

**SARS-CoV-2 Antigen Rapid Test**  
**(Colloidal Gold Method)**

**Clinical Validation Report**

**Biohit Healthcare (Hefei) Co., Ltd.**

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## **1. Research Purpose**

The objective of this study was to evaluate the diagnostic performances of SARS-CoV-2 Antigen Rapid Test (Colloidal Gold Method) produced by Biohit Healthcare (Hefei) Co., Ltd. carried out on nasal swab samples collected.

## **2. Research Method**

This was a retrospective study carried out using nasal swab samples from 129 patients with COVID-19 infection confirmed by PCR and 196 negative nasal swab samples confirmed by PCR.

### **2.1 Research sample**

Clinical nasal swab samples were collected from 129 patients with COVID-19 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-CoV-2 used was produced by BGI Genomics Co., Ltd. (FDA EUA Approved). The samples were stored at - 80 ° C in 2ml PBS.

196 nasal swab samples were collected from the local hospital and tested negative for SARS-CoV-2 by PCR. The samples were stored at -80 °C in 2ml PBS.

### **2.2 Reagents**

The SARS-CoV-2 Antigen Rapid Test (Colloidal Gold Method), produced by Biohit Healthcare (Hefei) Co., Ltd.

Lot number: 200707.

## **3. Research Results**

Performance of SARS-CoV-2 Antigen Rapid Test (Colloidal Gold Method) was evaluated using nasal swab sample from 129 PCR confirmed positive patients and 196 PCR confirmed negative. A sensitivity of 96.12% and a specificity of 99.49% were determined for the SARS-CoV-2 Antigen Rapid Test (Colloidal Gold Method).

Statistical test results

		PCR results	
		Positive	Negative
SARS-CoV-2 Antigen Rapid Test	Positive	124	1
	Negative	5	195
	Total	129	196
Sensitivity		96.12% (95CI: 91.19%~98.73%)	
Specificity		99.49% (95CI:97.19%~99.99%)	

**4. Research Conclusion**

A sensitivity of 96.12% (95CI: 91.19%~98.73%) and a specificity of 99.49% (95CI:97.19%~99.99%) were determined for the SARS-CoV-2 Antigen Rapid Test (Colloidal Gold Method).

Sample information and test results

Basic Information		Test results	
Serial number	Sample number	PCR test results CT value	SARS-CoV-2 Antigen Rapid Test
1	145	17.45	+
2	1129	29.34	+
3	1589	31.22	+
4	1739	30.98	+
5	1799	35.89	+
6	243	26.98	+
7	686	27.45	+
8	411	18.21	+
9	1356	29.32	+
10	1533	31.98	+
11	1822	33.11	+
12	395	26.33	+
13	670	35.13	+
14	682	25.99	+
15	451	30.66	+
16	864	29.11	+
17	946	30.56	+
18	1103	34.99	+
19	1312	36.45	+
20	1488	33.56	+
21	1510	23.44	+
22	1659	29.21	+
23	349	24.87	+
24	6	25.56	+
25	74	27.44	+
26	324	20.32	+
27	350	31.56	+
28	456	32.87	-
29	632	18.34	+
30	1005	27.11	+
31	1486	24.45	+
32	1914	24.56	+
33	244	24.23	+
34	358	33.43	+
35	443	22.89	+

36	1245	21.86	+
37	1297	37.43	+
38	1802	21.56	+
39	3192	21.23	+
40	7	26.45	+
41	37	31.57	+
42	298	28.56	+
43	858	27.59	+
44	1324	22.45	+
45	1326	29.32	+
46	1386	22.34	+
47	1800	31.23	+
48	1935	33.34	+
49	348	23.56	+
50	67	31.34	+
51	321	22.43	+
52	322	25.76	+
53	352	35.56	+
54	820	36.24	+
55	851	24.35	+
56	573	21.32	+
57	630	30.22	+
58	1413	32.42	+
59	1487	34.11	+
60	1660	28.22	+
61	1989	31.12	+
62	832	27.45	+
63	833	19.95	+
64	857	18.34	+
65	956	25.35	+
66	1038	23.21	+
67	1787	22.11	+
68	1814	34.89	+
69	1828	31.34	+
70	569	25.89	+
71	169	33.54	+
72	580	25.12	+
73	1021	29.23	+
74	1234	32.77	-
75	1506	26.67	+
76	1618	26.34	+

77	1656	31.3	+
78	1841	37.21	+
79	137	28.23	+
80	1302	31.27	+
81	1314	35.97	+
82	1483	36.64	+
83	1661	24.99	+
84	1633	26.45	+
85	1916	31.9	-
86	241	21.89	+
87	1643	33.45	+
88	1296	34.12	+
89	1759	37.45	-
90	17	32.46	+
91	20	34.54	+
92	1238	32.65	+
93	1987	29.47	+
94	847	34.21	+
95	983	27.47	+
96	894	24.36	+
97	1474	25.11	+
98	1890	32.83	+
99	2550	35.56	+
100	1868	34.14	-
101	1693	31.34	+
102	ESI 155	20	+
103	ESI 156	17	+
104	ESI 204	26	+
105	ESI 206	23	+
106	ESI 229	28	+
107	ESI 340	19	+
108	ESI 348	17	+
109	ESI 359	19	+
110	SW 48	20	+
111	ESI 373	17	+
112	ESI 403	22	+
113	ESI 486	25	+
114	ESI 585	17	+
115	ESI 626	20	+
116	SW 129	16	+
117	ESI 658	16	+

118	SW 138	18	+
119	ESI 740	18	+
120	ESI 752	15	+
121	ESI 754	17	+
122	ESI 758	22	+
123	SW 241	9	+
124	ESI 792	18	+
125	ESI 793	16	+
126	ESI 794	14	+
127	SW 266	21	+
128	ESI 837	17	+
129	ESI 841	20	+