AccuPlex™ Quality Solutions for Respiratory Disease Diagnostics

ASSAY VERIFICATION AND ONGOING PERFORMANCE MONITORING FOR ROUTINE PATIENT TESTING

HIGHLIGHTS

NON-INFECTIOUS AND REPLICATION DEFICIENT; ENSURES SAFE HANDLING IN CONTRAST TO VIRAL SAMPLES

FULLY EXTRACTABLE WITH A REAL VIRAL PROTEIN COAT; SUPERIOR TO "NAKED" TRANSCRIBED RNA

OPTIMIZED FOR ASSAY VERIFICATION AND DAYTO- DAY PERFORMANCE MONITORING

2 YEAR STABILITY AT 2 – 8°C

Whether your laboratory is utilizing multiplex or sequential molecular testing workflows, AccuPlex™ offers quality solutions with targets for SARS-CoV-2, influenza A/B and respiratory syncytial virus (RSV). These full-process quality solutions are designed to challenge the entire molecular test procedure from extraction to detection, ensuring clinical laboratories can have confidence in their assay results.

AccuPlex Verification Panels are optimized for assay verification at installation by documenting test performance along the assay's range, enabling laboratories to establish lower limits of detection, perform assay comparisons, and evaluate staff proficiency.

AccuPlex Reference Material and Molecular Controls Kits are designed to measure day-to-day performance of the assay, providing both a positive and negative reference solution.

MULTIPLEXED SOLUTIONS

SARS-CoV-2, Flu A/B and RSV

Product Description	Material Numbers	Pack Size	Concentration
AccuPlex SARS-CoV-2, Flu A/B and RSV Verification Panel*	0505-0278	Positive 1 1 x 3 mL Positive 2 1 x 3 mL Positive 3 1 x 3 mL Negative 1 x 3 mL	100,000 copies/mL 10,000 copies/mL 1,000 copies/mL 5,000 copies/mL (RNase P)
AccuPlex SARS-CoV-2, Flu A/B and RSV Molecular Controls Kit**	0505-0260	Positive 5 x 1.5 mL Negative 5 x 1.5 mL	5,000 copies/mL 5,000 copies/mL (RNase P)

**Not for In Vitro Diagnostic Use. Research Use Only.*

***For In Vitro Diagnostic Use. CE-IVD marked.*

SEQUENTIAL SOLUTIONS

SARS-CoV-2

Product Description	Material Numbers	Pack Size	Concentration
AccuPlex SARS-CoV-2 Verification Panel*	0505-0168	Positive 1 1 x 3 mL Positive 2 1 x 3 mL Positive 3 1 x 3 mL Negative 1 x 3 mL	100,000 copies/mL 10,000 copies/mL 1,000 copies/mL 5,000 copies/mL (RNase P)
AccuPlex SARS-CoV-2 Molecular Controls Kit**	0505-0159	Positive 5 x 1.5 mL Negative 5 x 1.5 mL	5,000 copies/mL 5,000 copies/mL (RNase P)

**Not for In Vitro Diagnostic Use. Research Use Only.*

***For In Vitro Diagnostic Use. CE-IVD marked.*

Flu A/B and RSV

Product Description	Material Numbers	Pack Size	Concentration
AccuPlex Flu A/B and RSV Verification Panel	0515-0002	Positive 1 1 x 3 mL Positive 2 1 x 3 mL Positive 3 1 x 3 mL Negative 1 x 3 mL	100,000 copies/mL 10,000 copies/mL 1,000 copies/mL 5,000 copies/mL (RNase P)
AccuPlex Flu A/B and RSV Reference Material Kit	0515-0001	Positive 5 x 1.5 mL Negative 5 x 1.5 mL	5,000 copies/mL 5,000 copies/mL (RNase P)

Not for In Vitro Diagnostic Use. Research Use Only.

ABOUT LGC SERACARE

TRUSTED SUPPLIER TO THE DIAGNOSTIC TESTING INDUSTRY FOR OVER 30 YEARS

HIGH-QUALITY CONTROL PRODUCTS, RAW BIOLOGICAL MATERIALS, AND IMMUNOASSAY REAGENTS

INNOVATIVE TOOLS AND TECHNOLOGIES TO PROVIDE ASSURANCE IN DIAGNOSTIC ASSAY PERFORMANCE AND TEST RESULTS

FOR MORE INFORMATION, PLEASE VISIT OUR WEBSITE: WWW.SERACARE.COM

LGC SeraCare's AccuPlex recombinant material serves as a true full process molecular control for your diagnostic assays. Compatible with multiplexed RT-PCR and NGS-based assays, AccuPlex custom recombinant materials are constructed with a replication-deficient mammalian virus, producing a safe, noninfectious material (Figure 1). With a protein coat and lipid bilayer, these mammalian virus-based reference materials resemble the complexity of virus targets found in true patient samples.

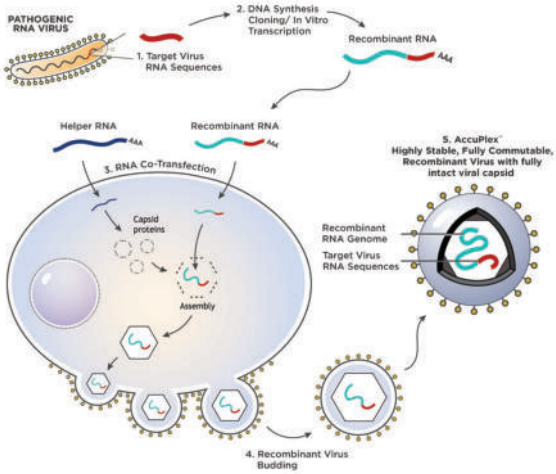

FIGURE 1: 1) RNA sequence from the pathogenic virus of interest is chosen. 2) DNA synthesis and cloning occur to produce the recombinant RNA. 3) Recombinant RNA and helper RNA are co-transfected into the mammalian cells, allowing the encapsulation of recombined RNA. 4) Exocytosis of the mature enveloped non-infectious and replication deficient RNA virus containing the assay target RNA sequence of interest

MOST 'PATIENT SAMPLE-LIKE' MATERIAL EVALUATES ENTIRE WORKFLOW

Unlike RNA-spiked buffer, or technologies that package viral RNA into a bacteriophage, the AccuPlex recombinant closely resembles the wild-type mammalian pathogenic virus. This enables the release of the viral genome at a similar rate to the wild-type virus during the nucleic acid sample preparation process. AccuPlex recombinant material mimics a real patient sample in your workflow, serving as a full-process control for your assay.

ACCUPLEX SOLVES ASSAY DEVELOPMENT CHALLENGES

If you're developing diagnostics for emerging viral diseases and have the challenge of including safe, noninfectious controls in your test kit, partner with LGC SeraCare's talented R&D team to produce your custom AccuPlex recombinant virus material (DNA or RNA-based). Utilizing your sequences of interest and productspecifications, we will develop a custom solution which meets your unique requirements.

ORDERING INFORMATION

To place an order, or learn more about our SARS-CoV-2 Quality Solutions, please contact us at +1.508.244.6400 and 800.676.1881 or email CDx-CustomerService@lgcgroup.com.

MKT-00609-02

AccuPlex™ SARS-CoV-2, Flu A/B and RSV v2

Verification Panel

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.

LGC Clinical Diagnostics, Inc. | 37 Birch Street, Milford, MA 01757 USA
Phone: +1 508.244.6400 | CDx-Info@LGCGroup.com

13989US-01 October 2021

AccuPlex™ SARS-CoV-2, Flu A/B and RSV v2 Verification Panel

NAME AND INTENDED USE

AccuPlex™ SARS-CoV-2, Flu A/B and RSV Verification Panel v2 (0505-0278) is formulated for use with multiplex test methods that can detect SARS-CoV-2, influenza A/B and respiratory syncytial virus. The panel contains different concentrations of positive reference material to enable evaluation of test performance at multiple points across the assay range; it is designed to support SARS-CoV-2, Flu A/B and RSV multiplex test verification at installation. 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 3 vials of positive reference material that contain recombinant virus particles with following sequence coverage:

Virus	Genbank Accession #	Regions Included
Influenza A	KU933490 - KU933497	Full Genome
Influenza B	CY236601.1- CY236608.1	Full Genome
RSV	NC_001803	1..4280; 5619..15191
SARS-CoV-2	NC_045512.2	Full Genome

Positive vials are included at the following concentrations: Member 1 – 100,000 copies/mL, Member 2 – 10,000 copies/mL, Member 3 – 1000 copies/mL.

There is also 1 vial of negative reference material that contains recombinant virus particles with sequences from human RNase P gene (RP) at a concentration of 5000 copies/mL.

The recombinant viruses used to produce the AccuPlex SARS-CoV-2, Flu A/B and RSV 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:	0505-0278
Positive:	Member 1: 1 x 3.0 mL; 100,000 copies/mL
	Member 2: 1 x 3.0 mL; 10,000 copies/mL
	Member 3: 1 x 3.0 mL; 1000 copies/mL
Negative:	Negative: 1 x 3.0 mL; 5000 copies/mL (RNase P)

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, Flu A/B and RSV verification panel members 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 verification panel 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, Flu A/B and RSV materials may vary with different types of tests and different test kit lots, but positive reference materials are expected to give positive results, and negative reference materials are expected to give negative results. This product contains targeted formulations of 100,000, 10,000, and 1000 copies/mL for all viral targets for positive members and 5000 copies/mL for the negative member as measured using reverse transcription digital PCR. 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, Flu A/B and RSV verification panel 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, Flu A/B and RSV verification panel 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, Flu A/B and RSV materials 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.

Phone: +1 508.244.6400 | Toll Free (US Only) 800.676.1881
Fax: +1.508.634.3334 | SeraCare.com