Detection Report of Omicron (B.1.1.529) Variant Virus for Accu-Tell®SARS-CoV-2 Ag Cassette (Nasopharyngeal Swab) No. TDL-B367-BT(C81)/02

1. Background

Omicron (number: B.1.1.529), a variant of the COVID-19. It was first detected in South Africa as early as November 9, 2021.
On November 26, 2021, the World Health Organization defined it as the fifth "variant of concern" and named it the Greek letter Omicron mutant.
On November 29, the WHO stated that the global overall risk assessment of the mutated strain of the new crown virus Omicron was “very high” and may spread widely in the world.
As of 14:00 on December 21, Central European Time, Omicron strain has appeared in 106 countries and regions around the world.
To verify the effectiveness of AccuBioTech’s product Accu-Tell®SARS-CoV-2 Ag Cassette (Nasopharyngeal Swab) Device (Colloidal Gold) in detecting mutated virus, especially for Omicron viruses, we conducted the following experiments.

2. Purpose

Evaluation Accu-Tell®SARS-CoV-2 Ag Cassette (Nasopharyngeal Swab) product by detect the specimens which contains SARS-CoV-2 Omicron variant

3. Material

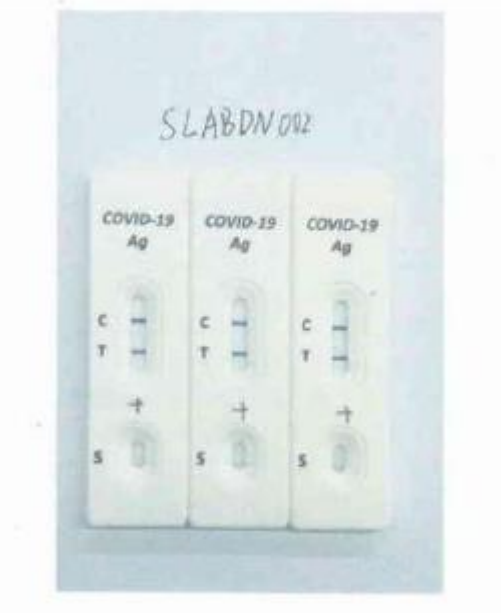
Accu-Tell®SARS-CoV-2 Ag Cassette (Nasopharyngeal Swab)
Lot: COVN2111008-S
Sample ID: SLABDN002, SLABDN004, SLABDN006
Sample Type: Nasopharyngeal swab in transportation media.

4. Method

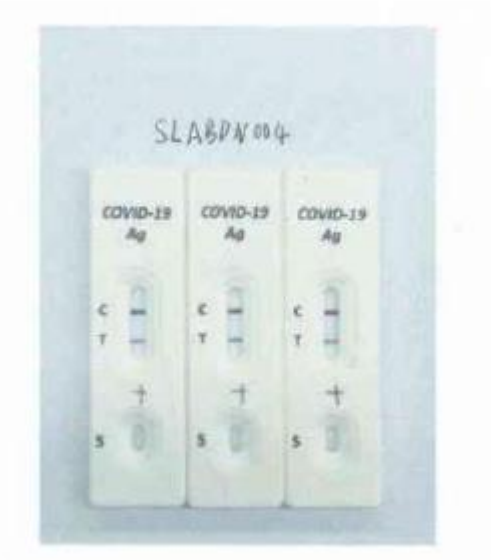
- Operate according to the instruction of use
- Specimen volume: 50ul was added to the swab;
- Detection: 3 drops of sample extracted solution (about 80ul) are transferred to the sample cell; the result is read in 10 minutes

5. Result

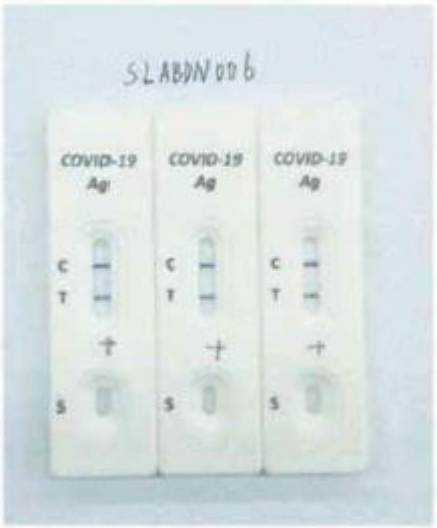
- The result of SLABDN002



The result of SLABDN004



The result of SLABDN006



Sample ID	Sample Type	Intended Result	Accu-Tell®SARS-CoV-2 Ag Cassette (Nasopharyngeal Swab) Test Result
SLABDN002	Nasopharyngeal swab in transportation media	Positive	Positive
SLABDN004	Nasopharyngeal swab in transportation media	Positive	Positive
SLABDN006	Nasopharyngeal swab in transportation media	Positive	Positive

6.Conclusion

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

7. Remark

The information contained in this report is the latest version we have researched, and we may continue to update it in the future.

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