Assay Verification and Ongoing Performance Monitoring for Routine Patient Testing



SeraCare AccuPlex™ SARS-CoV-2 & Flu Multiplexed Quality Solutions

AccuPlex™ SARS-CoV-2, Flu A/B and RSV Verification Panel and Reference Material Kit offer a complete Quality Solution designed for use with multiplexed molecular assays that can detect SARS-CoV-2, influenza A/B and respiratory syncytial virus (RSV). These reference materials are designed to challenge the entire molecular test procedure ensuring clinical laboratories can have confidence in their multiplex assay results.

AccuPlex™ SARS-CoV-2, Flu A/B and RSV Verification Panel is optimised 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™ SARS-CoV-2, Flu A/B and RSV Reference Material Kit is designed to measure day-to-day performance of the assay, providing both a positive and a negative reference solution.

| Product Description | Material Number | Pack size | Concentrations | Release Testing |
|---|-----------------|---|---|---|
| AccuPlex SARS CoV-2, Flu A/B and RSV Verification Panel | 0505-0183 | 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) | US CDC Influenza SARS-CoV-2 (Flu-SC2) Multiplex Assay |
| AccuPlex SARS-CoV-2, Flu A/B and RSV Reference Material Kit | 0505-0174 | Positive 5 x 1.5 mL Negative 5 x 1.5 mL | 5,000 copies/mL 5,000 copies/mL (RNase P) | Cepheid GeneXpert® Xpress SARS-CoV-2 and Flu/RSV Assays |

Not for In Vitro Diagnostic Use. Research Use Only.

For custom requests, please contact TECHNOPATH customer service.

SARS-CoV-2, Flu A/B and RSV AccuPlex solution:

- 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
- Optimised for assay verification and day-to-day performance monitoring
- 2 year stability at 2 8°C



TRUSTED SUPPLIER TO DIAGNOSTIC MANUFACTURERS AND CLINICAL LABS 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.

Table 1: Regions included in AccuPlex SARS-CoV-2, Flu A/B and RSV Positive Reference Material

| Virus | Genbank Accession # | Regions included |
|-------------|-------------------------|------------------|
| Influenza A | KU933490 – KU933497 | Full Genome |
| Influenza B | CY236601.1 - CY236608.1 | Full Genome |
| RSV | NC 001803 | 14380; |
| 1137 | 140_001003 | 846015191 |
| SARS-CoV-2 | NC_045512.2 | Full Genome |

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.

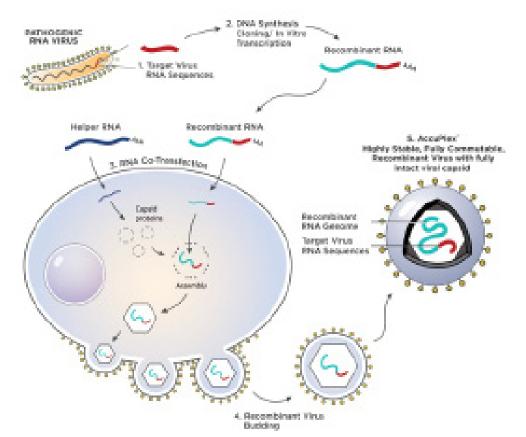


FIGURE 1:

- 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 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, non-infectious controls in your test kit, partner with SeraCare's talented R&D team to produce your custom AccuPlex recombinant virus material (DNA or RNA-based). Utilising your sequences of interest and product specifications, SeraCare will develop a custom solution which meets your unique requirements.

To place an order, or learn more about the SeraCare SARS-CoV-2 & Flu Multiplexed quality control solutions, please contact TECHNOPATH directly on the below details and a local representative will contact you to discuss further.

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