ACCURUN® 810

Multi-Marker Negative Control

CE 2797

EC REP

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Explanation of symbols used in LGC Clinical Diagnostics product labeling

Upper limit of temperature

Temperature limitation

EC REP

Authorized Representative in the European Community

Biological risks

Use By

IVD

In Vitro Diagnostic Medical Device

CONTROL –

Negative control

REF

Catalogue number

Consult instructions for use

CONTROL +

Positive control

LOT

Batch code

Manufacturer

CONTROL

Control

Highly Flammable

Toxic by inhalation, in contact with skin and if swallowed

Health Hazard

Importer

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

ACCURUN® 810 Multi-Marker Negative Control

NAME AND INTENDED USE

ACCURUN® Controls are intended for use as negative qualitative controls to monitor laboratory testing precision and detect errors in laboratory testing procedures. ACCURUN 810 Multi-Marker Negative Control has been formulated for use with in vitro diagnostic test kits for the qualitative determination of Hepatitis B Surface Antigen (HBsAg), Hepatitis B e Antigen (HBeAg), Syphilis RPR, and antibodies to Hepatitis B Surface Antigen (HBs), Hepatitis B Core Antigen (HBc and HBc IgM), Hepatitis B e Antigen (HBe), Hepatitis C Virus (HCV), Hepatitis A Virus (HAV and HAV IgM), Cytomegalovirus (CMV), *Treponema pallidum* (Syphilis ATA), *Borrelia burgdorferi* (Lyme IgG and Lyme IgM), HIV 1 and 2, and HTLV I and II. Positive controls for many of these analytes are available separately from LGC Clinical Diagnostics.
ACCURUN controls do not have quantitative assigned values. *For professional laboratory use only.*

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 independent controls may provide valuable information concerning laboratory proficiency and kit lot variation that may affect assay sensitivity[1].

PRINCIPLES OF THE PROCEDURE

ACCURUN 810 Multi-Marker Negative Control is designed for use with *in vitro* assay procedures for purposes of monitoring test performance. ACCURUN 810 Multi-Marker Negative Control is manufactured from human serum or plasma nonreactive for HBsAg, HBeAg, anti-HBs, anti-HBc, anti-HBc IgM, anti-HBe, anti-HCV, anti-HAV, anti-HAV IgM, anti-CMV and Syphilis RPR, and antibodies to HIV 1 and 2, HTLV I and II, Lyme IgG and Lyme IgM, Syphilis ATA. ACCURUN controls do not have assigned values. Examples of assays with which this control may be compatible are 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. 2010-0020 6 vials, 3.5 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.

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 810 Multi-Marker Negative Control is manufactured from human serum or plasma nonreactive for HBsAg, and antibodies to HIV 1 and 2, HTLV I and II and HCV with current FDA licensed tests.

Safety Precautions

Use the Centers for Disease Control (CDC) recommended universal precautions for handling ACCURUN 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. Additional safety information can be found in the product Safety Data Sheet (SDS) found on the company website.

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 810 Multi-Marker Negative Control at 2-8°C. Once opened, ACCURUN 810 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 on 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 810 Multi-Marker Negative Control is manufactured from human serum or plasma nonreactive for HBsAg, HBeAg, Syphilis RPR and antibodies to HBs, HBc, HBc IgM, CMV, HBe, HCV, HAV, HAV IgM, HIV 1 and 2, HTLV I and II, Lyme IgG and IgM, and Syphilis ATA.

Materials Required but Not Provided

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

Instructions for Use

Allow the controls to reach room temperature prior to use, then return controls to refrigerated storage immediately after use. Mix the contents of the vials by gently swirling. 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

Levels of reactivity of ACCURUN 810 Multi-Marker Negative 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 a range for each lot of ACCURUN 810 Multi-Marker Negative Control. When results for ACCURUN 810 Multi-Marker Negative Control 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 qualitative, not automated, and 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 CONTROLS DO NOT HAVE ASSIGNED VALUES. This control has been formulated to produce negative reactivity 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. 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 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 810 Multi-Marker Negative Control is manufactured from human serum or plasma nonreactive for HBsAg, HBeAg, Syphilis RPR and antibodies to HBs, HBc, HBc IgM, CMV, HBe, HCV, HAV, HAV IgM, HIV 1 and 2, HTLV I and II, Lyme IgG and IgM, and Syphilis ATA. ACCURUN controls 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. Quality control materials should be used in accordance with local, state, and federal regulations and accreditation requirements.

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–Fourth Edition. CLSI document C24, 2016.

Table 1. This product is tested at release using the following assays:

Analyte	Manufacturer	Product Name
HBsAg	DiaSorin, Stillwater MN	LIAISON® HBsAg
HBsAg	Bio-Rad Laboratories, Redmond, WA	Genetic Systems HBsAg EIA 3.0, proc. B
anti-CMV	Trinity Biotech, Bray, Ireland	CAPTIA™ CMV
anti-HBc	DiaSorin, Stillwater MN	LIAISON® Anti-HBc
anti-HBc	Ortho Diagnostics, Raritan, NJ	HBc ELISA
anti-HBc IgM	Abbott Laboratories, Abbott Park, IL	Abbott ARCHITECT® CORE-M™
anti-HBs	DiaSorin, Stillwater MN	LIAISON® Anti-HBs
anti-HBe	DiaSorin, Stillwater, MN	LIAISON® Anti-HBe
HBeAg	DiaSorin, Stillwater, MN	LIAISON® HBeAg
anti-HCV	Ortho Diagnostics, Raritan, NJ	HCV 3.0 ELISA
anti-HAV	DiaSorin, Stillwater, MN	LIAISON® Anti-HAV
anti-HAV IgM	DiaSorin, Stillwater, MN	LIAISON® HAV IgM
anti-HIV 1/2	Bio-Rad Laboratories, Redmond, WA	Genetic Systems HIV-1/HIV-2 Plus O EIA
anti-HIV 2	Bio-Rad Laboratories, Redmond, WA	Genetic Systems HIV-2 EIA
anti-HTLV I/II	Abbott Laboratories, Abbott Park, IL	ALINITY s HTLV-I/HTLV-II
Lyme IgG	Zeus Scientific Inc., Branchburg, NJ	Wampole *B. burgdorferi* IgG ELISA II
Lyme IgM	Zeus Scientific Inc., Branchburg, NJ	Wampole *B. burgdorferi* IgM ELISA II
Syphilis ATA	Trinity Biotech plc, Dublin, Ireland	Captia Syphilis G EIA
Syphilis RPR	Arlington Scientific Inc., UT	RPR Screening test for Syphilis

For assistance, contact LGC Clinical Diagnostics Technical Support at +1.508.244.6400.

Any serious incident that has occurred in relation to the device shall be reported to LGC Clinical Diagnostics Technical Support and, if in use in the EU, the competent authority of the Member State in which the incident occurred.

Date	Description of Change
October 2024	Update for IVDR

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