ACCURUN® Anti-SARS-CoV-2 Controls Kit SERIES 2000

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

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 Controls Kit SERIES 2000

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® Anti-SARS-CoV-2 Controls Kit Series 2000 (2015-0225) is formulated as an external run control for use with *in vitro* diagnostic test kits for the qualitative determination of antibodies to SARS-CoV-2 virus, the causative agent of COVID-19 disease. *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 Anti-SARS-CoV-2 Controls Kit Series 2000 is designed for use with *in vitro* assay procedures for purposes of monitoring test performance. The ACCURUN Anti-SARS-CoV-2 Controls kit includes both antibody positive and negative controls. The positive control material is manufactured from human serum or plasma reactive for SARS-CoV-2 antibodies 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. Specific levels of reactivity will vary among different manufacturers' assays, different procedures, different lot numbers, and different laboratories.

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 material (clear caps) contained within each kit.

REAGENTS

Item No.:	2015-0225
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. Anti-SARS-CoV-2 Controls Kit Series 2000 is manufactured from human serum or plasma nonreactive for HBsAg and antibodies to HIV 1 and 2 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, control materials, and other materials used in testing as though they contain infectious agents.

Handling Precautions

Do not use ACCURUN control materials beyond the expiration date. Avoid microbial contamination of the control materials when opening and closing the vials.

STORAGE INSTRUCTIONS

Store ACCURUN Anti-SARS-CoV-2 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. Multiple 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 Anti-SARS-CoV-2 controls. Solutions that are visibly turbid should be discarded.

PROCEDURE

Materials Provided

ACCURUN Anti-SARS-CoV-2 Controls Kit Series 2000 is manufactured from human serum or plasma, including materials reactive for SARS-CoV-2 antibodies and nonreactive for 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

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 Anti-SARS-CoV-2 controls do not have assigned values, it is recommended that each laboratory validate the use of each lot of ACCURUN Anti-SARS-CoV-2 control with each specific assay system prior to its routine use in the laboratory.

INTERPRETATION OF RESULTS

Levels of reactivity for the ACCURUN Anti-SARS-CoV-2 controls may vary with different types of tests and different test kit lots. Positive controls give positive results and negative controls give negative results. When results for ACCURUN Anti-SARS-CoV-2 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 Anti-SARS-CoV-2 CONTROLS MUST NOT BE SUBSTITUTED FOR THE 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 materials are not calibrators and should not be used for assay calibration. These materials should be used when testing serum or plasma specimens. Performance characteristics for ACCURUN Anti-SARS-CoV-2 Controls Kit Series 2000 have been established only for SARS-CoV-2 antibodies. Adverse shipping and storage conditions or use of outdated product may produce erroneous results.

EXPECTED RESULTS

ACCURUN Anti-SARS-CoV-2 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. Each laboratory should establish its own range of acceptable values.

SPECIFIC PERFORMANCE CHARACTERISTICS

ACCURUN controls are designed for use with *in vitro* assay procedures for purposes of monitoring assay performance. ACCURUN Anti-SARS-CoV-2 Controls are manufactured from human serum or plasma including materials reactive for SARS-CoV-2 antibodies and nonreactive for 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.

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.

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.

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