BioGX
Molecular Made Easy

Mycoplasma-Ureaplasma OSR for BD MAX™

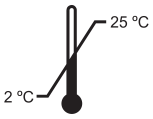
REF **400-003-C-MAX**

Σ 24 Reactions

Instructions For Use

For *In Vitro* Diagnostic Use

For use with BD MAX™ System

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400-003-C-MAX BVPI Rev. 12-22SEP2023

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* (MgPa operon gene[1]), *Mycoplasma hominis* (*gap* gene[2]), *Ureaplasma urealyticum* (*UUR10_0680* gene[3]), *Ureaplasma parvum (UP063* gene[3]*)* from the following specimens:

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

- **Boric acid preserved 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%[4-7].

The BioGX Mycoplasma - Ureaplasma – OSR for BD MAX™ is an automated *in vitro* diagnostic test reagent for the multiplex qualitative detection of DNA from *Mycoplasma genitalium, Mycoplasma hominis*, *Ureaplasma urealyticum, Ureaplasma parvum* and a DNA sample processing control (SPC).

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* 475/520 channel
- *Ureaplasma urealyticum* 530/565 channel
- *Mycoplasma hominis* 585/630 channel
- *Ureaplasma parvum* 630/665 channel
- Sample Processing Control 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 BioGX 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**	**BioGX Rehydration Buffer Tube (C) Open System Reagents for BD MAX™** Reagent tube containing BioGX 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 or by request.

EQUIPMENT AND MATERIALS REQUIRED BUT NOT PROVIDED

- BD MAX™ automated nucleic acid extraction and real-time PCR instrument
- 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.
- Appropriate sterile collection device for boric acid preserved urine.
- 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

- BioGX Mycoplasma-Ureaplasma – OSR for BD MAX™ 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.
- 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[8] and in Biosafety in Microbiological and Biomedical Laboratories[9].
- 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 2-8°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 BioGX Rehydration Buffer tube is used to process a single sample. Do not reuse Master Mix or BioGX 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 of unopened pouches at 2-25°C. Refer to the product pouch label for shelf life duration.
- Reagents are stable at a temperature range of 2-30°C during shipment for 5 days.

- 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 2 months when stored at 2-8°C.

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 at **www.biogx.com** by using the drop down menu at the top right of the home page. Select "Education Center" then select "Int. Product Documents". Choose the appropriate product number under "Instructions for Use Manual & Product Inserts" and download the eUDP. Please refer to the BD MAX™ user manual[10] for uploading instructions**.**

Specimen Collection/Transport

Hologic ThinPrep®, Copan UTM®/BD™ UVT, neat urine and boric acid preserved urine specimens should be collected, transported, and stored according to local, state, federal, international, institutional, and laboratory standard operating procedures.

Specimen Preparation

Cervical Swab (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) (3 mL collection volume)

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.

Vaginal Swab (Copan UTM® or BD™ UVT) (1 mL collection volume)

Pipette 50 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.

Boric Acid Preserved Urine

Pipette 500 µL of boric acid preserved 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™ Master Mix 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-1) of each Unitized Reagent Strip (Figure 1).
5. Snap one BioGX Sample-Ready™ lyophilized PCR Master Mix reagent tube into position 2 (Snap-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 ***bottom*** of the tube.
6. Snap one BioGX Rehydration Buffer tube into position 3 (Snap-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.

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. Snap-4 will remain empty.

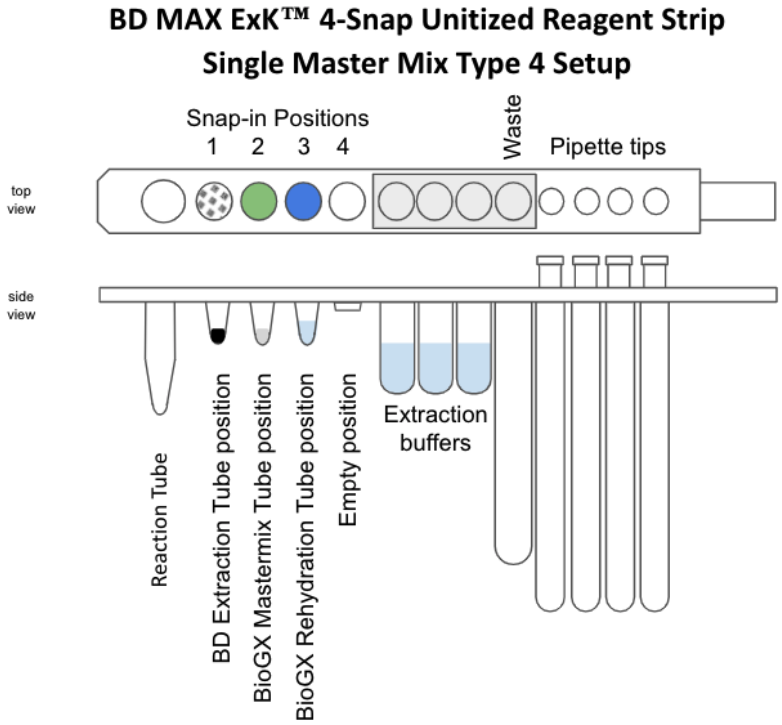

Figure 1 – Diagram of BD MAX™ ExK™ 4-snap Unitized Reagent Strips

QUALITY CONTROL

CONTROL

Calibration of BioGX Mycoplasma-Ureaplasma – OSR for BD MAX™ is not required. 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).

Laboratories must establish the number, type, and frequency of testing of control materials according to guidelines or requirements of local, provincial, state, and federal and/or country regulations or accreditation organizations in order to monitor the effectiveness of the entire analytical process. For general Quality Control guidance, the user may wish to refer to CLSI, MM3, and EP12[8,11]. External Controls available from BioGX are treated as if they were patient samples (Refer to Table 1. 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 run at least daily until adequate process validation is achieved on the BD MAX™ System in each laboratory setting. Reduced frequency of control testing should be in accordance with applicable regulations.

The External Negative Control is intended to detect reagent or environmental contamination (or carry-over) by target nucleic acids. Various types of External Controls are recommended including a previously characterized sample known to be negative or a No Template Control (NTC) to allow the user to select the most appropriate for their laboratory quality control program. BioGX recommends the NTC consist of molecular grade water to be added to the SBT. The same quantity of molecular grade water as sample volume that is being processed should be used. BioGX also recommends the External Negative Control be prepared prior to the External Positive Control in order to reduce the potential for cross-contamination during control preparation.

The External Positive Control is intended to monitor for substantial reagent failure. Commercially available control material from BioGX or other authorized sources may be used. For the BioGX External Control suspensions, it is recommended the DNA suspensions be prepared according to their respective IFU and then added to the Sample Buffer Tube (SBT). Please refer to BioGX Instructions for Use available for download at www.biogx.com by clicking on "Int. Product Documents" under "Education Center" and selecting the appropriate product under "Template Controls".

All External Controls should yield the expected results outlined in Table 1. Briefly, positive results for External Positive Control, and negative for External Negative Controls. An External Negative Control yielding a positive result is indicative of environmental and/or sample cross-contamination. An External Positive Control that yields a negative result is indicative of a specimen handling or reagent preparation problem.

An External Control that yields an Unresolved, Indeterminate, or Incomplete test result is indicative of a reagent or a BD MAX™ System failure. Check the BD MAX™ System monitor for any error messages. Refer to the “System Error Summary” section of the BD MAX™ System User’s Manual[10] for interpretation of warning and error codes. If the problem persists, use reagents from an unopened pouch or use a new assay kit.

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 for patient samples are shown in Table 2. Presence of one or more of the targets is possible and will result in multiple targets being positive at once.

External Negative and Positive Controls

If the positive or negative control does not exhibit the expected performance as described in Table 1., the assay may have been set up/or executed improperly, or reagent or equipment malfunction could have occurred. In this case, invalidate the run and re-test all samples in that run.

The Sample Processing Control serves as sample extraction control and an internal amplification control. In the event that target results are negative, an SPC result must be positive for the viral target result to be identified as a valid negative result.

For further reference, please reference the product insert for Lyophilized Control Template Beads (BioGX Product Number Series 720-XXXX) which is available for download at www.biogx.com by using the drop down menu at the top right of the home page. Select "Education Center" then select "Int. Product Documents". Choose the appropriate product number under "Template Controls".

Table 1. Interpretation of BioGX external controls.

Control Type	Applicability for Monitoring	Expected Results				
		Mgen	*Mhom*	*Uurea*	*Uparv*	SPC
Negative Control -Addition of molecular grade water*	Reagent and/or environmental contamination	**NEG**	**NEG**	**NEG**	**NEG**	**POS**
Negative Control -Known Negative Sample		**NEG**	**NEG**	**NEG**	**NEG**	**POS**
M. genitalium Positive Control	Substantial reagent failure including primer and probe integrity	**POS**	**NEG**	**NEG**	**NEG**	**POS**
M. hominis Positive Control	Substantial reagent failure including primer and probe integrity	**NEG**	**POS**	**NEG**	**NEG**	**POS**
U. urealyticum Positive Control	Substantial reagent failure including primer and probe integrity	**NEG**	**NEG**	**POS**	**NEG**	**POS**
U. parvum Positive Control	Substantial reagent failure including primer and probe integrity	**NEG**	**NEG**	**NEG**	**POS**	**POS**

*BioGX recommends the NTC consist of molecular grade water to be added to the SBT. The same quantity of molecular grade water as sample volume that is being processed should be used.

Examination and Interpretation of Patient Specimen Results

Assessment of clinical specimen test results should be performed after the external positive and negative controls have been examined and determined to be valid and acceptable. If the controls are not valid, the patient results cannot be interpreted. The list of expected results is outlined in Table 2. If results are obtained that do not follow these guidelines, re-extract and re-test the sample. If repeat testing yields similar results, collect a fresh sample from the patient for testing.

Table 2. Interpretation of patient sample results.

Results[a]	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[b])
INC	• Incomplete Run (with Warning or Error Codes[b])

[a]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.

[b]Refer to the "Troubleshooting" section of the BD MAX™ System User's Manual[10] 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 device is not designed as the sole means of diagnosis of infectious disease. By the inherent nature of the technology used for nucleic acid extraction and detection, nucleic acid can be detected from dead organisms. The Intended Use is limited to the detection of the presence of the nucleic acid signature of an organism, and not the diagnosis of disease or disease state.
- This product is intended for use with 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[10] is 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: Dilution series of quantified genomic DNA samples (Vircell, *M. genitalium* Cat. No. MBC085-R*, U.urealyticum* Cat. No. MC112-R*, M. hominis* Cat. No. MDC084-R*, U. parvum* Cat. No. MBC133-R) for each target and clinical matrix were added to the SBT. All samples were tested in duplicate. The LOD for each collection device and sample type (cervical swab in Hologic ThinPrep™ , vaginal swab in Copan UTM™ and neat urine) was determined for 20 independent contrived samples. Analytical sensitivity (Limit of Detection, LoD) was defined as the lowest concentration at which 95% of all replicates tested positive (Table 3).

Table 3. Analytical sensitivity for BioGX Mycoplasma - Ureaplasma - OSR for BD MAX™

Target	LoD (copies per mL) Cervical Swab in Hologic ThinPrep	LoD (copies per mL) Vaginal Swab in Copan UTM (3 mL collection volume)	LoD (copies per mL) Vaginal Swab in Copan UTM (1 mL collection volume)	LoD (copies per mL) Neat urine
Mycoplasma genitalium	9.80×10^2	1.96×10^3	3.92×10^3	3.92×10^2
Ureaplasma urealyticum	9.65×10^2	1.93×10^3	3.86×10^3	3.86×10^2
Mycoplasma hominis	9.65×10^2	1.93×10^3	3.86×10^3	3.86×10^2
Ureaplasma parvum	9.65×10^2	1.93×10^3	3.86×10^3	3.86×10^2

The BioGX Mycoplasma - Ureaplasma - OSR for BD MAX™ was tested against the QCMD 2017 Sexually Transmitted Infections I EQA Pilot Study (Table 4). All core and educational samples reported out were concordant with the expected result.

Table 4. 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

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REVISION HISTORY

Revision	Date	Description of Change
12	22 SEP 2023	Clarification of long-term storage conditions and specify open pouch storage at 2-8°C of reagents.
11	28 OCT 2021	Correction of manufacturing address on last page.
10	01 SEP 2021	Correction of clerical errors.
09	27 AUG 2021	Updated pathway to BioGX documents on BioGX website. Updated 4-snap unitized reagent strip figure. Updated unit of measure of LoD. Updated symbol table, branding and shipment temperature.
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	Symbol	Meaning
	Catalog number		Contains sufficient for <n> tests
	CE mark of conformity		*In vitro* diagnostic medical device
	Do not reuse		Temperature limitation
	Batch code		Keep dry
	Caution		Keep away from sunlight
	Consult instructions for use		Expiration date
	Manufacturer		Biological Risks
	Control		

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