AccuPlex™ SARS-CoV-2 Omicron Variant

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 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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14050US-01 January 2022

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

AccuPlex™ SARS-CoV-2 Omicron Variant Reference Material Kit

NAME AND INTENDED USE

AccuPlex™ SARS-CoV-2 Omicron Variant Reference Material Kit (0505-0298) is formulated for use with test methods that can detect SARS-CoV-2 virus, the causative agent of COVID-19 disease. The kit contains positive reference material representing the full SARS-CoV-2 genome with mutations identified in the S and N gene of the SARS-CoV-2 Omicron variant B.1.1.529. Also included is positive material containing wild type (Wuhan) sequence, as well as negative material based on the human RNase P gene. The reference materials are designed to support SARS-CoV-2 test verification at installation and can also be utilized for long-term performance monitoring. 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 2 vials of positive reference material (red caps) that contain recombinant virus particles with sequences containing the entire SARS-CoV-2 genome based on the Genbank accession number NC_045512.2.

One member contains S and N gene mutations identified in the Omicron variant B.1.1.529 respectively. For details on specific mutations captured in each variant, see Table 1. Member 2 contains the wild type (Wuhan) S gene sequence.

There is also 1 vial of negative reference material (clear cap) that contains only recombinant virus particles with sequences from human RNase 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:	0505-0298	
Positive:	Member 1:	Omicron (B.1.1.529) variant; 1 x 1.5 mL
	Member 2:	Wild Type (Wuhan); 1 x 1.5 mL
Negative:	Negative:	RNase P; 1 x 1.5 mL

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. 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 targeted formulations of 15,000 copies/mL for positive members and 5,000 copies/mL for the negative member as measured using reverse transcription digital PCR. Each positive member is also confirmed positive on a SARS-CoV-2 genotyping test. Note that the positive reference material may contain traces of RNase P and therefore generate a positive RNase P result due to the presence of a human plasma component in the product matrix; it is not designed or intended to be used as an RNase P reference material.

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 and sequencing 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[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.

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Table 1: SARS-CoV-2 Omicron Variant Mutation Overview

Amino Acid Change	Nucleotide Change
A67V	C21762T
HV 69-70 deletion	21765-21770 deletion
T95I	C21846T
G142D	21987 - 21995 deletion
NL211I	22194 - 22196 deletion
215EPEins	22205GAGCCAGAAins
G339D	G22578A
S371L	TC22673CT
S373P	T22679C
S375F	C22686T
K417N	G22813T
N440K	T22882G
G446S	G22898A
S477N	G22992A
T478K	C22995A
E484A	A23013C
Q493R	A23040G
G496S	G23048A
Q498R	A23055G
N501Y	A23063T
Y505H	T23075C
T547K	C23202A
D614G	A23403G
H655Y	C23525T
N679K	T23599G
P681H	C23604A
N764K	C23854A
D796Y	G23948T
N856K	C24130A
Q954H	A24424T
N969K	T24469A
L981F	C24503T
D1146D	C25000T
T64T	C25584T
n/a	A28271T
P13L	C28311T
ERS31del	28362 - 28370 deletion
RG203KR	G28881A, G28882A, G28883C

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