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	Clinical Performance Study Report	Rev No.	A/0

Clinical Performance Study Report Of COVID-19 Antigen Test Kit (Colloidal Gold)

Responsibility	Name	Position	Signature/Date
Drafter	Ming Zheng	Product Manager	Ming 2 deng 2021.03.16
Reviewer	Jin Wang	RA Manager	Jin Wang 2021.03.16
Reviewer	Xinjie zhang	Project Leader	Xingie zhang 2021.03.16
Approver	Weiqing Sun	General Manager	Weißing Sim 2021.03.16



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Change History

Rev.	Change Description	Date Changed
A0	New document	2021.03.15

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1 Research purpose

The clinical performance of COVID-19 Antigen Test Kit (colloidal gold) was verified by prospective clinical study. It is to verify that the accuracy of the product in clinical trial, by using PCR as control reagent, meets the requirement of 90% to determine that whether the product can meet the expected safety and effectiveness.

2 Clinical Trial Center

Center 1: Hosp.de ESPECIALIDADES DR.ABEL GILBERT PONTON, Hospital in Ecuador

Center 2: Hosp.General del Guasmo Sur, Hospital in Ecuador

Center 3: Hosp. Alfredo Paulson Junta de Beneficiencia Guayaquil, Hospital in Ecuador

Center 4: Laboratory of Hangzhou Singclean Medical Products Co., Ltd.

3 Reagent information

3.1 Test reagent

Manufacturer: Hangzhou Singclean Medical Products Co., Ltd.

Name: COVID-19 Antigen Test Kit (colloidal gold)

Packaging specification: 20 test/box

Storage: Store at $4\sim30^{\circ}$ C. The shelf life is 24 months.

3.2 Control reagent

3.2.1 Center 1:

Manufacturer: Thermo Fisher Scientific.

Name: TaqPath COVID-19 CE-IVD RT-PCR Kit (EUL-0525-156-00)

3.2.2 Center 2

Manufacturer: TIB Molbiol Name: RT-qPCR reaction kit

3.2.3 Center 3

Manufacturer: CerTest Biotec S.L.

Name: VIASURE SARS-CoV-2 Real Time PCR Detection Kit

3.2.4 Center 4:

Manufacturer: Huada Biotechnology (Wuhan) Co. LTD.

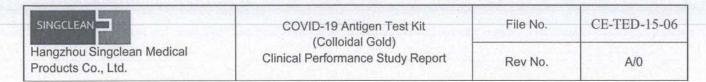
Name: Covid-19 Nucleic Acid Detection Kit (Fluorescence PCR method)

4 Product introduction

People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatically infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

5 Intended use

COVID-19 Antigen Test Kit (colloidal gold) is a solid phase immunochromatographic assay for



the rapid, qualitative detection of antigen to 2019 Novel Coronavirus in saliva swab. This test provides only a preliminary test result. Therefore, any reactive specimen with the COVID-19 Antigen Test Kit (colloidal gold)must be confirmed with alternative testing method(s) and clinical findings.

6 Principle of products

The COVID-19 Antigen Test Kit (colloidal gold) is a colloidal gold immunochromatographic assay. The test uses COVID-19 (SARS-CoV-2) antibody (test line T) and goat anti-mouse IgG (control line C) immobilised on a nitrocellulose strip. The burgundy colored conjugate pad contains colloidal gold conjugated to another COVID-19 (SARS-CoV-2) antibody conjugated with colloid gold and mouse IgG-gold conjugates. When the processed buffer containing the sample is added to the sample well, COVID-19 (SARS-CoV-2) will combine with the COVID-19 antibody conjugate to form an antigen-antibody complex. This complex migrates through nitrocellulose membrane by capillary action. When the complex meets the line of the COVID-19 antibody of test line T, the complex is trapped forming a burgundy colored band which confirm a reactive test result. Absence of a colored band in the test region indicates a non-reactive test result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex goat anti-mouse IgG/mouse IgG-gold conjugate regardless of the color development on any of the test bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

7 Selection of specimen

7.1 Inclusion criteria:

- 1) Positive specimens:
 - 167 prospective positive specimens, tested by PCR positive specimens.
- 2) Negative specimens
 - 230 COVID-19 negative specimens (confirmed by RT-PCR), collected from symptomatic individuals (preferably with respiratory symptoms) collected from the general population are required to be tested.

7.2 Exclusion criteria:

- > Specimen collection time or information is not clear;
- Specimens are not enough to complete test;
- Specimens are found to be contaminated during the preservation process prior to the test operation;
- Specimens with incomplete medical records;
- Specimen not stored in accordance with IFU.

7.3 Withdrawal criteria:

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- Specimens do not meet the requirements of specimen collection;
- The information needed for the original record of any clinical study is missing before statistical analysis;
- > Test data from excluded specimens;
- Test data not obtained in accordance with the specified SOP;
- Specimens known to have significant interference, known to be contaminated, confused, etc.

8 Specimen type

Specimen taken from the human saliva by a saliva swab. Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result.

9 Specimen requirements

Each specimen shall contain the following information:

- The specimen type;
- The specimen collection date;
- Date of onset of symptoms (if present);
- Severity or absence of symptoms; Date of PCR testing;
- PCR test results(containing CT value of PCR testing);
- Tests used to identify COVID-19 patients.

10 Experiment method

Allow test cassette, Antigen extraction buffer, specimen and controls to equilibrate to room temperature (15-30°C) prior to testing.

- a) Make sure there are no food residue in the mouth before sampling. If the patient just has eaten, gargle or tooth brushing is required. Remove the swab package, keep the swab on the tongue until the tip being fully soaking by saliva (at least two minutes).
- b) Place the antigen extraction tube on the workbench. Place the antigen extraction buffer bottle vertically downward, squeeze the bottle to make the buffer drip freely into the antigen extraction tube without touching the edge of the tube, and add all of the antigen extraction solution (about 450ul) to the antigen extraction tube.
- c) Put the swab specimen into the antigen extraction tube pre-added with the antigen extraction buffer and rotate the swab about 10 times while pressing the swab head against the tube wall to release the

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antigen in the swab, then let it stand for about 1 minute.

- d) Remove the swab while squeezing the tip of the swab so that as much liquid in the swab can be.discharged as possible. Dispose of used swabs in accordance with biohazard waste disposal methods.
- e) Install the dripper on the antigen extraction tube and cap it tightly, and let it stand for about 1 minute.
- f) Remove the test cassette from the sealed foil pouch and use it as soon as possible.
- g) Place the test device on a clean and level surface.
- h) Transfer 3 drops (about 100ul) of mix Liquids to the sample well of the test card (or use a pipette to add 100ul), and start the timer.
- i) Wait for the test result of the reagent. The result should be read in 15 minutes. Do not interpret the result after 20 minutes.

11 Test data

11.1 Hosp.de ESPECIALIDADES DR.ABEL GILBERT PONTON, Hospital in Ecuador

Testing Date		2021.03.04~2021.03.06					
Testing Method	PCR i			PCR results			
COVID-19 antigen Test kit	Positive	Negative Total	Remarks				
Positive	80	0	80				
Negative	0	0	0	Annex 1			
Total	80	0	80				

11.2 Hosp.General del Guasmo Sur, Hospital in Ecuador

Testing Date	2021.03.05~2021.03.06					
Testing Method	PCR results					
COVID-19 antigen Test kit	Positive	Negative	Total	Remarks		
Positive	53	0	60			
Negative	0	7	0	Annex 2		
Total	53	7	60			

11.3 Hosp.Alfredo Paulson Junta de Beneficiencia Guayaquil, Hospital in Ecuador



Testing Date		2021.03.08~2021.03.09					
Testing Method	PCR r	PCR results					
COVID-19 antigen Test kit	Positive	Negative	Total	Remarks			
Positive	34	0	34				
Negative	0	26	26	Annex 3			
Total	34	26	60				

11.4 Laboratory of Hangzhou Singclean Medical Products Co., Ltd.

Testing Date		2021.03.02~2021.03.11					
Testing Method	PCR r	esults					
COVID-19 antigen Test kit	Positive	Negative	Total	Remarks			
Positive	0	1	1				
Negative	0	196	196	Annex 4			
Total	0	197	197				

12 Data summary and analysis

12.1 Clinical performance

Method				
		Positive	Negative	Total
COVID-19 antigen	Positive	Positive 167 1	168	
Test kit	Negative	0	229	229
Tota	ıl	167	230	397
Sensiti	vity	>99.99%	95% confidence interval	97.75%~100%
Specifi	city	99.57%	95% confidence interval	97.58%~99.92%
Accura	асу	99.75%	95% confidence interval	98.59%~99.96%

12.1.1 Sensitivity calculation

Sensitivity =167/ (167+0) >99.99%

12.1.2 Specificity calculation

Specificity =229/ (1+229) =99.57%



12.1.3 Accuracy calculation

12.1.4 Sensitivity confidence interval calculation

Q1=2a+1.96²=337.8416

$$Q2=1.96\sqrt{1.96^2+4ac/(a+c)}=3.8416$$

Sensitivity confidence interval up limit =100%(Q1 -Q2)/Q3=97.75%

Sensitivity confidence interval lower limit =100%(Q1 +Q2)/Q3=100%

12.1.5 Specificity confidence interval calculation

Q1=2d+1.96²=416.8416

$$Q2=1.96\sqrt{1.96^2+4bd/(b+d)}=5.4824$$

$$Q3=2 (b+d+1.96^2) = 467.6832$$

Specificity confidence interval up limit =100%(Q1 -Q2)/Q3=97.58%

Specificity confidence interval lower limit =100%(Q1 +Q2)/Q3=99.92%

12.1.6 Accuracy confidence interval calculation

Q2=1.96
$$\sqrt{1.96^2 + 4(a+d)(b+c)/n}$$
=5.4850

Accuracy confidence interval up limit =100%(Q1 –Q2)/Q3=98.59%

Accuracy confidence interval lower limit =100%(Q1+Q2)/Q3= 99.96%

12.1.7 Kappa

$$PA = \frac{a+d}{n} = \frac{167+229}{397} = 0.9975$$

$$\mathsf{Pe} = \frac{(a+b)(a+c) + (c+d)(b+d)}{n^2} = \frac{(167+1)(167+0) + (1+229)(0+229)}{397^2} = 0.5122$$

Kappa=
$$\frac{P_A-P_e}{1-P_e} = \frac{0.9975-0.5122}{1-0.5122} = 0.9949$$

Kappa (k): k>0.75, means good consistency; 0.40<k<0.75, not very consistent; K <0.40, poor consistency.

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13 Conclusion

The expected research purpose has been achieved. The total number of samples studied is 397, of which 167 are positive and 230 are negative. Compared with PCR, the sensitivity of the product is >99.99% (confidence interval is 97.75%~100%), specificity is 99.57% (confidence interval is 97.58%~99.92%), and accuracy is 99.75% (confidence interval is 98.59%~99.96%). The Kappa is 0.9949, reach" K>0.75", which proves that the results of this study are in good consistency.

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Annex 1:

NO.	Geder	Age	COVID-19 antigen Test kit	RT-PCR	NO.	Geder	Age	COVID-19 antigen Test kit	RT-PCR
1	F	63	POSITIVE	POSITIVE	37	F	29	POSITIVE	POSITIVE
2	F	24	POSITIVE	POSITIVE	38	F	24	POSITIVE	POSITIVE
3	F	24	POSITIVE	POSITIVE	39	F	58	POSITIVE	POSITIVE
4	F	27	POSITIVE	POSITIVE	40	М	38	POSITIVE	POSITIVI
5	F	37	POSITIVE	POSITIVE	41	M	22	POSITIVE	POSITIVI
6	F	52	POSITIVE	POSITIVE	42	F	27	POSITIVE	POSITIV
7	M	33	POSITIVE	POSITIVE	43	M	18	POSITIVE	POSITIVI
8	М	29	POSITIVE	POSITIVE	44	F	42	POSITIVE	POSITIVI
9	M	48	POSITIVE	POSITIVE	45	F	18	POSITIVE	POSITIV
10	F	55	POSITIVE	POSITIVE	46	F	17	POSITIVE	POSITIVI
11	M	33	POSITIVE	POSITIVE	47	M	41	POSITIVE	POSITIV
12	F	45	POSITIVE	POSITIVE	48	M	33	POSITIVE	POSITIV
13	M	50	POSITIVE	POSITIVE	49	F	27	POSITIVE	POSITIV
14	F	50	POSITIVE	POSITIVE	50	F	28	POSITIVE	POSITIV
15	M	33	POSITIVE	POSITIVE	51	F	71	POSITIVE	POSITIV
16	M	64	POSITIVE	POSITIVE	52	M	21	POSITIVE	POSITIV
17	M	37	POSITIVE	POSITIVE	53	М	32	POSITIVE	POSITIV
18	M	32	POSITIVE	POSITIVE	54	F	48	POSITIVE	POSITIV
19	F	27	POSITIVE	POSITIVE	55	М	37	POSITIVE	POSITIV
20	M	66	POSITIVE	POSITIVE	56	М	43	POSITIVE	POSITIV
21	F	24	POSITIVE	POSITIVE	57	M	25	POSITIVE	POSITIV
22	М	27	POSITIVE	POSITIVE	58	М	39	POSITIVE	POSITIV
23	F	64	POSITIVE	POSITIVE	59	F	36	POSITIVE	POSITIV
24	F	41	POSITIVE	POSITIVE	60	М	30	POSITIVE	POSITIV
25	М	30	POSITIVE	POSITIVE	61	М	51	POSITIVE	POSITIV
26	F	31	POSITIVE	POSITIVE	62	М	50	POSITIVE	POSITIV
27	F	26	POSITIVE	POSITIVE	63	М	64	POSITIVE	POSITIV
28	М	44	POSITIVE	POSITIVE	64	М	18	POSITIVE	POSITIV
29	F	51	POSITIVE	POSITIVE	65	М	34	POSITIVE	POSITIV
30	F	52	POSITIVE	POSITIVE	66	М	35	POSITIVE	POSITIV
31	М	45	POSITIVE	POSITIVE	67	F	35	POSITIVE	POSITIV
32	М	32	POSITIVE	POSITIVE	68	М	26	POSITIVE	POSITIV
33	М	45	POSITIVE	POSITIVE	69	F	40	POSITIVE	POSITIV
34	F	36	POSITIVE	POSITIVE	70	М	19	POSITIVE	POSITIV
35	M	27	POSITIVE	POSITIVE	71	F	32	POSITIVE	POSITIV
36	М	25	POSITIVE	POSITIVE	72	М	67	POSITIVE	POSITIV



NO.	Geder	Age	COVID-19 antigen Test kit	RT-PCR	NO.	Geder	Age	COVID-19 antigen Test kit	RT-PCR
73	F	27	POSITIVE	POSITIVE	77	F	56	POSITIVE	POSITIVE
74	F	28	POSITIVE	POSITIVE	78	М	43	POSITIVE	POSITIVE
75	М	48	POSITIVE	POSITIVE	79	М	63	POSITIVE	POSITIVE
76	F	22	POSITIVE	POSITIVE	80	F	44	POSITIVE	POSITIVE

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Annex 2:

NO.	Geder	Age	COVID-19 antigen Test kit	RT-PCR	NO.	Geder	Age	COVID-19 antigen Test kit	RT-PCR
1	F	24	POSITIVE	POSITIVE	31	M	97	POSITIVE	POSITIVE
2	М	28	POSITIVE	POSITIVE	32	F	26	POSITIVE	POSITIVE
3	М	26	POSITIVE	POSITIVE	33	M	33	POSITIVE	POSITIVE
4	М	23	POSITIVE	POSITIVE	34	F	61	POSITIVE	POSITIVE
5	М	37	NEGATIVE	NEGATIVE	35	F	56	POSITIVE	POSITIVE
6	F	37	NEGATIVE	NEGATIVE	36	M	24	POSITIVE	POSITIVE
7	F	19	POSITIVE	POSITIVE	37	М	60	NEGATIVE	NEGATIVE
8	F	41	POSITIVE	POSITIVE	38	M	19	POSITIVE	POSITIVE
9	М	36	POSITIVE	POSITIVE	39	М	25	POSITIVE	POSITIVE
10	F	30	POSITIVE	POSITIVE	40	F	21	POSITIVE	POSITIVE
11	F	24	POSITIVE	POSITIVE	41	М	20	NEGATIVE	NEGATIVE
12	F	40	POSITIVE	POSITIVE	42	F	54	POSITIVE	POSITIVE
13	F	29	NEGATIVE	NEGATIVE	43	F	39	POSITIVE	POSITIVE
14	F	52	POSITIVE	POSITIVE	44	М	21	NEGATIVE	NEGATIVE
15	F	25	POSITIVE	POSITIVE	45	М	17	POSITIVE	POSITIVE
16	F	46	POSITIVE	POSITIVE	46	F	42	POSITIVE	POSITIVE
17	F	38	POSITIVE	POSITIVE	47	М	38	POSITIVE	POSITIVE
18	F	21	POSITIVE	POSITIVE	48	М	34	POSITIVE	POSITIVE
19	F	47	POSITIVE	POSITIVE	49	F	42	POSITIVE	POSITIVE
20	F	41	POSITIVE	POSITIVE	50	М	44	POSITIVE	POSITIVE
21	F	37	POSITIVE	POSITIVE	51	М	50	POSITIVE	POSITIVE
22	F	49	POSITIVE	POSITIVE	52	F	40	NEGATIVE	NEGATIVE
23	М	15	POSITIVE	POSITIVE	53	М	43	POSITIVE	POSITIVE
24	М	41	POSITIVE	POSITIVE	54	F	28	POSITIVE	POSITIVE
25	F	16	POSITIVE	POSITIVE	55	М	38	POSITIVE	POSITIVE
26	F	50	POSITIVE	POSITIVE	56	М	30	POSITIVE	POSITIVE
27	F	50	POSITIVE	POSITIVE	57	М	37	POSITIVE	POSITIVE
28	F	36	POSITIVE	POSITIVE	58	М	28	POSITIVE	POSITIVE
29	F	37	POSITIVE	POSITIVE	59	М	30	POSITIVE	POSITIVE
30	М	54	POSITIVE	POSITIVE	60	М	34	POSITIVE	POSITIVE

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Annex 3:

NO.	Geder	Age	COVID-19 antigen Test kit	RT-PCR	NO.	Geder	Age	COVID-19 antigen Test kit	RT-PCR
1	F	35	Negative	Negative	31	M	36	Negative	Negative
2	М	24	Positive	Positive	32	M	30	Positive	Positive
3	М	29	Positive	Positive	33	M	38	Positive	Positive
4	F	27	Negative	Negative	34	M	30	Negative	Negative
5	M	45	Positive	Positive	35	M	29	Negative	Negative
6	M	39	Negative	Negative	36	M	26	Positive	Positive
7	М	31	Negative	Negative	37	М	25	Negative	Negative
8	М	43	Negative	Negative	38	М	23	Positive	Positive
9	M	27	Negative	Negative	39	M	36	Negative	Negative
10	M	26	Positive	Positive	40	F	32	Negative	Negative
11	F	22	Negative	Negative	41	М	25	Negative	Negative
12	F	22	Positive	Positive	42	М	25	Positive	Positive
13	М	46	Negative	Negative	43	F	30	Positive	Positive
14	М	42	Positive	Positive	44	F	24	Positive	Positive
15	М	39	Negative	Negative	45	F	26	Positive	Positive
16	М	23	Positive	Positive	46	F	21	Positive	Positive
17	М	29	Positive	Positive	47	M	23	Positive	Positive
18	М	50	Positive	Positive	48	F	26	Positive	Positive
19	М	43	Negative	Negative	49	F	23	Positive	Positive
20	М	30	Positive	Positive	50	F	24	Positive	Positive
21	М	24	Negative	Negative	51	М	30	Negative	Negative
22	М	25	Positive	Positive	52	F	26	Positive	Positive
23	F	38	Negative	Negative	53	М	34	Positive	Positive
24	F	39	Positive	Positive	54	F	39	Positive	Positive
25	F	18	Positive	Positive	55	М	40	Positive	Positive
26	F	49	Negative	Negative	56	F	25	Negative	Negative
27	М	42	Negative	Negative	57	М	23	Negative	Negative
28	F	41	Positive	Positive	58	М	29	Negative	Negative
29	М	39	Positive	Positive	59	F	33	Positive	Positive
30	М	72	Positive	Positive	60	F	23	Negative	Negative



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NO.	Geder	Age	COVID-19 antigen Test kit	RT-PCR	NO.	Geder	Age	COVID-19 antigen Test kit	RT-PCR
1	F	32	Negative	Negative	37	M	28	Negative	Negative
2	F	33	Negative	Negative	38	F	24	Negative	Negative
3	F	23	Negative	Negative	39	M	39	Negative	Negative
4	F	35	Negative	Negative	40	F	49	Negative	Negative
5	F	35	Negative	Negative	41	М	31	Negative	Negative
6	М	30	Negative	Negative	42	F	58	Negative	Negative
7	F	39	Negative	Negative	43	M	35	Negative	Negative
8	F	30	Negative	Negative	44	F	40	Negative	Negative
9	F	28	Negative	Negative	45	M	33	Negative	Negative
10	M	28	Negative	Negative	46	М	63	Negative	Negative
11	F	30	Negative	Negative	47	F	33	Negative	Negative
12	F	25	Negative	Negative	48	F	30	Negative	Negative
13	F	44	Negative	Negative	49	F	24	Negative	Negative
14	F	37	Negative	Negative	50	М	34	Negative	Negative
15	F	32	Negative	Negative	51	M	42	Negative	Negative
16	F	38	Negative	Negative	52	F	37	Negative	Negative
17	F	31	Negative	Negative	53	F	- 39	Negative	Negative
18	M	29	Negative	Negative	54	F	33	Negative	Negative
19	F	31	Negative	Negative	55	F	35	Negative	Negative
20	М	43	Negative	Negative	56	M	26	Negative	Negative
21	M	35	Negative	Negative	57	M	22	Negative	Negative
22	F	31	Negative	Negative	58	М	35	Negative	Negative
23	F	39	Negative	Negative	59	F	28	Negative	Negative
24	F	33	Negative	Negative	60	F	30	Negative	Negative
25	F	50	Negative	Negative	61	F	37	Negative	Negative
26	F	37	Negative	Negative	62	F	37	Negative	Negative
27	F	34	Negative	Negative	63	F	27	Negative	Negative
28	F	32	Negative	Negative	64	M	43	Negative	Negative
29	M	22	Negative	Negative	65	М	37	Negative	Negative
30	F	42	Negative	Negative	66	F	60	Negative	Negative
31	F	58	Negative	Negative	67	М	44	Negative	Negative
32	М	25	Negative	Negative	68	F	37	Negative	Negative
33	M	26	Negative	Negative	69	F	40	Negative	Negative
34	F	37	Negative	Negative	70	F	33	Negative	Negative
35	F	28	Negative	Negative	71	F	30	Negative	Negative
36	F	32	Negative	Negative	72	М	23	Negative	Negative
NO.	Geder	Age	COVID-19 antigen Test kit	RT-PCR	NO.	Geder	Age	COVID-19 antigen Test kit	RT-PCF

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73	F	37	Negative	Negative	111	F	31	Negative	Negative
74	М	25	Negative	Negative	112	F	34	Negative	Negative
75	M	27	Negative	Negative	113	F	46	Negative	Negative
76	F	22	Negative	Negative	114	M	33	Negative	Negative
77	F	37	Negative	Negative	115	M	41	Negative	Negative
78	F	35	Negative	Negative	116	F	36	Negative	Negative
79	M	36	Negative	Negative	117	F	31	Negative	Negative
80	M	22	Negative	Negative	118	F	41	Negative	Negative
81	M	30	Negative	Negative	119	F	34	Negative	Negative
82	M	35	Negative	Negative	120	F	33	Negative	Negative
83	М	27	Negative	Negative	121	M	38	Negative	Negative
84	M	45	Negative	Negative	122	M	48	Negative	Negative
85	M	34	Negative	Negative	123	F	35	Negative	Negative
86	M	46	Negative	Negative	124	М	25	Negative	Negative
87	F	20	Negative	Negative	125	M	29	Negative	Negative
88	F	40	Negative	Negative	126	F	37	Negative	Negative
89	М	34	Negative	Negative	127	F	41	Negative	Negative
90	М	28	Negative	Negative	128	F	37	Negative	Negative
91	F	42	Negative	Negative	129	F	30	Negative	Negative
92	F	28	Negative	Negative	130	F	34	Negative	Negative
93	M	29	Negative	Negative	131	F	26	Negative	Negative
94	F	34	Negative	Negative	132	M	38	Negative	Negative
95	М	37	Negative	Negative	133	F	42	Negative	Negative
96	M	35	Negative	Negative	134	F	37	Negative	Negative
97	М	22	Negative	Negative	135	М	45	Negative	Negative
98	М	37	Negative	Negative	136	F	28	Negative	Negative
99	F	39	Negative	Negative	137	F	29	Negative	Negative
100	М	53	Negative	Negative	138	F	27	Negative	Negative
101	М	51	Negative	Negative	139	F	39	Negative	Negative
102	М	24	Negative	Negative	140	F	25	Negative	Negative
103	F	34	Negative	Negative	141	F	33	Negative	Negative
104	F	32	Negative	Negative	142	F	27	Negative	Negative
105	М	22	Negative	Negative	143	F	31	Negative	Negative
106	F	29	Negative	Negative	144	F	32	Negative	Negative
107	М	34	Negative	Negative	145	F	29	Negative	Negative
108	М	41	Negative	Negative	146	F	36	Negative	Negative
109	F	35	Negative	Negative	147	F	35	Negative	Negative
110	F	28	Negative	Negative	148	F	33	Negative	Negative
NO.	Geder	Age	COVID-19 antigen Test kit	RT-PCR	NO.	Geder	Age	COVID-19 antigen Test kit	RT-PCR

Hangzhou Singclean Medical Products Co., Ltd.	COVID-19 Antigen Test Kit (Colloidal Gold)	File No.	CE-TED-15-06	
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149	F	33	Negative	Negative	174	F	27	Negative	Negative
150	F	41	Negative	Negative	175	F	33	Negative	Negative
151	F	36	Negative	Negative	176	F	49	Negative	Negative
152	F	33	Negative	Negative	177	F	42	Negative	Negative
153	F	33	Negative	Negative	178	F	27	Positive	Negative
154	M	24	Negative	Negative	179	F	39	Negative	Negative
155	F	35	Negative	Negative	180	M	45	Negative	Negative
156	M	28	Negative	Negative	181	F	35	Negative	Negative
157	F	29	Negative	Negative	182	F	39	Negative	Negative
158	F	47	Negative	Negative	183	F	30	Negative	Negative
159	M	27	Negative	Negative	184	F	29	Negative	Negative
160	M	31	Negative	Negative	185	F	35	Negative	Negative
161	F	32	Negative	Positive	186	F	41	Negative	Negative
162	M	32	Negative	Negative	187	F	23	Negative	Negative
163	F	32	Negative	Negative	188	F	39	Negative	Negative
164	F	34	Negative	Negative	189	F	23	Negative	Negative
165	M	32	Negative	Negative	190	M	30	Negative	Negative
166	М	22	Negative	Negative	191	М	28	Negative	Negative
167	F	35	Negative	Negative	192	M	25	Negative	Negative
168	M	28	Negative	Negative	193	F	38	Negative	Negative
169	F	38	Negative	Negative	194	M	34	Negative	Negative
170	M	30	Negative	Negative	195	М	38	Negative	Negative
171	M	28	Negative	Negative	196	F	24	Positive	Negative
172	F	37	Negative	Negative	197	F	29	Negative	Negative
173	М	22	Negative	Negative	Revision 1				