

Summary of Comparison Detection Study on Omicron Variants

1. Purpose

This study performed in a Third Party CLIA Lab, is to evaluate if the Omicron variant impact the performance of iHealth COVID-19 Antigen Rapid Test using recombinant antigen targets with and without the Omicron mutation in negative clinical matrix.

2. Material and device used in this study

iHealth COVID-19 Antigen Rapid Test

4 lots iHealth COVID-19 Antigen Rapid Tests (lot number: 221CO20203 , 221CO20107-01 , 222CO20117 , 222CO20123) were tested.

SARS-CoV-2 recombinant N protein

SARS-CoV-2 recombinant N protein with and without the Omicron mutation is from Acro Biosystem.

Testing Samples

Negative sample was prepared by mixing raw nasal fluid bought from Lee Biosolutions, Inc. RT-PCR test kit was used to test the nasal fluid's SARS-CoV-2 RNA, and all three repeat tests show negative.

Positive sample was prepared by diluting recombinant antigen targets with and without the mutation to target concentration using negative sample prepared above.

3. Method

The comparison test includes preliminary testing and confirmation testing. **Preliminary testing** is to screen a preliminary scope of LoD by testing positive samples with concentration listed in table 1. The preliminary LoD is the lowest concentration that gives positive results 100% of the time.

Table 1 Concentrations of test sample used in preliminary testing

NO.	Concentration of test sample		
	Recombinant antigen with Omicron mutation(BA.4)	Recombinant antigen with Omicron mutation(BA.5)	Recombinant antigen without Omicron mutation
1	100 ng/mL	100 ng/mL	100 ng/mL
2	10 ng/mL	10 ng/mL	10 ng/mL
3	1 ng/mL	1 ng/mL	1 ng/mL
4	0.5 ng/mL	0.5 ng/mL	0.5 ng/mL

Confirmation testing is behind the preliminary testing. According to the results from preliminary testing, smaller concentration interval can be chosen to confirm the LoD. Test all the concentration interval in table 2 with 20 duplicate. The final LoD is determined as the lowest concentration at which 19 of 20 replicates are positive.

Table 2 Concentrations of test sample used in confirmation testing

NO.	Concentration of test sample		
	Recombinant antigen with Omicron mutation(BA.4)	Recombinant antigen with Omicron mutation(BA.5)	Recombinant antigen without Omicron mutation
1	1 ng/mL	1 ng/mL	1 ng/mL
2	0.5 ng/mL	0.5 ng/mL	0.5 ng/mL

4. Results

The LoD of iHealth COVID-19 Antigen Rapid Test determined by recombinant antigen with and without Omicron mutation is the same.

There is no impact on performance of iHealth COVID-19 Antigen Rapid Test from Omicron mutation according to the test result in this study.

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