

SARS-CoV-2 IgM/IgG Antibody
Assay Kit
(Immunochromatography)

Clinical Validation Data

Wuhan Life Origin Biotech Joint Stock Co., Ltd.

1、 Intention

To evaluate the sensitivity and specificity of the SARS-CoV-2 IgM/IgG Antibody Assay Kit (Immunochromatography) produced by Wuhan Life Origin Biotech Joint Stock Co., Ltd. in the detection of clinical samples.

2、 Method

2.1 Sample type

Sample type: Serum

2.2 Kit

Assay Kit: SARS-CoV-2 IgM/IgG Antibody Assay Kit (Immunochromatography) produced by Wuhan Life Origin Biotech Joint Stock Co., Ltd.

2.3 Experiment method

2.3.1 Coincidence rate of negative reference

Operate under the instructions of the "SARS-CoV-2 Dual Nucleic Acid Detection Kit (Fluorescent PCR Method)" to measure healthy human serum.

2.3.2 Coincidence rate of positive reference

Operate under the instructions of the "SARS-CoV-2 Dual Nucleic Acid Detection Kit (Fluorescent PCR Method)" to measure the serum of patients diagnosed with the new coronavirus infection.

3、 Result

3.1 Coincidence rate of negative reference

Table 1 Results of Coincidence rate of negative reference

Sample number	Wuhan Life Origin Biotech Joint Stock Co., Ltd.		Sample number	Wuhan Life Origin Biotech Joint Stock Co., Ltd.	
	IgM	IgG		IgM	IgG
1	-	-	51	-	-
2	-	-	52	-	-
3	-	-	53	-	-
4	-	-	54	-	-
5	-	-	55	-	-
6	-	-	56	-	-
7	-	-	57	-	-
8	-	-	58	-	-
9	-	-	59	-	-
10	-	-	60	-	-
11	-	-	61	-	-
12	-	-	62	-	-
13	-	-	63	-	-
14	-	-	64	-	-

15	-	-	65	-	-
16	-	-	66	-	-
17	-	-	67	-	-
18	-	-	68	-	-
19	-	-	69	-	-
20	-	-	70	-	-
21	-	-	71	-	-
22	-	-	72	-	-
23	-	-	73	-	-
24	-	-	74	-	-
25	-	-	75	-	-
26	-	-	76	-	-
27	-	-	77	-	-
28	-	-	78	-	-
29	-	-	79	-	-
30	-	-	80	-	-
31	-	+	81	-	-
32	-	-	82	-	-
33	-	-	83	-	-
34	-	-	84	-	-
35	-	-	85	-	-
36	-	-	86	-	-
37	-	-	87	-	-
38	-	-	88	-	-
39	-	-	89	-	-
40	-	-	90	-	-
41	-	-	91	-	-
42	-	-	92	-	-
43	-	-	93	-	-
44	-	-	94	-	-
45	-	-	95	-	-
46	-	-			
47	-	-			
48	-	-			
49	-	-			
50	-	-			

Table 2 Statistics of Coincidence rate of negative reference

Clinically confirmed	Life Origin	Life Origin	Coincidence rate of negative reference
negative cases	Positive	Negative	
95	1	94	98.9%

95 healthy human serum was measured, and one result was positive, the other 94 was negative. The coincidence rate of negative reference was 98.9%.

3.2 Coincidence rate of positive reference

Table 3 Results of Coincidence rate of positive reference
(Patient infection days : 4-10 days)

Sample number	Life Origin		Sample number	Life Origin	
	IgM	IgG		IgM	IgG
1	+++	++	32	-	+
2	±	±	33	-	-
3	-	-	34	±	±
4	±	-	35	±	±
5	+	-	36	±	-
6	++	+	37	+	±
7	+	+	38	±	-
8	±	±	39	-	+
9	+	±	40	-	-
10	-	+	41	+	-
11	±	±	42	±	-
12	+	+	43	+	+
13	±	-	44	±	-
14	±	±	45	±	+
15	±	±	46	++	±
16	+	-	47	±	+
17	-	-	48	++	+
18	±	+	49	+	+
19	±	-	50	-	-
20	+	+	51	+	+
21	±	-	52	-	+
22	±	+	53	±	±
23	+	+	54	+	++
24	+	+	55	+	+
25	+	+	56	-	-
26	+	±	57	+	+

Table 4 Results of Coincidence rate of positive reference
(Patient infection days : 11-24 days)

Sample number	Wuhan Life Origin Biotech Joint Stock Co., Ltd.		Sample number	Wuhan Life Origin Biotech Joint Stock Co., Ltd.	
	IgM	IgG		IgM	IgG
1	-	-	36	+	+++
2	±	+	37	-	+
3	-	+	38	±	+++
4	-	+	39	±	+++
5	-	-	40	±	++
6	-	+	41	+	++
7	-	+	42	+	+++
8	-	+	43	±	+
9	+	+	44	++	+++
10	-	+	45	±	++
11	-	+	46	-	++
12	-	-	47	-	+
13	+	+	48	+	++
14	-	+	49	-	+
15	±	+	50	±	++
16	-	+	51	+	++
17	-	+	52	+	++
18	-	+	53	-	-
19	-	+	54	+	+
20	-	+	55	±	++
21	±	+	56	+	++
22	+++	++	57	+	+++
23	-	-	58	±	+
24	-	++	59	++	+++
25	-	-	60	±	++
26	-	-	61	-	++
27	-	++	62	-	+
28	-	+	63	+	++
29	-	-	64	-	+
30	-	++	65	±	++
31	-	++	66	+	++
32	+	++	67	+	++
33	-	-	68	-	++
34	-	++	69	+	+
35	-	++			

Table 5 Statistics of Coincidence rate of positive reference

Infection	Clinically	Life Origin	Life Origin	Coincidence
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days	confirmed			rate of positive reference
	positive cases	Positive	Negative	
4-10 days	61	53	8	86.9%
11-24 days	69	60	9	87.0%
Total	130	113	17	86.9%

A total of 130 confirmed patients' serum was measured, and 61 cases whose infection day was 4-10, with positive results 53, and the coincidence rate of positive reference was 86.9.%; there were 69 cases whose infection day was 11-24, and 60 cases of sample results were positive, the coincidence rate of positive reference was 87.0%. A total of 130 confirmed samples were measured, and 113 samples were measured positive, the coincidence rate of positive reference was 86.9.%.

4、 Conclusion

The sensitivity and specificity of the SARS-CoV-2 IgM/IgG Antibody Assay Kit (Immunochromatography) produced by Wuhan Life Origin Biotech Joint Stock Co., Ltd. can meet needs of clinical use, with its Coincidence rate of negative reference 98.9% and Coincidence rate of positive reference 86.9%.