

Inclusivity Testing of the Clarity COVID-19 Antigen Rapid Test Cassette

Product Code: CLA-COV19AG-VIS

Purpose

The purpose of this study is to determine the ability of the Clarity COVID-19 Antigen Rapid Test Cassette to detect variants of SARS-CoV-2.

Introduction

Since the start of the SARS-CoV-2 pandemic, a variety of SARS-CoV-2 variants have evolved with increased transmissibility rate and in some cases severity of the infection. Most of the variants of concern have shared mutations, mostly on the spike protein, which may lead to decreased vaccine efficacy and performance with certain molecular and/or antigen tests.

It is known that the test performance of certain molecular tests, especially tests that target the spike gene, can be affected by SARS-CoV-2 mutations. However, the effect of the SARS-CoV-2 variants on the performance of antigen tests has not been well-studied. This is largely due to the fact that most antigen tests use the nucleocapsid protein as the target analytes.

In this study, both dry (epitope mapping) and wet testing were performed to evaluate the potential effect the variants have on the performance of the Clarity COVID-19 Antigen Rapid Test Cassette which uses monoclonal antibodies specific to the **Nucleocapsid (N) protein** for detection of SARS-CoV-2.

Methods

To determine the potential effect of the variants, have on the performance of the Clarity COVID-19 Antigen Rapid Test Cassette, the following analysis were performed:

1. The epitope(s) locations for anti-SARS-CoV-2 antibodies used for the Clarity COVID-19 Antigen Rapid Test Cassette were compared with the sequences of each mutant virus strain.
2. The Clarity COVID-19 Antigen Rapid Test Cassette was tested with inactivated virus culture medium.

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Results- Epitope Mapping

The epitope(s) locations of anti-SARS-CoV-2 antibody used for Clarity COVID-19 Antigen Rapid Test Cassette are listed below. Highlighted in **Red** (44-175aa), is the epitope locations of the anti-SAR-CoV-2 antibody used on the test line region of the test; Highlighted **Blue** (74-105), is the epitope locations of the anti-SARS-CoV-2 antibody used on the conjugate.

Consensus	MSDNGPQNRNAPRITFGGPPSDSTGSNQNERSGARSQRRPDLPNNTASWFTALTQHGEDELKFFRGGQVINTNSSPDDIIGYRRATRIRIGDQKMKDLSRWYF	
NC_045512 Pro	MSDNGPQNRNAPRITFGGPPSDSTGSNQNERSGARSQRRPDLPNNTASWFTALTQHGEDELKFFRGGQVINTNSSPDDIIGYRRATRIRIGDQKMKDLSRWYF	110
A23.1 N Pro	MSDNGPQNRNAPRITFGGPPSDSTGSNQNERSGARSQRRPDLPNNTASWFTALTQHGEDELKFFRGGQVINTNSSPDDIIGYRRATRIRIGDQKMKDLSRWYF	110
AT.1 N Pro	MSDNGPQNRNAPRITFGGPPSDSTGSNQNERSGARSQRRPDLPNNTASWFTALTQHGEDELKFFRGGQVINTNSSPDDIIGYRRATRIRIGDQKMKDLSRWYF	110
B.1.427 N Pro	MSDNGPQNRNAPRITFGGPPSDSTGSNQNERSGARSQRRPDLPNNTASWFTALTQHGEDELKFFRGGQVINTNSSPDDIIGYRRATRIRIGDQKMKDLSRWYF	110
B.1.429 N Pro	MSDNGPQNRNAPRITFGGPPSDSTGSNQNERSGARSQRRPDLPNNTASWFTALTQHGEDELKFFRGGQVINTNSSPDDIIGYRRATRIRIGDQKMKDLSRWYF	110
B.1.525 N Pro	-MNGPQNRNAPRITFGGPPSDSTGSNQNERSGARSQRRPDLPNNTASWFTALTQHGEDELKFFRGGQVINTNSSPDDIIGYRRATRIRIGDQKMKDLSRWYF	109
B.1.526 N Pro	MSDNGPQNRNAPRITFGGPPSDSTGSNQNERSGARSQRRPDLPNNTASWFTALTQHGEDELKFFRGGQVINTNSSPDDIIGYRRATRIRIGDQKMKDLSRWYF	110
B.1.619 N Pro	MSDNGPQNRNAPRITFGGPPSDSTGSNQNERSGARSQRRPDLPNNTASWFTALTQHGEDELKFFRGGQVINTNSSPDDIIGYRRATRIRIGDQKMKDLSRWYF	110
B.1.621 N Pro	MSDNGPQNRNAPRITFGGPPSDSTGSNQNERSGARSQRRPDLPNNTASWFTALTQHGEDELKFFRGGQVINTNSSPDDIIGYRRATRIRIGDQKMKDLSRWYF	110
B.1.17 N Pro	MSDNGPQNRNAPRITFGGPPSDSTGSNQNERSGARSQRRPDLPNNTASWFTALTQHGEDELKFFRGGQVINTNSSPDDIIGYRRATRIRIGDQKMKDLSRWYF	110
B.1.135 N Pro	MSDNGPQNRNAPRITFGGPPSDSTGSNQNERSGARSQRRPDLPNNTASWFTALTQHGEDELKFFRGGQVINTNSSPDDIIGYRRATRIRIGDQKMKDLSRWYF	110
B.1.167 N Pro	MSDNGPQNRNAPRITFGGPPSDSTGSNQNERSGARSQRRPDLPNNTASWFTALTQHGEDELKFFRGGQVINTNSSPDDIIGYRRATRIRIGDQKMKDLSRWYF	110
B.1.617.1 N Pro	MSDNGPQNRNAPRITFGGPPSDSTGSNQNERSGARSQRRPDLPNNTASWFTALTQHGEDELKFFRGGQVINTNSSPDDIIGYRRATRIRIGDQKMKDLSRWYF	110
B.1.617.2 N Pro2	MSDNGPQNRNAPRITFGGPPSDSTGSNQNERSGARSQRRPDLPNNTASWFTALTQHGEDELKFFRGGQVINTNSSPDDIIGYRRATRIRIGDQKMKDLSRWYF	110
B.1.618 N Pro	MSDNGPQNRNAPRITFGGPPSDSTGSNQNERSGARSQRRPDLPNNTASWFTALTQHGEDELKFFRGGQVINTNSSPDDIIGYRRATRIRIGDQKMKDLSRWYF	110
C.36 N Pro	MSDNGPQNRNAPRITFGGPPSDSTGSNQNERSGARSQRRPDLPNNTASWFTALTQHGEDELKFFRGGQVINTNSSPDDIIGYRRATRIRIGDQKMKDLSRWYF	110
C.37 N Pro	MSDNGPQNRNAPRITFGGPPSDSTGSNQNERSGARSQRRPDLPNNTASWFTALTQHGEDELKFFRGGQVINTNSSPDDIIGYRRATRIRIGDQKMKDLSRWYF	110
P.1 N Pro-2	MSDNGPQNRNAPRITFGGPPSDSTGSNQNERSGARSQRRPDLPNNTASWFTALTQHGEDELKFFRGGQVINTNSSPDDIIGYRRATRIRIGDQKMKDLSRWYF	110
P.2 N Pro	MSDNGPQNRNAPRITFGGPPSDSTGSNQNERSGARSQRRPDLPNNTASWFTALTQHGEDELKFFRGGQVINTNSSPDDIIGYRRATRIRIGDQKMKDLSRWYF	110
P.3 N Pro	MSDNGPQNRNAPRITFGGPPSDSTGSNQNERSGARSQRRPDLPNNTASWFTALTQHGEDELKFFRGGQVINTNSSPDDIIGYRRATRIRIGDQKMKDLSRWYF	110
Consensus	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTLLPKGFVYEGRGGSQASSRSSRSRNSRSTPSSRRGTSIPARMAGNGDAAALA	
NC_045512 Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTLLPKGFVYEGRGGSQASSRSSRSRNSRSTPSSRRGTSIPARMAGNGDAAALA	220
A23.1 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTLLPKGFVYEGRGGSQASSRSSRSRNSRSTPSSRRGTSIPARMAGNGDAAALA	220
AT.1 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTLLPKGFVYEGRGGSQASSRSSRSRNSRSTPSSRRGTSIPARMAGNGDAAALA	220
B.1.427 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTLLPKGFVYEGRGGSQASSRSSRSRNSRSTPSSRRGTSIPARMAGNGDAAALA	220
B.1.429 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTLLPKGFVYEGRGGSQASSRSSRSRNSRSTPSSRRGTSIPARMAGNGDAAALA	220
B.1.525 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTLLPKGFVYEGRGGSQASSRSSRSRNSRSTPSSRRGTSIPARMAGNGDAAALA	219
B.1.526 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTLLPKGFVYEGRGGSQASSRSSRSRNSRSTPSSRRGTSIPARMAGNGDAAALA	220
B.1.619 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTLLPKGFVYEGRGGSQASSRSSRSRNSRSTPSSRRGTSIPARMAGNGDAAALA	220
B.1.621 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTLLPKGFVYEGRGGSQASSRSSRSRNSRSTPSSRRGTSIPARMAGNGDAAALA	220
B.1.17 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTLLPKGFVYEGRGGSQASSRSSRSRNSRSTPSSRRGTSIPARMAGNGDAAALA	220
B.1.135 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTLLPKGFVYEGRGGSQASSRSSRSRNSRSTPSSRRGTSIPARMAGNGDAAALA	220
B.1.167 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTLLPKGFVYEGRGGSQASSRSSRSRNSRSTPSSRRGTSIPARMAGNGDAAALA	220
B.1.617.1 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTLLPKGFVYEGRGGSQASSRSSRSRNSRSTPSSRRGTSIPARMAGNGDAAALA	220
B.1.617.2 N Pro2	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTLLPKGFVYEGRGGSQASSRSSRSRNSRSTPSSRRGTSIPARMAGNGDAAALA	220
B.1.618 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTLLPKGFVYEGRGGSQASSRSSRSRNSRSTPSSRRGTSIPARMAGNGDAAALA	220
C.36 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTLLPKGFVYEGRGGSQASSRSSRSRNSRSTPSSRRGTSIPARMAGNGDAAALA	220
C.37 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTLLPKGFVYEGRGGSQASSRSSRSRNSRSTPSSRRGTSIPARMAGNGDAAALA	220
P.1 N Pro-2	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTLLPKGFVYEGRGGSQASSRSSRSRNSRSTPSSRRGTSIPARMAGNGDAAALA	220
P.2 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTLLPKGFVYEGRGGSQASSRSSRSRNSRSTPSSRRGTSIPARMAGNGDAAALA	220
P.3 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTLLPKGFVYEGRGGSQASSRSSRSRNSRSTPSSRRGTSIPARMAGNGDAAALA	220
Consensus	LLLLDRNLQLESKMSGKQQQQQVTKKSAEASKKPRKRTATKAYNVQAFGRGPEQTNQGNFDQELIRQDGYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	
NC_045512 Pro	LLLLDRNLQLESKMSGKQQQQQVTKKSAEASKKPRKRTATKAYNVQAFGRGPEQTNQGNFDQELIRQDGYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
A23.1 N Pro	LLLLDRNLQLESKMSGKQQQQQVTKKSAEASKKPRKRTATKAYNVQAFGRGPEQTNQGNFDQELIRQDGYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
AT.1 N Pro	LLLLDRNLQLESKMSGKQQQQQVTKKSAEASKKPRKRTATKAYNVQAFGRGPEQTNQGNFDQELIRQDGYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
B.1.427 N Pro	LLLLDRNLQLESKMSGKQQQQQVTKKSAEASKKPRKRTATKAYNVQAFGRGPEQTNQGNFDQELIRQDGYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
B.1.429 N Pro	LLLLDRNLQLESKMSGKQQQQQVTKKSAEASKKPRKRTATKAYNVQAFGRGPEQTNQGNFDQELIRQDGYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
B.1.525 N Pro	LLLLDRNLQLESKMSGKQQQQQVTKKSAEASKKPRKRTATKAYNVQAFGRGPEQTNQGNFDQELIRQDGYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	329
B.1.526 N Pro	LLLLDRNLQLESKMSGKQQQQQVTKKSAEASKKPRKRTATKAYNVQAFGRGPEQTNQGNFDQELIRQDGYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
B.1.619 N Pro	LLLLDRNLQLESKMSGKQQQQQVTKKSAEASKKPRKRTATKAYNVQAFGRGPEQTNQGNFDQELIRQDGYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
B.1.621 N Pro	LLLLDRNLQLESKMSGKQQQQQVTKKSAEASKKPRKRTATKAYNVQAFGRGPEQTNQGNFDQELIRQDGYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
B.1.17 N Pro	LLLLDRNLQLESKMSGKQQQQQVTKKSAEASKKPRKRTATKAYNVQAFGRGPEQTNQGNFDQELIRQDGYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
B.1.135 N Pro	LLLLDRNLQLESKMSGKQQQQQVTKKSAEASKKPRKRTATKAYNVQAFGRGPEQTNQGNFDQELIRQDGYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
B.1.167 N Pro	LLLLDRNLQLESKMSGKQQQQQVTKKSAEASKKPRKRTATKAYNVQAFGRGPEQTNQGNFDQELIRQDGYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
B.1.617.1 N Pro	LLLLDRNLQLESKMSGKQQQQQVTKKSAEASKKPRKRTATKAYNVQAFGRGPEQTNQGNFDQELIRQDGYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
B.1.617.2 N Pro2	LLLLDRNLQLESKMSGKQQQQQVTKKSAEASKKPRKRTATKAYNVQAFGRGPEQTNQGNFDQELIRQDGYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
B.1.618 N Pro	LLLLDRNLQLESKMSGKQQQQQVTKKSAEASKKPRKRTATKAYNVQAFGRGPEQTNQGNFDQELIRQDGYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
C.36 N Pro	LLLLDRNLQLESKMSGKQQQQQVTKKSAEASKKPRKRTATKAYNVQAFGRGPEQTNQGNFDQELIRQDGYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
C.37 N Pro	LLLLDRNLQLESKMSGKQQQQQVTKKSAEASKKPRKRTATKAYNVQAFGRGPEQTNQGNFDQELIRQDGYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
P.1 N Pro-2	LLLLDRNLQLESKMSGKQQQQQVTKKSAEASKKPRKRTATKAYNVQAFGRGPEQTNQGNFDQELIRQDGYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
P.2 N Pro	LLLLDRNLQLESKMSGKQQQQQVTKKSAEASKKPRKRTATKAYNVQAFGRGPEQTNQGNFDQELIRQDGYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
P.3 N Pro	LLLLDRNLQLESKMSGKQQQQQVTKKSAEASKKPRKRTATKAYNVQAFGRGPEQTNQGNFDQELIRQDGYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
Consensus	LYTGAIKLDDKDPNFKDQVILLNKHI DAYKTFPPTEPKDKKKKADETQALPQRQKQQT VTL PAADLDFSKLQ QSSMSADSTQA	
NC_045512 Pro	LYTGAIKLDDKDPNFKDQVILLNKHI DAYKTFPPTEPKDKKKKADETQALPQRQKQQT VTL PAADLDFSKLQ QSSMSADSTQA	419
A23.1 N Pro	LYTGAIKLDDKDPNFKDQVILLNKHI DAYKTFPPTEPKDKKKKADETQALPQRQKQQT VTL PAADLDFSKLQ QSSMSADSTQA	419
AT.1 N Pro	LYTGAIKLDDKDPNFKDQVILLNKHI DAYKTFPPTEPKDKKKKADETQALPQRQKQQT VTL PAADLDFSKLQ QSSMSADSTQA	419
B.1.427 N Pro	LYTGAIKLDDKDPNFKDQVILLNKHI DAYKTFPPTEPKDKKKKADETQALPQRQKQQT VTL PAADLDFSKLQ QSSMSADSTQA	419
B.1.429 N Pro	LYTGAIKLDDKDPNFKDQVILLNKHI DAYKTFPPTEPKDKKKKADETQALPQRQKQQT VTL PAADLDFSKLQ QSSMSADSTQA	419
B.1.525 N Pro	LYTGAIKLDDKDPNFKDQVILLNKHI DAYKTFPPTEPKDKKKKADETQALPQRQKQQT VTL PAADLDFSKLQ QSSMSADSTQA	418
B.1.526 N Pro	LYTGAIKLDDKDPNFKDQVILLNKHI DAYKTFPPTEPKDKKKKADETQALPQRQKQQT VTL PAADLDFSKLQ QSSMSADSTQA	419
B.1.619 N Pro	LYTGAIKLDDKDPNFKDQVILLNKHI DAYKTFPPTEPKDKKKKADETQALPQRQKQQT VTL PAADLDFSKLQ QSSMSADSTQA	419
B.1.621 N Pro	LYTGAIKLDDKDPNFKDQVILLNKHI DAYKTFPPTEPKDKKKKADETQALPQRQKQQT VTL PAADLDFSKLQ QSSMSADSTQA	419
B.1.17 N Pro	LYTGAIKLDDKDPNFKDQVILLNKHI DAYKTFPPTEPKDKKKKADETQALPQRQKQQT VTL PAADLDFSKLQ QSSMSADSTQA	419
B.1.135 N Pro	LYTGAIKLDDKDPNFKDQVILLNKHI DAYKTFPPTEPKDKKKKADETQALPQRQKQQT VTL PAADLDFSKLQ QSSMSADSTQA	419
B.1.167 N Pro	LYTGAIKLDDKDPNFKDQVILLNKHI DAYKTFPPTEPKDKKKKADETQALPQRQKQQT VTL PAADLDFSKLQ QSSMSADSTQA	419
B.1.617.1 N Pro	LYTGAIKLDDKDPNFKDQVILLNKHI DAYKTFPPTEPKDKKKKADETQALPQRQKQQT VTL PAADLDFSKLQ QSSMSADSTQA	419
B.1.617.2 N Pro2	LYTGAIKLDDKDPNFKDQVILLNKHI DAYKTFPPTEPKDKKKKADETQALPQRQKQQT VTL PAADLDFSKLQ QSSMSADSTQA	419
B.1.618 N Pro	LYTGAIKLDDKDPNFKDQVILLNKHI DAYKTFPPTEPKDKKKKADETQALPQRQKQQT VTL PAADLDFSKLQ QSSMSADSTQA	419
C.36 N Pro	LYTGAIKLDDKDPNFKDQVILLNKHI DAYKTFPPTEPKDKKKKADETQALPQRQKQQT VTL PAADLDFSKLQ QSSMSADSTQA	419
C.37 N Pro	LYTGAIKLDDKDPNFKDQVILLNKHI DAYKTFPPTEPKDKKKKADETQALPQRQKQQT VTL PAADLDFSKLQ QSSMSADSTQA	419
P.1 N Pro-2	LYTGAIKLDDKDPNFKDQVILLNKHI DAYKTFPPTEPKDKKKKADETQALPQRQKQQT VTL PAADLDFSKLQ QSSMSADSTQA	419
P.2 N Pro	LYTGAIKLDDKDPNFKDQVILLNKHI DAYKTFPPTEPKDKKKKADETQALPQRQKQQT VTL PAADLDFSKLQ QSSMSADSTQA	419
P.3 N Pro	LYTGAIKLDDKDPNFKDQVILLNKHI DAYKTFPPTEPKDKKKKADETQALPQRQKQQT VTL PAADLDFSKLQ QSSMSADSTQA	419

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Comparing the sequence of the antibody epitopes used in the Clarity COVID-19 Antigen Rapid Test Cassette and the sequences of the published mutations of various variants (https://www.ncbi.nlm.nih.gov/nuccore/NC_045512), it was determined the Clarity COVID-19 Antigen Rapid Test is able to detect the following SARS-CoV-2 variants: A.23.1, AT.1, B.1.427, B.1.429, B.1.525, B.1.526, B.1.619, B.1.621, B.1.1.7, B.1.135, B.1.617, B.1.617.1, B.1.617.2, B.1.618, C.36, C.37, P.1, P.2, P.3.

Results- LoD of SARS-CoV-2 Variants

To further validate that the Clarity COVID-19 Antigen Rapid Test Cassette is able to detect SARS-CoV-2 variants, limit of detection analysis was performed using 6 different inactivated SARS-CoV-2 variants virus. The following key variants were tested in the study:

Item	Variant	Source	Description
1	Alpha	ZeptoMeterix; SARS-CoV-2 variant virus; 0810613CFHI #326230 (England)	4.57x10 ⁶ TCID ₅₀ /ml SARS-Related Coronavirus 2 (SARS-CoV-2) Variant B.1.1.7 Isolate: England/204820464/2020 Three important mutations, including N501Y (in RBD), P681H and HV69-70 delete, were found in the spike protein.
2	Alpha	ZeptoMeterix; SARS-CoV-2 variant virus; 0810612CFHI #326228 (USA)	1.26x10 ⁶ TCID ₅₀ /ml SARS-Related Coronavirus 2 (SARS-CoV-2) Variant B.1.1.7 Isolate: USA/CA_CDC_5574/2020 Three important mutations, including N501Y (in RBD), P681H and HV69-70 delete, were found in the spike protein.

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3	Beta	ZeptoMeterix; SARS-CoV-2 variant virus; 0810613CFHI #326229 (South Africa)	3.16×10^6 TCID ₅₀ /ml SARS-Related Coronavirus 2 (SARS-CoV-2) Variant B.1.351 Isolate: South Africa/KRISP-K005325/2020 Three at important residues in the receptor-binding domain (K417N, E484K and N501Y in RBD) that may have functional significance
4	Gamma	ZeptoMetrix; SARS-CoV-2 Brazil Variant (Heat Inactivated); 0810616CFHI #326739	1.26×10^6 TCID ₅₀ /mL
5	Gamma	ZeptoMetrix; SARS-CoV-2 Brazil Variant (UV Inactivated); 0810616UV #326741	1.26×10^6 TCID ₅₀ /mL
6	Delta	State Key Laboratory for Diagnosis and Treatment of Infectious Disease, the First Affiliated Hospital, School of Medicine, Zhejiang University	1×10^7 TCID ₅₀ /mL

All materials were diluted to the desired concentration and were tested with the Clarity COVID-19 Antigen Rapid Test Cassettes. Results were interpreted using a line intensity color card (0-10; the higher the number, the darker the line shade is). If the test line intensity was <3, the test result was considered negative. If the test line intensity was 3-10, the test result was considered positive.

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Dilutions	0810613CFHI #326230 (England) Concentration (TCID₅₀/ml)	Line Intensity	Result Interpretation
1	9.14x10 ⁵	10	Positive
2	4.57x10 ⁵	10	Positive
3	9.14x10 ⁴	8	Positive
4	4.57x10 ⁴	7	Positive
5	9.14x10 ³	4.5	Positive
6	4.57x10 ³	4	Positive
7	1.52x10³	3	Positive
8	9.14x10 ²	1	Negative

Dilutions	0810612CFHI #326228 (USA) Concentration (TCID₅₀/ml)	Line Intensity	Result Interpretation
1	2.52x10 ⁵	10	Positive
2	1.26x10 ⁵	10	Positive
3	2.52x10 ⁴	9	Positive
4	1.26x10 ⁴	8	Positive
5	2.52x10 ³	5-	Positive
6	1.26x10 ³	3+	Positive
7	0.63x10 ³	3	Positive
8	0.6x10 ³	3	Positive

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9	0.572×10^3	3-	Positive
10	0.504×10^3	2+	Negative
11	2.52×10^2	1	Negative

Dilutions	0810613CFHI #326229 (South Africa) Concentration (TCID ₅₀ /ml)	Line Intensity	Result Interpretation
1	6.32×10^5	10	Positive
2	3.16×10^5	10	Positive
3	6.23×10^4	9	Positive
4	3.16×10^4	8	Positive
5	6.23×10^3	6	Positive
6	3.16×10^3	3+	Positive
7	1.05×10^3	3	Positive
8	6.23×10^2	1	Negative

Dilutions	ZeptoMetrix 0810616CFHI #326739 Concentration (TCID ₅₀ /ml)	Line Intensity	Result Interpretation
1	4.20×10^5	10+	Positive
2	1.40×10^5	9+	Positive

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3	4.67x10 ⁴	8	Positive
4	1.56x10 ⁴	6	Positive
5	5.19x10³	4	Positive
6	1.73x10 ³	2	Negative
7	5.76x10 ²	1	Negative

Dilutions	ZeptoMetrix 0810616UV #326741 Concentration (TCID₅₀/ml)	Line Intensity	Result Interpretation
1	4.20x10 ⁵	10+	Positive
2	1.40x10 ⁵	10	Positive
3	4.67x10 ⁴	9	Positive
4	1.56x10 ⁴	6+	Positive
5	5.19x10³	3+	Positive
6	1.73x10 ³	2	Negative
7	5.76x10 ²	1	Negative

Dilutions	Heat inactivated COVID-19 delta variant virus culture medium Concentration (TCID₅₀/ml)	Line Intensity	Result Interpretation
1	1.5625x10 ⁵	10+	Positive

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2	9.765x10 ³	6.5	Positive
3	2.441x10 ³	4	Positive
4	6.1025x10 ²	2	Negative

Conclusion

Based on the epitope mapping analysis, it was determined that the epitope(s) of the antibody used in the Clarity Antigen Rapid Test Cassette is not affected by the SARS-CoV-2 variants and is able to detect the following mutant virus strains:

A.23.1, AT.1, B.1.427, B.1.429, B.1.525, B.1.526, B.1.619, B.1.621, B.1.1.7, B.1.135, B.1.617, B.1.617.1, B.1.617.2, B.1.618, C.36, C.37, P.1, P.2, P.3.

In addition, based on testing with inactivated SARS-CoV-2 virus culture medium, **it was further confirmed that the test is able to detect the following mutant virus stains (w/ following LoD):**

Variant	Standard sample	Concentration (TCID ₅₀ /ml)
Alpha	ZeptoMeterix; SARS-CoV-2 variant virus; 0810613CFHI #326230 (England) 4.57x10 ⁶ TCID ₅₀ /ml SARS-Related Coronavirus 2 (SARS-CoV-2) Variant B.1.1.7 Isolate: England/204820464/2020	1.52x10 ³
Alpha	ZeptoMeterix; SARS-CoV-2 variant virus; 0810612CFHI #326228 (USA) 1.26x10 ⁶ TCID ₅₀ /ml SARS-Related Coronavirus 2 (SARS-CoV-2) Variant B.1.1.7 Isolate: USA/CA_CDC_5574/2020	0.6x10 ³
Beta	ZeptoMeterix; SARS-CoV-2 variant virus; 0810613CFHI #326229 (South Africa) 3.16x10 ⁶ TCID ₅₀ /ml SARS-Related Coronavirus 2 (SARS-CoV-2) Variant B.1.351 Isolate: South Africa/KRISP-K005325/2020	1.05x10 ³
Gamma	ZeptoMetrix ; SARS-CoV-2 Brazil Variant (<i>Heat Inactivated</i>); 0810616CFHI #326739, 1.26x10 ⁶ TCID ₅₀ /ml	5.19x10 ³

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Gamma	ZeptoMetrix; SARS-CoV-2 Brazil Variant (<i>UV Inactivated</i>); 0810616UV #326741, 1.26x10 ⁶ TCID ₅₀ /ml;	5.19x10 ³
Delta	State Key Laboratory for Diagnosis and Treatment of Infectious Disease, the First Affiliated Hospital, School of Medicine, Zhejiang University, Heating inactivated COVID-19 delta variant virus culture medium, 1x10 ⁷ TCID ₅₀ /mL	2.441x10 ³



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