ACCURUN® Anti-SARS-CoV-2 Reference Material Kit

Series 2000

About this package insert

Thank you for your interest in this ACCURUN® product. This package insert consists of two pages.

The first page contains the product name, the SeraCare logo, and contact information.

The second page contains the complete package insert text. If the package insert you view or print does not contain two pages, or if you experience any problems, please email us at info@seracare.com, or call us at +1.508.244.6400.

A printed package insert will be sent to you upon request.

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

ACCURUN® Anti-SARS-CoV-2 Reference Material Kit Series 2000

NAME AND INTENDED USE

ACCURUN® Anti-SARS-CoV-2 Reference Material Kit Series 2000 (2015-0225) is formulated for use with test methods for the qualitative determination of total antibodies to SARS-CoV-2 virus, the causative agent of COVID-19 disease. *For Research Use Only. Not for use in diagnostic procedures.*

PRODUCT DESCRIPTION

ACCURUN Anti-SARS-CoV-2 Reference Material Kit Series 2000 includes both antibody positive and negative reference materials. The positive is manufactured from human serum or plasma reactive for anti-SARS-CoV-2 and nonreactive for HBsAg and antibodies to HIV 1 and 2, HTLV I and II, and HCV. There are 2 vials of positive reference material (red caps) contained within each kit.

The negative reference material 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, HTLV I and II, and HCV. There are 2 vials of negative reference material (clear caps) contained within each kit.

Material Number:	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 Research Use Only. Not for use in diagnostic procedures.

CAUTION: Handle ACCURUN reference materials and all human blood products as though capable of transmitting infectious agents. Anti-SARS-CoV-2 Reference Material Kit Series 2000 is manufactured from human serum or plasma nonreactive for HBsAg and antibodies to HIV 1 and 2, HTLV I and II, and HCV with current FDA approved tests.

Safety Precautions

Use the Centers for Disease Control (CDC) recommended universal precautions for handling ACCURUN and human blood[1]. 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, reference materials, and other materials used in testing as though they contain infectious agents.

Handling Precautions

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

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

Alterations in physical appearance may indicate instability or deterioration of ACCURUN Anti-SARS-CoV-2 reference materials. Solutions that are visibly turbid should be discarded.

STORAGE INSTRUCTIONS

Store ACCURUN Anti-SARS-CoV-2 reference material at 2-8°C. Once opened, vials should be stored at 2-8°C and discarded after 30 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.

INSTRUCTIONS FOR USE

Allow the reference materials 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 reference materials should be included in a test run using exactly the same procedure provided by the manufacturer for unknown specimens. ACCURUN reference materials must NOT be substituted for the positive and negative control reagents provided with manufactured test kits.

INTERPRETATION OF RESULTS

Levels of reactivity for the ACCURUN Anti-SARS-CoV-2 reference material may vary with different types of tests and different test kit lots. Although not specifically intended for use with the Roche cobas® Elecsys®, each lot is tested at release using the Roche cobas® Elecsys® Anti-SARS-CoV-2 assay. Positive reference material gives positive results and negative reference material gives negative results.

LIMITATIONS OF THE PROCEDURE

ACCURUN SARS-CoV-2 reference material 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 Reference Material Kit Series 2000 have been established only for total SARS-CoV-2 antibodies. Adverse shipping and storage conditions or use of outdated product may produce erroneous results.

EXPECTED RESULTS

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.

REFERENCES

1. 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 SeraCare Technical Support a t+1 508.244.6400.

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