

# **SeraCare AccuPlex™ SARS-CoV-2 Quality Solutions**

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 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.

| Product Description                           | Material Number | Sequence Coverage    | Pack size        | Concentrations                             |
|---|-----------------|----------------------|------------------|--|
| AccuPlex SARS-<br>CoV-2 Verification<br>Panel | 0505-0129       | ORF1a, RdRp, E, N    | Positive 1 1 x 3 | 3 mL 100,000 copies/mL                     |
|   | 0505-0132       | ORF1a, RdRp, E, N, S | Positive 2 1 x 3 | 3 mL 10,000 copies/mL 3 mL 1,000 copies/mL |
|   | 0505-0168       | Full Genome          |                  | 3 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 Number | Sequence Coverage    | Pack size            |                          | Concentrations                               |
|---|-----------------|----------------------|----------------------|--------------------------|--|
| AccuPlex SARS-<br>CoV-2 Reference<br>Material Kit | 0505-0126       | ORF1a, RdRp, E, N    |                      | 5 x 1.5 mL<br>5 x 1.5 mL | 5,000 copies/mL<br>5,000 copies/mL (RNase P) |
|   | 0505-0133       | ORF1a, RdRp, E, N, S | Positive<br>Negative |                          |  |
|   | 0505-0159       | Full Genome          | rvegative            |                          |  |

For custom requests, please contact TECHNOPATH customer service.

#### **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
- Customisable to sequences of interest to meet unique assay design requirements



TRUSTED SUPPLIER TO DIAGNOSTIC MANUFACTURERS AND CLINICAL LABS FOR OVER 30 YEARS.

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

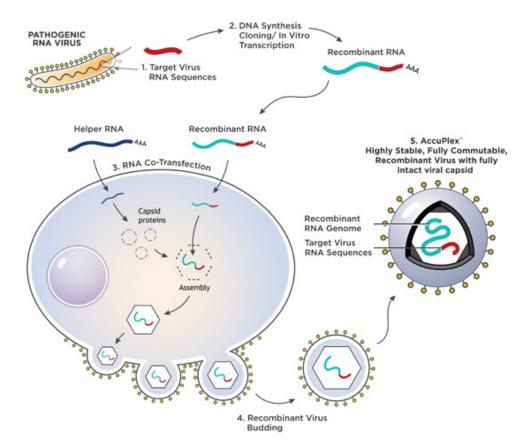
INNOVATIVE TOOLS AND TECHNOLOGIES TO PROVIDE ASSURANCE IN DIAGNOSTIC ASSAY PERFORMANCE AND TEST RESULTS.

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

| Region           | Version 1            | Version 2  | Version 3               |        |
|------------------|----------------------|------------|-------------------------|--------|
|                  | Included Nucleotides |            |                         | ×21/20 |
| ORF1a            | 4171899              | 4171899    | Full Genome<br>Coverage |        |
| Ohria            | 30943360             | 30943360   |                         |        |
|                  | 1329113560           | 1329113560 |                         |        |
| RdRp             | 1470015950           | 1470015950 |                         |        |
|                  | 1857719051           | 1857719051 |                         |        |
| S (Spike)*       | -                    | 2136326001 |                         |        |
| E (Envelope)     | 2580128200           | 2580128200 |                         |        |
| N (Nucleocapsid) | 2795229873           | 2795229873 |                         |        |

<sup>\*</sup>S gene included in enhanced version 2 products only. Numbers refer to sequence of GenBank NC\_045512.2

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 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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