CLINICAL PERFORMANCE EVALUATION REPORT OF COVID-19 ANTIGEN DETECTION KIT

Product Name	COVID-19 Ag Detection Kit (Colloidal Gold)
Test start date	20200622
Test end date	20201015
Sample source	SHENZHEN CDC
Applicant	SINGUWAY BIOTECH
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Report date	20201110
Evaluate the storage location	Singuway Biotech Inc.

Content

1. Basic Information

Coronaviruses are a large family of viruses which may cause illness in animals or humans. SARSCoV-2 is an enveloped, single-stranded RNA virus of the β genus. The virus can cause mild to severe respiratory illness and has spread globally.

COVID-19 Antigen Detection Kit is a rapid lateral flow immunoassay for the qualitative detection and diagnosis of SARS-CoV-2 directly from nasopharyngeal swabs, without viral transport media. Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in nasal swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status.

2. Retrospective Study

A. General Information

The COVID-19 Antigen detection kit is a qualitative product. The purpose of the study is to compare the clinical performance of the COVID-19 Antigen detection kit clinical performance with FDA Emergency Use Authorized Real-time Polymerase Chain Reaction (RT-PCR) assay for the detection of SARS-CoV-2, and to demonstrate the robust use of the COVID-19 Antigen detection kit.

The study is conducted at Fourth Hospital of Shenzhen and Shenzhen CDC from 06/22/20 to 06/23/2020. The research team composed of principal investigators and five sub-investigators. The principal investigator is responsible for study protocol is strictly followed and the test samples are collected correctly. All sub-investigators are the staff of the clinic at the Fourth Hospital of Shenzhen operators with no laboratory experience andwho are representative of the intended users. Operators are only using the QRI for the testwithout any training provided.

The RT-PCR includes achemical lysis step followed by solid-phase RNA extraction step.

All the observation results and findings in the clinical study are verified to ensure the reliability of the data and ensure that the conclusions in the clinical trial come from the original data. There are corresponding data management measures in clinical study and data processing stage.

B. Experimental Design

Sample size

The overall study sizewas determined to be not less than 100 individualsto obtain adequate analytical power.

To initially evaluate the clinical performance of the COVID-19 Antigen detection test, a total of 145 blinded cryopreserved swab samples, including 125 retrospective clinical specimens and 20 contrived specimens, were tested in one (1) CLIA waived setting investigational site by five (5) minimally trained operators in Shenzhen during the 2020 COVID-19 season.Each sample was

tested with both methods.

In addition to the clinical specimen samples, a total of 20 contrived near the cut-off samples, 10 low positives near the Limit of Detection (LoD) (2xLoD (600$TCID_{50}$/mL)), and 10 negatives (zero analytes) samples, were prepared using the inactivated SARS-CoV-2 strain spiked into the simulated nasal swab matrix, Rongye universal transport media. The heat-inactivated SARS-CoV-2 isolate was used to prepare the positive samples. The contrived near the cut-off samples were addedto the clinical specimen samples and tested at the same study site by the same operators. All the studysamples were randomized and assigned with unique study subject ID by the principal investigator prior totesting at the study site. The expected results of the samples were completely blinded to theoperators.

Acceptable standards

After the completion of the test, the test results were statistically analyzed, and the clinical application performance of the reagent in the clinical test was evaluated.

Acceptable standard for clinical performance indicators was set before the experiment. To have comparable performance, the Kappa consistency was set to be >0.75.

Sub-investigator selection

The sub-investigators in the study are medical staff at the Fourth Hospital of Shenzhen with no laboratory experience and who are representative of the intended users at CLIA waived setting testing sites. In this study, testing was conducted by five (5) intended users. Testing is performed with quick reference guide for the test without any training provided.

Inclusion criteria

The sample is not limited to age or sex, but requires a certain number of positive, negative and suspected cases

Exclusion criteria

The exclusion criteria include improper sampling, samples with bacteria growth, contaminated samples.

Blind requirement

This is a retrospective study. All study samples were sequentially labeled and tested blindly. The clinical diagnosis and other information of selected samples were kept confidential to the operators before the test to ensure the blind method. The blind rule was used throughout the test. After the studywas completed, the blinding wasremoved.

The number of selected samples were numbered by the designated personnel. The samples were randomized.

Sample specifications and preparation

Samplespecifications

According to the clinical indications, a total of 145cryopreserved samples consisting of 54 positive nasopharyngeal (NP) swabs, 71 negativeNP swab

specimens, and 20 contrived near the cut-off samples (10 positives and 10 negatives).NP swab specimens collected from the patients with COVID-19 like symptoms in Shenzhen duringthe 2020 COVID-19 season and stored in BD Rongye universal transport media tube were provided by Shenzhen CDC.

All the NP swab specimens were confirmed as positive or negativeand validated with Ct value by the FDA EUA RT-PCR as a comparator method prior to the study.

The specimens were aliquoted, randomized, and blinded into sample panels that was tested byeach operator, using the instructions provided by the Quick Product Guide Instructions

The lysis solution sample used for testing must be appropriate not less than 0.5ml, so as to be enough for repeated test.

Samplepreparation

All clinical specimen samples were thawed to the room temperature conditions and were tested with COVID-19 Antigen detection kit within 30 minutes of thawing.

C. Experimental method information

Comparator Method	**Manufacturer**	Sansure BioTech Inc.
	Name	SARS-CoV-2 antigen detection kit (RT-PCR method)
	Principles	RT-PCR
	Authorization	Yes
COVID19 Antigen Detection Kit	**Manufacturer**	Singuway Biotech Inc.
	Name	COVID-19 antigen Detection Kit (Colloidal goal)
	Principles	Rapid lateral flow immunoassay test

D. DataManagement

The original records shall be kept by a specially assigned person in two forms of paper version and electronic version。

E. Dataanalysis for retrospective study

The positive and negative analysis and Kappa consistency test of the two reagents were carried out.

	Number of Positive Results	Number of Negative Results
COVID-19 Antigen detection kit	118	182
RT-PCR Method	121	179

The specific data are asfollows：

Table 1: COVID-19 Antigen detection kit performance with contrived samples (near the cut-off samples)

Sample category	Overall % Agreement (result count)
True negative (zero analytes)	100.0% (10/10)
Low positive (2x LoD)	100.0% (10/10)

Table 2: COVID-19 Antigen detection kit performance against the comparator method

Antigen \ PCR	Positive	Negative	Total
Positive	117	1	118
Negative	4	178	182
Total	121	179	300

Positive Percent Agreement (PPA): 96.7% (95% CI: 93.5%-99.9%)
Negative Percent Agreement (NPA): 99.4% (95% CI: 98.3%-100%)
Total Percent Agreement (NPA): 98.3% (95% CI: 96.9%-99.8%)

KappaConsistencyCalculationz

Kappa

value	sig
	375
300	

Symmetrical measurement

		value	P[a]	T[b]	sig
measure	Kappa	.965	.015	16.722	.000
N		300			

The detection results showed that kappa is 0.965. It is greater than 0.75, the preset acceptable standard.

The result showed that the COVID-19 Antigen detection kit and the RT-PCR method had excellent consistency for synchronous tests performed on the same samples.

F. Conclusions

The result shows that the detection of antigen have the sensitivity of 94.2% , and the specificity of 99.4% ,the false negative always give a ct that bigger than 32.

The COVID-19 Antigen detection kit and the RT-PCR method had excellent consistency for synchronous tests performed on the same samples in retrospective study, including contrived samples at near the Limit of Detection (LoD) (2xLoD (600$TCID_{50}$/mL)).

3. Flex Studies

From the above COVID-19 Antigen detection kit test was demonstrated at near patient or Point of Care (POC)testing that non-laboratory personnel can perform the test accurately in the intended useenvironment.

We conducted a thorough hazard analysis considering the main known sources of errors. Based upon our hazard analysis.Some of the sources of errors are:

- Delay in reading time
- Diluent volume
- Lysis time
- Specimen volume
- Room conditions
- Disturbance events

The robust use of the COVID-19 Antigen detection kit for near patient for Point of Care (POC) testing was demonstrated by six (6) Flex studiesto evaluate the impact of errors, or out-of-specifications conditions, on the assay performance.

A. Purpose of the study: to demonstrate the robustness of the FACU COVID-19 Antigen Detection kit, a flex study was conducted to evaluate the effect of out-of-specifications conditions on the assay performance.

B. Sample preparation

For the flex study, the experiment was conducted at the Singuway Biotech Inc in controlled conditions. All tests were done at the room temperature and humidity conditions (25°C and 40% room humidity), unless stated otherwise.

All samples were prepared using the inactivated SARS-CoV-2 isolates spiked into the simulated nasal swab to produce approximately 2xLoD (600$TCID_{50}$/mL) in 10 drops of lysis solution.

Each experimental condition under evaluation was tested in three replicates.

C. Delay in reading time study

The Singuway Biotech Inc. recommends the reading time at 10 minutes. To study to effect of delay in reading time, we conducted a study with reading times from four times below to three times above the recommended reading time.

The tested reading times were 2.5, 5, 10, 15, 20, and 30minutes. Each experimental condition under evaluation was tested in three replicates. A negative sample as included as control sample.

Results:

Reading time (min)	2.5	5	10	15	20	30	Negative control
Sample 1	Invalid	Positive	Positive	Positive	Positive	Positive	Negative
Sample 2	Positive	Positive	Positive	Positive	Positive	Positive	-
Sample 3	Positive	Positive	Positive	Positive	Positive	Positive	-

Conclusion: The COVID-19 Antigen detection kit test is robust for various reading time.

D. Specimen volume variability study

The Singuway Biotech Inc. recommends the Antigen detection test with two drops of specimen solution. To study to effect of specimen volume, we conducted a study with specimen volumetwo times below tothree times above the recommended specimenvolume.

The tested specimen volumes were 1, 2, 3, 4, and 6 drops. Each experimental condition under evaluation was tested in three replicates. A negative sample as included as control sample.

Results:

Specimen volumes (drops)	1	2	3	4	6	Negative control
Sample 1	Positive	Positive	Positive	Positive	Positive	Negative
Sample 2	Positive	Positive	Positive	Positive	Positive	-
Sample 3	Positive	Positive	Positive	Positive	Positive	-

At 6 drops, there was overflowing of the sample wells

Conclusion: The COVID-19 Antigen detection kit test is robust for various specimen volumes.

E. Buffer volume variability study

The Singuway Biotech Inc. recommends the Antigen detection test with ten drops of buffer solution. To study to effect of buffer volume, we conducted a study with buffer volumetwo times below tomaximum volume of the recommended buffervolume.

The tested buffer volumes were 5, 10, 15, 20 drops and the whole bottle. Each experimental condition under evaluation was tested in three replicates. A negative sample as included as control sample.

Results

Buffer volumes (drops)	5	10	15	20	Whole bottle	Negative control
Sample 1	Positive	Positive	Positive	Positive	Positive	Negative
Sample 2	Positive	Positive	Positive	Positive	Positive	-
Sample 3	Positive	Positive	Positive	Positive	Positive	-

Conclusion: The COVID-19 Antigen detection kit test is robust for various buffer volumes.

F. Lysis time variability study

The Singuway Biotech Inc. recommends the lysis time of one minute. To study to effect of lysis time, we conducted a study with lysis timetwo times below tothree times above the recommended lysis time.

The tested lysis time were 30 seconds, 1, 2, and 3 minutes. Each experimental condition under evaluation was tested in three replicates. A negative sample as included as control sample.

Results

Lysis time (seconds)	30	60	120	180	Negative control
Sample 1	Positive	Positive	Positive	Positive	Negative
Sample 2	Positive	Positive	Positive	Positive	-
Sample 3	Positive	Positive	Positive	Positive	-

Conclusion: The COVID-19 Antigen detection kit test is robust for various lysis time.

G. Temperature and humidity study

The Singuway Biotech Inc. recommends the Antigen detection test at room temperature conditions. To study to effect of testing conditions, we conducted a study with testing conditionsmimicking hot and humid climates and cold and dry climates.

The experimental conditions were 40°C and 95% room humidity (hot and humid climates), 25°C and 40% room humidity (room temperature climates), and 5°C and 5% room humidity (cold and dry climates). Each experimental condition under evaluation was tested in three replicates. A negative sample as included as control sample.

Results

Room conditions	Condition 1	Condition 1	Condition 1	Negative control
Sample 1	Positive	Positive	Positive	Negative
Sample 2	Positive	Positive	Positive	-
Sample 3	Positive	Positive	Positive	-

Condition 1: 5°C and 5% room humidity
Condition 2: 25°C and 40% room humidity
Condition 3:40°C and 95% room humidity

Conclusion: The COVID-19 Antigen detection kit test is robust for various room conditions.

H. Disturbance during study

Some unexpected events might occur while performing the test. To study to effect of

disturbance events during the test, we conducted a study with testing conditionsmimicking disturbing events such as:

- Condition 1: moving the test cassette to new location
- Condition 2: dropping the test cassette while test is ongoing
- Condition 3: losing electricity while the test is ongoing

Each experimental condition under evaluation was tested in three replicates. A negative sample as included as control sample.

Results

Room conditions	Condition 1	Condition 1	Condition 1	Negative control
Sample 1	Positive	Positive	Positive	Negative
Sample 2	Positive	Positive	Positive	-
Sample 3	Positive	Positive	Positive	-

Conclusion: The COVID-19 Antigen detection kit test is robust for various disturbance events.

4. Data Report Sheetfor Study-1

No.	Operator Identification	Gender	Age	COVID-19 Antigen Detection Kit	PCR			Days from Onset of Symptoms
				Results	Ct:FAM	Ct:Hex	Result	
1	C	F	39	Positive	25.12	25.16	Positive	8
2	A	M	54	Negative	N/A	N/A	Negative	3
3	B	M	55	Positive	27.14	27.51	Positive	4
4	F	F	64	Negative	N/A	N/A	Negative	6
5	E	-	-	Negative	N/A	N/A	Negative	-
6	A	F	77	Positive	30.23	30.34	Positive	5
7	B	F	79	Negative	N/A	N/A	Negative	6
8	E	F	49	Negative	N/A	N/A	Negative	10
9	A	F	56	Positive	30.22	30.57	Positive	4
10	B	M	39	Negative	N/A	N/A	Negative	9
11	C	-	-	Positive	29.29	29.78	Positive	-
12	F	M	59	Positive	20.27	20.45	Positive	5
13	E	M	65	Positive	27.19	27.57	Positive	7
14	B	M	46	Negative	N/A	N/A	Negative	3
15	C	M	21	Negative	N/A	N/A	Negative	6
16	A	M	34	Positive	21.35	21.64	Positive	4
17	A	M	48	Negative	33.18	33.25	Positive	3
18	F	F	64	Negative	N/A	N/A	Negative	5

19	E	M	62	Negative	N/A	N/A	Negative	4
20	E	-	-	Negative	N/A	N/A	Negative	-
21	A	M	35	Positive	32.14	32.14	Positive	8
22	E	M	62	Negative	34.26	34.7	Positive	4
23	D	M	64	Negative	N/A	N/A	Negative	6
24	C	F	29	Negative	N/A	N/A	Negative	10
25	B	M	75	Positive	18.65	19.15	Positive	10
26	A	M	54	Positive	20.26	20.3	Positive	4
27	F	F	72	Positive	21.3	21.34	Positive	4
28	E	F	53	Negative	N/A	N/A	Negative	9
29	A	M	49	Negative	N/A	N/A	Negative	6
30	F	F	49	Negative	N/A	N/A	Negative	9
31	A	M	77	Positive	30.58	30.62	Positive	6
32	B	F	59	Negative	N/A	N/A	Negative	4
33	F	F	65	Negative	N/A	N/A	Negative	9
34	B	M	43	Positive	31.14	31.24	Positive	3
35	F	M	47	Negative	N/A	N/A	Negative	5
36	D	M	25	Negative	N/A	N/A	Negative	7
37	C	M	47	Positive	27.33	27.7	Positive	4
38	F	F	58	Negative	N/A	N/A	Negative	9
39	B	F	25	Negative	32.37	32.76	Positive	9
40	E	F	44	Negative	N/A	N/A	Negative	7
41	D	M	54	Negative	N/A	N/A	Negative	5
42	E	F	46	Negative	N/A	N/A	Negative	3

43	C	-	-	Negative	N/A	N/A	Negative	-
44	F	F	42	Negative	N/A	N/A	Negative	9
45	C	F	33	Positive	28.43	28.5	Positive	7
46	B	M	34	Positive	25.21	25.7	Positive	6
47	A	M	24	Negative	N/A	N/A	Negative	2
48	B	M	49	Negative	N/A	N/A	Negative	7
49	E	M	55	Negative	N/A	N/A	Negative	6
50	A	-	-	Negative	N/A	N/A	Negative	-
51	D	F	24	Positive	30.25	30.36	Positive	5
52	E	F	40	Negative	N/A	N/A	Negative	10
53	B	F	74	Positive	30.21	30.48	Positive	8
54	F	F	73	Negative	N/A	N/A	Negative	6
55	F	F	60	Negative	N/A	N/A	Negative	6
56	E	F	23	Positive	28.29	28.78	Positive	5
57	A	F	70	Positive	27.16	27.21	Positive	5
58	B	F	66	Negative	N/A	N/A	Negative	9
59	D	M	37	Positive	27.03	27.09	Positive	6
60	E	F	65	Negative	N/A	N/A	Negative	4
61	C	M	71	Positive	28.09	28.14	Positive	9
62	D	F	47	Negative	N/A	N/A	Negative	6
63	E	M	37	Negative	N/A	N/A	Negative	10
64	B	F	34	Positive	21.31	21.62	Positive	3
65	F	-	-	Positive	28.77	28.89	Positive	-
66	F	M	51	Negative	N/A	N/A	Negative	5

67	D	-	-	Negative	N/A	N/A	Negative	-
68	D	-	-	Negative	N/A	N/A	Negative	-
69	A	F	65	Negative	N/A	N/A	Negative	9
70	A	F	66	Positive	32.17	32.21	Positive	4
71	D	M	52	Positive	31.16	31.45	Positive	10
72	C	F	59	Negative	N/A	N/A	Negative	4
73	E	F	33	Negative	N/A	N/A	Negative	3
74	E	F	47	Negative	N/A	N/A	Negative	7
75	F	F	89	Positive	30.37	30.62	Positive	5
76	C	M	45	Negative	N/A	N/A	Negative	2
77	A	F	54	Negative	N/A	N/A	Negative	10
78	C	M	54	Positive	32.12	32.28	Positive	4
79	E	F	42	Positive	19.48	19.67	Positive	5
80	B	-	-	Positive	28.13	28.43	Positive	-
81	A	F	64	Negative	N/A	N/A	Negative	7
82	D	F	26	Negative	N/A	N/A	Negative	10
83	B	M	74	Positive	22.36	22.38	Positive	4
84	A	F	50	Negative	N/A	N/A	Negative	10
85	E	F	45	Negative	N/A	N/A	Negative	3
86	B	-	-	Positive	29.37	29.43	Positive	-
87	F	M	45	Negative	N/A	N/A	Negative	5
88	C	F	62	Positive	25.15	25.42	Positive	7
89	F	-	-	Positive	28.71	28.87	Positive	-
90	E	M	31	Negative	N/A	N/A	Negative	8

91	B	M	16	Negative	N/A	N/A	Negative	10
92	A	F	54	Positive	26.33	26.77	Positive	6
93	C	M	18	Positive	29.17	29.24	Positive	6
94	B	F	56	Negative	N/A	N/A	Negative	8
95	C	-	-	Positive	29.21	29.43	Positive	-
96	C	M	31	Negative	N/A	N/A	Negative	8
97	B	M	84	Positive	27.31	27.54	Positive	8
98	D	M	73	Negative	N/A	N/A	Negative	2
99	A	M	46	Negative	N/A	N/A	Negative	10
100	C	F	59	Positive	29.24	29.35	Positive	7
101	E	M	68	Positive	29.35	29.5	Positive	3
102	D	M	70	Negative	N/A	N/A	Negative	5
103	F	-	-	Negative	N/A	N/A	Negative	-
104	B	F	61	Positive	30.51	30.96	Positive	10
105	E	M	62	Negative	N/A	N/A	Negative	7
106	A	M	48	Negative	N/A	N/A	Negative	4
107	A	-	-	Positive	28.43	28.61	Positive	-
108	D	M	67	Positive	29.18	N/A	Positive	6
109	F	F	45	Negative	N/A	N/A	Negative	7
110	E	F	65	Negative	N/A	N/A	Negative	8
111	B	F	60	Positive	24.23	24.55	Positive	5
112	A	F	35	Negative	N/A	N/A	Negative	10
113	E	M	51	Negative	N/A	N/A	Negative	5
114	D	F	47	Negative	N/A	N/A	Negative	10

115	E	-	-	Positive	24.37	24.43	Positive	-
116	A	F	49	Positive	32.1	32.38	Positive	7
117	E	M	54	Negative	N/A	N/A	Negative	7
118	C	F	53	Negative	N/A	N/A	Negative	10
119	F	M	47	Negative	N/A	N/A	Negative	4
120	E	M	37	Negative	N/A	N/A	Negative	10
121	F	-	-	Negative	N/A	N/A	Negative	-
122	C	F	66	Positive	N/A	N/A	Negative	8
123	C	M	60	Positive	30.28	30.48	Positive	4
124	F	M	64	Positive	23.14	23.27	Positive	5
125	E	F	50	Negative	N/A	N/A	Negative	7
126	B	-	-	Negative	N/A	N/A	Negative	-
127	D	F	64	Positive	28.26	28.65	Positive	4
128	B	M	16	Positive	24.53	24.67	Positive	7
129	E	F	86	Positive	27.21	27.3	Positive	6
130	A	F	70	Negative	N/A	N/A	Negative	7
131	A	-	-	Positive	28.17	28.33	Positive	-
132	A	M	59	Positive	23.26	23.68	Positive	6
133	F	F	22	Positive	24.37	24.43	Positive	4
134	C	F	32	Negative	N/A	N/A	Negative	10
135	E	M	61	Negative	N/A	N/A	Negative	8
136	A	F	44	Positive	29.41	29.68	Positive	4
137	A	F	16	Positive	22.36	22.84	Positive	6
138	B	F	46	Negative	N/A	N/A	Negative	8

139	F	F	48	Negative	N/A	N/A	Negative	10
140	C	-	-	Positive	29.11	29.33	Positive	-
141	E	M	61	Positive	27.64	27.73	Positive	5
142	A	F	49	Negative	32.29	32.7	Positive	2
143	F	F	19	Positive	18.27	18.72	Positive	4
144	B	F	46	Negative	N/A	N/A	Negative	8
145	A	-	-	Negative	N/A	N/A	Negative	-

5. Data Report Sheetfor Study-2

No.	Name/Operator Identification	Gender	Age	COVID-19 Antigen Detection Kit	PCR			Days from Onset of Symptoms
				Results	Ct:FAM	Ct:Hex	Results	
1	17034	M	75	Positive	25.22	25.41	Positive	3
2	17919	M	19	Negative	-	-	Negative	2
3	A	M	61	Negative	-	-	Negative	5
4	C	F	42	Positive	29.23	29.84	Positive	4
5	F	M	32	Negative	-	-	Negative	3
6	B	F	29	Negative	-	-	Negative	2
7	D	M	55	Positive	30.22	30.57	Positive	2
8	C	M	77	Negative	-	-	Negative	4
9	F	M	17	Negative	-	-	Negative	4
10	A	M	41	Negative	-	-	Negative	7
11	E	M	47	Negative	-	-	Negative	5
12	B	F	18	Negative	28.86	29.12	Positive	2
13	E	M	23	Negative	-	-	Negative	3
14	B	M	17	Negative	-	-	Negative	2
15	E	M	27	Negative	-	-	Negative	7
16	C	F	72	Negative	-	-	Negative	6
17	F	M	38	Negative	-	-	Negative	2
18	A	M	24	Negative	-	-	Negative	3
19	F	M	50	Negative	-	-	Negative	3
20	C	F	61	Positive	21.74	21.45	Positive	3
21	E	F	18	Negative	-	-	Negative	4
22	B	M	41	Positive	26.36	26.65	Positive	2
23	F	F	71	Negative	-	-	Negative	7
24	C	M	69	Negative	-	-	Negative	3
25	D	F	31	Positive	31.44	31.6	Positive	5
26	-	F	21	Negative	-	-	Negative	-

27	-	F	54	Negative	-	-	Negative	-
28	-	F	68	Negative	-	-	Negative	-
29	-	M	60	Negative	-	-	Negative	-
30	-	F	36	Negative	-	-	Negative	-
31	-	M	51	Negative	-	-	Negative	-
32	-	M	47	Negative	-	-	Negative	-
33	-	F	67	Negative	-	-	Negative	-
34	-	F	67	Negative	-	-	Negative	-
35	-	M	61	Negative	-	-	Negative	-
36	-	M	41	Negative	-	-	Negative	-
37	-	M	25	Negative	-	-	Negative	-
38	-	M	64	Negative	-	-	Negative	-
39	-	M	30	Negative	-	-	Negative	-
40	-	M	65	Negative	-	-	Negative	-
41	-	M	65	Negative	-	-	Negative	-
42	-	F	46	Negative	-	-	Negative	-
43	-	M	20	Negative	-	-	Negative	-
44	-	F	43	Negative	-	-	Negative	-
45	-	F	54	Negative	-	-	Negative	-
46	-	M	61	Negative	-	-	Negative	-
47	-	M	38	Negative	-	-	Negative	-
48	-	M	44	Negative	-	-	Negative	-
49	-	F	38	Negative	-	-	Negative	-
50	-	M	30	Negative	-	-	Negative	-
51	-	F	70	Negative	-	-	Negative	-
52	-	F	62	Negative	-	-	Negative	-
53	-	M	27	Negative	-	-	Negative	-
54	-	F	73	Negative	-	-	Negative	-
55	-	M	37	Negative	-	-	Negative	-
56	-	F	60	Negative	-	-	Negative	-
57	-	M	68	Negative	-	-	Negative	-
58	-	F	15	Negative	-	-	Negative	-
59	-	F	56	Negative	-	-	Negative	-
60	-	M	69	Negative	-	-	Negative	-
61	-	M	68	Negative	-	-	Negative	-
62	-	M	60	Negative	-	-	Negative	-
63	-	M	58	Negative	-	-	Negative	-
64	-	F	54	Negative	-	-	Negative	-
65	-	M	29	Negative	-	-	Negative	-
66	-	M	27	Negative	-	-	Negative	-
67	-	M	57	Negative	-	-	Negative	-

68	-	M	64	Negative	-	-	Negative	-
69	-	M	37	Negative	-	-	Negative	-
70	-	F	56	Negative	-	-	Negative	-
71	-	F	48	Negative	-	-	Negative	-
72	-	F	18	Negative	-	-	Negative	-
73	-	F	30	Negative	-	-	Negative	-
74	-	M	27	Negative	-	-	Negative	-
75	-	F	37	Negative	-	-	Negative	-
76	-	F	74	Negative	-	-	Negative	-
77	-	M	36	Negative	-	-	Negative	-
78	-	F	29	Negative	-	-	Negative	-
79	-	M	59	Negative	-	-	Negative	-
80	-	M	47	Negative	-	-	Negative	-
81	-	M	21	Negative	-	-	Negative	-
82	-	M	36	Negative	-	-	Negative	-
83	-	M	39	Negative	-	-	Negative	-
84	-	F	60	Negative	-	-	Negative	-
85	-	M	59	Negative	-	-	Negative	-
86	-	M	39	Negative	-	-	Negative	-
87	-	M	28	Negative	-	-	Negative	-
88	-	F	31	Negative	-	-	Negative	-
89	-	M	39	Negative	-	-	Negative	-
90	-	F	37	Negative	-	-	Negative	-
91	-	M	41	Negative	-	-	Negative	-
92	-	M	23	Negative	-	-	Negative	-
93	-	M	21	Negative	-	-	Negative	-
94	-	F	17	Negative	-	-	Negative	-
95	-	M	48	Negative	-	-	Negative	-
96	-	F	18	Negative	-	-	Negative	-
97	-	F	65	Negative	-	-	Negative	-
98	-	F	63	Negative	-	-	Negative	-
99	-	F	26	Negative	-	-	Negative	-
100	-	F	12	Negative	-	-	Negative	-
101	-	M	58	Negative	-	-	Negative	-
102	-	F	42	Negative	-	-	Negative	-
103	-	M	72	Negative	-	-	Negative	-

6. Data Report Sheetfor Study-3

Operator Identification	Gender	Age	COVID-19 Antigen Detection Kit	PCR			Days from Onset of Symptoms
			Results	Ct:FAM	Ct:Hex	Result	
-	F	39	Positive	26.44	26.01	Positive	-
-	F	53	Positive	27.31	27.10	Positive	-
-	F	36	Positive	20.53	19.81	Positive	-
-	M	32	Positive	28.60	28.19	Positive	-
-	M	50	Positive	22.49	22.29	Positive	-
-	F	41	Positive	27.30	27.26	Positive	-
-	M	27	Positive	20.16	18.55	Positive	-
-	F	40	Positive	25.50	25.19	Positive	-
-	M	45	Positive	19.65	18.10	Positive	-
-	M	54	Positive	22.90	22.53	Positive	-
-	F	33	Positive	23.29	22.03	Positive	-
-	M	42	Positive	25.80	24.72	Positive	-
-	M	38	Positive	22.84	21.25	Positive	-
-	M	41	Positive	21.17	20.73	Positive	-
-	M	45	Positive	28.72	28.62	Positive	-
-	F	19	Positive	25.71	23.97	Positive	-
-	F	46	Positive	25.46	24.98	Positive	-
-	F	47	Positive	24.31	23.18	Positive	-
-	F	19	Positive	23.63	21.76	Positive	-
-	M	54	Positive	24.81	22.86	Positive	-
-	F	48	Positive	23.43	21.48	Positive	-
-	M	22	Positive	18.80	17.46	Positive	-
-	F	19	Positive	26.03	25.53	Positive	-
-	F	39	Positive	28.32	28.13	Positive	-
-	M	35	Positive	22.44	21.52	Positive	-
-	M	34	Positive	23.99	22.11	Positive	-
-	M	43	Positive	24.64	23.17	Positive	-
-	M	40	Positive	22.29	21.58	Positive	-
-	M	33	Positive	19.72	18.37	Positive	-
-	M	51	Positive	24.70	24.00	Positive	-
-	M	38	Positive	24.18	22.85	Positive	-
-	F	44	Positive	26.79	26.70	Positive	-
-	M	56	Positive	26.74	26.13	Positive	-
-	M	57	Positive	29.08	28.59	Positive	-

-	M	45	Positive	26.85	25.72	Positive	-
-	M	36	Positive	22.47	20.93	Positive	-
-	F	55	Positive	24.04	23.82	Positive	-
-	F	19	Positive	22.43	20.50	Positive	-
-	F	36	Positive	23.29	22.92	Positive	-
-	M	39	Positive	21.83	21.81	Positive	-
-	F	29	Positive	18.96	18.13	Positive	-
-	F	41	Positive	22.24	22.17	Positive	-
-	M	50	Positive	26.96	25.78	Positive	-
-	F	40	Positive	22.73	20.98	Positive	-
-	M	24	Positive	20.06	18.39	Positive	-
-	F	32	Positive	26.08	25.68	Positive	-
-	M	41	Positive	29.83	28.68	Positive	-
-	F	52	Positive	24.26	23.70	Positive	-
-	M	46	Positive	22.07	21.64	Positive	-
-	F	25	Positive	23.30	23.00	Positive	-
-	F	33	Positive	26.55	25.51	Positive	-
-	M	33	Positive	23.89	23.01	Negative	-