

ACCURUN® Anti-SARS-CoV-2 Reference Material Kit Series 1000

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.



ACCURUN® Anti-SARS-CoV-2 Reference Material Kit Series 1000

NAME AND INTENDED USE

ACCURUN® Anti-SARS-CoV-2 Reference Material Kit Series 1000 (2015-0222) is formulated for use with test methods for the qualitative determination of IgG 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 1000 includes both antibody positive and negative reference materials. The positive is manufactured from human serum or plasma reactive for SARS-CoV-2 IgG 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:	2015-0222
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 1000 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 blood¹. 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 Abbott ARCHITECT, each lot is tested at release using the Abbott ARCHITECT SARS-CoV-2 IgG 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 1000 have been established only for SARS-CoV-2 IgG. 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 at +1 508.244.6400.



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

ENSURE ANTIBODY TESTING ACCURACY AND PERFORMANCE

ABOUT SERACARE

TRUSTED SUPPLIER
TO DIAGNOSTIC
MANUFACTURERS' AND
CLINICAL LABS FOR
OVER 30 YEARS

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PROVIDE ASSURANCE
IN DIAGNOSTIC ASSAY
PERFORMANCE AND
TEST RESULTS

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ACCURUN[®] Anti-SARS-CoV-2 Reference Material Kit offers positive materials for antibodies to the SARS-CoV-2 virus. Also included are complementary negative materials. The kit is designed to support assay installation and monitoring of day-to-day assay performance, providing a complete quality solution for SARS-CoV-2 antibody testing.

To support the many SARS-CoV-2 serology assay formats available, the kit is currently offered in two configurations, one designed for IgG-specific assays and the other for total antibody tests. Series 1000 is released using the Abbott ARCHITECT SARS-CoV-2 IgG assay, and Series 2000 is released using the Roche cobas[®] Elecsys[®] Anti-SARS-CoV-2 assay. Reference materials are specifically formulated to exhibit low positive reactivity in true patient-like matrices, to test assay performance near critical signal cutoff boundaries.

Product Description	Series	Material Number	Pack Size	Antibody Coverage	Release Testing
ACCURUN Anti-SARS-CoV-2 Reference Material Kit	1000	2015-0222	Positive 2 x 3 mL	IgG	Abbott ARCHITECT
	2000	2015-0225	Negative 2 x 3 mL	Total	Roche cobas [®]

Not for In Vitro Diagnostic Use. Research Use Only.

SARS-CoV-2 Serology Solution:

- **Patient-like Matrices:** Formulated from true human-sourced disease material to mimic patient samples encountered in a daily testing environment
- **Relevant Target Ranges:** Specifically designed to be weakly reactive, low positive reference materials to challenge assay performance
- **Ease of Use:** Liquid-ready format, requiring no reconstitution
- **Long Shelf Life:** 2 year stability at 2 - 8°C
- **Open Vial Stability:** Once opened, stable for 30 days

LEARN MORE

To learn more about ACCURUN SARS-CoV-2 Reference Materials and our complete line of SARS-CoV-2 Quality Solutions visit: www.seracare.com/SARSCoV2 or contact customer service at 800.676.1881.

ORDERING INFORMATION

To place an order, please contact us at +1.508.244.6400 and 800.676.1881 or email customerservice@seracare.com.