Performance Characteristics

1.Clinical Results:A total of 1686 samples from susceptible subjects were test by the PCR test and CT Detection from three hospitals. Comparison for all subjects is showed in the following table:

SARS-COV-2 Antigen Test	RT-PCR		
	Positive	Negative	Total
Positive	491	0	491
Negative	16	1179	1195
Total	507	1179	1686

Relative Sensitivity: 96.84%(95% confidence interval:98.36%-99.32%);
Relative Specificity:100%(95% confidence interval:100%-100%);
Overall agreement: 99.05%(95% confidence interval:98.57%-99.51%);

2.Different PCR CT-Value: Setting different PCR CT-value to did the comparative verification experiment. The results as below:

SARS-COV-2Antigen Test	RT-PCR(Ct-Value≤35)		
	Positive	Negative	Total
Positive	160	0	160
Negative	9	393	402
Total	169	393	562

Positive coincidence rate(Sensitivity)160/169=94.67%;
【95% confidence interval:91.28%-98.06%】
Negative coincidence rate(Specificity)＝393/393=100%;
【95% confidence interval:100%-100%】
Total coincidence rate＝(160+393)/(169+393)=98.39%.
【95% confidence interval:97.35%- 99.43%】
Kappa=0.9614(K>0.75),it can be considered that the strength of agreement between the assessment reagent result and the nucleic acid test result is extremely high.(K=0.9616>0.75)

SARS-COV-2Antigen Test	RT-PCR(Ct-Value≤30)		
	Positive	Negative	Total
Positive	165	0	165
Negative	4	393	39
Total	169	393	562

Positive coincidence rate(Sensitivity)165/169=97.63%;
【95% confidence interval:95.34%-99.92%】
Negative coincidence rate(Specificity)＝393/393=100%;
【95% confidence interval:100%-100%】
Total coincidence rate＝(165+393)/(169+393)=99.29%.
【95% confidence interval:98.60%- 99.98%】
Kappa=0.9829(K>0.75),it can be considered that the strength of agreement between the assessment reagent result and the nucleic acid test result is extremely high.(K=0.9829>0.75)

SARS-COV-2Antigen Test	RT-PCR(Ct-Value≤27)		
	Positive	Negative	Total
Positive	167	0	167
Negative	2	393	395
Total	169	393	562

Positive coincidence rate(Sensitivity)167/169=98.81%;
【95% confidence interval:97.18%-100%】
Negative coincidence rate(Specificity)＝393/393=100%;
【95% confidence interval:100%-100%】
Total coincidence rate＝(167+393)/(169+393)=99.64%.
【95% confidence interval:99.14%-100%】
Kappa=0.9915(K>0.75),it can be considered that the strength of agreement between the assessment reagent result and the nucleic acid test result is extremely high.(K=0.9915>0.75)

3.Conclusion:

The above results show that the sensitivity of the kit is 96.84%, the specificity is 100%, and the total coincidence rate is more than 99.05%, which is consistent with the clinical diagnosis results and has strong clinical application value. It can assist nucleic acid detection and SARS-CoV-2 IgG/IgM detection in clinical applications.

Limit Detection

1.Specimen to be tested:

Limit detection reference:

A:Recombinant Antigen:RS1(1000pg),R2(200pg),RS3(100pg),RS4(50pg),RS5(20pg),RS6(10pg),RS7(5pg)

B:SARS-COV-2 Culture Fluid(Heat Inacvtivated):(Order from ZeptoMetrix ,The Lot:324608)

CS1(1.51*106 TCID50/ml),CS2(1.51*104 TCID50/ml),CS3(1.51*103 TCID50/ml),CS4(1.51*102 TCID50/ml),CS5(1.51*101 TCID50/ml),CS6(1.51*100 TCID50/ml),

Repeatable reference:R1,R2

2.Test requirement:

The detection result of the Recombinant antigen reference RS1-RS5 should all be positive,RS6 and RS7 could be negative or positive.

The detection result of the Recombinant antigen reference CS1-CS4 should all be positive,CS5 and CS6could be negative or positive.

The repeatable reference R1 and R2 should be positive and the color rendering should be uniform.

3.Three different Lot: Lot:200910;Lot:200912;Lot:200915

4.The test result:

Table 1-1 Test results of limit detection studies for Lot 20200910

Test time	Recombinant Antigen reference							SARS-COV-2 Culture Fluid reference						Repeatability coincidence rate	
	RS1	RS2	RS3	RS4	RS5	RS6	RS7	CS1	CS2	CS3	CS4	CS5	CS6	R1	R2
0 days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
7 days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
14 days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
21days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
28days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
35days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
42days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
49days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
56days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
63days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
70days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
77days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
84days	+	+	+	+	+	+	-	+	+	+	+	-	-	10/10	10/10
91days	+	+	+	+	+	+	-	+	+	+	+	-	-	10/10	10/10
98days	+	+	+	+	+	+	-	+	+	+	+	-	-	10/10	10/10

Limit Detection

Table 1-2 Test results of limit detection studies for Lot 20200912

Test time	Recombinant Antigen reference							SARS-COV-2 Culture Fluid reference						Repeatability coincidence rate	
	RS 1	RS 2	RS 3	RS 4	RS 5	RS 6	RS 7	CS 1	CS 2	CS 3	CS 4	CS 5	CS 6	R1	R2
0 days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
7 days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
14 days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
21days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
28days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
35days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
42days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
49days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
56days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
63days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
70days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
77days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
84days	+	+	+	+	+	+	-	+	+	+	+	-	-	10/10	10/10
91days	+	+	+	+	+	+	-	+	+	+	+	-	-	10/10	10/10
98days	+	+	+	+	+	+	-	+	+	+	+	-	-	10/10	10/10

Table 1-3 Test results of limit detection studies for Lot 20200915

Test time	Recombinant Antigen reference							SARS-COV-2 Culture Fluid reference						Repeatability coincidence rate	
	RS 1	RS 2	RS 3	RS 4	RS 5	RS 6	RS 7	CS 1	CS 2	CS 3	CS 4	CS 5	CS 6	R1	R2
0 days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
7 days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
14 days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
21days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
28days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
35days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
42days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
49days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
56days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
63days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
70days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
77days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
84days	+	+	+	+	+	+	-	+	+	+	+	-	-	10/10	10/10
91days	+	+	+	+	+	+	-	+	+	+	+	-	-	10/10	10/10
98days	+	+	+	+	+	+	-	+	+	+	+	-	-	10/10	10/10

Conclusion:

After limit detection and repeat test research,the SARS-COV-2 antigen rapid test kit developed have a good performance. During testing the recombinant antigen reference the limit detection is 10pg, as well as $1.51*10^2$ TCID50/ml during testing Culture Fluid reference.

Limit Detection

Table 1-2 Test results of limit detection studies for Lot 20200912

Test time	Recombinant Antigen reference							SARS-COV-2 Culture Fluid reference						Repeatability coincidence rate	
	RS 1	RS 2	RS 3	RS 4	RS 5	RS 6	RS 7	CS 1	CS 2	CS 3	CS 4	CS 5	CS 6	R1	R2
0 days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
7 days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
14 days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
21days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
28days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
35days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
42days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
49days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
56days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
63days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
70days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
77days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
84days	+	+	+	+	+	+	-	+	+	+	+	-	-	10/10	10/10
91days	+	+	+	+	+	+	-	+	+	+	+	-	-	10/10	10/10
98days	+	+	+	+	+	+	-	+	+	+	+	-	-	10/10	10/10

Table 1-3 Test results of limit detection studies for Lot 20200915

Test time	Recombinant Antigen reference							SARS-COV-2 Culture Fluid reference						Repeatability coincidence rate	
	RS 1	RS 2	RS 3	RS 4	RS 5	RS 6	RS 7	CS 1	CS 2	CS 3	CS 4	CS 5	CS 6	R1	R2
0 days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
7 days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
14 days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
21days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
28days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
35days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
42days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
49days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
56days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
63days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
70days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
77days	+	+	+	+	+	+	-	+	+	+	+	+	-	10/10	10/10
84days	+	+	+	+	+	+	-	+	+	+	+	-	-	10/10	10/10
91days	+	+	+	+	+	+	-	+	+	+	+	-	-	10/10	10/10
98days	+	+	+	+	+	+	-	+	+	+	+	-	-	10/10	10/10

Conclusion:

After limit detection and repeat test research,the SARS-COV-2 antigen rapid test kit developed have a good performance. During testing the recombinant antigen reference the limit detection is 10pg, as well as $1.51*10^2$ TCID50/ml during testing Culture Fluid reference.