ACCURUN® SARS-CoV-2 Antigen

Reference Material Kit

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 LGC 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 CDx-info@LGCGroup.com, or call us at +1.508.244.6400.

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

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ACCURUN® SARS-CoV-2 Antigen Reference Material Kit

NAME AND INTENDED USE

ACCURUN® SARS-CoV-2 Antigen Reference Material Kit (2015-0231) is formulated for use with test methods that detect the nucleocapsid protein of SARS-CoV-2 virus, the causative agent of COVID-19 disease.
For Research Use Only. Not for use in diagnostic procedures.

PRODUCT DESCRIPTION

ACCURUN SARS-CoV-2 Antigen Reference Material Kit includes both antigen positive and negative reference materials. The positive is manufactured from purified recombinant SARS-CoV-2 nucleocapsid protein formulated in universal transport media that consists of Tris-buffered saline, with added glycerol, anti-microbial agents and human proteins. The negative contains transport media only. There are 5 vials of positive reference material (red caps) and 5 vials of negative reference material (clear caps) contained within each kit.

Item No.:	2015-0231
Positive (Red caps):	5 x 3.0 mL vials
Negative (Clear caps):	5 x 3.0 mL vials

STORAGE INSTRUCTIONS

Store ACCURUN SARS-CoV-2 antigen reference material at -20°C. Once opened, vials should be stored at 2-8°C and discarded after 5 days. After opening, record the date opened and the expiration date on the vial. Do not expose to multiple freeze-thaw cycles. To prevent leakage, store vials upright.

INSTRUCTIONS FOR USE

Allow the product vial to come to room temperature before use. Mix by vortexing to ensure a homogeneous suspension. ACCURUN reference materials should be added to a test run using the same procedure provided by the manufacturer for unknown specimens. Process the product according to the instructions for unknown samples provided by the test kit or the laboratory's standard operating procedures. 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 SARS-CoV-2 antigen reference material may vary with different types of tests and different test kit lots. Each lot is tested using the Ortho Vitros®. SARS-CoV-2 Antigen assay. Positive reference material gives positive results and negative reference material gives negative results.

LIMITATIONS OF THE PROCEDURE

ACCURUN SARS-CoV-2 antigen 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. Performance characteristics for ACCURUN SARS-CoV-2 antigen reference material have been established only for immunoassay tests for SARS-CoV-2 nucleocapsid antigen. Adverse shipping and storage conditions or use of outdated product may produce erroneous results.

WARNINGS AND PRECAUTIONS

Use Centers for Disease Control (CDC) recommended universal precautions for handling ACCURUN SARS-CoV-2 antigen reference material and human specimens[1]. Do not pipette by mouth; do not smoke, eat or drink in areas where specimens are being handled. Clean any spillage by immediately wiping with 0.5% sodium hypochlorite solution. Dispose of all specimens and materials used in testing as though they contain infectious agents.

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 LGC Clinical Diagnostics Technical Support at +1 508.244.6400.

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