



AccuPlex™ SARS-CoV-2 Quality Solutions

ASSAY VERIFICATION AND ONGOING PERFORMANCE MONITORING FOR ROUTINE PATIENT TESTING

HIGHLIGHTS

COMPATIBLE WITH CDC
AND WHO CONSENSUS
SEQUENCES FOR
SARS-COV-2

ENHANCED VERSIONS
ALSO AVAILABLE
OFFERING EXPANDED
SEQUENCE COVERAGE

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

AccuPlex™ SARS-CoV-2 Verification Panel, coupled with the AccuPlex™ SARS-CoV-2 Reference Material, is a complete Quality Solution. Both products are available in three versions with different SARS-CoV-2 sequence coverage: Version 1 covers the CDC and WHO consensus sequences, Version 2 has been enhanced to also include the S gene region, and Version 3 is expanded to include the full SARS-CoV-2 viral genome (Table 1). All products also include negative reference materials targeting the human RNase P gene.

AccuPlex™ SARS-CoV-2 Verification Panel is 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.

| Product Description | Material Numbers | Sequence Coverage | Pack Size | Concentration |
|---|------------------|----------------------|--|--|
| AccuPlex™ SARS-CoV-2 Verification Panel | 0505-0129 | ORF1a, RdRp, E, N | Positive 1 1 x 3 mL | 100,000 copies/mL |
| | 0505-0132 | ORF1a, RdRp, E, N, S | Positive 2 1 x 3 mL | 10,000 copies/mL |
| | 0505-0168 | Full Genome | Positive 3 1 x 3 mL Negative 1 x 3 mL | 1,000 copies/mL 5,000 copies/mL (RNase P) |

AccuPlex™ SARS-CoV-2 Reference Material is designed to measure day-to-day performance of the assay, providing both a positive and a negative reference solution.

| Product Description | Material Numbers | Sequence Coverage | Pack Size | Concentration |
|---|------------------|----------------------|---------------------|---------------------------|
| AccuPlex™ SARS-CoV-2 Reference Material Kit | 0505-0126 | ORF1a, RdRp, E, N | Positive 5 x 1.5 mL | 5,000 copies/mL |
| | 0505-0133 | ORF1a, RdRp, E, N, S | Negative 5 x 1.5 mL | 5,000 copies/mL (RNase P) |
| | 0505-0159 | Full Genome | | |

For custom requests, please contact sarscov2@seracare.com.

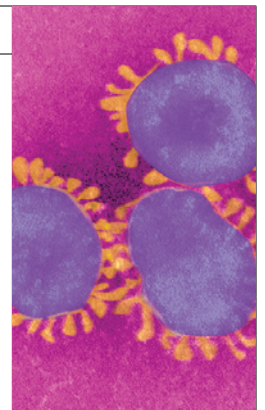
SARS-CoV-2 AccuPlex solution:

- 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
- 2 year stability at 2 - 8°C
- Customizable to sequences of interest to meet unique assay design requirements

Table 1: Regions included in AccuPlex SARS-CoV-2 Positive Reference Material.

| Region | Version 1 | Version 2 | Version 3 |
|------------------|----------------------|--------------|----------------------|
| | Included Nucleotides | | Full Genome Coverage |
| ORF1a | 417..1899 | 417..1899 | |
| | 3094..3360 | 3094..3360 | |
| RdRp | 13291..13560 | 13291..13560 | |
| | 14700..15950 | 14700..15950 | |
| | 18577..19051 | 18577..19051 | |
| S (Spike) | — | 21363..26001 | |
| E (Envelope) | 25801..28200 | 25801..28200 | |
| N (Nucleocapsid) | 27952..29873 | 27952..29873 | |

Numbers refer to sequence of GenBank NC_045512.2



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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.

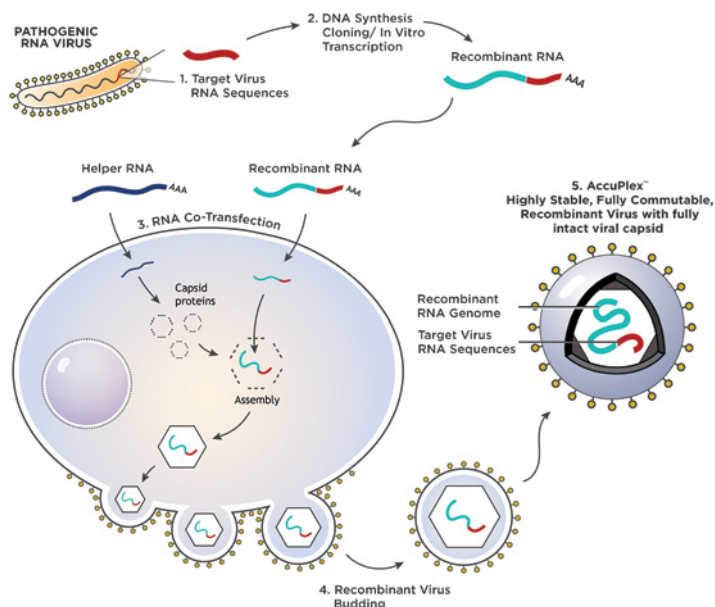


FIGURE 1: 1) RNA sequence from the pathogenic virus of interest is chosen. 2) DNA synthesis and cloning occur to produce the recombinant RNA. 3) Recombinant RNA and helper RNA are co-transfected into the mammalian cells, allowing the encapsulation of recombined RNA. 4) Exocytosis of the mature enveloped 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). Utilizing your sequences of interest and product specifications, we will develop a custom solution which meets your unique requirements.

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