ACCURUN® 21 SERIES 1000

Multi-Marker Positive Control

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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US | THESE REAGENTS MUST NOT BE SUBSTITUTED FOR THE MANDATORY POSITIVE AND NEGATIVE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.

ACCURUN® 21 SERIES 1000 Multi-Marker Positive Control

NAME AND INTENDED USE
ACCURUN controls are intended to estimate laboratory testing precision and can be used to detect errors in laboratory testing procedures. ACCURUN® 21 Multi-Marker Positive Controls are formulated for use with laboratory tests for the detection of antibodies to Human Immunodeficiency Virus Types 1 and 2 (HIV 1 and 2) antibodies to Hepatitis B Core Antigen (HBcAg), antibodies to Hepatitis C Virus (HCV), antibodies to Hepatitis A Virus (HAV), and Hepatitis B Surface Antigen (HBsAg). A negative control for these analytes is available separately from LGC Clinical Diagnostics. *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 controls may provide valuable information concerning assay sensitivity.

PRINCIPLES OF THE PROCEDURE
ACCURUN 21 Multi-Marker Positive Controls are manufactured from human serum or plasma, including materials reactive for HBsAg and antibodies to HIV 1 and 2, HBcAg, HCV, and HAV. ACCURUN 21 controls do not have assigned values. Specific levels of reactivity will vary with different procedures, different reagent lot numbers, and different laboratories.

REAGENTS
Item No. 2000-0027 6 vials, 3.5 mL per vial

ACCURUN 21 Multi-Marker Positive Control contains stabilizers (EDTA and buffering agents), and 0.1% ProClin® (5-chloro-2-methyl-4-isothiazolin-3-one & 2-methyl-4-isothiazolin-3-one) as preservative. Materials categorized as potentially infectious have been treated with beta-propiolactone and ultraviolet irradiation.

WARNINGS AND PRECAUTIONS
For Research Use Only. Not for use in diagnostic procedures.
CAUTION: Handle ACCURUN controls and all human blood products as though capable of transmitting infectious agents. ACCURUN 21 Multi-Marker Positive Controls are manufactured from human serum or plasma including materials reactive for HBsAg and antibodies to HIV 1 and 2, HBcAg, HCV and HAV.

Safety Precautions
Use the Centers for Disease Control (CDC) recommended universal precautions for handling ACCURUN controls and human blood[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 controls beyond the expiration date. Avoid microbial contamination of the controls when opening and closing the vials.

STORAGE INSTRUCTIONS
Store ACCURUN 21 Multi-Marker Positive Controls at 2-8°C. Once opened, ACCURUN 21 Controls should be stored at 2-8°C and discarded after 60 days. After opening, record the date opened and the expiration date on the vial. 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 21 controls. Solutions that are visibly turbid should be discarded.

PROCEDURE
Materials Provided
ACCURUN 21 Multi-Marker Positive Controls are manufactured from human serum or plasma, including materials reactive for HBsAg and antibodies to HIV 1 and 2, HBcAg, HCV, and HAV. See REAGENTS for a list of package sizes. A negative control for these analytes is also available separately from LGC Clinical Diagnostics.

Materials Required but not Provided
Refer to instructions supplied by manufacturers of the test kits to be used.

Instructions for Use
Mix the contents of the vials by gentle inversion. Allow the control to reach room temperature prior to use, then return controls to refrigerated storage immediately after use. ACCURUN controls should be included in a test run using exactly the same procedure provided by the manufacturer for unknown specimens. ACCURUN controls must NOT be substituted for the positive and negative control reagents provided with manufactured test kits.

Quality Control
Since ACCURUN controls 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
Different series of ACCURUN 21 controls are formulated to yield different reactivity levels for anti-HIV1, anti-HIV 2, and other analytes. Each laboratory must establish its own range of acceptable values for ACCURUN 21 controls with the particular test kits being used. When results for ACCURUN 21 controls are outside the established acceptable 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 CONTROLS 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 controls 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 21 Multi-Marker Positive Control Series 1000 DOES NOT HAVE AN ASSIGNED VALUE. Each laboratory should establish its own range of acceptable values for each analyte. 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[2].

SPECIFIC PERFORMANCE CHARACTERISTICS
ACCURUN controls are designed for use with laboratory testing for purposes of monitoring assay performance. ACCURUN 21 Multi-Marker Positive Controls are manufactured from human serum or plasma including material reactive for HBsAg and antibodies to HIV 1 and 2, HBcAg, HCV, and HAV. ACCURUN 21 controls do not have assigned values. Procedures for implementing a quality assurance program and monitoring test performance on a routine basis must be established by each individual laboratory.

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.
2. Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline– Second Edition. NCCLS document C24-A2, 1999.

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

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