BioGX
Molecular Made Easy

Manual

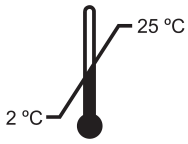
Mycoplasma - Ureaplasma – OSR for BD MAX™

Version 08

REF 400-003-C-MAX

24 reactions

For *In Vitro* Diagnostic Use
For use with BD MAX™ Open System Reagents on the BD MAX™ System




CE IVD

BioGX BV
Science Park 408, 1098 XH Amsterdam, The Netherlands
Phone: +31.20.893.4261 Fax: +31.20.240.9149

PROPRIETARY NAME

BioGX *Mycoplasma - Ureaplasma* – OSR for BD MAX™

INTENDED USE

The BioGX *Mycoplasma - Ureaplasma* – OSR for BD MAX™ is a multiplex real-time multiplex polymerase chain reaction (PCR) assay for use on the BD MAX™ platform for the qualitative detection of the presence of DNA from *Mycoplasma genitalium, Mycoplasma hominis, Ureaplasma urealyticum, Ureaplasma parvum* from the following specimens:

- **Cervical collection**
  - -Hologic ThinPrep®
- **Vaginal swab collection**
  - -Copan Universal Transport Media (UTM®)
  - -BD™ Universal Viral Transport (UVT)
- **Neat urine collection**

The assay can only be performed on the BD MAX™ automated nucleic acid extraction and real-time PCR instrument using the BD MAX™ ExK™ DNA-1 extraction strip and the accompanying BioGX UDP file.

The BD MAX™ extraction reagent contains a Sample Processing Control (SPC) DNA, the presence of which is also detected by the BioGX multiplex assay. This SPC serves as a control for the extraction of nucleic acids from the sample and as an internal amplification control. No external addition of SPC by the user is required.

The multiplex PCR assay is provided in a BioGX proprietary Sample-Ready™ lyophilized format sealed in a BD MAX™ tube. Each tube contains all PCR components such as primers, probes, enzymes, dNTPs, $MgCl_2$, and buffers required for real-time PCR-based testing of one sample.

SUMMARY AND EXPLANATION

Mycoplasma genitalium, Ureaplasma urealyticum, Mycoplasma hominis, and *Ureaplasma parvum* are small gram-negative bacteria that are sexually transmitted and considered to be either commensal or pathogenic. While there are decades of history studying these bacteria of the genital and urinary tracts, evidence points towards these bacteria playing dual roles in both the normal flora as well as contributing to chorioamnionitis, salpingitis, bacterial vaginosis, and postpartum endometritis.

Most management efforts focus on a syndromic approach to diagnose and treat patients with *Mycoplasma* and/or *Ureaplasma,* addressing symptoms such as inflammation and mucopurulent discharge. However, many patients will present as asymptomatic and diagnosis will be missed due to the difficulty of culturing these bacteria by conventional methods. The ability to simultaneously detect these organisms with high specificity and sensitivity using methods such as real time PCR is necessary to properly diagnose and prescribe the appropriate antibiotic treatment.

Prevalence of both *Mycoplasma* and *Ureaplasma* is particularly high but varies significantly by region. In a study of healthy women in Korea, approximately 50% of women tested had at least a single infection of either *Mycoplasma genitalium, Ureaplasma urealyticum, Mycoplasma hominis,* or *Ureaplasma parvum* and 10% had at least a double infection. The overall prevalence of *Mycoplasma* and *Ureaplasma* in sexually active female populations worldwide, as reported by the Centers for Disease Control, ranges between 1% and 64%.

PRINCIPLES OF THE PROCEDURE

The BioGX *Mycoplasma - Ureaplasma* – OSR for BD MAX™ is to be used with the BD MAX™ Open System for automated patient sample processing and molecular analysis. The BD MAX™ System uses a combination of lytic and extraction reagents to perform cell lysis and nucleic acid extraction. Following enzymatic cell lysis at elevated temperature, the released nucleic acids are captured by magnetic affinity beads. To control for extraction efficiency, a DNA Sample Processing Control is included in each BD MAX™ DNA Extraction Tube. The beads with bound nucleic acids are washed and the nucleic acids are eluted by heat in an elution buffer. The eluted nucleic acid is then mixed with the BioGX Rehydration Buffer, which is then transferred to the BioGX Sample-Ready™ lyophilized master mix tube in order to rehydrate the Sample-Ready™ lyophilized master mix. The rehydrated mix of amplification reagent and nucleic acid is then dispensed into the BD MAX™ PCR Cartridge. Microvalves in the BD MAX™ PCR Cartridge are sealed by the system prior to initiating PCR to prevent evaporation and amplicon contamination.

The amplified DNA targets are detected using hydrolysis probes labeled at one end with a fluorescent reporter dye (fluorophore) and at the other end with a quencher moiety. Probes labeled with different fluorophores are used to detect specific amplicons originating from *Mycoplasma genitalium, Mycoplasma hominis, Ureaplasma urealyticum, Ureaplasma parvum,* and a Sample Processing Control in five different optical channels of the BD MAX™ System: *Mycoplasma genitalium* amplicons are detected in the 475/520 channel, *Ureaplasma urealyticum* amplicons are detected in the 530/565 channel,

Mycoplasma hominis amplicons are detected in the 585/630 channel, *Ureaplasma parvum* amplicons are detected in the 630/665 channel, and the DNA Sample Processing Control is detected in the 680/715 channel. When the probes are in their native state, the fluorescence of the fluorophore is quenched due to its proximity to the quencher. However, in the presence of their specific target cDNA, the probes hybridize to their complementary sequences and are hydrolyzed by the 5'-3' exonuclease activity of the DNA polymerase as it synthesizes the nascent strand along the DNA template. As a result, the fluorophores are separated from their quencher molecules and fluorescence is emitted. The amount of fluorescence detected in the five optical channels used for the *Bio*GX *Mycoplasma - Ureaplasma* – OSR for BD MAX™ is directly proportional to the quantity of the corresponding probe that is hydrolyzed, and therefore proportional to the amount of synthesized target. The BD MAX™ System measures these signals at the end of each amplification cycle in real time, and interprets the data to provide a qualitative result for each of the above targets.

REAGENTS

Qty	REF	Contents	Tests
1	**400-003-MAX**	**BioGX *Mycoplasma - Ureaplasma* - OSR for BD MAX™** Sample-Ready™ lyophilized PCR Master Mix containing polymerase, nucleotides, specific molecular primers and probes, Sample Processing Control-specific molecular primers and probes.	24 tests per pouch
1	**800-028-C**	**Rehydration Buffer Tube (C) Open System Reagents for BD MAX™** Reagent tube containing a rehydration buffer for use in Lyophilized PCR Master Mix rehydration.	24 tests per pouch

NOTE: Safety Data Sheets (SDS) are available at www.biogx.com/eu or by request.

EQUIPMENT AND MATERIALS REQUIRED BUT NOT PROVIDED

- BD MAX™ ExK™ DNA-1 (BD catalog no. 442818)
  Extraction Kits include Sample Buffer Tubes (SBT), Septum Caps, Extraction Tubes, and Unitized Reagent Strips sufficient for 24 tests.
- BD MAX™ PCR Cartridges (BD catalog no. 437519)
- Hologic ThinPrep® sample collection device.
- Appropriate sterile swab for vaginal swab collection and storage in viral transport media (Copan UTM® or BD™ UVT).
- Appropriate sterile collection device for neat urine storage.
- Vortex Genie 2 Vortexer (VWR catalog no. 58815-234) or equivalent.
- Disposable nitrile gloves.
- BioGX lyophilized Positive Control Template DNA Beads (10^5 copies/bead)
  - Mycoplasma genitalium BioGX part number 720-0028
  - Ureaplasma urealyticum BioGX part number 720-0029
  - Mycoplasma hominis BioGX part number 720-0030
  - Ureaplasma parvum BioGX part number 720-0031

WARNINGS AND PRECAUTIONS

- Treat all biological specimens, 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 M29[3] and in Biosafety in Microbiological and biomedical Laboratories.[4]
- Performance characteristics of this test have been established only with the specimen types listed in “Intended Use” section. The performance of this assay with other specimen 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 2-25°C.
- Do not remove desiccant from the PCR Master Mix pouches.

- Do not use Master Mix if the desiccant is not present or is broken inside the 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 Master Mix and Rehydration Buffer tube is used to process a single sample. Do not reuse Master Mix or 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 specimens 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 AND STABILITY

- BioGX recommends long-term storage at 2-25°C.

- Reagents have been tested to demonstrate optimal performance when stored properly and consumed by the Expiration Date. Long-term stability studies are ongoing and the Expiration Date will be amended as additional data is available.

- Avoid exposing the reagents (lyophilized or rehydrated) to direct sunlight or long-term ambient lighting.

- Tightly reseal the pouch with unused reactions and immediately store the pouch in a dry location after opening.

- Avoid exposure to moisture and use the entire contents of the opened pouch within 1 month.

INSTRUCTIONS FOR USE

Install the BioGX Electronic User Defined Protocol on the BD MAX™

It will be necessary to import an Electronic User Defined Protocol (eUDP) onto the BD MAX™. The most current eUDP is available for download on **www.biogx.com/eu** by clicking on "Product Documentation" and selecting the appropriate platform and product name. eUDPs can also be obtained by emailing BioGX at **eu@biogx.com**. Please refer to the BD MAX™ user manual for uploading instructions**.**

NOTE: eUDPs are specific to extraction kit type and are programmed to be used with 3-snap strips unless otherwise indicated. If a 4-snap strip is used, it is necessary to modify the eUDP to a 4-snap program by opening the eUDP in "Test Editor" and selecting the corresponding 4-snap extraction strip type in the "Extraction Type" drop down.

Specimen Collection/Transport

Hologic ThinPrep, Copan UTM and neat urine specimens should be collected, transported, and stored according to local, state, federal, international, institutional, and laboratory standard operating procedures.

Specimen Preparation

Cervical Specimen (Hologic ThinPrep®)
Pipette 200 µL of specimen 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.

Vaginal Swab (Copan UTM® or BD™ UVT)
Pipette 100 µL of specimen 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.

Neat Urine
Pipette 500 µL of neat urine 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.

Other Sample Types

⚠ This assay has been optimized for use with the sample types and volumes described above. Use of any other specimen type, collection method, or sample volumes may be inhibitory to the PCR or disrupt extraction without appropriate Guardrail and processing volume adjustments. BioGX does not make claims for processing methods or sample types other than those described in this product insert.

Setting up the Unitized Reagent Strip on the BD MAX™

1. Wear nitrile gloves when handling Sample-Ready™ lyophilized reagents to reduce the generation of static charges. DO NOT use latex gloves.
2. ⚠ Use only BD MAX™ ExK™ DNA-1 extraction kits with the BioGX *Mycoplasma - Ureaplasma* – OSR for BD MAX™. DO NOT use BD MAX™ mastermix or the blank 0.3 mL conical tubes from the BD MAX™ ExK™ DNA-1 extraction kit.
3. Load one extraction cartridge into the extraction tray per specimen to be tested.
4. Snap one BD MAX™ ExK™ DNA-1 Extraction Tube into position 1 (Snap-in 1) of each Unitized Reagent Strip. (See Figure 1)

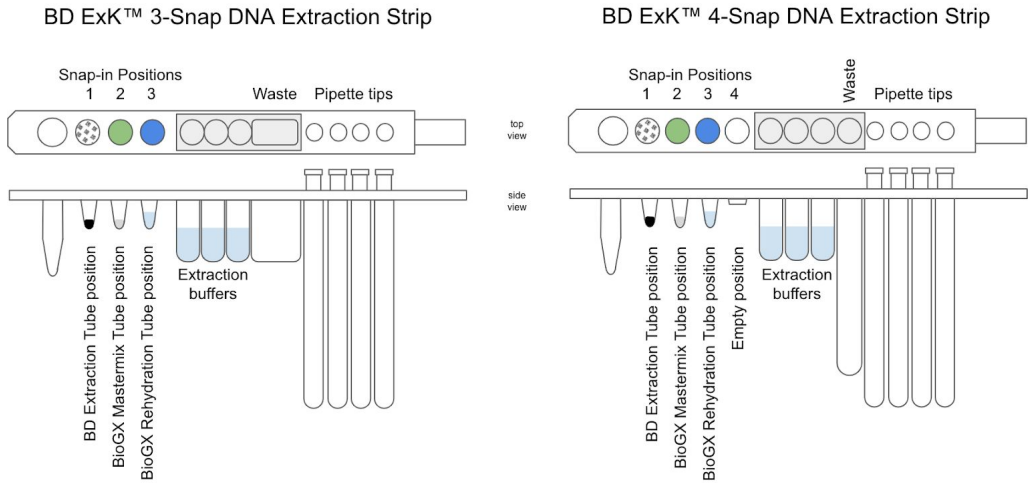


Figure 1 – Diagram of BD MAX™ ExK™ 3-snap and 4-snap Unitized Reagent Strips

5. Snap one BioGX Sample-Ready™ lyophilized PCR Master Mix reagent tube into <u>position 2</u> (Snap-in 2) of each Unitized Reagent Strip. Check to make sure the Sample-Ready™ lyophilized cake is at the bottom of the tube prior to inserting into the Unitized Reagent Strip. The funnel-shaped cake may be in any orientation (v, >, ^, <) in the ***<u>bottom</u>*** of the tube.

6. Snap one BioGX Rehydration Buffer tube into <u>position 3</u> (Snap-in 3) of each Unitized Reagent Strip. Check to make sure the buffer is at the bottom of the tube prior to inserting into the Unitized Reagent Strip.

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.

8. Proceed with worklist generation and sample loading per BD MAX™ operating instructions. Select the appropriate User Defined Protocol (eUDP) provided by BioGX. eUDPs are specific to extraction kit type and are programmed to be used with 3-snap strips unless otherwise indicated. If a 4-snap strip is used, it is necessary to modify the eUDP to a 4-snap program by opening the eUDP in “Test Editor” and selecting the corresponding 4-snap extraction strip type in the “Extraction Type” drop down.

9. Load the extraction tray and, if necessary, a new PCR card into the instrument, close the door, and click “Start Run.”

NOTE: Always first insert all Snap 1 tubes, then all Snap 2 tubes, then all Snap 3 tubes into the Unitized Reagent Strip.

NOTE: If using a 4-snap extraction strip, snap-in position 4 will remain empty.

QUALITY CONTROL

CONTROL

Each BioGX *Mycoplasma - Ureaplasma* – OSR for BD MAX™ includes molecular primers and probes specific for the detection of the DNA sample processing control (SPC) present in the BD MAX™ ExK™ DNA-1 Extraction Kit. No external addition of SPC is required. The SPC serves as both a sample extraction control and a PCR internal amplification control (IAC).

RESULTS INTERPRETATION

Results are available on the *Results* tab in the *Results* window on the BD MAX™ System monitor. The BD MAX™ System software automatically interprets the test result when the BioGX eUDP is used. Possible results for each target are shown in Table 1. Presence of one or more of the targets is possible, and will result in multiple targets being positive at once.

Table 1. BD MAX result interpretation.

Results*	Interpretation
Mgen POSITIVE	• The *Mycoplasma genitalium* target has a Ct within the valid range and endpoint above the minimum setting.
Mhom POSITIVE	• The *Mycoplasma hominis* target has a Ct within the valid range and endpoint above the minimum setting.
Uurea POSITIVE	• The *Ureaplasma urealyticum* target has a Ct within the valid range and endpoint above the minimum setting.
Uparv POSITIVE	• The *Ureaplasma parvum* target has a Ct within the valid range and endpoint above the minimum setting.
Mgen NEGATIVE, **Mhom NEGATIVE,** **Uurea NEGATIVE,** OR **Uparv NEGATIVE**	• The respective target did not amplify and the SPC has a Ct within the valid range and endpoint above the minimum setting.
UNR	• Unresolved Result. No target amplification; No SPC amplification.
IND	• Indeterminate due to BD MAX™ System failure (with Warning or Error Codes*)
INC	• Incomplete Run (with Warning or Error Codes*)

*A positive test result does not necessarily indicate the presence of viable infectious organisms. A positive result is indicative of the presence of target nucleic acid. A negative test result does not preclude the presence of infectious organisms and should not be used as the sole basis for treatment or other patient management decisions.

**Refer to the "Troubleshooting section of the BD MAX™ System User's Manual for interpretation of warning and error codes.

NOTE: In the presence of a high concentration positive result for any target, the SPC may or may not amplify. This is normal.

REPEAT TEST PROCEDURE

In case of instrument failure, repeat testing can be performed by setting up a new run using the original sample/specimen and a fresh SBT as described above in the Specimen Preparation section.

LIMITATIONS OF THE PROCEDURE

- This product is intended for use with ThinPrep or UTM specimens collected using specimen collection and transport devices listed in the "Equipment and Materials Required But Not Provided" section.
- This product should only be used with BD MAX™ Open System Reagents on the BD MAX™ System.
- Incorrect test results may occur from improper specimen collection, handling or storage, technical error, sample mix-up or because the number of organisms in the specimen is below the analytical sensitivity of the test. Careful compliance with the package insert instructions and the BD MAX™ System User's Manual are necessary to avoid erroneous results.
- Good laboratory technique is essential for the proper performance of this assay. Due to the high analytical sensitivity of this test, extreme care should be taken to preserve the purity of all materials and reagents.
- A positive test result does not necessarily indicate the presence of viable infectious organisms. A positive result is indicative of the presence of target nucleic acid. A negative test result does not preclude the presence of infectious organisms and should not be used as the sole basis for treatment or other patient management decisions.
- As with all PCR-based *in vitro* diagnostic tests, extremely low levels of target below the limit of detection of the assay may be detected, but the results may not be reproducible.
- False negative results may occur due to loss of nucleic acid from inadequate collection, transport or storage of specimens, or due to an inadequate cell lysis and/or extraction. The Sample Processing Control has been added to the test to aid in the identification of specimens that contain inhibitors to PCR amplification and as a control for reagent integrity and of the assay system as a whole. The Sample Processing Control does not indicate if nucleic acid has been lost due to inadequate

collection, transport or storage of specimens, or if cells have been adequately lysed.

- The BioGX *Mycoplasma - Ureaplasma* – OSR for BD MAX™ results may sometimes be Unresolved due to an invalid Sample Processing Control, or be Indeterminate or Incomplete due to instrument failure, and require retesting that can lead to a delay obtaining final results.
- Mutations or polymorphisms in primer- or probe-binding regions may affect detection of new or unknown *Mycoplasma genitalium, Ureaplasma urealyticum, Mycoplasma hominis,* and *Ureaplasma parvum* resulting in a false negative result with the BioGX *Mycoplasma - Ureaplasma* – OSR for BD MAX™
- The BioGX *Mycoplasma - Ureaplasma* – OSR for BD MAX™ requires the use of five (5) optical channels from the BD MAX™ System: 475/520 channel, 530/565 channel, 585/630 channel, 630/665 channel, and 680/715 channel.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

The analytical sensitivity for the BioGX *Mycoplasma - Ureaplasma* – OSR for BD MAX™ was determined as follows (Table 2): Dilution series of positive synthetic DNA samples for each target were added to the SBT in duplicate. Analytical sensitivity (Limit of Detection, LoD) was defined as the lowest concentration at which 95% of all replicates tested positive.

Table 2. Analytical sensitivity for BioGX *Mycoplasma - Ureaplasma* - OSR for BD MAX™

Target	LoD (copies per SBT)
Mycoplasma genitalium	1.96×10^2
Ureaplasma urealyticum	1.93×10^2
Mycoplasma hominis	1.93×10^2
Ureaplasma parvum	1.93×10^2

The *Mycoplasma - Ureaplasma* - OSR for BD MAX™ was tested against the QCMD 2017 Sexually Transmitted Infections I EQA Pilot Study (Table 3.). All core and educational samples reported out were concordant with the expected result.

Table 3. QCMD 2017 Sexually Transmitted Infections I EQA Pilot Results

Target	Expected Result	Result
Mycoplasma hominis	*Mycoplasma hominis* positive	100% concordant
Trichomonas vaginalis	Negative	100% concordant
Ureaplasma urealyticum	*Ureaplasma urealyticum* positive	100% concordant
Mycoplasma genitalium	*Mycoplasma genitalium* positive	100% concordant
Trichomonas vaginalis	Negative	100% concordant
Negative	Negative	100% concordant
Trichomonas vaginalis	Negative	100% concordant
Gardnerella vaginalis	Negative	100% concordant
Mycoplasma genitalium	*Mycoplasma genitalium* positive	100% concordant

Analytical Specificity

The BioGX *Mycoplasma - Ureaplasma* – OSR for BD MAX™ was tested against samples containing high levels of non-target organisms, using the BD MAX™System, to demonstrate the specificity of the assay for the detection of *Mycoplasma genitalium, Ureaplasma urealyticum, Mycoplasma hominis,* and *Ureaplasma parvum*. Testing against the following targets yielded negative results on the BioGX *Mycoplasma - Ureaplasma* – OSR for BD MAX™:

Adenovirus, *Atopobium vaginae, Bordetella holmesii, Bordetella parapertusis, Bordetella pertussis*, *Campylobacter jejuni, Campylobacter lari*, *Campylobacter upsaliensis*, *Campylobacter ureolyticus, Candida albicans, Candida glabrata*, *Candida krusei*, *Candida parapsilosis, Candida tropicalis*, *Citrobacter freundii*, *Coccidioides immitis*, *Cryptosporidium spp*., *Cyclospora cayetanensis, Dientamoeba fragilis*, Echovirus*, Entamoeba histolytica, Enterobacter aerogenes, Escherichia coli, Gardnerella vaginalis*, *Giardia intestinalis*, Group A Streptococcus spp., Group B Streptococcus spp., HSV-1, HSV-2, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, Listeria spp., *Mycobacterium tuberculosis*, Norovirus GI, Norovirus GII, Rotavirus, *Salmonella spp., Shigella spp., vanA, vanB.*

Analytical Inclusivity
An *in silico* analytical inclusivity study was performed using a variety of *Mycoplasma* and *Ureaplasma* strains. The BioGX *Mycoplasma - Ureaplasma* – OSR for BD MAX™ detected *Mycoplasma genitalium, Mycoplasma hominis, Ureaplasma urealyticum,* and *Ureaplasma parvum.*

Reproducibility
The reproducibility study was performed on *Ureaplasma parvum* synthetic target template by three separate technicians independently on two BD MAX™ instruments. Using one lot of reagents, a series dilution of DNA template was run between 100,000X LoD and 10-1 LoD dilutions of the stock template. All samples from 1X LoD to 100,000X LoD were concordant positive between samples and technologists. All samples run at 10-1 LoD were concordant negative, as expected.

Manufacturing Reproducibility
Two independent lots were manufactured and were found to be equivalent based on internally established QC acceptance procedures. The lots included a test lot: #016-337-435 and a verification/production lot #017-032-026.

REFERENCES

1. *Mycoplasma, Ureaplasma,* and Adverse Pregnancy Outcomes: A Fresh Look" Larsen B and Hwang J. Infect Dis Obstet Gynecol. 2010 Article ID 521921.
2. "Bacterial etiology of sexually transmitted infections at a STI clinic in Ghana; use of multiplex real time PCR" Sylverken AA, et. al. Ghana Med J 2016; 50(3): 142-149.
3. "Prevalence of sexually transmitted infections among healthy Korean women: Implication of multiplex PCR pathogen detection on antibiotic therapy" Kim YJ, Kim JW, and Lee KA. J Infect Chemother 20 (2014) 74-76.
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.

REVISION HISTORY

Version	Date	Description of Change
08	27 APR 2020	Included BioGX positive control template part numbers and updated table reference.
07	01 SEP 2019	Updated compatible collection devices, addition of urine as specimen type and reagent pouching configuration.
06	01 FEB 2019	Updated storage recommendations from 2-8°C to 2-25°C.
05	09 NOV 2018	Added use of BD ExK 4-snap
04	30 AUG 2018	Updated reagents section to reflect new packaging. Added new performance data. Updated Sample Preparation.
03	19 JUN 2018	Updated open pouch stability.
02	28 FEB 2018	Update to branding. No changes to product.
01	29 MAR 2017	Initial Release.

SYMBOLS

Symbol	Meaning
	Catalog number
	*In vitro* diagnostic medical device
	Do not reuse
	Batch code
	Caution
	Consult instructions for use
	Manufacturer
	Contains sufficient for <n> tests
	Authorized Representative in the European Community
	Temperature limitation
	Keep dry
	Keep away from sunlight

SYMBOLS

Symbol	Meaning
	Expiration date
	Biological Risks
	Control

BioGX BV

Science Park 408, 1098 XH Amsterdam, The Netherland
Phone: +31.20.893.4261 Fax: +31.20.240.9149