BOSON

Performance Characteristics Study of Rapid SARS-CoV-2 Antigen Test Card in United Kingdom

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Performance Characteristics Study

Entrusted by Xiamen Boson Biotech Co., Ltd., the performance of Rapid SARS-CoV-2 Antigen Test Card was verified by a UK customer in their specialist laboratory. Performance characteristics study of Rapid SARS-CoV-2 Antigen Test Card is composed of the experiments of Analytical Specificity Evaluation and The Limit of Detection.

The results of the study were shown below.

Analytical Specificity Evaluation using S-Protein, HKU1, NL63 & OC43

8 different concentration gradients (100μg/ml, 10μg/ml, 1μg/ml, 100ng/ml, 10ng/ml, 1ng/ml, 0.1ng/ml, 0.01ng/ml) were configured for the S-protein of SARS-CoV-2 and the N-protein of three other human coronaviruses (HKU1, NL63 and OC43), and these samples were added to the SARS-CoV-2 Antigen Test Card to verify that cross-reactivity is possible. The experiment was repeated three times for each concentration gradient. The results were recorded at 15-20 minutes.

Three blank specimens were first tested, as a negative quality control

SARS-CoV-2 S-Protein

	Reader 1		
S Protein	**1**	**2**	**3**
100µg/ml	NEG	NEG	NEG
10µg/ml	NEG	NEG	NEG
1µg/ml	NEG	NEG	NEG
100ng/ml	NEG	NEG	NEG
10ng/ml	NEG	NEG	NEG
1ng/ml	NEG	NEG	NEG
0.1ng/ml	NEG	NEG	NEG
0.01ng/ml	NEG	NEG	NEG

OC43	Reader 1		
	1	2	3
100μg/ml	NEG	NEG	NEG
10μg/ml	NEG	NEG	NEG
1μg/ml	NEG	NEG	NEG
100ng/ml	NEG	NEG	NEG
10ng/ml	NEG	NEG	NEG
1ng/ml	NEG	NEG	NEG
0.1ng/ml	NEG	NEG	NEG
0.01ng/ml	NEG	NEG	NEG

NL63 N Protein
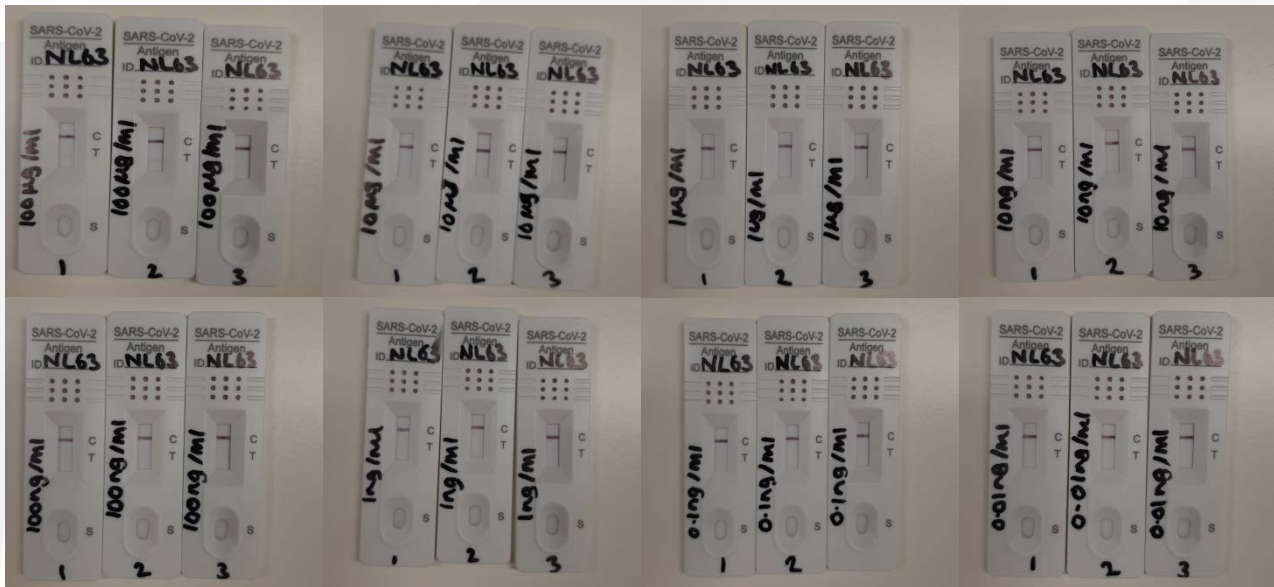
NL63	Reader 1		
	1	**2**	**3**
100μg/ml	P +1	P +1	P +1
10μg/ml	NEG	NEG	NEG
1μg/ml	NEG	NEG	NEG
100ng/ml	NEG	NEG	NEG
10ng/ml	NEG	NEG	NEG
1ng/ml	NEG	NEG	NEG
0.1ng/ml	NEG	NEG	NEG
0.01ng/ml	NEG	NEG	NEG

HKU1 N Protein
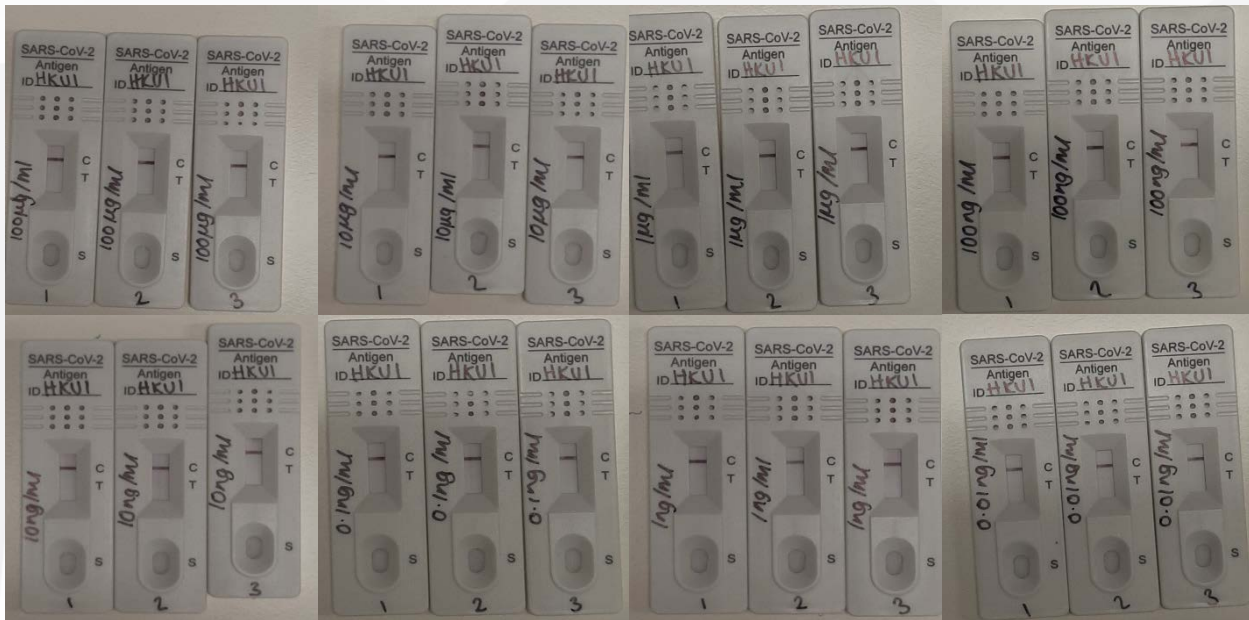
	Replicate		
HKU1	**1**	**2**	**3**
100µg/ml	NEG	NEG	NEG
10µg/ml	NEG	NEG	NEG
1µg/ml	NEG	NEG	NEG
100ng/ml	NEG	NEG	NEG
10ng/ml	NEG	NEG	NEG
1ng/ml	NEG	NEG	NEG
0.1ng/ml	NEG	NEG	NEG
0.01ng/ml	NEG	NEG	NEG

Conclusion

All the samples showed no effect on the specificity of Rapid SARS-CoV-2 Antigen Test Card at different concentrations, except for the NL63 N protein, which was weakly positive at the highest concentration.

This result shows that Rapid SARS-CoV-2 Antigen Test Card has good analytical specificity.

The Limit of Detection (LoD) using SARS-CoV-2 Nucleoprotein Dilutions and Viral Dilutions

Configure different concentration gradients for nucleoprotein dilutions and viral dilutions to be added to the SARS-CoV-2 Antigen Test Card for the LoD, and repeat the experiment ten times per concentration gradient. Read results 15-20 minutes after sample addition, and calculate the positive detection rate. The LoD was chosen at the antigen level with 95% positive detection rate.
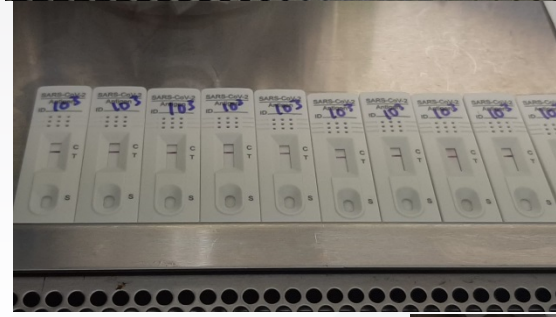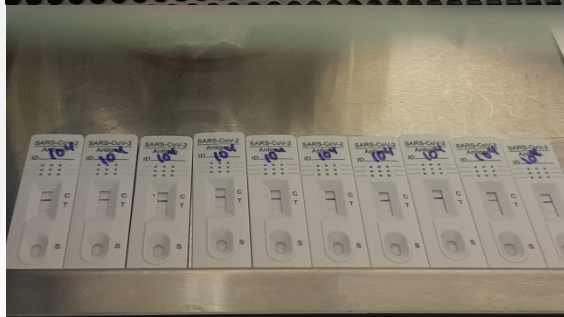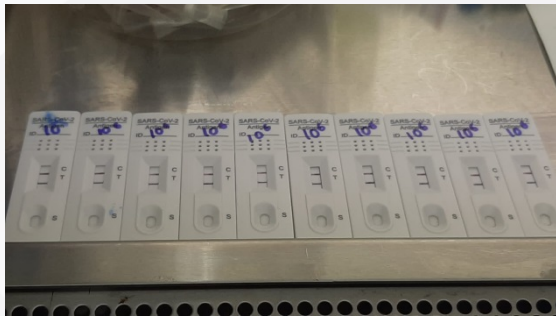
LOD using SARS-CoV-2 Nucleoprotein Dilutions

LOD using SARS-CoV-2 Nucleoprotein Dilutions

Concentration of Nucleoprotein	RDT Result									
	1	2	3	4	5	6	7	8	9	10
100µg/ml	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)
10µg/ml	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)
1µg/ml	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)
100ng/ml	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)
10ng/ml	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)	POS (+5)
1ng/ml	POS (+3)	POS (+3)	POS (+3)	POS (+3)	POS (+3)	POS (+3)	POS (+3)	POS (+3)	POS (+3)	POS (+3)
0.1ng/ml	POS (+2)	POS (+2)	POS (+2)	POS (+2)	POS (+2)	POS (+2)	POS (+2)	POS (+2)	POS (+2)	POS (+2)
0.05ng/ml	POS (+1)	POS (+1)	POS (+1)	POS (+1)	POS (+1)	POS (+1)	POS (+1)	POS (+1)	POS (+1)	POS (+1)
0.025ng/ml	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG

LOD using SARS-CoV-2 Viral Dilutions

Pfu/ml	Replicates									
	1	2	3	4	5	6	7	8	9	10
10^6	P+5	P+5	P+5	P+5	P+5	P+5	P+5	P+5	P+5	P+5
10^5	P+5	P+5	P+5	P+5	P+5	P+5	P+5	P+5	P+5	P+5
10^4	P+3	P+3	P+3	P+3	P+3	P+3	P+3	P+3	P+3	P+3
10^3	P+2	P+2	P+2	P+2	P+2	P+2	P+2	P+2	P+2	P+2
5×10^2	P+1	P+1	P+1	P+1	P+1	P+1	P+1	P+1	P+1	P+1
2.5×10^2	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
10^2	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG

The LoD result for viral dilutions may vary between different strains, the inactivation status of the strain can also affect the results of the experiment. Hence, fresh viral strains are recommended for testing.

Conclusion

Based on the test results, the limit of detection was 0.05 ng/mL for the recombinant antigens, which was better than it claimed by Xiamen Boson Biotech Co., Ltd.

The limit of detection $5×10^2$ Pfu/mL for the antigen viral cultures, which was able to meet clinical use standards.