



REDx™ FLOQ® SARS-CoV-2 Swab Negative Control



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Cat#: RED-S-99-M4

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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-S-99-M4.5RO

Explanation of symbols used in Microbix product labeling



Upper limit of temperature



Temperature limitation



Authorized Representative in the European Community



In Vitro Diagnostic Medical Device



Negative control



Use By



"Caution, consult accompanying documents"



Single-use only



Catalogue number



Batch code



Manufacturer



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



REDx™FLOQ® SARS-CoV-2 Swab Negative Control

FOR IVD USE.

INTENDED USE

REDx™ FLOQ® SARS-CoV-2 Swab Negative Control is a desiccated, 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 and anterior nares samples, collected on swabs.

PRODUCT DESCRIPTION

REDx™ FLOQ® SARS-CoV-2 Swab Negative Control is formulated with human fibroblast cells. REDx™ FLOQ® SARS-CoV-2 Swab Negative 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™ FLOQ® SARS-CoV-2 Swab Negative Control does not have an assigned value (“unassayed”). It is required that each laboratory establish an acceptance range for each lot of REDx™ FLOQ® SARS-CoV-2 Negative Swab with each assay procedure which it is intended to be run prior to routine use in the laboratory⁴.

PRINCIPLES OF THE PROCEDURE

REDx™ FLOQ® SARS-CoV-2 Swab Negative Control is designed as an external independent sample for use with laboratory testing of human housekeeping nucleic acid targets according to ISO15189 and CLIA regulations. REDx™ FLOQ® SARS-CoV-2 Swab Negative Control is manufactured from human fibroblast cells.

REAGENTS

Cat. No RED-S-99-M4 1 swab containing human fibroblast cells.

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™ FLOQ® SARS-CoV-2 Negative Swab 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 values⁴.

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

REDx™ FLOQ® SARS-CoV-2 Swab Negative Control is recommended for use with nucleic acid test only.

Adverse shipping and storage conditions or use of outdated Samples may produce erroneous results.

WARNINGS AND PRECAUTIONS

For IVD use.

For Professional and Trained Laboratory Personnel Use Only

Safety Precautions

1. **Raw material used for REDx™ FLOQ™ SARS-CoV-2 Swab Negative Control preparation is inactivated.**
2. Use Centers for Disease Control and Prevention (CDC) recommended universal precautions for handling the samples and human specimens².
3. REDx™ FLOQ® SARS-CoV-2 Swab Negative must be disposed of by following RCRA ID#D001 guidelines for ignitable waste³.
4. Keep REDx™ FLOQ® SARS-CoV-2 Swab Negative pouch closed when not in use.

Handling Precautions

1. Do not use samples beyond the expiration date.
2. Avoid contamination of samples when opening the swab pouches.

STORAGE INSTRUCTIONS

Store REDx™ FLOQ® SARS-CoV-2 Swab Negative Control at 2-30°C until use.

Once opened REDx™ FLOQ® SARS-CoV-2 Swab Negative Control should not be reused.

MATERIALS PROVIDED

REDx™ FLOQ® SARS-CoV-2 Swab Negative Control – 1 swab

MATERIALS REQUIRED, BUT NOT PROVIDED

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

PROCEDURE

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

1. Elute the REDx™ FLOQ® SARS-CoV-2 Swab Negative Control by referring to the preferred technique and volumes described in the assay instructions for use (usually 1-3 mL).
2. Use of 100-1000 µL from the eluted swab REDx™ FLOQ® SARS-CoV-2 Swab Negative Control for the nucleic acid extraction step.
3. After extraction, proceed with RT-PCR by using the eluted nucleic acid test volume specified in the assay instruction 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 Samples.

Levels of reactivity of REDx™ FLOQ® SARS-CoV-2 Swab Negative Control when Sample Adequacy Control (SAC) is used may vary with different manufacturer’s tests and different test kit lots. As REDx™ FLOQ® SARS-CoV-2 Swab Negative Control does not have an assigned value, the laboratory must establish an acceptance range for each lot of REDx™ FLOQ® SARS-CoV-2 Swab Negative Control.

TROUBLESHOOTING

When results REDx™ FLOQ® SARS-CoV-2 Swab Negative Controls 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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