

Detection Report of Omicron Variant Virus for ExactSign COVID-19 Antigen Rapid Test Cassette

Purpose

Evaluate ExactSign COVID-19 Antigen Rapid Test Cassette product by detect the specimens which contains SARS-CoV-2 Omicron variant.

Material:

Sample:

Sample ID: SLABDN002, SLABDN004, SLABDN006, see the attached COAs.

Sample Type: Nasopharyngeal swab in transportation media.

ExactSign COVID-19 Antigen Rapid Test Cassette

Lot: COVN2111008-S

2 Method:

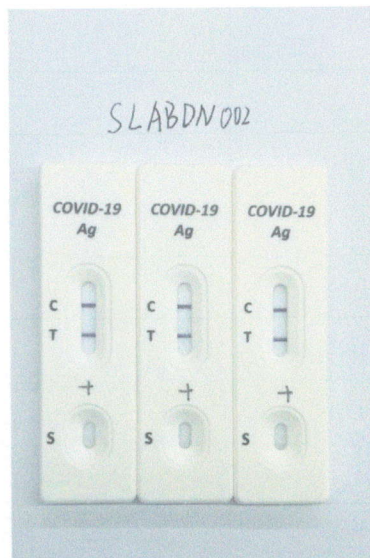
3.2.1 Operate according to the instruction manual;

3.2.2 Specimen volume: 50ul was added to the swab;

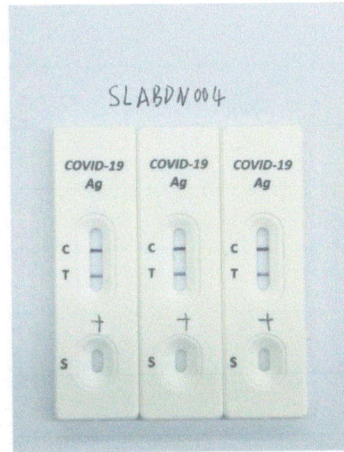
3.2.3 Detection: 3 drops of sample extracted solution (about 80ul) are transferred to the sample cell; the result is read in 10 minutes

3 Result:

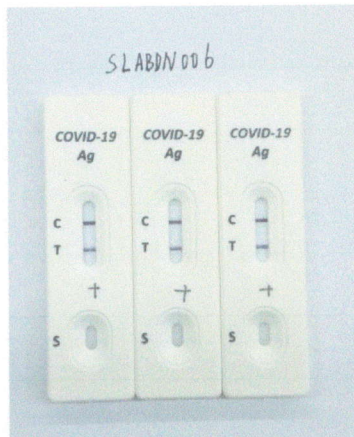
The result of SLABDN002



The result of SLABDN004



The result of SLABDN006



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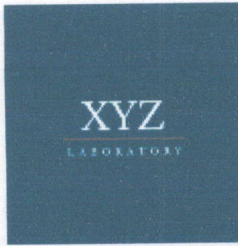
| | Sample ID | Sample Type | Intended Result | ExactSign COVID-19 Antigen Rapid Test Cassette Test Result |
|---|-----------|---------------------------------------------|-----------------|------------------------------------------------------------|
| 1 | SLABDN002 | Nasopharyngeal swab in transportation media | Positive | Positive |
| 2 | SLABDN004 | Nasopharyngeal swab in transportation media | Positive | Positive |
| 3 | SLABDN006 | Nasopharyngeal swab in transportation media | Positive | Positive |

Conclusion:

These specimens which contain SARS-CoV-2 Omicron variant were tested, and they could be detected.

Reported By: James Berry;

Date: 1/11/2022



Certificate of Analysis

Sample ID: SLABDN002

Sample Type: Nasopharyngeal swab in transportation media.

Test Method:

- RNA extraction with MagMax RNA isolation kit from Thermo Fisher Scientific.
- The SARS-CoV-2 S-gene fragment sequencing using ABI 3730XL sequencing analyzer along with Big Dye Terminator v3.0 sequencing kit.
- Sequence data processing using Scanner Software 2 by Thermo Fisher/Applied Biosystems
- Sequence alignment with the Reference Sequence (NC_045512.2:21563-25384) with the Clustal Omega software to identify the mutations.

Results:

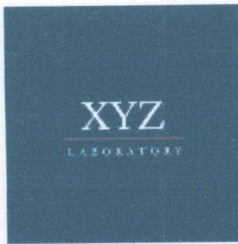
This specimen contains SARS-CoV-2 Omicron variant specific mutations:
G142D/del143-145, Del211/L212I + Ins 214EPE (GAG, CCA, GAA), N280K, E281K, K417N, N440K, G446S, S477N, T478K, E484A, Q493R, G496S, Q498R, N501Y, Y505H, N536T, D614G, H655Y, N679K, P681H

Dr. Keqin Gregg

A handwritten signature in black ink, appearing to read 'Keqin Gregg', written over a horizontal line.

Date: 01/07/2022





Certificate of Analysis

Sample ID: SLABDN004

Sample Type: Nasopharyngeal swab in transportation media.

Test Method:

- RNA extraction with MagMax RNA isolation kit from Thermo Fisher Scientific.
- The SARS-CoV-2 S-gene fragment sequencing using ABI 3730XL sequencing analyzer along with Big Dye Terminator v3.0 sequencing kit.
- Sequence data processing using Scanner Software 2 by Thermo Fisher/Applied Biosystems
- Sequence alignment with the Reference Sequence (NC_045512.2:21563-25384) with the Clustal Omega software to identify the mutations.

Results:

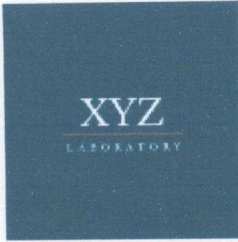
This specimen contains SARS-CoV-2 Omicron variant specific mutations:
G142D/del143-145, Del211/L212I + Ins 214EPE (GAG, CCA, GAA), N280K, E281K, K417N, N440K, G446S, S477N, T478K, E484A, Q493R, G496S, Q498R, N501Y, Y505H, N536T, D614G, H655Y, N679K, P681H

Dr. Keqin Gregg

A handwritten signature in black ink, appearing to read 'Keqin Gregg', written over a horizontal line.

Date: 01/07/2022





Certificate of Analysis

Sample ID: SLABDN006

Sample Type: Nasopharyngeal swab in transportation media.

Test Method:

- RNA extraction with MagMax RNA isolation kit from Thermo Fisher Scientific.
- The SARS-CoV-2 S-gene fragment sequencing using ABI 3730XL sequencing analyzer along with Big Dye Terminator v3.0 sequencing kit.
- Sequence data processing using Scanner Software 2 by Thermo Fisher/Applied Biosystems
- Sequence alignment with the Reference Sequence (NC_045512.2:21563-25384) with the Clustal Omega software to identify the mutations.

Results:

This specimen contains SARS-CoV-2 Omicron variant specific mutations:
G142D/del143-145, Del211/L212I + Ins 214EPE (GAG, CCA, GAA), N280K, E281K, K417N, N440K, G446S, S477N, T478K, E484A, Q493R, G496S, Q498R, N501Y, Y505H, N536T, D614G, H655Y, N679K, P681H

Dr. Keqin Gregg

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