

# Clinical Study Report of VivaDiag<sup>™</sup> SARS-CoV-2 Ag Test

Performance Evaluation--Clinical Study Report

Document No.: TF0025-002

Date of Issue: Nov 11, 2020

Ver 2.0

# 1. Introduction

VivaDiag<sup>™</sup> 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 or throat swab specimen.

# 2. Objective

Compare the clinical performance of VivaDiag<sup>™</sup> SARS-CoV-2 Ag Test with SARS-CoV-2 RT-PCR Test & CT by 552 clinical samples.

# 3. Method

# 3.1 Instruments and Materials

VivaDiag<sup>™</sup> SARS-CoV-2 Ag Rapid Test, Lot: T2007001, SARS-CoV-2 RT-PCR test kit, CT

# 3.2 Samples

Total 552 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 552 subjects, 431 are negative for SARS-CoV-2 infection and 121 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	121
Total	552

<u>Note:</u>

<u>Both nasal swab specimen and throat swab specimen can be used by VivaDiag<sup>™</sup> SARS-CoV-2 Ag</u> <u>Rapid Test to detect the presence of SARS-CoV-2 antigen in the specimen. Internal validation studies</u> <u>based on Matrix Equivalency were performed on both nasal swab specimens and throat swab</u> <u>specimens, no statistic difference was observed among those specimens.</u>

# 3.3 Procedure

# 1) Specimen collection

# Nasal swab specimen

In this clinical studies, 552 specimens are collected from the nasal swabs. It is important to obtain as much

#### Confidential

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<sup>™</sup> 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

#### 2) Specimen handling



Oropharyngeal swab



Nasopharyngeal swab

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.



#### 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 purplish-red in the detection area.

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

**Invalid:** No purplish-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 <sup>™</sup> SARS-CoV-2		PCR (CT value<30)			
Ag Rapid Test	Positive	Negative	Total		
Positive	115	0	115		
Negative	6	431	437		
Total	121	431	552		
Sensitivity	(115/12	95.04% 1, 95%Cl, 89.60%~97	7.71%)		
Specificity	100% (431/431, 95%Cl, 99.12%~100%)				
Accuracy	(546/55)	98.91% 2, 95%Cl, 97.65%~99	9.50%)		

The VivaDiagTM SARS-CoV-2 Ag Test showed a clinical sensitivity of 95.04%.

The VivaDiagTM SARS-CoV-2 Ag Test showed a clinical specificity of 100%.

The VivaDiagTM SARS-CoV-2 Ag Test showed a clinical accuracy of 98.91%.

From the results of 552 negative and positive samples, we can confirm that VivaDiag<sup>™</sup> 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 <sup>™</sup> SARS-CoV-2 Ag Test and SARS-CoV-2
RT-PCR and CT

				-	r	1
Sample	Clinical Site	Date of testing	VivaDiag™ SARS- CoV-2 Ag	PCR & CT	CT Value of PCR	VivaDiag <sup>™</sup> SARS-CoV- 2 Ag 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
43	No.1	15-Aug-20 15-Aug-20	Negative	Negative	UNDET	Yes
44	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
45	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
46	No.1	15-Aug-20 15-Aug-20	Negative	Negative	UNDET	Yes
40	No.1			-	UNDET	Yes
48	No.1	15-Aug-20 15-Aug-20	Negative	Negative	UNDET	Yes
40	-		Negative	Negative		
49 50	No.1 No.1	15-Aug-20 15-Aug-20	Negative	Negative Negative	UNDET UNDET	Yes Yes
50	No.1	-	Negative	-		Yes
		15-Aug-20	Negative	Negative		
52	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
53	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
54	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
55	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
56	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
57	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
58	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
59	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
60	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
61	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
62	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
63	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
64	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
65	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
66	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
67	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
68	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
69	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
70	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
71	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
72	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
73	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
74	No.1	15-Aug-20	Negative	Negative	UNDET	Yes
75	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
76	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
77	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
78	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
79	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
80	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
81	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
82	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
83	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
84	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
85	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
86	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
87	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
88	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
89	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
90	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
91	No.1	16-Aug-20	Negative	Negative	UNDET	Yes

92	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
93	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
94	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
95	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
96	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
97	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
98	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
99	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
100	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
101	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
102	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
103	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
104	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
105	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
105	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
100	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
107	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
109	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
110	No.1	16-Aug-20			UNDET	Yes
111		-	Negative	Negative	UNDET	
	No.1	16-Aug-20	Negative	Negative		Yes
112	No.1	16-Aug-20	Negative	Negative		Yes
113	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
114	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
115	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
116	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
117	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
118	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
119	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
120	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
121	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
122	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
123	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
124	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
125	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
126	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
127	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
128	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
129	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
130	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
131	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
132	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
133	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
134	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
135	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
136	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
137	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
138	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
139	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
140	No.1	16-Aug-20	Negative	Negative	UNDET	Yes
141	No.1	16-Aug-20	Negative	Negative	UNDET	Yes

142	No.1	16-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™ SARS- CoV-2 Ag	PCR & CT	CT Value of PCR	VivaDiag <sup>™</sup> 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

400		45 4	Newsters	Newstern		N/
186	No.2	15-Aug-20	Negative	Negative		Yes
187	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
188	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
189	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
190	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
191	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
192	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
193	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
194	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
195	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
196	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
197	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
198	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
199	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
200	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
201	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
202	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
203	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
204	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
205	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
206	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
207	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
208	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
209	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
210	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
211	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
212	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
213	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
214	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
215	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
216	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
217	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
218	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
219	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
220	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
221	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
222	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
223	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
224	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
225	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
226	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
227	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
228	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
229	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
230	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
231	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
231	No.2	15-Aug-20 15-Aug-20	Negative	Negative	UNDET	Yes
232	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
233	No.2	15-Aug-20 15-Aug-20	Negative	Negative	UNDET	Yes
234		-	-	-	UNDET	Yes
230	No.2	15-Aug-20	Negative	Negative	UNDET	res

000		45 4	Newsters	Newstern		N/
236	No.2	15-Aug-20	Negative	Negative		Yes
237	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
238	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
239	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
240	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
241	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
242	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
243	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
244	No.2	15-Aug-20	Negative	Negative	UNDET	Yes
245	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
246	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
247	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
248	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
249	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
250	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
251	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
252	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
253	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
254	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
255	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
256	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
257	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
258	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
259	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
260	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
261	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
262	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
263	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
264	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
265	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
266	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
267	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
268	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
269	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
270	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
271	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
272	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
273	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
274	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
275	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
276	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
277	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
278	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
279	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
280	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
281	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
282	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
283	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
284	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
285	No.2	18-Aug-20	Negative	Negative	UNDET	Yes
200	110.2	10-Aug-20	negative	negative	UNDET	103

286	No.2	18-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™ SARS- CoV-2 Ag	PCR & CT	CT Value of PCR	VivaDiag™ 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

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331	No.3	15-Aug-20	Negative	Negative	UNDET	Yes
332	No.3	15-Aug-20	Negative	Negative	UNDET	Yes
333	No.3	15-Aug-20	Negative	Negative	UNDET	Yes
334	No.3	15-Aug-20	Negative	Negative	UNDET	Yes
335	No.3	15-Aug-20	Negative	Negative	UNDET	Yes
336	No.3	15-Aug-20	Negative	Negative	UNDET	Yes
337	No.3	15-Aug-20	Negative	Negative	UNDET	Yes
338	No.3	15-Aug-20	Negative	Negative	UNDET	Yes
339	No.3	15-Aug-20	Negative	Negative	UNDET	Yes
340	No.3	15-Aug-20	Negative	Negative	UNDET	Yes
341	No.3	15-Aug-20	Negative	Negative	UNDET	Yes
342	No.3	15-Aug-20	Negative	Negative	UNDET	Yes
343	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
344	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
345	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
346	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
347	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
348	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
349	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
350	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
351	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
352	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
353	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
354	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
355	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
356	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
357	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
358	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
359	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
360	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
361	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
362	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
363	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
364	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
365	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
366	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
367	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
368	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
369	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
370	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
371	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
372	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
373	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
374	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
375	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
376	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
377	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
378	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
379	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
	No.3	20-Aug-20	Negative	Negative	UNDET	Yes

381	No.3	20 Aug 20	Nogotivo	Nogotivo	UNDET	Yes
382	No.3	20-Aug-20 20-Aug-20	Negative Negative	Negative Negative	UNDET	Yes
383	No.3	20-Aug-20 20-Aug-20		Negative	UNDET	Yes
384	No.3	20-Aug-20 20-Aug-20	Negative	-	UNDET	Yes
		-	Negative	Negative		
385 386	No.3	20-Aug-20	Negative	Negative		Yes
	No.3	20-Aug-20	Negative	Negative		Yes
387	No.3	20-Aug-20	Negative	Negative		Yes
388	No.3	20-Aug-20	Negative	Negative		Yes
389	No.3	20-Aug-20	Negative	Negative		Yes
390	No.3	20-Aug-20	Negative	Negative		Yes
391	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
392	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
393	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
394	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
395	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
396	No.3	20-Aug-20	<u> </u>		UNDET	Yes
397	No.3	20-Aug-20	Negative Negative		UNDET	Yes
398	No.3	-	20-Aug-20 Negative Negative		UNDET	Yes
399	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
400	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
401	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
402	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
403	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
404	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
405	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
406	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
407	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
408	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
409	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
410	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
411	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
412	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
413	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
414	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
415	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
416	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
417	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
418	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
419	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
420	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
421	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
422	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
423	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
424	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
425	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
426	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
427	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
428	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
429	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
430	No.3	20-Aug-20	Negative	Negative	UNDET	Yes

		431	No.3	20-Aug-20	Negative	Negative	UNDET	Yes
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# 5.2 Results of positive samples

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

sample	Clinical Site	Date of testing	Days from onset of	VivaDiag <sup>™</sup> SARS-	PCR & CT	CT Value of	VivaDiag™ SARS-CoV- 2 Ag
			symptoms	CoV-2 Ag		PCR	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	Negative	Positive	<30	No
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	Negative	Positive	<30	No
19	No.1	18-Aug-20	1	Positive	Positive	<30	Yes
20	No.1	18-Aug-20	6	Positive	Positive	<30	Yes
21	No.2	20-Aug-20	2	Positive	Positive	<30	Yes
22	No.2	20-Aug-20	3	Positive	Positive	<30	Yes
23	No.2	20-Aug-20	5	Positive	Positive	<30	Yes
24	No.2	20-Aug-20	2	Positive	Positive	<30	Yes
25	No.2	20-Aug-20	2	Positive	Positive	<30	Yes
26	No.2	20-Aug-20	6	Negative	Positive	<30	No
27	No.2	20-Aug-20	2	Positive	Positive	<30	Yes
28	No.2	20-Aug-20	3	Positive	Positive	<30	Yes
29	No.2	20-Aug-20	2	Positive	Positive	<30	Yes
30	No.2	20-Aug-20	1	Positive	Positive	<30	Yes
31	No.2	20-Aug-20	2	Positive	Positive	<30	Yes
32	No.2	20-Aug-20	1	Positive	Positive	<30	Yes
33	No.2	20-Aug-20	3	Positive	Positive	<30	Yes
34	No.2	20-Aug-20	0	Positive	Positive	<30	Yes
35	No.2	20-Aug-20	2	Positive	Positive	<30	Yes
36	No.2	22-Aug-20	1	Positive	Positive	<30	Yes
37	No.2	22-Aug-20	0	Positive	Positive	<30	Yes
38	No.2	22-Aug-20	1	Positive	Positive	<30	Yes
39	No.2	22-Aug-20	1	Positive	Positive	<30	Yes
40	No.2	22-Aug-20	4	Positive	Positive	<30	Yes
41	No.2	25-Aug-20	1	Positive	Positive	<30	Yes
42	No.2	25-Aug-20	2	Positive	Positive	<30	Yes

43	No.2	25-Aug-20	3	Positive	Positive	<30	Yes
44	No.2	25-Aug-20	1	Positive	Positive	<30	Yes
45	No.2	25-Aug-20	1	Positive	Positive	<30	Yes
46	No.2	25-Aug-20	2	Positive	Positive	<30	Yes
47	No.2	25-Aug-20	1	Positive	Positive	<30	Yes
48	No.2	25-Aug-20	3	Positive	Positive	<30	Yes
49	No.2	25-Aug-20	1	Positive	Positive	<30	Yes
50	No.2	25-Aug-20	5	Negative	Positive	<30	No
51	No.2	25-Aug-20	3	Positive	Positive	<30	Yes
52	No.2	25-Aug-20	2	Positive	Positive	<30	Yes
53	No.2	25-Aug-20	5	Positive	Positive	<30	Yes
54	No.3	20-Aug-20	1	Positive	Positive	<30	Yes
55	No.3	20-Aug-20	6	Positive	Positive	<30	Yes
56	No.3	20-Aug-20	2	Positive	Positive	<30	Yes
57	No.3	20-Aug-20	3	Positive	Positive	<30	Yes
58	No.3	20-Aug-20	5	Positive	Positive	<30	Yes
59	No.3	21-Aug-20	2	Positive	Positive	<30	Yes
60	No.3	21-Aug-20	2	Positive	Positive	<30	Yes
61	No.3	21-Aug-20	6	Positive	Positive	<30	Yes
62	No.3	21-Aug-20	2	Positive	Positive	<30	Yes
63	No.3	21-Aug-20	7	Negative	Positive	<30	No
64	No.3	21-Aug-20	9	Negative	Positive	<30	No
65	No.3	21-Aug-20	1	Positive	Positive	<30	Yes
66	No.3	21-Aug-20	2	Positive	Positive	<30	Yes

Table 4 - Results of positive samples were tested with VivaDiag<sup>™</sup> SARS-CoV-2 Ag Rapid Test and SARS-CoV-2 RT-PCR and CT (Complementary Clinical Study on Oct 2020)

sample	Clinical Site	Date of testing	Days from onset of symptoms	VivaDiag™ SARS- CoV-2 Ag	PCR & CT	CT Value of PCR	VivaDiag™ SARS-CoV-2 Ag coincidence
1	No.1	26-Oct-20	1	Positive	Positive	<30	Yes
2	No.1	26-Oct-20	1	Positive	Positive	<30	Yes
3	No.1	26-Oct-20	4	Positive	Positive	<30	Yes
4	No.1	26-Oct-20	1	Positive	Positive	<30	Yes
5	No.1	26-Oct-20	2	Positive	Positive	<30	Yes
6	No.1	26-Oct-20	2	Positive	Positive	<30	Yes
7	No.1	26-Oct-20	1	Positive	Positive	<30	Yes
8	No.1	28-Oct-20	2	Positive	Positive	<30	Yes
9	No.1	28-Oct-20	3	Positive	Positive	<30	Yes
10	No.1	28-Oct-20	5	Positive	Positive	<30	Yes
11	No.1	28-Oct-20	2	Positive	Positive	<30	Yes
12	No.1	28-Oct-20	2	Positive	Positive	<30	Yes
13	No.1	28-Oct-20	1	Positive	Positive	<30	Yes
14	No.1	30-Oct-20	2	Positive	Positive	<30	Yes
15	No.1	30-Oct-20	1	Positive	Positive	<30	Yes
16	No.1	30-Oct-20	3	Positive	Positive	<30	Yes
17	No.1	30-Oct-20	1	Positive	Positive	<30	Yes
18	No.1	30-Oct-20	4	Positive	Positive	<30	Yes

19	No.1	30-Oct-20	1	Positive	Positive	<30	Yes
20	No.2	27-Oct-20	4	Positive	Positive	<30	Yes
21	No.2	27-Oct-20	1	Positive	Positive	<30	Yes
22	No.2	27-Oct-20	2	Positive	Positive	<30	Yes
23	No.2	27-Oct-20	3	Positive	Positive	<30	Yes
24	No.2	27-Oct-20	5	Positive	Positive	<30	Yes
25	No.2	27-Oct-20	2	Positive	Positive	<30	Yes
26	No.2	27-Oct-20	2	Positive	Positive	<30	Yes
27	No.2	27-Oct-20	4	Positive	Positive	<30	Yes
28	No.2	27-Oct-20	2	Positive	Positive	<30	Yes
29	No.2	27-Oct-20	3	Positive	Positive	<30	Yes
30	No.2	29-Oct-20	2	Positive	Positive	<30	Yes
31	No.2	29-Oct-20	1	Positive	Positive	<30	Yes
32	No.2	29-Oct-20	2	Positive	Positive	<30	Yes
33	No.2	29-Oct-20	2	Positive	Positive	<30	Yes
34	No.2	29-Oct-20	3	Positive	Positive	<30	Yes
35	No.2	29-Oct-20	2	Positive	Positive	<30	Yes
36	No.2	29-Oct-20	1	Positive	Positive	<30	Yes
37	No.2	29-Oct-20	2	Positive	Positive	<30	Yes
38	No.3	26-Oct-20	5	Positive	Positive	<30	Yes
39	No.3	26-Oct-20	2	Positive	Positive	<30	Yes
40	No.3	26-Oct-20	2	Positive	Positive	<30	Yes
41	No.3	26-Oct-20	4	Positive	Positive	<30	Yes
42	No.3	26-Oct-20	2	Positive	Positive	<30	Yes
43	No.3	26-Oct-20	3	Positive	Positive	<30	Yes
44	No.3	26-Oct-20	2	Positive	Positive	<30	Yes
45	No.3	26-Oct-20	1	Positive	Positive	<30	Yes
46	No.3	26-Oct-20	2	Positive	Positive	<30	Yes
47	No.3	25-Aug-20	2	Positive	Positive	<30	Yes
48	No.3	25-Aug-20	3	Positive	Positive	<30	Yes
49	No.3	28-Oct-20	2	Positive	Positive	<30	Yes
50	No.3	28-Oct-20	1	Positive	Positive	<30	Yes
51	No.3	28-Oct-20	2	Positive	Positive	<30	Yes
52	No.3	28-Oct-20	1	Positive	Positive	<30	Yes
53	No.3	28-Oct-20	4	Positive	Positive	<30	Yes
54	No.3	28-Oct-20	2	Positive	Positive	<30	Yes
55	No.3	28-Oct-20	3	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.