AccuPlex™ SARS-CoV-2

Reference Material Kit

About this package insert

Thank you for your interest in this AccuPlex™ 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.

AccuPlex™ SARS-CoV-2 Reference Material Kit

NAME AND INTENDED USE

AccuPlex™ SARS-CoV-2 Reference Material 0505-0126 is formulated for use with test methods that can detect SARS-CoV-2 virus, the causative agent of COVID-19 disease. AccuPlex virus products are non-replicative recombinant viruses that are intended to assess the performance of the full process of a molecular test. AccuPlex can be used to evaluate test proficiency and accuracy through the full process because they are encapsulated viruses which require extraction and amplification.

For Research Use Only. Not for use in diagnostic procedures.

PRODUCT DESCRIPTION

This product contains recombinant Alphavirus. There are 5 vials of positive reference material (red caps) that contain recombinant virus particles with sequences from SARS-CoV-2 genome. The sequences are based on the Genbank accession number NC_045512.2 and are detailed in Table 1.

Table 1: Sequences contained in positive reference material

Regions included	Location
ORF1a region	417..1899
	3094..3360
RdRp region	13291..13560
	14700..15950
	18577..19051
E (Envelop) region	25801..28200
N (Nucleocapsid) region	27952..29873

There are also 5 vials of negative reference material (clear caps) that contain recombinant virus particles with sequences from human RNAase P gene (RP).

The recombinant viruses used to produce the AccuPlex SARS-CoV-2 reference material are replication defective and heat-treated. However, handle AccuPlex products and all human blood products as though they can transmit infectious agents.

The product is formulated in viral transport media that consists of Tris-buffered saline, with added glycerol, anti-microbial agents and human proteins. **This material must go through extraction, similar to the patient sample.**

Material Number:	0505-0126
Positive (Red caps):	5 x 1.5 mL vials
Negative (Clear caps):	5 x 1.5 mL vials

STORAGE INSTRUCTIONS

This product should be stored at 2 - 8 °C during regular use. It may also be initially stored at -20 °C, but subsequently maintain thawed material at 2 - 8 °C. Do not expose to multiple freeze thaw cycles. Each vial can be used multiple times up until the date of expiry.

INSTRUCTIONS FOR USE

Allow the product vial to come to room temperature before use. Mix by vortexing to ensure a homogeneous suspension. AccuPlex reference materials should be added to a test run using the same procedure provided by the manufacturer for unknown specimens. AccuPlex SARS-CoV-2 reference material must go through an extraction process prior to detection by PCR. Process the product according to the instructions for unknown samples provided by the test kit or the laboratory's standard operating procedures. AccuPlex reference materials must NOT be substituted for the positive and negative control reagents provided with the manufactured test kits.

INTERPRETATION OF RESULTS

Levels of reactivity for the AccuPlex SARS-CoV-2 reference material may vary with different types of tests and different test kit lots. This product contains a targeted formulation of 5000 copies/mL as measured using reverse transcription digital PCR. This concentration is roughly five times the lower limit of detection of published real time quantitative PCR assays[1]. Each lot is tested using 2019-nCoVprimers/probes described in the US CDC Assay publication and using testing protocols similar to that described in CDC published instructions for use[1]: positive reference material gives positive results when using the US CDC testing protocol; negative reference material gives negative results when using the US CDC testing protocol.

LIMITATIONS OF THE PROCEDURE

AccuPlex 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. AccuPlex materials are not calibrators and should not be used for assay calibration. Performance characteristics for AccuPlex SARS-CoV-2 reference material have been established only for amplified nucleic acid tests for RNA. 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 AccuPlex SARS-CoV-2 reference material and human specimens[2]. 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. CDC 2019-Novel Coronavirus (2019-nCoV) Real Time RT-PCR Diagnostic Panel Instructions for use. CDC-006-00019 Revision: 01. Effective 2/4/2020.
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 SeraCare Technical Support at+1 508.244.6400.

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