MICROBIX

RED™ controls

REDx HPV Negative Control

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About this package insert

Thank you for your interest in this REDx Controls 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.

CE IVD

EC REP

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P/N RED-62-16.5RO

Explanation of symbols used in Microbix product labeling


Upper limit of temperature


Temperature limitation


Highly flammable

IVD
In Vitro Diagnostic Medical Device


Biological risks


Use By


"Caution, consult accompanying documents"


Toxic by inhalation, in contact with skin and if swallowed

CONTROL –
Negative control

REF
Catalogue number

EC REP
Authorized Representative in the European Community


Single-use only

CONTROL +
Positive control

LOT
Batch code


Manufacturer

EN

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

REDx HPV Negative Control

INTENDED USE

REDx HPV Negative Control is a whole cell unassayed control intended to evaluate laboratory testing performance, procedures, and workflow with nucleic acid assays that detect Human Papillomavirus (HPV) DNA and/or RNA in human cervical, anal, penile or oropharyngeal samples collected in an alcohol based transport medium. or oropharyngeal samples collected in an alcohol based transport medium.

PRODUCT DESCRIPTION

REDx HPV Negative Control is formulated from whole human fibroblast cells without any presence of HPV DNA and/or RNA. HPV Negative Controls can be utilized as an external control to monitor the entire process of HPV nucleic acid detection assays including extraction and purification, amplification, and detection.[1].

REDx HPV Negative Control does not have an assigned value ("unassayed"). It is required that each laboratory establish an acceptance range for each lot of REDx HPV Negative Control with each assay procedure which it is intended to be run prior to routine use in the laboratory[4].

PRINCIPLES OF THE PROCEDURE

REDx HPV Negative Control is designed as an external independent control for use with laboratory testing of HPV DNA and/or RNA according to ISO15189 and CLIA regulations. REDx HPV Negative Control is manufactured from human fibroblast cells without detectable presence of HPV genome. The fibroblast cells are suspended in an alcohol based transport medium.

REAGENTS

Cat. No RED-99-M1 1 vial containing human fibroblast cells

NOTE: REDx HPV Negative Control contains a suspension of cells in an alcohol solution and may therefore exhibit slight cloudiness.

LIMITATIONS OF THE PROCEDURE

REDx CONTROLS MUST NOT BE SUBSTITUTED FOR THE POSITIVE AND NEGATIVE CONTROL 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 HPV NEGATIVE COTROL DOES NOT HAVE AN ASSIGNED VALUE and may not be suitable for use with all HPV 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 should establish its own range of acceptable values[4].

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

REDx HPV Negative Control is recommended for use with HPV DNA and/or RNA only.

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

WARNINGS AND PRECAUTIONS

For In Vitro Diagnostic Use.

For Professional and Trained Laboratory Personnel Use Only

WARNING: Handle controls as capable of transmitting infectious agents. REDx HPV Negative Control is manufactured from fibroblast cells that are grown in tissue culture and preserved in a buffered solution.

Safety Precautions

1. **Raw material used for REDx HPV Negative Control preparation is inactivated.**
2. Use Centers for Disease Control (CDC) recommended universal precautions for handling the controls and human specimens[2].
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, controls and materials used in testing as though they contain infectious agents.
4. REDx HPV Negative Control must be disposed of by following RCRA ID#D001 guidelines for ignitable waste3.
5. Keep REDx HPV Negative Control closed when not in use; avoid direct inhalation of the solution and use with ventilation.

Handling Precautions

1. Do not use Controls beyond the expiration date.
2. Avoid contamination of controls when opening and closing the vials.
3. REDx HPV Negative Control diluent contains a FLAMMABLE liquid; keep away from all sources of ignition.

STORAGE INSTRUCTIONS

Store REDx HPV Negative Control at 2-8°C until use.

Once opened REDx HPV Negative Control should not be reused. Store vials upright to prevent leakage.

MATERIALS PROVIDED

RED-99-M1 – REDx HPV Negative Control – 1mL vial x1

MATERIALS REQUIRED, BUT NOT PROVIDED

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

PROCEDURE

When including the REDx HPV Negative Control in a test run, the exact same procedure for unknown specimens collected in an alcohol based transport medium must be used. Refer to the manufacturer supplied instructions for use provided with the HPV test kit.

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

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

TROUBLESHOOTING

When results for REDx HPV Negative 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 Control 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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