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November 29, 2021

To whom it may concern,

We, as the manufacturer of COVID-19/Influenza A+B Antigen Combo Rapid Test, COVID-19 Antigen Rapid Test Cassette (Saliva), COVID-19 Antigen Rapid Test Cassette (Nasal swab) and COVID-19 Antigen Rapid Test assure that the following major SARS-CoV-2 variants which seem to spread more easily and quickly than other variants, can be detected by these antigen tests:

- ✓ **B.1.1.7 (Alpha)**
- ✓ **B.1.351 (Beta)**
- ✓ **P.1 (Gamma)**
- ✓ **B.1.617.2 (Delta)**
- ✓ **C.37 (Lambda)**
- ✓ **B.1.1.529 (Omicron)**

Yours sincerely,

Hangzhou Clongene Biotech Co., Ltd.

杭州隆基生物技术有限公司
HANGZHOU CLONGENE BIOTECH CO., LTD.

Hangzhou Clongene Biotech Co., Ltd.

COVID-19 Antigen Rapid Test, nasal swab

Analytical Sensitivity (Limit of Detection) Study Report - Omicron

Author: Guoqin Chen

Final report date: 2021.12.17

Management of the study: Hangzhou Clongene Biotech Co., Ltd.
R& D Department
Quality Management department

Place of study: Hangzhou

Sponsor: Hangzhou Clongene Biotech Co., Ltd.

Study Director Signature and Verification Dates

Study Director: Guoqin Chen

Company: Hangzhou Clongene Biotech Co., Ltd.

Position: Director of R&D Department

Signature: _____ Date: 2021.12.17

Study Handlers: Lulu Zhang

Signature: _____ Date: 2021.12.17

Verifier: Yuanyuan Hou

Signature: _____ Date: 2021.12.17

The study dates were as follows:

Protocol Effective Date: 2021-12-14
Test Starting Date: 2021-12-16
Test Duration Date: 2021-12-16 ~ 2021-12-16
Final Report Date: 2021-12-17

Study Summary

Analytical sensitivity of the COVID-19 Antigen Rapid Test was determined in limit of detection (LoD) studies using a heat-inactivated Omicron variant to determine the lowest concentration of Omicron variant at which 95% of all replicates are positive. In this study, the cultured variant stock was spiked into the natural nasal swab matrix pool.

An initial range finding study was performed testing 3 batches of the devices in triplicate using a 10-fold dilution series. The lowest concentration at which Omicron variant target demonstrated 100% positivity (3 out of 3 replicates) was chosen as basis for further study.

Using this concentration, the LoD was further refined with a 2-fold dilution series. The last dilution demonstrating 95% positivity was then tested in an additional 20 replicates tested in the same way.

The LoD of COVID-19 Antigen Rapid Test was confirmed as 2.30×10^{2} $TCID_{50}$/mL, by testing of nasal swab specimen of a heat-inactivated Omicron variant stock.

1. Purpose

Inclusivity study was performed to demonstrate that the COVID-19 Antigen Rapid Test can detect the Omicron variant.

2. Materials

2.1 IVD Reagents: three batches of the COVID-19 Antigen Rapid Test (Lot1: 2020070143, Lot2: 2020070144, Lot3: 2020070145).

2.2 Samples:

a. Omicron variant stocks as shown in the table below

Variant	Titer of Stock ($TCID_{50}$/mL)	Sample Type	Source
Omicron	4.60×10^{6}	Heat-inactivated	Shenzhen Center for Disease Control and Prevention

b. Presumed negative natural nasal swab specimens from healthy donors were extracted in extraction reagent provided in the kit. Swab extracted solution was combined and mixed thoroughly to create a clinical matrix pool to be used as the diluents.

3. Method and Result

3.1 Screening of Critical Positive Concentration

3.1.1 Method

Serial, 10-fold dilutions of each inactivated virus were prepared with the natural nasal swab matrix pool as described above. 50 μL of the viral particle solution was added to dry swabs and the swab was then placed into 0.3 mL extraction reagent for test. Triplicate samples of each serial dilution were tested using one batch of 3 combinations (Lot1: 2020070143, Lot2: 2020070144, Lot3: 2020070145). The lowest concentration at which Omicron variant target demonstrated 100% positivity (3 out of 3 replicates) was chosen for further study.

3.1.2 Result

The results of critical positive concentration screening are presented in Table below. The concentration of 4.60×10^{2} $TCID_{50}$/mL met the criteria we settled up for further study.

Table 1. Inactivated Omicron Variant

Omicron tested ($TCID_{50}$/mL)	Test Result of COVID-19 Antigen (+/+)		
	Lot1: 2020070143	Lot2: 2020070144	Lot3: 2020070145
4.60×10^{6}	3/3	3/3	3/3
4.60×10^{5}	3/3	3/3	3/3
4.60×10^{4}	3/3	3/3	3/3
4.60×10^{3}	3/3	3/3	3/3
4.60×10^{2}	3/3	3/3	3/3
4.60×10	0/3	0/3	0/3

3.2 Confirmation of Critical Positive Concentration

3.2.1 Method

The critical positive concentration was further confirmed with a 2-fold dilution series using the chosen concentration above. Three samples of each serial dilution were tested using each batch of the COVID-19 Antigen Rapid Test. The critical positive concentration was defined as the lowest concentration at which Omicron variant target demonstrated 100% positivity (3 out of 3 replicates).

3.2.2 Result

The results are presented in Table 2 as below, 2.30×10^2 $TCID_{50}$/mL was final specified as LoD of the product.

Table 2. Inactivated Omicron Variant

Omicron tested ($TCID_{50}$/mL)	Test Result of COVID-19 Antigen (+/+)		
	Lot1: 2020070143	Lot2: 2020070144	Lot3: 2020070145
4.60×10^2	3/3	3/3	3/3
2.30×10^2	3/3	3/3	3/3
1.15×10^2	2/3	2/3	2/3

3.3 LoD Confirmation

3.3.1 Method

20 individually extracted samples at the estimated LoD were prepared with the natural nasal swab matrix pool. Extracted samples were then tested using each batch. Acceptance criteria is that at least 95% of the test results are positive with each lot of product at the concentration specified as the study results of chap. 3.2 as above.

3.3.2 Result

The results of LoD confirmation are summarized in Table 3 as below, 100% of the test are positive with each lot of product at the concentration specified as the study results of chap. 3.2 as above.

Table 3. Inactivated Omicron Variant

Lot No.	Test Results (+/+) at 2.30×10^2 $TCID_{50}$/mL
Lot1: 2020070143	20/20
Lot2: 2020070144	20/20
Lot3: 2020070145	20/20

4. Conclusion

Based on this study the LoD of COVID-19 Antigen Rapid Test for nasal swab specimens was confirmed as follows:

Variant	LoD ($TCID_{50}$/mL)
Omicron	2.30×10^2

Hangzhou Clongene Biotech Co., Ltd.

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