

**Clinical Study Report
of
VivaDiag™ Pro SARS-CoV-2 Ag Test**

Performance Evaluation--Clinical Study Report

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Ver2.0

1. Introduction

The VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test is for the rapid, qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human nasal swab, oropharyngeal swab or nasopharyngeal swab specimen.

2. Objective

Compare the clinical performance of VivaDiag™ Pro SARS-CoV-2 Ag Test with SARS-CoV-2 RT-PCR Test & CT by 533 clinical samples.

3. Method

3.1 Instruments and Materials

VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test, Lot: T2007009

SARS-CoV-2 RT-PCR test kit

Timer

CT

3.2 Samples

Total 533 subjects were invited to participate in this comparison study at 3 clinical sites. All nasal swab samples were obtained from the subjects were analyzed by RT-PCR for the presence of SARS-CoV-2 and CT method was employed to confirm the infection. From the 533 subjects, 431 are negative for SARS-CoV-2 infection and 102 are positive.

Table 1 - Distribution of SARS-CoV-2 clinical specimen tested by RT-PCR & CT

SARS-CoV-2 clinical sample (by RT-PCT & CT)	Quantity
Negative	431
Positive	102
Total	533

Note:

Nasal swab, oropharyngeal swab and nasopharyngeal swab can be used by VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test to detect the presence of SARS-CoV-2 antigen in the specimen. Internal validation studies based on Matrix Equivalency were performed on nasal swab, oropharyngeal swab and nasopharyngeal swab specimens, no statistic difference was observed among those specimens.

3.3 Procedure

1) Specimen collection

- Nasal swab specimen

In this clinical studies, 533 specimens are collected from the nasal swabs. It is important to obtain as much secretion as possible.

Insert the sterile swab into one nostril. The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected. Repeat this process for the other nostril to ensure that an adequate specimen is collected from both nasal cavities (use the same swab).

Oropharyngeal and Nasopharyngeal are also acceptable for VivaDiag™ Pro SARS-CoV-2 Ag Test.

- **Oropharyngeal swab specimen (optional)**

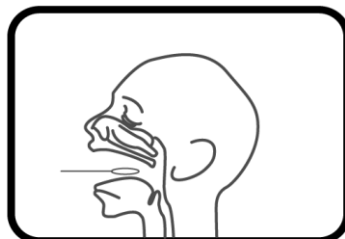
It is important to obtain as much secretion as possible. Insert the sterile swab into throat that presents the most secretion from the red area of the throat wall and maxillary tonsils to collect throat swab specimen. Rub the bilateral throat tonsils and throat wall moderately to obtain the specimen. Please do not touch the tongue when remove the swab.

- **Nasopharyngeal swab specimen (optional)**

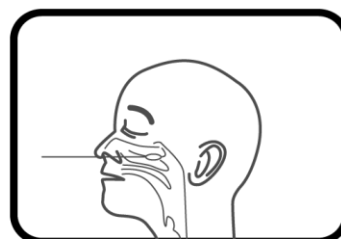
It is important to obtain as much secretion as possible. Insert the sterile swab into the nostril that presents the most secretion under visual inspection. Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx. Rotate the swab 5 times then remove it from the nasopharynx.



Nasal swab



Oropharyngeal swab



Nasopharyngeal swab

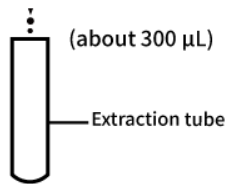
2) Specimen handling

Freshly collected specimens should be tested as soon as possible. It is essential that correct specimen collection and preparation methods are followed.

3) Testing Procedure

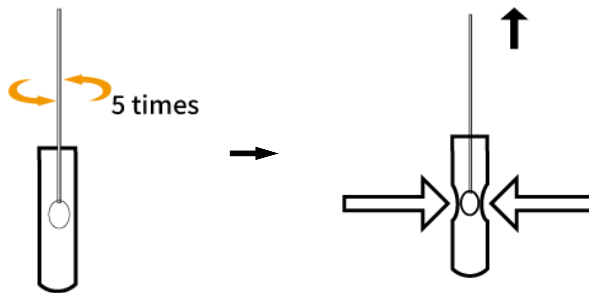
Allow the Test Devices and Extraction Solution to equilibrate to 15-30°C prior to testing.

(1) Add 300 µL extraction solution into extraction tube on tube stand. Please avoid bubbles when operation.



(2) Collect specimen refer to **Specimen Collection**.

(3) Insert sterile swab with collected specimen into extraction tube. Roll the swab 5 times, while pressing the head against the bottom and side of the extraction tube. Roll the swab head against the inside of the extraction tube when remove it. Try to release as much liquid as possible. Dispose of the used swab in the biohazard waste.

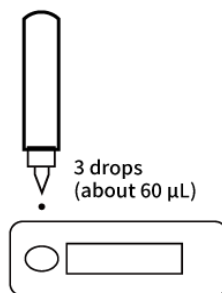


(4) Put on the tube tip.



(5) Take out a test device from sealed foil pouch and put it on a clean and level surface

(6) Apply 3 drops (about 60 µL) of extracted specimen onto the specimen well. Please avoid bubbles when operation.



(7) Read the test result at 15 minutes. Don't read the result after 20 minutes.



15 min



Note:

- Do not interchange or mix extraction solution from different lots.
- Handle extraction solution with caution, do not contact with eyes or skin. If spilled on eyes or skin, wash thoroughly with water.
- Please follow local regulations to handle the used materials.

3.4 Interpretation of Test Results

Positive result:

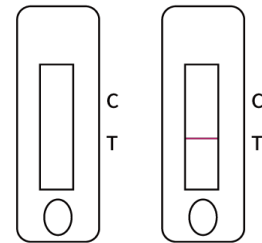
Both the quality control line C and the detection line T appear.

Negative result:

Only the quality control line C appears, with no other line appearing on the detection line.

Invalid result:

Quality control line C fails to appear indicating the test is invalid, no matter if the detection line appears or not. Collect a new specimen and perform another test with a new test device.



Positive: Both detection line (T) and quality control line (C) appear red in the detection area.

Negative: Only the quality control line (C) appears in the detection area.

Invalid: No red quality control line (C) appears in the detection area no matter the detection (T) line is colored or not.

4. Results and Conclusions

VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test	PCR (CT value<30)		
	Positive	Negative	Total
Positive	99	0	99
Negative	3	431	434
Total	102	431	533
Sensitivity	97.06% (99/102, 95%CI, 91.71%~98.99%)		
Specificity	100% (431/431 95%CI, 99.12%~100%)		
Accuracy	99.44% (530/533 95%CI, 98.36%~99.81%)		

The VivaDiag™ Pro SARS-CoV-2 Ag Test showed a clinical sensitivity of 97.06%.

The VivaDiag™ Pro SARS-CoV-2 Ag Test showed a clinical specificity of 100%.

The VivaDiag™ Pro SARS-CoV-2 Ag Test showed a clinical accuracy of 99.44%.

From the results of 533 negative and positive samples, we can confirm that VivaDiag™ Pro SARS-CoV-2 Ag test has good clinical performance compare with RT-PCR & CT.

5. Testing data

5.1 Results of negative samples

Table 2 - Results of negative samples were tested with VivaDiag™ Pro SARS-CoV-2 Ag Test and SARS-CoV-2 RT-PCR and CT

Sample	Clinical Site	Date of testing	VivaDiag™ Pro SARS-CoV-2 Ag	PCR & CT	CT Value of PCR	VivaDiag™ test coincidence
1	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
2	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
3	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
4	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
5	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
6	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
7	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
8	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
9	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
10	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
11	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
12	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
13	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
14	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
15	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
16	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
17	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
18	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
19	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
20	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
21	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
22	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
23	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
24	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
25	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
26	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
27	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
28	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
29	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
30	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
31	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
32	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
33	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
34	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
35	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
36	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
37	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
38	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
39	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
40	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
41	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
42	No.1	15-Aug-20	Negative	Negative	UNDET	Yes

143	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
144	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
145	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
146	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
147	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
148	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
149	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
150	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
151	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
152	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
153	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
154	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
155	No.1	16-Aug-20	Negative	Negative	UNDET	Yes

Sample	Clinical Site	Date of testing	VivaDiag™ Pro SARS-CoV-2 Ag	PCR & CT	CT Value of PCR	VivaDiag™ Pro SARS-CoV-2 Ag coincidence
156	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
157	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
158	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
159	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
160	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
161	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
162	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
163	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
164	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
165	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
166	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
167	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
168	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
169	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
170	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
171	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
172	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
173	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
174	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
175	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
176	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
177	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
178	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
179	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
180	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
181	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
182	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
183	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
184	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
185	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
186	No.2	15-Aug-20	Negative	Negative	UNDET	Yes

287	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
288	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
289	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
290	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
291	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
292	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
293	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
294	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
295	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
296	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
297	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
298	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
299	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
300	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
301	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
302	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
303	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
304	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
305	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
306	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
307	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
308	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
309	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
310	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
311	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
312	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
313	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
314	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
315	No.2	18-Aug-20	Negative	Negative	UNDET	Yes

Sample	Clinical Site	Date of testing	VivaDiag™ Pro SARS-CoV-2 Ag	PCR & CT	CT Value of PCR	VivaDiag™ Pro SARS-CoV-2 Ag coincidence
316	No.3	15-Aug-20	Negative	Negative	UNDET	Yes
317	No.3	15-Aug-20	Negative	Negative	UNDET	Yes
318	No.3	15-Aug-20	Negative	Negative	UNDET	Yes
319	No.3	15-Aug-20	Negative	Negative	UNDET	Yes
320	No.3	15-Aug-20	Negative	Negative	UNDET	Yes
321	No.3	15-Aug-20	Negative	Negative	UNDET	Yes
322	No.3	15-Aug-20	Negative	Negative	UNDET	Yes
323	No.3	15-Aug-20	Negative	Negative	UNDET	Yes
324	No.3	15-Aug-20	Negative	Negative	UNDET	Yes
325	No.3	15-Aug-20	Negative	Negative	UNDET	Yes
326	No.3	15-Aug-20	Negative	Negative	UNDET	Yes
327	No.3	15-Aug-20	Negative	Negative	UNDET	Yes
328	No.3	15-Aug-20	Negative	Negative	UNDET	Yes
329	No.3	15-Aug-20	Negative	Negative	UNDET	Yes
330	No.3	15-Aug-20	Negative	Negative	UNDET	Yes
331	No.3	15-Aug-20	Negative	Negative	UNDET	Yes

5.2 Results of positive samples

Table 3 - Results of positive samples were tested with VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test and SARS-CoV-2 RT-PCR and CT

sample	Clinical Site	Date of testing	Days from onset of symptoms	VivaDiag™ Pro SARS-CoV-2 Ag	PCR & CT	CT Value of PCR	VivaDiag™ Pro SARS-CoV-2 Ag coincidence
1	No.1	15-Aug-20	1	Positive	Positive	<30	Yes
2	No.1	15-Aug-20	0	Positive	Positive	<30	Yes
3	No.1	15-Aug-20	1	Positive	Positive	<30	Yes
4	No.1	16-Aug-20	1	Positive	Positive	<30	Yes
5	No.1	16-Aug-20	4	Positive	Positive	<30	Yes
6	No.1	16-Aug-20	1	Positive	Positive	<30	Yes
7	No.1	16-Aug-20	2	Positive	Positive	<30	Yes
8	No.1	16-Aug-20	2	Positive	Positive	<30	Yes
9	No.1	16-Aug-20	1	Positive	Positive	<30	Yes
10	No.1	16-Aug-20	1	Positive	Positive	<30	Yes
11	No.1	18-Aug-20	2	Positive	Positive	<30	Yes
12	No.1	18-Aug-20	1	Positive	Positive	<30	Yes
13	No.1	18-Aug-20	3	Positive	Positive	<30	Yes
14	No.1	18-Aug-20	1	Positive	Positive	<30	Yes
15	No.1	18-Aug-20	5	Positive	Positive	<30	Yes
16	No.1	18-Aug-20	1	Positive	Positive	<30	Yes
17	No.1	18-Aug-20	2	Positive	Positive	<30	Yes
18	No.1	18-Aug-20	5	Positive	Positive	<30	Yes
19	No.1	18-Aug-20	1	Positive	Positive	<30	Yes
20	No.1	18-Aug-20	6	Positive	Positive	<30	Yes
21	No.1	20-Aug-20	2	Positive	Positive	<30	Yes
22	No.1	20-Aug-20	1	Positive	Positive	<30	Yes
23	No.1	20-Aug-20	2	Positive	Positive	<30	Yes
24	No.1	20-Aug-20	1	Positive	Positive	<30	Yes
25	No.1	20-Aug-20	3	Positive	Positive	<30	Yes
26	No.1	20-Aug-20	1	Positive	Positive	<30	Yes
27	No.1	20-Aug-20	3	Positive	Positive	<30	Yes
28	No.1	20-Aug-20	1	Positive	Positive	<30	Yes
29	No.1	20-Aug-20	2	Positive	Positive	<30	Yes
30	No.1	20-Aug-20	1	Positive	Positive	<30	Yes
31	No.1	20-Aug-20	4	Positive	Positive	<30	Yes
32	No.1	20-Aug-20	3	Positive	Positive	<30	Yes
33	No.2	20-Aug-20	2	Positive	Positive	<30	Yes
34	No.2	20-Aug-20	3	Positive	Positive	<30	Yes
35	No.2	20-Aug-20	5	Positive	Positive	<30	Yes
36	No.2	20-Aug-20	2	Positive	Positive	<30	Yes
37	No.2	20-Aug-20	2	Positive	Positive	<30	Yes
38	No.2	20-Aug-20	6	Negative	Positive	<30	No
39	No.2	20-Aug-20	2	Positive	Positive	<30	Yes
40	No.2	20-Aug-20	3	Positive	Positive	<30	Yes
41	No.2	20-Aug-20	2	Positive	Positive	<30	Yes
42	No.2	20-Aug-20	1	Positive	Positive	<30	Yes
43	No.2	20-Aug-20	2	Positive	Positive	<30	Yes

44	No.2	20-Aug-20	1	Positive	Positive	<30	Yes
45	No.2	20-Aug-20	3	Positive	Positive	<30	Yes
46	No.2	20-Aug-20	0	Positive	Positive	<30	Yes
47	No.2	20-Aug-20	2	Positive	Positive	<30	Yes
48	No.2	22-Aug-20	1	Positive	Positive	<30	Yes
49	No.2	22-Aug-20	0	Positive	Positive	<30	Yes
50	No.2	22-Aug-20	1	Positive	Positive	<30	Yes
51	No.2	22-Aug-20	1	Positive	Positive	<30	Yes
52	No.2	22-Aug-20	4	Positive	Positive	<30	Yes
53	No.2	25-Aug-20	1	Positive	Positive	<30	Yes
54	No.2	25-Aug-20	2	Positive	Positive	<30	Yes
55	No.2	25-Aug-20	3	Positive	Positive	<30	Yes
56	No.2	25-Aug-20	1	Positive	Positive	<30	Yes
57	No.2	25-Aug-20	1	Positive	Positive	<30	Yes
58	No.2	25-Aug-20	2	Positive	Positive	<30	Yes
59	No.2	25-Aug-20	1	Positive	Positive	<30	Yes
60	No.2	25-Aug-20	3	Positive	Positive	<30	Yes
61	No.2	25-Aug-20	1	Positive	Positive	<30	Yes
62	No.2	25-Aug-20	5	Positive	Positive	<30	Yes
63	No.2	25-Aug-20	3	Positive	Positive	<30	Yes
64	No.2	25-Aug-20	2	Positive	Positive	<30	Yes
65	No.2	25-Aug-20	5	Positive	Positive	<30	Yes
66	No.2	27-Aug-20	1	Positive	Positive	<30	Yes
67	No.2	27-Aug-20	0	Positive	Positive	<30	Yes
68	No.2	27-Aug-20	1	Positive	Positive	<30	Yes
69	No.2	27-Aug-20	1	Positive	Positive	<30	Yes
70	No.2	27-Aug-20	4	Positive	Positive	<30	Yes
71	No.2	27-Aug-20	1	Positive	Positive	<30	Yes
72	No.2	27-Aug-20	2	Positive	Positive	<30	Yes
73	No.2	27-Aug-20	3	Positive	Positive	<30	Yes
74	No.2	27-Aug-20	1	Positive	Positive	<30	Yes
75	No.2	27-Aug-20	2	Positive	Positive	<30	Yes
76	No.2	27-Aug-20	3	Positive	Positive	<30	Yes
77	No.2	27-Aug-20	2	Positive	Positive	<30	Yes
78	No.3	20-Aug-20	1	Positive	Positive	<30	Yes
79	No.3	20-Aug-20	6	Positive	Positive	<30	Yes
80	No.3	20-Aug-20	2	Positive	Positive	<30	Yes
81	No.3	20-Aug-20	3	Positive	Positive	<30	Yes
82	No.3	20-Aug-20	5	Positive	Positive	<30	Yes
83	No.3	21-Aug-20	2	Positive	Positive	<30	Yes
84	No.3	21-Aug-20	2	Positive	Positive	<30	Yes
85	No.3	21-Aug-20	6	Positive	Positive	<30	Yes
86	No.3	21-Aug-20	2	Positive	Positive	<30	Yes
87	No.3	21-Aug-20	7	Negative	Positive	<30	No
88	No.3	21-Aug-20	9	Negative	Positive	<30	No
89	No.3	21-Aug-20	1	Positive	Positive	<30	Yes
90	No.3	21-Aug-20	2	Positive	Positive	<30	Yes
91	No.3	23-Aug-20	2	Positive	Positive	<30	Yes
92	No.3	23-Aug-20	3	Positive	Positive	<30	Yes
93	No.3	23-Aug-20	5	Positive	Positive	<30	Yes

94	No.3	23-Aug-20	2	Positive	Positive	<30	Yes
95	No.3	23-Aug-20	2	Positive	Positive	<30	Yes
96	No.3	23-Aug-20	1	Positive	Positive	<30	Yes
97	No.3	23-Aug-20	6	Positive	Positive	<30	Yes
98	No.3	23-Aug-20	2	Positive	Positive	<30	Yes
99	No.3	23-Aug-20	3	Positive	Positive	<30	Yes
100	No.3	23-Aug-20	2	Positive	Positive	<30	Yes
101	No.3	23-Aug-20	6	Positive	Positive	<30	Yes
102	No.3	23-Aug-20	2	Positive	Positive	<30	Yes

6. Reference

WHO - Instructions and requirements for Emergency Use Listing (EUL) submission: In vitro diagnostics detecting SARS-CoV-2 nucleic acid and rapid diagnostics tests detecting SARS-CoV-2 antigens.