AccuPlex™ Quality Solutions for Respiratory Disease Diagnostics

Assay verification and ongoing performance monitoring for routine patient testing

INTRODUCTION

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. Products are released using the US CDC Influenza SARS-CoV-2 (Flu-SC2) Multiplex Assay and Cepheid GeneXpert® Xpress SARSCoV- 2 and Flu/RSV Assays.

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.

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 customerservice@seracare.com.

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

Material #	Product	Pack Size	Concentration
0505-0183	AccuPlex SARS-CoV-2, Flu A/B and RSV Verification Panel	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)
0505-0174	AccuPlex SARS-CoV-2, Flu A/B and RSV Reference Material Kit	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.

SEQUENTIAL SOLUTIONS SARS-CoV-2

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

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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 day-to-day performance monitoring.

2 year stability at 2 – 8°c

Flu A/B and RSV

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

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TABLE 1: REGIONS INCLUDED IN ACCUPLEX POSITIVE REFERENCE MATERIAL

Virus	Genbank Accession #	Strain Information	Regions Included
Influenza A	KU933490 – KU933497	A/Michigan/45/2015(H1N1)	Full Genome
Influenza B	CY236601.1 – CY236608.1	B/Colorado/06/2017	Full Genome
RSV	NC_001803	Subtype A	1..4380; 8460..15191
SARS-CoV-2	NC_045512.2	Wuhan-Hu-1	Full Genome

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.

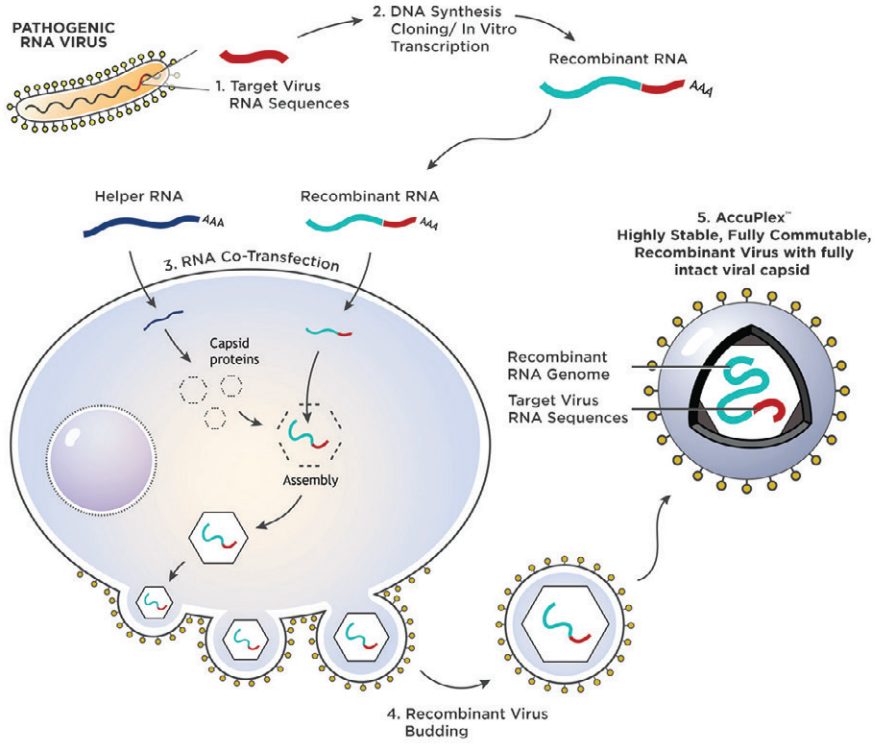

FIGURE 1: 1) RNA sequence from the pathogenic virus of interest is chosen. 2) DNA synthesis and cloning occur to produce the recombinant RNA. 3) Recombinant RNA and helper RNA are co-transfected into the mammalian cells, allowing the encapsulation of recombined RNA. 4) Exocytosis of the mature enveloped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

ABOUT US

SeraCare offers a comprehensive portfolio of reference materials for oncology and reproductive health, designed and manufactured to meet the precision demanded by NGS assays. The portfolio includes high quality ground-truth RNA, ctDNA and genomic DNA-based reference materials that are NGS platform agnostic for tumor profiling, immuno-oncology, liquid biopsy, NIPT and germline cancer assay workflows. **For more information visit seracare.com**

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seracare.com • 508.244.6400 • 800.676.1881 Toll Free • 508.634.3334 Fax