

AccuPlex[™] SARS-CoV-2 in Synthetic Oral Fluid

ASSAY VERIFICATION AND ONGOING PERFORMANCE MONITORING FOR SALIVA-BASED TESTING

In support of industry efforts to develop SARS-CoV-2 testing formats compatible with alternative sample types, LGC SeraCare now offers its proprietary AccuPlex SARS-CoV-2 reference material in a synthetic oral fluid matrix. The product is designed to challenge the entire molecular test procedure for oral fluid-based tests, ensuring laboratories can have confidence in their SARS-CoV-2 assay results.

HIGHLIGHTS

DESIGNED FOR SALIVA BASED SARS-COV-2 ASSAYS

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 in Synthetic Oral Fluid is an ideal research tool for assay developers creating novel saliva-based SARS-CoV-2 assays, as well as a complete quality solution for laboratories employing such tests. The product includes positive vials containing the full SARS-CoV-2 viral genome, and human RNase P sequences to monitor sample collection. The positive material is configured at 3 different concentrations to enable performance evaluation across the assay range and limit of detection studies. Negative material containing only RNase P sequences is also included.

Product Description	Material Number	Pack Size	Concentration	
			SARS-CoV-2	RNase P
AccuPlex [™] SARS CoV-2 in Synthetic Oral Fluid	0505-0222	Positive 1 1 x 1 mL Positive 2 1 x 1 mL Positive 3 1 x 1 mL Negative 1 x 1 mL Diluent 2 x 1.5 mL	24,000 cp/mL 12,000 cp/mL 6,000 cp/mL 0 cp/mL N/A	24,000 cp/mL 24,000 cp/mL 24,000 cp/mL 24,000 cp/mL N/A

Not for In Vitro Diagnostic Use. Research Use Only.

AccuPlex[™] SARS-CoV-2 in Synthetic Oral Fluid can be utilized 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. The product may also be utilized as a quality tool to measure day-to-day performance of the assay. Additional synthetic oral fluid diluent is included to allow additional dilutions as required.

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

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

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.

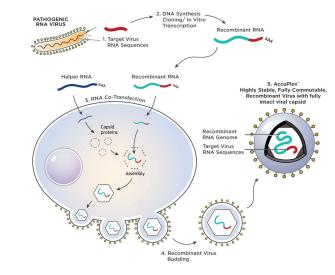


FIGURE 1: 1) RNA sequence from the pathogenic virus of interest is chosen. 2) DNA synthesis and cloning occur to produce the recombinant RNA. 3) Recombinant RNA and helper RNA are co-transfected into the mammalian cells, allowing the encapsulation of recombined RNA. 4) Exocytosis of the mature enveloped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

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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ABOUT LGC SERACARE

TRUSTED SUPPLIER TO THE DIAGNOSTIC TESTING INDUSTRY 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

FOR MORE INFORMATION, PLEASE VISIT OUR WEBSITE: WWW.SERACARE.COM