ACCURUN® 350

CMV DNA Positive Control

IVD

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

14292US-01 September 2024

Explanation of symbols used in LGC Clinical Diagnostics product labeling


Upper limit of temperature


Temperature limitation

In Vitro Diagnostic Medical Device


Biological risks


Use By


Consult instructions for use

Negative control

Catalogue number


Manufacturer

Positive control

Batch code


Toxic by inhalation, in contact with skin and if swallowed

Control


Highly Flammable


Health Hazard


Single Use

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

ACCURUN® 350 CMV DNA Positive Control

NAME AND INTENDED USE

ACCURUN® are intended to estimate laboratory testing precision and can be used to detect errors in laboratory testing procedures. ACCURUN 350 CMV DNA Positive Control has been formulated for use in nucleic acid-based amplification *in vitro* diagnostic test procedures that detect Cytomegalovirus (CMV) 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 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 350 CMV DNA Positive Control has been designed for use with *in vitro* assay procedures for purposes of monitoring test performance. ACCURUN 350 CMV DNA Positive Control is manufactured by diluting cultured virus reactive for CMV DNA with defibrinated plasma nonreactive for HBsAg and antibodies to HIV 1 and 2, HTLV I and II, HCV and CMV. 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. 2020-0162 10 vials, 1.2 mL per vial

ACCURUN 350 CMV DNA 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 350 is manufactured from human serum or plasma, including materials 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 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. 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

Store ACCURUN 350 CMV DNA Positive Control at -20°C until use. Once thawed, ACCURUN 350 controls should stored at 2 - 8°C and discarded after 30 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 350 CMV DNA Positive Controls are manufactured from cultured virus reactive for CMV DNA and defibrinated plasma negative for HBsAg and antibodies to HIV 1 and 2, HTLV I and II, HCV and CMV.

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 and mix the contents of the vials gently prior to 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 350 controls do not have assigned values, it is recommended that each laboratory validate the use of each lot of ACCURUN 350 controls with each specific assay system prior to its routine use in the laboratory.

INTERPRETATION OF RESULTS

Levels of reactivity of ACCURUN 350 CMV DNA controls may vary with different manufacturers' tests and different test kit lots. Since the control does not have an assigned value, each laboratory must establish its own range of acceptable values for ACCURUN 350 controls with the particular test kits being used. When results for ACCURUN 350 controls are outside the established acceptable range of values, it may be an indication of unsatisfactory test performance. Possible sources of error 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 350 controls are provided for quality assurance purposes and must not be used for calibration or as a primary reference preparation in any test procedure. Performance characteristics for ACCURUN 350 CMV DNA Positive Control have been established only for CMV DNA. Adverse shipping and/or storage conditions or use of outdated controls may produce erroneous results.

EXPECTED RESULTS

ACCURUN 350 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. 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 350 CMV DNA Positive Control has been designed for use with *in vitro* assay procedures for purposes of monitoring assay performance. The controls are designed for nucleic acid-based detection assays only. ACCURUN 350 is manufactured from human serum or plasma, including materials nonreactive for HBsAg and antibodies to HIV 1 and 2, HTLV I and II, and HCV with current FDA licensed tests. ACCURUN 350 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– Fourth Edition. CLSI document C24, 2016.

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.

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