

Performance Evaluation Report

Product Name: Coronavirus Disease 2019 Antibody
(IgM/IgG) Combined Test Kit

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1. Introduce

This study has evaluated the performances of Coronavirus Disease 2019 Antibody (IgM/IgG) Combined Test Kit, including width of film strip, migration speed, coincidence rate of positive control and negative control, limit of detection and repeatability.

2. Evaluation Plan

2.1 Duration of test

2020.2.24.

2.2 Site

MedicalSystem Quality Control Laboratory.

2.3 Product information

3 batches of Coronavirus Disease 2019 Antibody (IgM/IgG) Combined Test Kit are used in the performance evaluation study.

Table 1 List of Product in Performance Testing

Performance Studied	Lot
width of film strip	20200217; 20200218; 20200219
migration speed	
coincidence rate of positive control	
coincidence rate of negative control	
limit of detection	
repeatability	

2.4 Instrument

N/A

2.5 Precautions

- Read all the information in this package insert before performing the test.
- The test should remain in the sealed pouch until ready to use.

- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.

2.6 The Performance Claims

Table 2 Performance Claims

width of film strip	≥2.5mm
migration speed of liquid	≥10mm/min
coincidence rate of positive reference material	3/3
coincidence rate of negative reference material	8/8
limit of detection	Test manufacture LoD reference materials S1-S3, S1 is negative, S2 and S3 are positive.
repeatability	Test manufacture repeatable reference materials CV1-CV2, the results should be consistent and the color should be uniform.

3. Evaluation Methods

3.1 Sample Information

Different kind of manufacture reference materials are used in the performance test according to the test method.

3.2 Performance Characteristics

3.2.1 Width of film strip

Measure the width of 2 test strips with a universal gauge, mean value of the tests should meet the requirements described in section 2.6.

3.2.2 Migration speed

Add the liquid sample to the sample location and start timing with a stopwatch. Stop counting when the liquid moves to the C line. Measure the distance from sample location to the Cline

where the samples moved with a universal gage. Calculate the travel speed by distance and seconds. Repeat 2 times and calculate the mean value. Test result should meet the requirements described in section 2.6.

3.2.3 Coincidence rate of positive reference material

Test manufacture positive reference material P1-P3 according to package insert. Test result should meet the requirements described in section 2.6. Negative result is recorded as “-” and positive result is recorded as “+”.

3.2.4 Coincidence rate of negative reference material

Test manufacture negative reference material N1-N8 according to package insert. Test result should meet the requirements described in section 2.6. Negative result is recorded as “-” and positive result is recorded as “+”.

3.2.5 Limit of detection

Test manufacture LoD reference materials S1-S3, S1 is negative, S2 and S3 are positive. Negative result is recorded as “-” and positive result is recorded as “+”.

3.2.6 Repeatability

Test manufacture repeatable reference materials CV1-CV2. Test result should meet the requirements described in section 2.6. Negative result is recorded as “-” and positive result is recorded as “+”.

4. Results

4.1 Width of film strip

Lot	Width (mm)	
	Test 1	Test 2
20200217	3.98	4.02
20200218	4.00	4.02
20200219	4.02	4.00

4.2 Migration speed of liquid

Lot	Speed (mm/min)	
	Test 1	Test 2
20200217	46.95	47.22
20200218	45.15	45.57
20200219	44.17	44.54

4.3 coincidence rate of positive reference material

Lot	Result		
	P1	P2	P3
20200217	+	+	+
20200218	+	+	+
20200219	+	+	+

4.4 Coincidence rate of negative reference material

Lot	Result							
	N1	N2	N3	N4	N5	N6	N7	N8
20200217	-	-	-	-	-	-	-	-
20200218	-	-	-	-	-	-	-	-
20200219	-	-	-	-	-	-	-	-

4.5 Limit of detection

Lot	Result		
	S1	S2	S3
20200217	-	+	+
20200218	-	+	+
20200219	-	+	+

4.6 Repeatability

Lot	Sample	Result									
20200217	CV1	-	-	-	-	-	-	-	-	-	-
	CV2	+	+	+	+	+	+	+	+	+	+
20200218	CV1	-	-	-	-	-	-	-	-	-	-
	CV2	+	+	+	+	+	+	+	+	+	+
20200219	CV1	-	-	-	-	-	-	-	-	-	-
	CV2	+	+	+	+	+	+	+	+	+	+

5. Conclusions

The results of performance evaluation study indicate that the performances of The COVID-19 IgM/IgG Antibody (IgM/IgG) Combined Test Kit, including width of film strip, migration speed, coincidence rate of positive control and negative control, limit of detection and repeatability, have contented with the design requirement.