ACCURUN® Anti-SARS-CoV-2
IgM Controls Kit

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Explanation of symbols used in LGC Clinical Diagnostics product labeling


Upper limit of temperature


Temperature limitation

Authorized Representative in the European Community


Biological risks


Use By

In Vitro Diagnostic Medical Device

Negative control

Catalogue number


Consult instructions for use

Positive control

Batch code


Manufacturer

Control


Highly Flammable


Toxic by inhalation, in contact with skin and if swallowed


Health Hazard


Single Use


Importer

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

ACCURUN® Anti-SARS-CoV-2 IgM Controls Kit

NAME AND INTENDED USE

ACCURUN® Controls are intended for use as positive qualitative controls to monitor laboratory testing precision and detect errors in laboratory testing procedures. ACCURUN Anti-SARS-CoV-2 IgM Controls Kit (2015-0232) is formulated for use with *in vitro* diagnostic test methods that detect IgM antibodies to SARS-CoV-2 virus, the causative agent of COVID-19 disease. 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 controls are designed for use with in vitro assay procedures for the purpose of monitoring assay performance. The kit includes both antibody positive and negative controls. The positive is manufactured from human serum or plasma reactive for SARS-CoV-2 IgM and nonreactive for HBsAg and antibodies to HIV 1 and 2 and HCV. There are 2 vials of positive control (red caps) contained within each kit. The negative control is manufactured from human serum or plasma nonreactive for antibodies to SARS-CoV-2, as well as HBsAg and antibodies to HIV 1 and 2 and HCV. There are 2 vials of negative control (clear caps) contained within each kit. 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.	2015-0232
Positive (Red caps):	2 x 3.0 ml vials
Negative (Clear caps):	2 x 3.0 ml vials

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. The positive control is manufactured from human serum or plasma reactive for SARS-CoV-2 IgM and nonreactive for HBsAg and antibodies to HIV 1 and 2 and HCV; the negative control is manufactured from human serum or plasma nonreactive for antibodies to SARS-CoV-2, as well as HBsAg and antibodies to HIV 1 and 2 and HCV.

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. 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 Anti-SARS-CoV-2 IgM controls at 2-8°C. Once opened, vials 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. 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

The positive control is manufactured from human serum or plasma reactive for SARS-CoV-2 IgM and nonreactive for HBsAg and antibodies to HIV 1 and 2 and HCV; the negative control is manufactured from human serum or plasma nonreactive for antibodies to SARS-CoV-2, as well as HBsAg and antibodies to HIV 1 and 2 and HCV. See REAGENTS for a list of package sizes.

Materials Required but not Provided

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

Instructions for Use

Mix the contents of the vials by gently swirling. Allow the controls to reach room temperature prior to use, then return controls to refrigerated storage immediately after 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 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 control with each specific assay system prior to its routine use in the laboratory.

INTERPRETATION OF RESULTS

Levels of reactivity of ACCURUN Controls may vary with different manufacturers' tests and different test kit lots. Each laboratory must establish its own range of acceptable values for ACCURUN controls with the particular test kits being used. When results for ACCURUN controls 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. 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. 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 controls are designed for use with in vitro assay procedures for purposes of monitoring assay performance. The positive control is manufactured from human serum or plasma reactive for SARS-CoV-2 IgM and nonreactive for HBsAg and antibodies to HIV 1 and 2 and HCV; the negative control is manufactured from human serum or plasma nonreactive for antibodies to SARS-CoV-2, as well as HBsAg and antibodies to HIV 1 and 2 and HCV. ACCURUN 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. 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.

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
February 2022	Initial release

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