ACCURUN® 325 SERIES 700

Hepatitis B Virus DNA Positive Control

CE 2797

EC REP

LGC Clinical Diagnostics, Inc. | 37 Birch Street, Milford, MA 01757 USA
Phone: +1 508.244.6400 | CDx-Info@LGCGroup.com

MEDIMARK® Europe
11, rue Émile Zola BP 2332
38033 Grenoble Cedex 2 – France
+ 33 (0) 4 76 86 43 22
info@medimark-europe.com

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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® 325 SERIES 700 Hepatitis B Virus DNA 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® 325 Hepatitis B Virus DNA Positive Control Series 700 is formulated for use in genetic amplification based laboratory tests that detect Hepatitis B Virus (HBV) DNA. *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 independent controls may provide valuable information concerning laboratory proficiency and kit lot variation that may affect assay sensitivity[1].

PRINCIPLES OF THE PROCEDURE
ACCURUN 325 Hepatitis B Virus DNA Positive Control Series 700 is designed for use with laboratory testing for purposes of monitoring test performance. ACCURUN 325 Hepatitis B Virus DNA Positive Control Series 700 is manufactured from human serum or plasma reactive for HBV DNA and nonreactive for antibodies to HIV 1 and 2, HTLV I and II, 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. 2020-0098 5 vials, 4.0 mL per vial

ACCURUN 325 Hepatitis B Virus DNA Positive Control Series 700 contains stabilizers and 0.09% sodium azide 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 325 is manufactured from human serum or plasma nonreactive for 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 patient samples[2]. Do not pipette by mouth; do not smoke, 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. To prevent formation of potentially explosive compounds due to reactions of sodium azide and copper or lead pipes, flush waste lines with large quantities of water.
Nucleic acid amplification reactions are sensitive to amplicon contamination. Inconsistent or invalid results could occur if clinical specimens or quality control reagents become contaminated. Use aerosol barrier pipette tips in a biosafety hood or other containment facility for dispensing patient samples and controls, and open only one sample at a time. The risk of contaminating ACCURUN 325 Hepatitis B Virus DNA Positive Control Series 700 will be greatly reduced by discarding the control immediately after first use.

STORAGE INSTRUCTIONS
Store ACCURUN 325 Hepatitis B Virus DNA Positive Control Series 700 at -20°C or colder until use. 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 325 Hepatitis B Virus DNA Positive Control Series 700 is manufactured from human serum or plasma reactive for HBV DNA and nonreactive for antibodies to HIV 1 and 2, HTLV I and II, and HCV.

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

Instructions for Use
- Prior to each use, allow the control to reach room temperature and mix by gentle inversion.
- Each vial of ACCURUN 325 should not be used more than three times and must be used within 10 days after first opening.
- Immediately after each use, refrigerate ACCURUN 325 at 2-8°C.
- When the vial is opened for the first time, record the date opened and the expiration date on the vial.
- To minimize the chance of contamination, discard the vial after first 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 as part of the test kit.

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 325 Hepatitis B Virus DNA Positive Control Series 700 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 325. When results for ACCURUN 325 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 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. Performance characteristics for ACCURUN 325 Hepatitis B Virus DNA Positive Control Series 700 have been established only for Hepatitis B Virus DNA. Adverse shipping and storage conditions or use of outdated controls may produce erroneous results.

EXPECTED RESULTS
ACCURUN 325 Hepatitis B Virus DNA Positive Control Series 700 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 are designed for use with laboratory testing for purposes of monitoring assay performance. ACCURUN 325 Hepatitis B Virus DNA Positive Control Series 700 is manufactured from human serum or plasma reactive for HBV DNA and nonreactive for antibodies to HIV 1 and 2, HTLV I and II, 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.

Phone: +1 508.244.6400 | Toll Free (US Only) 800.676.1881
Fax: +1.508.634.3334 | SeraCare.com