AccuPlex™ H5N1 Influenza

Reference Material Kit

About this package insert

Thank you for your interest in this AccuPlex™ 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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AccuPlex™ H5N1 Influenza Reference Material Kit

NAME AND INTENDED USE

AccuPlex™ H5N1 Influenza Reference Material is formulated for use with test methods that detect the H5N1 Influenza virus. AccuPlex virus products are non-replicative recombinant viruses that are intended to assess the performance of the full process of a molecular test. AccuPlex can be used to evaluate test proficiency and accuracy through the full process because they are encapsulated viruses which require extraction and amplification. *For Research Use only. Not for use in diagnostic procedures.*

PRODUCT DESCRIPTION

This product contains recombinant Alphavirus. There are 5 vials of positive controls that contain full genome reference material based on the genome A/cattle/Texas/56283/2024(H5N1).

There are also 5 vials of negative reference material (clear caps) that contain recombinant virus particles with sequences from human RNase P gene (RP).

The recombinant viruses used to produce the AccuPlex H5N1 Influenza Reference Material are replication defective. However, handle AccuPlex products and all human blood products as though capable of transmitting infectious agents.

The product is formulated in viral transport media that consists of Tris-buffered saline, with added glycerol, anti-microbial agents and human proteins. **This material must go through extraction, similar to the patient sample.**

Material Number:	0505-0422
Positive (Red caps):	5 x 1.5 mL vials
Negative (Clear caps):	5 x 1.5 mL vials

WARNINGS AND PRECAUTIONS

For Research Use only. Not for use in diagnostic procedures.

Use Centers for Disease Control (CDC) recommended universal precautions for handling AccuPlex and human specimens[1]. 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 and materials used in testing as though they contain infectious agents.

STORAGE INSTRUCTIONS

Store AccuPlex H5N1 Influenza Reference Material at 2-8 °C.

INSTRUCTIONS FOR USE

Allow the product vial to come to room temperature before use. Mix by vortexing to ensure a homogeneous suspension. AccuPlex reference materials should be added to a test run using the same procedure provided by the manufacturer for unknown specimens. AccuPlex H5N1 Influenza Reference Material must go through an extraction process prior to detection by PCR. Process the product according to the instructions for unknown samples provided by the test kit or the laboratory's standard operating procedures. AccuPlex reference materials must NOT be substituted for the positive and negative control reagents provided with the manufactured test kits.

INTERPRETATION OF RESULTS

Levels of reactivity of AccuPlex H5N1 Influenza Reference Material may vary with different types of tests and different test kit lots. This product contains targeted formulations of 5,000 copies/mL for positive members as measured using digital PCR. Note that the positive reference material may contain traces of RNase P and therefore generate a positive RNase P result due to the presence of a human plasma component in the product matrix; it is not designed or intended to be used as an RNase P reference material.

LIMITATIONS OF THE PROCEDURE

AccuPlex H5N1 Influenza Reference Material must not be substituted for the control 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. AccuPlex materials are not calibrators and should not be used for assay calibration. Performance characteristics for AccuPlex H5N1 Influenza Reference Material have been established only for amplified nucleic acid and sequencing tests for RNA. Adverse shipping and storage conditions or use of outdated product may produce erroneous results.

EXPECTED RESULTS

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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