MICROBIX

RED™ controls

REDx™ Influenza A and Influenza B Positive Control

Microbix Biosystems Inc.
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Cat#: RED-13-02

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-13-02.5R0

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 CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.

REDx™ Influenza A and Influenza B Positive Control

FOR IVD USE.

INTENDED USE

REDx™ Influenza A and Influenza B Positive Control is an unassayed control intended to monitor laboratory testing performance, procedures, and workflow with immunoassays and nucleic acid tests (NATs) that detect Influenza A and Influenza B in human nasal swab, nasopharyngeal swab, nasal/nasopharyngeal aspirate, and nasal/ nasopharyngeal wash samples.

PRODUCT DESCRIPTION

REDx™ Influenza A and Influenza B Positive Control is formulated with inactivated native Influenza A virus and Influenza B virus. REDx™ Influenza A and Influenza B Positive Control can be utilized as an external sample to monitor the processes of (1) respiratory viral immunoassays and (2) respiratory viral nucleic acid detection assays, including sample extraction and purification, amplification, and detection[1].

REDx™ Influenza A and Influenza B Positive Control does not have an assigned value ("unassayed"). Laboratories are required to establish an acceptance range for each lot of REDx™ Influenza A and Influenza B 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™ Influenza A and Influenza B Positive Control is designed as an external independent sample for use with laboratory testing of Influenza immunoassay and nucleic acid targets, according to ISO 15189 and CLIA regulations.

REAGENTS

Cat. No RED-13-02; 1 vial formulated with inactivated native Influenza A virus and Influenza B virus.

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™ Influenza A and Influenza B Positive Control DOES NOT HAVE AN ASSIGNED VALUE and may not be suitable for use with all Influenza viral 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].

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

Adverse shipping and storage conditions or use of outdated samples may produce erroneous results.

REDx™ Influenza A and Influenza B Positive Control might not be suitable for NATs without an extraction step.

WARNINGS AND PRECAUTIONS

For IVD use.

For Professional and Trained Laboratory Personnel Use Only

WARNING: Handle controls as if they are capable of transmitting infectious agents. REDx™ Influenza A and Influenza B Positive Control is manufactured from non-infectious cells that are grown in tissue culture and preserved in a buffered solution.

Safety Precautions

1. Raw materials used for REDx™ Influenza A and Influenza B Positive Control are inactivated.
2. Use Centers for Disease Control and Prevention (CDC) recommended universal precautions for handling the samples and human specimens[4].
3. REDx™ Influenza A and Influenza B Positive Control must be disposed of by following RCRA ID#D001 guidelines for ignitable waste[5].
4. 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, controls, and materials used in testing as though they contain infectious agents.
5. Keep REDx™ Influenza A and Influenza B Positive Control vial closed when not in use. Avoid direct inhalation of the solution and use with ventilation.

HANDLING PRECAUTIONS

1. Do not use controls beyond the expiration date.
2. Avoid contamination of controls when opening and closing the vials.

STORAGE INSTRUCTIONS

Store REDx™ Influenza A and Influenza B Positive Control at 2-8°C until use.

Once opened, REDx™ Influenza A and Influenza B Positive Control should not be reused. Store the vials upright to prevent leakage.

MATERIALS PROVIDED

REDx™ Influenza A and Influenza B Positive Control – 1mL vial

MATERIALS REQUIRED, BUT NOT PROVIDED

Refer to the instructions supplied by the test kit manufacturer for guidance on how to use the REDx™ Influenza A and Influenza B Positive Control.

PROCEDURE

Before use, the REDx™ Influenza A and Influenza B Positive Control should be thoroughly mixed by vortexing for 30 seconds. When including the REDx™ Influenza A and Influenza B Positive Control in a test run, the exact same procedure for unknown specimens collected in a liquid-based transport medium or swab-based collection device must be used. Refer to the manufacturer's supplied instructions for use provided with the Influenza test kit.

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

Levels of reactivity of REDx™ Influenza A and Influenza B Positive Control may vary with different manufacturers' test kits and different kit lots. Since REDx™ Influenza A and Influenza B Positive Control does not have an assigned value, the laboratory must establish an acceptance range for each lot of REDx™ Influenza A and Influenza B Positive Control.

TROUBLESHOOTING

When REDx™ Influenza A and Influenza B 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-13-02.5R0
29 August, 2022

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CERTIFICATE OF ANALYSIS

REDx™ Influenza A and Influenza B Positive Control

Product Information

Product Name	REDx™ Influenza A and Influenza B Positive Control
Catalogue Number	RED-13-02
Strain/Cell line	*Influenza A* / H1N1 Subtype *Influenza B* / Hong Kong/5/72. ICTV 00.046.0.04.001
Lot number	13020006A4
Analyte Value	Unassayed. Value not assigned by the manufacturer
Product Description	Unassayed qualitative positive control for the detection of Influenza A and Influenza B viruses.
Fill Volume	1.0 mL
Buffer	Buffer solution contains 0.02% sodium azide (CAS No. 26628-22-8) as a preservative solution.
Storage conditions	2-8°C
Expiry Date	10 Jun 2026
Intended Use	For *In vitro* Diagnostic Use.

Quality Control Information

Test method(s)	Cepheid Xpert® Xpress Flu/RSV or Cepheid Xpert® Xpress SARS-CoV-2/Flu/RSV Assay BinaxNOW Influenza A+B Card
Test Result(s)	Observed Result
Influenza A	Positive
Influenza B	Positive
RSV	Negative
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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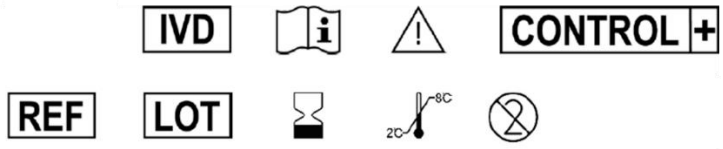

Information Please ensure that your institution is consulted before recycling an item.

Quality Assurance Signature: **Date: 25 Jul, 2025**