

Sera Care™ AccuPlex™ Recombinant Viral Technology

A SAFE, FULL-PROCESS CONTROL SOLUTION FOR YOUR INFECTIOUS DISEASE **MOLECULAR ASSAYS**

INTRODUCTION

Emerging infectious diseases pose a severe threat to public health due to their pathogenic, contagious nature. Quick development, validation, and implementation of precision diagnostic tests are necessary to ensure accurate detection of these infectious agents in order to ensure public safety and rapid treatment. Positive controls are a crucial component for these diagnostic assays to ensure accurate performance, but can potentially harm assay developers and laboratory end-users in their infectious state.

The key to the successful, rapid development of an infectious disease molecular diagnostic assay is to utilize non-infectious, manufactured controls. These controls should adequately represent the virus genetically and function in the appropriate assay format and sample matrix. In addition, these controls should evaluate the entire process from viral nucleic acid extraction through amplification and detection and not just a portion of the workflow (process control).

THE SAFEST, TRUE FULL-PROCESS CONTROL ON THE MARKET

SeraCare's AccuPlex recombinant material serves as a true molecular process 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 patient samples.

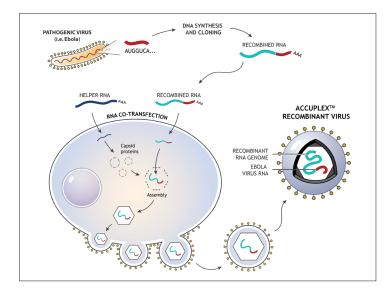


FIGURE 1: 1) RNA sequence from the pathogenic virus of interest is chosen. 2) DNA synthesis and cloning occur to produce the recombinant RNA. 3) Recombinant RNA and helper RNA are co-transfected into the mammalian cells, allowing the encapsulation of recombined RNA. 4) Exocytosis of the mature enveloped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

HIGHLIGHTS

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 UTILITY.

ACCEPTS MULTIPLE SEQUENCES FROM SAME OR DIFFERENT RNA VIRUSES; OFFERS FULL GENOME COVERAGE

ABOUT 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.

MOST 'PATIENT SAMPLE-LIKE' MATERIAL EVALUATES ENTIRE WORKFLOW

Unlike other technologies that package the 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.

Technology	Packaged Insert Size	Analyte	Complex Viral Structure	Replication Deficient	Flexible Sequence Design	True Process Control
AccuPlex	4 kb	Virus	Yes	Yes	Yes	Yes
Cultured virus	Full genome	Virus	Yes	No	No	Yes
MS-2	1 kb	Bacteriophage	No	Yes	Yes	No

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.

SeraCare's AccuPlex solution:

- Non-infectious and replication deficient, enables safe and effective handling of positive material
- Fully-extractable with a real viral protein coat; serves as a full-process control
- Accepts multiple sequences from same or different RNA viruses, customizable to your sequences of interest
- Digital PCR (ddPCR) QC step allows for a wide range of titer levels, offers flexible concentrations
- Compatible with any sample matrix (e.g. DBS, buffer, serum)
- Stability studies confirm product is stable at 4 °C, room temperature, and elevated temperatures

RELATED PRODUCTS

Material #	Product	Target Regions	Fill Size
0505-0034	AccuPlex Zika Reference Material	Entire genome	1 X 1.5 mL vial
0505-0001	AccuPlex rEbola GP/NP Reference Material	Glycoprotein (GP), nucleoprotein (NP) and VP24 regions	5 X 0.25 mL vial
2410-0327	AccuSpan HCV RNA Linearity Panel	5' UTR region	8 x 1.2 mL vial
2410-0318	AccuSpan Zika RNA Linearity Panel	Entire genome	7 x 1.5 mL vial

Inquire about AccuPlex recombinant products under development for chikunguyna, dengue-2. MERS, and norovirus GII.

LEARN MORE

To learn more about AccuPlex Recombinant Viral Technology and SeraCare's products for infectious disease diagnostics, visit www.seracare.com/accuplex. Contact us at +1.508.244.6400 and 800.676.1881 or email info@seracare.com.



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