



MICROBIX

REDx™ FLOQ®

REDx™FLOQ® Group A Strep Swab Positive Control (M2)



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Cat#: RED-S-70-M2

FLOQ® is a trademark of Copan Italia Spa



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-70-M2.5R0

Explanation of symbols used in Microbix product labeling



Upper limit
of temperature



Temperature
limitation



*In Vitro Diagnostic
Medical Device*



Single-use only



Positive control



Use By



"Caution, consult
accompanying documents"



Catalogue
number



Batch code



Manufacturer

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



REDx™ FLOQ® Group A Strep Swab Positive Control (M2)

FOR IVD USE.

INTENDED USE

REDx™ FLOQ® Group A Strep Swab Positive Control (M2) is a desiccated, unassayed control intended to monitor laboratory testing performance, procedures, and workflows of nucleic acid amplification tests and immunoassays that detect Group A Streptococcus (GAS) in human throat samples, collected on swabs.

PRODUCT DESCRIPTION

REDx™ FLOQ® Group A Strep Swab Positive Control (M2) is formulated with inactivated native GAS and human fibroblast cells. REDx™ FLOQ® Group A Strep Swab Positive Control (M2) can be utilized as an external sample to monitor the processes of (1) GAS immunoassays and (2) GAS molecular assays, including sample extraction and purification, amplification, and detection¹.

REDx™ FLOQ® Group A Strep Swab Positive Control (M2) does not have an assigned value ("unassayed"). Laboratories are required to establish an acceptance range for each lot of REDx™ FLOQ® Group A Strep Swab Positive Control (M2) with all assay procedures that the control is intended to be used with, prior to routine use in the laboratory^{2,3}.

PRINCIPLES OF THE PROCEDURE

REDx™ FLOQ® Group A Strep Swab Positive Control (M2) is designed as an external independent sample for use with laboratory testing of GAS targets, according to ISO15189 and CLIA regulations.

REAGENTS

Cat. No RED-S-70-M2; 1 swab containing inactivated GAS and human fibroblast cells.

LIMITATIONS OF THE PROCEDURE

REDx™ CONTROLS MUST NOT BE SUBSTITUTED FOR THE POSITIVE AND NEGATIVE CONTROL REAGENTS PROVIDED WITH THE 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® Group A Strep Swab Positive Control (M2) DOES NOT HAVE AN ASSIGNED VALUE and may not be suitable for use with all GAS test kits and procedures. 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^{2,3}.

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

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

REDx™ FLOQ® Group A Strep Swab Positive Control (M2) might not be suitable for nucleic acid amplification 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™ FLOQ® Group A Strep Swab Positive Control (M2) preparation is inactivated.
2. Use Centers for Disease Control and Prevention (CDC) recommended universal precautions for handling the samples and human specimens⁴.
3. REDx™ FLOQ® Group A Strep Swab Positive Control (M2) must be disposed of by following RCRA ID#D001 guidelines for ignitable waste⁵.
4. Keep REDx™ FLOQ® Group A Strep Swab Positive Control (M2) pouch closed when not in use.

HANDLING PRECAUTIONS

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

STORAGE INSTRUCTIONS

Store REDx™ FLOQ® Group A Strep Swab Positive Control (M2) at 2-30°C until use.

Once opened, REDx™ FLOQ® Group A Strep Swab Positive Control (M2) should not be reused.

MATERIALS PROVIDED

REDx™ FLOQ® Group A Strep Swab Positive Control (M2) – 1 swab

MATERIALS REQUIRED, BUT NOT PROVIDED

Refer to the Instructions For Use supplied by the test kit manufacturer.

PROCEDURE

When including the REDx™ FLOQ® Group A Strep Swab Positive Control (M2) in a test run, the exact same procedure for unknown specimens collected on a swab must be used. Refer to the manufacturer's supplied instructions for use provided with the GAS test kit.

For Use with nucleic acid amplification tests:

1. Elute the REDx™ FLOQ® Group A Strep Swab Positive Control (M2) by referring to the preferred technique and volumes described in the assay's Instructions For Use (usually 1-3 mL).
2. For better volume recovery, after incubation, swirl the swab 5-10 times in the vial and remove the swab by pressing it towards the walls of the elution vial.
3. Use 100-1000 µL from the eluted REDx™ FLOQ® Group A Strep Swab Positive Control (M2) Swab Positive Control for the nucleic acid extraction step.
4. After extraction, proceed with the molecular assay by using the eluted nucleic acid test volume specified in the assay's Instructions For Use (usually 5-20 µL from the eluted purified nucleic acid volume).

For Use with Immunoassays:

1. Elute the REDx™ FLOQ® Group A Strep Swab Positive Control (M2) by referring to the preferred technique and volumes described in the assay's Instructions For Use (usually 0.2-0.5 mL).
2. For better volume recovery, after incubation, swirl the swab 5-10 times in the vial and remove the swab by pressing it towards the walls of the elution vial.
3. Proceed with the detection step by using the test volume specified in the assay's Instruction For Use (usually 50-200 µL from the eluted swab volume).

NOTE: Controls must NOT be substituted for the internal positive and negative controls supplied with the test kit.

As the REDx™ FLOQ® Group A Strep Swab Positive Control (M2) does not have an assigned value, the laboratory must establish an acceptance range for each lot of REDx™ FLOQ® Group A Strep Swab Positive Control (M2).

TROUBLESHOOTING

When REDx™ FLOQ® Group A Strep Swab Positive Control (M2) results are outside of the established laboratory acceptance range for internal controls, 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. *Kinns H, Pitkin S, Housley D, et al. J Clin Pathol 2013;66:1027–1032.*
3. *Statistical Quality Sample for Quantitative Measurements: Principles and Definitions; Approved Guideline—Second Edition. NCCLS document C24-A2, 1999.*
4. *CDC Recommendations for prevention of HIV transmission in health care settings. MMWR 36 (suppl. 2), 1987.*
5. *Treatment standards for hazardous waste; 40 CFR 268.40 Subpart D. D001: Ignitable characteristics of waste.*

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



P/N RED-S-70-M2.5R0
04 April, 2023



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CERTIFICATE OF ANALYSIS

REDx™ FLOQ® Group A Strep Swab Positive Control (M2)

Product Information

Product Name	REDx™ FLOQ® Group A Strep Swab Positive Control (M2)
Catalogue Number	RED-S-70-M2
Strain/Cell line	CECT 189/ Streptococcus pyogenes Rosenbach 1884/ NCIMB 8884; MRC-5 cells
Lot number	70M20002A2
Analyte Value	Unassayed. Value not assigned by the manufacturer
Product Description	Unassayed qualitative positive control for the detection of <i>Group A Streptococcus</i> . Contains human DNA.
Elution Volume	1-3 mL for nucleic acid amplification tests 0.2-0.5 mL for immunoassays
Storage conditions	2-30°C
Expiry Date	15 Oct 2026
Intended Use	For <i>In vitro</i> Diagnostic Use.

Quality Control Information

Test method(s)	Quidel Sofia Strep A FIA Cepheid Xpert® Xpress Strep A Cepheid Xpert® TV
Test Result(s)	Observed Result
Group A Streptococcus	Positive
Human DNA	Positive
Inactivation	Inactivated

This product is an unassayed control. The reported QC information is not intended to represent product specifications in any commercial or lab developed test. The laboratory should establish its own analyte value and ranges.



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IVD

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CONTROL +

REF

LOT



2°C
30°C



Information



Please ensure that your institution is
consulted before recycling an item.



Quality Assurance Signature:

jenn lee

Date: 09 Jan 2026