



BioGX

Molecular Made Easy

Gardnerella vaginalis, Trichomonas vaginalis, Candida albicans, Candida glabrata Open System PCR Reagents

REF 450-037-Series



24 Reactions 450-037-C-MAX



64 Reactions 450-037-LMP

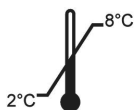


64 Reactions 450-037-PXL

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™, BioGX pixl.16 real-time PCR platform



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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 Gardnerella vaginalis, Trichomonas vaginalis, Candida albicans, Candida glabrata 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), Applied Biosystems QuantStudio™ 5 (Design & Analysis software version 1.5.1 or later), Bio-Rad CFX96 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 Sample-Ready™ OSR has been formulated in lyophilized format for the multiplex real-time PCR-based detection of DNA from Gardnerella vaginalis (16S rRNA gene¹), Trichomonas vaginalis (repeated DNA target gene²), Candida albicans (ITS2 gene^{3,4}), Candida glabrata (ITS2 gene^{3,4}) and a Sample Processing Control (SPC) (Drosophila DNA) for use with BD MAX extraction kit. The Drosophila DNA serves as both a sample processing control and an internal amplification control. The configuration compatible with the ABI and Bio-Rad platform targets the human RNase P gene to serve as an endogenous extraction control. Three different formats for the lyophilized Sample-Ready OSR kits are available:

1. BD MAX™ System
REF 450-037-C-MAX
2. ABI QuantStudio™ 5 and Bio-Rad CFX96 Touch™ Platforms
REF 450-037-LMP
3. BioGX pixl.16 Platform
REF 450-037-PXL

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Note:

BD MAX™ System OSR (450-037-C-MAX) contains all PCR primers, probes, enzymes, dNTPs, MgCl₂, 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.

OSR for ABI and Bio-Rad Platforms (450-037-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.

BioGX pixl.16 Platform (450-037-PXL) contains all PCR primers, probes, enzymes, dNTPs, MgCl₂, buffers, and other components required for the PCR reaction. Refer to product 450-102-PXL for use in a separate reaction to detect human RNase P endogenous extraction control.

PACKAGE CONTENTS

BioGX REF: 450-037-C-MAX

Platform(s): BD MAX™ System

Each 24-reaction package contains two pouches:

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

BioGX REF: 450-037-LMP

Platform(s): ABI QuantStudio™ 5 and Bio-Rad CFX96 Touch™

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 and Bio-Rad CFX96 Touch™ instruments.

Gardnerella vaginalis, Trichomonas vaginalis, Candida albicans, Candida glabrata Open System PCR Reagents

BioGX REF: 450-037-PXL

Platform(s): BioGX pixl.16 Platform

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 lyophilized reagents require rehydration and dispensing step into clean pixl-compatible tubes before use. Refer to Section *BioGX Quality Control Test Setup Procedure for BioGX pixl.16 Platform* below.

EQUIPMENT AND MATERIALS REQUIRED BUT NOT PROVIDED

- Lyophilized Positive Control Template DNA Beads (10^5 copies/bead)
 - BioGX Gardnerella vaginalis (Part number 720-0205)
 - BioGX Trichomonas vaginalis (Part number 720-0152)
 - BioGX Candida albicans (Part number 720-0038)
 - BioGX Candida glabrata (Part number 720-0039)
- Lyophilized Positive Control Template DNA Beads (10^5 copies/bead) for ABI and Bio-Rad platforms
 - BioGX RNaseP (DNA) (Part number 720-0009)
- BioGX Molecular Grade Water or equivalent
 - BioGX Rehydration Water (Part number 800-0035-12)
- BioGX Lyophilized Far Red Dye Calibration Kit for Applied Biosystems QuantStudio 5 (Part number 720-0219)
- BioGX human RNase P Open System PCR Reagents (Part number 450-102-PXL)
- 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)
- Vortex Genie 2 Vortexer (VWR catalog no. 58815-234) or equivalent
- Disposable nitrile gloves
- 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-R)
- BioGX pixl.16 consumables.

Gardnerella vaginalis, Trichomonas vaginalis, Candida albicans, Candida glabrata Open System PCR Reagents

- 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)

WARNINGS AND PRECAUTIONS



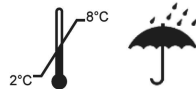
- For research use only. Not intended for use in diagnostic procedures.
- If handling biological samples, including used Extraction Kits and PCR Cartridges, treat as if capable of transmitting infectious agents in accordance with safe laboratory procedures such as those described in CLSI Document M29⁵ and in Biosafety in Microbiological and Biomedical Laboratories⁶.
- BioGX REF: 450-037-C-MAX has been quality control tested only with the BD Open System Extraction Kits on the BD MAX™ System.
- BioGX REF: 450-037-LMP has been quality control tested only with the Applied Biosystems QuantStudio™ 5 and Bio-Rad CFX96 Touch™ real-time PCR platforms.
- BioGX REF: 450-037-PXL has been quality control tested only with the BioGX pixl.16 real-time PCR platform.
- 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.
- 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.



Gardnerella vaginalis, Trichomonas vaginalis, Candida albicans, Candida glabrata Open System PCR Reagents

- 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 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

- Urine (neat or boric acid preserved)
- Swab samples collected in Copan Universal Transport Media (UTM[®]) or Hologic ThinPrep[®]

**Gardnerella vaginalis, Trichomonas vaginalis,
Candida albicans, Candida glabrata
Open System PCR Reagents**

REAGENT OPTICAL CONFIGURATION

Table 1A. Optical Channel Configuration for REF 450-037-C-MAX.

Optical Channel (Fluorophore Equivalent)	Target
FAM	Candida glabrata
HEX	Gardnerella vaginalis
Texas Red	Candida albicans
Cy5	Trichomonas vaginalis
Cy5.5	SPC

Table 1B. Optical Channel Configuration for REF 450-037-LMP^a.

Optical Channel (Fluorophore Equivalent)	Target
FAM	Candida glabrata
HEX	Gardnerella vaginalis
Texas Red	Candida albicans
Cy5	Trichomonas vaginalis
Cy5.5 ^a	RNase P

^a*When using the Applied Biosystems Quantstudio 5 instrument, the BioGX Lyophilized Far Red Dye Calibration Kit for Applied Biosystems QuantStudio 5 (Part number 720-0219) will be needed to add this dye to the instrument dye library. Please refer to the Product Insert of 720-0219 available on www.biogx.com for instructions and further details¹⁰.*

Gardnerella vaginalis, Trichomonas vaginalis, Candida albicans, Candida glabrata Open System PCR Reagents

Table 1C. Optical Channel Configuration for REF 450-037-PXL^b.

Optical Channel (Fluorophore Equivalent)	Target
FAM	Candida glabrata
HEX	Gardnerella vaginalis
Texas Red	Candida albicans
Cy5	Trichomonas vaginalis

^bREF 450-037-PXL does not include primers and probes for human RNase P detection which serves as endogenous extraction control. Use of BioGX Product 450-102-PXL in parallel will support detection of the human RNase P endogenous extraction control. Please refer to the Product Insert of 450-102-PXL available on www.bioqix.com for instructions and further details.

QUALITY CONTROL AND EXTRACTION TESTING PARAMETERS

BD MAX™ System (BioGX REF: 450-037-C-MAX)

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@bioqix.com. Please refer to the BD MAX™ user manual⁷ for uploading instructions.

ABI and Bio-Rad Platforms (BioGX REF: 450-037-LMP)

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)

BioGX's most current ABI QuantStudio™ 5 and Bio-Rad CFX96 Touch™ PCR run files utilized for quality control of this product can be obtained by sending an email to TS@bioqix.com. Please refer to the Applied Biosystems QuantStudio™5 user manual⁸ for uploading instructions. Please refer to the Bio-Rad CFX96 Touch™ user manual⁹ for uploading instructions.

Gardnerella vaginalis, Trichomonas vaginalis, Candida albicans, Candida glabrata Open System PCR Reagents

BioGX pixl.16 Platform (REF: 450-037-PXL)

As a starting point, users can import and install a PCR run file onto:

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

BioGX's most current BioGX pixl.16 PCR run file utilized for quality control of this product can be obtained by sending an email to TS@biogx.com. Please refer to the BioGX pixl.16 user manual¹¹ 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.

Urine collection (neat urine or boric acid preserved urine)

BD MAX™ System (REF: 450-037-C-MAX)

Thoroughly vortex the sample prior to addition to the Sample Buffer Tube (SBT). Pipette 500 µL of neat urine or boric acid preserved 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 QuantStudio™ 5, Bio-Rad CFX96 Touch™ and BioGX pixl.16 Platform (validated magnetic bead or silica column extraction kits) (REF: 450-037-LMP and REF: 450-037-PXL)

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: *BioGX Quality Control Test Setup Procedure for ABI QuantStudio™ 5, Bio-Rad CFX96 Touch™ and BioGX pixl.16 Platforms.*

Gardnerella vaginalis, Trichomonas vaginalis, Candida albicans, Candida glabrata Open System PCR Reagents

Swab sample (3 mL Copan Universal Transport Media (UTM[®]))

BD MAX[™] System (REF: 450-037-C-MAX)

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

ABI QuantStudio[™] 5, Bio-Rad CFX96 Touch[™] and BioGX pixl.16 Platform (validated magnetic bead or silica column extraction kits) (REF: 450-037-LMP and REF: 450-037-PXL)

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: *BioGX Quality Control Test Setup Procedure for ABI QuantStudio[™] 5, Bio-Rad CFX96 Touch[™] and BioGX pixl.16 Platforms.*

Swab sample (1 mL Copan Universal Transport Media (UTM[®]))

BD MAX[™] System (REF: 450-037-C-MAX)

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.

ABI QuantStudio[™] 5, Bio-Rad CFX96 Touch[™] and BioGX pixl.16 Platform (validated magnetic bead or silica column extraction kits) (REF: 450-037-LMP and REF: 450-037-PXL)

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: *BioGX Quality Control Test Setup Procedure for ABI QuantStudio[™] 5, Bio-Rad CFX96 Touch[™] and BioGX pixl.16 Platforms.*

Gardnerella vaginalis, Trichomonas vaginalis, Candida albicans, Candida glabrata Open System PCR Reagents

Swab (Hologic ThinPrep[®])

BD MAX[™] System (REF: 450-037-C-MAX)

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

ABI QuantStudio[™] 5, Bio-Rad CFX96 Touch[™] and BioGX pixl.16 Platform (validated magnetic bead or silica column extraction kits) (REF: 450-037-LMP and REF: 450-037-PXL)

Thoroughly vortex the sample prior to processing. Follow manufacturer recommendations for extraction of appropriate sample volume. Transfer 5 μ L of purified nucleic acid to master mix as described in Section: *BioGX Quality Control Test Setup Procedure for ABI QuantStudio[™] 5, Bio-Rad CFX96 Touch[™] and BioGX pixl.16 Platforms.*

BioGX QUALITY CONTROL TEST SETUP PROCEDURE

BD MAX™ System Quality Control Test Setup (REF: 450-037-C-MAX)

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 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.
6. 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.
7. 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.”
8. 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**

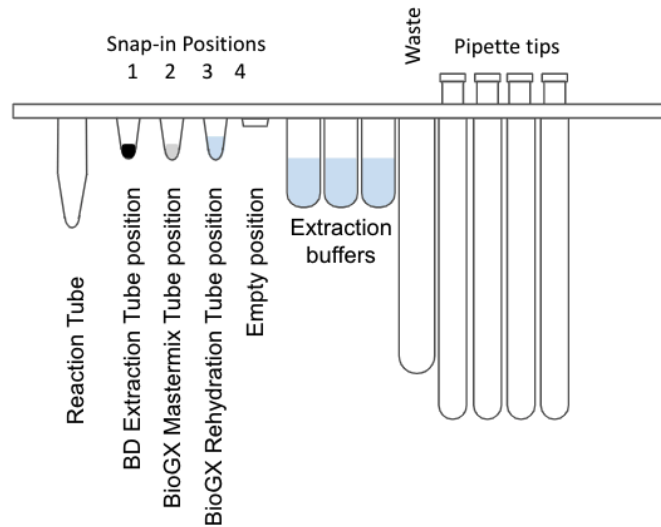


Figure 1. Diagram of BD MAX™ ExK™ 4-snap Unitized Reagent Strips.

Important Note

Always first insert all Snap-1 tubes, 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 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.

Gardnerella vaginalis, Trichomonas vaginalis, Candida albicans, Candida glabrata Open System PCR Reagents

ABI QuantStudio™ 5, Bio-Rad CFX96 Touch™ and BioGX pixl.16 Platforms Quality Control Test Setup
(REF: 450-037-LMP and 450-037-PXL)

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

Assembly of BioGX Reagents

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

Note: 8-tube strips containing reagents **ARE NOT** compatible with ABI QuantStudio™ 5 and Bio-Rad CFX96 Touch™ instruments. Rehydrated master mix must be transferred to 8-tube PCR strips or 96-well PCR plates compatible with appropriate instruments.

3. Mix by gently pipetting up and down. (IMPORTANT: Keep rehydrated master mix in a cold block or on ice if setup cannot not 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 empty wells.
5. To each well containing 10 µL of rehydrated master mix, add 5 µL of extracted sample.
6. Affix the appropriate optical caps or optical plate seals.
7. Pulse spin the sealed PCR plate or tube to mix and bring liquid to the bottom.
8. Load 8-tube PCR strips or 96-well PCR plates into the real-time PCR platform and start the run. Avoid unnecessary delay once tubes/plates 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.

Gardnerella vaginalis, Trichomonas vaginalis, Candida albicans, Candida glabrata Open System PCR Reagents

INTERPRETATION OF RESULTS

Table 2A. Multiplex PCR Results Interpretation for 450-037-C-MAX.

Candida glabrata	Gardnerella vaginalis	Candida albicans	Trichomonas vaginalis	SPC	Interpretation
+	-	-	-	+/-	Candida glabrata POSITIVE
-	+	-	-	+/-	Gardnerella vaginalis POSITIVE
-	-	+	-	+/-	Candida albicans POSITIVE
-	-	-	+	+/-	Trichomonas vaginalis POSITIVE
-	-	-	-	+	Candida glabrata, Gardnerella vaginalis, Candida albicans, Trichomonas vaginalis NEGATIVE
-	-	-	-	-	Unresolved*

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

Table 2B. Multiplex PCR Results Interpretation for 450-037-LMP.

Candida glabrata	Gardnerella vaginalis	Candida albicans	Trichomonas vaginalis	RNase P	Interpretation
+	-	-	-	+/-	Candida glabrata POSITIVE
-	+	-	-	+/-	Gardnerella vaginalis POSITIVE
-	-	+	-	+/-	Candida albicans POSITIVE
-	-	-	+	+/-	Trichomonas vaginalis POSITIVE
-	-	-	-	+	Candida glabrata, Gardnerella vaginalis, Candida albicans, Trichomonas vaginalis NEGATIVE
-	-	-	-	-	Unresolved*

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

Gardnerella vaginalis, Trichomonas vaginalis, Candida albicans, Candida glabrata Open System PCR Reagents

Table 2C. Multiplex PCR Results Interpretation for 450-037-PXL.

Candida glabrata	Gardnerella vaginalis	Candida albicans	Trichomonas vaginalis	RNase P**	Interpretation
+	-	-	-	+/-	Candida glabrata POSITIVE
-	+	-	-	+/-	Gardnerella vaginalis POSITIVE
-	-	+	-	+/-	Candida albicans POSITIVE
-	-	-	+	+/-	Trichomonas vaginalis POSITIVE
-	-	-	-	+	Candida glabrata, Gardnerella vaginalis, Candida albicans, Trichomonas vaginalis NEGATIVE
-	-	-	-	-	Unresolved*

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

**RNase P amplification can only be assessed when running 450-102-PXL in parallel.

REFERENCES









1. Schabereiter-Gurtner, Claudia, et al. "Development of novel real-time PCR assays for detection and differentiation of eleven medically important Aspergillus and Candida species in clinical specimens." *Journal of clinical microbiology* 45.3 (2007): 906-914.
2. Muir, Alastair, et al. "Rapid electrochemical identification of pathogenic Candida species." *Journal of medical microbiology* 58.9 (2009): 1182-1189.
3. Zozaya-Hinchliffe, Marcela, et al. "Quantitative PCR assessments of bacterial species in women with and without bacterial vaginosis." *Journal of clinical microbiology* 48.5 (2010): 1812-1819.
4. Saleh, Amir M., et al. "Diagnosis of Trichomonas vaginalis by microscopy, latex agglutination, diamond's media, and PCR in symptomatic women, Khartoum, Sudan." *Diagnostic Pathology* 9.1 (2014): 1-5.
5. Clinical and Laboratory Standards Institute. Protection of laboratory workers from occupationally acquired infections; Approved Guideline. Document M29 (Refer to the latest edition).
6. 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.
7. BD MAX™ System User's Manual (refer to the latest revision) BD Life Sciences, Sparks, Maryland 21152 USA.
8. QuantStudio™ Design and Analysis software User Guide, ThermoFisher Scientific, Waltham, Massachusetts, USA (Refer to the latest version).
9. 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).
10. BioGX Lyophilized Far Red Dye Calibration Kit for Applied Biosystems QuantStudio™ 5 Real-Time PCR system Product number series 720-0219 (www.biogx.com)
11. BioGX pixl.16 Real-Time PCR Platform Instructions for Use (refer to the latest version), BioGX, Inc., Birmingham, Alabama, USA.

Gardnerella vaginalis, Trichomonas vaginalis, Candida albicans, Candida glabrata Open System PCR Reagents

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

Rev. #	Effective Date	Summary of Changes
05	12 NOV 2025	Updated research use only text.
04	DD MMM 2023	Update to include 450-037-PXL and associated workflows
03	25 JAN 2022	Update to include reference to BioGX Far Red Dye Calibration Kit for use with Applied Biosystems Quantstudio 5
02	04 AUG 2021	Update branding, extraction control for ABI and Bio-Rad platforms. and storage conditions.
01	28 MAY 2021	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



BioGX

BioGX
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