ACCURUN® Swab
Flu A/B
Reference Material

About this package insert

Thank you for your interest in this ACCURUN® product. This package insert consists of two pages.

The first page contains the product name, the LGC logo, and contact information.

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 CDx-Info@LGCGroup.com, or call us at +1.508.244.6400.

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

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ACCURUN® Swab Flu A/B Reference Material

NAME AND INTENDED USE

ACCURUN® reference materials are intended to estimate laboratory testing precision and can be used to detect errors in laboratory testing procedures. ACCURUN Swab Flu A/B Reference Material is formulated for use with molecular test methods used to detect Influenza A and B. They are designed as whole organism reference materials that can be used to assess accuracy and performance of the full testing process – extraction, amplification, and detection – of molecular assays for Influenza A and B. *For Research Use Only. Not for use in diagnostic procedures.*

SUMMARY

A well-designed quality control program can provide added confidence in the reliability of results obtained for unknown specimens. The use of low reactive samples as independent reference materials may provide valuable information concerning: assay sensitivity, lot-to-lot performance, operator performance, and the presence of random or systemic error.

PRODUCT DESCRIPTION

ACCURUN Swab Flu A/B reference materials are manufactured with inactivated Influenza A and B whole virus diluted in a proprietary stabilizing matrix and coated on a ready-to-use swab. Swabs are individually packaged for single use only.

REAGENTS

Material Number: 2020-0178 6 positive swabs

STORAGE INSTRUCTIONS

Store ACCURUN swabs at 2°C - 25°C. Swabs are packaged in single use only format; use immediately after opening.

WARNINGS AND PRECAUTIONS

Use the Centers for Disease Control (CDC) recommended universal precautions for handling ACCURUN reference materials and human specimens[1]. Do not pipette by mouth; do not 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.

Handling Precautions

Do not use ACCURUN swabs beyond the expiration date. Avoid microbial contamination when handling the swab or extraction solution.

INSTRUCTIONS FOR USE

Direct Load

Insert the swab directly into the test cartridge and process according to the manufacturer's instructions.

Liquid Extraction

Soak swab in a vial containing up to 1mL of appropriate stabilizing solution (such as phosphate-buffered saline or viral transport media) for 30 seconds, then swirl 10 times and compress swab head against vial wall to release residual liquid. Load extraction solution into the test cartridge and process according to the manufacturer's instructions. Use extraction solution immediately; discard any remaining extraction solution.

INTERPRETATION OF RESULTS

Levels of reactivity for the ACCURUN Swab Flu A/B reference material may vary with different types of tests and different test kit lots. Each lot is tested using the Cepheid Xpert® Xpress CoV-2/Flu/RSV plus and the Abbott ID NOW™ Influenza A & B 2 assays. Positive reference materials give positive results when using these tests. Each laboratory must establish its own range of acceptable values for ACCURUN Swab Flu A/B reference materials with the particular test kits being used.

LIMITATIONS OF THE PROCEDURE

ACCURUN REFERENCE MATERIALS MUST NOT BE SUBSTITUTED FOR THE POSITIVE AND NEGATIVE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.
TEST PROCEDURES and INTERPRETATION OF RESULTS provided by manufacturers of test kits must be followed. Deviations from procedures recommended by test kit manufacturers may produce unreliable results. ACCURUN reference materials are provided for quality assurance purposes and must not be used for calibration or as a primary reference preparation in any test procedure. Adverse shipping and/or storage conditions or use of outdated reference materials may produce erroneous results.

EXPECTED RESULTS

ACCURUN Swab Flu A/B Reference Materials DO NOT HAVE AN ASSIGNED VALUE. Specific levels of reactivity will vary among different manufacturers' assays, different procedures, different lot numbers 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 values.

REFERENCES

1. Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

For assistance, contact LGC Clinical Diagnostics Technical Support at +1 508.244.6400.

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