

COVID-19 Antigen Detection Kit (Colloidal Gold) (Nasal)

Clinical Evaluation Report

Product Name: COVID-19 Antigen Detection Kit (Colloidal Gold)

Start Date: August 2020

Finish Date: November 2020

Kit supplier: DNA Diagnostic A/S

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Summary

The clinical trial followed the guidelines in ‘The Technical Guidelines for In Vitro Diagnostic Reagents Clinical Trial (CFDA notice No. 16 2014)’. The clinical evaluation, of the COVID-19 Antigen Detection Kit (Colloidal Gold) (referred to as “Kit”) offered by DNA Diagnostic A/S, was performed by a medical institution in Hebei.

The clinical trial was compared with (RT-)PCR test results and clinical diagnosis results to investigate the consistency of the Kit with the clinical diagnosis results.

370 patients’ Nasal swabs were collected in this clinical trial in total. Kit found 135 positives out of 144 PCR positives, 225 negatives out of 226 PCR negatives. Compared to the results of PCR and clinical diagnosis, the clinical sensitivity of the Kit was 93.75%, the clinical specificity of the Kit was 99.56%, the total coincidence rate was 97.29%. There was no statistically significant difference between the test results of the Kit and the clinical diagnosis results, and the results of the Kit were highly consistent with the results of clinical diagnosis and PCR test.

COVID-19 Antigen Detection Kit (Colloidal Gold) (Nasal)**Introduction**

Medical studies around the globe indicate that the incubation period of novel coronavirus infection is 1-14 days, with an average of about 5 days. Patients infected can have symptoms at different levels and in some cases, patients will not have symptoms, but still be contagious. A portion of patients will rapidly deteriorate into severe pneumonia, respiratory distress, asphyxia, etc. Therefore, screening of Novel Coronavirus infection is of great significance for controlling the epidemic.

Novel Coronavirus antigens can be detected from approximately 0 to 3 days after infection (with or without symptoms). The antigens are generally detectable in upper respiratory samples during the acute phase of infection, but positive results do not rule out bacterial infection or cross infection with other viruses, meaning that the agent detected may not be the definite cause of disease.

Objective

In order to evaluate the suitability of the device, Nasal specimens are to be obtained, and kit test results compared to the clinical diagnosis results and (RT-) PCR results, to evaluate the sensitivity, specificity, and accuracy of the product in clinical determination to determine whether it meets the requirements of safety and effectiveness.

Design of the trial**Overall design and scheme description of the trial**

The blinded method was adopted in this clinical trial to evaluate the sensitivity and specific coincidence rate of this product and verify the accuracy of this product in clinical determination by comparing to the clinical diagnosis results and PCR test results.

One nasal swab sample collected for each subject after enrolment and one sample collected by a specialist for PCR detection. The two samples will be sent to be blinded by the person in charge of statistics at the trial site. After that, different operators will test these two blinded samples with the antigen Kit and Reference PCR Test according to the instructions of the corresponding methods.

Trial design and study method selection

The design aims to ensure at least 100 positive samples of nasal swabs to be collected. The intended use of the kit is qualitatively testing coronavirus antigens in human nasal specimens. The inclusion criteria for this validation involve patients which have more than one of the identified related coronavirus symptoms such as fever, cough, sore throat, muscle pain, nausea, nasal congestion, headache, diarrhea, palpitations, chest tightness, etc.

Product information used in clinical trials:

	The reagent to be evaluated	Reference
Product Name	COVID-19 Antigen Detection Kit (Colloidal Gold) (Nasal)	Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) Sansure BioTech Inc
Validity& Storage	Stored dry at 2~30°C away from direct sunlight, valid for 18 months. Shall be used as soon as possible within 30 minutes after opening the foil.	
Batch No.	2028034	
Supplier	DNA Diagnostic A/S	
Sample- and Preservation solution	Buffer supplied in the kit	0.9% NaCl

Test Procedure used overall

1. All specimens were handled as if they were capable of transmitting infectious agents.
2. Collection of Specimen: Carefully insert the swab into one nostril of the patient. The swab tip should be inserted up to 2-3 cm until resistance is met (anterior nares). Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected. Using the same swab, repeat the process for the other nostril to ensure that an adequate sample are collected from both nasal cavities. Withdraw the swab from the nasal cavity.
3. Sample elution: Twist the buffer ampoule head off from the notch point and add all content into the extraction tube, insert the swab head (with specimen) into the extraction buffer, mix well, squeeze the swab 10-15 times by compressing the walls of the tube against the swab. Discard the swab.
4. Swab specimens were tested as soon as possible after collection.

Preparation before testing

- a) The specimens to be tested and the required reagents shall be removed from the storage conditions and equilibrated to room temperature;
- b) The kit shall be removed from the packaging bag and placed flat on a dry bench.

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Testing steps

- a) Place the test kit horizontally on the table.
- b) Place a clean dropper tip on the extraction tube and invert the tube so that it is perpendicular to the sample hole (S) and add 3 drops of the sample. Set timer for 15 minutes.
- c) Read out results 15 minutes after sample addition

Test Results

Table 1 Kit results and PCR

		PCR		Total
		Positive(+)	Negative(-)	
Antigen Test	Positive(+)	135	1	136
	Negative(-)	9	225	234
	Total	144	226	370

Clinical Sensitivity: $135 / 144 \times 100\% = 93.75\%$

95% CI: $p \pm 1.96 \times [p (1-p) / n]^{1/2} = [89.80\%, 97.70\%]$

Clinical Specificity: $225 / 226 \times 100\% = 99.56\%$

95% CI: $p \pm 1.96 \times [p (1-p) / n]^{1/2} = [98.69\%, 100.00\%]$

Total coincidence rate: $360 / 370 \times 100\% = 97.30\%$

95% CI: $p \pm 1.96 \times [p (1-p) / n]^{1/2} = [94.04\%, 98.55\%]$

Consistency analysis:

Kappa: 0.943. It can be considered that the Kit and that the PCR results are consistent.

Conclusions

370 patients' Nasal swabs were collected in this clinical trial in total. The Kit tested 135 positives out of 144 PCR positives, 225 negatives out of 226 PCR negatives. Compared with the results of PCR, the clinical sensitivity of the Kit was 93.75%, the clinical specificity of the Kit was 99.56%, the total coincidence rate was 96.30%, Kappa: 0.943.

Based on the above results there was not found any significant difference between the test results of the Kit and the PCR results. The results of the Kit were highly consistent with the results of clinical PCR tests. Furthermore, the kit was suitable for use at any levels of professional use.

Appendix: Test results

No.	Sex	Age	Date of test	Days from symptom offset	KIT result	PCR result	CT value
1	M	18	27/08/2020	0	+	+	21
2	M	39	27/08/2020	2	+	+	27
3	M	21	27/08/2020	2	+	+	23
4	M	41	27/08/2020	4	+	+	27
5	M	61	27/08/2020	3	+	+	19
6	M	12	27/08/2020	6	+	+	27
7	M	36	27/08/2020	7	+	+	24
8	M	24	27/08/2020	8	+	+	26
9	M	67	27/08/2020	9	+	+	22
10	M	39	27/08/2020	2	+	+	28
11	M	44	27/08/2020	4	+	+	23
12	M	70	27/08/2020	5	+	+	22
13	M	38	27/08/2020	7	+	+	22
14	M	27	27/08/2020	8	+	+	20
15	M	35	27/08/2020	9	+	+	20
16	M	32	27/08/2020	6	+	+	25
17	M	63	27/08/2020	5	+	+	25
18	M	42	27/08/2020	2	+	+	23
19	M	35	27/08/2020	12	-	+	34
20	M	80	27/08/2020	3	+	+	24
21	M	64	27/08/2020	5	+	+	24
22	M	37	27/08/2020	5	+	+	32
23	M	19	27/08/2020	6	+	+	25
24	M	27	27/08/2020	8	+	+	25
25	M	43	27/08/2020	5	+	+	26
26	M	66	27/08/2020	N/A	-	-	N/A
27	M	34	27/08/2020	N/A	-	-	N/A
28	M	28	27/08/2020	N/A	-	-	N/A
29	M	42	27/08/2020	N/A	-	-	N/A
30	M	70	27/08/2020	N/A	-	-	N/A
31	M	30	27/08/2020	N/A	-	-	N/A
32	M	45	27/08/2020	N/A	-	-	N/A
33	M	32	27/08/2020	N/A	-	-	N/A
34	M	29	27/08/2020	N/A	-	-	N/A
35	M	71	27/08/2020	N/A	-	-	N/A
36	M	33	27/08/2020	N/A	-	-	N/A
37	M	67	27/08/2020	N/A	-	-	N/A
38	M	21	27/08/2020	N/A	-	-	N/A
39	M	24	27/08/2020	N/A	-	-	N/A
40	M	66	27/08/2020	N/A	-	-	N/A
41	M	13	27/08/2020	N/A	-	-	N/A
42	M	39	27/08/2020	N/A	-	-	N/A
43	M	83	27/08/2020	N/A	-	-	N/A
44	M	63	27/08/2020	N/A	-	-	N/A
45	M	31	27/08/2020	N/A	-	-	N/A
46	M	56	27/08/2020	N/A	-	-	N/A
47	M	65	27/08/2020	N/A	-	-	N/A
48	M	80	27/08/2020	N/A	-	-	N/A
49	M	57	27/08/2020	N/A	-	-	N/A
50	M	68	27/08/2020	N/A	-	-	N/A

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**DNA
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No.	Sex	Age	Date of test	Days from symptom offset	KIT result	PCR result	CT value
51	M	79	24/09/2020	0	+	+	27
52	M	13	24/09/2020	3	+	+	28
53	M	57	24/09/2020	2	+	+	20
54	M	61	24/09/2020	6	+	+	28
55	M	71	24/09/2020	7	+	+	28
56	M	49	24/09/2020	6	-	+	31
57	M	61	24/09/2020	3	+	+	24
58	M	32	24/09/2020	1	+	+	20
59	M	14	24/09/2020	2	+	+	25
60	M	67	24/09/2020	0	+	+	24
61	M	58	24/09/2020	4	+	+	27
62	M	32	24/09/2020	7	+	+	24
63	M	78	24/09/2020	2	+	+	23
64	M	80	24/09/2020	4	+	+	24
65	M	44	24/09/2020	7	+	+	24
66	M	41	24/09/2020	12	+	+	23
67	M	66	24/09/2020	5	+	+	24
68	M	34	24/09/2020	6	+	+	26
69	M	78	24/09/2020	2	+	+	22
70	M	44	24/09/2020	1	+	+	24
71	M	77	24/09/2020	8	+	+	22
72	M	24	24/09/2020	6	+	+	23
73	M	14	24/09/2020	N/A	-	-	N/A
74	M	69	24/09/2020	N/A	-	-	N/A
75	M	51	24/09/2020	N/A	-	-	N/A
76	M	71	24/09/2020	N/A	-	-	N/A
77	M	39	24/09/2020	N/A	-	-	N/A
78	M	60	24/09/2020	N/A	-	-	N/A
79	M	82	24/09/2020	N/A	-	-	N/A
80	M	80	24/09/2020	N/A	-	-	N/A
81	M	46	24/09/2020	N/A	-	-	N/A
82	M	64	24/09/2020	N/A	-	-	N/A
83	M	49	24/09/2020	N/A	-	-	N/A
84	M	71	24/09/2020	N/A	-	-	N/A
85	M	45	24/09/2020	N/A	-	-	N/A
86	M	80	24/09/2020	N/A	-	-	N/A
87	M	45	24/09/2020	N/A	-	-	N/A
88	M	62	24/09/2020	N/A	-	-	N/A
89	M	44	24/09/2020	N/A	-	-	N/A
90	M	47	24/09/2020	N/A	-	-	N/A
91	M	15	24/09/2020	N/A	-	-	N/A
92	M	74	24/09/2020	N/A	-	-	N/A
93	M	21	24/09/2020	N/A	-	-	N/A
94	M	38	24/09/2020	N/A	-	-	N/A
95	M	42	24/09/2020	N/A	-	-	N/A
96	M	51	24/09/2020	N/A	-	-	N/A
97	M	67	24/09/2020	N/A	-	-	N/A
98	M	41	24/09/2020	N/A	-	-	N/A
99	M	80	24/09/2020	N/A	-	-	N/A
100	M	15	24/09/2020	N/A	-	-	N/A

COVID-19 Antigen Detection Kit (Colloidal Gold) (Nasal)

**DNA
DIAGNOSTIC**

No.	Sex	Age	Date of test	Days from symptom offset	KIT result	PCR result	CT value
101	M	58	29/10/2020	8	+	+	25
102	M	23	29/10/2020	2	+	+	25
103	M	69	29/10/2020	4	+	+	20
104	M	48	29/10/2020	3	+	+	22
105	M	90	29/10/2020	6	+	+	20
106	M	70	29/10/2020	2	+	+	24
107	M	60	29/10/2020	4	+	+	24
108	M	61	29/10/2020	2	+	+	23
109	M	37	29/10/2020	6	+	+	22
110	M	66	29/10/2020	10	+	+	27
111	M	16	29/10/2020	8	+	+	21
112	M	49	29/10/2020	3	+	+	28
113	M	67	29/10/2020	5	+	+	24
114	M	50	29/10/2020	4	+	+	22
115	M	61	29/10/2020	7	+	+	25
116	M	80	29/10/2020	8	+	+	24
117	M	49	29/10/2020	8	-	+	34
118	M	66	29/10/2020	3	+	+	22
119	M	29	29/10/2020	2	+	+	32
120	M	72	29/10/2020	1	+	+	33
121	M	36	29/10/2020	6	+	+	34
122	M	59	29/10/2020	7	+	+	22
123	M	40	29/10/2020	N/A	-	-	N/A
124	M	56	29/10/2020	N/A	-	-	N/A
125	M	13	29/10/2020	N/A	-	-	N/A
126	M	61	29/10/2020	N/A	-	-	N/A
127	M	44	29/10/2020	N/A	-	-	N/A
128	M	50	29/10/2020	N/A	-	-	N/A
129	M	78	29/10/2020	N/A	-	-	N/A
130	M	43	29/10/2020	N/A	-	-	N/A
131	M	67	29/10/2020	N/A	-	-	N/A
132	M	42	29/10/2020	N/A	-	-	N/A
133	M	63	29/10/2020	N/A	-	-	N/A
134	M	37	29/10/2020	N/A	-	-	N/A
135	M	24	29/10/2020	N/A	-	-	N/A
136	M	33	29/10/2020	N/A	-	-	N/A
137	M	19	29/10/2020	N/A	-	-	N/A
138	M	87	29/10/2020	N/A	-	-	N/A
139	M	58	29/10/2020	N/A	-	-	N/A
140	M	69	29/10/2020	N/A	-	-	N/A
141	M	58	29/10/2020	N/A	-	-	N/A
142	M	33	29/10/2020	N/A	-	-	N/A
143	M	48	29/10/2020	N/A	-	-	N/A
144	M	77	29/10/2020	N/A	-	-	N/A
145	M	38	29/10/2020	N/A	-	-	N/A
146	M	51	29/10/2020	N/A	-	-	N/A
147	M	71	29/10/2020	N/A	-	-	N/A
148	M	43	29/10/2020	N/A	-	-	N/A
149	M	80	29/10/2020	N/A	-	-	N/A
150	M	59	29/10/2020	N/A	-	-	N/A
151	M	78	29/10/2020	N/A	-	-	N/A

COVID-19 Antigen Detection Kit (Colloidal Gold) (Nasal)

**DNA
DIAGNOSTIC**

No.	Sex	Age	Date of test	Days from symptom offset	KIT result	PCR result	CT value
152	M	49	26/11/2020	6	+	+	24
153	M	36	26/11/2020	4	+	+	24
154	M	19	26/11/2020	2	+	+	27
155	M	67	26/11/2020	8	+	+	25
156	M	46	26/11/2020	4	+	+	26
157	M	22	26/11/2020	1	+	+	19
158	M	44	26/11/2020	8	+	+	28
159	M	56	26/11/2020	9	+	+	27
160	M	44	26/11/2020	4	+	+	22
161	M	77	26/11/2020	6	+	+	29
162	M	33	26/11/2020	5	+	+	25
163	M	15	26/11/2020	8	+	+	23
164	M	52	26/11/2020	4	+	+	26
165	M	49	26/11/2020	1	+	+	24
166	M	61	26/11/2020	10	-	+	33
167	M	46	26/11/2020	4	+	+	23
168	M	69	26/11/2020	4	+	+	24
169	M	25	26/11/2020	9	-	+	33
170	M	56	26/11/2020	3	+	+	22
171	M	45	26/11/2020	4	+	+	26
172	M	81	26/11/2020	6	-	+	33
173	M	71	26/11/2020	3	+	+	32
174	M	32	26/11/2020	6	+	+	28
175	M	56	26/11/2020	9	+	+	26
176	M	72	26/11/2020	11	+	+	23
177	M	16	26/11/2020	N/A	-	-	N/A
178	M	29	26/11/2020	N/A	-	-	N/A
179	M	53	26/11/2020	N/A	-	-	N/A
180	M	79	26/11/2020	N/A	-	-	N/A
181	M	13	26/11/2020	N/A	-	-	N/A
182	M	45	26/11/2020	N/A	-	-	N/A
183	M	80	26/11/2020	N/A	-	-	N/A
184	M	33	26/11/2020	N/A	-	-	N/A
185	M	41	26/11/2020	N/A	-	-	N/A
186	M	62	26/11/2020	N/A	-	-	N/A
187	M	42	26/11/2020	N/A	-	-	N/A
188	M	88	26/11/2020	N/A	-	-	N/A
189	M	44	26/11/2020	N/A	-	-	N/A
190	M	18	26/11/2020	N/A	-	-	N/A
191	M	27	26/11/2020	N/A	-	-	N/A
192	M	50	26/11/2020	N/A	-	-	N/A
193	M	60	26/11/2020	N/A	-	-	N/A
194	M	59	26/11/2020	N/A	-	-	N/A
195	M	34	26/11/2020	N/A	-	-	N/A
196	M	59	26/11/2020	N/A	-	-	N/A
197	M	69	26/11/2020	N/A	-	-	N/A
198	M	40	26/11/2020	N/A	-	-	N/A
199	M	54	26/11/2020	N/A	-	-	N/A
200	M	66	26/11/2020	N/A	-	-	N/A
201	M	19	26/11/2020	N/A	-	-	N/A
202	M	60	26/11/2020	N/A	-	-	N/A
203	M	24	26/11/2020	N/A	-	-	N/A
204	M	33	26/11/2020	N/A	-	-	N/A
205	M	41	26/11/2020	N/A	-	-	N/A
206	M	43	26/11/2020	N/A	-	-	N/A
207	M	39	26/11/2020	N/A	-	-	N/A
208	M	23	26/11/2020	N/A	-	-	N/A
209	M	15	26/11/2020	N/A	-	-	N/A
210	M	59	26/11/2020	N/A	-	-	N/A
211	M	55	26/11/2020	N/A	-	-	N/A
212	M	23	26/11/2020	N/A	-	-	N/A
213	M	39	26/11/2020	N/A	-	-	N/A
214	M	92	26/11/2020	N/A	-	-	N/A
215	M	17	26/11/2020	N/A	-	-	N/A

COVID-19 Antigen Detection Kit (Colloidal Gold) (Nasal)

No.	Sex	Age	Date of test	Days from symptom offset	KIT result	PCR result	CT value
216	F	40	27/08/2020	2	+	+	20
217	F	41	27/08/2020	6	+	+	27
218	F	57	27/08/2020	9	+	+	24
219	F	21	27/08/2020	13	-	+	32
220	F	60	27/08/2020	1	+	+	28
221	F	66	27/08/2020	5	+	+	19
222	F	43	27/08/2020	7	+	+	26
223	F	30	27/08/2020	5	+	+	28
224	F	44	27/08/2020	3	+	+	22
225	F	12	27/08/2020	5	+	+	23
226	F	39	27/08/2020	N/A	-	-	N/A
227	F	50	27/08/2020	N/A	-	-	N/A
228	F	41	27/08/2020	N/A	-	-	N/A
229	F	22	27/08/2020	N/A	-	-	N/A
230	F	58	27/08/2020	N/A	-	-	N/A
231	F	56	27/08/2020	N/A	-	-	N/A
232	F	44	27/08/2020	N/A	-	-	N/A
233	F	39	27/08/2020	N/A	-	-	N/A
234	F	59	27/08/2020	N/A	-	-	N/A
235	F	77	27/08/2020	N/A	-	-	N/A
236	F	13	27/08/2020	N/A	-	-	N/A
237	F	38	27/08/2020	N/A	-	-	N/A
238	F	90	27/08/2020	N/A	-	-	N/A
239	F	23	27/08/2020	N/A	-	-	N/A
240	F	45	27/08/2020	N/A	-	-	N/A
241	F	46	27/08/2020	N/A	-	-	N/A
242	F	49	27/08/2020	N/A	-	-	N/A
243	F	40	27/08/2020	N/A	-	-	N/A
244	F	42	27/08/2020	N/A	-	-	N/A
245	F	14	27/08/2020	N/A	-	-	N/A
246	F	34	27/08/2020	N/A	-	-	N/A
247	F	25	27/08/2020	N/A	-	-	N/A

COVID-19 Antigen Detection Kit (Colloidal Gold) (Nasal)

No.	Sex	Age	Date of test	Days from symptom offset	KIT result	PCR result	CT value
248	F	80	24/09/2020	0	+	+	22
249	F	60	24/09/2020	1	+	+	27
250	F	44	24/09/2020	3	+	+	25
251	F	14	24/09/2020	4	+	+	24
252	F	37	24/09/2020	8	+	+	24
253	F	51	24/09/2020	10	-	+	31
254	F	56	24/09/2020	3	+	+	20
255	F	22	24/09/2020	1	+	+	24
256	F	55	24/09/2020	7	+	+	28
257	F	15	24/09/2020	5	+	+	22
258	F	92	24/09/2020	10	-	+	32
259	F	23	24/09/2020	N/A	-	-	N/A
260	F	57	24/09/2020	N/A	-	-	N/A
261	F	36	24/09/2020	N/A	-	-	N/A
262	F	79	24/09/2020	N/A	-	-	N/A
263	F	45	24/09/2020	N/A	-	-	N/A
264	F	44	24/09/2020	N/A	-	-	N/A
265	F	30	24/09/2020	N/A	-	-	N/A
266	F	86	24/09/2020	N/A	-	-	N/A
267	F	16	24/09/2020	N/A	-	-	N/A
268	F	44	24/09/2020	N/A	-	-	N/A
269	F	42	24/09/2020	N/A	-	-	N/A
270	F	47	24/09/2020	N/A	-	-	N/A
271	F	33	24/09/2020	N/A	-	-	N/A
272	F	58	24/09/2020	N/A	-	-	N/A
273	F	21	24/09/2020	N/A	-	-	N/A
274	F	56	24/09/2020	N/A	-	-	N/A
275	F	87	24/09/2020	N/A	-	-	N/A
276	F	14	24/09/2020	N/A	-	-	N/A
277	F	35	24/09/2020	N/A	-	-	N/A
278	F	71	24/09/2020	N/A	-	-	N/A
279	F	57	24/09/2020	N/A	-	-	N/A
280	F	69	24/09/2020	N/A	-	-	N/A
281	F	16	24/09/2020	N/A	-	-	N/A
282	F	43	24/09/2020	N/A	-	-	N/A
283	F	55	24/09/2020	N/A	-	-	N/A
284	F	34	24/09/2020	N/A	-	-	N/A
285	F	22	24/09/2020	N/A	-	-	N/A
286	F	44	24/09/2020	N/A	-	-	N/A
287	F	41	24/09/2020	N/A	-	-	N/A
288	F	56	24/09/2020	N/A	-	-	N/A
289	F	55	24/09/2020	N/A	-	-	N/A
290	F	81	24/09/2020	N/A	-	-	N/A

COVID-19 Antigen Detection Kit (Colloidal Gold) (Nasal)DNA
DIAGNOSTIC

No.	Sex	Age	Date of test	Days from symptom offset	KIT result	PCR result	CT value
291	F	65	29/10/2020	5	+	+	20
292	F	34	29/10/2020	4	+	+	19
293	F	23	29/10/2020	6	+	+	26
294	F	59	29/10/2020	2	+	+	28
295	F	17	29/10/2020	8	+	+	27
296	F	77	29/10/2020	1	+	+	26
297	F	39	29/10/2020	9	+	+	26
298	F	33	29/10/2020	3	+	+	24
299	F	59	29/10/2020	6	+	+	22
300	F	45	29/10/2020	4	+	+	25
301	F	55	29/10/2020	6	+	+	25
302	F	33	29/10/2020	5	+	+	19
303	F	52	29/10/2020	3	+	+	28
304	F	18	29/10/2020	1	+	+	21
305	F	31	29/10/2020	2	+	+	27
306	F	55	29/10/2020	N/A	-	-	N/A
307	F	60	29/10/2020	N/A	-	-	N/A
308	F	80	29/10/2020	N/A	-	-	N/A
309	F	18	29/10/2020	N/A	-	-	N/A
310	F	55	29/10/2020	N/A	-	-	N/A
311	F	32	29/10/2020	N/A	-	-	N/A
312	F	82	29/10/2020	N/A	-	-	N/A
313	F	32	29/10/2020	N/A	-	-	N/A
314	F	45	29/10/2020	N/A	-	-	N/A
315	F	44	29/10/2020	N/A	-	-	N/A
316	F	43	29/10/2020	N/A	-	-	N/A
317	F	59	29/10/2020	N/A	-	-	N/A
318	F	44	29/10/2020	N/A	-	-	N/A
319	F	13	29/10/2020	N/A	-	-	N/A
320	F	30	29/10/2020	N/A	-	-	N/A
321	F	33	29/10/2020	N/A	-	-	N/A
322	F	88	29/10/2020	N/A	-	-	N/A
323	F	21	29/10/2020	N/A	-	-	N/A
324	F	19	29/10/2020	N/A	-	-	N/A

COVID-19 Antigen Detection Kit (Colloidal Gold) (Nasal)

No.	Sex	Age	Date of test	Days from symptom offset	KIT result	PCR result	CT value
325	F	45	26/11/2020	1	+	+	24
326	F	67	26/11/2020	3	+	+	20
327	F	44	26/11/2020	5	+	+	26
328	F	24	26/11/2020	7	+	+	21
329	F	71	26/11/2020	9	+	+	21
330	F	41	26/11/2020	11	+	+	27
331	F	43	26/11/2020	2	+	+	20
332	F	56	26/11/2020	4	+	+	28
333	F	49	26/11/2020	5	+	+	26
334	F	46	26/11/2020	6	+	+	28
335	F	27	26/11/2020	11	-	+	31
336	F	18	26/11/2020	10	+	+	26
337	F	40	26/11/2020	4	+	+	21
338	F	50	26/11/2020	2	+	+	18
339	F	44	26/11/2020	N/A	-	-	N/A
340	F	45	26/11/2020	N/A	-	-	N/A
341	F	43	26/11/2020	N/A	-	-	N/A
342	F	49	26/11/2020	N/A	-	-	N/A
343	F	22	26/11/2020	N/A	-	-	N/A
344	F	80	26/11/2020	N/A	-	-	N/A
345	F	56	26/11/2020	N/A	-	-	N/A
346	F	34	26/11/2020	N/A	-	-	N/A
347	F	49	26/11/2020	N/A	-	-	N/A
348	F	60	26/11/2020	N/A	-	-	N/A
349	F	59	26/11/2020	N/A	-	-	N/A
350	F	51	26/11/2020	N/A	-	-	N/A
351	F	26	26/11/2020	N/A	-	-	N/A
352	F	17	26/11/2020	N/A	-	-	N/A
353	F	59	26/11/2020	N/A	-	-	N/A
354	F	78	26/11/2020	N/A	-	-	N/A
355	F	55	26/11/2020	N/A	-	-	N/A
356	F	22	26/11/2020	N/A	-	-	N/A
357	F	56	26/11/2020	N/A	-	-	N/A
358	F	62	26/11/2020	N/A	-	-	N/A
359	F	41	26/11/2020	N/A	-	-	N/A
360	F	21	26/11/2020	N/A	-	-	N/A
361	F	25	26/11/2020	N/A	-	-	N/A
362	F	42	26/11/2020	N/A	-	-	N/A
363	F	23	26/11/2020	N/A	-	-	N/A
364	F	52	26/11/2020	N/A	-	-	N/A
365	F	59	26/11/2020	N/A	-	-	N/A
366	F	71	26/11/2020	N/A	-	-	N/A
367	F	49	26/11/2020	N/A	-	-	N/A
368	F	42	26/11/2020	N/A	-	-	N/A
369	F	39	26/11/2020	N/A	-	-	N/A
370	F	28	26/11/2020	N/A	-	-	N/A