ACCURUN® 121

HAV IgM Positive Control

CE

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

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

ACCURUN® 121 HAV IgM 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® 121 HAV IgM Positive Control has been formulated for use with *in vitro* diagnostic test kits for the qualitative determination of IgM antibodies to Hepatitis A Virus (HAV IgM). This product is not FDA cleared for use in testing blood or plasma donors. A negative control for HAV IgM is available separately from LGC Clinical Diagnostics.
For In Vitro Diagnostic Use.

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 121 HAV IgM Positive Control has been designed for use with *in vitro* assay procedures for purposes of monitoring test performance. ACCURUN 121 HAV IgM Positive Control is manufactured from human serum or plasma reactive for anti-Hepatitis A and nonreactive for HBsAg and antibodies to HIV 1 and 2, HTLV, and HCV. 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.

REAGENTS
Item No.2015-0074	1 vial, 5.0 ml per vial
Item No. 2015-0076	6 vials, 3.5 ml per vial

This control contains HAV IgM antibody as assayed by EIA, EDTA and buffering agents as stabilizers, 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 121 HAV IgM Positive Control is manufactured from human serum or plasma nonreactive for HBsAg and antibodies to HIV 1 and 2, HTLV, 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.

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 121 HAV IgM Positive Control at 2-8°C. Once opened, ACCURUN 121 HAV IgM Positive Control should be stored at 2-8°C when not in use, and 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 121 HAV IgM Positive Control is manufactured from human serum or plasma nonreactive for HBsAg and antibodies to HIV 1 and 2, HTLV, and HCV.

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 121 HAV IgM Positive 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 121 HAV IgM Positive Control. When results for ACCURUN 121 HAV IgM Positive Control are outside the established acceptable range of values, it may be an indication of unsatisfactory test performance. Possible sources of discrepancy are: 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 not calibrators and should not be used for assay calibration. These controls should be used when testing serum or plasma specimens. Performance characteristics for ACCURUN 121 HAV IgM Positive Control have been established only for HAV IgM. Adverse shipping and/or storage conditions or use of outdated controls may produce erroneous results.

EXPECTED RESULTS
ACCURUN 121 HAV IgM Positive Control 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 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 have been designed for use with *in vitro* assay procedures for purposes of monitoring assay performance. ACCURUN 121 HAV IgM Positive Control is manufactured from human serum or plasma nonreactive for HBsAg and antibodies to HIV 1 and 2, HTLV, and HCV. 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.

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.

For assistance, contact LGC Clinical Diagnostics Technical Support at +1 508.244.6400.

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