SARS-CoV-2 Antigen Test Kit
(Colloidal Gold Immunochromatography)

Analytical Performance Evaluation Data

Beijing Lepu Medical Technology Co., Ltd.

Analytical Performance Evaluation Data for SARS-CoV-2 Antigen Test Kit (Colloidal Gold Immunochromatography)

1、 Overview

This report contains the analytical performance evaluation data about the SARS-CoV-2 Antigen Test Kit (Colloidal Gold Immunochromatography) (the Kit below for short); the performance indicators about the Kir are tested respectively to evalue whether it complies with its design requirements.

2、 SARS-CoV-2 Antigen Test Kit and Related Information

Specification for SARS-CoV-2 Antigen Test Kit (Colloidal Gold Immunochromatography) 25 tests/kit, batch No. 20CG2701X-y (valid until: March 2, 2021), 20CG2702X-y (valid until: March 3, 2021), 20CG2703X-y (valid until: March 8, 2021), the appearance, width, liquid migration speed, LOD, coincidence rates of negative reference product, positive referenceproduct and repeatability were tested respectively.

Human body sample: Nasal swab samples from Beijing IPE Center for Medical Laboratory.

The negative samples are tested negative according to the *Guidelines on the Novel Coronavirus-Infected Pneumonia Diagnosis and Treatment (Provisional 7th Edition)*.

The positive samples are tested positive according to the *Guidelines on the Novel Coronavirus-Infected Pneumonia Diagnosis and Treatment (Provisional 7th Edition)*.

Samples: This study involves the test data onLOD, coincidence rates of negative reference product, positive reference product, repeatability, testing time and cross reaction.

3、 Performance Evaluation Data

3.1 Physical Characteristics

3.1.1 Appearance

The test strip should be clean and complete, free of burr, damage and contamination; the material should be firmly attached; the label text should be legible without damage. The dilute solution should be clear and transparent, free of impurities and floccules.

3.1.1.1 Test method

Take a test strip randomly and observe it under natural light. The results should meet the requirements.

3.1.1.2Test related information

Batch No.: 20CG2701X-y, 20CG2702X-y, 20CG2703X-y

Testers: Zhang Bo & Liu Yanjuan

Test date: March 9, 2020

Test location: Beijing IPE Center for Medical Laboratory

3.1.1.3 Test result

Specification	Batch No.	Test results
25 tests/kit	20CG2701X-y	Conforming
	20CG2702X-y	Conforming
	20CG2703X-y	Conforming

3.1.1.4 Conclusion

The appearance of the three batches of reagents met the requirements of development and design.

3.1.2 Width of membrane strip

Width of membrane strip of the test strip is ≥2.5mm.

3.1.2.1 Test method

Use a vernier caliper (accuracy not less than 0.05mm) to randomly measure a test strip, and the measurement result shall meet the requirements.

3.1.2.2 Test related information

Batch No.: 20CG2701X-y, 20CG2702X-y, 20CG2703X-y

Digital caliper (No: LS-01-005) measurement range: (0- 150) mm

Testers: Zhang Bo & Liu Yanjuan

Test date: March 9, 2020

Test location: Beijing IPE Center for Medical Laboratory

3.1.2.3 Test result

Specification	Batch No.	Test results
25 tests/kit	20CG2701X-y	4.02mm
	20CG2702X-y	4.03mm
	20CG2703X-y	4.02mm

3.1.2.3 Conclusion

The width of the three batches of reagents met the requirements of development and design.

3.1.3 Fluid migration speed

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

3.1.3.1 Test method

Take a test strip and operate according to the manufacturer's instructions. From the time when the blank

control solution is added into the test strip, count the time with a stop watch until the blank control solution reaches the boundary between the nitrocellulose membrane and the absorbent paper, the time used is recorded as (t), measure the total length of the sample pad, colloidal gold pad and nitrocellulose membrane with a vernier caliper, and the total length is recorded as (L), then the result of L/t is the migration speed; the test results should meet the requirements.

3.1.3.2 Test related information

Batch No.: 20CG2701X-y, 20CG2702X-y, 20CG2703X-y

Digital caliper (No: LS-01-005) measurement range: (0-150) mm

Timer (No: HT-01-001)

Blank control solution: newborn calf serum, Batch No.: 180428

Testers: Zhang Bo & Liu Yanjuan

Test date: March 9, 2020

Test location: Beijing IPE Center for Medical Laboratory

3.1.3.3 Test result

Specification	Batch No.	Test results
25 tests/kit	20CG2701X-y	20 mm/min
	20CG2702X-y	22 mm/min
	20CG2703X-y	23 mm/min

3.1.3.4 Conclusion

The liquid migration speed of the three batches of reagents met the requirements of development and design.

3.2 Minimum LOD

3.2.1 Test method

Take 30 test strips from each of three batches, and test three sensitivity reference products according to the manufacturer's instructions. Repeatedly test each reference product for 10 times, and judge the test results. The positive rate should not be less than 90%.

3.2.2Test related information

Determination of sample fluid: Sensitivity reference product

Batch No.: 20CG2701X-y, 20CG2702X-y, 20CG2703X-y

Testers: Zhang Bo & Liu Yanjuan

Test date: March 9, 2020

Test location: Beijing IPE Center for Medical Laboratory

3.2.3 Test result

		1	2	3	4	5	6	7	8	9	10
20CG2701X-y	L1	Positive	Positive	Positive	Positive	Positive	Negative	Positive	Positive	Positive	Positive
	L2	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
	L3	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
20CG2702X-y	L1	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
	L2	Positive	Positive	Positive	Positive	Negative	Positive	Positive	Positive	Positive	Positive
	L3	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
20CG2703X-y	L1	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
	L2	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
	L3	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive

3.2.4 Conclusion

The result shows: The positive rate of the three batches of reagents was not lower than 90% and the result met the requirements of development and design.

3.3 Negative reference coincidence rate

The negative detection rate should be 100%.

3.3.1 Test method

Take 10 test strips in each of three batches, and test 10 negative reference products of SARS-CoV-2 antigen according to the instructions of the Kit.

3.3.2Test related information

Negative reference products: N1-N10;

Batch No.: 20CG2701X-y, 20CG2702X-y, 20CG2703X-y

Testers: Zhang Bo & Liu Yanjuan

Test date: March 9, 2020

Test location: Beijing IPE Center for Medical Laboratory

3.3.3 Test result

	Test results									
	1	2	3	4	5	6	7	8	9	10
20CG2701X-y	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
20CG2702X-y	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
20CG2703X-y	Negat	Negat	Negat	Negat	Negat	Negat	Negat	Negat	Negat	Negat

	ive	ive	ive	ive	ive	ive	ive	ive	ive	ive

3.3.4 Conclusion

The negative reference products of SARS-CoV-2 antigen were studied with three batches of test strip. The test results were negative, which met the requirements of development and design.

3.4 Positive reference coincidence rate

The positive rate should be 100%

3.4.1 Test method

Take 5 test strips in each of three batches, and test 10 positive reference products of SARS-CoV-2 antigen according to the instructions of the Kit.

3.4.2 Test related information

Positive reference products: P1-P5;

Batch No.: 20CG2701X-y, 20CG2702X-y, 20CG2703X-y

Testers: Zhang Bo & Liu Yanjuan

Test date: March 10, 2020

Test location: Beijing IPE Center for Medical Laboratory

3.4.3 Test result

	1	2	3	4	5
20CG2701X-y	Positive	Positive	Positive	Positive	Positive
20CG2702X-y	Positive	Positive	Positive	Positive	Positive
20CG2703X-y	Positive	Positive	Positive	Positive	Positive

3.4.4 Conclusion

The positive reference products of SARS-CoV-2 antigen were studied with three batches of test strip. The test results were positive, which met the requirements of development and design.

3.5 Precision

The results of tested enterprise reference products P2 and P4 shall be positive with uniform color rendering index;

3. 5.1 Test method

Take 10 test strips in the same batch to test the enterprise reference products according to the instructions. Repeatedly test each enterprise reference product for 10 times, and judge the test results.

3.5.2 Test related information

Test sample: Precision reference product P2, P4;

Batch No.: 20CG2701X-y, 20CG2702X-y, 20CG2703X-y

Testers: Zhang Bo & Liu Yanjuan

Test date: March 10, 2020

Test location: Beijing IPE Center for Medical Laboratory

3.5.3 Test result

	Test results											
		1	2	3	4	5	6	7	8	9	10	Colour rendering index
20CG2701X-y	P2	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Uniform
	P4	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Uniform
20CG2702X-y	P2	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Uniform
	P4	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Uniform
20CG2703X-y	P2	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Uniform
	P4	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Uniform

3.5.4 Conclusion

The repeatability study was conducted with three batches of test strip. The test results were positive with uniform color rendering index, which met the requirements of development and design.

3.6 Testing time

3.6.1 Test method

Select the SARS-CoV-2 Antigen Test Kit in one batch to evaluate the testing time. The sample is enterprise reference product P4. The testing time is 5min, 10min, 15min, 20min and 25min. Test each sample once in each testing time. Finally provide the allowed testing time range.

3.6.2 Test related information

Determination of sample fluid: Enterprise reference products P2 and P4

Batch No.: 20CG2701X-y

Test date: March 10, 2020

Testers: Zhang Bo & Liu Yanjuan

Test location: Beijing IPE Center for Medical Laboratory

3.6.3 Test result

5 min		
Test item	Technical requirements	Test results
Minimum LOD	For the tested LOD samples, the positive rate shall not be lower than 90%.	Non-conforming
Antigennegative coincidence rate	The negative detection rate should be 100%.	Conforming
Antigenpositive coincidence rate	The positive detection rate should be 100%;	The test result is negative
Repeatability	The tested enterprise reference product P2 and P4 shall be positive with uniform color rendering index	The test result is negative
10 min		
Test item	Technical requirements	Test results
Minimum LOD	For the tested LOD samples, the positive rate shall not be lower than 90%.	Conforming
Antigennegative coincidence rate	The negative detection rate should be 100%.	Conforming
Antigenpositive coincidence rate	The positive detection rate should be 100%;	Conforming
Repeatability	The tested enterprise reference product P2 and P4 shall be positive with uniform color rendering index	Positive but the background is unclear
15 min		
Test item	Technical requirements	Test results
Minimum LOD	For the tested LOD samples, the positive rate shall not be lower than 90%.	Conforming
Antigennegative coincidence rate	The negative detection rate should be 100%.	Conforming
Antigenpositive coincidence rate	The positive detection rate should be 100%;	Conforming
Repeatability	The result of tested enterprise reference product P4 shall be positive with uniform color rendering index	Conforming
20 min		
Test item	Technical requirements	Test results
Minimum LOD	For the tested LOD samples, the positive rate shall not be lower than 90%.	Conforming

Antigennegative coincidence rate	The negative detection rate should be 100%.	Conforming
Antigenpositive coincidence rate	The positive detection rate should be 100%;	Conforming
Repeatability	The result of tested enterprise reference product P4 shall be positive with uniform color rendering index	Conforming
25 min		
Test item	Technical requirements	Test results
Minimum LOD	For the tested LOD samples, the positive rate shall not be lower than 90%.	Conforming
Antigennegative coincidence rate	The negative detection rate should be 100%.	Conforming
Antigenpositive coincidence rate	The positive detection rate should be 100%;	Conforming
Repeatability	The result of tested enterprise reference product P4 shall be positive with uniform color rendering index	Positive but the color rendering index is not uniform

3.6.4 Conclusion

The testing time of our SARS-CoV-2 Antigen Test Kit is 15-20min; after 20 min, the read result is invalid.

3.7 Analytical specificity

Select three batches of SARS-CoV-2 Antigen Test Kit to evaluate their cross reaction. Test each sample once for cross reaction.

3.7.1 Validation Content

Three batches are validated for cross reaction.

Endemic human coronavirus OC43: Manufacturer: medix; species: E.coli

Seasonal H1N1 influenza virus: Manufacturer: ViroStat; species: E.coli

H3N2: Manufacturer: ViroStat; species: E.coli

Respiratory syncytial virus: Manufacturer: Eastcoast Bio; species: E.coli

Adenovirus 1, 2, 3, 4, 5 and 7: Manufacturer: meridian; species: E.coli

EB virus: Manufacturer: Eastcoast Bio; species: E.coli

Measles virus: Manufacturer: ViroStat; species: E.coli

Human cytomegalovirus: Manufacturer: Eastcoast Bio; species: E.coli

Rotavirus: Manufacturer: Eastcoast Bio; species: E.coli

Norovirus: Manufacturer: BBI solutions; species: E.coli

Mumps virus: Manufacturer: ViroStat; species: E.coli

Varicella-zoster virus: Manufacturer: ViroStat; species: E.coli

Mycoplasma pneumoniae: Manufacturer: BBI solutions; species: E.coli

Human metapneumovirus: Manufacturer: Creative Diagnostics; species: E.coli

Validate the cross reaction of high-concentration SARS-CoV-2 N protein

3.7.2 Validation information

Batch No.: 20CG2701X-y, 20CG2702X-y, 20CG2703X-y

Testers: Zhang Bo & Liu Yanjuan

Test date: March 11, 2020

Test location: Beijing IPE Center for Medical Laboratory

3.7.3 Validation result

Table 4 Determination Results of Cross Reactants

	20CG2701X-y	20CG2702X-y	20CG2703X-y
OC43	Negative	Negative	Negative
Novel influenza A(H1N1) (2009)	Negative	Negative	Negative
Seasonal H1N1 influenza virus	Negative	Negative	Negative
H3N2	Negative	Negative	Negative
Respiratory syncytial virus	Negative	Negative	Negative
Adenovirus 1	Negative	Negative	Negative
Adenovirus 2	Negative	Negative	Negative
Adenovirus 3	Negative	Negative	Negative
Adenovirus 4	Negative	Negative	Negative
Adenovirus 5	Negative	Negative	Negative
Adenovirus 7	Negative	Negative	Negative
EB virus	Negative	Negative	Negative
Measles virus	Negative	Negative	Negative
Human cytomegalovirus	Negative	Negative	Negative
Rotavirus	Negative	Negative	Negative
Norovirus	Negative	Negative	Negative
Mumps virus	Negative	Negative	Negative
Varicella-zoster virus	Negative	Negative	Negative
Mycoplasma pneumoniae	Negative	Negative	Negative

Human metapneumovirus	Negative	Negative	Negative
High-concentration SARS-CoV-2 N protein	Positive	Positive	Positive

3.7.4 Validation conclusion

The results of cross reaction showed that the presence of the selected virus antigens which may produce cross reaction would not interfere with the test results of the Kit.

3.8 Investigation on HOOK effect

3.8.1 Test method

Collect and test 5 high-concentration samples in each of three batches. Repeatedly test the sample in each concentration for 10 times to observe whether there is false negative test result.

3.8.2 Test related information

Kit batch No: 20CG2701X-y, 20CG2702X-y, 20CG2703X-y

Testers: Zhang Bo & Liu Yanjuan

Test date: March 12, 2020

Test location: Beijing IPE Center for Medical Laboratory

3.8.3 Test result

Table 7 Investigation on HOOK Effect

	Test results										
Sample 1	Batch No.	1	2	3	4	5	6	7	8	9	10
	20CG2701X-y	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
	20CG2702X-y	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
	20CG2703X-y	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
Sample 2	Batch No.	1	2	3	4	5	6	7	8	9	10
	20CG2701X-y	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
	20CG2702X-y	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
	20CG2703X-y	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
Sample 3	Batch No.	1	2	3	4	5	6	7	8	9	10
	20CG2701X-y	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive

	20CG2702X-y	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
	20CG2703X-y	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
Sample 4	Batch No.	1	2	3	4	5	6	7	8	9	10
	20CG2701X-y	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
	20CG2702X-y	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
	20CG2703X-y	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
Sample 5	Batch No.	1	2	3	4	5	6	7	8	9	10
	20CG2701X-y	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
	20CG2702X-y	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive
	20CG2703X-y	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive

3.8.4 Conclusion

No false negative test results were found in high concentration samples tested, which met the development requirements.

3.9 Reproducibility

The results of tested enterprise reference products P2 and P4 shall be positive with uniform color rendering index.

3.9.1 Test method

Take test strips in the same batch to test the enterprise reference products P2 and P4 by different operators from Beijing IPE Center for Medical Laboratory and Beijing Lepu Medical Technology Co., Ltd. according to the instructions. Repeatedly test each enterprise reference product for 10 times, and judge the test results.

3.9.2 Test related information

Test sample: Precision reference product P2, P4;

Batch No.: 20CG2701X-y, 20CG2702X-y, 20CG2703X-y

Testers: Zhao Mancang, Gong Lingyan, Zhang Bo, and Liu Yanjuan

Test date: March 12, 2020

Test location: Beijing IPE Center for Medical Laboratory & Beijing Lepu Medical Technology Co., Ltd.

3.9.3 Test result

3.9.3.1 Test results by Beijing IPE Center for Medical Laboratory

Table 8 Test Results (Beijing IPE Center for Medical Laboratory)

	Test results (Beijing IPE Center for Medical Laboratory)											
		1	2	3	4	5	6	7	8	9	10	Colour rendering index
20CG2701X-y	P2	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Uniform
	P4	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Uniform
20CG2702X-y	P2	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Uniform
	P4	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Uniform
20CG2703X-y	P2	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Uniform
	P4	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Uniform

3.9.3.2 Beijing Lepu Medical Technology Co., Ltd.Test results

Table 9 Test Results (Beijing Lepu Medical Technology Co., Ltd.)

	Test Results (Beijing Lepu Medical Technology Co., Ltd.)											
		1	2	3	4	5	6	7	8	9	10	Colour rendering index
20CG2701X-y	P2	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Uniform
	P4	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Uniform
20CG2702X-y	P2	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Uniform
	P4	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Uniform
20CG2703X-y	P2	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Uniform
	P4	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Positive	Uniform

3.9.4 Conclusion

The test strips in three batches were tested by different operators from Beijing IPE Center for Medical Laboratory and Beijing Lepu Medical Technology Co., Ltd. according to the instructions. The test results were positive with uniform color rendering index, which met the requirements of development and design.

4. Conclusion

Through the study and analysis on physical properties, minimum LOD, negative sample coincidence rate, positive sample coincidence rate, testing time and cross reaction of SARS-CoV-2 Antigen Test Kit (Colloidal Gold Immunochromatography) produced by us, the test results show that all the indicators of the product met the design requirements and the product can meet the needs of clinical use.