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Project Name: <p style="text-align: center;">SARS-CoV-2 Antigen Test Kit (Colloidal Gold)</p> Document Name: <p style="text-align: center;">Clinical Evaluation Report</p>			
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R e v i s i o n r e c o r d s			
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V1.0	Initialization Version	5.1.2e	2021.04.25

Clinical Evaluation Report

1. General Information

According to the *Guidelines for Clinical Trials of In vitro diagnostic reagents (No.16 of 2014)*, We entrusted 3 medical institutions in Hubei, Heilongjiang and Guangdong to perform the clinical evaluation of SARS-CoV-2 Antigen Test Kit (Colloidal Gold) developed by Shenzhen Dymind Biotechnology Co., Ltd.

The specimens used in this clinical evaluation study were collected from patients in nasal (NS) swab specimens directly from individuals who are suspected of COVID-19.

2. Study Design and Method Report

2.1. Purpose

This evaluation study was performed in comparison with a commercial RT-PCR kit, which was used as gold standard assay.

2.2 Samples

In this study, clinical samples were collected from a total 240 individuals, 117 among them were viral infection patients confirmed by RT-PCR and 123 were normal volunteers.

2.3 Test Kits

SARS-CoV-2 Antigen Test Kit, manufactured by the company.

Lot No.	Date of Manufacture	Estimated Expiration Date
2020042101	20200421	20210420

2.4 Test procedure

All specimens were tested according to kit's instructions for use.

3. Results

3.1. test results

Sn.No.	Patient's ID	Gender	Age	Education	Profession	Province	Specimen Type	RT-PCR(Ct)		SARS-CoV-2 Antigen Test Kit
								Lab	N	
1	5.1.2e	Male	68	Middle School	Jobless	Hubei	NS	23	22	+
2		Female	56	Middle School	Migrant workers	Hubei	NS	28	27	+
3		Male	16	High School	Student	Hubei	NS	30	30.5	+

4	5.1.2e	Female	53	Middle School	Student	Hubei	NS	32.5	32	+
5		Male	46	Bachelor	Sales	Hubei	NS	26.5	26	+
6		Female	20	Bachelor	Engineer	Hubei	NS	29.5	30	+
7		Female	19	High School	Student	Hubei	NS	31	31.5	+
8		Male	45	Bachelor	Sales	Hubei	NS	30	30	+
9		Female	52	Middle School	Migrant workers	Hubei	NS	35	35	+
10		Male	30	Bachelor	Doctor	Hubei	NS	37	37	-
11		Female	23	Bachelor	Engineer	Hubei	NS	31	31	+
12		Male	85	Other	Jobless	Hubei	NS	28	29	+
13		Female	49	Middle School	Migrant workers	Hubei	NS	29	30	+
14		Male	13	Middle School	Student	Hubei	NS	36	35.5	+
15		Female	18	High School	Student	Hubei	NS	31	31	+
16		Male	8	Primary school	Student	Hubei	NS	29.5	29.5	+
17		Male	53	High School	Sales	Hubei	NS	21	22	+
18		Female	28	Bachelor	Engineer	Heilongjiang	NS	37	36.5	-
19		Male	26	Bachelor	Engineer	Heilongjiang	NS	35	36	+
20		Female	33	Bachelor	Sales	Heilongjiang	NS	26.5	27	+
21		Male	31	Bachelor	Engineer	Heilongjiang	NS	31	30.5	+
22		Female	52	High School	Other	Heilongjiang	NS	34	33.5	+
23		Male	42	Primary school	Other	Heilongjiang	NS	28	27.5	+
24		Female	56	Middle School	Other	Heilongjiang	NS	28	29	+
25		Male	29	Bachelor	Doctor	Heilongjiang	NS	34	35	+
26		Male	15	Primary school	Student	Heilongjiang	NS	26.5	27	+
27		Female	24	Bachelor	Doctor	Heilongjiang	NS	28.5	29	+

28	5.1.2e	Female	36	Bachelor	Engineer	Heilongjiang	NS	24	25	+	
29		Male	23	Bachelor	Engineer	Heilongjiang	NS	29.5	29	+	
30		Female	30	Bachelor	Sales	Heilongjiang	NS	32	32.5	+	
31		Male	9	Primary school	Student	Heilongjiang	NS	35	34	+	
32		Male	12	Middle School	Student	Heilongjiang	NS	28	29	+	
33		Female	34	Bachelor	Sales	Heilongjiang	NS	26	25	+	
34		Male	17	High School	Student	Heilongjiang	NS	26.5	27	+	
35		Male	16	High School	Student	Heilongjiang	NS	23	24	+	
36		Female	19	Bachelor	Student	Heilongjiang	NS	37	37	-	
37		Female	17	High School	Student	Heilongjiang	NS	32	31	+	
38		Male	16	High School	Student	Heilongjiang	NS	24.5	25	+	
39		Female	45	Other	Migrant workers	Heilongjiang	NS	23	22.5	+	
40		Male	80	Other	Jobless	Heilongjiang	NS	33	33	+	
41		Female	23	Bachelor	Engineer	Heilongjiang	NS	29	28.5	+	
42		Male	13	Primary school	Student	Heilongjiang	NS	34	35	+	
43		Female	67	Other	Jobless	Heilongjiang	NS	25	25.5	+	
44		5.1.2e	Male	6	Primary school	Student	Heilongjiang	NS	26.5	26	+
45			Female	53	Other	Migrant workers	Heilongjiang	NS	30	29	+
46			Male	8	Primary school	Student	Heilongjiang	NS	35	35.5	+
47			Female	26	Bachelor	Engineer	Heilongjiang	NS	30	29.5	+
48	Male		33	Bachelor	Engineer	Heilongjiang	NS	29.5	29	+	
49	Male		31	Bachelor	Engineer	Heilongjiang	NS	28	28.5	+	
50	Female		52	Other	Sales	Heilongjiang	NS	32	32.5	+	
51	Male		11	Middle	Student	Heilongjiang	NS	23	24	+	

	3			School		ang				
52	5.1.2e	Male	22	Bachelor	Engineer	Heilongjiang	NS	27	28	+
53		Female	68	Other	Jobless	Heilongjiang	NS	36	35.5	+
54		Male	57	High School	Jobless	Heilongjiang	NS	35.5	36	+
55		Female	13	Middle School	Student	Heilongjiang	NS	28	29	+
56		Female	52	Bachelor	Engineer	Heilongjiang	NS	32.5	32.5	+
57		Male	60	High School	Other	Heilongjiang	NS	32.5	32	+
58		Female	16	High School	Student	Heilongjiang	NS	24	25	+
59		Male	29	Bachelor	Engineer	Heilongjiang	NS	23	23.5	+
60		Female	26	Bachelor	Engineer	Heilongjiang	NS	37	37	-
61		Male	15	Primary school	Student	Heilongjiang	NS	36	36	+
62		Male	16	High School	Student	Heilongjiang	NS	26.5	27	+
63		Female	9	Primary school	Student	Heilongjiang	NS	25	26	+
64		Male	28	Bachelor	Other	Heilongjiang	NS	29	30	+
65		Female	16	High School	Student	Heilongjiang	NS	30	31	+
66		Male	11	Primary school	Student	Heilongjiang	NS	27.5	28	+
67		Male	24	Bachelor	Engineer	Heilongjiang	NS	28	29	+
68		Female	50	Other	Migrant workers	Heilongjiang	NS	34	35	+
69		Female	29	Bachelor	Doctor	Heilongjiang	NS	25	26	+
70		Male	15	High School	Student	Heilongjiang	NS	29	29.5	+
71		Female	24	Bachelor	Doctor	Heilongjiang	NS	28.5	28	+
72		Male	16	High School	Student	Heilongjiang	NS	29	28.5	+
73		Female	18	High School	Student	Heilongjiang	NS	36	36.5	+
74		Male	58	Other	Migrant workers	Heilongjiang	NS	25	26	+
75		Male	29	Bachelor	Engineer	Heilongjiang	NS	33	33	+

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76	5.1.2e	Male	26	Bachel or	Engineer	Heilongji ang	NS	32	32. 5	+	
77		Fem ale	52	High School	Migrant workers	Heilongji ang	NS	22	22. 5	+	
78		Male	60	High School	Jobless	Heilongji ang	NS	24	25	+	
79		Fem ale	15	High School	Student	Heilongji ang	NS	32. 5	32	+	
80		Male	27	Bachel or	Engineer	Heilongji ang	NS	24	24. 5	+	
81		Male	17	High School	Student	Heilongji ang	NS	28	27	+	
82		Fem ale	36	Bachel or	Sales	Heilongji ang	NS	35	36	+	
83		Fem ale	8	Primar y school	Student	Heilongji ang	NS	36	36. 5	+	
84		Male	12	Primar y school	Student	Heilongji ang	NS	28	29	+	
85		Fem ale	13	Middle School	Student	Heilongji ang	NS	23	23. 5	+	
86		Male	26	Bachel or	Engineer	Heilongji ang	NS	22. 5	23	+	
87		Fem ale	26	Bachel or	Engineer	Heilongji ang	NS	29	30	+	
88		Male	52	Bachel or	Engineer	Heilongji ang	NS	26	27	+	
89		Fem ale	60	Bachel or	Enginccr	Heilongji ang	NS	22	22. 5	+	
90		Male	58	Bachel or	Engineer	Heilongji ang	NS	23	22	+	
91		5.1.2e	Male	16	High School	Student	Guangdo ng	NS	29	28	+
92			Fem ale	16	High School	Other	Guangdo ng	NS	24. 5	24	+
93			Fem ale	67	Bachel or	Jobless	Guangdo ng	NS	36	36	+
94			Male	8	Primar y school	Student	Guangdo ng	NS	27. 5	27	+
95			Male	26	Bachel or	Engineer	Guangdo ng	NS	29	30	+
96	Fem ale		15	High School	Student	Guangdo ng	NS	23	24	+	
97	Fem ale		33	Bachel or	Enginccr	Guangdo ng	NS	36	35	+	
98	Male		58	Bachel or	Engineer	Guangdo ng	NS	33	33	+	
99	Fem		25	Bachel	Engineer	Guangdo	NS	35	36	+	

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100	5.1.2e	Male	80	Other	Jobless	Guangdong	NS	28	27.5	+
101		Female	16	High School	Student	Guangdong	NS	28.5	29	+
102		Female	8	Primary school	Student	Guangdong	NS	25	24	+
103		Male	24	Bachelor	Engineer	Guangdong	NS	28	29	+
104		Male	16	High School	Student	Guangdong	NS	29	30	+
105		Male	26	Bachelor	Other	Guangdong	NS	26.5	26	+
106		Female	17	High School	Student	Guangdong	NS	35.5	35	+
107		Male	12	Middle School	Student	Guangdong	NS	32	32	+
108		Female	26	Bachelor	Other	Guangdong	NS	26	26.5	+
109		Male	52	Other	Migrant workers	Guangdong	NS	27	26.5	+
110		Male	15	High School	Student	Guangdong	NS	27.5	28	+
111		Female	54	Bachelor	Jobless	Guangdong	NS	30	30	+
112		Male	29	Bachelor	Engineer	Guangdong	NS	34	34.5	+
113		Female	8	Primary school	Student	Guangdong	NS	28	27	+
114	Male	53	High School	Other	Guangdong	NS	30.5	31	+	
115	5.1.2e	Female	16	High School	Student	Guangdong	NS	31	32	+
116		Male	26	Bachelor	Other	Guangdong	NS	32.5	32	+
117		Male	51	Other	Migrant workers	Guangdong	NS	30	29.5	+
118		Female	60	Bachelor	Doctor	Hubei	NS	≥40	≥40	-
119		Male	58	Bachelor	Engineer	Hubei	NS	≥40	≥40	-
120		Female	22	Bachelor	Student	Hubei	NS	≥40	≥40	-
121		Male	52	Bachelor	Engineer	Hubei	NS	≥40	≥40	-
122		Female	62	Bachelor	Jobless	Hubei	NS	≥40	≥40	-
123		Female	55	Bachelor	Jobless	Hubei	NS	≥40	≥40	-



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124	7	Male	20	Bachelor	Student	Hubei	NS	≥4 0	≥4 0	-
125	8	Female	13	Primary school	Student	Hubei	NS	≥4 0	≥4 0	-
126	9	Male	34	Bachelor	Sales	Hubei	NS	≥4 0	≥4 0	-
127	10	Male	9	Primary school	Student	Hubei	NS	≥4 0	≥4 0	-
128	11	Male	53	Bachelor	Engineer	Hubei	NS	≥4 0	≥4 0	-
129	12	Female	28	Bachelor	Sales	Hubei	NS	≥4 0	≥4 0	-
130	13	Male	26	Bachelor	Sales	Hubei	NS	≥4 0	≥4 0	+
131	14	Female	10	Primary school	Student	Hubei	NS	≥4 0	≥4 0	-
132	15	Male	52	Bachelor	Engineer	Hubei	NS	≥4 0	≥4 0	-
133	16	Male	60	Bachelor	Engineer	Hubei	NS	≥4 0	≥4 0	-
134	17	Female	58	Bachelor	Engineer	Hubei	NS	≥4 0	≥4 0	-
135	18	Female	28	Bachelor	Engineer	Hubei	NS	≥4 0	≥4 0	-
136	19	Male	26	Bachelor	Sales	Hubei	NS	≥4 0	≥4 0	+
137	20	Male	32	Bachelor	Engineer	Hubei	NS	≥4 0	≥4 0	-
138	21	Female	33	Bachelor	Engineer	Hubei	NS	≥4 0	≥4 0	-
139	22	Male	60	Bachelor	Engineer	Hubei	NS	≥4 0	≥4 0	-
140	23	Female	26	Bachelor	Other	Hubei	NS	≥4 0	≥4 0	-
141	24	Male	52	Bachelor	Engineer	Hubei	NS	≥4 0	≥4 0	-
142	25	Male	15	High School	Student	Hubei	NS	≥4 0	≥4 0	-
143	26	Male	13	Middle School	Student	Hubei	NS	≥4 0	≥4 0	-
144	27	Female	26	Bachelor	Doctor	Hubei	NS	≥4 0	≥4 0	-
145	28	Male	14	Primary school	Student	Hubei	NS	≥4 0	≥4 0	-
146	29	Female	67	Bachelor	Jobless	Hubei	NS	≥4 0	≥4 0	-
147	30	Male	8	Primary	Student	Hubei	NS	≥4 0	≥4 0	-



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				y school				0	0	
148	31	Female	26	Bachelor	Sales	Hubei	NS	≥40	≥40	-
149	32	Male	29	Bachelor	Sales	Hubei	NS	≥40	≥40	-
150	33	Male	18	High School	Student	Hubei	NS	≥40	≥40	-
151	34	Female	67	Bachelor	Jobless	Hubei	NS	≥40	≥40	-
152	35	Male	8	Primary school	Student	Hubei	NS	≥40	≥40	-
153	36	Female	53	High School	Student	Hubei	NS	≥40	≥40	-
154	37	Female	30	Bachelor	Sales	Hubei	NS	≥40	≥40	-
155	38	Female	26	Bachelor	Sales	Heilongjiang	NS	≥40	≥40	-
156	39	Female	9	Primary school	Student	Heilongjiang	NS	≥40	≥40	-
157	40	Male	7	Primary school	Student	Heilongjiang	NS	≥40	≥40	-
158	41	Female	53	High School	Other	Heilongjiang	NS	≥40	≥40	-
159	42	Male	28	Bachelor	Doctor	Heilongjiang	NS	≥40	≥40	-
160	43	Female	26	Bachelor	Engineer	Heilongjiang	NS	≥40	≥40	-
161	44	Male	65	Bachelor	Other	Heilongjiang	NS	≥40	≥40	-
162	45	Male	15	Middle School	Student	Heilongjiang	NS	≥40	≥40	-
163	46	Female	32	Bachelor	Engineer	Heilongjiang	NS	≥40	≥40	-
164	47	Male	13	Middle School	Student	Heilongjiang	NS	≥40	≥40	-
165	48	Female	55	High School	Sales	Heilongjiang	NS	≥40	≥40	-
166	49	Female	8	Primary school	Student	Heilongjiang	NS	≥40	≥40	-
167	50	Male	53	High School	Sales	Heilongjiang	NS	≥40	≥40	-
168	51	Male	12	Middle School	Student	Heilongjiang	NS	≥40	≥40	-
169	52	Male	26	Bachelor	Engineer	Heilongjiang	NS	≥40	≥40	-
170	53	Female	26	Bachelor	Engineer	Heilongjiang	NS	≥40	≥40	-

		ale		or		ang		0	0	
171	54	Fem ale	16	High School	Student	Heilongji ang	NS	≥4 0	≥4 0	-
172	55	Male	32	Bachel or	Other	Heilongji ang	NS	≥4 0	≥4 0	-
173	56	Fem ale	28	Bachel or	Other	Heilongji ang	NS	≥4 0	≥4 0	-
174	57	Male	21	Bachel or	Student	Heilongji ang	NS	≥4 0	≥4 0	-
175	58	Fem ale	26	Bachel or	Other	Heilongji ang	NS	≥4 0	≥4 0	-
176	59	Fem ale	50	Bachel or	Engineer	Heilongji ang	NS	≥4 0	≥4 0	-
177	60	Male	60	Bachel or	Engineer	Heilongji ang	NS	≥4 0	≥4 0	-
178	61	Fem ale	25	Bachel or	Engineer	Heilongji ang	NS	≥4 0	≥4 0	-
179	62	Fem ale	27	Bachel or	Sales	Heilongji ang	NS	≥4 0	≥4 0	-
180	63	Fem ale	57	Bachel or	Sales	Heilongji ang	NS	≥4 0	≥4 0	-
181	64	Male	15	High School	Student	Heilongji ang	NS	≥4 0	≥4 0	-
182	65	Fem ale	53	High School	Sales	Heilongji ang	NS	≥4 0	≥4 0	-
183	66	Male	45	Bachel or	Sales	Heilongji ang	NS	≥4 0	≥4 0	-
184	67	Fem ale	11	Middle School	Student	Heilongji ang	NS	≥4 0	≥4 0	-
185	68	Male	17	High School	Student	Heilongji ang	NS	≥4 0	≥4 0	-
186	69	Fem ale	10	Primar y school	Student	Heilongji ang	NS	≥4 0	≥4 0	-
187	70	Fem ale	16	High School	Student	Heilongji ang	NS	≥4 0	≥4 0	-
188	71	Male	32	Bachel or	Doctor	Heilongji ang	NS	≥4 0	≥4 0	-
189	72	Male	26	Bachel or	Sales	Heilongji ang	NS	≥4 0	≥4 0	-
190	73	Male	34	Bachel or	Sales	Heilongji ang	NS	≥4 0	≥4 0	-
191	74	Fem ale	58	Other	Engineer	Guangdo ng	NS	≥4 0	≥4 0	-
192	75	Male	29	Bachel or	Engineer	Guangdo ng	NS	≥4 0	≥4 0	-
193	76	Fem ale	13	Middle School	Student	Guangdo ng	NS	≥4 0	≥4 0	-
194	77	Male	10	Primar y school	Student	Guangdo ng	NS	≥4 0	≥4 0	-

195	78	Female	6	Primary school	Student	Guangdong	NS	≥4 0	≥4 0	-
196	79	Male	53	Other	Migrant workers	Guangdong	NS	≥4 0	≥4 0	-
197	80	Male	28	Bachelor	Doctor	Guangdong	NS	≥4 0	≥4 0	-
198	81	Female	30	Bachelor	Engineer	Guangdong	NS	≥4 0	≥4 0	-
199	82	Male	32	Bachelor	Engineer	Guangdong	NS	≥4 0	≥4 0	-
200	83	Female	16	High School	Student	Guangdong	NS	≥4 0	≥4 0	-
201	84	Male	12	Middle School	Student	Guangdong	NS	≥4 0	≥4 0	-
202	85	Female	28	High School	Student	Guangdong	NS	≥4 0	≥4 0	-
203	86	Male	8	Primary school	Student	Guangdong	NS	≥4 0	≥4 0	-
204	87	Female	13	Middle School	Student	Guangdong	NS	≥4 0	≥4 0	-
205	88	Male	15	Middle School	Student	Guangdong	NS	≥4 0	≥4 0	-
206	89	Female	21	Bachelor	Student	Guangdong	NS	≥4 0	≥4 0	-
207	90	Female	26	Bachelor	Engineer	Guangdong	NS	≥4 0	≥4 0	-
208	91	Female	16	High School	Student	Guangdong	NS	≥4 0	≥4 0	-
209	92	Male	26	Bachelor	Engineer	Guangdong	NS	≥4 0	≥4 0	-
210	93	Female	37	Bachelor	Sales	Guangdong	NS	≥4 0	≥4 0	-
211	94	Male	13	Middle School	Student	Guangdong	NS	≥4 0	≥4 0	-
212	95	Male	67	Bachelor	Engineer	Guangdong	NS	≥4 0	≥4 0	-
213	96	Male	7	Primary school	Student	Guangdong	NS	≥4 0	≥4 0	-
214	97	Male	53	Other	Sales	Guangdong	NS	≥4 0	≥4 0	-
215	98	Female	28	Bachelor	Engineer	Guangdong	NS	≥4 0	≥4 0	-
216	99	Male	16	High School	Student	Guangdong	NS	≥4 0	≥4 0	-
217	100	Female	26	Bachelor	Engineer	Guangdong	NS	≥4 0	≥4 0	-
218	101	Female	32	Bachelor	Engineer	Guangdong	NS	≥4 0	≥4 0	-



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219	102	Male	68	Middle School	Jobless	Guangdong	NS	≥40	≥40	-
220	103	Male	27	Bachelor	Engineer	Guangdong	NS	≥40	≥40	-
221	104	Male	29	Bachelor	Engineer	Guangdong	NS	≥40	≥40	-
222	105	Female	13	Primary school	Student	Guangdong	NS	≥40	≥40	-
223	106	Male	18	High School	Student	Guangdong	NS	≥40	≥40	-
224	107	Male	8	Primary school	Student	Guangdong	NS	≥40	≥40	-
225	108	Female	11	Primary school	Student	Guangdong	NS	≥40	≥40	-
226	109	Male	26	Bachelor	Engineer	Guangdong	NS	≥40	≥40	-
227	110	Female	52	Other	Other	Guangdong	NS	≥40	≥40	-
228	111	Female	12	Middle School	Student	Guangdong	NS	≥40	≥40	-
229	112	Male	58	Bachelor	Other	Guangdong	NS	≥40	≥40	-
230	113	Male	29	Bachelor	Engineer	Guangdong	NS	≥40	≥40	-
231	114	Male	42	Bachelor	Engineer	Guangdong	NS	≥40	≥40	-
232	115	Female	35	Bachelor	Engineer	Guangdong	NS	≥40	≥40	-
233	116	Male	21	High School	Other	Guangdong	NS	≥40	≥40	-
234	117	Male	37	Bachelor	Sales	Guangdong	NS	≥40	≥40	-
235	118	Male	19	High School	Student	Guangdong	NS	≥40	≥40	-
236	119	Female	17	High School	Student	Guangdong	NS	≥40	≥40	-
237	120	Male	12	Middle School	Student	Guangdong	NS	≥40	≥40	-
238	121	Male	16	High School	Student	Guangdong	NS	≥40	≥40	-
239	122	Female	66	Other	Migrant workers	Guangdong	NS	≥40	≥40	-
240	123	Male	14	Middle School	Student	Guangdong	NS	≥40	≥40	-

3.2 Participants Information

Gender of the participants

Gender	Number	% of total
Male	129	53.74%
Female	111	46.25%

Age distribution of the participants

Age group	Number	% of total
≤20	89	37.08%
21~40	84	35.00%
41~60	53	22.08%
61~80	13	5.42%
Above 80	1	0.42%

Educational background of the participants

Educational group	Number	% of total
Primary school	32	13.33%
Middle School	26	10.83%
High School	50	20.83%
Bachelor	115	47.91%
Others	17	7.10%

Occupational background of the participants

Profession	Number	% of total
Migrant workers	12	5.00%
Sales	28	11.67%
Engineer	64	26.67%
Student	92	38.33%
Doctor	10	4.17%
Jobless	15	6.25%
Others	19	7.91%

Regional distribution the participants

Province	Number	% of total
Hubei	54	22.50%
Heilongjiang	109	45.42%
Guangdong	77	32.08%

The participants' ages range from 6 to 85, and most of them were from 6 to 60. They have also showed different culture background. None of the participants had used SARS-CoV-2

Antigen Test Kit before. 52.09% reported that they were high-school graduates or lower and 53.74% participants were male.

3.3 Test Results and Accuracy

A total of 240 samples were tested:

SARS-CoV-2 Antigen Test Kit	Comparator Method (NAT)		
	Positive	Negative	Total
Positive	113	2	115
Negative	4	121	125
Total	117	123	240
Positive Agreement (95% CI): 113/117 96.58% (91.48% -99.06%)			
Negative Agreement (95% CI): 121/123 98.37% (94.25% - 99.80%)			

The performance of SARS-CoV-2 Antigen Test Kit with positive results stratified by the NAT method Ct counts were assessed to more understand the correlation of assay performance to the NAT Ct value, estimating the viral amount present in the clinical sample. As showed in the following table, the positive agreement of the SARS-CoV-2 Antigen Test Kit is higher with samples of a Ct count <33.

SARS-CoV-2 Antigen Test Kit	NAT Method (Ct)	
	POS (Ct < 33)	POS (Ct ≥ 33)
Positive	90	23
Negative	0	4
Total	90	27
Positive Agreement (95% CI)	100.0%(95.98%, 100.0%)	85.19%(66.27%, 95.81%)

4. Conclusions

SARS-CoV-2 Antigen Test Kit (Colloidal Gold) produced by Shenzhen Dymind Biotechnology Co., Ltd. showed no statistically significant difference between SARS-CoV-2 Antigen Kit test results tested by patients and the clinical diagnosis results, which were highly consistent. That showed SARS-CoV-2 Antigen Test Kit (Colloidal Gold) was suitability for no professional use.