Performance Study Report

<Product name: SARS-CoV-2 Antigen Test Cassette >

<Status: Controlled>

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Date	2021.12.22	**Date**	2021.12.22

Applicant: Jiangsu Mole Bioscience Co., Ltd.

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1. Introduction

This test cassette is only used for in vitro qualitative detection of SARS-CoV-2 antigen in human nasopharyngeal, nasal swabs and saliva specimens within 14 days after clinical symptoms. The test cassette is intended for screening of patients suspected for infection with SARS-CoV-2, and as an aid in the diagnosis of the coronavirus disease (COVID-19).

In order to investigate its appearance, physical properties, migration velocity, negative coincidence rate, positive coincidence rate, sensitivity, repeatability(precision), specificity, cross reactivity, interfering substances and limit of detection (LOD), the following tests are carried out according to the requirements of inspection procedure of this product.

2. Information of SARS-CoV-2 Antigen Test Cassette

Three batches of SARS-CoV-2 Antigen Test Cassette were produced by Jiangsu Mole Bioscience Co. Ltd. Batch numbers are M0120101, M0120105, M0120107. The following table shows the components of the test cassette.

Table 1 Main components of the Test Cassette

Components	Usage
SARS-CoV-2-NP antibody	Applied to the nitrocellulose membrane in the test area
Goat anti rabbit Ig G polyclonal antibody	Applied to the nitrocellulose membrane in the control area
SARS-CoV-2 monoclonal antibody Colloidal gold conjugate	Applied to the conjugate pad

Packaging Size: 20 Tests/Pack.

3. Quality Inspection Standards

3.1 Appearance

The appearance should be smooth, materials should be firmly attached and the components should be complete.

3.2 Physical Inspection

The width of the test strip is 3.0±0.1mm, and the volume of the sample extraction solution is not less than 12mL (20 Test).

3.3 Migration Velocity

The migration velocity should not be less than 10mm/min.

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3.4 Sensitivity

(1) Sensitivity References Test

Three reference solutions were used for testing, the detection results of three SARS-CoV-2 antigen sensitivity references (S1, S2, S3) require that the reference S1 must be tested as negative, and the references S2 and S3 should be tested as positive.

(2) Clinical Sensitivity

SARS-Cov-2 Antigen Test Cassette and the SARS-CoV-2 detection kit (RT-PCR method) were used to test the same sample to determine its clinical sensitivity.

3.5 Negative Coincidence Rate

Ten SARS-CoV-2 antigen negative references (N1-N10) were tested with the three batches of products, and all test results should be negative.

3.6 Positive Coincidence Rate

Test Five SARS-CoV-2 antigen positive references (P1-P5) were tested with three batches of products, and all the test results should be positive.

3.7 Repeatability (Precision)

The test of samples from three batches of products was repeated 10 times via using the same reference solution (R) and positive solution with different concentrations (P1, P2). The color density of the test line should be uniform and consistent. The test results of negative solution should be all negative and the test results of positive solution should be all positive.

3.8 Specificity

(1) Specificity Testing with Strains

Following strains at specified concentrations were spiked onto swabs (or saliva specimen) and tested according to the Instruction for Use. Read the results at 15 minutes. Results should all be negative.

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Table 2 Specificity Testing with Strains

Description	Concentration
Human coronaviruses 229E	2.35 x 10^6 $TCID_{50}$/ml
Human Coronavirus OC43	2.45 × 10^6 $TCID_{50}$/ml
Coronavirus NL63	1 × 10^5 $TCID_{50}$/ml
Influenza A H1N1	3.16 × 10^5 $TCID_{50}$/ml
Influenza A H3N2	1 x 10^5 $TCID_{50}$/ml
Influenza B	1 ×10^5 $TCID_{50}$/ml
Human Rhinovirus 2	2.81× 10^4 $TCID_{50}$/ml
Human Rhinovirus 14	1.58 x 10^6 $TCID_{50}$/ml
Human Rhinovirus 16	8.89 x 10^6 $TCID_{50}$/ml
Measles virus	1.58x 10^4 $TCID_{50}$/ml
Adenovirus 3	1.58 x 10^4 $TCID_{50}$/ml
Parainfluenza virus 2	1.58 x 10^6 $TCID_{50}$/ml
Parainfluenza virus 3	1.58 x 10^7 $TCID_{50}$/ml
Respiratory syncytial virus	8.89 x 10^4 $TCID_{50}$/ml

(2) Clinical Specificity

Use the SARS-Cov-2 Antigen Test Cassette and the SARS-CoV-2 detection kit (RT-PCR method) to test the same sample to determine its clinical specificity.

3.9 Cross Reactivity

Substances in different concentrations were spiked onto swabs (saliva specimens) and tested according to the Instruction for Use in triplicate. Read results at 15 minutes. Results should be negative.

Table 3 Cross reaction substances

Substances	Concentration
Arcanobacterium bernardiae	1×10^7 CFU/ml
Arcanobacterium haemolyticum	1×10^7 CFU/ml
Candida albicans	1×10^7 CFU/ml
Corynebacterium	1×10^7 CFU/ml
Moraxella catarrhalis	1×10^7 CFU/ml
Neisseria lactamica	1×10^7 CFU/ml
Pseudomonas aeruginosa	1×10^7 CFU/ml
Staphylococcus aureus subspaureus	1×10^7 CFU/ml
Influenza B (Yamagata and Victoria) virus	3.16 × 10^6 $TCID_{50}$/ml
Human Rhinovirus 2	2.81× 10^4 $TCID_{50}$/ml
Human Rhinovirus 14	1.58 × 10^6 $TCID_{50}$/ml
Human Rhinovirus 16	8.89 × 10^6 $TCID_{50}$/ml
Measles virus	1.58 × 10^4 $TCID_{50}$/ml
Adenovirus 3	1.58 × 10^4 $TCID_{50}$/ml
Human coronaviruses 229E	2.35 x 10^6 $TCID_{50}$/ml
Staphylococcus epidermidis	1×10^7 CFU/ml
Streptococcus pneumoniae	1×10^7 CFU/ml
Streptococcus salivarius	1×10^7 CFU/ml
Streptococcus sp. Group F	1×10^7 CFU/ml
Human Coronavirus OC43	2.45 x 10^6 $TCID_{50}$/ml
Coronavirus NL63	1 × 10^5 $TCID_{50}$/ml
Influenza A H1N1	3.16 × 10^5 $TCID_{50}$/ml
Influenza A H3N2	1 ×10^5 $TCID_{50}$/ml
Parainfluenza virus 2	1.58 x $10^6$$TCID_{50}$/ml
Parainfluenza virus 3	1.58 x $10^7$$TCID_{50}$/ml
Respiratory syncytial virus	8.89 × 10^4 $TCID_{50}$/ml

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MERS-coronavirus	10^5 PFU/ml
Epstein-Barr virus	10^5 PFU/ml
human metapneumovirus (hMPV)	$2.25x10^5$ $TCID_{50}$/ml
Coronavirus HKU1	1 $x10^5$ $TCID_{50}$/ml

3.10 Interfering Substances

We use the substances in the table to perform interference experiments. Repeat the test three times for each batch of the test cassette. The results should be negative.

Table 4 Interfering substances

Analytes	Concentration
Whole Blood	20μl/ml
Mucin	50μg/ml
Budesonide Nasal Spray	200μl/ml
Dexamethasone	0.8mg/ml
Flunisolide	6.8ng/ml
Mupirocin	12mg/ml
Oxymetazoline	0.6mg/ml
Phenylephrine	12mg/ml
Sterimar Nasal Spray (Saline)	1:1 (V/V)
Relenza	282ng/ml
Tamiflu	1.1μg/ml
Tobramycin	2.43mg/ml
Naso Gel	5% (V/V)
CVS Nasal Spray(Cromolyn)	15% (V/V)

3.11 Determination of Limit of detection (LoD, analytical sensitivity)

To determine the limit of detection, a recombine SARS-CoV-2 nucleocapsid protein was diluted to a series of concentrations, comparing with the SARS-CoV-2 virus (inactivated). The assays were performed according to the Instruction for Use.

4. Performance Evaluation

4.1 Appearance

The appearance of 3 batches test cassette were smooth, and materials were firmly attached and the components were complete.

4.2 Physical Inspection

4.2.1 The width of Test Strip

Measure the width of the test strip with vernier caliper, and the results are shown in the following table:

Table 5 Test results

Batches	M0120101			M0120105			M0120107		
Repeat	1	2	3	1	2	3	1	2	3
Strip Width (mm)	3.01	2.98	3.04	2.96	2.96	3.02	3.00	2.99	2.99

Conclusion: The results of experiments showed that the width of the test strip of the SARS-CoV-2 Antigen Test

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Cassette is (3.0±0.1) mm.

4.2.2 The Volume of The Sample Extraction Solution

Use a calibrated graduated cylinder to measure the volume of the sample extraction solution, and the results are shown in the following table:

Table 6 Test results

Batches	M0120101			M0120105			M0120107		
Repeat	1	2	3	1	2	3	1	2	3
Volume (mL)	12.8	12.6	13.4	12.7	12.9	13.0	12.8.0	13.0	12.7

Conclusion: The results of experiments showed that the volume of the sample extraction solution is not less than 12mL.

4.3 Migration Velocity

Take three test cards from each of the three batches of Test Cassette, drop the sample extraction solution into the sampling well and start timing with a timer. Stop timing when the liquid enters the upper edge of the observation window (test area). Record the time taken as T (min), and the distance from the center of the sample well to the upper edge of the observation window as S (mm). The migration velocity is equal to S/T, which should be not less than 10mm/min.

Table 7 Test results

Batches	M0120101			M0120105			M0120107		
	1	2	3	1	2	3	1	2	3
Migration distance(mm)	33	35	32	31	32	34	32	32	32
Migration time(s)	34	33	32	30	33	32	34	33	33
Migration velocity (mm/min)	58.2	63.6	60.0	62.0	58.2	63.75	56.5	58.2	58.2

Conclusion: The results of experiments show that the migration velocity of the SARS-CoV-2 Antigen Test Cassette is not less than 10mm/min.

4.4 Sensitivity

(1) Results of The References Test

Repeatedly test the three batches of Test Cassettes with sensitivity references (S1, S2, and S3) for 3 times respectively, and interpret the results within 15 to 20 minutes. The results are shown in the following tables.

Table 8 The Nasopharyngeal swab test results

Batches	M0120101			M0120105			M0120107		
	1	2	3	1	2	3	1	2	3
S1	—	—	—	—	—	—	—	—	—
S2	+	+	+	+	+	+	+	+	+
S3	+	+	+	+	+	+	+	+	+

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Table 9 The Nasal swab test results

Batches	M0120101			M0120105			M0120107		
	1	2	3	1	2	3	1	2	3
S1	—	—	—	—	—	—	—	—	—
S2	+	+	+	+	+	+	+	+	+
S3	+	+	+	+	+	+	+	+	+

Table 10 Saliva specimen test results

Batches	M0120101			M0120105			M0120107		
	1	2	3	1	2	3	1	2	3
S1	—	—	—	—	—	—	—	—	—
S2	+	+	+	+	+	+	+	+	+
S3	+	+	+	+	+	+	+	+	+

Note: "—" means negative result, "+" means positive result and "±" means critical state.

Conclusion: The results of experiments show that the sensitivity of the SARS-CoV-2 Antigen Test Cassette meets the requirements.

(2) Clinical Sensitivity

The compare results between the SARS-CoV-2 Antigen Test Cassette with the commercial RT-PCR detection reagent on the below tables.

Table 11 The nasal swab samples test results

Assessment reagent	Nucleic acid test (PCR)		Total
	Positive (+)	Negative (-)	
Positive (+)	146	1	147
Negative (-)	4	123	127
Total	150	124	274

Clinical sensitivity (positive coincidence rate): 146/ (146+4) ×100%＝97.30%
95% confidence interval: [0.933, 0.990]

Table 12 The nasopharyngeal swab samples test results

Assessment reagent	Nucleic acid test (PCR)		Total
	Positive (+)	Negative (-)	
Positive (+)	116	1	117
Negative (-)	2	120	122
Total	118	121	239

Clinical sensitivity (positive coincidence rate): 116/ (116+2) ×100%＝98.31%
95% confidence interval: [0.940, 0.995]

Table 13 The saliva samples test results

Assessment reagent	Nucleic acid test (PCR)		Total
	Positive (+)	Negative (-)	
Positive (+)	116	0	116
Negative (-)	7	120	127
Total	123	120	243

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Clinical sensitivity (positive coincidence rate): 116/ (116+7) ×100%＝94.31%
95% confidence interval: [0.8872, 0.9722]

4.5 Negative Coincidence Rate

Test the three batches of kits with negative references (N1-N10), and interpret the results in 15 to 20 minutes.

The results are shown in the following table.

Table 14 The negative coincidence test results

Batches	M0120101			M0120105			M0120107		
	1	2	3	1	2	3	1	2	3
N1	—	—	—	—	—	—	—	—	—
N2	—	—	—	—	—	—	—	—	—
N3	—	—	—	—	—	—	—	—	—
N4	—	—	—	—	—	—	—	—	—
N5	—	—	—	—	—	—	—	—	—
N6	—	—	—	—	—	—	—	—	—
N7	—	—	—	—	—	—	—	—	—
N8	—	—	—	—	—	—	—	—	—
N9	—	—	—	—	—	—	—	—	—
N10	—	—	—	—	—	—	—	—	—

Note: "—" means negative result, "＋" means positive result and "±" means critical state.

Conclusion: The results of experiments show that negative coincidence rate of the SARS--CoV-2 Antigen Test Cassette is 100%, which meets the requirements.

4.6 Positive Coincidence Rate

Test the three batches of kits with positive references (P1-P5), and interpret the results in 15 to 20 minutes. The results are shown in the following table:

Table 15 The positive coincidence test results

Batches	M0120101			M0120105			M0120107		
	1	2	3	1	2	3	1	2	3
P1	＋	＋	＋	＋	＋	＋	＋	＋	＋
P2	＋	＋	＋	＋	＋	＋	＋	＋	＋
P3	＋	＋	＋	＋	＋	＋	＋	＋	＋
P4	＋	＋	＋	＋	＋	＋	＋	＋	＋
P5	＋	＋	＋	＋	＋	＋	＋	＋	＋

Note: "—" means negative result, "＋" means positive result and "±" means critical state .

Conclusion: The results of experiments show that the positive coincidence rate of the SARS-CoV-2 Antigen Test Cassette is 100%, which meets the requirements.

4.7 Repeatability (Precision)

Repeatedly test the three batches of kits with repeatability reference (R, P1, P2) for 10 times respectively, and interpret the results in 15 to 20 minutes. The results are shown in the following table:

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Table 16 The repeatability test results of positive solution(P1)

Batches	M0120101	M0120105	M0120107
Test repeat 1	＋	＋	＋
Test repeat 2	＋	＋	＋
Test repeat 3	＋	＋	＋
Test repeat 4	＋	＋	＋
Test repeat 5	＋	＋	＋
Test repeat 6	＋	＋	＋
Test repeat 7	＋	＋	＋
Test repeat 8	＋	＋	＋
Test repeat 9	＋	＋	＋
Test repeat 10	＋	＋	＋
Color depth	uniform and consistent	uniform and consistent	uniform and consistent

Note: “－” means negative result, “＋”means positive result and “±” means critical state.

Table 17 The repeatability test results of positive solution(P2)

Batches	M0120101	M0120105	M0120107
Test repeat 1	＋	＋	＋
Test repeat 2	＋	＋	＋
Test repeat 3	＋	＋	＋
Test repeat 4	＋	＋	＋
Test repeat 5	＋	＋	＋
Test repeat 6	＋	＋	＋
Test repeat 7	＋	＋	＋
Test repeat 8	＋	＋	＋
Test repeat 9	＋	＋	＋
Test repeat 10	＋	＋	＋
Color density	uniform and consistent	uniform and consistent	uniform and consistent

Note: “－” means negative result, “＋”means positive result and “±” means critical state.

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Table 18 The repeatability test results of negative solution(R)

Batches	M0120101	M0120105	M0120107
Test repeat 1	—	—	—
Test repeat 2	—	—	—
Test repeat 3	—	—	—
Test repeat 4	—	—	—
Test repeat 5	—	—	—
Test repeat 6	—	—	—
Test repeat 7	—	—	—
Test repeat 8	—	—	—
Test repeat 9	—	—	—
Test repeat 10	—	—	—
Color density	uniform and consistent	uniform and consistent	uniform and consistent

Note: "—" means negative result, "＋"means positive result and "±" means critical state.

Conclusion: The results of experiments show that the repeatability of the SARS-CoV-2 Antigen Test Cassette meets the requirements.

4.8 Specificity

(1) Specificity Testing with Strains

Following strains at specified concentrations were spiked onto swabs (or saliva specimen) and tested according to the Instruction for Use. Read the results at 15 minutes. Results were presented in table below.

Table 19 The test results

Description	Concentration	Batch No.								
		M0120101			M0120105			M0120107		
Human coronavirus OC43	2.45 x 10^6 LD_{50}/ml	—	—	—	—	—	—	—	—	—
Coronavirus NL63	1 x$10^{5.07}$ U/ml	—	—	—	—	—	—	—	—	—
Influenza A H1N1	3.16 x 10^5 $TCID_{50}$/ml	—	—	—	—	—	—	—	—	—
Influenza A H3N2	1 x 10^5 $TCID_{50}$/ml	—	—	—	—	—	—	—	—	—
Influenza B	3.16 x 10^6 $TCID_{50}$/ml	—	—	—	—	—	—	—	—	—
Human Rhinovirus 2	2.81 x 10^4 $TCID_{50}$/ml	—	—	—	—	—	—	—	—	—
Human Rhinovirus 14	1.58 x 10^6 $TCID_{50}$/ml	—	—	—	—	—	—	—	—	—
Human Rhinovirus 16	8.89 x 10^6 $TCID_{50}$/ml	—	—	—	—	—	—	—	—	—
Measles virus	1.58x 10^4 $TCID_{50}$/ml	—	—	—	—	—	—	—	—	—
Adenovirus 3	1.58 x 10^4 $TCID_{50}$/ml	—	—	—	—	—	—	—	—	—
Parainfluenza virus 2	1.58 x 10^7 $TCID_{50}$/ml	—	—	—	—	—	—	—	—	—
Parainfluenza virus 3	1.58 x 10^8 $TCID_{50}$/ml	—	—	—	—	—	—	—	—	—
Respiratory syncytial virus	8.89 x 10^4 $TCID_{50}$/ml	—	—	—	—	—	—	—	—	—

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(2) Clinical Specificity

The compare results between the SARS-CoV-2 Antigen Test Cassette with the commercial RT-PCR detection reagent on the tables below.

Table 20 The nasal swab samples test results

Assessment reagent	Nucleic acid test (PCR)		Total
	Positive (+)	Negative (-)	
Positive (+)	146	1	147
Negative (-)	4	123	127
Total	150	124	274

Clinical specificity (negative coincidence rate): 123/ (1+123) ×100%＝99.19%
95% Confidence interval: [0.960，0.999]

Table 21 The nasopharyngeal swab samples test results

Assessment reagent	Nucleic acid test (PCR)		Total
	Positive (+)	Negative (-)	
Positive (+)	116	1	117
Negative (-)	2	120	122
Total	118	121	239

Clinical specificity (negative coincidence rate): 120/ (1+120) ×100%＝99.17%
95% Confidence interval: [0.955，0.999]

Table 22 The saliva samples test results

Assessment reagent	Nucleic acid test (PCR)		Total
	Positive (+)	Negative (-)	
Positive (+)	116	0	116
Negative (-)	7	120	127
Total	123	120	243

Clinical specificity (negative coincidence rate): 120/ (0+120) ×100%＝100%
95% Confidence interval: [0.969, 1.000]

4.9 Cross Reactivity Test Results

Three batches of reagents were tested three times with potential different concentrations of the cross substances shown in the following table respectively, and the results were consistent, and interpret the results in 15 to 20 minutes. The results are shown in the following table.

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Table 23 The Cross-reactivity evaluation results

Substances	Concentration	Batch No								
		M0120101			M0120105			M0120107		
Arcanobacterium	$1x10^8$org/ml	—	—	—	—	—	—	—	—	—
Candida albicans	$1x10^8$org/ml	—	—	—	—	—	—	—	—	—
Corynebacterium	$1x10^8$org/ml	—	—	—	—	—	—	—	—	—
Escherichia coli.	$1x10^8$org/ml	—	—	—	—	—	—	—	—	—
Moraxella catarrhalis	$1x10^8$org/ml	—	—	—	—	—	—	—	—	—
Neisseria lactamica	$1x10^8$org/ml	—	—	—	—	—	—	—	—	—
Nesseria subflava	$1x10^8$org/ml	—	—	—	—	—	—	—	—	—
Pseudomonas aeruginosa	$1x10^8$org/ml	—	—	—	—	—	—	—	—	—
Staphylococcus aureus subspaureus	$1x10^8$org/ml	—	—	—	—	—	—	—	—	—
Staphylococcus epidermidis	$1x10^8$org/ml	—	—	—	—	—	—	—	—	—
Streptococcus pneumoniae	$1x10^8$org/ml	—	—	—	—	—	—	—	—	—
Streptococcus pygenes	$1x10^8$org/ml	—	—	—	—	—	—	—	—	—
Streptococcus salivarius	$1x10^8$org/ml	—	—	—	—	—	—	—	—	—
Streptococcus sp group F	$1x10^8$org/ml	—	—	—	—	—	—	—	—	—
Human Coronavirus OC43	2.45×10^6 LD_{50}/ml	—	—	—	—	—	—	—	—	—
Coronavirus NL63	$1 \times 10^{5.07}$ U/ml	—	—	—	—	—	—	—	—	—
Influenza A H1N1	3.16×10^5 $TCID_{50}$/ml	—	—	—	—	—	—	—	—	—
Influenza A H3N2	$1 x10^5$ $TCID_{50}$/ml	—	—	—	—	—	—	—	—	—
Influenza B (Yamagata and Victoria) virus	3.16×10^6 $TCID_{50}$/ml	—	—	—	—	—	—	—	—	—
Human Rhinovirus 2	$2.81 \times 10^4$$TCID_{50}$/ml	—	—	—	—	—	—	—	—	—
Human Rhinovirus 14	$1.58 \times 10^6$$TCID_{50}$/ml	—	—	—	—	—	—	—	—	—
Human Rhinovirus 16	$8.89 \times 10^6$$TCID_{50}$/ml	—	—	—	—	—	—	—	—	—
Measles virus	$1.58x\ 10^4$ $TCID_{50}$/ml	—	—	—	—	—	—	—	—	—
Adenovirus 3	$1.58 \times 10^4$$TCID_{50}$/ml	—	—	—	—	—	—	—	—	—
Parainfluenza virus 2	$1.58 \times 10^7$$TCID_{50}$/ml	—	—	—	—	—	—	—	—	—
Parainfluenza virus 3	1.58×10^8 $TCID_{50}$/ml	—	—	—	—	—	—	—	—	—
Respiratory syncytial virus	$8.89 \times 10^4$$TCID_{50}$/ml	—	—	—	—	—	—	—	—	—
MERS-coronavirus	10^5 PFU/ml	—	—	—	—	—	—	—	—	—
EB virus	10^5 PFU/ml	—	—	—	—	—	—	—	—	—

Note: "—" means negative result, "＋"means positive result and "±" means critical state.

4.10 Interfering Substances Results

We use the substances in the table to perform interference experiments. Repeat the test three times for each batch of the test cassette. The results should be negative.

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Table 24 Interfering substances test results

Analytes	Concentration	Batch No								
		M0120101			M0120105			M0120107		
Whole Blood	20μl/ml	—	—	—	—	—	—	—	—	—
Mucin	50μg/ml	—	—	—	—	—	—	—	—	—
Budesonide Nasal Spray	200μl/ml	—	—	—	—	—	—	—	—	—
Dexamethasone	0.8mg/ml	—	—	—	—	—	—	—	—	—
Flunisolide	6.8ng/ml	—	—	—	—	—	—	—	—	—
Mupirocin	12mg/ml	—	—	—	—	—	—	—	—	—
Oxymetazoline	0.6mg/ml	—	—	—	—	—	—	—	—	—
Phenylephrine	12mg/ml	—	—	—	—	—	—	—	—	—
Rebetol	4.5μg/ml	—	—	—	—	—	—	—	—	—
Relenza	282ng/ml	—	—	—	—	—	—	—	—	—
Tamiflu	1.1μg/ml	—	—	—	—	—	—	—	—	—
Tobramycin	2.43mg/ml	—	—	—	—	—	—	—	—	—

Note: "—" means negative result, "+"means positive result and "±" means critical state.

Conclusion: The results of experiments show that potential cross substances and common interfering substances in samples have no influence on the detection results.

4.11 Results of The Limit of Detection (LOD, analytical sensitivity)

The test results are shown in the table blow.

Table 25-1 The test results of SARS-Cov-2 nucleocapsid protein

Batches \ Positive		100ng/ml	10ng/ml	1ng/ml	500pg/ml	200pg/ml	100pg/ml	50pg/ml
M0120101	Test 1	+	+	+	+	+	+	—
	Test 2	+	+	+	+	+	+	—
	Test 3	+	+	+	+	+	+	—
	Test 4	+	+	+	+	+	+	—
	Test 5	+	+	+	+	+	+	—
	Test 6	+	+	+	+	+	+	—
	Test 7	+	+	+	+	+	+	—
	Test 8	+	+	+	+	+	+	—
	Test 9	+	+	+	+	+	+	—
	Test 10	+	+	+	+	+	+	—
	Test 11	+	+	+	+	+	+	—
	Test 12	+	+	+	+	+	+	—
	Test 13	+	+	+	+	+	+	—
	Test 14	+	+	+	+	+	+	—
	Test 15	+	+	+	+	+	+	—
	Test 16	+	+	+	+	+	+	—
	Test 17	+	+	+	+	+	+	—
	Test 18	+	+	+	+	+	+	—
	Test 19	+	+	+	+	+	+	—
	Test 20	+	+	+	+	+	+	—
	Test 21	+	+	+	+	+	+	—
	Test 22	+	+	+	+	+	+	—
	Test 23	+	+	+	+	+	+	—
	Test 24	+	+	+	+	+	+	—
	Test 25	+	+	+	+	+	+	—
	Test 26	+	+	+	+	+	+	—
	Test 27	+	+	+	+	+	+	—
	Test 28	+	+	+	+	+	+	—
	Test 29	+	+	+	+	+	+	—
	Test 30	+	+	+	+	+	+	—

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Table 26-2 The test results of SARS-Cov-2 nucleocapsid protein

Batches \ Positive		100ng/ml	10ng/ml	1ng/ml	500pg/ml	200pg/ml	100pg/ml	50pg/ml
M0120105	Test 1	+	+	+	+	+	+	−
	Test 2	+	+	+	+	+	+	−
	Test 3	+	+	+	+	+	+	−
	Test 4	+	+	+	+	+	+	−
	Test 5	+	+	+	+	+	+	−
	Test 6	+	+	+	+	+	+	−
	Test 7	+	+	+	+	+	+	−
	Test 8	+	+	+	+	+	+	−
	Test 9	+	+	+	+	+	+	−
	Test 10	+	+	+	+	+	+	−
	Test 11	+	+	+	+	+	+	−
	Test 12	+	+	+	+	+	+	−
	Test 13	+	+	+	+	+	+	−
	Test 14	+	+	+	+	+	+	−
	Test 15	+	+	+	+	+	+	−
	Test 16	+	+	+	+	+	+	−
	Test 17	+	+	+	+	+	+	−
	Test 18	+	+	+	+	+	+	−
	Test 19	+	+	+	+	+	+	−
	Test 20	+	+	+	+	+	+	−
	Test 21	+	+	+	+	+	+	−
	Test 22	+	+	+	+	+	+	−
	Test 23	+	+	+	+	+	+	−
	Test 24	+	+	+	+	+	+	−
	Test 25	+	+	+	+	+	+	−
	Test 26	+	+	+	+	+	+	−
	Test 27	+	+	+	+	+	+	−
	Test 28	+	+	+	+	+	+	−
	Test 29	+	+	+	+	+	+	−
	Test 30	+	+	+	+	+	+	−

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Table 27-3 The test results of SARS-Cov-2 nucleocapsid protein

Batches \ Positive		100ng/ml	10ng/ml	1ng/ml	500pg/ml	200pg/ml	100pg/ml	50pg/ml
M0120107	Test 1	+	+	+	+	+	+	−
	Test 2	+	+	+	+	+	+	−
	Test 3	+	+	+	+	+	+	−
	Test 4	+	+	+	+	+	+	−
	Test 5	+	+	+	+	+	+	−
	Test 6	+	+	+	+	+	+	−
	Test 7	+	+	+	+	+	+	−
	Test 8	+	+	+	+	+	+	−
	Test 9	+	+	+	+	+	+	−
	Test 10	+	+	+	+	+	+	−
	Test 11	+	+	+	+	+	+	−
	Test 12	+	+	+	+	+	+	−
	Test 13	+	+	+	+	+	+	−
	Test 14	+	+	+	+	+	+	−
	Test 15	+	+	+	+	+	+	−
	Test 16	+	+	+	+	+	+	−
	Test 17	+	+	+	+	+	+	−
	Test 18	+	+	+	+	+	+	−
	Test 19	+	+	+	+	+	+	−
	Test 20	+	+	+	+	+	+	−
	Test 21	+	+	+	+	+	+	−
	Test 22	+	+	+	+	+	+	−
	Test 23	+	+	+	+	+	+	−
	Test 24	+	+	+	+	+	+	−
	Test 25	+	+	+	+	+	+	−
	Test 26	+	+	+	+	+	+	−
	Test 27	+	+	+	+	+	+	−
	Test 28	+	+	+	+	+	+	−
	Test 29	+	+	+	+	+	+	−
	Test 30	+	+	+	+	+	+	−

Note:"+" mean positive result,"-"mean negative result.

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Table 28 The test results of SARS-CoV-2 virus (inactivated)

Batches \ Positive		100 $TCID_{50}$/ml	50 $TCID_{50}$/ml	25 $TCID_{50}$/ml
M0120101	Test 1	+	+	−
	Test 2	+	+	−
	Test 3	+	+	−
	Test 4	+	+	−
	Test 5	+	+	−
	Test 6	+	+	−
	Test 7	+	+	−
	Test 8	+	+	−
	Test 9	+	+	−
	Test 10	+	+	−
M0120105	Test 1	+	+	−
	Test 2	+	+	−
	Test 3	+	+	−
	Test 4	+	+	−
	Test 5	+	+	−
	Test 6	+	+	−
	Test 7	+	+	−
	Test 8	+	+	−
	Test 9	+	+	−
	Test 10	+	+	−
M0120107	Test 1	+	+	−
	Test 2	+	+	−
	Test 3	+	+	−
	Test 4	+	+	−
	Test 5	+	+	−
	Test 6	+	+	−
	Test 7	+	+	−
	Test 8	+	+	−
	Test 9	+	+	−
	Test 10	+	+	−

Note:"+" mean positive result,"-"mean negative result.

Conclusion: The minimal limit of detection of SARS-CoV-2 Antigen Test Cassette is 100pg/ml for recombine SARS-CoV-2 nucleocapsid protein. Minimal limit of detection of SARS-Cov-2 Antigen Test Cassette is 50 $TCID_{50}$/ml for SARS-CoV-2 virus.

5. Conclusion

The physical properties, migration velocity, negative coincidence rate, positive coincidence rate, sensitivity, repeatability(precision), specificity, cross reactivity, interfering substances and limit of detection (LOD) of the SARS-CoV-2 Antigen Test Cassette meet the product quality inspection standards and are all qualified.

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