ACCURUN® 305 SERIES 400

HCV RNA Positive Control

CE 2797

EC REP

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

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

10963GB-10 April 2024

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

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

ACCURUN® 305 SERIES 400 HCV RNA 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® 305 HCV RNA Positive Control Series 400 is formulated for use with *in vitro* diagnostic test methods that detect and quantitate HCV RNA. Additional controls at different concentrations of HCV RNA are available separately from LGC Clinical Diagnostics.

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 305 HCV RNA Positive Control is designed for use with *in vitro* assay procedures for the purpose of monitoring test performance. ACCURUN 305 HCV RNA Positive Control is manufactured from human serum or plasma reactive for HCV RNA genotype 1 and nonreactive for HBsAg and antibodies to HIV 1 and HIV 2 and HTLV. ACCURUN controls do not have assigned values. Specific levels of reactivity will vary among different manufacturer's assays, different procedures, different lot numbers and different laboratories.

REAGENTS

Item No. 2020-0085 5 vials, 4.0 ml per vial

ACCURUN 305 HCV RNA Positive Control 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 305 HCV RNA Positive Control is manufactured from human serum or plasma nonreactive for HBsAg and antibodies to HIV 1 and HIV 2, and HTLV with current FDA licensed tests.

Safety Precautions

Use World Health Organization (WHO) recommended universal precautions for handling ACCURUN and human blood[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. Avoid contamination of the controls when opening and closing the vials. 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.

STORAGE INSTRUCTIONS

For maximum stability, ACCURUN 305 HCV RNA Positive Control should be stored at -70°C. If preferred, vials may be stored at -20°C for up to six months. 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 305 HCV RNA Positive Control is manufactured from human serum or plasma reactive for HCV RNA genotype 1 and nonreactive for HBsAg and antibodies to HIV 1 and HIV 2 and HTLV.

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 305 should not be used more than three times and must be used within 10 days after first opening.
- Immediately after each use, refrigerate ACCURUN 305 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 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 305 HCV RNA 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 305 HCV RNA Positive Control. When results for ACCURUN 305 HCV RNA Positive Control 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 305 HCV RNA Positive Control have been established only for HCV RNA. Adverse shipping and storage conditions or use of outdated controls may produce erroneous results.

EXPECTED RESULTS

ACCURUN 305 HCV RNA 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 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].

Table 1 lists typical data for ACCURUN 305 HCV RNA Positive Control. Data are expressed in units as specified by the assay manufacturer.

SPECIFIC PERFORMANCE CHARACTERISTICS

ACCURUN controls are designed for use with *in vitro* assay procedures for purposes of monitoring assay performance. ACCURUN 305 HCV RNA Positive Control is manufactured from human serum or plasma reactive for HCV RNA genotype 1 and nonreactive for HBsAg and antibodies to HIV 1 and HIV 2 and HTLV. 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. Joint ILO/WHO Guidelines on Health Services and HIV/AIDS, 2005.
3. Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline– Fourth Edition. CLSI document C24, 2016.

Table 1. Typical Data for ACCURUN 305 HCV RNA Positive Control Series 400.

Manufacturer	Assay	Result
Roche Molecular Systems, Inc. Pleasanton, CA	COBAS® 5800/6800/8800 HCV Test	1.0 x 10^5 IU/ml

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