

## 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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Clarity Diagnostics - 1060 Holland Drive, Suite B, Boca Raton, Florida 33487

Phone: 877.722.6339 Fax: 561.288.3929 [www.claritydiagnostics.com](http://www.claritydiagnostics.com)

## 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	MSDNGPQNRNAPRITFGGSDSTGSNQNGERSGARSQRRPDLPNNTASWFTALTQHGEDELKFRGGQVPIINTSSPDDQIGYVRATRRIRGGDGKMKDLSRWYF	110
NC_045512 Pro	MSDNGPQNRNAPRITFGGSDSTGSNQNGERSGARSQRRPDLPNNTASWFTALTQHGEDELKFRGGQVPIINTSSPDDQIGYVRATRRIRGGDGKMKDLSRWYF	110
A23.1 N Pro	MSDNGPQNRNAPRITFGGSDSTGSNQNGERSGARSQRRPDLPNNTASWFTALTQHGEDELKFRGGQVPIINTSSPDDQIGYVRATRRIRGGDGKMKDLSRWYF	110
B.1.427 N Pro	MSDNGPQNRNAPRITFGGSDSTGSNQNGERSGARSQRRPDLPNNTASWFTALTQHGEDELKFRGGQVPIINTSSPDDQIGYVRATRRIRGGDGKMKDLSRWYF	110
B.1.429 N Pro	MSDNGPQNRNAPRITFGGSDSTGSNQNGERSGARSQRRPDLPNNTASWFTALTQHGEDELKFRGGQVPIINTSSPDDQIGYVRATRRIRGGDGKMKDLSRWYF	110
B.1.525 N Pro	-MYNGPQNRNAPRITFGGSDSTGSNQNGERSGARSQRRPDLPNNTASWFTALTQHGEDELKFRGGQVPIINTSSPDDQIGYVRATRRIRGGDGKMKDLSRWYF	109
B.1.526 N Pro	MSDNGPQNRNAPRITFGGSDSTGSNQNGERSGARSQRRPDLPNNTASWFTALTQHGEDELKFRGGQVPIINTSSPDDQIGYVRATRRIRGGDGKMKDLSRWYF	110
B.1.619 N Pro	MSDNGPQNRNAPRITFGGSDSTGSNQNGERSGARSQRRPDLPNNTASWFTALTQHGEDELKFRGGQVPIINTSSPDDQIGYVRATRRIRGGDGKMKDLSRWYF	110
B.1.621 N Pro	MSDNGPQNRNAPRITFGGSDSTGSNQNGERSGARSQRRPDLPNNTASWFTALTQHGEDELKFRGGQVPIINTSSPDDQIGYVRATRRIRGGDGKMKDLSRWYF	110
B.1.7 N Pro	MSDNGPQNRNAPRITFGGSDSTGSNQNGERSGARSQRRPDLPNNTASWFTALTQHGEDELKFRGGQVPIINTSSPDDQIGYVRATRRIRGGDGKMKDLSRWYF	110
B.1.135 N Pro	MSDNGPQNRNAPRITFGGSDSTGSNQNGERSGARSQRRPDLPNNTASWFTALTQHGEDELKFRGGQVPIINTSSPDDQIGYVRATRRIRGGDGKMKDLSRWYF	110
B.1.167 N Pro	MSDNGPQNRNAPRITFGGSDSTGSNQNGERSGARSQRRPDLPNNTASWFTALTQHGEDELKFRGGQVPIINTSSPDDQIGYVRATRRIRGGDGKMKDLSRWYF	110
B.1.617.1 N Pro	MSDNGPQNRNAPRITFGGSDSTGSNQNGERSGARSQRRPDLPNNTASWFTALTQHGEDELKFRGGQVPIINTSSPDDQIGYVRATRRIRGGDGKMKDLSRWYF	110
B.1.617.2 N Pro2	MSDNGPQNRNAPRITFGGSDSTGSNQNGERSGARSQRRPDLPNNTASWFTALTQHGEDELKFRGGQVPIINTSSPDDQIGYVRATRRIRGGDGKMKDLSRWYF	110
B.1.618 N Pro	MSDNGPQNRNAPRITFGGSDSTGSNQNGERSGARSQRRPDLPNNTASWFTALTQHGEDELKFRGGQVPIINTSSPDDQIGYVRATRRIRGGDGKMKDLSRWYF	110
C.36 N Pro	MSDNGPQNRNAPRITFGGSDSTGSNQNGERSGARSQRRPDLPNNTASWFTALTQHGEDELKFRGGQVPIINTSSPDDQIGYVRATRRIRGGDGKMKDLSRWYF	110
C.37 N Pro	MSDNGPQNRNAPRITFGGSDSTGSNQNGERSGARSQRRPDLPNNTASWFTALTQHGEDELKFRGGQVPIINTSSPDDQIGYVRATRRIRGGDGKMKDLSRWYF	110
P.1 N Pro-2	MSDNGPQNRNAPRITFGGSDSTGSNQNGERSGARSQRRPDLPNNTASWFTALTQHGEDELKFRGGQVPIINTSSPDDQIGYVRATRRIRGGDGKMKDLSRWYF	110
P.2 N Pro	MSDNGPQNRNAPRITFGGSDSTGSNQNGERSGARSQRRPDLPNNTASWFTALTQHGEDELKFRGGQVPIINTSSPDDQIGYVRATRRIRGGDGKMKDLSRWYF	110
P.3 N Pro	MSDNGPQNRNAPRITFGGSDSTGSNQNGERSGARSQRRPDLPNNTASWFTALTQHGEDELKFRGGQVPIINTSSPDDQIGYVRATRRIRGGDGKMKDLSRWYF	110
Consensus	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTTLPKGFYAEGRGQSASSRSSSSRSRNSNSTPSSSRGTSARMAGNGDAAALA	220
NC_045512 Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTTLPKGFYAEGRGQSASSRSSSSRSRNSNSTPSSSRGTSARMAGNGDAAALA	220
A23.1 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTTLPKGFYAEGRGQSASSRSSSSRSRNSNSTPSSSRGTSARMAGNGDAAALA	220
B.1.427 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTTLPKGFYAEGRGQSASSRSSSSRSRNSNSTPSSSRGTSARMAGNGDAAALA	220
B.1.429 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTTLPKGFYAEGRGQSASSRSSSSRSRNSNSTPSSSRGTSARMAGNGDAAALA	220
B.1.525 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTTLPKGFYAEGRGQSASSRSSSSRSRNSNSTPSSSRGTSARMAGNGDAAALA	219
B.1.526 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTTLPKGFYAEGRGQSASSRSSSSRSRNSNSTPSSSRGTSARMAGNGDAAALA	220
B.1.619 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTTLPKGFYAEGRGQSASSRSSSSRSRNSNSTPSSSRGTSARMAGNGDAAALA	220
B.1.621 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTTLPKGFYAEGRGQSASSRSSSSRSRNSNSTPSSSRGTSARMAGNGDAAALA	220
B.1.7 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTTLPKGFYAEGRGQSASSRSSSSRSRNSNSTPSSSRGTSARMAGNGDAAALA	220
B.1.135 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTTLPKGFYAEGRGQSASSRSSSSRSRNSNSTPSSSRGTSARMAGNGDAAALA	220
B.1.167 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTTLPKGFYAEGRGQSASSRSSSSRSRNSNSTPSSSRGTSARMAGNGDAAALA	220
B.1.617.1 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTTLPKGFYAEGRGQSASSRSSSSRSRNSNSTPSSSRGTSARMAGNGDAAALA	220
B.1.617.2 N Pro2	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTTLPKGFYAEGRGQSASSRSSSSRSRNSNSTPSSSRGTSARMAGNGDAAALA	220
B.1.618 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTTLPKGFYAEGRGQSASSRSSSSRSRNSNSTPSSSRGTSARMAGNGDAAALA	220
C.36 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTTLPKGFYAEGRGQSASSRSSSSRSRNSNSTPSSSRGTSARMAGNGDAAALA	220
C.37 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTTLPKGFYAEGRGQSASSRSSSSRSRNSNSTPSSSRGTSARMAGNGDAAALA	220
P.1 N Pro-2	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTTLPKGFYAEGRGQSASSRSSSSRSRNSNSTPSSSRGTSARMAGNGDAAALA	220
P.2 N Pro	YYLGTGPESLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTTLPKGFYAEGRGQSASSRSSSSRSRNSNSTPSSSRGTSARMAGNGDAAALA	220
P.3 N Pro	YYLGTGPEAGLPYGANKDGIIVATEGALNTPKDHIGTRNPANNAALVQLPQGTTLPKGFYAEGRGQSASSRSSSSRSRNSNSTPSSSRGTSARMAGNGDAAALA	220
Consensus	LLLLDRNLQLESKMSGKGQGGQGTQVTKKSAEASKKPRKQRTATKAYNVQAFGRGPEQTQGNFGDQELIRQGTQYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
NC_045512 Pro	LLLLDRNLQLESKMSGKGQGGQGTQVTKKSAEASKKPRKQRTATKAYNVQAFGRGPEQTQGNFGDQELIRQGTQYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
A23.1 N Pro	LLLLDRNLQLESKMSGKGQGGQGTQVTKKSAEASKKPRKQRTATKAYNVQAFGRGPEQTQGNFGDQELIRQGTQYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
B.1.427 N Pro	LLLLDRNLQLESKMSGKGQGGQGTQVTKKSAEASKKPRKQRTATKAYNVQAFGRGPEQTQGNFGDQELIRQGTQYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
B.1.429 N Pro	LLLLDRNLQLESKMSGKGQGGQGTQVTKKSAEASKKPRKQRTATKAYNVQAFGRGPEQTQGNFGDQELIRQGTQYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
B.1.525 N Pro	LLLLDRNLQLESKMSGKGQGGQGTQVTKKSAEASKKPRKQRTATKAYNVQAFGRGPEQTQGNFGDQELIRQGTQYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	329
B.1.526 N Pro	LLLLDRNLQLESKMSGKGQGGQGTQVTKKSAEASKKPRKQRTATKAYNVQAFGRGPEQTQGNFGDQELIRQGTQYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
B.1.619 N Pro	LLLLDRNLQLESKMSGKGQGGQGTQVTKKSAEASKKPRKQRTATKAYNVQAFGRGPEQTQGNFGDQELIRQGTQYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
B.1.621 N Pro	LLLLDRNLQLESKMSGKGQGGQGTQVTKKSAEASKKPRKQRTATKAYNVQAFGRGPEQTQGNFGDQELIRQGTQYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
B.1.7 N Pro	LLLLDRNLQLESKMSGKGQGGQGTQVTKKSAEASKKPRKQRTATKAYNVQAFGRGPEQTQGNFGDQELIRQGTQYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
B.1.135 N Pro	LLLLDRNLQLESKMSGKGQGGQGTQVTKKSAEASKKPRKQRTATKAYNVQAFGRGPEQTQGNFGDQELIRQGTQYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
B.1.167 N Pro	LLLLDRNLQLESKMSGKGQGGQGTQVTKKSAEASKKPRKQRTATKAYNVQAFGRGPEQTQGNFGDQELIRQGTQYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
B.1.617.1 N Pro	LLLLDRNLQLESKMSGKGQGGQGTQVTKKSAEASKKPRKQRTATKAYNVQAFGRGPEQTQGNFGDQELIRQGTQYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
B.1.617.2 N Pro2	LLLLDRNLQLESKMSGKGQGGQGTQVTKKSAEASKKPRKQRTATKAYNVQAFGRGPEQTQGNFGDQELIRQGTQYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
B.1.618 N Pro	LLLLDRNLQLESKMSGKGQGGQGTQVTKKSAEASKKPRKQRTATKAYNVQAFGRGPEQTQGNFGDQELIRQGTQYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
C.36 N Pro	LLLLDRNLQLESKMSGKGQGGQGTQVTKKSAEASKKPRKQRTATKAYNVQAFGRGPEQTQGNFGDQELIRQGTQYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
C.37 N Pro	LLLLDRNLQLESKMSGKGQGGQGTQVTKKSAEASKKPRKQRTATKAYNVQAFGRGPEQTQGNFGDQELIRQGTQYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
P.1 N Pro-2	LLLLDRNLQLESKMSGKGQGGQGTQVTKKSAEASKKPRKQRTATKAYNVQAFGRGPEQTQGNFGDQELIRQGTQYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
P.2 N Pro	LLLLDRNLQLESKMSGKGQGGQGTQVTKKSAEASKKPRKQRTATKAYNVQAFGRGPEQTQGNFGDQELIRQGTQYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
P.3 N Pro	LLLLDRNLQLESKMSGKGQGGQGTQVTKKSAEASKKPRKQRTATKAYNVQAFGRGPEQTQGNFGDQELIRQGTQYKHWPIAQFAPSASAFFGMSRIGMEVTPSGTW	330
Consensus	LTYYGAKLDDKDPNFKDQVILLNKHIDAYKTFPPEPKDKKKKADETQALPQKQKQQTVTLPAADLDDFSKQLQSSMSADSTQA	419
NC_045512 Pro	LTYYGAKLDDKDPNFKDQVILLNKHIDAYKTFPPEPKDKKKKADETQALPQKQKQQTVTLPAADLDDFSKQLQSSMSADSTQA	419
A23.1 N Pro	LTYYGAKLDDKDPNFKDQVILLNKHIDAYKTFPPEPKDKKKKADETQALPQKQKQQTVTLPAADLDDFSKQLQSSMSADSTQA	419
B.1.427 N Pro	LTYYGAKLDDKDPNFKDQVILLNKHIDAYKTFPPEPKDKKKKADETQALPQKQKQQTVTLPAADLDDFSKQLQSSMSADSTQA	419
B.1.429 N Pro	LTYYGAKLDDKDPNFKDQVILLNKHIDAYKTFPPEPKDKKKKADETQALPQKQKQQTVTLPAADLDDFSKQLQSSMSADSTQA	419
B.1.525 N Pro	LTYYGAKLDDKDPNFKDQVILLNKHIDAYKTFPPEPKDKKKKADETQALPQKQKQQTVTLPAADLDDFSKQLQSSMSADSTQA	418
B.1.526 N Pro	LTYYGAKLDDKDPNFKDQVILLNKHIDAYKTFPPEPKDKKKKADETQALPQKQKQQTVTLPAADLDDFSKQLQSSMSADSTQA	419
B.1.619 N Pro	LTYYGAKLDDKDPNFKDQVILLNKHIDAYKTFPPEPKDKKKKADETQALPQKQKQQTVTLPAADLDDFSKQLQSSMSADSTQA	419
B.1.621 N Pro	LTYYGAKLDDKDPNFKDQVILLNKHIDAYKTFPPEPKDKKKKADETQALPQKQKQQTVTLPAADLDDFSKQLQSSMSADSTQA	419
B.1.7 N Pro	LTYYGAKLDDKDPNFKDQVILLNKHIDAYKTFPPEPKDKKKKADETQALPQKQKQQTVTLPAADLDDFSKQLQSSMSADSTQA	419
B.1.135 N Pro	LTYYGAKLDDKDPNFKDQVILLNKHIDAYKTFPPEPKDKKKKADETQALPQKQKQQTVTLPAADLDDFSKQLQSSMSADSTQA	419
B.1.167 N Pro	LTYYGAKLDDKDPNFKDQVILLNKHIDAYKTFPPEPKDKKKKADETQALPQKQKQQTVTLPAADLDDFSKQLQSSMSADSTQA	419
B.1.617.1 N Pro	LTYYGAKLDDKDPNFKDQVILLNKHIDAYKTFPPEPKDKKKKADETQALPQKQKQQTVTLPAADLDDFSKQLQSSMSADSTQA	419
B.1.617.2 N Pro2	LTYYGAKLDDKDPNFKDQVILLNKHIDAYKTFPPEPKDKKKKADETQALPQKQKQQTVTLPAADLDDFSKQLQSSMSADSTQA	419
B.1.618 N Pro	LTYYGAKLDDKDPNFKDQVILLNKHIDAYKTFPPEPKDKKKKADETQALPQKQKQQTVTLPAADLDDFSKQLQSSMSADSTQA	419
C.36 N Pro	LTYYGAKLDDKDPNFKDQVILLNKHIDAYKTFPPEPKDKKKKADETQALPQKQKQQTVTLPAADLDDFSKQLQSSMSADSTQA	419
C.37 N Pro	LTYYGAKLDDKDPNFKDQVILLNKHIDAYKTFPPEPKDKKKKADETQALPQKQKQQTVTLPAADLDDFSKQLQSSMSADSTQA	419
P.1 N Pro-2	LTYYGAKLDDKDPNFKDQVILLNKHIDAYKTFPPEPKDKKKKADETQALPQKQKQQTVTLPAADLDDFSKQLQSSMSADSTQA	419
P.2 N Pro	LTYYGAKLDDKDPNFKDQVILLNKHIDAYKTFPPEPKDKKKKADETQALPQKQKQQTVTLPAADLDDFSKQLQSSMSADSTQA	419
P.3 N Pro	LTYYGAKLDDKDPNFKDQVILLNKHIDAYKTFPPEPKDKKKKADETQALPQKQKQQTVTLPAADLDDFSKQLQSSMSADSTQA	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](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	<b>Alpha</b>	ZeptoMeterix;  SARS-CoV-2 variant virus; 0810613CFHI  #326230  (England)	4.57x10 <sup>6</sup> TCID <sub>50</sub> /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	<b>Alpha</b>	ZeptoMeterix;  SARS-CoV-2 variant virus; 0810612CFHI  #326228  (USA)	1.26x10 <sup>6</sup> TCID <sub>50</sub> /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	<b>Beta</b>	ZeptoMeterix;  SARS-CoV-2 variant virus; 0810613CFHI  #326229  (South Africa)	3.16x10 <sup>6</sup> TCID <sub>50</sub> /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	<b>Gamma</b>	ZeptoMetrix;  SARS-CoV-2 Brazil Variant (Heat Inactivated); 0810616CFHI  #326739	1.26x10 <sup>6</sup> TCID <sub>50</sub> /mL
5	<b>Gamma</b>	ZeptoMetrix;  SARS-CoV-2 Brazil Variant (UV Inactivated); 0810616UV  #326741	1.26x10 <sup>6</sup> TCID <sub>50</sub> /mL
6	<b>Delta</b>	State Key Laboratory for Diagnosis and Treatment of Infectious Disease, the First Affiliated Hospital, School of Medicine, Zhejiang University	1×10 <sup>7</sup> TCID <sub>50</sub> /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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<b>Dilutions</b>	<b>0810613CFHI #326230 (England) Concentration (TCID<sub>50</sub>/ml)</b>	<b>Line Intensity</b>	<b>Result Interpretation</b>
1	9.14x10 <sup>5</sup>	10	Positive
2	4.57x10 <sup>5</sup>	10	Positive
3	9.14x10 <sup>4</sup>	8	Positive
4	4.57x10 <sup>4</sup>	7	Positive
5	9.14x10 <sup>3</sup>	4.5	Positive
6	4.57x10 <sup>3</sup>	4	Positive
7	<b>1.52x10<sup>3</sup></b>	<b>3</b>	<b>Positive</b>
8	9.14x10 <sup>2</sup>	1	Negative

<b>Dilutions</b>	<b>0810612CFHI #326228 (USA) Concentration (TCID<sub>50</sub>/ml)</b>	<b>Line Intensity</b>	<b>Result Interpretation</b>
1	2.52x10 <sup>5</sup>	10	Positive
2	1.26x10 <sup>5</sup>	10	Positive
3	2.52x10 <sup>4</sup>	9	Positive
4	1.26x10 <sup>4</sup>	8	Positive
5	2.52x10 <sup>3</sup>	5-	Positive
6	1.26x10 <sup>3</sup>	3+	Positive
7	0.63x10 <sup>3</sup>	3	Positive
8	0.6x10 <sup>3</sup>	3	Positive

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9	$0.572 \times 10^3$	3-	Positive
10	$0.504 \times 10^3$	2+	Negative
11	$2.52 \times 10^2$	1	Negative

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

Dilutions	ZeptoMetrix 0810616CFHI #326739 Concentration (TCID <sub>50</sub> /ml)	Line Intensity	Result Interpretation
1	$4.20 \times 10^5$	10+	Positive
2	$1.40 \times 10^5$	9+	Positive

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3	$4.67 \times 10^4$	8	Positive
4	$1.56 \times 10^4$	6	Positive
<b>5</b>	<b><math>5.19 \times 10^3</math></b>	<b>4</b>	<b>Positive</b>
6	$1.73 \times 10^3$	2	Negative
7	$5.76 \times 10^2$	1	Negative

<b>Dilutions</b>	<b>ZeptoMetrix 0810616UV #326741 Concentration (TCID<sub>50</sub>/ml)</b>	<b>Line Intensity</b>	<b>Result Interpretation</b>
1	$4.20 \times 10^5$	10+	Positive
2	$1.40 \times 10^5$	10	Positive
3	$4.67 \times 10^4$	9	Positive
4	$1.56 \times 10^4$	6+	Positive
<b>5</b>	<b><math>5.19 \times 10^3</math></b>	<b>3+</b>	<b>Positive</b>
6	$1.73 \times 10^3$	2	Negative
7	$5.76 \times 10^2$	1	Negative

<b>Dilutions</b>	<b>Heat inactivated COVID-19 delta variant virus culture medium  Concentration (TCID<sub>50</sub>/ml)</b>	<b>Line Intensity</b>	<b>Result Interpretation</b>
1	$1.5625 \times 10^5$	10+	Positive

### Clear Vision - Clear Results

Clarity Brand Rapid Diagnostics

Clarity Diagnostics - 1060 Holland Drive, Suite B, Boca Raton, Florida 33487

Phone: 877.722.6339 Fax: 561.288.3929 [www.claritydiagnostics.com](http://www.claritydiagnostics.com)

2	$9.765 \times 10^3$	6.5	Positive
3	$2.441 \times 10^3$	4	Positive
4	$6.1025 \times 10^2$	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 <sub>50</sub> /ml)
Alpha	ZeptoMeterix; SARS-CoV-2 variant virus; 0810613CFHI #326230 (England) $4.57 \times 10^6$ TCID <sub>50</sub> /ml SARS-Related Coronavirus 2 (SARS-CoV-2) Variant B.1.1.7 Isolate: England/204820464/2020	$1.52 \times 10^3$
Alpha	ZeptoMeterix; SARS-CoV-2 variant virus; 0810612CFHI #326228 (USA) $1.26 \times 10^6$ TCID <sub>50</sub> /ml SARS-Related Coronavirus 2 (SARS-CoV-2) Variant B.1.1.7 Isolate: USA/CA_CDC_5574/2020	$0.6 \times 10^3$
Beta	ZeptoMeterix; SARS-CoV-2 variant virus; 0810613CFHI #326229 (South Africa) $3.16 \times 10^6$ TCID <sub>50</sub> /ml SARS-Related Coronavirus 2 (SARS-CoV-2) Variant B.1.351 Isolate: South Africa/KRISP-K005325/2020	$1.05 \times 10^3$
Gamma	ZeptoMetrix ; SARS-CoV-2 Brazil Variant ( <i>Heat Inactivated</i> ); 0810616CFHI #326739, $1.26 \times 10^6$ TCID <sub>50</sub> /ml	$5.19 \times 10^3$

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<b>Gamma</b>	ZeptoMetrix; SARS-CoV-2 Brazil Variant ( <i>UV Inactivated</i> ); 0810616UV #326741, 1.26x10 <sup>6</sup> TCID <sub>50</sub> /ml;	5.19x10 <sup>3</sup>
<b>Delta</b>	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 <sup>7</sup> TCID <sub>50</sub> /mL	2.441x10 <sup>3</sup>



Ashish Parikh  
Director of Product and Business Development  
Clarity Diagnostics LLC  
Cell: (224) 360-7669  
Email: [ashish.parikh@claritydiagnostics.com](mailto:ashish.parikh@claritydiagnostics.com)  
[covid19techsupport@claritydiagnostics.com](mailto:covid19techsupport@claritydiagnostics.com)  
[www.claritydiagnostics.com](http://www.claritydiagnostics.com)

Rev: 0181821

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Phone: 877.722.6339 Fax: 561.288.3929 [www.claritydiagnostics.com](http://www.claritydiagnostics.com)