

SARS-CoV-2 Antigen Rapid Test Kit

(Fluorescence Immunochromatography)

Clinical Specificity 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 specificity in clinical application.

2、 Research methods

A retrospective method was used in this study. A SARS-CoV-2 Antigen Rapid Test Kit (fluorescence immunochromatography) produced by Biohit Healthcare (Hefei) Co., Ltd. was used, serum samples were collected from non-new corona virus infected population.

2.1 Research sample

188 samples were collected from the local hospital, confirmed PCR results of nucleic acid detection of new corona virus were negative, the nucleic acid detection reagent was produced by BGI genomics Co., Ltd. (FDA EUA Approved). Among these samples, 48 serum samples from patients with other respiratory pathogens infection, 40 serum samples from patients with elevated rheumatoid factor, 100 serum samples from Physical examination crowd. The samples were stored at 2 ~ 8 °C.

2.2 Instruments and reagents

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, Ultraviolet flashlight; manufacturer: Shenzhen Zhong Dao Electronics Co., Ltd.

2.3 Research process

The above 188 serum samples were tested by SARS-CoV-2 Antigen Rapid Test Kit (Fluorescence immunochromatography) produced by the Biohit Healthcare (Hefei) Co., Ltd. According to the test method provided by the instructions for use.

3、 Research results

3.1 In 188 serum samples, 186 serum samples were negative, the results of 2 serum samples with positive results were all weakly positive, the specificity of the kit was 98.94% (186/188).

3.2 The specific test results are shown in the table below:

Serial number	Sample type	Sample number	Detection result
1	Physical serum sample 1	0924-2201	-
2	Physical serum sample 2	0924-2202	-
3	Physical serum sample 3	0924-2203	-
4	Physical serum sample 4	0924-2204	-
5	Physical serum sample 5	0924-2205	-
6	Physical serum sample 6	0924-2206	-
7	Physical serum sample 7	0924-2207	-
8	Physical serum sample 8	0924-2208	-
9	Physical serum sample 9	0924-2209	-
10	Physical serum sample 10	0924-2210	-
11	Physical serum sample 11	0924-2211	-
12	Physical serum sample 12	0924-2212	-
13	Physical serum sample 13	0924-2213	-
14	Physical serum sample 14	0924-2214	-
15	Physical serum sample 15	0924-2215	-
16	Physical serum sample 16	0924-2216	-
17	Physical serum sample 17	0924-2217	-
18	Physical serum sample 18	0924-2218	-
19	Physical serum sample 19	0924-2219	-
20	Physical serum sample 20	0924-2220	-
21	Physical serum sample 21	0924-2221	-
22	Physical serum sample 22	0924-2222	-

23	Physical serum sample 23	0924-2223	-
24	Physical serum sample 24	0924-2224	-
25	Physical serum sample 25	0924-2225	-
26	Physical serum sample 26	0924-2226	-
27	Physical serum sample 27	0924-2227	-
28	Physical serum sample 28	0924-2228	-
29	Physical serum sample 29	0924-2229	-
30	Physical serum sample 30	0924-2230	-
31	Physical serum sample 31	0924-2231	-
32	Physical serum sample 32	0924-2232	-
33	Physical serum sample 33	0924-2233	-
34	Physical serum sample 34	0924-2234	-
35	Physical serum sample 35	0924-2235	-
36	Physical serum sample 36	0924-2236	-
37	Physical serum sample 37	0924-2237	-
38	Physical serum sample 38	0924-2238	-
39	Physical serum sample 39	0924-2239	-
40	Physical serum sample 40	0924-2240	-
41	Physical serum sample 41	0924-2241	-
42	Physical serum sample 42	0924-2242	-
43	Physical serum sample 43	0924-2243	-
44	Physical serum sample 44	0924-2244	-
45	Physical serum sample 45	0924-2245	-
46	Physical serum sample 46	0924-2246	-
47	Physical serum sample 47	0924-2247	-
48	Physical serum sample 48	0924-2248	-
49	Physical serum sample 49	0924-2249	-
50	Physical serum sample 50	0924-2250	-
51	Physical serum sample 51	0924-2251	-

52	Physical serum sample 52	0924-2252	-
53	Physical serum sample 53	0924-2253	-
54	Physical serum sample 54	0924-2254	-
55	Physical serum sample 55	0924-2255	-
56	Physical serum sample 56	0924-2256	-
57	Physical serum sample 57	0924-2257	-
58	Physical serum sample 58	0924-2258	-
59	Physical serum sample 59	0924-2259	-
60	Physical serum sample 60	0924-2260	-
61	Physical serum sample 61	0924-2261	-
62	Physical serum sample 62	0924-2262	-
63	Physical serum sample 63	0924-2263	-
64	Physical serum sample 64	0924-2264	-
65	Physical serum sample 65	0924-2265	-
66	Physical serum sample 66	0924-2266	-
67	Physical serum sample 67	0924-2267	-
68	Physical serum sample 68	0924-2268	-
69	Physical serum sample 69	0924-2269	-
70	Physical serum sample 70	0924-2270	-
71	Physical serum sample 71	0924-2271	-
72	Physical serum sample 72	0924-2272	-
73	Physical serum sample 73	0924-2273	-
74	Physical serum sample 74	0924-2274	-
75	Physical serum sample 75	0924-2275	-
76	Physical serum sample 76	0924-2276	-
77	Physical serum sample 77	0924-2277	-
78	Physical serum sample 78	0924-2278	-
79	Physical serum sample 79	0924-2279	-
80	Physical serum sample 80	0924-2280	-

81	Physical serum sample 81	0924-2281	-
82	Physical serum sample 82	0924-2282	-
83	Physical serum sample 83	0924-2283	-
84	Physical serum sample 84	0924-2284	-
85	Physical serum sample 85	0924-2285	-
86	Physical serum sample 86	0924-2286	-
87	Physical serum sample 87	0924-2287	-
88	Physical serum sample 88	0924-2288	-
89	Physical serum sample 89	0924-2289	-
90	Physical serum sample 90	0924-2290	-
91	Physical serum sample 91	0924-2291	-
92	Physical serum sample 92	0924-2292	-
93	Physical serum sample 93	0924-2293	-
94	Physical serum sample 94	0924-2294	-
95	Physical serum sample 95	0924-2295	-
96	Physical serum sample 96	0924-2296	-
97	Physical serum sample 97	0924-2297	-
98	Physical serum sample 98	0924-2298	-
99	Physical serum sample 99	0924-2299	-
100	Physical serum sample 100	0924-2300	-
101	Rheumatoid factor sample 1	0513-149	-
102	Rheumatoid factor sample 2	0513-164	-
103	Rheumatoid factor sample 3	0513-185	-
104	Rheumatoid factor sample 4	0513-195	-
105	Rheumatoid factor sample 5	0513-201	-
106	Rheumatoid factor sample 6	0513-269	-
107	Rheumatoid factor sample 7	0513-279	-
108	Rheumatoid factor sample 8	0513-282	-
109	Rheumatoid factor sample 9	0513-289	-

110	Rheumatoid factor sample 10	0513-297	-
111	Rheumatoid factor sample 11	0513-304	-
112	Rheumatoid factor sample 12	0513-306	-
113	Rheumatoid factor sample 13	0513-364	-
114	Rheumatoid factor sample 14	0513-481	-
115	Rheumatoid factor sample 15	0513-535	-
116	Rheumatoid factor sample 16	0513-539	-
117	Rheumatoid factor sample 17	0513-548	-
118	Rheumatoid factor sample 18	0513-567	-
119	Rheumatoid factor sample 19	0513-689	-
120	Rheumatoid factor sample 20	0513-745	-
121	Rheumatoid factor sample 21	0513-767	-
122	Rheumatoid factor sample 22	0514-239	-
123	Rheumatoid factor sample 23	0514-255	-
124	Rheumatoid factor sample 24	0514-340	-
125	Rheumatoid factor sample 25	0514-346	-
126	Rheumatoid factor sample 26	0514-350	-
127	Rheumatoid factor sample 27	0514-376	-
128	Rheumatoid factor sample 28	0514-383	-
129	Rheumatoid factor sample 29	0514-387	-
130	Rheumatoid factor sample 30	0514-388	-
131	Rheumatoid factor sample 31	0514-394	-
132	Rheumatoid factor sample 32	0514-402	-
133	Rheumatoid factor sample 33	0514-405	-
134	Rheumatoid factor sample 34	0514-414	-
135	Rheumatoid factor sample 35	0514-419	-
136	Rheumatoid factor sample 36	0514-478	-
137	Rheumatoid factor sample 37	0514-534	-
138	Rheumatoid factor sample 38	0514-592	-

139	Rheumatoid factor sample 39	0514-633	-
140	Rheumatoid factor sample 40	0514-647	-
141	Other respiratory tract sample 1	0211-3505	-
142	Other respiratory tract sample 2	0211-3507	-
143	Other respiratory tract sample 3	0211-3508	-
144	Other respiratory tract sample 4	0214-3504	-
145	Other respiratory tract sample 5	0214-3505	-
146	Other respiratory tract sample 6	0214-3506	-
147	Other respiratory tract sample 7	0214-3507	+
148	Other respiratory tract sample 8	0217-3501	-
149	Other respiratory tract sample 9	0217-3503	-
150	Other respiratory tract sample 10	0217-3509	-
151	Other respiratory tract sample 11	0217-3510	-
152	Other respiratory tract sample 12	0217-3511	+
153	Other respiratory tract sample 13	0219-3501	-
154	Other respiratory tract sample 14	0219-3502	-
155	Other respiratory tract sample 15	0219-3503	-
156	Other respiratory tract sample 16	0219-3504	-
157	Other respiratory tract sample 17	0219-3506	-
158	Other respiratory tract sample 18	0219-3507	-
159	Other respiratory tract sample 19	0219-3508	-
160	Other respiratory tract sample 20	0219-3509	-
161	Other respiratory tract sample 21	0219-3510	-
162	Other respiratory tract sample 22	0204-3506	-
163	Other respiratory tract sample 23	0320-3501	-
164	Other respiratory tract sample 24	0320-3502	-
165	Other respiratory tract sample 25	0320-3503	-
166	Other respiratory tract sample 26	0320-3504	-
167	Other respiratory tract sample 27	0320-3505	-

168	Other respiratory tract sample 28	0320-3506	-
169	Other respiratory tract sample 29	0320-3508	-
170	Other respiratory tract sample 30	0319-3501	-
171	Other respiratory tract sample 31	0319-3502	-
172	Other respiratory tract sample 32	0319-3504	-
173	Other respiratory tract sample 33	0319-3506	-
174	Other respiratory tract sample 34	0319-3507	-
175	Other respiratory tract sample 35	0319-3508	-
176	Other respiratory tract sample 36	0924-3501	-
177	Other respiratory tract sample 37	0924-3503	-
178	Other respiratory tract sample 38	0924-3504	-
179	Other respiratory tract sample 39	0924-3505	-
180	Other respiratory tract sample 40	0924-3506	-
181	Other respiratory tract sample 41	0924-3507	-
182	Other respiratory tract sample 42	0924-3508	-
183	Other respiratory tract sample 43	0924-3509	-
184	Other respiratory tract sample 44	0924-3510	-
185	Other respiratory tract sample 45	0924-3511	-
186	Other respiratory tract sample 46	0924-3512	-
187	Other respiratory tract sample 47	0924-3513	-
188	Other respiratory tract sample 48	0924-3514	-

4、Conclusion

By using SARS-CoV-2 Antigen Rapid Test Kit (fluorescence immunochromatography) produced by Biohit Healthcare (Hefei) Co., Ltd., clinical specificity of SARS-CoV-2 N antigen in serum samples from 188 patients with non-new corona virus infection (which is consistent with the results of nucleic acid detection) is 98.9% (95CI: 96.21%~99.87%) .