REDx™ FLOQ®SARS-CoV-2 Ag Swab Positive Control

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Cat#: RED-S-19-02

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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

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

P/N RED-S-19-02.5RO

Explanation of symbols used in Microbix product labeling

Upper limit of temperature

Temperature limitation

EC REP
Authorized Representative in the European Community

IVD
In Vitro Diagnostic Medical Device

CONTROL +
Positive control

Use By

"Caution, consult accompanying documents"

Single-use only

REF
Catalogue number

LOT
Batch code

Manufacturer

EN

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 Ag Swab Positive Control

FOR IVD USE.

INTENDED USE

REDx™ FLOQ® SARS-CoV-2 Ag Swab Positive Control is a desiccated, unassayed control intended to monitor laboratory testing performance, procedures, and workflow with antigen tests that detect SARS-CoV-2 nucleocapsid protein in human nasopharyngeal, oropharyngeal, nasal mid-turbinate and anterior nares samples, collected on swabs.

PRODUCT DESCRIPTION

REDx™ FLOQ® SARS-CoV-2 Ag Swab Positive Control is formulated with SARS-CoV-2 nucleocapsid (N) protein. SARS-CoV-2 Ag Swab Positive Control can be utilized as an external sample to monitor the process of SARS-CoV-2 nucleocapsid protein antigen detection assays including sample elution, separation and detection.[1]

REDx™ FLOQ® SARS-CoV-2 Ag Swab Positive 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 Ag Swab Positive Control with each assay procedure, with which it is intended to be run, prior to routine use in the laboratory.[3,4]

PRINCIPLES OF THE PROCEDURE

REDx™ FLOQ® SARS-CoV-2 Ag Swab Positive Control is designed as an external independent sample for use with laboratory testing of SARS-CoV-2 nucleocapsid protein according to ISO15189 and CLIA regulations. REDx™ FLOQ® SARS-CoV-2 Ag Swab Positive Control is manufactured from SARS-CoV-2 nucleocapsid protein.

REAGENTS

Cat. No RED-S-19-02 1 swab containing SARS-CoV-2 nucleocapsid (N) protein

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 Swab 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 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 values.[3,4]

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

REDx™ FLOQ® SARS-CoV-2 Ag Swab Positive Control is recommended for use with antigen 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. Use Centers for Disease Control and Prevention (CDC) recommended universal precautions for handling the samples and human specimens[2].
2. Keep REDx™ FLOQ® SARS-CoV-2 Ag Swab Positive pouch sealed prior to 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 Ag Swab Positive Control at 2-30°C until use.

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

MATERIALS PROVIDED

REDx™ FLOQ® SARS-CoV-2 Ag Swab Positive 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 Ag Swab Positive 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 Ag Swab Positive Control by referring to the preferred technique and volumes described in the assay instructions for use (usually 0.2-0.7 mL).
2. After elution, proceed with detection step by using the test volume specified in the assay instruction for use (usually 50-200 µL from the eluted swab volume).

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

As REDx™ FLOQ® SARS-CoV-2 Ag Swab Positive Control does not have an assigned value, the laboratory is required to establish an acceptance range for each lot of REDx™ FLOQ® SARS-CoV-2 Ag Swab Positive Control.

TROUBLESHOOTING

When results REDx™ FLOQ® SARS-CoV-2 Ag Swab Positive Controls are outside of the established laboratory acceptance range, 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. *Kinns H, Pitkin S, Housley D, et al. J Clin Pathol 2013;66:1027–1032.*
4. *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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