MICROBIX

RED™ FLOQ®

REDx™FLOQ® HPV 18 Swab Positive Control

Microbix Biosystems Inc.
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Cat#: RED-S-62-18

IVD

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-62-18.5R1

Explanation of symbols used in Microbix product labeling


Upper limit of temperature


Temperature limitation

IVD
In Vitro Diagnostic Medical Device


Single-use only

CONTROL +
Positive control


Use By


"Caution, consult accompanying documents"

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® HPV 18 Swab Positive Control

FOR IVD USE.

INTENDED USE

REDx™FLOQ® HPV 18 Swab Positive Control is a desiccated, unassayed control intended to monitor laboratory testing performance, procedures, and workflows of nucleic acid amplification tests that detect high-risk Human papillomavirus (HPV) in human cervical, endocervical, vaginal, and anal samples collected on swabs.

PRODUCT DESCRIPTION

REDx™FLOQ® HPV 18 Swab Positive Control is formulated with inactivated cells that contain HPV 18 genome desiccated on a Copan FLOQSwab®. REDx™FLOQ® HPV 18 Swab Positive Control can be utilized as an external sample to monitor the process of HPV nucleic acid detection assays, including sample extraction and purification, amplification, and detection[1].

REDx™FLOQ® HPV 18 Swab Positive Control does not have an assigned value ("unassayed"). Laboratories are required to establish an acceptance range for each lot of REDx™FLOQ® HPV 18 Swab Positive Control 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® HPV 18 Swab Positive Control is designed as an external independent sample for use with laboratory testing of HPV 18 nucleic acid targets, according to ISO15189 and CLIA regulations.

REAGENTS

Cat. No RED-S-62-18; 1 swab formulated with inactivated cells that contain HPV 18 genome. The formulation also contains 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® HPV 18 Swab Positive Control DOES NOT HAVE AN ASSIGNED VALUE and may not be suitable for use with all HPV 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.

REDx™FLOQ® HPV 18 Swab Positive Control is recommended for use with nucleic acid amplification tests only.

Adverse shipping and storage conditions or use of outdated samples may produce erroneous results.

REDx™FLOQ® HPV 18 Swab Positive Control 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 materials used for REDx™FLOQ® HPV 18 Swab Positive Control preparation are inactivated.
2. Use Centers for Disease Control and Prevention (CDC) recommended universal precautions for handling the samples and human specimens[4].
3. REDx™FLOQ® HPV 18 Swab Positive Control must be disposed of by following RCRA ID#D001 guidelines for ignitable waste[5].
4. Keep REDx™FLOQ® HPV 18 Swab Positive Control 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® HPV 18 Swab Positive Control at 2-30°C until use.

Once opened, REDx™FLOQ® HPV 18 Swab Positive Control should not be reused.

MATERIALS PROVIDED

REDx™FLOQ® HPV 18 Swab Positive Control – 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® HPV 18 Swab Positive Control 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 HPV test kit.

1. Elute the REDx™FLOQ® HPV 18 Swab Positive Control by referring to the preferred technique and volumes described in the assay instructions for use (usually 1-5 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. Use 100-1000 µL from the eluted REDx™FLOQ® HPV 18 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 instruction for use (usually 5-20 µL from the eluted purified nucleic acid volume).

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

Since the REDx™FLOQ® HPV 18 Swab Positive Control does not have an assigned value, the laboratory must establish an acceptance range for each lot of the REDx™FLOQ® HPV 18 Swab Positive Control.

TROUBLESHOOTING

When REDx™FLOQ® HPV 18 Swab Positive Control 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.

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P/N RED-S-62-18.5R1
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CERTIFICATE OF ANALYSIS

REDx™FLOQ® HPV 18 Swab Positive Control

Product Information

Product Name	REDx™FLOQ® HPV 18 Swab Positive Control
Catalogue Number	RED-S-62-18
Strain/Cell line	HPV type 18 and MRC-5 cells
Lot number	62180010A2
Analyte Value	Unassayed. Value not assigned by the manufacturer
Product Description	Unassayed qualitative positive control for the detection of *HPV 18*. Contains human DNA.
Elution Volume	1-5 mL
Storage conditions	2-30°C
Expiry Date	13 Jan 2030
Intended Use	For *In vitro* Diagnostic Use.

Quality Control Information

Test method(s)	Cepheid Xpert® HPV Assay
Test Result(s)	Observed Result
HPV 16	Negative
HPV18/45	Positive
Other high-risk HPV	Negative
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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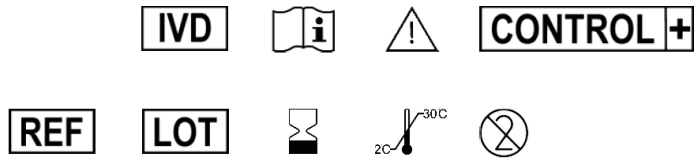

Information

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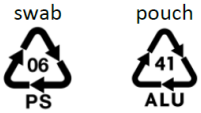

Quality Assurance Signature: *jenn Lee* **Date: 14 Oct 2025**