

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 VERSION 2 ALSO COMPATIBLE WITH MOLECULAR ASSAYS TARGETING THE S GENE REGION

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. Products contain positive materials directed against the published CDC and WHO consensus sequences and the S gene (Table 1). Also includes negative 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
			Positive 2	1 x 3 mL	10,000 copies/mL
	0505-0132	ORF1a, RdRp, E, N, S	Positive 3	1 x 3 mL	1,000 copies/mL
			Negative	1 x 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 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)

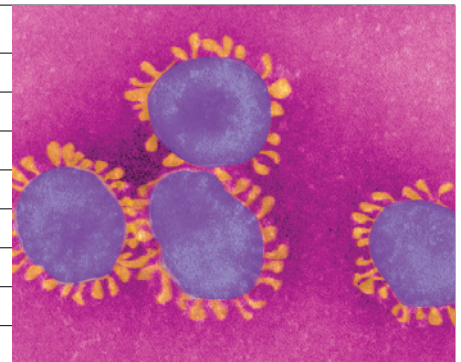
For custom requests, please contact sarscov2@seracare.com.

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	Included Nucleotides
ORF1a	417..1899
	3094..3360
RdRp	13291..13560
	14700..15950
	18577..19051
S (Spike)*	21363..26001
E (Envelope)	25801..28200
N (Nucleocapsid)	27952..29873



**S gene included in enhanced version 2 products only. Numbers refer to sequence of GenBank NC_045512.2*

To learn more about AccuPlex SARS-CoV-2 Quality Solutions visit:
www.seracare.com/SARSCoV2 or contact customer service at 800.676.1881

Not for In Vitro Diagnostic Use. Research Use Only.

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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.

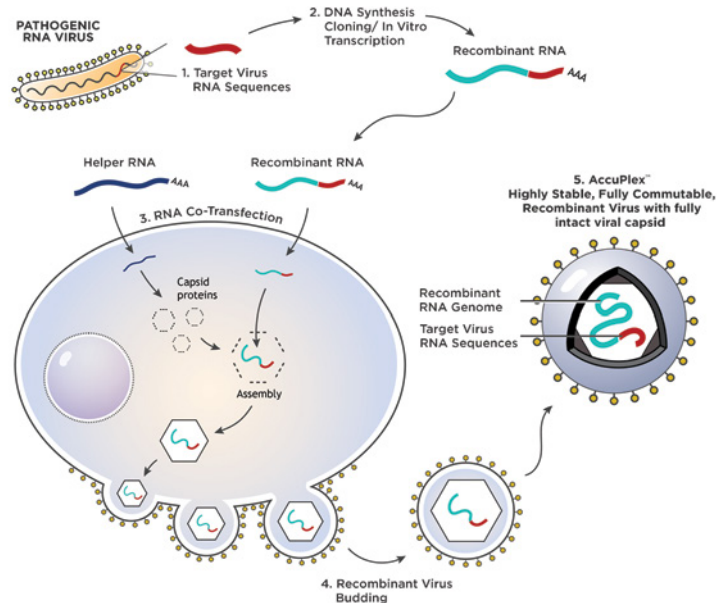


FIGURE 1: 1) RNA sequence from the pathogenic virus of interest is chosen. 2) DNA synthesis and cloning occur to produce the recombinant RNA. 3) Recombinant RNA and helper RNA are co-transfected into the mammalian cells, allowing the encapsulation of recombinant RNA. 4) Exocytosis of the mature enveloped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

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.



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