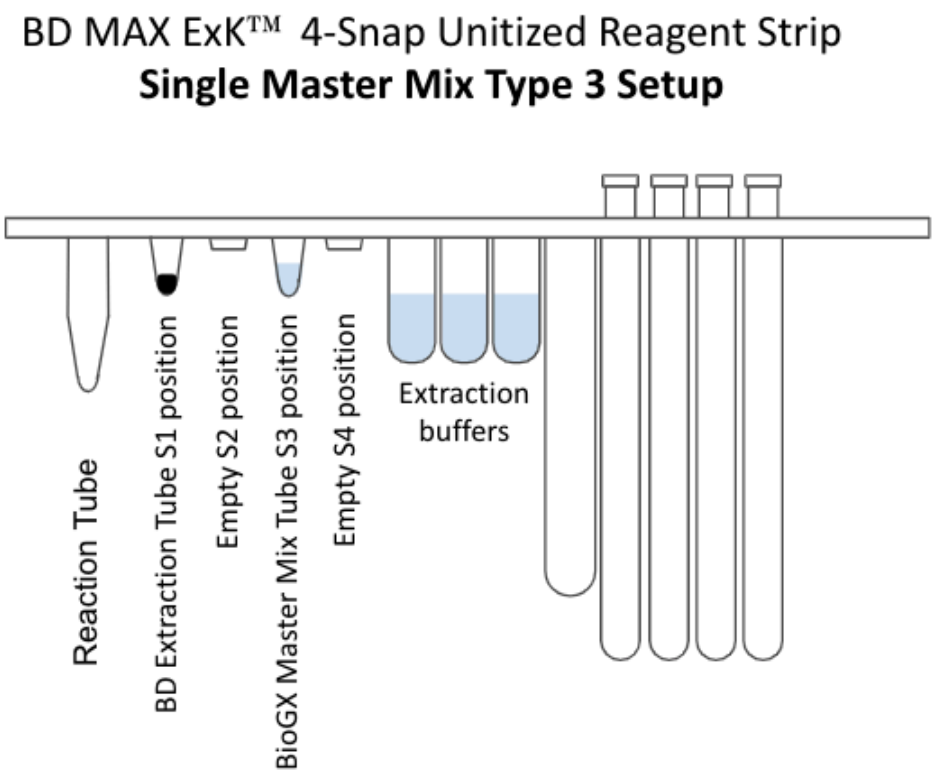


Figure 1. Diagram of BD MAX™ ExK™ 4-snap Unitized Reagent Strips.

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 EXTRACTED SAMPLES TESTED ON ABI QuantStudio™ 5, 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 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 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. Interpretation of Microbix External Control for 450-086-E-PXL.

Control Type	Applicability for Monitoring	Monkeypox virus	Orthopox virus	RNase P
Microbix PROCEEDx™ FLOQ® Monkeypox West African Positive Swab (Microbix catalog no. VP-S-81-02)	Substantial reagent failure including primer and probe integrity	+	+	+

Note: Microbix PROCEEDx™ FLOQ® Monkeypox West African Positive Swab (Microbix catalog no. VP-S-81-02) contains human cellular material to control for the amplification of human RNase P.

Table 3. Multiplex PCR Results Interpretation for 450-086-E-PXL.

Monkeypox virus	Orthopox virus	RNase P	Interpretation
+	+	+/-	Monkeypox virus POSITIVE
-	+/-	+	Monkeypox virus NEGATIVE
-	+	+/-	Orthopox virus POSITIVE*
-	-	+	Monkeypox and Orthopox virus NEGATIVE
-	-	-	Unresolved**

*Orthopox only amplification should be retested to confirm lack of detection of Monkeypox detection was due to poor collection. Upon retesting, Orthopox only detection indicates detection of a non-Monkeypox virus.
**Failed PCR due to inhibition, reagent failure or incorrect assembly of PCR reaction.

REFERENCES

1. Li, Daniel, et al. "Evaluation of the GeneXpert for human monkeypox diagnosis." The American Journal of Tropical Medicine and Hygiene 96.2 (2017): 405.
2. Li, Yu, et al. "Real-time PCR assays for the specific detection of monkeypox virus West African and Congo Basin strain DNA." Journal of virological methods 169.1 (2010): 223-227.
3. Li, Yu, et al. "Detection of monkeypox virus with real-time PCR assays." Journal of Clinical Virology 36.3 (2006): 194-203.
4. Clinical and Laboratory Standards Institute. Protection of laboratory workers from occupationally acquired infections; Approved Guideline. Document M29 (Refer to the latest edition).
5. 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.
6. BD MAX™ System User's Manual (refer to the latest revision) BD Life Sciences, Sparks, Maryland 21152 USA.
7. QuantStudio™ Design and Analysis software User Guide, ThermoFisher Scientific, Waltham, Massachusetts, USA (Refer to the latest version).
8. pixl™ Real-Time PCR Platform Instructions for Use Manual (refer to the latest version)
9. Microbix, PROCEEDx™FLOQ® Monkeypox West African Swab Positive Sample VP-S-81-02, Product Information Sheet (Refer to the latest edition).

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

Rev. #	Effective Date	Summary of Changes
06	30 AUG 2024	Update to recommend extracted sample workflow with BD MAX™ System
05	06 MAR 2024	Update to recommend direct sample and extracted sample workflow with BioGX pixl.16 and ABI QuantStudio™ 5 platform.
04	22 AUG 2023	Addition of Microbix PROCEEDx™FLOQ® Monkeypox West African Positive Swab (Microbix catalog no. VP-S-81-02) as positive control alternative
03	20 JAN 2023	Update of title page to include number of tests per kit for extraction-free and extracted workflow
02	06 JAN 2023	Addition of extraction based workflow
01	01 SEP 2022	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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