

SARS-CoV-2 VERIFICATION and REFERENCE MATERIALS



HiSS
Diagnostics

HiSS Diagnostics GmbH
Tullastr. 70, 79108 Freiburg

hiss@hiss-dx.de
www.hiss-dx.de

Fax: +49 761 389 4920
Tel.: +49 761 389 490

LGC SeraCare SARS-CoV-2 Overview

| | |
|---|---|
| AccuPlex™ SARS-CoV-2 Quality Solutions | 4 |
| AccuPlex™ SARS-CoV-2 Verification Panel | |
| AccuPlex™ SARS-CoV-2 Molecular Controls Kit | |
| AccuPlex SARS-CoV-2 Variant Panel 1 | |
| AccuPlex SARS-CoV-2 Variant Panel 2 | |
| AccuPlex SARS-CoV-2 Omicron Variant Reference Material Kit | |
| AccuPlex™ Quality Solutions for Respiratory Disease Diagnostics | 5 |
| AccuPlex™ SARS-CoV-2 in Synthetic Oral Fluid | 6 |
| Seraseq® SARS-CoV-2 Mutation RNA Mix | 6 |
| SARS-CoV-2 Serology Panel Solutions | 7 |
| AccuVert SARS-CoV-2 Seroconversion Panel | |
| AccuSet SARS-CoV-2 Performance Panel | 7 |
| ACCURUN® SARS-CoV-2 Antigen Reference Material Kit | 7 |
| ORDERING INFORMATION | 8 |

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

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.

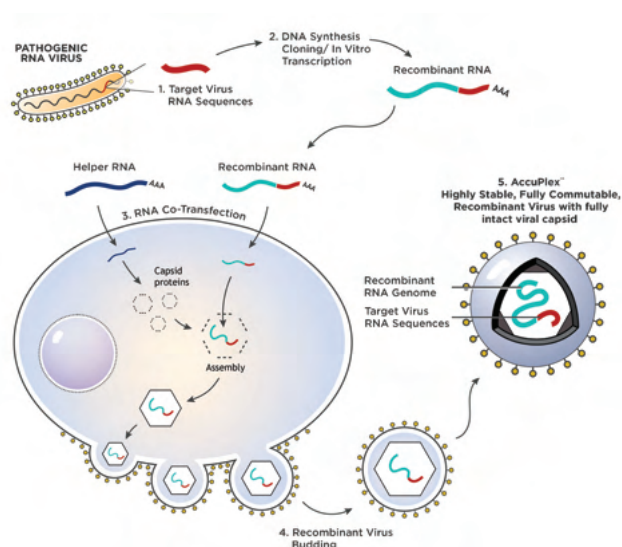


FIGURE 1: 1) RNA sequence from the pathogenic virus of interest is chosen. 2) DNA synthesis and cloning occur to produce the recombinant RNA. 3) Recombinant RNA and helper RNA are co-transfected into the mammalian cells, allowing the encapsulation of recombined RNA. 4) Exocytosis of the mature enveloped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

AccuPlex™ SARS-CoV-2 Quality Solutions

ASSAY VERIFICATION AND ONGOING PERFORMANCE MONITORING FOR ROUTINE PATIENT TESTING

HIGHLIGHTS

OFFERING FULL VIRAL
GENOME COVERAGE -
COMPATIBLE WITH ANY
SARS-COV-2 TARGET OF
INTEREST

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

2 YEAR STABILITY
AT 2 - 8°C

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. The product contains positive materials including the full SARS-CoV-2 viral genome, and negative materials targeting the human RNase P gene.

| Product Description | Material Number | Sequence Coverage | Pack Size | Concentration |
|---|-----------------|-------------------|--|---|
| AccuPlex™ SARS-CoV-2 Verification Panel | 0505-0168 | Full Genome | 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) |

Not for In Vitro Diagnostic Use. Research Use Only.

AccuPlex™ SARS-CoV-2 Molecular Controls Kit is designed to measure day-to-day performance of the assay. The product contains positive materials including the full SARS-CoV-2 viral genome, and negative materials targeting the human RNase P gene. The controls are formulated for use with in vitro diagnostic test methods that detect SARS-CoV-2 virus, the causative agent of COVID-19 disease.

| Product Description | Material Number | Sequence Coverage | Pack Size | Concentration |
|---|-----------------|-------------------|--|--|
| AccuPlex™ SARS-CoV-2 Molecular Controls Kit | 0505-0159 | Full Genome | Positive 5 x 1.5 mL Negative 5 x 1.5 mL | 5,000 copies/mL 5,000 copies/mL (RNase P) |

For In Vitro Diagnostic Use. CE-IVD Marked.

AccuPlex SARS-CoV-2 Variant Reference Materials offer complete SARS-CoV-2 genome coverage with a focus on representative S and N gene mutations (Table 1) in prominent variants of concern (VOC). Each kit has one vial for each included variant, a wild type (reference sequence NC_045512) control vial, and an RNase P negative control vial.

| Product Description | Material Number | Strain | Pack Size | Concentration |
|--|-----------------|--|--|---|
| AccuPlex SARS-CoV-2 Variant Panel 1 | 0505-0241 | UK B.1.1.7 S.Africa B.1.351 Brazil P.1 Wuhan Wild Type RNase P negative | Positive 4 x 1.5 mL Negative 1 x 1.5 mL | Positive 15,000 cp/mL Negative 5,000 cp/mL |
| AccuPlex SARS-CoV-2 Variant Panel 2 | 0505-0276 | Kappa B.1.617 Delta B.1.617.2 Delta Plus AY.1 Wuhan Wild Type RNase P negative | | |
| AccuPlex SARS-CoV-2 Omicron Variant Reference Material Kit | 0505-0298 | Omicron B.1.1.529 Wuhan Wild Type RNase P negative | Positive 2 x 1.5 mL Negative 1 x 1.5 mL | |

Not for In Vitro Diagnostic Use. Research Use Only.

AccuPlex™ Quality Solutions for Respiratory Disease Diagnostics

ASSAY VERIFICATION AND ONGOING PERFORMANCE MONITORING FOR ROUTINE PATIENT TESTING

HIGHLIGHTS

NON-INFECTIOUS
AND REPLICATION
DEFICIENT; ENSURES
SAFE HANDLING IN
CONTRAST TO VIRAL
SAMPLES

FULLY EXTRACTABLE
WITH A REAL VIRAL
PROTEIN COAT;
SUPERIOR TO "NAKED"
TRANSCRIBED RNA

OPTIMIZED FOR
ASSAY VERIFICATION
AND DAYTO- DAY
PERFORMANCE
MONITORING

2 YEAR STABILITY
AT 2 – 8°C

Whether your laboratory is utilizing multiplex or sequential molecular testing workflows, AccuPlex™ offers quality solutions with targets for SARS-CoV-2, influenza A/B and respiratory syncytial virus (RSV). These full-process quality solutions are designed to challenge the entire molecular test procedure from extraction to detection, ensuring clinical laboratories can have confidence in their assay results.

AccuPlex Verification Panels are 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.

AccuPlex Reference Material and Molecular Controls Kits are designed to measure day-to-day performance of the assay, providing both a positive and negative reference solution.

MULTIPLEXED SOLUTIONS

SARS-CoV-2, Flu A/B and RSV

| Product Description | Material Numbers | Pack Size | Concentration |
|---|------------------|--|---|
| AccuPlex SARS-CoV-2, Flu A/B and RSV Verification Panel* | 0505-0278 | 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) |
| AccuPlex SARS-CoV-2, Flu A/B and RSV Molecular Controls Kit** | 0505-0260 | Positive 5 x 1.5 mL Negative 5 x 1.5 mL | 5,000 copies/mL 5,000 copies/mL (RNase P) |

*Not for In Vitro Diagnostic Use. Research Use Only.

**For In Vitro Diagnostic Use. CE-IVD marked.

SEQUENTIAL SOLUTIONS

SARS-CoV-2

| Product Description | Material Numbers | Pack Size | Concentration |
|--|------------------|--|---|
| AccuPlex SARS-CoV-2 Verification Panel* | 0505-0168 | 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) |
| AccuPlex SARS-CoV-2 Molecular Controls Kit** | 0505-0159 | Positive 5 x 1.5 mL Negative 5 x 1.5 mL | 5,000 copies/mL 5,000 copies/mL (RNase P) |

*Not for In Vitro Diagnostic Use. Research Use Only.

**For In Vitro Diagnostic Use. CE-IVD marked.

Flu A/B and RSV

| Product Description | Material Numbers | Pack Size | Concentration |
|---|------------------|--|---|
| AccuPlex Flu A/B and RSV Verification Panel | 0515-0002 | 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) |
| AccuPlex Flu A/B and RSV Reference Material Kit | 0515-0001 | Positive 5 x 1.5 mL Negative 5 x 1.5 mL | 5,000 copies/mL 5,000 copies/mL (RNase P) |

Not for In Vitro Diagnostic Use. Research Use Only.

AccuPlex™ SARS-CoV-2 in Synthetic Oral Fluid

ASSAY VERIFICATION AND ONGOING PERFORMANCE MONITORING FOR SALIVA-BASED TESTING

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 | 24,000 cp/mL | 24,000 cp/mL |
| | | Positive 2 1 x 1 mL | 12,000 cp/mL | 24,000 cp/mL |
| | | Positive 3 1 x 1 mL | 6,000 cp/mL | 24,000 cp/mL |
| | | Negative 1 x 1 mL | 0 cp/mL | 24,000 cp/mL |
| | | Diluent 2 x 1.5 mL | N/A | 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.

Seraseq® SARS-CoV-2 Mutation RNA Mix

ACCELERATING NGS ASSAY DEVELOPMENT, VALIDATION, AND IMPLEMENTATION FOR SARS-COV-2 SURVEILLANCE

HIGHLIGHTS

READY-TO-USE,
PURIFIED RNA
FORMAT - NO
EXTRACTION
REQUIRED

MULTIPLE ALLELE
FREQUENCY LEVELS
INCLUDED - USE TO
DETERMINE ASSAY
SENSITIVITY AND LOD

Seraseq SARS-CoV-2 Mutation RNA Mix is a highly multiplexed positive reference material which contains 82 variants of interest blended with Wuhan wild type SARS-CoV-2 genomic RNA (reference sequence NC_045512) in a background of human total RNA from the well characterized GM24385 cell line. The kit has three vials with 1%, 5% and 20% variant allele frequency respectively.

| Product Description | Material Number | Pack Size | Concentration | Buffer |
|-------------------------------------|-----------------|--|-------------------------------|-------------------|
| Seraseq SARS-CoV-2 Mutation RNA Mix | 0740-0075 | AF 1% 1 x 25 QL AF 5% 1 x 25 QL AF 20% 1 x 25 QL | 5 x 10 ⁶ copies/mL | 1 mM Tris, pH 8.0 |

Not for In Vitro Diagnostic Use. Research Use Only.

HIGHLY MULTIPLEYED POSITIV REFERENCE MATERIAL FOR SARS-CoV-2

INCORPORATES 82 VARIANTS OF INTEREST IN NSP, S, M, N, E AND ORF GENES

SARS-CoV-2 Serology Panel Solutions

ACCELERATING SEROLOGY ASSAY DEVELOPMENT, VALIDATION AND IMPLEMENTATION

HIGHLIGHTS

TRUE PATIENT
SPECIMENS: Unique,
individual plasma
members confirmed
positive for SARS-
CoV-2 antibodies

HIGHLY
CHARACTERIZED:
Comprehensive data
sheet with results from
leading commercially
available assays for
SARS-CoV-2 antibody
detection

AccuVert™ SARS-CoV-2 Seroconversion Panel is intended for use by diagnostic manufacturers, researchers, and clinical laboratories to develop, evaluate, or troubleshoot SARS-CoV-2 test methods. The panel consists of undiluted, naturally occurring plasma samples collected longitudinally from a single donor over the course of development and subsequent immunological response of a natural SARS-CoV-2 infection. Each sample represents a single collection event and has been evaluated extensively on leading commercial SARS-CoV-2 antibody tests.

| Product Description | Material Number | Configuration | Fill Size |
|--|-----------------|----------------|-----------|
| AccuVert SARS-CoV-2 Seroconversion Panel | 0820-0465 | 14 collections | 1.0 mL |

Not for In Vitro Diagnostic Use. Research Use Only.

AccuSet™ SARS-CoV-2 Performance Panel is intended to provide an out-of-the-box solution to evaluate SARS-CoV-2 antibody detection assays with highly characterized human specimens. The eleven-member validation panel consists of undiluted, naturally occurring human-plasma members. Ten panel members represent collections from multiple individuals positive for antibodies to SARS-CoV-2; a single negative member is also included.

| Product Description | Material Number | Configuration | Fill Size |
|--------------------------------------|-----------------|--|-----------|
| AccuSet SARS-CoV-2 Performance Panel | 0820-0410 | 10 positive members 1 negative member | 1.0 mL |

Not for In Vitro Diagnostic Use. Research Use Only.

ACCURUN® SARS-CoV-2 Antigen Reference Material Kit

ASSAY VERIFICATION AND PERFORMANCE MONITORING FOR SARS-COV-2 ANTIGEN TESTS

HIGHLIGHTS

TRUE PATIENT
SPECIMENS: Unique,
individual plasma
members confirmed
positive for SARS-
CoV-2 antibodies

HIGHLY
CHARACTERIZED:
Comprehensive data
sheet with results from
leading commercially
available assays for
SARS-CoV-2 antibody
detection

ACCURUN® SARS-CoV-2 Antigen Reference Material Kit is formulated for use with test methods that detect the nucleocapsid (NP) protein of SARS-CoV-2 virus. The kit offers both positive and negative materials for SARS-CoV-2 nucleocapsid antigen tests. The kit is designed to support assay installation and monitoring of day-to-day assay performance, providing a complete quality solution for SARS-CoV-2 antigen testing.

| Product Description | Material Number | Pack Size | Antigen Coverage |
|--|-----------------|--|------------------|
| ACCURUN® SARS-CoV-2 Antigen Reference Material Kit | 2015-0231 | Positive 5 x 3 mL Negative 5 x 3 mL | Nucleocapsid |

Not for In Vitro Diagnostic Use. Research Use Only.

- **Nucleocapsid Target:** Formulated with purified, recombinant SARS-CoV-2 nucleocapsid protein in universal transport media
- **Relevant Ranges:** Specifically designed to be weakly reactive, low positive reference material to challenge assay performance
- **Ease of Use:** Liquid-ready format, requiring no reconstitution

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

Distributor in Germany and Austria



HiSS Diagnostics GmbH

Tullastr. 70
79108 Freiburg

hiss@hiss-dx.de
www.hiss-dx.de

Fax: +49 761 389 4920
Tel.: +49 761 389 4910

Zur Etablierung eines Workflows oder zu Produktspezifikationen stehen Ihnen gerne unsere promovierten Naturwissenschaftlern mit langjähriger Erfahrung zur Verfügung.

For the establishment of a workflow or for product specifications, our PhD scientists with many years of experience are at your disposal.



FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.
SeraSeq™ is a trademark of SeraCare Life Sciences, Inc.
© 2021 SeraCare Life Sciences, Inc. All rights reserved.