

AccuPlex™ SARS-CoV-2, Flu A/B and RSV Molecular Controls Kit

Ongoing performance monitoring for routine patient testing

INTRODUCTION

AccuPlex SARS-CoV-2, Flu A/B and RSV Molecular Controls Kit is a full-process quality solution designed to challenge the entire multiplexed molecular test procedure from extraction to detection, ensuring clinical laboratories can have confidence in their assay results. The product contains positive materials directed against targets for SARS-CoV-2, influenza A/B and respiratory syncytial virus (RSV), and negative materials targeting the human RNase P gene. Product is released using the Cepheid GeneXpert® Xpress SARS-CoV-2/Flu/RSV Assay.

FEATURES AND BENEFITS

- Non-infectious and replication deficient, enables safe handling in contrast to viral samples
- Fully-extractable with a real viral protein coat; superior to “naked” transcribed RNA
- Long shelf life: 2 year stability at 2 - 8°C

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..4280; 5619..15191
SARS-CoV-2	NC_045512.2	Wuhan-Hu-1	Full Genome

ORDERING INFORMATION

Material #	Product	Concentration	Pack Size
0505-0260	AccuPlex SARS-CoV-2, Flu A/B and RSV Molecular Controls Kit	5,000 copies/mL 5,000 copies/mL (RNase P)	Positive 5 x 1.5 mL Negative 5 x 1.5 mL

For In Vitro Diagnostic Use. CE-IVD marked.

HIGHLIGHTS

Compatible with multiplexed molecular assays that detect SARS-CoV-2, flu A/B, and RSV

Real mammalian virus enables full process QC for RT-PCR based viral disease assays

Non-infectious and replication deficient; ensures safety during assay development and end-user QC applications

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, non-infectious 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.

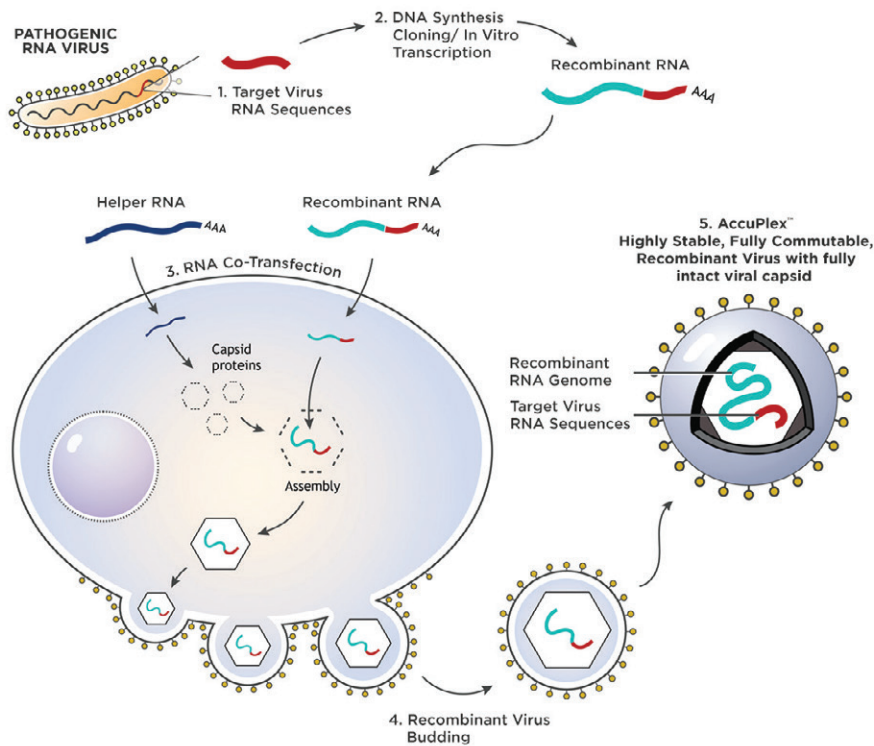


FIGURE 1: 1) RNA sequence from the pathogenic virus of interest is chosen. 2) DNA synthesis and cloning occur to produce the recombinant RNA. 3) Recombinant RNA and helper RNA are co-transfected into the mammalian cells, allowing the encapsulation of recombinant RNA. 4) Exocytosis of the mature enveloped 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, non-infectious 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 product specifications, 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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MKT-00671 Rev. 02

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