Performance Evaluation Data

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Table of Contents

Overview 2

I. Reagent and instrument 2

1. Reagent 2

2. Instrument 2

II. Study on the analytical performance of detection kit 3

1. Appearance 3

2. Test response time 3

3. Coincidence ratio of negative reference product 4

4. Coincidence ratio of positive reference product 6

5. Minimum detectable quantity 7

6. Precision 7

7. Clinical Evaluation 8

III. Summary of performance analysis 10

Tests have been validated but the FDA's independent review of this validation is pending.

Overview

SARS-CoV-2 IgM/IgG Rapid Test by Colloidal Gold Method (hereinafter referred to as 'detection kit') is developed by Shanghai Biotecan Pharmaceuticals Co., Ltd. It is used for qualitative detection of IgG/IgM antibodies against novel coronavirus in human serum.

The detection kit size is 50 test/kit.

In accordance with the 'In vitro diagnostic reagent registration management measures' and 'In vitro diagnostic reagent clinical research technical guidelines' and other relevant provisions, tests have been performed to evaluate the performance of the detection kit.

I. Reagent and instrument

1. Reagent

Test reagent and reference	Size	Lot number
SARS-CoV-2 IgM/IgG Rapid Test by Colloidal Gold Method	50 test/kit	US20200301
		US20200302
		US20200303
Reference product	Precision reference 1	20200301
	Precision reference 2	20200302
	Minimum detectable quantity reference	20200303
	Positive reference	20200304
	Negative reference	20200305

2. Instrument

Chronometer

II. Study on the analytical performance of detection kit

1. Appearance

1.1 Method and requirement

Visual inspection under natural light, reagent card/strip appearance is flat, material adhesion is firm, content is complete. All components of the kit are complete and intact, the outer packaging box is clean and smooth, the self-sealing bag is well sealed, the label are clear, no abrasion, the name/lot number/preservation method and expiry date on the label are accurate.

1.2 Test result

Table 1 Test result of appearance

Product name	Lot number	Visual inspection results
SARS-CoV-2 IgM/IgG Rapid Test by Colloidal Gold Method	US20200301	Requirement met
	US20200302	Requirement met
	US20200303	Requirement met

1.3 Conclusion

According to the table above, the appearance of the three lots of detection kit meet the requirements.

2. Test response time

2.1 Method and requirement

Measured with a chronometer, the C line on the strip should appear within 5 minutes after enough sample is added. Repeat the test seven times.

2.2 Test result

2.2.1

Lot number	1	2	3	4	5	6	7
US20200301	02:48	02:53	02:58	02:48	02:49	02:52	03:00
US20200302	02:56	02:49	02:50	03:05	02:55	02:51	02:52

US20200303	03:01	03:01	03:00	03:02	03:04	02:56	03:05

2.3 Conclusion

From the table above, it can be concluded that the occurrence time of C line of the three lots is less than 5 minutes.

3. Coincidence ratio of negative reference product

3.1 Method and requirement

Test 10 enterprise-made negative reference product (N1-N10), the compliance rate of enterprise-made negative reference product should be 100%. Repeat 3 times for each reference.

3.2 Test result

3.2.1 Test result of negative reference of detection kit (Lot US20200301)

Test result of enterprise-made negative reference product (the first time)

Indicator	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Coincidence ratio
IgG	-	-	-	-	-	-	-	-	-	-	（-/-）10/10
IgM	-	-	-	-	-	-	-	-	-	-	（-/-）10/10

Test result of enterprise-made negative reference product (the second time)

Indicator	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Coincidence ratio
IgG	-	-	-	-	-	-	-	-	-	-	（-/-）10/10
IgM	-	-	-	-	-	-	-	-	-	-	（-/-）10/10

Test result of enterprise-made negative reference product (the third time)

Indicator	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Coincidence ratio
IgG	-	-	-	-	-	-	-	-	-	-	（-/-） 10/10
IgM	-	-	-	-	-	-	-	-	-	-	（-/-） 10/10

3.2.2 Result of negative reference of detection kit (Lot US20200302)

Test result of enterprise-made negative reference product (the first time)

Indicator	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Coincidence ratio
IgG	-	-	-	-	-	-	-	-	-	-	（-/-）10/10
IgM	-	-	-	-	-	-	-	-	-	-	（-/-）10/10

Test result of enterprise-made negative reference product (the second time)

Indicator	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Coincidence ratio
IgG	-	-	-	-	-	-	-	-	-	-	（-/-）10/10
IgM	-	-	-	-	-	-	-	-	-	-	（-/-）10/10

Test result of enterprise-made negative reference product (the third time)

Indicator	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Coincidence ratio
IgG	-	-	-	-	-	-	-	-	-	-	（-/-）10/10
IgM	-	-	-	-	-	-	-	-	-	-	（-/-）10/10

3.2.3 Result of negative reference of detection kit (Lot US20200303)

Test result of enterprise-made negative reference product (the first time)

Indicator	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Coincidence ratio
IgG	-	-	-	-	-	-	-	-	-	-	（-/-）10/10
IgM	-	-	-	-	-	-	-	-	-	-	（-/-）10/10

Test result of enterprise-made negative reference product (the second time)

Indicator	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Coincidence ratio
IgG	-	-	-	-	-	-	-	-	-	-	（-/-）10/10

IgM	-	-	-	-	-	-	-	-	-	-	（-/-）10/10

Test result of enterprise-made negative reference product (the third time)

Indicator	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Coincidence ratio
IgG	-	-	-	-	-	-	-	-	-	-	（-/-）10/10
IgM	-	-	-	-	-	-	-	-	-	-	（-/-）10/10

3.3 Conclusion

The results showed that the test results of the three batches negative reference kit were all negative, and the compliance rate was 100%.

4. Coincidence ratio of positive reference product

4.1 Method and requirement

Test 3 enterprise-made positive reference (P1, P2, P3), the compliance rate of the enterprise-made positive reference products should be 100%.

4.2 Test result

4.2.1 Test result of positive reference of detection kit (Lot20200304)

Test result of enterprise-made positive reference product (the first time)

Indicator	P1	P2	P3	Coincidence ratio
IgG	+	++	+++	（+/+）3/3
IgM	+	++	+++	（+/+）3/3

Test result of enterprise-made positive reference product (the second time)

Indicator	P1	P2	P3	Coincidence ratio
IgG	+	++	+++	（+/+）3/3
IgM	+	++	+++	（+/+）3/3

Test result of enterprise-made positive reference product (the third time)

Indicator	P1	P2	P3	Coincidence ratio
IgG	+	++	+++	（+/+）3/3
IgM	+	++	+++	（+/+）3/3

4.3 Conclusion

The results showed that the test results of three batches of positive reference were all positive, the compliance rate was 100%, and the test values of all the reference products met the requirements.

5. Minimum detectable quantity

5.1 Method and requirement

Test the minimum detectable quantity reference product. The test result should be positive.

Test result of minimum detectable quantity reference product

Lot number	1	2	3	4	5	6	7
US20200301	+	+	+	+	+	+	+
US20200302	+	+	+	+	+	+	+
US20200303	+	+	+	+	+	+	+

5.2 Conclusion

The results showed that the three batches of minimum detectable quantity reference products were all positive.

6. Precision

6.1 Method and requirement

6.1.1 Within-run precision

The same lot of detection kit should be used to test the positive reference products of the enterprise (n=10), and the reaction results should be consistent and the chroma of the C line should be uniform.

6.1.2 Between-run precision

Three lots of detection kit should be used to test the positive reference products of the enterprise (n=10), and the reaction results should be consistent and the chroma of the C line should be uniform.

6.2 Test result

6.2.1 Test result of within-run precision reference product (US20200301)

Test result of within-run precision reference product

IgG	++	++	++	++	++	++	++	++	++	++
IgM	++	++	++	++	++	++	++	++	++	++

6.2.2 Test result of between-run precision reference product

Test result of between-run precision reference product (Lot US20200301)

IgG	++	++	++	++	++	++	++	++	++	++
IgM	++	++	++	++	++	++	++	++	++	++

Test result of between-run precision reference product (Lot US20200302)

IgG	++	++	++	++	++	++	++	++	++	++
IgM	++	++	++	++	++	++	++	++	++	++

Test result of between-run precision reference product (Lot US20200303)

IgG	++	++	++	++	++	++	++	++	++	++
IgM	++	++	++	++	++	++	++	++	++	++

6.3 Conclusion

The reaction results of both the within-run and between-run precision reference product were consistent and the chroma was uniform.

7. Clinical Evaluation

The 40 patients in the case group were clinically diagnosed COVID-19 patients and 50 healthy controls were recruited for the evaluation. A total of 90 specimens have valid results. The data of the invalid specimen is excluded from the data analysis. The test results are summarized in the Table below.

Clinical Evaluation Result

Sample collection site	Sample testing site	Positive (Ig G/Ig M)	Negative (Ig G/Ig M)	Percentage (%)
A third-party clinical laboratory	Shanghai Biotecan Pharmaceuticals Co. , Ltd.	38	52	Positive = 42.2% Negative = 57.8%

Clinical performance study using clinical "gold standard" diagnosis

ALL of the 90 patients were tested using PCR based test, which is the current "gold standard" diagnosis of COVID-19. The PPA and NPA (Positive Percent Agreement, Negative Percent Agreement) analysis are used to evaluate the clinical performance of this detection kit. The results are summarized in the following table.

Biotcan product result	Clinical "gold standard" diagnosis result		Total
	Positive	Negative	
Positive	37	1	38
Negative	3	49	52
Total	40	50	90

PPA (%) = 100% x 37/(37+3) = 92.5%

NPA (%) = 100% x 49/(49+1) = 98%

III. Summary of performance analysis

Three lots of the detection kit produced by our company all meet the following requirements:

1）Appearance: all met the requirements；

2）Response time: the occurrence time of C line was less than 5 minutes;

3）Coincidence ratio of negative reference product: the test results were all negative, and the compliance rate was 100%;

4）Coincidence ratio of positive reference product: the test results were all positive, and the compliance rate was 100%;

5）Minimum detectable quantity: the test results of the minimum detectable quantity reference product were positive;

6）Precision: the results are consistent and the chroma was uniform;

7）Clinical performance evaluation: PPA = 92.5%　　NPA = 98%

Tests have been validated but the FDA's independent review of this validation is pending.