



REDx™ *Mycoplasma genitalium* Positive Control



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Cat#: RED-63-01



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About this package insert

Thank you for your interest in this REDx™ quality control product.

This package insert consists of two pages.

- The first page contains the product name and an explanation of the symbols used on the labeling.
- The second page contains the complete package insert text.

If the package insert you view or print does not contain two pages, or if you experience any problems, please email us at customer.service@microbix.com.

By phone: US customers call +1-800-794-6694; International customers call collect +1-905-361-8910.

A printed package insert will be sent to you upon request.

P/N RED-63-01.5RO

Explanation of symbols used in Microbix product labeling



Upper limit
of temperature



Temperature
limitation



Highly flammable



In Vitro Diagnostic
Medical Device



Manufacturer



Use By



"Caution, consult
accompanying documents"



Toxic by inhalation, in contact
with skin and if swallowed



Positive control



Catalogue
number



Authorized Representative in
the European Community



Single-use only



Batch code



REDx™ *Mycoplasma genitalium* Positive Control

WARNING: THESE REAGENTS MUST NOT BE SUBSTITUTED FOR THE MANDATORY POSITIVE AND NEGATIVE SAMPLE REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.

FOR IVD USE.

INTENDED USE

REDx™ *Mycoplasma genitalium* (MG) Positive Control is a whole genome unassayed control intended to monitor laboratory testing performance, procedures, and workflow with nucleic acid assays that detect *Mycoplasma genitalium* specific DNA and/or RNA in human cervical, endo-cervical, vaginal, penile and urine samples collected in a methanol based transport medium.

PRODUCT DESCRIPTION

REDx™ *Mycoplasma genitalium* Positive Control is formulated with whole inactivated bacterial and human fibroblast cells. REDx™ *Mycoplasma genitalium* Positive Control can be utilized as an external sample to monitor the process of *Mycoplasma genitalium* nucleic acid detection assays including extraction and purification, amplification, and detection.¹

REDx™ *Mycoplasma genitalium* Positive Control does not have an assigned value ("unassayed"). It is required that each laboratory establish an acceptance range for each lot of REDx™ *Mycoplasma genitalium* Positive Control and for each assay procedure with which it is intended to be run, prior to routine use in the laboratory⁴.

PRINCIPLES OF THE PROCEDURE

REDx™ *Mycoplasma genitalium* Positive Control is designed as an external independent sample for use with laboratory testing of *Mycoplasma genitalium* (MG) nucleic acid targets, according to ISO15189 and CLIA regulations. REDx™ *Mycoplasma genitalium* Positive Control is manufactured from nucleic acid containing human fibroblast and bacterial cells. The cells are suspended in ThinPrep PreservCyt® medium.

REAGENTS

Cat. No RED-63-01 1 vial containing inactivated human fibroblast and bacterial cells.

NOTE: REDx™ *Mycoplasma genitalium* Positive Sample contains a suspension of cells in an alcohol solution and may therefore exhibit slight cloudiness.

LIMITATIONS OF THE PROCEDURE

REDx™ SAMPLES MUST NOT BE SUBSTITUTED FOR THE POSITIVE AND NEGATIVE SAMPLE REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.

TEST PROCEDURES and INTERPRETATION OF RESULTS provided by manufacturers of test kits must be followed closely.

Deviations from procedures recommended by test kit manufacturers may produce unreliable results.

REDx™ *Mycoplasma genitalium* Positive Control DOES NOT HAVE AN ASSIGNED VALUE and may not be suitable for use with all *Mycoplasma genitalium* test kits and procedures. Specific levels of reactivity, when Sample Adequacy Control (SAC) is used, will vary among difference manufacturers' assays, different procedures and different laboratories. Procedures for implementing a quality assurance program and monitoring test performance on a routine basis, must be established by each individual laboratory. Each laboratory is required to establish its own range of acceptable values⁴.

Samples are not calibrators and should not be used for assay calibration.

REDx™ *Mycoplasma genitalium* Positive Control is recommended for use with nucleic acid test only.

Adverse shipping and storage conditions or use of outdated samples may produce erroneous results.

REDx™ *Mycoplasma genitalium* Positive Control might not be suitable for nucleic acid tests without an extraction step.

WARNINGS AND PRECAUTIONS

For IVD use.

For Professional and Trained Laboratory Personnel Use Only

Safety Precautions

1. **Raw material used for REDx™ *Mycoplasma genitalium* Positive Control preparation is inactivated.**
2. Use Centers for Disease Control and Prevention (CDC) recommended universal precautions for handling the samples and human specimens².
3. Do not pipette by mouth; do not smoke, eat or drink in areas where specimens are being handled. Clean any spillage by immediately wiping up with 0.5% sodium hypochlorite solution. Dispose of all specimens, samples and materials used in testing as though they contain infectious agents.

4. REDx™ *Mycoplasma genitalium* Positive Control must be disposed of by following RCRA ID#D001 guidelines for ignitable waste³.
5. Keep REDx™ *Mycoplasma genitalium* Positive Sample closed when not in use; avoid direct inhalation of the solution and use with ventilation.

Handling Precautions

1. Do not use samples beyond the expiration date.
2. Avoid contamination of samples when opening and closing the vials
3. REDx™ *Mycoplasma genitalium* Positive Control diluent contains a FLAMMABLE liquid; keep away from all sources of ignition.

STORAGE INSTRUCTIONS

Store REDx™ *Mycoplasma genitalium* Positive Control at 2-8°C until use.

Once opened REDx™ *Mycoplasma genitalium* Control should not be reused. Store vials upright to prevent leakage.

MATERIALS PROVIDED

REDx™ *Mycoplasma genitalium* Positive Control – 1 vial x 1 mL

MATERIALS REQUIRED, BUT NOT PROVIDED

Refer to the instructions supplied by manufacturer of the test kit to be used.

PROCEDURE

When including the REDx™ *Mycoplasma genitalium* Positive Control in a test run, the exact same procedure for unknown specimens collected in STM (sample transport medium) must be used. Refer to the manufacturer supplied instructions for use provided with the *Mycoplasma genitalium* test kit.

1. Mix by vortexing the REDx™ *Mycoplasma genitalium* Positive Control immediately prior use.
2. Use 200-1000 µL from the sample for the kit nucleic acid extraction step.
3. After extraction proceed with NAAT by using the sample test volume specified in the assay instructions for use (usually 5-20 µL from the eluted purified nucleic acid volume).

NOTE: Samples must NOT be substituted for the internal kit positive and negative controls.

Levels of reactivity of REDx™ *Mycoplasma genitalium* Positive Control, when Sample Adequacy Control (SAC) is used, may vary with different manufacturer's tests and different test kit lots. As REDx™ *Mycoplasma genitalium* Positive Control does not have an assigned value, the laboratory must establish an acceptance range for each lot of REDx™ *Mycoplasma genitalium* Positive Control.

TROUBLESHOOTING

When results for the REDx™ *Mycoplasma genitalium* Positive Control are outside of the established laboratory acceptance range for SAC, it may be an indication of unsatisfactory test performance.

Possible sources of error include: deterioration of test kit reagents, operator error, faulty performance of equipment, or contamination of reagents; internal laboratory procedures should be followed.

REFERENCES

1. *Accurate Results in the Clinical Laboratory 2013*, ISBN: 978-0-12-415783-5
2. *CDC Recommendations for prevention of HIV transmission in health care settings. MMWR 36 (suppl. 2), 1987.*
3. *Treatment standards for hazardous waste; 40 CFR 268.40 Subpart D. D001: Ignitable characteristics of waste.*
4. *Kinns H, Pitkin S, Housley D, et al. J Clin Pathol 2013;66:1027-1032.*
5. *Statistical Quality Sample for Quantitative Measurements: Principles and Definitions; Approved Guideline- Second Edition. NCCLS document C24-A2, 1999.*

For assistance, contact Microbix Technical Support at +1-905-361-8910.



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