ACCURUN® 24

Multi-Marker Confirmatory 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® 24 Multi-Marker Confirmatory Control

NAME AND INTENDED USE

ACCURUN® 24 Multi-Marker Confirmatory Control is intended to estimate laboratory testing precision and can be used to detect errors in laboratory testing procedures. ACCURUN 24 Multi-Marker Confirmatory Control is formulated for use with *in vitro* diagnostic test kits for the detection of antibodies to Human Immunodeficiency Virus Types 1 and 2 (HIV 1 and 2), antibodies to Human T-Lymphotropic Virus Type I (HTLV I), and antibodies to Hepatitis C Virus (HCV).

SUMMARY

Frequent testing of independent quality control samples provides the analyst with a means of monitoring the performance of laboratory assays. Routine use of controls enables laboratories to monitor day-to-day test variation, lot-to-lot performance of test kits, and operator variation, and can assist in identifying increases in random or systematic error. 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 laboratory proficiency and kit lot variation that may affect assay sensitivity[1].

PRINCIPLES OF THE PROCEDURE

ACCURUN 24 Multi-Marker Confirmatory Control is designed for use with *in vitro* assay procedures for purposes of monitoring test performance. ACCURUN 24 Multi-Marker Confirmatory Control is manufactured from human serum or plasma, including materials reactive for antibodies to HIV 1 and 2, HTLV I, and HCV. ACCURUN 24 control does not have assigned values. This control is formulated for use in those manufacturers' assays listed in Table 1. Specific levels of reactivity will vary among different manufacturers' assays, different procedures, different lot numbers, and different laboratories.

REAGENTS

Item No. 2000-0032 3 vials, 1 mL per vial

This control contains stabilizers (EDTA, 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 In Vitro Diagnostic Use

CAUTION: Handle ACCURUN controls and all human blood products as though capable of transmitting infectious agents. ACCURUN 24 Multi-Marker Confirmatory Control is manufactured from human serum or plasma, including materials reactive for antibodies to HIV 1 and 2, HTLV I, and HCV with current FDA licensed tests.

Safety Precautions

Use the Centers for Disease Control (CDC) recommended universal precautions for handling ACCURUN controls and human blood[2]. 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 controls refrigerated at 2-8°C. Once opened, ACCURUN controls should be discarded after 60 days. 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 controls. Solutions that are visibly turbid should be discarded.

PROCEDURE

Materials Provided

ACCURUN 24 Multi-Marker Confirmatory Control is manufactured from human serum or plasma, including materials reactive for antibodies to HIV 1 and 2, HTLV I, and HCV. See REAGENTS for a list of package sizes.

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 vial by gently swirling. Allow the control to reach room temperature prior to use, then return control 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 licensed 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 control with each specific assay system prior to its routine use in the laboratory.

INTERPRETATION OF RESULTS

Levels of reactivity of ACCURUN 24 Multi-Marker Confirmatory Control may vary with different manufacturers' tests and different test kit lots. Since the control does not have an assigned value, the laboratory must establish its own range of acceptable values for this ACCURUN control with the particular test kits being used. When results for ACCURUN 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 closely. 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 24 Multi-Marker Confirmatory Control DOES NOT HAVE AN ASSIGNED VALUE. This control is formulated for use in those manufacturers' assays listed in Table 1. Specific levels of reactivity will vary among different manufacturers' assays, different procedures, different reagent lot numbers, and different laboratories. 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[3].

SPECIFIC PERFORMANCE CHARACTERISTICS

ACCURUN controls are designed for use with *in vitro* assay procedures for purposes of monitoring assay performance. ACCURUN 24 Multi-Marker Confirmatory Control is manufactured from human serum or plasma including materials reactive for antibodies to HIV 1 and 2, HTLV I, and HCV. ACCURUN controls do not have assigned values. Specific levels of reactivity will vary among different manufacturers' assays, different procedures, different reagent 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. 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.
3. Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline – Second Edition. NCCLS document C24-A2, 1999.

Table 1: ACCURUN 24 Multi-Marker Confirmatory Control is formulated for use with the following manufacturers' assays:

Marker	Manufacturer/Product Name
HIV-1	Genetic Systems (BioRad) HIV-1 Western Blot or Calypte HIV-1 Western Blot
HIV-1	Genetic Systems (BioRad) rLAV (HIV-1 EIA)
HIV-2	Genetic Systems (BioRad) HIV-2 EIA
HTLV I/II	Genelabs HTLV I/II Western Blot
HCV	ORTHO HCV 3.0 ELISA
HCV	Innogenetics Inno-Lia HCV Score

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