

SARS-CoV-2 Antigen Test Kit (LFIA)
Jiangsu Medomics Medical Technology Co., Ltd.
Clinical Evaluation Report

Date of Issue: Oct. 15, 2020

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1. Introduction and Description of the Assay

Medomics SARS-CoV-2 Antigen Test Kit (LFIA) is intended for rapid, qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antigen (Ag) extracted from the swab specimen in vitro with an immunochromatographic assay.

Medomics SARS-CoV-2 Antigen Test Kit (LFIA) is based on the test principle of colloidal gold immunochromatography and a double antibody sandwich assay for determination of SARS-CoV-2 antigen extracted from the swab specimen. The test cassette contains (1) colloidal gold-labeled anti-SARS-CoV-2 antibody, (2) one detection line (T line) and one quality control line (C) fixed on a nitrocellulose membrane. T is fixed with another anti-SARS-CoV-2 antibody for detecting the novel coronavirus. The quality control antibody is fixed on the C line.

When the appropriate amount of test sample treated with lysis buffer is added to the sample well of the test cassette, the sample will move forward along the test strip via capillary action. If the sample contains the novel coronavirus antigens and concentration of antigens is higher than the limit of detection, the antigen will bind to the colloidal gold-labeled anti-SARS-CoV-2 antibody. The immune complex will be captured by another anti-SARS-CoV-2 antibody immobilized on the membrane in the Test Region (T), forming a red T line and indicating a positive result for the novel coronavirus. If the sample contains no novel coronavirus antigens or the antigens concentration is lower than the limit of detection, a negative result is displayed.

Additionally, the test cassette also contains a quality control line C in the Control Region (C). Regardless of what antigens are present the C line should appear to indicate that the sample has been transported properly through the membrane. If the C line does not appear it indicates that the test result is invalid and the sample is required to retest.

2. Evaluation Method

In this study, based on the real-time Polymerase Chain Reaction (RT-PCR) assay as contrastive method, clinical application study of Medomics SARS-CoV-2 Antigen Test Kit (LFIA) was performed to verify the safety and effectiveness.

3. Clinical Sample

A total of 843 clinical samples (627 nasopharyngeal or throat swabs and 216 anterior nasal swabs) were validated at Jiangsu Provincial Center for Disease Control and

Prevention (Jiangsu CDC), Nanjing, China. Two swabs were collected from one person and were tested with Medomics SARS-CoV-2 Antigen Test Kit (LFIA) and 2019-nCoV RT-PCR kit separately. All swabs were stored at -80°C.

4. Clinical Trial Period

October 08 to October 15, 2020

5. Results and Analysis

5.1 Test procedure

Throughout the evaluation, all samples should be tested with the Medomics SARS-CoV-2 Antigen Test Kit (LFIA) according to the Instruction for Use.

SARS-CoV-2 Antigen Test Kit (LFIA) Lot Number : 2020072201, expiration DATE: 20220722

2019-nCoV RT-PCR kit manufactured by Shanghai BioGerm Medical Technology Co., Ltd. was used for diagnosis. The kits were approved by The National Medical Products Administration (NMPA), NMPA registration # 20203400065.

5.2 Comparative Analysis of Results

Trial Completion

A total of 220 PCR positive cases and 407 PCR negative cases were included in this trial.

Major Effectiveness Statistical Methods

Compared with RT-PCR results, the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), accuracy and the 95% confidence interval (CI) of test kit were analyzed. Confidence intervals for sensitivity, specificity, PPV, NPV and accuracy are calculated per a score method described in CLSI EP12-A2 (2008). Sensitivity, specificity, PPV, NPV, accuracy: range from 0%~100%, the closer the value is to 100%, the higher the degree of compliance with clinical diagnosis.

5.3 Result Analysis

Test results are shown as Table 1 and Table 2, clinical results are detailed in Annex I Clinical verification data list.

Table 1: 2×2 Contingency Table Analysis of RT-PCR Results and Evaluation Reagent Test Results for nasopharyngeal or throat swabs .

	RT-PCR		
Medomics COVID-19 Ag test	Positive	Negative	Total
Positive	215	2	217
Negative	5	405	410
Total	220	407	627
Sensitivity: 97.73% (94.78%~99.26%)			
Specificity: 99.51% (98.24%~99.94%)			
PPV: 99.08% (96.71%~99.89%)			
NPV: 98.78% (97.18%~99.60%)			
Accuracy: 98.88% (97.71%~99.55%)			

Table 2: 2×2 Contingency Table Analysis of RT-PCR Results and Evaluation Reagent Test Results for anterior nasal swabs.

	RT-PCR		
Medomics COVID-19 Ag test	Positive	Negative	Total
Positive	107	1	108
Negative	5	103	108
Total	112	104	216
Sensitivity: 95.54% (89.89%~98.53%)			
Specificity: 99.04% (94.76%~99.98%)			
PPV: 99.07% (94.95%~99.98%)			
NPV: 95.37% (89.53%~98.48%)			
Accuracy: 97.22% (94.05%~98.97%)			

Explanation of terms

Sensitivity = True Positives / (True Positives + False Negatives)

Specificity = True Negatives / (True Negatives + False Positives)

PPV (Positive Predictive Value) = True Positives / (True Positives + False Positives)

NPV (Negative Predictive Value) = True Negatives / (True Negatives + False Negatives)

Accuracy = (True Negatives + True Positives) / Total Samples

The performance of Medomics COVID-19 Antigen Test Kit (LFIA) was established with 627 nasopharyngeal or throat swabs collected from clinical patients. The SARS-CoV-2 antigen detection results of 215 positive samples and 405 negative samples were consistent with RT-PCR results. 5 cases were confirmed RT-PCR positive and meanwhile tested negative by Medomics SARS-CoV-2 Antigen Test Kit (LFIA) and 2 case was confirmed RT-PCR negative and meanwhile tested positive by Medomics SARS-CoV-2 Antigen Test Kit (LFIA).

The performance of Medomics COVID-19 Antigen Test Kit (LFIA) was established with 216 anterior nasal swabs collected from clinical patients. The SARS-CoV-2 antigen detection results of 107 positive samples and 103 negative samples were consistent with RT-PCR results. 5 cases were confirmed RT-PCR positive and meanwhile tested negative by Medomics SARS-CoV-2 Antigen Test Kit (LFIA) and 1 case was confirmed RT-PCR negative and meanwhile tested positive by Medomics SARS-CoV-2 Antigen Test Kit (LFIA).

6. Conclusion

The results from 843 clinical samples show that SARS-CoV-2 Antigen Test Kit (LFIA) developed by Medomics meet the requirement of clinical intended use.

Annex I Clinical Verification Data List

Results of negative samples for nasopharyngeal or throat swabs:

Sample	Data of testing	Medomics Ag test result	RT-PCR result	Coincidence
1	8-Oct-20	N	N	Yes
2	8-Oct-20	N	N	Yes
3	8-Oct-20	N	N	Yes
4	8-Oct-20	N	N	Yes
5	8-Oct-20	N	N	Yes
6	8-Oct-20	N	N	Yes
7	8-Oct-20	N	N	Yes
8	8-Oct-20	N	N	Yes
9	8-Oct-20	N	N	Yes
10	8-Oct-20	N	N	Yes
11	8-Oct-20	N	N	Yes
12	8-Oct-20	N	N	Yes
13	8-Oct-20	N	N	Yes
14	8-Oct-20	N	N	Yes
15	8-Oct-20	N	N	Yes
16	8-Oct-20	N	N	Yes
17	8-Oct-20	N	N	Yes
18	8-Oct-20	N	N	Yes
19	8-Oct-20	N	N	Yes
20	8-Oct-20	N	N	Yes
21	8-Oct-20	N	N	Yes
22	8-Oct-20	N	N	Yes
23	8-Oct-20	N	N	Yes
24	8-Oct-20	N	N	Yes
25	8-Oct-20	N	N	Yes
26	8-Oct-20	N	N	Yes
27	8-Oct-20	N	N	Yes
28	8-Oct-20	N	N	Yes
29	8-Oct-20	N	N	Yes
30	8-Oct-20	N	N	Yes
31	8-Oct-20	N	N	Yes
32	8-Oct-20	N	N	Yes
33	8-Oct-20	N	N	Yes
34	8-Oct-20	N	N	Yes
35	8-Oct-20	N	N	Yes
36	8-Oct-20	N	N	Yes
37	8-Oct-20	N	N	Yes
38	8-Oct-20	N	N	Yes

39	8-Oct-20	N	N	Yes
40	8-Oct-20	N	N	Yes
41	8-Oct-20	N	N	Yes
42	8-Oct-20	N	N	Yes
43	8-Oct-20	N	N	Yes
44	8-Oct-20	N	N	Yes
45	8-Oct-20	N	N	Yes
46	8-Oct-20	N	N	Yes
47	8-Oct-20	N	N	Yes
48	8-Oct-20	N	N	Yes
49	8-Oct-20	N	N	Yes
50	8-Oct-20	N	N	Yes
51	8-Oct-20	N	N	Yes
52	8-Oct-20	N	N	Yes
53	8-Oct-20	N	N	Yes
54	8-Oct-20	N	N	Yes
55	8-Oct-20	N	N	Yes
56	8-Oct-20	N	N	Yes
57	8-Oct-20	N	N	Yes
58	8-Oct-20	N	N	Yes
59	8-Oct-20	N	N	Yes
60	8-Oct-20	N	N	Yes
61	8-Oct-20	N	N	Yes
62	8-Oct-20	N	N	Yes
63	9-Oct-20	N	N	Yes
64	9-Oct-20	N	N	Yes
65	9-Oct-20	N	N	Yes
66	9-Oct-20	N	N	Yes
67	9-Oct-20	N	N	Yes
68	9-Oct-20	N	N	Yes
69	9-Oct-20	N	N	Yes
70	9-Oct-20	N	N	Yes
71	9-Oct-20	N	N	Yes
72	9-Oct-20	N	N	Yes
73	9-Oct-20	N	N	Yes
74	9-Oct-20	N	N	Yes
75	9-Oct-20	N	N	Yes
76	9-Oct-20	N	N	Yes
77	9-Oct-20	N	N	Yes
78	9-Oct-20	N	N	Yes
79	9-Oct-20	N	N	Yes
80	9-Oct-20	N	N	Yes

81	9-Oct-20	N	N	Yes
82	9-Oct-20	N	N	Yes
83	9-Oct-20	N	N	Yes
84	9-Oct-20	N	N	Yes
85	9-Oct-20	N	N	Yes
86	9-Oct-20	N	N	Yes
87	9-Oct-20	N	N	Yes
88	9-Oct-20	N	N	Yes
89	9-Oct-20	N	N	Yes
90	9-Oct-20	N	N	Yes
91	9-Oct-20	N	N	Yes
92	9-Oct-20	N	N	Yes
93	9-Oct-20	N	N	Yes
94	9-Oct-20	N	N	Yes
95	9-Oct-20	N	N	Yes
96	9-Oct-20	N	N	Yes
97	9-Oct-20	N	N	Yes
98	9-Oct-20	N	N	Yes
99	9-Oct-20	N	N	Yes
100	9-Oct-20	N	N	Yes
101	9-Oct-20	N	N	Yes
102	9-Oct-20	N	N	Yes
103	9-Oct-20	N	N	Yes
104	9-Oct-20	N	N	Yes
105	9-Oct-20	N	N	Yes
106	9-Oct-20	N	N	Yes
107	9-Oct-20	N	N	Yes
108	9-Oct-20	N	N	Yes
109	9-Oct-20	N	N	Yes
110	9-Oct-20	N	N	Yes
111	9-Oct-20	N	N	Yes
112	9-Oct-20	N	N	Yes
113	9-Oct-20	N	N	Yes
114	9-Oct-20	N	N	Yes
115	9-Oct-20	N	N	Yes
116	9-Oct-20	N	N	Yes
117	9-Oct-20	N	N	Yes
118	9-Oct-20	N	N	Yes
119	9-Oct-20	N	N	Yes
120	9-Oct-20	N	N	Yes
121	10-Oct-20	N	N	Yes
122	10-Oct-20	N	N	Yes

123	10-Oct-20	N	N	Yes
124	10-Oct-20	N	N	Yes
125	10-Oct-20	N	N	Yes
126	10-Oct-20	N	N	Yes
127	10-Oct-20	N	N	Yes
128	10-Oct-20	N	N	Yes
129	10-Oct-20	N	N	Yes
130	10-Oct-20	N	N	Yes
131	10-Oct-20	N	N	Yes
132	10-Oct-20	N	N	Yes
133	10-Oct-20	N	N	Yes
134	10-Oct-20	N	N	Yes
135	10-Oct-20	N	N	Yes
136	10-Oct-20	N	N	Yes
137	10-Oct-20	N	N	Yes
138	10-Oct-20	N	N	Yes
139	10-Oct-20	N	N	Yes
140	10-Oct-20	N	N	Yes
141	10-Oct-20	N	N	Yes
142	10-Oct-20	N	N	Yes
143	10-Oct-20	N	N	Yes
144	10-Oct-20	N	N	Yes
145	10-Oct-20	N	N	Yes
146	10-Oct-20	N	N	Yes
147	10-Oct-20	N	N	Yes
148	10-Oct-20	N	N	Yes
149	10-Oct-20	N	N	Yes
150	10-Oct-20	N	N	Yes
151	10-Oct-20	N	N	Yes
152	10-Oct-20	N	N	Yes
153	10-Oct-20	N	N	Yes
154	10-Oct-20	N	N	Yes
155	10-Oct-20	N	N	Yes
156	10-Oct-20	N	N	Yes
157	10-Oct-20	N	N	Yes
158	10-Oct-20	N	N	Yes
159	10-Oct-20	N	N	Yes
160	10-Oct-20	N	N	Yes
161	10-Oct-20	N	N	Yes
162	10-Oct-20	N	N	Yes
163	10-Oct-20	N	N	Yes
164	10-Oct-20	N	N	Yes

165	10-Oct-20	N	N	Yes
166	10-Oct-20	N	N	Yes
167	10-Oct-20	N	N	Yes
168	10-Oct-20	N	N	Yes
169	10-Oct-20	N	N	Yes
170	10-Oct-20	N	N	Yes
171	10-Oct-20	N	N	Yes
172	10-Oct-20	N	N	Yes
173	10-Oct-20	N	N	Yes
174	10-Oct-20	N	N	Yes
175	10-Oct-20	N	N	Yes
176	10-Oct-20	N	N	Yes
177	10-Oct-20	P	N	No
178	10-Oct-20	N	N	Yes
179	10-Oct-20	N	N	Yes
180	10-Oct-20	N	N	Yes
181	10-Oct-20	N	N	Yes
182	10-Oct-20	N	N	Yes
183	10-Oct-20	N	N	Yes
184	10-Oct-20	N	N	Yes
185	10-Oct-20	N	N	Yes
186	10-Oct-20	N	N	Yes
187	10-Oct-20	N	N	Yes
188	10-Oct-20	N	N	Yes
189	10-Oct-20	N	N	Yes
190	10-Oct-20	N	N	Yes
191	10-Oct-20	N	N	Yes
192	10-Oct-20	N	N	Yes
193	10-Oct-20	N	N	Yes
194	11-Oct-20	N	N	Yes
195	11-Oct-20	N	N	Yes
196	11-Oct-20	N	N	Yes
197	11-Oct-20	N	N	Yes
198	11-Oct-20	N	N	Yes
199	11-Oct-20	N	N	Yes
200	11-Oct-20	N	N	Yes
201	11-Oct-20	N	N	Yes
202	11-Oct-20	N	N	Yes
203	11-Oct-20	N	N	Yes
204	11-Oct-20	N	N	Yes
205	11-Oct-20	N	N	Yes
206	11-Oct-20	N	N	Yes

207	11-Oct-20	N	N	Yes
208	11-Oct-20	N	N	Yes
209	11-Oct-20	N	N	Yes
210	11-Oct-20	N	N	Yes
211	11-Oct-20	N	N	Yes
212	11-Oct-20	N	N	Yes
213	11-Oct-20	N	N	Yes
214	11-Oct-20	N	N	Yes
215	11-Oct-20	N	N	Yes
216	11-Oct-20	N	N	Yes
217	11-Oct-20	N	N	Yes
218	11-Oct-20	N	N	Yes
219	11-Oct-20	N	N	Yes
220	11-Oct-20	N	N	Yes
221	11-Oct-20	N	N	Yes
222	11-Oct-20	N	N	Yes
223	11-Oct-20	N	N	Yes
224	11-Oct-20	N	N	Yes
225	11-Oct-20	N	N	Yes
226	11-Oct-20	N	N	Yes
227	11-Oct-20	N	N	Yes
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231	11-Oct-20	N	N	Yes
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233	11-Oct-20	N	N	Yes
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235	11-Oct-20	N	N	Yes
236	11-Oct-20	N	N	Yes
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238	11-Oct-20	N	N	Yes
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243	11-Oct-20	N	N	Yes
244	11-Oct-20	N	N	Yes
245	11-Oct-20	N	N	Yes
246	11-Oct-20	N	N	Yes
247	11-Oct-20	N	N	Yes
248	11-Oct-20	N	N	Yes

249	11-Oct-20	N	N	Yes
250	11-Oct-20	N	N	Yes
251	11-Oct-20	N	N	Yes
252	11-Oct-20	N	N	Yes
253	11-Oct-20	N	N	Yes
254	11-Oct-20	N	N	Yes
255	11-Oct-20	N	N	Yes
256	11-Oct-20	N	N	Yes
257	11-Oct-20	N	N	Yes
258	11-Oct-20	N	N	Yes
259	11-Oct-20	N	N	Yes
260	11-Oct-20	N	N	Yes
261	11-Oct-20	N	N	Yes
262	11-Oct-20	N	N	Yes
263	11-Oct-20	N	N	Yes
264	11-Oct-20	N	N	Yes
265	11-Oct-20	N	N	Yes
266	11-Oct-20	N	N	Yes
267	11-Oct-20	N	N	Yes
268	11-Oct-20	N	N	Yes
269	11-Oct-20	N	N	Yes
270	11-Oct-20	N	N	Yes
271	12-Oct-20	N	N	Yes
272	12-Oct-20	N	N	Yes
273	12-Oct-20	N	N	Yes
274	12-Oct-20	N	N	Yes
275	12-Oct-20	N	N	Yes
276	12-Oct-20	N	N	Yes
277	12-Oct-20	N	N	Yes
278	12-Oct-20	N	N	Yes
279	12-Oct-20	N	N	Yes
280	12-Oct-20	N	N	Yes
281	12-Oct-20	P	N	No
282	12-Oct-20	N	N	Yes
283	12-Oct-20	N	N	Yes
284	12-Oct-20	N	N	Yes
285	12-Oct-20	N	N	Yes
286	12-Oct-20	N	N	Yes
287	12-Oct-20	N	N	Yes
288	12-Oct-20	N	N	Yes
289	12-Oct-20	N	N	Yes
290	12-Oct-20	N	N	Yes

291	12-Oct-20	N	N	Yes
292	12-Oct-20	N	N	Yes
293	12-Oct-20	N	N	Yes
294	12-Oct-20	N	N	Yes
295	12-Oct-20	N	N	Yes
296	12-Oct-20	N	N	Yes
297	12-Oct-20	N	N	Yes
298	12-Oct-20	N	N	Yes
299	12-Oct-20	N	N	Yes
300	12-Oct-20	N	N	Yes
301	12-Oct-20	N	N	Yes
302	12-Oct-20	N	N	Yes
303	12-Oct-20	N	N	Yes
304	12-Oct-20	N	N	Yes
305	12-Oct-20	N	N	Yes
306	12-Oct-20	N	N	Yes
307	12-Oct-20	N	N	Yes
308	12-Oct-20	N	N	Yes
309	12-Oct-20	N	N	Yes
310	12-Oct-20	N	N	Yes
311	12-Oct-20	N	N	Yes
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314	12-Oct-20	N	N	Yes
315	12-Oct-20	N	N	Yes
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317	12-Oct-20	N	N	Yes
318	12-Oct-20	N	N	Yes
319	12-Oct-20	N	N	Yes
320	12-Oct-20	N	N	Yes
321	12-Oct-20	N	N	Yes
322	12-Oct-20	N	N	Yes
323	12-Oct-20	N	N	Yes
324	12-Oct-20	N	N	Yes
325	12-Oct-20	N	N	Yes
326	12-Oct-20	N	N	Yes
327	12-Oct-20	N	N	Yes
328	13-Oct-20	N	N	Yes
329	13-Oct-20	N	N	Yes
330	13-Oct-20	N	N	Yes
331	13-Oct-20	N	N	Yes
332	13-Oct-20	N	N	Yes

333	13-Oct-20	N	N	Yes
334	13-Oct-20	N	N	Yes
335	13-Oct-20	N	N	Yes
336	13-Oct-20	N	N	Yes
337	13-Oct-20	N	N	Yes
338	13-Oct-20	N	N	Yes
339	13-Oct-20	N	N	Yes
340	13-Oct-20	N	N	Yes
341	13-Oct-20	N	N	Yes
342	13-Oct-20	N	N	Yes
343	13-Oct-20	N	N	Yes
344	13-Oct-20	N	N	Yes
345	13-Oct-20	N	N	Yes
346	13-Oct-20	N	N	Yes
347	13-Oct-20	N	N	Yes
348	13-Oct-20	N	N	Yes
349	13-Oct-20	N	N	Yes
350	13-Oct-20	N	N	Yes
351	13-Oct-20	N	N	Yes
352	13-Oct-20	N	N	Yes
353	13-Oct-20	N	N	Yes
354	13-Oct-20	N	N	Yes
355	13-Oct-20	N	N	Yes
356	13-Oct-20	N	N	Yes
357	13-Oct-20	N	N	Yes
358	13-Oct-20	N	N	Yes
359	13-Oct-20	N	N	Yes
360	13-Oct-20	N	N	Yes
361	13-Oct-20	N	N	Yes
362	13-Oct-20	N	N	Yes
363	13-Oct-20	N	N	Yes
364	13-Oct-20	N	N	Yes
365	13-Oct-20	N	N	Yes
366	13-Oct-20	N	N	Yes
367	13-Oct-20	N	N	Yes
368	13-Oct-20	N	N	Yes
369	13-Oct-20	N	N	Yes
370	13-Oct-20	N	N	Yes
371	13-Oct-20	N	N	Yes
372	13-Oct-20	N	N	Yes
373	13-Oct-20	N	N	Yes
374	13-Oct-20	N	N	Yes

375	13-Oct-20	N	N	Yes
376	13-Oct-20	N	N	Yes
377	13-Oct-20	N	N	Yes
378	13-Oct-20	N	N	Yes
379	13-Oct-20	N	N	Yes
380	13-Oct-20	N	N	Yes
381	13-Oct-20	N	N	Yes
382	13-Oct-20	N	N	Yes
383	13-Oct-20	N	N	Yes
384	13-Oct-20	N	N	Yes
385	13-Oct-20	N	N	Yes
386	13-Oct-20	N	N	Yes
387	13-Oct-20	N	N	Yes
388	13-Oct-20	N	N	Yes
389	13-Oct-20	N	N	Yes
390	13-Oct-20	N	N	Yes
391	13-Oct-20	N	N	Yes
392	13-Oct-20	N	N	Yes
393	13-Oct-20	N	N	Yes
394	13-Oct-20	N	N	Yes
395	13-Oct-20	N	N	Yes
396	13-Oct-20	N	N	Yes
397	13-Oct-20	N	N	Yes
398	13-Oct-20	N	N	Yes
399	13-Oct-20	N	N	Yes
400	13-Oct-20	N	N	Yes
401	13-Oct-20	N	N	Yes
402	13-Oct-20	N	N	Yes
403	13-Oct-20	N	N	Yes
404	13-Oct-20	N	N	Yes
405	13-Oct-20	N	N	Yes
406	13-Oct-20	N	N	Yes
407	13-Oct-20	N	N	Yes

Results of negative samples for anterior nasal swabs :

Sample	Data of testing	Medomics Ag test result	RT-PCR result	Coincidence
1	14-Oct-20	N	N	Yes
2	14-Oct-20	N	N	Yes
3	14-Oct-20	N	N	Yes
4	14-Oct-20	N	N	Yes
5	14-Oct-20	N	N	Yes

6	14-Oct-20	N	N	Yes
7	14-Oct-20	N	N	Yes
8	14-Oct-20	N	N	Yes
9	14-Oct-20	N	N	Yes
10	14-Oct-20	N	N	Yes
11	14-Oct-20	N	N	Yes
12	14-Oct-20	N	N	Yes
13	14-Oct-20	N	N	Yes
14	14-Oct-20	N	N	Yes
15	14-Oct-20	N	N	Yes
16	14-Oct-20	N	N	Yes
17	14-Oct-20	N	N	Yes
18	14-Oct-20	N	N	Yes
19	14-Oct-20	N	N	Yes
20	14-Oct-20	N	N	Yes
21	14-Oct-20	N	N	Yes
22	14-Oct-20	N	N	Yes
23	14-Oct-20	N	N	Yes
24	14-Oct-20	N	N	Yes
25	14-Oct-20	N	N	Yes
26	14-Oct-20	N	N	Yes
27	14-Oct-20	N	N	Yes
28	14-Oct-20	N	N	Yes
29	14-Oct-20	N	N	Yes
30	14-Oct-20	N	N	Yes
31	14-Oct-20	N	N	Yes
32	14-Oct-20	N	N	Yes
33	14-Oct-20	N	N	Yes
34	14-Oct-20	N	N	Yes
35	14-Oct-20	N	N	Yes
36	14-Oct-20	N	N	Yes
37	14-Oct-20	N	N	Yes
38	14-Oct-20	N	N	Yes
39	14-Oct-20	Y	N	No
40	14-Oct-20	N	N	Yes
41	14-Oct-20	N	N	Yes
42	14-Oct-20	N	N	Yes
43	14-Oct-20	N	N	Yes
44	14-Oct-20	N	N	Yes
45	14-Oct-20	N	N	Yes
46	14-Oct-20	N	N	Yes
47	14-Oct-20	N	N	Yes

48	14-Oct-20	N	N	Yes
49	14-Oct-20	N	N	Yes
50	14-Oct-20	N	N	Yes
51	14-Oct-20	N	N	Yes
52	14-Oct-20	N	N	Yes
53	14-Oct-20	N	N	Yes
54	14-Oct-20	N	N	Yes
55	14-Oct-20	N	N	Yes
56	14-Oct-20	N	N	Yes
57	14-Oct-20	N	N	Yes
58	14-Oct-20	N	N	Yes
59	14-Oct-20	N	N	Yes
60	14-Oct-20	N	N	Yes
61	14-Oct-20	N	N	Yes
62	14-Oct-20	N	N	Yes
63	14-Oct-20	N	N	Yes
64	14-Oct-20	N	N	Yes
65	14-Oct-20	N	N	Yes
66	14-Oct-20	N	N	Yes
67	14-Oct-20	N	N	Yes
68	14-Oct-20	N	N	Yes
69	14-Oct-20	N	N	Yes
70	14-Oct-20	N	N	Yes
71	14-Oct-20	N	N	Yes
72	14-Oct-20	N	N	Yes
73	14-Oct-20	N	N	Yes
74	14-Oct-20	N	N	Yes
75	14-Oct-20	N	N	Yes
76	14-Oct-20	N	N	Yes
77	14-Oct-20	N	N	Yes
78	15-Oct-20	N	N	Yes
79	15-Oct-20	N	N	Yes
80	15-Oct-20	N	N	Yes
81	15-Oct-20	N	N	Yes
82	15-Oct-20	N	N	Yes
83	15-Oct-20	N	N	Yes
84	15-Oct-20	N	N	Yes
85	15-Oct-20	N	N	Yes
86	15-Oct-20	N	N	Yes
87	15-Oct-20	N	N	Yes
88	15-Oct-20	N	N	Yes
89	15-Oct-20	N	N	Yes

90	15-Oct-20	N	N	Yes
91	15-Oct-20	N	N	Yes
92	15-Oct-20	N	N	Yes
93	15-Oct-20	N	N	Yes
94	15-Oct-20	N	N	Yes
95	15-Oct-20	N	N	Yes
96	15-Oct-20	N	N	Yes
97	15-Oct-20	N	N	Yes
98	15-Oct-20	N	N	Yes
99	15-Oct-20	N	N	Yes
100	15-Oct-20	N	N	Yes
101	15-Oct-20	N	N	Yes
102	15-Oct-20	N	N	Yes
103	15-Oct-20	N	N	Yes
104	15-Oct-20	N	N	Yes

Note: N=Negative, P=Positive.

Results of positive samples for nasopharyngeal or throat swabs:

Sample	Data of testing	Medomics Ag test result	RT-PCR result	Coincidence
1	8-Oct-20	P	P	Yes
2	8-Oct-20	P	P	Yes
3	8-Oct-20	P	P	Yes
4	8-Oct-20	P	P	Yes
5	8-Oct-20	P	P	Yes
6	8-Oct-20	P	P	Yes
7	8-Oct-20	P	P	Yes
8	8-Oct-20	P	P	Yes
9	8-Oct-20	P	P	Yes
10	8-Oct-20	P	P	Yes
11	8-Oct-20	P	P	Yes
12	8-Oct-20	P	P	Yes
13	8-Oct-20	P	P	Yes
14	8-Oct-20	P	P	Yes
15	8-Oct-20	P	P	Yes
16	8-Oct-20	P	P	Yes
17	8-Oct-20	P	P	Yes
18	8-Oct-20	P	P	Yes
19	8-Oct-20	P	P	Yes
20	8-Oct-20	P	P	Yes
21	8-Oct-20	P	P	Yes
22	8-Oct-20	P	P	Yes

23	8-Oct-20	P	P	Yes
24	8-Oct-20	P	P	Yes
25	8-Oct-20	P	P	Yes
26	8-Oct-20	P	P	Yes
27	8-Oct-20	P	P	Yes
28	8-Oct-20	P	P	Yes
29	8-Oct-20	P	P	Yes
30	8-Oct-20	P	P	Yes
31	8-Oct-20	P	P	Yes
32	8-Oct-20	P	P	Yes
33	8-Oct-20	P	P	Yes
34	8-Oct-20	P	P	Yes
35	8-Oct-20	P	P	Yes
36	8-Oct-20	P	P	Yes
37	8-Oct-20	P	P	Yes
38	8-Oct-20	P	P	Yes
39	8-Oct-20	P	P	Yes
40	8-Oct-20	P	P	Yes
41	8-Oct-20	P	P	Yes
42	8-Oct-20	P	P	Yes
43	8-Oct-20	P	P	Yes
44	8-Oct-20	P	P	Yes
45	8-Oct-20	P	P	Yes
46	8-Oct-20	P	P	Yes
47	8-Oct-20	P	P	Yes
48	8-Oct-20	P	P	Yes
49	8-Oct-20	P	P	Yes
50	8-Oct-20	P	P	Yes
51	9-Oct-20	P	P	Yes
52	9-Oct-20	P	P	Yes
53	9-Oct-20	P	P	Yes
54	9-Oct-20	P	P	Yes
55	9-Oct-20	P	P	Yes
56	9-Oct-20	P	P	Yes
57	9-Oct-20	P	P	Yes
58	9-Oct-20	P	P	Yes
59	9-Oct-20	P	P	Yes
60	9-Oct-20	P	P	Yes
61	9-Oct-20	P	P	Yes
62	9-Oct-20	P	P	Yes
63	9-Oct-20	P	P	Yes
64	9-Oct-20	P	P	Yes

65	9-Oct-20	P	P	Yes
66	9-Oct-20	P	P	Yes
67	9-Oct-20	P	P	Yes
68	9-Oct-20	P	P	Yes
69	9-Oct-20	P	P	Yes
70	9-Oct-20	P	P	Yes
71	9-Oct-20	P	P	Yes
72	9-Oct-20	P	P	Yes
73	9-Oct-20	P	P	Yes
74	9-Oct-20	P	P	Yes
75	9-Oct-20	P	P	Yes
76	9-Oct-20	P	P	Yes
77	9-Oct-20	P	P	Yes
78	9-Oct-20	P	P	Yes
79	9-Oct-20	P	P	Yes
80	9-Oct-20	P	P	Yes
81	9-Oct-20	P	P	Yes
82	9-Oct-20	P	P	Yes
83	9-Oct-20	P	P	Yes
84	9-Oct-20	P	P	Yes
85	9-Oct-20	P	P	Yes
86	9-Oct-20	P	P	Yes
87	9-Oct-20	P	P	Yes
88	9-Oct-20	P	P	Yes
89	9-Oct-20	P	P	Yes
90	9-Oct-20	P	P	Yes
91	9-Oct-20	P	P	Yes
92	9-Oct-20	P	P	Yes
93	9-Oct-20	P	P	Yes
94	9-Oct-20	P	P	Yes
95	9-Oct-20	P	P	Yes
96	10-Oct-20	P	P	Yes
97	10-Oct-20	P	P	Yes
98	10-Oct-20	N	P	No
99	10-Oct-20	P	P	Yes
100	10-Oct-20	P	P	Yes
101	10-Oct-20	P	P	Yes
102	10-Oct-20	P	P	Yes
103	10-Oct-20	P	P	Yes
104	10-Oct-20	P	P	Yes
105	10-Oct-20	P	P	Yes
106	10-Oct-20	P	P	Yes

107	10-Oct-20	P	P	Yes
108	10-Oct-20	P	P	Yes
109	10-Oct-20	P	P	Yes
110	10-Oct-20	P	P	Yes
111	10-Oct-20	P	P	Yes
112	10-Oct-20	P	P	Yes
113	10-Oct-20	P	P	Yes
114	10-Oct-20	P	P	Yes
115	10-Oct-20	P	P	Yes
116	10-Oct-20	P	P	Yes
117	10-Oct-20	P	P	Yes
118	10-Oct-20	P	P	Yes
119	10-Oct-20	P	P	Yes
120	10-Oct-20	P	P	Yes
121	10-Oct-20	P	P	Yes
122	10-Oct-20	P	P	Yes
123	10-Oct-20	P	P	Yes
124	10-Oct-20	P	P	Yes
125	10-Oct-20	P	P	Yes
126	10-Oct-20	P	P	Yes
127	10-Oct-20	N	P	No
128	10-Oct-20	P	P	Yes
129	10-Oct-20	P	P	Yes
130	10-Oct-20	P	P	Yes
131	10-Oct-20	P	P	Yes
132	10-Oct-20	P	P	Yes
133	10-Oct-20	P	P	Yes
134	11-Oct-20	P	P	Yes
135	11-Oct-20	P	P	Yes
136	11-Oct-20	P	P	Yes
137	11-Oct-20	P	P	Yes
138	11-Oct-20	P	P	Yes
139	11-Oct-20	P	P	Yes
140	11-Oct-20	P	P	Yes
141	11-Oct-20	P	P	Yes
142	11-Oct-20	P	P	Yes
143	11-Oct-20	P	P	Yes
144	11-Oct-20	P	P	Yes
145	11-Oct-20	P	P	Yes
146	11-Oct-20	P	P	Yes
147	11-Oct-20	P	P	Yes
148	11-Oct-20	P	P	Yes

149	11-Oct-20	P	P	Yes
150	11-Oct-20	P	P	Yes
151	11-Oct-20	P	P	Yes
152	11-Oct-20	P	P	Yes
153	11-Oct-20	P	P	Yes
154	11-Oct-20	P	P	Yes
155	11-Oct-20	P	P	Yes
156	11-Oct-20	P	P	Yes
157	11-Oct-20	P	P	Yes
158	11-Oct-20	P	P	Yes
159	11-Oct-20	P	P	Yes
160	11-Oct-20	P	P	Yes
161	11-Oct-20	P	P	Yes
162	11-Oct-20	P	P	Yes
163	11-Oct-20	P	P	Yes
164	11-Oct-20	P	P	Yes
165	11-Oct-20	P	P	Yes
166	11-Oct-20	P	P	Yes
167	11-Oct-20	P	P	Yes
168	11-Oct-20	P	P	Yes
169	11-Oct-20	P	P	Yes
170	11-Oct-20	P	P	Yes
171	11-Oct-20	P	P	Yes
172	11-Oct-20	N	P	No
173	11-Oct-20	P	P	Yes
174	11-Oct-20	P	P	Yes
175	12-Oct-20	P	P	Yes
176	12-Oct-20	P	P	Yes
177	12-Oct-20	P	P	Yes
178	12-Oct-20	N	P	No
179	12-Oct-20	P	P	Yes
180	12-Oct-20	P	P	Yes
181	12-Oct-20	P	P	Yes
182	12-Oct-20	P	P	Yes
183	12-Oct-20	P	P	Yes
184	12-Oct-20	P	P	Yes
185	12-Oct-20	P	P	Yes
186	12-Oct-20	P	P	Yes
187	12-Oct-20	P	P	Yes
188	12-Oct-20	P	P	Yes
189	12-Oct-20	P	P	Yes
190	12-Oct-20	P	P	Yes

191	12-Oct-20	P	P	Yes
192	12-Oct-20	P	P	Yes
193	12-Oct-20	P	P	Yes
194	12-Oct-20	P	P	Yes
195	12-Oct-20	P	P	Yes
196	12-Oct-20	P	P	Yes
197	12-Oct-20	P	P	Yes
198	12-Oct-20	P	P	Yes
199	12-Oct-20	P	P	Yes
200	12-Oct-20	P	P	Yes
201	13-Oct-20	P	P	Yes
202	13-Oct-20	P	P	Yes
203	13-Oct-20	P	P	Yes
204	13-Oct-20	P	P	Yes
205	13-Oct-20	P	P	Yes
206	13-Oct-20	P	P	Yes
207	13-Oct-20	N	P	No
208	13-Oct-20	P	P	Yes
209	13-Oct-20	P	P	Yes
210	13-Oct-20	P	P	Yes
211	13-Oct-20	P	P	Yes
212	13-Oct-20	P	P	Yes
213	13-Oct-20	P	P	Yes
214	13-Oct-20	P	P	Yes
215	13-Oct-20	P	P	Yes
216	13-Oct-20	P	P	Yes
217	13-Oct-20	P	P	Yes
218	13-Oct-20	P	P	Yes
219	13-Oct-20	P	P	Yes
220	13-Oct-20	P	P	Yes

Results of positive samples for anterior nasal swabs :

Sample	Data of testing	Medomics Ag test result	RT-PCR result	Coincidence
1	14-Oct-20	P	P	Yes
2	14-Oct-20	P	P	Yes
3	14-Oct-20	P	P	Yes
4	14-Oct-20	P	P	Yes
5	14-Oct-20	P	P	Yes
6	14-Oct-20	P	P	Yes
7	14-Oct-20	P	P	Yes
8	14-Oct-20	P	P	Yes

9	14-Oct-20	P	P	Yes
10	14-Oct-20	P	P	Yes
11	14-Oct-20	P	P	Yes
12	14-Oct-20	P	P	Yes
13	14-Oct-20	P	P	Yes
14	14-Oct-20	P	P	Yes
15	14-Oct-20	P	P	Yes
16	14-Oct-20	P	P	Yes
17	14-Oct-20	P	P	Yes
18	14-Oct-20	P	P	Yes
19	14-Oct-20	P	P	Yes
20	14-Oct-20	P	P	Yes
21	14-Oct-20	P	P	Yes
22	14-Oct-20	P	P	Yes
23	14-Oct-20	P	P	Yes
24	14-Oct-20	P	P	Yes
25	14-Oct-20	P	P	Yes
26	14-Oct-20	P	P	Yes
27	14-Oct-20	P	P	Yes
28	14-Oct-20	P	P	Yes
29	14-Oct-20	P	P	Yes
30	14-Oct-20	P	P	Yes
31	14-Oct-20	P	P	Yes
32	14-Oct-20	N	P	No
33	14-Oct-20	P	P	Yes
34	14-Oct-20	P	P	Yes
35	14-Oct-20	P	P	Yes
36	14-Oct-20	P	P	Yes
37	14-Oct-20	P	P	Yes
38	14-Oct-20	P	P	Yes
39	14-Oct-20	P	P	Yes
40	14-Oct-20	P	P	Yes
41	14-Oct-20	P	P	Yes
42	14-Oct-20	P	P	Yes
43	14-Oct-20	P	P	Yes
44	14-Oct-20	P	P	Yes
45	14-Oct-20	P	P	Yes
46	14-Oct-20	P	P	Yes
47	14-Oct-20	P	P	Yes
48	14-Oct-20	P	P	Yes
49	14-Oct-20	P	P	Yes
50	14-Oct-20	P	P	Yes

51	14-Oct-20	P	P	Yes
52	14-Oct-20	P	P	Yes
53	14-Oct-20	P	P	Yes
54	14-Oct-20	P	P	Yes
55	14-Oct-20	P	P	Yes
56	14-Oct-20	P	P	Yes
57	14-Oct-20	P	P	Yes
58	15-Oct-20	P	P	Yes
59	15-Oct-20	P	P	Yes
60	15-Oct-20	P	P	Yes
61	15-Oct-20	P	P	Yes
62	15-Oct-20	P	P	Yes
63	15-Oct-20	P	P	Yes
64	15-Oct-20	P	P	Yes
65	15-Oct-20	P	P	Yes
66	15-Oct-20	P	P	Yes
67	15-Oct-20	N	P	No
68	15-Oct-20	P	P	Yes
69	15-Oct-20	P	P	Yes
70	15-Oct-20	P	P	Yes
71	15-Oct-20	P	P	Yes
72	15-Oct-20	P	P	Yes
73	15-Oct-20	P	P	Yes
74	15-Oct-20	P	P	Yes
75	15-Oct-20	P	P	Yes
76	15-Oct-20	P	P	Yes
77	15-Oct-20	P	P	Yes
78	15-Oct-20	P	P	Yes
79	15-Oct-20	P	P	Yes
80	15-Oct-20	P	P	Yes
81	15-Oct-20	P	P	Yes
82	15-Oct-20	P	P	Yes
83	15-Oct-20	P	P	Yes
84	15-Oct-20	P	P	Yes
85	15-Oct-20	P	P	Yes
86	15-Oct-20	P	P	Yes
87	15-Oct-20	P	P	Yes
88	15-Oct-20	P	P	Yes
89	15-Oct-20	P	P	Yes
90	15-Oct-20	P	P	Yes
91	15-Oct-20	P	P	Yes
92	15-Oct-20	P	P	Yes

93	15-Oct-20	P	P	Yes
94	15-Oct-20	P	P	Yes
95	15-Oct-20	N	P	No
96	15-Oct-20	P	P	Yes
97	15-Oct-20	N	P	No
98	15-Oct-20	P	P	Yes
99	15-Oct-20	P	P	Yes
100	15-Oct-20	P	P	Yes
101	15-Oct-20	P	P	Yes
102	15-Oct-20	P	P	Yes
103	15-Oct-20	P	P	Yes
104	15-Oct-20	P	P	Yes
105	15-Oct-20	P	P	Yes
106	15-Oct-20	P	P	Yes
107	15-Oct-20	P	P	Yes
108	15-Oct-20	N	P	No
109	15-Oct-20	P	P	Yes
110	15-Oct-20	P	P	Yes
111	15-Oct-20	P	P	Yes
112	15-Oct-20	P	P	Yes

Note: N=Negative, P=Positive.