DEWEI MEDICAL EQUIPMENT CO.,LTD

Covid-19 (2019-nCoV) Antigen Rapid Test Cassette

Performance Evaluation Report

DEWEI MEDICAL started to research and develop Covid-19 (2019-nCoV) Antigen Rapid Test Cassette from 2020, and finished 3 batches of trial products in Jul, 2020. According to the guidelines of 《2019 review of new coronavirus antigen / antibody detected tests technology》 and EN13612：2002, we evaluated the product performance and made the following summary:

1. Intended use

The product is used for the qualitative detection of SARS-COV-2 infection. The entire detection process takes only 15-20 minutes, and the operation is simple and sensitive. No instrument required. It can be used for the screening of early infected patients and asymptomatic patients. This method is an effective supplement for nucleic acid detection.

2. Diagnostic principles

The detection of SARS-COV-2 adopts the principle of double antibody sandwich method and colloidal gold immunochromatography to qualitatively detect SARS-COV-2 antigen in human Nasal swabs, pharyngeal swabs, sputum, bronchoalveolar lavage fluid, etc., with two highly specific and highly sensitive SARS-COV-2 N antigen monoclonal antibodies, wherein monoclonal antibody I is a capture antibody, fixed in the detection area on the NC membrane, monoclonal antibody II is a colloidal gold-labeled antibody, sprayed on the binding pad, and the NC membrane quality control area C is coated with goat anti-mouse IgG antibody and goat anti-rabbit IgG antibody . The double antibody sandwich method is used in the detection area, and the antigen-antibody reaction is used in the quality control area, combined with colloidal gold immunochromatography technology to detect the SARS-COV-2 in the human body. During detection, the sample is chromatographed under the capillary effect. If the tested sample contains SARS-COV-2, the gold-labeled SARS-COV-2 N antigen monoclonal antibody I combines with SARS-COV-2 to form a complex, and combines with the a SARS-COV-2 N antigen monoclonal antibody II fixed at the detection line during the chromatography process, which will form the "Au-antibody I-N antigen- antibody II" sandwich, so that a purple band appears in the detection area (T); Otherwise, no magenta bands appear in the detection area (T). Regardless of whether there is a SARS-COV-2 antigen in the sample, the complex will continue to be chromatographed up to the control area (C), and a purple band appears when reacting with the goat anti-mouse IgG antibody and goat anti-rabbit IgG antibody.

The purple-red band presented in the control area (C) is a standard for judging whether the chromatographic process is normal, and also serves as an internal control standard for reagents.

3. Performance Criteria

3.1. Manufacturer inner reference panel

3.1.1 Positive control, 3 positive specimens,P1-P3.

3.1.2 Negative control : 5 negative specimens , N1-N5.

3.2. Quality standard of finished products.

3.2.1 Physical character

A. Appearance: the strip is smooth and integrated, without burr, not broken, not polluted.

B. Migration speed: ≥10mm/min

3.2.2 Positive Conformity

The results are positive for 3 positive control.

3.2.3 Specificity:

The results are negative for 5 negative control.

3.2.4 Repeatability: Take 10 test samples from the same lot. Test them with the positive control. All the tests show the same results

4. Evaluated Product and Comparison Method

4.1 Evaluated Reagent

Reagent Name: Covid-19 (2019-nCoV) Antigen Rapid Test Cassette

(Lot No.：20200701,20200702,20200703)

Manufacturer: Dewei Medical Equipment Co.,Ltd

Storage: 2-30℃, sealed and stored in dry conditions

4.2 Comparison Method: RT-PCR method

Analyzer: RT-PCR analyzer

Reagent: Detection Kit for 2019-nCoV (PCR-Fluorescence)

Manufacturer: Da An Gene Co., Ltd. of Sun Yat-sen University

5. Performance evaluation data

5.1. Precision.

The material we used for precision studies were 3 positive control and 5 negative control ,which were confirmed with PCR. The controls were blind coded.Separate sets of the blind coded were assigned. Samples were also randomized prior to testing.The study was conducted 3 runs /day and lasted 10 days. 3 lots Covid-19 (2019-nCoV) Antigen Rapid Test Cassette were tested. The result was recorded as the following:

Table 1:The results of precision

Control No.	20200701		20200702		20200703	
	Positive	Negative	Positive	Negative	Positive	Negative
P1	30	0	30	0	30	0
P2	30	0	30	0	30	0
P3	30	0	30	0	30	0
N1	0	30	0	30	0	30
N2	0	30	0	30	0	30
N3	0	30	0	30	0	30
N4	0	30	0	30	0	30
N5	0	30	0	30	0	30

According to the result, the test cassette show concordant results.

5.2 Specificity study

5.2.1 Cross reactivity:

Collected specimens wit H1N1、H3N2、H5N1、H7N9，Influenza B，MERS-coronavirus, Human coronavirus (NL63), Human coronavirus (229E), Human coronavirus (OC43), Respiratory syncytial virus，Adenovirus，Enterovirus，EB *virus*, measles virus, human cytomegalovirus, Rotavirus, norovirus, Rubulavirus, varicella-zoster virus, mycoplasma pneumoniae. Each sample was tested in 3 replicates with 3 lots of the test cassette. Result was recorded as the following:

Table 2: The results of Cross reactivity

Interfering substances	20200701	20200702	20200703
H1N1	3/3 -	3/3 -	3/3 -
H3N2	3/3 -	3/3 -	3/3 -
H5N1	3/3 -	3/3 -	3/3 -
H7N9	3/3 -	3/3 -	3/3 -
Influenza B	3/3 -	3/3 -	3/3 -
MERS-coronavirus	3/3 -	3/3 -	3/3 -
Human coronavirus (NL63)	3/3 -	3/3 -	3/3 -
Human coronavirus (229E)	3/3 -	3/3 -	3/3 -
Human coronavirus (OC43)	3/3 -	3/3 -	3/3 -
Respiratory syncytial virus	3/3 -	3/3 -	3/3 -
Adenovirus	3/3 -	3/3 -	3/3 -
Enterovirus	3/3 -	3/3 -	3/3 -
Epstein-Barr virus	3/3 -	3/3 -	3/3 -
Measles virus	3/3 -	3/3 -	3/3 -
Human cytomegalovirus	3/3 -	3/3 -	3/3 -
Rotavirus	3/3 -	3/3 -	3/3 -
Norovirus	3/3 -	3/3 -	3/3 -
Rubulavirus	3/3 -	3/3 -	3/3 -
Varicella-zoster virus	3/3 -	3/3 -	3/3 -
Mycoplasma pneumoniae	3/3 -	3/3 -	3/3 -

5.2.2 Endogenous substances

Clinical samples may contain substances that could potentially interfere with the test. The following compounds were added to positive control and negative control. All potential interfering substances were added at a concentration of 2%. Each sample was tested in 3 replicates with 3 lots of the test cassette. Result was recorded as the following:

Table 3: The results of Endogenous Interfering substances

Endogenous substances	20200701	20200702	20200703
Mucin	3/3 -	3/3 -	3/3 -
Whole Blood	3/3 -	3/3 -	3/3 -

The above data show that the compounds had no interference on the test result.

5.2.3 Interfering substances

Clinical samples may contain substances that could potentially interfere with the test. The following compounds were added to positive control and negative control. All potential interfering substances were added at a concentration of 1000μg/mL. Each sample was tested in 3 replicates with 3 lots of the test cassette. Result was recorded as the following:

Table 4: The results of Interfering substances

LOT	20200701		20200702		20200703	
Interfering substances	positive control	negative control	positive control	negative control	positive control	negative control
Phenylephrine	3/3 +	3/3 -	3/3 +	3/3 -	3/3 +	3/3 -
Nasal Gel Sodium Chloride	3/3 +	3/3 -	3/3 +	3/3 -	3/3 +	3/3 -
Cromolyn	3/3 +	3/3 -	3/3 +	3/3 -	3/3 +	3/3 -
Oxymetazoline	3/3 +	3/3 -	3/3 +	3/3 -	3/3 +	3/3 -
Fluconazole	3/3 +	3/3 -	3/3 +	3/3 -	3/3 +	3/3 -
Throat Lozenge Benzocaine	3/3 +	3/3 -	3/3 +	3/3 -	3/3 +	3/3 -
Sabadilla	3/3 +	3/3 -	3/3 +	3/3 -	3/3 +	3/3 -
Zincum gluconium	3/3 +	3/3 -	3/3 +	3/3 -	3/3 +	3/3 -
Alkalol	3/3 +	3/3 -	3/3 +	3/3 -	3/3 +	3/3 -
Fluticasone Propionate	3/3 +	3/3 -	3/3 +	3/3 -	3/3 +	3/3 -
Phenol	3/3 +	3/3 -	3/3 +	3/3 -	3/3 +	3/3 -
Tamiflu	3/3 +	3/3 -	3/3 +	3/3 -	3/3 +	3/3 -
Nasal Ointment Mupirocin	3/3 +	3/3 -	3/3 +	3/3 -	3/3 +	3/3 -
Systemic Tobramycin	3/3 +	3/3 -	3/3 +	3/3 -	3/3 +	3/3 -

The above data show that the compounds had no interference on the test result.

5.3. Comparison with the reference method PCR:

218 clinical samples, include nasopharyngeal and oropharyngeal swab, collected from several hospitals. All samples were unaltered clinical specimens and confirmed with PCR. Each samples were blindly labeled by a nonparticipant. Separate sets of the blind coded were assigned. Samples were also randomized prior to testing. Result was recorded as the following:

Table 5: The results of method comparison

Cassette	Comparison Method		
	Positive	Negative	Total
Positive	99	3	102
Negative	3	113	116
Total	102	116	218

Sensitivity (PPA) = 99/102x100%=97.06% (95% CI: 93.78% - 99.99%)

Specificity (NPA) = 113/116×100％＝97.41％(95% CI: 94.52% - 99.99%)

Accuracy (OPA) =（99+113）/（102+116）×100％＝97.25% (95% CI: 96.14% - 98.36%)

5.4 Limit of Detection (LoD)

Limit of detection (LOD) was determined by evaluating different concentrations of heat inactivated 2019-Novel Coronavirus, include the following concentrations:1:100, 1:200, 1:400, 1:800, 1:1600, 1:3200, 1:6400, 1:12800, 1:25600. Concentrations Contrived nasal swab samples were prepared by absorbing 20 microliters of each virus dilution onto the swab. The contrived swab samples were tested with 3 lots of products, with each concentration repeated 20 times.More than 19 should be positive at a concentration of 1:6400.Result was recorded as the following:

Table 6: The results of Limit of Detection

concentration	20200701	20200702	20200703
1:100	20/20 +	20/20 +	20/20 +
1:200	20/20 +	20/20 +	20/20 +
1:400	20/20 +	20/20 +	20/20 +
1:800	20/20 +	20/20 +	20/20 +
1:1600	20/20 +	20/20 +	20/20 +
1:3200	20/20 +	20/20 +	20/20 +
1:6400	20/20 +	20/20 +	20/20 +
1:12800	19/20 +	18/20 +	19/20 +
1:25600	10/20 +	9/20 +	11/20 +

The above data show that 20 were positive at a concentration of 1:6400.

5.5 Analytical Sensitivity & Specificity

According to the data of the clause 5.3, Sensitivity of Covid-19 (2019-nCoV) Antigen Rapid Test Cassette is 97.06%.

According to the data of the clause 5.3, Specificity of Covid-19 (2019-nCoV) Antigen Rapid Test Cassette is 97.41%.

5.6 Detection Rate of Positive Samples

Detection rate of positive samples with different onset days

Onset days	Number of Samples	Detection Rate
1-3 days	59	57/59, 96.61%
4-7 days	43	41/43, 95.35%

Detection rate of 1-3 days = 57/59×100% = 96.61% (95% CI: 91.99% - 99.99%)

Detection rate of 4-7 days = 41/43×100% = 95.35% (95% CI: 89.05% - 99.99%)

5.7 HOOK effect study

Free specimens spiked with the heat inactivated 2019-Novel Coronavirus at different concentration containing 1.0 x 10^3 TCID, 1.0 x 10^4 TCID, 1.0 x 10^5 TCID, 1.0 x 10^6 TCID. Three lots of tests were tested. The result was recorded as the following:

Table 7: Results of HOOK effect

Lot	20200701		20200702		20200703	
Concentration	Positive	Negative	Positive	Negative	Positive	Negative
1.0 x 10^3 TCID	3	0	3	0	3	0
1.0 x 10^4 TCID	3	0	3	0	3	0
1.0 x 10^5 TCID	3	0	3	0	3	0
1.0 x 10^6 TCID	3	0	3	0	3	0

The results show that the test cassette had no HOOK effect on the concentration of 1.0 x 10^6 TCID.

6. Conclusion

Through the performance evaluation test, the stability of product production process and product quality can be effectively controlled, and as an important basis for the formulation of product standards, the performance indicators of Covid-19 (2019-nCoV) Antigen Rapid Test Cassette have reached the expected requirements.

7. Appendix of Sample Result List

No.	Pat. No.	Gender	Age	Sample Type	Clinical Diagnosis Background	Evaluated Reagent Results	Nucleic Acid Results	Nucleic Acid Testing Value	Disease Onset Time
1	D2001	M	42	Nasopharyngeal Swab	COVID-19	+	+	25.1	5 days
2	D2002	M	65	Nasopharyngeal Swab	COVID-19	+	+	28.9	1 day
3	D2003	F	20	Nasopharyngeal Swab	COVID-19	+	+	21.4	3 days
4	D2004	F	38	Nasopharyngeal Swab	COVID-19	+	+	21.0	1 day
5	D2005	F	72	Nasopharyngeal Swab	COVID-19	+	+	22.1	3 days
6	D2006	M	66	Nasopharyngeal Swab	COVID-19	+	+	24.3	2 days
7	D2007	F	37	Nasopharyngeal Swab	COVID-19	+	+	23.3	2 days
8	**D2008**	**M**	**38**	**Nasopharyngeal Swab**	**COVID-19**	**-**	**+**	**27.1**	**4 days**
9	D2009	M	20	Nasopharyngeal Swab	COVID-19	+	+	22.6	2 days
10	D2010	F	26	Nasopharyngeal Swab	COVID-19	+	+	27.8	7 days
11	D2011	F	53	Nasopharyngeal Swab	COVID-19	+	+	23.0	1 day
12	D2012	F	86	Nasopharyngeal Swab	COVID-19	+	+	21.2	3 days
13	D2013	M	56	Nasopharyngeal Swab	COVID-19	+	+	22.2	4 days
14	D2014	F	58	Nasopharyngeal Swab	COVID-19	+	+	24.1	2 days
15	D2015	M	10	Nasopharyngeal Swab	COVID-19	+	+	23.1	3 days
16	D2016	M	34	Nasopharyngeal Swab	COVID-19	+	+	28.2	1 day
17	D2017	F	39	Nasopharyngeal Swab	COVID-19	+	+	27.4	2 days
18	D2018	F	47	Nasopharyngeal Swab	COVID-19	+	+	22.3	2 days
19	D2019	F	61	Nasopharyngeal Swab	COVID-19	+	+	27.3	6 days
20	D2020	M	30	Nasopharyngeal Swab	COVID-19	+	+	25.5	4 days
21	D2021	F	15	Nasopharyngeal Swab	COVID-19	+	+	23.6	1 day
22	D2022	F	47	Nasopharyngeal Swab	COVID-19	+	+	25.1	2 days
23	D2023	F	29	Nasopharyngeal Swab	COVID-19	+	+	26.2	2 days
24	D2024	F	49	Nasopharyngeal Swab	COVID-19	+	+	27.1	2 days
25	D2025	F	43	Nasopharyngeal Swab	COVID-19	+	+	31.2	4 days
26	D2026	M	58	Nasopharyngeal Swab	COVID-19	+	+	28.5	6 days

27	D2027	F	18	Nasopharyngeal Swab	COVID-19	+	+	24.1	2 days
28	D2028	F	13	Nasopharyngeal Swab	COVID-19	+	+	25.2	2 days
29	D2029	F	50	Nasopharyngeal Swab	COVID-19	+	+	22.5	2 days
30	D2030	F	55	Nasopharyngeal Swab	COVID-19	+	+	24.4	1 day
31	**D2031**	**M**	**48**	**Nasopharyngeal Swab**	**COVID-19**	**-**	**+**	**26.6**	**3 days**
32	D2032	F	74	Nasopharyngeal Swab	COVID-19	+	+	26.3	4 days
33	D2033	F	36	Nasopharyngeal Swab	COVID-19	+	+	28.1	2 days
34	D2034	M	25	Nasopharyngeal Swab	COVID-19	+	+	29.2	4 days
35	D2035	F	34	Nasopharyngeal Swab	COVID-19	+	+	28.9	1 days
36	D2036	M	19	Nasopharyngeal Swab	COVID-19	+	+	26.7	2 days
37	D2037	F	28	Nasopharyngeal Swab	COVID-19	+	+	32.8	4 days
38	D2038	M	45	Nasopharyngeal Swab	COVID-19	+	+	34.1	3 days
39	D2039	F	34	Nasopharyngeal Swab	COVID-19	+	+	26.7	2 days
40	D2040	M	55	Nasopharyngeal Swab	COVID-19	+	+	32.8	5 days
41	D2041	M	32	Nasopharyngeal Swab	COVID-19	+	+	34.1	3 days
42	D2042	F	22	Nasopharyngeal Swab	COVID-19	+	+	26.7	5 days
43	D2043	F	28	Nasopharyngeal Swab	COVID-19	+	+	31.2	3 days
44	D2044	F	35	Nasopharyngeal Swab	COVID-19	+	+	29.3	4 days
45	D2045	M	56	Nasopharyngeal Swab	COVID-19	+	+	25.3	1 days
46	D2046	M	61	Nasopharyngeal Swab	COVID-19	+	+	25.2	5 days
47	D2047	F	23	Nasopharyngeal Swab	COVID-19	+	+	24.8	2 days
48	D2048	F	21	Nasopharyngeal Swab	COVID-19	+	+	29.4	1 day
49	D2049	F	34	Nasopharyngeal Swab	COVID-19	+	+	27.4	2 days
50	D2050	M	27	Nasopharyngeal Swab	COVID-19	+	+	31.2	3 days
51	D2051	M	26	Nasopharyngeal Swab	COVID-19	+	+	25.6	3 days
52	D2052	F	56	Nasopharyngeal Swab	COVID-19	+	+	26.5	2 days
53	D2053	F	32	Nasopharyngeal Swab	COVID-19	+	+	26.8	5 days
54	D2054	F	27	Nasopharyngeal Swab	COVID-19	+	+	23.6	3 days

55	D2055	M	43	Nasopharyngeal Swab	COVID-19	+	+	25.2	1 days
56	D2056	M	36	Nasopharyngeal Swab	COVID-19	+	+	26.8	2 days
57	D2057	F	43	Nasopharyngeal Swab	COVID-19	+	+	23.6	5 days
58	D2058	F	34	Nasopharyngeal Swab	COVID-19	+	+	25.1	6 days
59	D2059	M	56	Nasopharyngeal Swab	COVID-19	+	+	26.8	4 days
60	D2060	M	54	Nasopharyngeal Swab	COVID-19	+	+	20.7	2 days
61	D2061	M	47	Nasopharyngeal Swab	COVID-19	+	+	26.1	3 days
62	D2062	F	46	Nasopharyngeal Swab	COVID-19	+	+	20.2	5 days
63	D2063	M	22	Nasopharyngeal Swab	COVID-19	+	+	27.1	6 days
64	D2064	F	32	Nasopharyngeal Swab	COVID-19	+	+	22.8	2 days
65	D2065	M	48	Nasopharyngeal Swab	COVID-19	+	+	27.4	3 days
66	D2066	F	43	Nasopharyngeal Swab	COVID-19	+	+	29.7	1 days
67	D2067	F	19	Nasopharyngeal Swab	COVID-19	+	+	30.5	1 days
68	D2068	F	22	Nasopharyngeal Swab	COVID-19	+	+	30.2	2 days
69	D2069	M	76	Nasopharyngeal Swab	COVID-19	+	+	20.1	5days
70	D2070	M	75	Nasopharyngeal Swab	COVID-19	+	+	27.7	4days
71	D2071	F	82	Nasopharyngeal Swab	COVID-19	+	+	22.7	4days
72	D2072	F	66	Nasopharyngeal Swab	COVID-19	+	+	18.2	3days
73	D2073	M	56	Nasopharyngeal Swab	COVID-19	+	+	27.2	7days
74	D2074	F	59	Nasopharyngeal Swab	COVID-19	+	+	20.2	2days
75	D2075	F	68	Nasopharyngeal Swab	COVID-19	+	+	18.5	1day
76	D2076	F	62	Nasopharyngeal Swab	COVID-19	+	+	24.2	4days
77	D2077	M	83	Nasopharyngeal Swab	COVID-19	+	+	24.0	5days
78	D2078	M	52	Nasopharyngeal Swab	COVID-19	+	+	16.0	3days
79	**D2079**	**M**	**73**	**Nasopharyngeal Swab**	**COVID-19**	**-**	**+**	**25.1**	**3days**
80	D2080	F	24	Nasopharyngeal Swab	COVID-19	+	+	17.8	3days
81	D2081	F	59	Nasopharyngeal Swab	COVID-19	+	+	29.5	7days
82	D2082	F	66	Nasopharyngeal Swab	COVID-19	+	+	33.9	5days

83	D2083	F	36	Nasopharyngeal Swab	COVID-19	+	+	26.9	4days
84	D2084	F	24	Nasopharyngeal Swab	COVID-19	+	+	33.1	3days
85	D2085	F	27	Nasopharyngeal Swab	COVID-19	+	+	17.9	6days
86	D2086	M	27	Nasopharyngeal Swab	COVID-19	+	+	20.2	2days
87	D2087	M	23	Nasopharyngeal Swab	COVID-19	+	+	20.4	4days
88	D2088	F	64	Nasopharyngeal Swab	COVID-19	+	+	16.6	3days
89	D2089	M	67	Nasopharyngeal Swab	COVID-19	+	+	21.7	6days
90	D2090	F	32	Nasopharyngeal Swab	COVID-19	+	+	22.8	1day
91	D2091	M	79	Nasopharyngeal Swab	COVID-19	+	+	27.4	5days
92	D2092	F	59	Nasopharyngeal Swab	COVID-19	+	+	22.1	4days
93	D2093	M	64	Nasopharyngeal Swab	COVID-19	+	+	24.4	5days
94	D2094	F	62	Nasopharyngeal Swab	COVID-19	+	+	25.6	7days
95	D2095	F	63	Nasopharyngeal Swab	COVID-19	+	+	24.8	5days
96	D2096	F	55	Nasopharyngeal Swab	COVID-19	+	+	24.2	2days
97	D2097	F	58	Nasopharyngeal Swab	COVID-19	+	+	27.8	4days
98	D2098	M	57	Nasopharyngeal Swab	COVID-19	+	+	16.2	7days
99	D2099	F	57	Nasopharyngeal Swab	COVID-19	+	+	31.3	3days
100	D2100	F	60	Nasopharyngeal Swab	COVID-19	+	+	30.1	4days
101	D2101	F	30	Nasopharyngeal Swab	COVID-19	+	+	34.2	6days
102	D2102	F	66	Nasopharyngeal Swab	COVID-19	+	+	31.3	5days
103	D2103	M	70	Nasopharyngeal Swab	Lung Shadow	-	-	> 40	/
104	D2104	M	39	Nasopharyngeal Swab	AIDS	-	-	> 40	/
105	D2105	M	51	Nasopharyngeal Swab	HIV, Cervical Cancer	-	-	> 40	/
106	D2106	F	38	Nasopharyngeal Swab	Lung Shadow	-	-	> 40	/
107	D2107	M	65	Nasopharyngeal Swab	Tuberculosis	-	-	> 40	/
108	D2108	M	44	Nasopharyngeal Swab	Tuberculous Meningitis	-	-	> 40	/
109	D2109	M	22	Nasopharyngeal Swab	Cough to be tested	-	-	> 40	/
110	D2110	M	34	Nasopharyngeal Swab	Tuberculosis	-	-	> 40	/

111	D2111	M	25	Nasopharyngeal Swab	Lung Shadow	-	-	> 40	/
112	D2112	M	25	Nasopharyngeal Swab	Tuberculosis re-treatment	-	-	> 40	/
113	**D2113**	**M**	**56**	**Nasopharyngeal Swab**	**Tuberculosis, Culture-positive**	+	**-**	**> 40**	**/**
114	D2118	F	31	Nasopharyngeal Swab	Fever to be tested	-	-	> 40	/
115	D2119	F	13	Nasopharyngeal Swab	Fever to be tested	-	-	> 40	/
116	D2120	M	54	Nasopharyngeal Swab	Fever to be tested	-	-	> 40	/
117	D2121	M	74	Nasopharyngeal Swab	Fever to be tested, Obsolete Tuberculosis	-	-	> 40	/
118	D2122	M	75	Nasopharyngeal Swab	Fever to be tested,	-	-	> 40	/
119	**D2123**	**F**	**37**	**Nasopharyngeal Swab**	**Fever to be tested**	+	**-**	**> 40**	**/**
120	D2124	F	20	Nasopharyngeal Swab	Fever to be tested	-	-	> 40	/
121	D2125	F	69	Nasopharyngeal Swab	Fever to be tested	-	-	> 40	/
122	D2126	F	30	Nasopharyngeal Swab	Fever to be tested	-	-	> 40	/
123	D2127	M	26	Nasopharyngeal Swab	Fever to be tested	-	-	> 40	/
124	D2128	F	38	Nasopharyngeal Swab	Fever to be tested	-	-	> 40	/
125	D2129	M	9	Nasopharyngeal Swab	URTI?	-	-	> 40	/
126	D2130	F	49	Nasopharyngeal Swab	COPD with acute exacerbation	-	-	> 40	/
127	D2131	M	30	Nasopharyngeal Swab	Skin ulcer of both legs to be tested	-	-	> 40	/
128	D2132	M	37	Nasopharyngeal Swab	URTI?	-	-	> 40	/
129	D2133	F	81	Nasopharyngeal Swab	Trochanteric fracture of left femur	-	-	> 40	/
130	D2134	M	72	Nasopharyngeal Swab	COPD with acute exacerbation	-	-	> 40	/
131	D2135	F	82	Nasopharyngeal Swab	Fever to be tested	-	-	> 40	/
132	D2136	F	89	Nasopharyngeal Swab	Fever to be tested	-	-	> 40	/
133	D2137	M	56	Nasopharyngeal Swab	/	-	-	> 40	/
134	D2138	M	38	Nasopharyngeal Swab	Fever to be tested	-	-	> 40	/
135	D2139	M	66	Nasopharyngeal Swab	COPD with acute exacerbation	-	-	> 40	/
136	**D2140**	**M**	**60**	**Nasopharyngeal Swab**	**Skin ulcer of both legs to be tested**	+	**-**	**> 40**	**/**
137	D2141	F	82	Nasopharyngeal Swab	Fell and hurt	-	-	> 40	/
138	D2142	F	39	Nasopharyngeal Swab	Early Pregnancy Miscarriage	-	-	> 40	/

139	D2143	F	48	Nasopharyngeal Swab	AIDS	-	-	> 40	/
140	D2144	M	64	Nasopharyngeal Swab	Tuberculosis	-	-	> 40	/
141	D2145	M	38	Nasopharyngeal Swab	Lung Shadow	-	-	> 40	/
142	D2146	M	33	Nasopharyngeal Swab	Lung Shadow	-	-	> 40	/
143	D2147	M	80	Nasopharyngeal Swab	Tuberculosis	-	-	> 40	/
144	D2148	M	73	Nasopharyngeal Swab	Tuberculosis	-	-	> 40	/
145	D2149	M	25	Nasopharyngeal Swab	AIDS	-	-	> 40	/
146	D2150	F	54	Nasopharyngeal Swab	AIDS	-	-	> 40	/
147	D2151	M	77	Nasopharyngeal Swab	Tuberculosis	-	-	> 40	/
148	D2152	M	60	Nasopharyngeal Swab	AIDS	-	-	> 40	/
149	D2153	M	25	Nasopharyngeal Swab	AIDS	-	-	> 40	/
150	D2154	F	14	Nasopharyngeal Swab	Cervical and abdominal lymph node TB	-	-	> 40	/
151	D2155	M	78	Nasopharyngeal Swab	Lung Shadow	-	-	> 40	/
152	D2156	M	84	Nasopharyngeal Swab	Tuberculosis, post-operative multiple-drug resistance	-	-	> 40	/
153	D2157	M	57	Nasopharyngeal Swab	Lung Shadow	-	-	> 40	/
154	D2158	M	65	Nasopharyngeal Swab	Chronic HBV	-	-	> 40	/
155	D2159	M	44	Nasopharyngeal Swab	Tuberculosis, Drug-induced liver damage	-	-	> 40	/
156	D2160	M	37	Nasopharyngeal Swab	Fever to be tested	-	-	> 40	/
157	D2161	F	28	Nasopharyngeal Swab	Fever to be tested	-	-	> 40	/
158	D2162	M	21	Nasopharyngeal Swab	Fever to be tested	-	-	> 40	/
159	D2163	M	40	Nasopharyngeal Swab	Fever to be tested	-	-	> 40	/
160	D2164	M	75	Nasopharyngeal Swab	Fever to be tested	-	-	> 40	/
161	D2165	M	35	Nasopharyngeal Swab	Abdominal distention to be tested	-	-	> 40	/
162	D2166	F	52	Nasopharyngeal Swab	Liver Cirrhosis	-	-	> 40	/
163	D2167	M	49	Nasopharyngeal Swab	HBV	-	-	> 40	/
164	D2168	M	51	Nasopharyngeal Swab	Upper Gastrointestinal Bleeding	-	-	> 40	/
165	D2169	F	63	Nasopharyngeal Swab	Paravertebral Abscess	-	-	> 40	/

166	D2170	M	63	Nasopharyngeal Swab	AIDS, Lung Infection, Headache to be tested	-	-	> 40	/
167	D2171	M	23	Nasopharyngeal Swab	Lung Shadow,	-	-	> 40	/
168	D2172	M	25	Nasopharyngeal Swab	Cough to be tested	-	-	> 40	/
169	D2173	F	30	Nasopharyngeal Swab	Lung Shadow	-	-	> 40	/
170	D2174	M	66	Nasopharyngeal Swab	Tuberculosis	-	-	> 40	/
171	D2175	F	26	Nasopharyngeal Swab	Tuberculosis	-	-	> 40	/
172	D2176	M	55	Nasopharyngeal Swab	Tuberculosis	-	-	> 40	/
173	D2177	M	35	Nasopharyngeal Swab	AIDS, fever to be tested	-	-	> 40	/
174	D2178	F	23	Nasopharyngeal Swab	Fever	-	-	> 40	/
175	D2179	M	50	Nasopharyngeal Swab	Fever to be tested	-	-	> 40	/
176	D2180	M	39	Nasopharyngeal Swab	Fever to be tested	-	-	> 40	/
177	D2181	M	40	Nasopharyngeal Swab	Fever to be tested	-	-	> 40	/
178	D2182	M	81	Nasopharyngeal Swab	Fever to be tested	-	-	> 40	/
179	D2183	M	64	Nasopharyngeal Swab	Fever to be tested	-	-	> 40	/
180	D2184	M	29	Nasopharyngeal Swab	Fever to be tested	-	-	> 40	/
181	D2185	M	10	Nasopharyngeal Swab	Fever to be tested	-	-	> 40	/
182	D2186	M	36	Nasopharyngeal Swab	Pleural Effusion	-	-	> 40	/
183	D2187	M	23	Nasopharyngeal Swab	Fever to be tested	-	-	> 40	/
184	D2188	F	34	Nasopharyngeal Swab	Fever to be tested	-	-	> 40	/
185	D2189	F	31	Nasopharyngeal Swab	Pharyngitis	-	-	> 40	/
186	D2190	M	57	Nasopharyngeal Swab	Fever to be tested	-	-	> 40	/
187	D2191	M	69	Nasopharyngeal Swab	Lung Infection?	-	-	> 40	/
188	D2192	M	21	Nasopharyngeal Swab	Acute Tonsillitis	-	-	> 40	/
189	D2193	F	39	Nasopharyngeal Swab	URTI?	-	-	> 40	/
190	D2194	F	16	Nasopharyngeal Swab	Pharyngitis	-	-	> 40	/
191	D2195	F	38	Nasopharyngeal Swab	Pharyngitis	-	-	> 40	/
192	D2196	M	31	Nasopharyngeal Swab	Lung Infection, Fever	-	-	> 40	/
193	D2197	M	80	Nasopharyngeal Swab	Asthma to be tested	-	-	> 40	/

194	D2198	M	73	Nasopharyngeal Swab	Community Acquired Pneumonia	-	-	> 40	/
195	D2199	F	47	Nasopharyngeal Swab	Chest tightness to be tested	-	-	> 40	/
196	D2200	M	61	Nasopharyngeal Swab	HIV, Primary Liver Cancer	-	-	> 40	/
197	D2205	F	54	Nasopharyngeal Swab	Lung Infection, Fever	-	-	> 40	/
198	D2206	M	59	Nasopharyngeal Swab	Rhinitis	-	-	> 40	/
199	D2207	M	88	Nasopharyngeal Swab	Rhinitis	-	-	> 40	/
200	D2208	F	53	Nasopharyngeal Swab	Bronchial Asthma	-	-	> 40	/
201	D2209	M	64	Nasopharyngeal Swab	HBV, Lung Infection	-	-	> 40	/
202	D2210	M	82	Nasopharyngeal Swab	Community Acquired Pneumonia	-	-	> 40	/
203	D2211	M	65	Nasopharyngeal Swab	Foreign body in bronchus?	-	-	> 40	/
204	D2212	M	83	Nasopharyngeal Swab	Community Acquired Pneumonia, non-severe	-	-	> 40	/
205	D2213	M	46	Nasopharyngeal Swab	Chronic HBV, fever	-	-	> 40	/
206	D2214	M	51	Nasopharyngeal Swab	Cough to be tested	-	-	> 40	/
207	D2215	F	77	Nasopharyngeal Swab	Renal Pelvis Tumor, Acute Gastroenteritis	-	-	> 40	/
208	D2216	F	30	Nasopharyngeal Swab	Ectopic Pregnancy	-	-	> 40	/
209	D2217	F	62	Nasopharyngeal Swab	HIV, Cervical Cancer	-	-	> 40	/
210	D2218	M	72	Nasopharyngeal Swab	Community Acquired Pneumonia	-	-	> 40	/
211	D2219	F	82	Nasopharyngeal Swab	COPD with acute exacerbation	-	-	> 40	/
212	D2220	F	88	Nasopharyngeal Swab	Fever to be tested? Severe Malnutrition	-	-	> 40	/
213	D2221	F	29	Nasopharyngeal Swab	Cough to be tested	-	-	> 40	/
214	D2222	F	34	Nasopharyngeal Swab	Community Acquired Pneumonia, non-severe	-	-	> 40	/
215	D2223	F	59	Nasopharyngeal Swab	Diabetes	-	-	> 40	/
216	D2224	F	36	Nasopharyngeal Swab	HBV,Early Intrauterine Pregnancy	-	-	> 40	/
217	D2226	F	55	Nasopharyngeal Swab	Community Acquired Pneumonia	-	-	> 40	/
218	D2229	M	84	Nasopharyngeal Swab	Lung Infection	-	-	> 40	/

Double Testing on PCR of Sample with Different Results

No.	Pat. No.	Gender	Age	Sample Type	Clinical Diagnosis Background	Evaluated Reagent Results	First Time Nucleic Acid Results & Testing Value		Second Time Nucleic Acid Results & Testing Value	
1	D2008	M	38	Nasopharyngeal Swab	COVID-19	-	+	27.1	+	26.9
2	D2031	M	48	Nasopharyngeal Swab	COVID-19	-	+	26.6	+	26.8
3	D2079	M	73	Nasopharyngeal Swab	COVID-19	-	+	25.1	+	25.1
4	D2113	M	56	Nasopharyngeal Swab	Tuberculosis, Culture-positive	+	-	> 40	-	> 40
5	D2123	F	37	Nasopharyngeal Swab	Fever to be tested	+	-	> 40	-	> 40
6	D2140	M	60	Nasopharyngeal Swab	Skin ulcer of both legs to be tested	+	-	> 40	-	> 40