Performance Evaluation

Product Name: GenSure™ COVID-19 Antigen Rapid Test Kit

Chief Tester: Bing Qiao

Test company: Hebei GenSure Biotech Inc.,

Test start date: 2020.10.12

Test completion date: 2020.10.15

1. Performance Evaluation Plan

Objective

1. To evaluate the Read time of GenSure™ COVID-19 Antigen Rapid Test Kit
2. To study the Analytical Sensitivity of GenSure™ COVID-19 Antigen Rapid Test Kit
3. To study the Analytical Specificity of GenSure™ COVID-19 Antigen Rapid Test Kit
4. To study the Repeability of GenSure™ COVID-19 Antigen Rapid Test Kit
5. To evaluate the Clinical Performance of GenSure™ COVID-19 Antigen Rapid Test Kit
6. To study the Dose Hook Effect of GenSure™ COVID-19 Antigen Rapid Test Kit

2. Define and Work Principle of the Kit

The polymer immunochromatographic technology and double antibody sandwich principle were used to detect the novel coronavirus antigen in human nasal swab samples with the principle of capture method.

During the test, a sample solution is added to the sample well of the kit. The sample is first mixed with the colored polymer-labeled the novel coronavirus monoclonal antibody 1 on the release pad, and then chromatographed on a nitrocellulose membrane. If the sample contains novel coronavirus antigens, these antigens will first bind to colored polymer-labeled the novel coronavirus monoclonal antibody 1, so that when the mixture is chromatographed on a nitrocellulose membrane, it will be immobilized with the the novel coronavirus monoclonal antibody 2. The detection line (T line) was captured to form a colored polymer-labeled the novel coronavirus monoclonal antibody1-antigen- the novel coronavirus monoclonal antibody 2 immune complex. Therefore, a red line appeared on the T line, which was a positive result. If no novel coronavirus antigen is present in the nasal swab samples of the subject, a red line will not be formed on the test line (T line), which is a negative result. The quality control line (C line) on the test cassette is coated with goat anti-mouse antibody. Under normal circumstances, a red line should appear on the quality control line(C line) during the test to prove that the test cassette is working properly.

3. Function Specification of GenSure™ COVID-19 Antigen Rapid Test Kit

Examination Item	Result
Low Positive Control	+
Negative Control	-
Time for control line appearance	≤5 minutes
Background of the kit during the assay	Clear, and the flowing of the specimen is even.

4.Test Materials

4.1. Test kit: GenSure™ COVID-19 Antigen Rapid Test Kit

4.2. References: Prepared by our company according to the reference preparation method.

4.2.1. Positive references

The Positive Controls(P1~ P5) were SARS-CoV-2 positive samples.

4.2.2. Negative references

The Negative Controls(N1~ N10) were SARS-CoV-2 negative samples.

4.2.3. Repetitive references

The Repetitive Controls(R1~ R3) consisted of one negative control(N1), one minimum detection limit control(L3), and one positive control(P5).

4.2.4. Limit of Detection (LoD) references

The Limit of Detection (LoD) Controls(L1~ L3).

4.3. Inactivated novel coronavirus strain, the virus concentration is 3.6 x 10^5 $TCID_{50}$/mL.

5.Test Procedure

5.1. Specimen Collection and Preparation

5.1.1 The applicable sample type for this test kit is nasal swab.

5.1.2 The nasal swabs are drawn according to the standard clinical laboratory method: Insert the polypropylene fiber head / synthetic flocking head plastic rod swab into one nostril of the patient. The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected, then repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities. Withdraw the swab from the nasal cavity.

5.1.3 Specimens that can be detected within 24 hours can be stored at 4 ℃; specimens that cannot be detected within 24 hours should be stored at - 70 ℃ or below (if there is no - 70 ℃ storage condition, they should be temporarily stored in - 20 ℃ refrigerator).

Please do not use long bacteria, long time or repeatedly frozen and thawed samples to avoid pollution or non-specific reaction caused by long bacteria.

5.1.4 The sample must be returned to room temperature before testing.

5.2 Test Procedure

5.2.1 Please read the instruction manual carefully before testing.

5.2.2 Take out the test cassette, test specimen, etc., and use it after returning to room temperature. When everything is ready, tear off the aluminum foil bag, remove the test cassette and place it on the platform. After opening the aluminum foil bag, the test cassette should be used as soon as possible within 1 hour. The specimen extraction buffer should be capped immediately after opening.

5.2.3 Specimen solution preparation:

a. Gently mix specimen extraction buffer. Add 12 drops of specimen extraction buffer into the specimen processing tube;

b. Insert the swab into the extraction tube. Mix well and squeeze the swab 10-15 times by compressing the walls of the tube against the swab;

c.Squeezing the sides of the tube as you remove it. Try to release as much liquid as possible. Dispose of the used swab in accordance with your biohazard waste disposal protocol;

d. Insert dripper into specimen processing tube.

5.2.4 Sample adding: Put the tip of the sample processing tube straight down, then squeeze the sides of the tube, so that the sample drips out from the tube. Add 2~3 drops of sample solution to the sample adding hole of the cassette, and wait for the result to appear.

5.2.5 Timing observation: judge the result 15 minutes after sample adding, do not observe the result 20 minutes later.

6. Responsibilities

6.1. Coordinator of performance evaluation is responsible for overall process of the performance evaluation, and assures that adequate resources are available, and appropriately review the study.

6.2. Quality Assurance is responsible for ensuring that all processes of performance evaluation are identified and validated.

6.3. The manufacturing and Quality Control Department is responsible for developing and routing performance evaluation protocols, conducting the actual performance evaluation activity, and writing and routing performance evaluation records. This activity will be performed under the guidance of coordinator of performance evaluation, quality assurance, and quality control. Input and support form various departments (Research and Development Department) will be solicited on as needed basis.

6.4. The validation Committee is responsible for determining all process requiring validation and documenting decisions not to validate. The committee will also review and approve all validation protocols and reports. The Validation Committee will consist of, at minimum, the heads of Quality Assurance, Quality Control, and manufacturing.

7. Note:All the tests were performed according to the instruction insert.

8. Read Time Study

8.1 Objective: To evaluate the read time of the GenSure™ COVID-19 Antigen Rapid Test Kit

8.2 Materials:

8.2.1 GenSure™ COVID-19 Antigen Rapid Test Kit：

LOT P2005005, LOT P2005006, LOT P2005007

8.2.2 Samples:

Sample extraction:lot 2001005

Positive control number: P1,lot 2001006

Negative control number: N1,lot 2001011

8.2.3 Methods: The above three lot devices were run by the above 3 samples in five times repeatedly. The test results were read visually as positive or negative at 1, 2, 4, 6, 8, 10, 12, 15, 18, 20,25,30 minutes.

Results:

Lot 1: P2005005

	buffer					Negative control					Positive control				
	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
1 min	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
2 min	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
4 min	—	—	—	—	—	—	—	—	—	—	+	—	—	—	—
6 min	—	—	—	—	—	—	—	—	—	—	+	+	—	—	+
8 min	—	—	—	—	—	—	—	—	—	—	+	+	+	+	+
10 min	—	—	—	—	—	—	—	—	—	—	+	+	+	+	+
12 min	—	—	—	—	—	—	—	—	—	—	+	+	+	+	+
15 min	—	—	—	—	—	—	—	—	—	—	+	+	+	+	+
18 min	—	—	—	—	—	—	—	—	—	—	+	+	+	+	+
20 min	—	—	—	—	—	—	—	—	—	—	+	+	+	+	+
25 min	—	—	—	—	—	—	+	—	—	—	+	+	+	+	+
30 min	—	—	—	—	—	—	+	—	+	—	+	+	+	+	+

Lot 2: P2005006

	buffer					Negative control					Positive control				
	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
1 min	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
2 min	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
4 min	—	—	—	—	—	—	—	—	—	—	—	+	—	—	—
6 min	—	—	—	—	—	—	—	—	—	—	—	+	—	+	+
8 min	—	—	—	—	—	—	—	—	—	—	+	+	+	+	+
10 min	—	—	—	—	—	—	—	—	—	—	+	+	+	+	+
12 min	—	—	—	—	—	—	—	—	—	—	+	+	+	+	+
15 min	—	—	—	—	—	—	—	—	—	—	+	+	+	+	+
18 min	—	—	—	—	—	—	—	—	—	—	+	+	+	+	+
20 min	—	—	—	—	—	—	—	—	—	—	+	+	+	+	+
25 min	—	—	—	—	—	—	—	+	—	+	+	+	+	+	+
30 min	—	—	—	—	—	—	—	+	—	+	+	+	+	+	+

Lot3: P2005007

	buffer					Negative control					Positive control				
	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
1 min	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
2 min	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
4 min	—	—	—	—	—	—	—	—	—	—	—	+	—	—	—
6 min	—	—	—	—	—	—	—	—	—	—	—	+	+	+	—
8 min	—	—	—	—	—	—	—	—	—	—	—	+	+	—	—
10 min	—	—	—	—	—	—	—	—	—	—	—	+	+	+	—
12 min	—	—	—	—	—	—	—	—	—	—	+	+	+	+	—
15 min	—	—	—	—	—	—	—	—	—	—	+	+	+	+	+
18 min	—	—	—	—	—	—	—	—	—	—	+	+	+	+	+
20 min	—	—	—	—	—	—	—	—	—	+	+	+	+	+	+
25 min	—	—	—	—	—	—	+	—	—	+	+	+	+	+	+
30 min	—	—	—	—	—	+	+	—	—	+	+	+	+	+	+

Conclusion:

The result of this study demonstrated that the devices could give correct result after 15 minutes. The results were consistent in the three different lots. And because the background of the device was sometime not clear after 20 minutes, we defined the test result should be read within 15 to 10 minutes.

9. Analytical Sensitivity (LoD) Study

9.1 Objective: To study the analytical sensitivity of the GenSure™ COVID-19 Antigen Rapid Test Kit.

9.2 Materials:

9.2.1 GenSure™ COVID-19 Antigen Rapid Test Kit：

LOT P2005005, LOT P2005006, LOT P2005007

9.2.2 Inactivated novel coronavirus strain, the virus concentration is 3.6 x 10^5 $TCID_{50}$/mL.

9.3 Method

9.3.1 Limit of Detection (LoD) Screening

Take the inactivated novel coronavirus (concentration 3.6×10^5 $TCID_{50}$/mL) and use the extract of the negative nasal swab sample as the clinical matrix diluent of the virus for serial dilution, and use three batches of kits to test the above samples. Each batch of the kit was detected 5 tests in parallel, and the test results are shown in the table below.

Lot P2005005

Virus Concentration（$TCID_{50}$/mL）	Dilution Factor	GenSure™ COVID-19 Antigen Rapid Test Kit				
		1	2	3	4	5
3.6×10^5	1x	+++	+++	+++	+++	+++
3.6×10^4	10x	+++	+++	+++	+++	+++
3.6×10^3	10^2x	++	++	++	++	++
3.6×10^2	10^3x	++	++	++	++	++
50	7.2×10^3x	+	+	+	+	+
10	3.6×10^4x	-	-	-	-	-

P2005006

Virus Concentration（$TCID_{50}$/mL）	Dilution Factor	GenSure™ COVID-19 Antigen Rapid Test Kit				
		1	2	3	4	5
3.6×10^5	1x	+++	+++	+++	+++	+++
3.6×10^4	10x	+++	+++	+++	+++	+++
3.6×10^3	10^2x	++	++	++	++	++
3.6×10^2	10^3x	++	++	++	++	++
50	7.2×10^3x	+	+	+	+	+
10	3.6×10^4x	-	-	-	-	-

P2005007

Virus Concentration（$TCID_{50}$/mL）	Dilution Factor	GenSure™ COVID-19 Antigen Rapid Test Kit				
		1	2	3	4	5
3.6×10^5	1x	+++	+++	+++	+++	+++
3.6×10^4	10x	+++	+++	+++	+++	+++
3.6×10^3	10^2x	++	++	++	++	++
3.6×10^2	10^3x	++	++	++	++	++

50	7.2×10^3x	+	+	+	+	+
10	3.6×10^4x	-	-	-	-	-

It can be seen from the above experimental results that when the virus solution with a concentration of 3.6×10^5 $TCID_{50}$/mL is diluted 7.2×10^3 times (50 $TCID_{50}$/mL) by the negative clinical matrix diluent, the GenSure™ COVID-19 Antigen Rapid Test Kit can detect a positive result. Therefore, the virus solution with a concentration of 3.6×10^5 $TCID_{50}$/mL is diluted by 7.2×10^3 times (50 $TCID_{50}$/mL) as the LoD Range finding of the GenSure™ COVID-19 Antigen Rapid Test Kit.

9.3.2 Limit of Detection (LoD) Range Finding

Use the extract of the negative nasal swab sample as the clinical matrix diluent of the virus to perform several gradient dilutions of the novel coronavirus inactivated at a dilution factor of 7.2×10^3 times (50 $TCID_{50}$/mL), and test three batches of kits for each concentration. Repeat the test 20 times, with the lowest concentration with 95% positive detection rate as the Limit of Detection. The test results are shown in the table below.

P2005005

Detection times	GenSure™ COVID-19 Antigen Rapid Test Kit				
Virus Concentration（$TCID_{50}$/mL）	200	100	50	25	10
1	Positive	Positive	Positive	Positive	Negative
2	Positive	Positive	Positive	Positive	Negative
3	Positive	Positive	Positive	Positive	Negative
4	Positive	Positive	Positive	Positive	Negative
5	Positive	Positive	Positive	Positive	Negative
6	Positive	Positive	Positive	Positive	Negative
7	Positive	Positive	Positive	Positive	Positive
8	Positive	Positive	Positive	Negative	Negative
9	Positive	Positive	Positive	Positive	Negative
10	Positive	Positive	Positive	Positive	Negative
11	Positive	Positive	Positive	Positive	Positive
12	Positive	Positive	Positive	Positive	Negative
13	Positive	Positive	Positive	Positive	Negative
14	Positive	Positive	Positive	Positive	Negative
15	Positive	Positive	Positive	Positive	Negative
16	Positive	Positive	Positive	Negative	Negative
17	Positive	Positive	Positive	Positive	Negative
18	Positive	Positive	Positive	Positive	Negative
19	Positive	Positive	Positive	Positive	Negative
20	Positive	Positive	Positive	Positive	Negative
Positive detection rate	100%	100%	100%	90%	10%

P2005006

Detection times	GenSure™ COVID-19 Antigen Rapid Test Kit				
Virus Concentration ($TCID_{50}$/mL)	200	100	50	25	10
1	Positive	Positive	Positive	Positive	Negative
2	Positive	Positive	Positive	Positive	Negative
3	Positive	Positive	Positive	Positive	Negative
4	Positive	Positive	Positive	Positive	Negative
5	Positive	Positive	Positive	Positive	Negative
6	Positive	Positive	Positive	Positive	Negative
7	Positive	Positive	Positive	Positive	Negative
8	Positive	Positive	Positive	Positive	Negative
9	Positive	Positive	Positive	Positive	Negative
10	Positive	Positive	Positive	Positive	Negative
11	Positive	Positive	Positive	Positive	Negative
12	Positive	Positive	Positive	Negative	Negative
13	Positive	Positive	Positive	Positive	Negative
14	Positive	Positive	Positive	Positive	Negative
15	Positive	Positive	Positive	Positive	Negative
16	Positive	Positive	Positive	Positive	Positive
17	Positive	Positive	Negative	Positive	Negative
18	Positive	Positive	Positive	Positive	Negative
19	Positive	Positive	Positive	Positive	Negative
20	Positive	Positive	Positive	Positive	Negative
Positive detection rate	100%	100%	95%	95%	5%

P2005007

Detection times	GenSure™ COVID-19 Antigen Rapid Test Kit				
Virus Concentration ($TCID_{50}$/mL)	200	100	50	25	5
1	Positive	Positive	Positive	Positive	Negative
2	Positive	Positive	Positive	Positive	Positive
3	Positive	Positive	Positive	Positive	Negative
4	Positive	Positive	Positive	Positive	Negative
5	Positive	Positive	Positive	Positive	Negative
6	Positive	Positive	Positive	Positive	Negative
7	Positive	Positive	Positive	Positive	Positive
8	Positive	Positive	Positive	Positive	Negative

9	Positive	Positive	Positive	Positive	Negative
10	Positive	Positive	Positive	Negative	Negative
11	Positive	Positive	Positive	Positive	Negative
12	Positive	Positive	Positive	Positive	Negative
13	Positive	Positive	Positive	Positive	Positive
14	Positive	Positive	Positive	Positive	Negative
15	Positive	Positive	Positive	Positive	Negative
16	Positive	Positive	Positive	Positive	Negative
17	Positive	Positive	Positive	Positive	Negative
18	Positive	Positive	Positive	Negative	Negative
19	Positive	Positive	Positive	Positive	Negative
20	Positive	Positive	Positive	Positive	Negative
Positive detection rate	100%	100%	100%	90%	15%

According to the above test, the Limit of Detection for this product is 50 $TCID_{50}$/mL.

9.3.3 Limit of Detection (LoD) Confirmation

Three batches of test kits were used to test the samples with the LoD concentration determined above, and each batch of product was tested in parallel for 3 tests. The results are shown in the following table.

Batch No.	LoD reference	Test Number	Test Result		
			1	2	3
P2005005	Virus strain LoD reference	3	Positive	Positive	Positive
P2005006	Virus strain LoD reference	3	Positive	Positive	Positive
P2005007	Virus strain LoD reference	3	Positive	Positive	Positive

The test results showed that three consecutive batches of products were tested with the LoD reference material, and the test results were all positive, which met the product quality requirements.

10. Analytical Specificity Study

10.1 Cross-Reactivity

10.1.1 Objective: To study cross-reactivity of the GenSure™ COVID-19 Antigen Rapid Test Kit

10.1.2 Method: Add a certain concentration of pathogen (see "Pathogen Name" in the cross-reaction test results) to the sample of normal people. Use three batches of kits to test the above samples, and record the test results in the table below

P2005005

Pathogen Name	Concentration	10 normal human samples or test results after adding pathogens									
		1#	2#	3#	4#	5#	6#	7#	8#	9#	10#
Normal human	/	-	-	-	-	-	-	-	-	-	-

samples											
Influenza A (H1N1, H3N2)	1.0 x 10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-	-
Avian influenza (H5N1, H7N9)	1.7 x 10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-	-
Influenza B (Victoria, Yamagata)	2.5 x 10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-	-
Respiratory Syncytial Virus	3.8 x 10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-	-
Rhinovirus	1.4 x 10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-	-
Adenovirus	1.1 x 10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-	-
Measles virus	1.0 x 10^6 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-	-
Human coronavirus (OC43, 229E, NL63)	1.0 x 10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-	-
MERS coronavirus	1.2 x 10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-	-
Mycoplasma pneumoniae	1.0 x 10^6 CFU/mL	-	-	-	-	-	-	-	-	-	-

P2005006

Pathogen Name	Concentration	10 normal human samples or test results after adding pathogens									
		1#	2#	3#	4#	5#	6#	7#	8#	9#	10#
Normal human samples	/	-	-	-	-	-	-	-	-	-	-
Influenza A (H1N1, H3N2)	1.0 x 10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-	-
Avian influenza (H5N1, H7N9)	1.7 x 10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-	-
Influenza B (Victoria, Yamagata)	2.5 x 10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-	-
Respiratory Syncytial Virus	3.8 x 10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-	-
Rhinovirus	1.4 x 10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-	-
Adenovirus	1.1 x 10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-	-

Measles virus	1.0 x 10^6 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-	-
Human coronavirus (OC43, 229E, NL63)	1.0 x 10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-	-
MERS coronavirus	1.2 x 10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-	-
Mycoplasma pneumoniae	1.0 x 10^6 CFU/mL	-	-	-	-	-	-	-	-	-	-

P2005007

Pathogen Name	Concentration	10 normal human samples or test results after adding pathogens									
		1#	2#	3#	4#	5#	6#	7#	8#	9#	10#
Normal human samples	/	-	-	-	-	-	-	-	-	-	-
Influenza A (H1N1, H3N2)	1.0 x 10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-	-
Avian influenza (H5N1, H7N9)	1.7 x 10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-	-
Influenza B (Victoria, Yamagata)	2.5 x 10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-	-
Respiratory Syncytial Virus	3.8 x 10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-	-
Rhinovirus	1.4 x 10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-	-
Adenovirus	1.1 x 10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-	-
Measles virus	1.0 x 10^6 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-	-
Human coronavirus (OC43, 229E, NL63)	1.0 x 10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-	-
MERS coronavirus	1.2 x 10^5 $TCID_{50}$/mL	-	-	-	-	-	-	-	-	-	-
Mycoplasma pneumoniae	1.0 x 10^6 CFU/mL	-	-	-	-	-	-	-	-	-	-

The test results show that the above-mentioned common pathogens that easily cause the cross-reaction of the novel coronavirus are added to 10 normal human samples, and the GenSure™ COVID-19 Antigen Rapid Test Kit is used to carry out the above samples. The test results of each sample were all negative, and the average inhibition rate = 0.

In summary, there is no cross-reaction between common clinical pathogens and this test kit, and does not affect the detection performance of this product. This product has good analytical

specificity.

10.2 Interference Study

10.2.1 Objective: To study the interference of the related substances to the GenSure™ COVID-19 Antigen Rapid Test Kit

10.2.2 Materials:

10.2.2.1 GenSure™ COVID-19 Antigen Rapid Test Kit：

LOT P2005005, LOT P2005006, LOT P2005007

10.2.2.2 The Negative Control: N1,lot 2001011

10.2.3 Methods: The following substances were used to test the interference of GenSure™ COVID-19 Antigen Rapid Test Kit. The substances were spiked into the above negative controls and tested by GenSure™ COVID-19 Antigen Rapid Test Kit in duplicate.

Selected analytes:

Selected Analyte	Concentration
Purified mucin	10mg/ml
ribavirin	2.0mg/ml
Oseltamivir	375 μ g /L
Azithromycin	0.15g/L
Tobramycin	0.125 mg/mL
Sodium chloride	0.90%
Levofloxacin	5 ug/ml
Interferon alpha	3000000U
Meropenem	1ug/ml
Pa Rami Vee	20 ug/ml
Cefatriaxone	100mg/ml
Beclomethasone	200ug/L
Budesonide	0.64nmol/L
Oxazole	500ug/ml
Hemoglobin	25g/L
Bilirubin	200mg/L
Triglyceride	2500mg/L

Results:

Lot / Selected Analyte	P2005005	P2005006	P2005007
Purified mucin	-	-	-
ribavirin	-	-	-
Oseltamivir	-	-	-

Azithromycin	-	-	-
Tobramycin	-	-	-
sodium chloride	-	-	-
Levofloxacin	-	-	-
Interferon alpha	-	-	-
Meropenem	-	-	-
Pa Rami Vee	-	-	-
Cefatriaxone	-	-	-
Beclomethasone	-	-	-
Budesonide	-	-	-
Oxazole	-	-	-
Hemoglobin	-	-	-
Bilirubin	-	-	-
Triglyceride	-	-	-

Conclusion:No materials above interferes the kits' results at the concentrations tested.

11.Repeability (Intra-Batch and Inter-Batch Difference) Study

11.1 Objective: To evaluate intra-batch and inter-batch difference of the GenSure™ COVID-19 Antigen Rapid Test Kit

11.2 Materials:

11.2.1 GenSure™ COVID-19 Antigen Rapid Test Kit：

LOT P2005005, LOT P2005006, LOT P2005007

11.2.2 The Negative Controls: N1~N10,lot 2001011

The Positive Controls:P1~P5,lot 2001006

11.2.3 Method: All above negative controls will be tested in 10 replicates with each lot and positive controls wil be tested 5 replicates to examine whether they are consistency in characteristic. The test results are shown in the table below.

P2005005 Negative controls

Sample	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10
n=10										
Number of Positive	0	0	0	0	0	0	0	0	0	0
Number of Negative	10	10	10	10	10	10	10	10	10	10

P2005005 Positive controls

Sample	P1	P2	P3	P4	P5
n=10					

Number of Positive	10	10	10	10	10
Number of Negative	0	0	0	0	0

P2005006 Negative controls

Sample	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10
n=10										
Number of Positive	0	0	0	0	0	0	0	0	0	0
Number of Negative	10	10	10	10	10	10	10	10	10	10

P2005006 Positive controls

Sample	P1	P2	P3	P4	P5
n=10					
Number of Positive	10	10	10	10	10
Number of Negative	0	0	0	0	0

P2005007 Negative controls

Sample	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10
n=10										
Number of Positive	0	0	0	0	0	0	0	0	0	0
Number of Negative	10	10	10	10	10	10	10	10	10	10

P2005007 Positive controls

Sample	P1	P2	P3	P4	P5
n=10					
Number of Positive	10	10	10	10	10
Number of Negative	0	0	0	0	0

Conclusion: According to the test results, there is no obvious difference between lot to lot and between test and test.

12. Clinical Studies

12.1 Objective: To evaluate the clinical performance of the GenSure™ COVID-19 Antigen Rapid Test Kit with the commercially available device.

12.2 Materials:

12.2.1 GenSure™ COVID-19 Antigen Rapid Test Kit，LOT P2005005

12.2.2 Samples: 548 selected samples of virus colletion solution from CDC.

12.3 Method: The 548 samples were assayed by the GenSure™ COVID-19 Antigen Rapid Test Kit in parallel with commercial available SARS-CoV-2 molecular test kit. This evaluation was run as a blind study. Samples were randomized and tested. The results were read within 15 minutes.

Total	**Ct Value of PCR**	Number case	negative	positive
548	Ct ≤20	46	0	46

	Ct [20-25]	85	1	84
	Ct [25-30]	48	1	47
	Ct [30-33]	12	4	8
	Ct＞33	357	357	0

		SARS-CoV-2 Molecular		Total	PPV	NPV
		Positive	Negative			
GenSure™ COVID-19 Antigen Rapid Test Kit	Positive	185	0	185	100.00%	98.35%
	Negative	6	357	363		
Total		191	357	548		
Sensitivity		96.86% (95% CI= 93.29% ~ 98.84%)				
Specificity		100.00% (95% CI= 98.97% ~ 100.00%)				
Total Coincidence Rate		98.91% (95% CI= 97.63% ~ 99.60%)				

Result: The sensitivity of GenSure™ COVID-19 Antigen Rapid Test Kit is 96.86% (95% CI= 93.29% ~ 98.84%), the specificity is 100.00% (95% CI= 98.97% ~ 100.00%), and the total coincidence rate is 98.91% (95% CI= 97.63% ~ 99.60%).

13. Dose Hook Effect Study:

13.1 Objective: To evaluate potential dose hook effect for GenSure™ COVID-19 Antigen Rapid Test Kit

13.2 Materials:

13.2.1 GenSure™ COVID-19 Antigen Rapid Test Kit

LOT P2005005, LOT P2005006, LOT P2005007

13.2.2 Inactivated novel coronavirus strain, the virus concentration is 3.6 x 10^5 $TCID_{50}$/mL.

13.3 Method:

Three batches of test kits were used to test virus samples with a concentration of 3.6×10^5 $TCID_{50}$/mL, and each sample was tested in parallel for 3 times. The results are shown in the table.

Batch No.	Virus Concentration	1	2	3
P2005005	3.6×$10^5$$TCID_{50}$/mL	+++	+++	+++
	3.6×$10^4$$TCID_{50}$/mL	+++	+++	+++
	3.6×$10^3$$TCID_{50}$/mL	++	++	++
P2005006	3.6×$10^5$$TCID_{50}$/mL	+++	+++	+++
	3.6×$10^4$$TCID_{50}$/mL	+++	+++	+++
	3.6×$10^3$$TCID_{50}$/mL	++	++	++
P2005007	3.6×$10^5$$TCID_{50}$/mL	+++	+++	+++
	3.6×$10^4$$TCID_{50}$/mL	+++	+++	+++
	3.6×$10^3$$TCID_{50}$/mL	++	++	++

Conclusion: No high dose hook effect was observed up to 3.6 x 10^5 $TCID_{50}$/mL from SARS-CoV-2 with the GenSure™ COVID-19 Antigen Rapid Test Kit.

17. Reference

Registration of technical review points of SARS-CoV-2 (palingenesis)

18. Note

All the above data are only responsible for the test samples. Because there are differences in the course of disease and individuals, and will be affected by other factors, the specific test results will vary.