COVID-19 Antigen Rapid Test (Latex)

Performance Validation Report

Prepared By: Yanhua ZHANG Date: 02/09/2020

Reviewed By: Qian XU Date: 02/09/2020

Approval By: Zhong WANG Date: 03/09/2020

1. Review overall product performance vs. targeted performance goals

Condition		Accepted standards
Limit of Detection		Positive detection rate≥95%
Positive coincidence rate		no negative results
Negative coincidence rate		no positive results
Cross-reactivity		no Cross-reactivity
Interference		no differences
Precision	Intra assay	No distinct difference was detected in intra lots
	Inter assay	No significant differences were detected between batches

2. Limit of Detection

2.1 Materials:

Reagent name and specifications	Lot 1	Lot 2	Lot 3
COVID-19 Antigen Rapid Test (Latex) 25T/Kit	LCOVADEV001	LCOVADEV002	LCOVADEV003

2.2 Method:

Use COVID-19 Antigen Rapid Test (Latex) product to detect spike negative sample into buffer, respectively. Prepare the supernatant for subsequent use. Spiked a group of serially diluted SARS-COV-2 spike glycoprotein(40ng/mL, 20ng/mL, 10ng/mL, 5ng/mL, 2.5ng/mL, 0ng/mL) in supernatant described above, respectively. Each supernatant are tested 20 times.

2.3 Results:

According to the standard procedure of reagent use operation, the results are read in 15 minutes and repeated 20 times.

The results are as follows ("+" indicates a positive result, "-" indicates a negative result):

LOT	LCOVADEV001			LCOVADEV002			LCOVADEV003		
Repeat Times	1	2	3	1	2	3	1	2	3
40ng/mL	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20
20ng/mL	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20
10ng/mL	19/20	20/20	20/20	20/20	20/20	20/20	20/20	19/20	20/20
5ng/mL	19/20	20/20	20/20	20/20	20/20	19/20	20/20	20/20	20/20
2.5ng/mL	11/20	9/20	13/20	8/20	10/20	12/20	14/20	11/20	13/20
0 ng/mL	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20

2.4 Conclusion:

By the above experimental results it can be seen that the limit of detection (LOD) of COVID-19 Antigen Rapid Test (Latex) is 5ng/mL SARS-COV-2 spike glycoprotein.

3. Positive coincidence rate

3.1 Materials:

Reagent name and specifications	Lot 1	Lot 2	Lot 3
COVID-19 Antigen Rapid Test (Latex) 25T/Kit	LCOVADEV001	LCOVADEV002	LCOVADEV003

3.2 Method

Use COVID-19 Antigen Rapid Test (Latex) product to detect the positive L、M、H quality control products as the evaluation sample, and each batch of reagents is tested, and the results are required to be positive.

3.3 Results:

According to the standard procedure of reagent use operation, the results are read in 15 minutes and repeated 3 times.

The results are as follows ("+" indicates a positive result, "-" indicates a negative result):

LOT	LCOVADEV001			LCOVADEV002			LCOVADEV003		
Repeat Times	L	M	H	L	M	H	L	M	H
1	+	+	+	+	+	+	+	+	+
2	+	+	+	+	+	+	+	+	+
3	+	+	+	+	+	+	+	+	+

3.4 Conclusion

By the above experimental results it can be seen that the positive control of COVID-19 Antigen Rapid Test (Latex) can reliably detect positive results, the positive compliance rate meets the requirements, and the results of the three batches of reagents can be satisfied.

4. Negative coincidence rate

4.1 Materials:

Reagent name and specifications	Lot 1	Lot 2	Lot 3
COVID-19 Antigen Rapid Test (Latex) 25T/Kit	LCOVADEV001	LCOVADEV002	LCOVADEV003

4.2 Method

Use COVID-19 Antigen Rapid Test (Latex) product to detect the negative sample as the evaluation sample, each batch of reagents was repeatedly tested 1 time for the negative quality control characters, and the results are supposed to be all negative.

4.3 Results：

According to the standard procedure of reagent use operation, the results are read in 15 minutes and 1 time.

The results are as follows:

Lot / Negative Quality Control	LCOVADEV001	LCOVADEV002	LCOVADEV003
N1	-	-	-
N2	-	-	-
N3	-	-	-
N4	-	-	-
N5	-	-	-
N6	-	-	-
N7	-	-	-
N8	-	-	-

4.4 Conclusion

By the above experimental results it can be seen that the negative control of COVID-19 Antigen Rapid Test (Latex) can reliably detect negative results, the negative compliance rate meets the requirements, and the results of the three batches of reagents can be satisfied.

5. Cross-reactivity

5.1 Materials:

Reagent name and specifications	Lot 1	Lot 2	Lot 3
COVID-19 Antigen Rapid Test (Latex) 25T/Kit	LCOVADEV001	LCOVADEV002	LCOVADEV003

5.2 Method

Spike negative sample into buffer, respectively. Prepare the supernatant for subsequent use. And use different concentrations of the recombinant protein of the coronavirus to conduct experiments to test its performance. Ten kinds of recombinant proteins of samples are spiked in supernatant described above, respectively.

Concentration of Recombinant Proteins(μg/ml)
SARS-CoV-2 S1 Protein
SARS-CoV-2 S1 Protein(D614G)
SARS-CoV S1 Protein
HCoV-NL63 S1 Protein
HCoV-229E S1 Protein
HCoV-HKU1 S1 Protein
MERS-CoV S1 Protein
Human RSV (B1) G Protein
Influenza A H1N1 HA Protein
Influenza B HA Protein

5.3 Results:

Follow the standard operating procedures for reagent use and read the results in 15 minutes. The results are as follows ("+" indicates a positive result, "-" indicates a negative result):

LCOVADEV001

Concentration of Recombinant Proteins(μg/ml)	0	0.001	0.01	0.1	1	10
SARS-CoV-2 S1 Protein	-	-	+	++	+++	+++
SARS-CoV-2 S1 Protein(D614G)	-	+	+	++	+++	+++
SARS-CoV S1 Protein	-	-	-	-	-	-
HCoV-NL63 S1 Protein	-	-	-	-	-	-
HCoV-229E S1 Protein	-	-	-	-	-	-
HCoV-HKU1 S1 Protein	-	-	-	-	-	-
MERS-CoV S1 Protein	-	-	-	-	-	-

Human RSV (B1) G Protein	-	-	-	-	-	-
Influenza A H1N1 HA Protein	-	-	-	-	-	-
Influenza B HA Protein	-	-	-	-	-	-

LCOVADEV002

Concentration of Recombinant Proteins(μg/ml)	0	0.001	0.01	0.1	1	10
SARS-CoV-2 S1 Protein	-	-	+	++	+++	+++
SARS-CoV-2 S1 Protein(D614G)	-	+	+	++	+++	+++
SARS-CoV S1 Protein	-	-	-	-	-	-
HCoV-NL63 S1 Protein	-	-	-	-	-	-
HCoV-229E S1 Protein	-	-	-	-	-	-
HCoV-HKU1 S1 Protein	-	-	-	-	-	-
MERS-CoV S1 Protein	-	-	-	-	-	-
Human RSV (B1) G Protein	-	-	-	-	-	-
Influenza A H1N1 HA Protein	-	-	-	-	-	-
Influenza B HA Protein	-	-	-	-	-	-

LCOVADEV003

Concentration of Recombinant Proteins(μg/ml)	0	0.001	0.01	0.1	1	10
SARS-CoV-2 S1 Protein	-	-	+	++	+++	+++
SARS-CoV-2 S1 Protein(D614G)	-	+	+	++	+++	+++
SARS-CoV S1 Protein	-	-	-	-	-	-
HCoV-NL63 S1 Protein	-	-	-	-	-	-
HCoV-229E S1 Protein	-	-	-	-	-	-
HCoV-HKU1 S1 Protein	-	-	-	-	-	-
MERS-CoV S1 Protein	-	-	-	-	-	-
Human RSV (B1) G Protein	-	-	-	-	-	-
Influenza A H1N1 HA Protein	-	-	-	-	-	-
Influenza B HA Protein	-	-	-	-	-	-

5.4 Conclusion

The results show specific response to the S protein of SARS-CoV-2, and showed better specificity of some mutation novel coronavirus (such as D614G, the surface S protein increases, and the infection ability is enhanced) has increased. But it does not cross-react with other coronaviruses, such as SARS-CoV.

6. Interference test

6.1 Materials:

Reagent name and specifications	Lot 1	Lot 2	Lot 3
COVID-19 Antigen Rapid Test (Latex) 25T/Kit	LCOVADEV001	LCOVADEV002	LCOVADEV003

6.2 Method:

Spike negative sample and control product sample into buffer, respectively. Prepare the supernatant for subsequent use. Combined with the actual situation of clinical samples, potential interfering substances in positive and negative samples, includ Hemoglobin、unconjugated bilirubin、triglycerides are spiked in supernatant described above, respectively.

substance	concentration
Triglyceride	50mg/dl
Hemoglobin	1000mg/dl
Ascorbic Acid	20mg/dl
Bilirubin	60mg/dl

The concentration of these substances is greater than the concentrations listed in the following table, Mix the interference substance with samples (Negative, positive samples) and repeat the test three times for each sample. Then use each batch of kits for testing to verify the interference of these common potential interfering substances in the test results of the COVID-19 Antigen Rapid Test (Latex).

6.3 Results

According to the standard procedure of reagent use operation, the results are read in 15 minutes and repeated 3 times. The results are as follows ("+" indicates a positive result, "-" indicates a negative result):

Substance	Lot **1**					
	Negative			positive		
Triglyceride	-	-	-	+	+	+
Hemoglobin	-	-	-	+	+	+
Ascorbic Acid	-	-	-	+	+	+
Bilirubin	-	-	-	+	+	+
Substance	Lot **2**					
	Negative			positive		
Triglyceride	-	-	-	+	+	+
Hemoglobin	-	-	-	+	+	+
Ascorbic Acid	-	-	-	+	+	+

Bilirubin	-	-	-	+	+	+
Substance	Lot **3**					
	Negative			positive		
Triglyceride	-	-	-	+	+	+
Hemoglobin	-	-	-	+	+	+
Ascorbic Acid	-	-	-	+	+	+
Bilirubin	-	-	-	+	+	+

6.4 Conclusion

According to the results above, there are no obvious interference introduced by materials listed above to the COVID-19 Antigen Rapid Test (Latex).

7. Intra assay

7.1 Materials:

Reagent name and specifications	Lot 1	Lot 2	Lot 3
COVID-19 Antigen Rapid Test (Latex) 25T/Kit	LCOVADEV001	LCOVADEV002	LCOVADEV003

7.2 Method:

Use COVID-19 Antigen Rapid Test (Latex) product to detect the company's internal quality control products and negative specimen as the evaluation sample, each batch of reagents is tested 10 times and runed individually on 3 separate days repeatedly to see the intra-batch differences of each batch of reagents.

7.3 Results:

Follow the standard operating procedures for reagent use and read the results in 15 minutes. The results are as follows ("+" indicates a positive result, "-" indicates a negative result):

Day1 Operator 1

No.	LCOVADEV001				LCOVADEV002				LCOVADEV003			
	Negative N	Positive L	Positive M	Positive H	Negative N	Positive L	Positive M	Positive H	Negative N	Positive L	Positive M	Positive H
1	-	+	+	+	-	+	+	+	-	+	+	+
2	-	+	+	+	-	+	+	+	-	+	+	+
3	-	+	+	+	-	+	+	+	-	+	+	+
4	-	+	+	+	-	+	+	+	-	+	+	+
5	-	+	+	+	-	+	+	+	-	+	+	+
6	-	+	+	+	-	+	+	+	-	+	+	+
7	-	+	+	+	-	+	+	+	-	+	+	+
8	-	+	+	+	-	+	+	+	-	+	+	+

9	-	+	+	+	-	+	+	+	-	+	+	+
10	-	+	+	+	-	+	+	+	-	+	+	+
11	-	+	+	+	-	+	+	+	-	+	+	+
12	-	+	+	+	-	+	+	+	-	+	+	+
13	-	+	+	+	-	+	+	+	-	+	+	+
14	-	+	+	+	-	+	+	+	-	+	+	+
15	-	+	+	+	-	+	+	+	-	+	+	+
16	-	+	+	+	-	+	+	+	-	+	+	+
17	-	+	+	+	-	+	+	+	-	+	+	+
18	-	+	+	+	-	+	+	+	-	+	+	+
19	-	+	+	+	-	+	+	+	-	+	+	+
20	-	+	+	+	-	+	+	+	-	+	+	+

Day3 Operator 2

No.	LCOVADEV001				LCOVADEV002				LCOVADEV003			
	Negative N	Positive L	Positive M	Positive H	Negative N	Positive L	Positive M	Positive H	Negative N	Positive L	Positive M	Positive H
1	-	+	+	+	-	+	+	+	-	+	+	+
2	-	+	+	+	-	+	+	+	-	+	+	+
3	-	+	+	+	-	+	+	+	-	+	+	+
4	-	+	+	+	-	+	+	+	-	+	+	+
5	-	+	+	+	-	+	+	+	-	+	+	+
6	-	+	+	+	-	+	+	+	-	+	+	+
7	-	+	+	+	-	+	+	+	-	+	+	+
8	-	+	+	+	-	+	+	+	-	+	+	+
9	-	+	+	+	-	+	+	+	-	+	+	+
10	-	+	+	+	-	+	+	+	-	+	+	+
11	-	+	+	+	-	+	+	+	-	+	+	+
12	-	+	+	+	-	+	+	+	-	+	+	+
13	-	+	+	+	-	+	+	+	-	+	+	+
14	-	+	+	+	-	+	+	+	-	+	+	+
15	-	+	+	+	-	+	+	+	-	+	+	+
16	-	+	+	+	-	+	+	+	-	+	+	+
17	-	+	+	+	-	+	+	+	-	+	+	+
18	-	+	+	+	-	+	+	+	-	+	+	+
19	-	+	+	+	-	+	+	+	-	+	+	+
20	-	+	+	+	-	+	+	+	-	+	+	+

Day5 Operator 3

No.	LCOVADEV001				LCOVADEV002				LCOVADEV003			
	Negative N	Positive L	Positive M	Positive H	Negative N	Positive L	Positive M	Positive H	Negative N	Positive L	Positive M	Positive H
1	-	+	+	+	-	+	+	+	-	+	+	+
2	-	+	+	+	-	+	+	+	-	+	+	+
3	-	+	+	+	-	+	+	+	-	+	+	+
4	-	+	+	+	-	+	+	+	-	+	+	+
5	-	+	+	+	-	+	+	+	-	+	+	+
6	-	+	+	+	-	+	+	+	-	+	+	+
7	-	+	+	+	-	+	+	+	-	+	+	+
8	-	+	+	+	-	+	+	+	-	+	+	+
9	-	+	+	+	-	+	+	+	-	+	+	+
10	-	+	+	+	-	+	+	+	-	+	+	+
11	-	+	+	+	-	+	+	+	-	+	+	+
12	-	+	+	+	-	+	+	+	-	+	+	+
13	-	+	+	+	-	+	+	+	-	+	+	+
14	-	+	+	+	-	+	+	+	-	+	+	+
15	-	+	+	+	-	+	+	+	-	+	+	+
16	-	+	+	+	-	+	+	+	-	+	+	+
17	-	+	+	+	-	+	+	+	-	+	+	+
18	-	+	+	+	-	+	+	+	-	+	+	+
19	-	+	+	+	-	+	+	+	-	+	+	+
20	-	+	+	+	-	+	+	+	-	+	+	+

7.4 Conclusion

According to the results above, the intraassay precision of the product was no significant differences among the three batches of reagents.

8. Inter assay

8.1 Materials:

Reagent name and specifications	Lot 1	Lot 2	Lot 3
COVID-19 Antigen Rapid Test (Latex) 25T/Kit	LCOVADEV001	LCOVADEV002	LCOVADEV003

8.2 Method:

Use COVID-19 Antigen Rapid Test (Latex) product to detect the company's internal quality control products and negative specimen as the evaluation sample,the three batches of reagents were measured in parallel, and each quality control product was repeated 20 times to see the differences between the three batches of reagents.

8.3 Results

Follow the standard operating procedures for reagent use and read the results in 15 minutes. The results are as follows ("+" indicates a positive result, "-" indicates a negative result):

No.	Negative N			Positive L			Positive			Positive H		
	Lot 1	Lot2	Lot3	Lot 1	Lot 2	Lot3	Lo	Lo	Lo	Lo	Lo	Lo
1	-	-	-	+	+	+	+	+	+	+	+	+
2	-	-	-	+	+	+	+	+	+	+	+	+
3	-	-	-	+	+	+	+	+	+	+	+	+
4	-	-	-	+	+	+	+	+	+	+	+	+
5	-	-	-	+	+	+	+	+	+	+	+	+
6	-	-	-	+	+	+	+	+	+	+	+	+
7	-	-	-	+	+	+	+	+	+	+	+	+
8	-	-	-	+	+	+	+	+	+	+	+	+
9	-	-	-	+	+	+	+	+	+	+	+	+
10	-	-	-	+	+	+	+	+	+	+	+	+
11	-	-	-	+	+	+	+	+	+	+	+	+
12	-	-	-	+	+	+	+	+	+	+	+	+
13	-	-	-	+	+	+	+	+	+	+	+	+
14	-	-	-	+	+	+	+	+	+	+	+	+
15	-	-	-	+	+	+	+	+	+	+	+	+
16	-	-	-	+	+	+	+	+	+	+	+	+
17	-	-	-	+	+	+	+	+	+	+	+	+
18	-	-	-	+	+	+	+	+	+	+	+	+
19	-	-	-	+	+	+	+	+	+	+	+	+
20	-	-	-	+	+	+	+	+	+	+	+	+

8.4 Conclusion

According to the results above, the intraassay precision of the product was no significant differences among the three batches of reagents.