ACCURUN® HIV-1 LOD

Reference Material Kit

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.

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ACCURUN® HIV-1 LOD Reference Material Kit

NAME AND INTENDED USE

ACCURUN® LOD Reference Material Kits are intended to measure the limit of detection and analytical sensitivity of molecular assays and can be used to detect errors in laboratory testing procedures. ACCURUN HIV-1 LOD Reference Material Kit is formulated for use with laboratory tests for the detection of HIV-1 RNA. *For Research Use Only. Not for use in diagnostic procedures.*

SUMMARY

The use of ACCURUN LOD Reference Material Kits can provide added confidence in the reliability of results obtained for unknown specimens. These kits may provide valuable information concerning assay sensitivity[1].

PRINCIPLES OF THE PROCEDURE

ACCURUN HIV-1 LOD Reference Material Kit is prepared by diluting a cultured HIV-1 type B virus (8E5) in HIV-1 RNA negative defibrinated human plasma. The 8E5 virus contains an intact but defective viral genome[2]. ACCURUN HIV-1 LOD Reference Material Kit is nonreactive for HBsAg and antibodies to HIV-1 and HIV-2, HCV, and HTLV. ACCURUN LOD Reference Material Kits do not have assigned values. Specific levels of reactivity will vary with different procedures, different reagent lot numbers, and different laboratories.

REAGENTS

Item No. 2020-0212 20 vials, 1.2 mL per vial

ACCURUN HIV-1 LOD Reference Material Kit contains 0.09% sodium azide as preservative.

WARNINGS AND PRECAUTIONS

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

CAUTION: Handle ACCURUN LOD Reference Material Kits and all human blood products as though capable of transmitting infectious agents. ACCURUN HIV-1 LOD Reference Material Kit is manufactured from human plasma nonreactive for HBsAg and antibodies to HIV-1 and HIV-2, HCV, and HTLV with current FDA licensed tests.

Safety Precautions

Use the Centers for Disease Control (CDC) recommended universal precautions for handling ACCURUN controls and human blood[3]. 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 LOD Reference Material Kits beyond the expiration date. Avoid microbial contamination of the controls when opening and closing the vials.

STORAGE INSTRUCTIONS

Store ACCURUN HIV-1 LOD Reference Material Kit at -70°C. Multiple freeze-thaw cycles are not recommended and may have variable adverse effects upon test results. To prevent leakage, store vials upright.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

Alterations in physical appearance may indicate instability or deterioration of ACCURUN LOD Reference Material Kits. Solutions that are visibly turbid should be discarded.

PROCEDURE

Materials Provided

ACCURUN HIV-1 LOD Reference Material Kit is formulated to be reactive for HIV-1 RNA and nonreactive for HBsAg and antibodies to HIV-1 and HIV-2, HCV, and HTLV.

Materials Required but not Provided

Refer to instructions supplied by manufacturers of the test kits to be used.

Instructions for Use

Thaw at room temperature and mix by gentle inversion before use. Once thawed, use immediately.

ACCURUN LOD Reference Material Kits should be included in a test run using exactly the same procedure provided by the manufacturer for unknown specimens. ACCURUN LOD Reference Material Kits must NOT be substituted for the positive and negative control reagents provided with manufactured test kits.

Quality Control

Since ACCURUN LOD Reference Material Kits do not have assigned values, it is recommended that each laboratory validate the use of each lot of ACCURUN with each specific assay system prior to its routine use in the laboratory.

INTERPRETATION OF RESULTS

Levels of reactivity of ACCURUN HIV-1 LOD Reference Material Kit may vary with different manufacturers' tests and different test kit lots. Since the kit does not have an assigned value, the laboratory must establish a range for each lot of ACCURUN HIV-1 LOD Reference Material Kit. When results for ACCURUN HIV-1 LOD Reference Material Kit are outside the established acceptance range of values, 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.

LIMITATIONS OF THE PROCEDURE

ACCURUN LOD REFERENCE MATERIAL KITS 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 LOD Reference Material Kits 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 controls may produce erroneous results.

EXPECTED RESULTS

ACCURUN HIV-1 LOD REFERENCE MATERIAL KIT DOES 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. For example, the acceptable range might include all values within 2 standard deviations of the mean of 20 data points obtained in 20 runs over a period of 30 days[4].

SPECIFIC PERFORMANCE CHARACTERISTICS

ACCURUN LOD Reference Material Kits have been designed for use with laboratory tests for purposes of measuring analytical sensitivity. ACCURUN HIV-1 LOD Reference Material Kit is formulated to be reactive for HIV-1 RNA and nonreactive for HBsAg and antibodies to HIV-1 and HIV-2, HCV, and HTLV. ACCURUN LOD Reference Material Kits do not have assigned values. 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.

REFERENCES

1. Green IV GA, Carey RN, Westgard JO, Carten T, Shablesky LA, Achord D, Page E, and Le AV. Quality control for qualitative assays: quantitative QC procedure designed to assure analytical quality required for an ELISA for hepatitis B surface antigen. Clin. Chem. 43:9 1618-1621, 1997.
2. Folks TM, Benn S, Rabson A, Theodore T, Hoggan MD, Marting M, Lightfoote M, Sell K. Characterization of a continuous T-cell line susceptible to the cytopathic effects of the acquired immunodeficiency syndrome (AIDS) associated retrovirus. Proc. Natl. Acad. Sci. USA 82:4539-4543,1985.
3. 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.
4. Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline– Fourth Edition. CLSI document C24, 2016.

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