AccuPlex™ SARS-CoV-2 Variant Reference Materials

CLINICAL DIAGNOSTIC QUALITY SOLUTIONS FOR SARS-COV-2 VARIANT ANALYSIS

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.

LGC sera

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

2 YEAR STABILITY AT 2 - 8°C

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			
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	Negative 1 x 1.5 mL	Positive 15,000 cp/mL Negative 5,000 cp/mL		
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.

SARS-COV-2 VARIANT SOLUTION:

- Performance confirmation of existing SARS-CoV-2 molecular assays with different variants
- Reference materials for SARS-CoV-2 variant genotyping assays

• Reference materials for SARS-CoV-2 NGS assays

LEARN MORE

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.

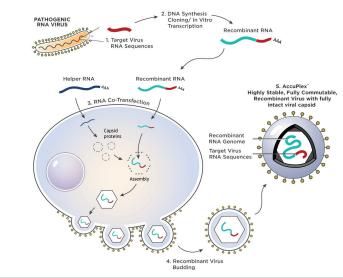


FIGURE 1: 1) RNA sequence from the pathogenic virus of interest is chosen. 2) DNA synthesis and cloning occur to produce the recombinant RNA. 3) Recombinant RNA and helper RNA are co-transfected into the mammalian cells, allowing the encapsulation of recombined RNA. 4) Exocytosis of the mature enveloped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



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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

Table 1: Mutations and variant strains contained in the AccuPlex SARS-CoV-2 Variant Reference Materials

Nucleotide Change	Amino Acid Change	UK B.1.1.7	S. Africa B.1.351	Brazil P.1	Kappa B.1.617	Delta B.1.617.2	Delta Plus AY.1	Omicron B.1.1.529
C21614T	L18F			X				
C21618G	T19R			1		Х	Х	
C21621A	T20N			Х				
C21638T	P26S			Х				
C21762T	A67V			İ				Х
21765-21770 deletion	HV 69-70 deletion	Х		İ				Х
A21801C	D80A		Х					
C21846T	Т95І			1	Х	Х	Х	Х
T21895C	Silent				Х			
G21974T	D138Y		1	Х	1		1	
G21987A	G142D		1	1	Х	Х		
21987 - 21995 deletion	G142D			1	1		1	Х
21991-21993 deletion	Y144 deletion	Х						
G22022A	E154K				Х		1	
22029-22034 del AGTTCA	E156G					Х	Х	
22029-22034 del AGTTCA	F157 and R158Del					Х	Х	
G22132T	R190S			Х				
22194 - 22196 deletion	NL2111			1				Х
A22206G	D215G		Х	1				
22205GAGCCAGAAins	215EPEins			1				Х
22286-22294 Del	242_244 DelLAL		Х					
G22335T	W258L			1			Х	
G22578A	G339D							Х
TC22673CT	S371L			1				Х
T22679C	S373P			1				Х
С22686Т	S375F			1				Х
G22813T	K417N		Х	1			Х	Х
A22812C	K417T			Х				
T22882G	N440K			1				Х
G22898A	G446S							Х
T22917G	L452R				X	Х	Х	
G22992A	S477N			1				Х
C22995A	T478K					Х	Х	Х
G23012A	E484K		Х	X			[i	
G23012C	E484Q				Х			
A23013C	E484A						1	Х
A23040G	Q493R						[i	Х
G23048A	G496S						1	Х
A23055G	Q498R						ĺ	Х
A23063T	N501Y	Х	Х	Х			1	Х
T23075C	Y505H						1	Х
C23202A	T547K		1					Х
C23271A	A570D	Х	1	Ì	l			

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Nucleotide Change	Amino Acid Change	UK B.1.1.7	S. Africa B.1.351	Brazil P.1	Kappa B.1.617	Delta B.1.617.2	Delta Plus AY.1	Omicron B.1.1.529
A23403G	D614G	Х	Х	X	Х	Х	Х	Х
C23525T	H655Y			Х				Х
T23599G	N679K							Х
C23604A	P681H	Х						Х
C23604G	P681R				Х	X	Х	
C23664T	A701V		×					
C23709T	Т716І	Х						
C23854A	N764K							Х
G23948T	D796Y							Х
C24130A	N856K							Х
G24410A	D950N					Х	Х	
A24424T	Q954H							Х
T24469A	N969K							Х
C24503T	L981F							Х
T24506G	S982A	Х						
C24642T	T1027I			Х				
A24775T	Q1071H				Х			
G24914C	D1118H	Х						
C25000T	D1146D							Х
G25088T	V1176F			Х				
C25584T	Т64Т							Х
A28271T	n/a							Х
C28311T	P13L							Х
28362 - 28370 deletion	ERS31del							Х
G28881A, G28882A, G28883C	RG203KR							Х