REDx™ SARS-CoV-2 Positive Control

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Cat#: RED-19-01

CE IVD

EC REP
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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-19-01.5RO

Explanation of symbols used in Microbix product labeling


Upper limit of temperature


Temperature limitation


Highly flammable

IVD
In Vitro Diagnostic Medical Device


Manufacturer


Use By


"Caution, consult accompanying documents"


Toxic by inhalation, in contact with skin and if swallowed

CONTROL +
Positive control

REF
Catalogue number

EC REP
Authorized Representative in the European Community


Single-use only

LOT
Batch code

EN

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

RED™ controls

REDx™ SARS-CoV-2 Positive Control

FOR IVD USE.

INTENDED USE

REDx™ SARS-CoV-2 Positive Control is a whole genome (cDNA) unassayed control intended to monitor laboratory testing performance, procedures, and workflow with nucleic acid tests (NATs) that detect SARS-CoV-2 in human nasopharyngeal, oropharyngeal, nasal mid-turbinate, anterior nares and lower respiratory samples.

PRODUCT DESCRIPTION

REDx™ SARS-CoV-2 Positive Control is formulated with whole SARS-CoV-2 cDNA genome and fibroblast cells. REDx™ SARS-CoV-2 Positive Control can be utilized as an external sample to monitor the process of SARS-CoV-2 nucleic acid detection assays including extraction and purification, amplification, and detection.[1].

REDx™ SARS-CoV-2 Positive Control does not have an assigned value ("unassayed"). It is required that each laboratory to establish an acceptance range for each lot of REDx™ SARS-CoV-2 Positive 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™ SARS-CoV-2 Positive Control is designed as an external independent sample for use with laboratory testing of SARS-CoV-2 nucleic acid targets, according to ISO15189 and CLIA regulations. REDx™ SARS-CoV-2 Positive Control is manufactured from human fibroblast cells and whole SARS-CoV-2 genome (cDNA). The fibroblast cells are suspended in an alcohol-based transport medium.

REAGENTS

Cat. No RED-19-01 1 vial containing human fibroblast cells and whole SARS-CoV-2 cDNA genome.

NOTE: REDx™ SARS-CoV-2 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™ SARS-CoV-2 Positive Control DOES NOT HAVE AN ASSIGNED VALUE and may not be suitable for use with all SARS-CoV-2 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].

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

REDx™ SARS-CoV-2 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™ SARS-CoV-2 Positive Control evaluates only the PCR steps of the RT-PCR methods for detection of SARS-CoV-2.

REDx™ SARS-CoV-2 Positive Control might not be suitable for nucleic acid tests without extraction step.

WARNINGS AND PRECAUTIONS

For IVD use.

For Professional and Trained Laboratory Personnel Use Only

Safety Precautions

1. **Raw material used for REDx™ SARS-CoV-2 Positive Control preparation is inactivated.**
2. Use Centers for Disease Control and Prevention (CDC) recommended universal precautions for handling the samples 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, samples and materials used in testing as though they contain infectious agents.
4. REDx™ SARS-CoV-2 Positive Control must be disposed of by following RCRA ID#D001 guidelines for ignitable waste[3].
5. Keep REDx™ SARS-CoV-2 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™ SARS-CoV-2 Positive Control diluent contains a FLAMMABLE liquid; keep away from all sources of ignition.

STORAGE INSTRUCTIONS

Store REDx™ SARS-CoV-2 Positive Control at 2-8°C until use.

Once opened REDx™ SARS-CoV-2 Positive Control should not be reused. Store vials upright to prevent leakage.

MATERIALS PROVIDED

REDx™ SARS-CoV-2 Positive Control – 1 vial x 0.5mL

MATERIALS REQUIRED, BUT NOT PROVIDED

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

PROCEDURE

When including the REDx™ SARS-CoV-2 Positive Control in a test run, the exact same procedure for unknown specimens collected in STM must be used. Refer to the manufacturer supplied instructions for use provided with the SARS-CoV-2 test kit.

1. Mix by micropipette aspiration of 200 µL from the sample volume and vortex the REDx™ SARS-CoV-2 Positive Control immediately prior use.
2. Skip the swab elution step (described in some assay instructions for use)
3. Use 100-400 µL from the sample for the kit nucleic acid extraction step.
4. After extraction proceed with RT-PCR 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™ SARS-CoV-2 Positive Control when Sample Adequacy Control (SAC) is used may vary with different manufacturer's tests and different test kit lots. As REDx™ SARS-CoV-2 Positive Control does not have an assigned value, the laboratory must establish an acceptance range for each lot of REDx™ SARS-CoV-2 Positive Control.

TROUBLESHOOTING

When results of REDx™ SARS-CoV-2 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.

MICROBIX

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