SARS-CoV-2 Antigen Rapid Test Kit

(Fluorescence Immunochromatography)

Clinical Sensitivity Study Report

Biohit Healthcare (Hefei) Co., Ltd.

1、Research purpose

The SARS-CoV-2 Antigen Rapid Test Kit (fluorescence immunochromatography) produced by Biohit Healthcare (Hefei) Co., Ltd. was evaluated for its clinical sensitivity in clinical application.

2、Research methods

A retrospective method was used in this study. The SARS-CoV-2 Antigen Rapid Test Kit produced by Biohit Healthcare (Hefei) Co., Ltd. (Fluorescence immunochromatography) was used for the detection of novel corona virus infected patients (Nasopharynx swab or sputum was nucleic acid positive for Novel Corona virus) and serum samples were retained on the day of diagnosis.

2.1 Research samples

Clinical samples were collected from 62 patients with new corona virus infection confirmed by PCR from local Center for Disease Control and Prevention from January to the end of February 2020. Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV was produced by BGI Genomics Co., Ltd. (FDA EUA Approved). The sample were serum samples collected on the day of confirmed diagnosis of new corona virus infection (the day of nucleic acid test result is positive) and stored at - 80 ° C. Among these samples, 5 samples were from the patients without clinical symptoms on the day of diagnosis of infection (that is, 0 days from the onset of the disease); the sampling time of 24 samples was 1-3 days after the onset of symptoms; the sampling time of the 33 samples was 4-7 days from the onset of symptoms.

2.2 Instrument and Reagent

2.2.1 Reagent

The SARS-CoV-2 Antigen Rapid Test Kit (fluorescence immunochromatography) produced by Biohit Healthcare (Hefei) Co., Ltd., batch number: SA200703.

2.2.2 Instrument

Ultraviolet flashlight：TANK007 (365nm wavelength) Ultraviolet flashlight; Mnufacturer：Shenzhen Zhong Dao Electronics Co., Ltd.

2.3 Research process

The above 62 serum samples were tested by Biohit Healthcare (Hefei) Co., Ltd. SARS-CoV-2 Antigen Rapid Test Kit (Fluorescence immunochromatography) according to the test method provided by the instructions for use.

3、Research results

3.1 Among the 62 sera from patients with new corona virus infection, 60 were positive for N antigen, and the clinical sensitivity was 96.77% (60/62) (95CI:88.83%~99.61%), among them, the sensitivity of N antigen detection of samples within 0-3 days and 4-7 days after the onset of the disease were 93.10% (27/29) (95CI:77.23%~99.15%) and 100% (33/33) (95CI:89.42% ～ 100.00%), respectively.

Statistical table of serum antigen test results

Serial number	Days from onset	Number of antigen positive samples	Total number of samples	Positive consistency
1	0-3	27	29	93.10%（95CI:77.23%~99.15%）
2	4-7	33	33	100%（95CI:89.42%～100.00%）
3	≤7	60	62	96.77%（95CI:88.83%~99.61%）

3.2 Nasopharyngeal swabs were collected in 51 out of 62 patients with Novel Corona Virus infection, the positive rate of nucleic acid detection in nasopharyngeal swab samples was 60.78% (31/51); the positive rate of antigen detection in serum of the same group of virus infected patients was 98.04% (50 / 51).

3.3 Sputum samples were collected in 55 out of 62 patients with new corona virus infection, the positive rate of nucleic acid detection in sputum samples was 100% (55 / 55); the positive rate of antigen detection in serum of the same group of virus infected patients was 98.18% (54/55).

3.4 Specific data of all 62 new corona virus infected persons, the test information and results are shown in the following table:

Basic information						Detection result		
Serial number	Sample number	Gender	Age	Sampling date	Days from onset	PCR results (CT value)		Results of fluorescence immunochromatography
						Throat swab	Sputum	
1	145	M	39	2020/1/23	0	17.45	14.67	+
2	1129	F	50	2020/2/1	0	29.34	27.21	+
3	1589	F	70	2020/2/5	0	31.22	29.26	+
4	1739	M	55	2020/2/6	0	30.98	29.69	+
5	1799	F	34	2020/2/7	0	35.89	/	-
6	686	M	28	2020/1/29	1	（-）	18.21	+
7	411	F	52	2020/1/27	1	27.45	22.45	+
8	1356	F	53	2020/2/4	1	29.32	/	+
9	1533	M	92	2020/2/5	1	31.98	25.45	+
10	1822	F	31	2020/2/7	1	（-）	33.11	+
11	395	M	26	2020/1/27	2	35.13	33.13	+
12	670	M	30	2020/1/29	2	30.66	/	+
13	682	F	27	2020/1/29	2	（-）	29.11	+
14	451	F	17	2020/1/28	2	25.99	24.87	+
15	864	F	56	2020/1/31	2	30.56	29.34	+
16	946	M	22	2020/2/1	2	（-）	34.99	+
17	1103	M	40	2020/2/1	2	/	36.45	+
18	1312	M	44	2020/2/3	2	33.56	31.34	+
19	1488	M	51	2020/2/4	2	23.44	/	+
20	1510	F	25	2020/2/5	2	（-）	29.21	-
21	1659	M	62	2020/2/6	2	/	24.87	+
22	6	F	47	2020/1/20	3	25.56	23.11	+
23	74	M	32	2020/1/23	3	27.44	/	+
24	324	M	21	2020/1/27	3	/	20.32	+

25	350	M	22	2020/1/27	3	31.56	27.90	+
26	456	F	23	2020/1/28	3	32.87	/	+
27	632	M	49	2020/1/29	3	（-）	18.34	+
28	1486	M	29	2020/2/4	3	/	24.45	+
29	1914	M	68	2020/2/8	3	24.56	21.21	+
30	244	M	23	2020/1/26	4	（-）	24.23	+
31	358	F	45	2020/1/27	4	33.43	/	+
32	443	F	71	2020/1/28	4	/	22.89	+
33	1245	F	44	2020/2/3	4	（-）	21.86	+
34	7	M	50	2020/1/20	5	26.45	23.31	+
35	37	M	31	2020/1/22	5	31.57	25.33	+
36	298	M	29	2020/1/26	5	（-）	28.56	+
37	858	M	68	2020/1/31	5	22.45	28.24	+
38	1324	M	18	2020/2/3	5	29.32	26.47	+
39	1326	F	51	2020/2/3	5	（-）	22.34	+
40	1386	F	49	2020/2/4	5	（-）	31.23	+
41	1800	M	56	2020/2/7	5	（-）	33.34	+
42	1935	M	39	2020/2/8	5	（-）	23.56	+
43	67	M	52	2020/1/23	6	（-）	31.34	+
44	321	M	48	2020/1/27	6	22.43	25.88	+
45	322	F	34	2020/1/27	6	25.76	23.32	+
46	352	M	40	2020/1/27	6	35.56	30.34	+
47	820	M	32	2020/1/30	6	（-）	21.32	+
48	851	M	48	2020/1/31	6	（-）	30.22	+
49	573	F	52	2020/1/29	6	/	36.24	+
50	630	M	53	2020/1/29	6	（-）	24.35	+
51	1413	F	28	2020/2/4	6	32.42	24.33	+
52	1487	M	35	2020/2/4	6	/	34.11	+
53	1660	M	70	2020/2/6	6	/	28.22	+

54	1989	M	63	2020/2/8	6	31.12	26.56	+
55	832	F	31	2020/1/31	7	19.95	23.56	+
56	833	F	51	2020/1/31	7	/	18.34	+
57	857	F	53	2020/1/31	7	（-）	25.35	+
58	956	M	33	2020/2/1	7	/	23.21	+
59	1038	F	43	2020/2/1	7	（-）	22.11	+
60	1787	M	30	2020/2/7	7	/	34.89	+
61	1814	M	31	2020/2/7	7	（-）	31.34	+
62	1828	M	78	2020/2/7	7	25.89	21.37	+

4、Research conclusion

Using the SARS-CoV-2 Antigen Rapid Test Kit (fluorescence immunochromatography) produced by Biohit Healthcare (Hefei) Co., Ltd., 62 serum samples collected from 62 patients with SARS-CoV-2 coronavirus infection within 7 days of clinical symptoms onset were tested for SARS-CoV-2 N antigen, the clinical sensitivity of the kit (consistent with nucleic acid detection results) is 96.77% (95CI: 88.83%~99.61%).