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SARS-CoV-2 antigen IVD kit SWAB Clinical Evaluation Report

1. Purpose

This report is intended to evaluate the clinical performance of SARS-CoV-2 antigen IVD kit SWAB(Colloidal Gold Method).

2. Mechanism Of Reaction

This kit adopts the detection principle of double antigen sandwich method. The binding pad of the detection card contains colloidal gold-labeled mouse N protein monoclonal antibody I; the detection line (T line) of the nitrocellulose membrane is coated with mouse N protein monoclonal antibody Antibody II, quality control line (line C) is coated with goat anti-mouse antibody.

The collected samples are processed by the sample extract and added. During the test, when the extract containing the N protein of the SARS-CoV-2 is added to the sample hole of the test card, under the action of chromatography, the sample moves to the end of the absorbent paper and first passes through the binding pad. The N protein and colloidal gold labeled mice The source N protein monoclonal antibody I specifically binds and continues to move to the absorbent paper end. When the sample moves to the T line, the N protein bound to the labeled antibody specifically binds to the N protein monoclonal antibody II coated in the T line in a double antibody sandwich mode, and stays at the T line; the remaining liquid continues to absorb water The paper end moves. When it moves to the C line, the mouse N protein antibody I labeled with colloidal gold specifically binds to the goat anti-mouse antibody in the C line. The T line shows a red band, indicating that the SARS-CoV-2 antigen is positive. No matter whether the T line is colored or not, the C line should show red. If the C line is not colored, the test is invalid and the sample needs to be tested again.

3. Product Function

The kit is used for qualitative detection of SARS-CoV-2 antigen in human nasopharyngeal swab and oropharyngeal swab samples.

4. Applicable Medical Stages

This product can be used for diagnostic screening.

5. Test Design

5.1 Overall test design

In this test, the total number of specimen selected for nasopharyngeal swabs and oropharyngeal swabs was not less than 100, respectively. The same specimen were performed a single test using the test reagent (SARS-CoV-2 antigen IVD kit) and PCR detection method to evaluate whether the SARS-CoV-2 antigen IVD kit meets the requirements. If the test results cannot meet the preset standards, the sample size should be appropriately expanded for evaluation.

5.2 Experimental design and research method selection

5.2.1 Specimen source

The sample was from a suspected case of new coronary pneumonia in a clinical trial institution.The same suspected case collected a respiratory secretion from a nasopharyngeal swab and anoropharyngeal swab. The samples should have corresponding basic clinical information. The total number of samples selected for the nasopharyngeal swabs and oropharyngeal swabs is not less than 100, and the number of positive samples for the two sample types should be not less than 100 respectively.

5.2.2 Specimen deletion criteria

All the selected samples have one item that cannot meet the information required for this verification shall be deleted.

5.2.3 Specimen removal criteria

Specimens with no results or failures are excluded.

5.2.4 Collection and storage of specimens

(1) Oropharyngeal swab specimen:

Use a dedicated sampling swab to wipe the posterior pharyngeal wall and tonsils on both sides with moderate force. Avoid touching the tongue; quickly immerse the swab head in the specimen extraction buffer.

(2) Nasopharynageal swab specimen:

Insert the swab into the nasal cavity with the most secretions. Rotate gently and push into the nasal cavity, then press the swab against the wall of the nose three times, remove the swab head; quickly immerse the swab head in the sample extraction buffer.

(3) After collection, the specimens should be processed with the extraction buffer provided by this kit as soon as possible. And complete the test within 10 minutes.

(4) Take two specimens of the same patient, one for the antigen IVD kit and one for PCR reagent detection.

6. Test Implementation

This testing specimen is a secretion specimen of nasopharyngeal swabs and oropharyngeal swabs from hospital, which were tested with the reagents to be evaluted and PCR, respectively. 260 specimens were selected this time. According to the statistics of PCR test results, there were 105 positive samples for nasopharyngeal swabs and oropharyngeal swabs for each, and 155 negative specimen for each.

7. Evaluation and Statistics Method

Calculate sensitivity and specificity with test results and clinical reference standards.

Test Product	Clinical Reference Standard		Total
	Positive	Negative	
Positive	a（True positive）	b（False positive）	a+b
Negative	c（False negative）	d（True negative）	c+d
Total	a+c	b+d	N=a+b+c+d

Perform Kappa evaluation. If Kappa ≥0.75, it means the test results of test product and control products are highly accordance, these two systems are equivalent. If Kappa ≥0.4, it means the test results of test product and control products are accordance, however, statistics evaluation for sensitivity and specificity should be performed. If Kappa <0.4, it means the test results of test product and control products are not accordance, these two systems are not equivalent.

Kappa calculate formula：

$$Kappa=(P_A-P_e)/(1-P_e)$$

P_A ="Actual Consistency Rate"，P_e="Theoretical Consistency Rate". Take an example as table 1, calculate method are below:

$$P_A=(a+d)/(a+b+c+d)$$

$$P_e=[(a+b)(a+c)+(c+d)(b+d)]/(a+b+c+d)^2$$

Sensitivity and specitivity shall meet clinical requirement (sensitivity should no less than 90%, specitivity should no less than 90%). The test product and control product shoule be equivalent.

Sensitivity= a/(a+c)；measures the proportion of positives that are correctly identified as such.

Speciificity = d/(b+d)；measures the proportion of negatives that are correctly identified as such.

8. Test Results

Table 1：Test results for oropharyngeal swab/ nasopharyngeal swab sample

Oropharyngeal Swab Samples			Nasopharyngeal Swab Samples		
Sample No.	Test Results of antigen IVD kit	PCR Test Results	Sample No.	Test Results of antigen IVD kit	PCR Test Results
1	–	–	1	–	–
2	–	–	2	–	–
3	–	–	3	–	–
4	+	+	4	+	+
5	–	–	5	–	–
6	+	+	6	–	+
7	–	–	7	–	–
8	+	+	8	+	+
9	+	+	9	+	+
10	–	–	10	–	–
11	–	–	11	–	–
12	–	–	12	–	–

13	–	–	13	–	–
14	–	–	14	–	–
15	–	–	15	–	–
16	+	+	16	+	+
17	+	+	17	+	+
18	+	+	18	+	+
19	–	–	19	–	–
20	–	–	20	–	–
21	–	–	21	–	–
22	–	–	22	–	–
23	–	+	23	–	+
24	–	–	24	–	–
25	–	–	25	–	–
26	+	+	26	+	+
27	+	+	27	+	+
28	–	–	28	–	–
29	–	–	29	–	–
30	–	–	30	–	–
31	–	–	31	–	–
32	–	–	32	–	–
33	+	–	33	–	–
34	–	–	34	–	–
35	–	–	35	–	–
36	+	+	36	+	+
37	–	–	37	–	–
38	+	+	38	+	+
39	–	–	39	–	–

40	+	+	40	+	+
41	_	_	41	_	_
42	+	+	42	+	+
43	+	+	43	+	+
44	_	_	44	_	_
45	+	+	45	+	+
46	_	_	46	_	_
47	_	_	47	_	_
48	_	_	48	_	_
49	_	_	49	_	_
50	+	+	50	+	+
51	_	_	51	_	_
52	_	_	52	_	_
53	+	+	53	+	+
54	_	_	54	_	_
55	_	_	55	_	_
56	_	_	56	_	_
57	_	_	57	_	_
58	+	+	58	+	+
59	+	+	59	+	+
60	+	+	60	+	+
61	_	_	61	_	_
62	_	_	62	_	_
63	_	_	63	_	_
64	_	_	64	_	_
65	_	+	65	−	+
66	+	+	66	+	+

67	–	–	67	–	–
68	–	–	68	–	–
69	+	+	69	+	+
70	–	–	70	–	–
71	+	+	71	+	+
72	–	–	72	–	–
73	–	–	73	–	–
74	–	–	74	–	–
75	+	+	75	+	+
76	–	–	76	–	–
77	–	–	77	–	–
78	–	–	78	–	–
79	+	+	79	+	+
80	+	+	80	+	+
81	–	–	81	–	–
82	–	–	82	–	–
83	+	–	83	+	–
84	–	–	84	–	–
85	–	–	85	–	–
86	+	+	86	+	+
87	–	–	87	–	–
88	–	–	88	–	–
89	+	+	89	+	+
90	+	+	90	+	+
91	–	–	91	–	–
92	–	–	92	–	–
93	–	–	93	–	–

94	–	–	94	–	–
95	–	+	95	–	+
96	+	+	96	+	+
97	–	–	97	–	–
98	–	–	98	–	–
99	–	–	99	–	–
100	+	+	100	+	+
101	+	+	101	+	+
102	–	–	102	–	–
103	–	–	103	–	–
104	+	+	104	+	+
105	–	–	105	–	–
106	+	+	106	+	+
107	+	+	107	+	+
108	–	–	108	–	–
109	+	+	109	+	+
110	–	–	110	–	–
111	–	–	111	–	–
112	–	–	112	–	–
113	+	+	113	+	+
114	–	–	114	–	–
115	–	–	115	–	–
116	+	–	116	+	–
117	–	–	117	–	–
118	–	–	118	–	–
119	+	+	119	+	+
120	–	–	120	–	–

121	_	_	121	_	_
122	+	+	122	+	+
123	_	_	123	_	_
124	_	_	124	_	_
125	_	_	125	_	_
126	_	_	126	_	_
127	_	_	127	_	_
128	_	_	128	_	_
129	+	+	129	+	+
130	_	_	130	_	_
131	_	_	131	_	_
132	_	_	132	_	_
133	_	_	133	_	_
134	_	_	134	_	_
135	+	+	135	+	+
136	_	_	136	_	_
137	_	_	137	_	_
138	_	_	138	_	_
139	_	_	139	_	_
140	_	_	140	_	_
141	_	_	141	_	_
142	_	_	142	_	_
143	+	+	143	+	+
144	_	_	144	_	_
145	_	_	145	_	_
146	_	_	146	_	_
147	_	_	147	_	_

148	–	–	148	–	–
149	–	–	149	–	–
150	–	–	150	–	–
151	–	–	151	–	–
152	+	+	152	+	+
153	+	+	153	+	+
154	–	–	154	–	–
155	–	–	155	–	–
156	–	–	156	–	–
157	+	+	157	+	+
158	–	–	158	–	–
159	–	–	159	–	–
160	+	+	160	+	+
161	–	–	161	–	–
162	+	+	162	+	+
163	+	+	163	+	+
164	+	+	164	+	+
165	–	–	165	–	–
166	–	–	166	–	–
167	+	+	167	+	+
168	+	+	168	+	+
169	–	–	169	–	–
170	–	–	170	–	–
171	+	+	171	+	+
172	–	–	172	–	–
173	–	–	173	–	–
174	+	+	174	+	+

175	–	–	175	–	–
176	+	+	176	+	+
177	+	+	177	+	+
178	–	–	178	–	–
179	+	+	179	+	+
180	–	–	180	–	–
181	–	–	181	–	–
182	+	+	182	+	+
183	–	–	183	–	–
184	+	+	184	+	+
185	+	+	185	+	+
186	–	–	186	–	–
187	+	+	187	+	+
188	–	–	188	–	–
189	–	–	189	–	–
190	–	–	190	–	–
191	+	+	191	+	+
192	+	+	192	+	+
193	+	+	193	+	+
194	–	–	194	–	–
195	–	–	195	–	–
196	+	+	196	+	+
197	–	+	197	–	+
198	–	–	198	–	–
199	–	–	199	–	–
200	+	+	200	+	+
201	+	+	201	+	+

202	–	–	202	–	–
203	+	+	203	+	+
204	+	+	204	+	+
205	–	–	205	–	–
206	+	+	206	+	+
207	+	+	207	+	+
208	+	+	208	+	+
209	+	+	209	+	+
210	–	–	210	–	–
211	+	+	211	+	+
213	–	–	213	–	–
213	+	+	213	+	+
214	–	–	214	–	–
215	–	–	215	–	–
216	+	+	216	+	+
217	+	+	217	+	+
218	–	–	218	–	–
219	+	+	219	+	+
220	+	+	220	+	+
221	+	+	221	+	+
222	+	+	222	+	+
223	–	–	223	–	–
224	–	–	224	–	–
225	+	+	225	+	+
226	+	+	226	+	+
227	–	–	227	–	–
228	+	+	228	+	+

229	+	+	229	+	+
230	_	_	230	_	_
231	+	+	231	+	+
232	+	+	232	+	+
233	_	_	233	_	_
234	_	_	234	_	_
235	+	+	235	+	+
236	+	+	236	+	+
237	_	_	237	_	_
238	_	_	238	_	_
239	+	+	239	+	+
240	+	+	240	+	+
241	+	+	241	+	+
242	_	_	242	_	_
243	+	+	243	+	+
244	+	+	244	+	+
245	_	_	245	_	_
246	_	_	246	_	_
247	_	_	247	_	_
248	+	+	248	+	+
249	+	+	249	+	+
250	_	_	250	_	_
251	_	_	251	_	_
252	+	+	252	+	+
253	+	+	253	+	+
254	_	_	254	_	_
255	+	+	255	+	+

257	+	+	257	+	+
258	+	+	258	+	+
259	_	_	259	_	_
260	+	+	260	+	+

Note: “＋”means positive，“-”means negative.

According to test results, when test oropharyngeal swab samples, SARS-CoV-2 antigen IVD kit has 3 false-positive, 4 false-negative,when test nasopharyngeal swab samples, SARS-CoV-2 antigen IVD kit has 2 false-positive, 5 false-negative, results compare to PCR products. Calculate the Kappa, sensitivity and specificity.

Oropharyngeal Swab Samples:

Sensitivity =a/(a+c)= 96.19%（95%CI:85.25%-98.46%）;

Specificity =d/(b+d)= 98.06%（95%CI:85.32%-99.65%）;

Kappa =(PA-Pe)/(1-Pe)=0.95;

Nasopharyngeal Swab Samples:

Sensitivity =a/(a+c)=95.23%;（95%CI:85.56%-98.28%）

Specificity=d/(b+d)=98.71%（95%CI:86.35%-99.42%）;

Kappa=(PA-Pe)/(1-Pe)=0.94;

The antigen test Kappa of oropharyngeal swab/ nasopharyngeal swab sample ≥0.75,

Sensitivity of oropharyngeal swab/ nasopharyngeal swab sample is no less than 90%,

Specificity of oropharyngeal swab/ nasopharyngeal swab sample is no less than 90%.

9. Conclusion

SARS-CoV-2 antigen IVD kit SWAB(Colloidal Gold Method) has great sensitivity and specificity.