CLINICAL SUMMARY REPORT

SARS-CoV-2/FluA/FluB

Antigen Combo Rapid Test Kit (Colloidal Gold)

Responsibility	Name	Position	Signature/Date
Drafter	Shawn Chen	Product manager	*Shawn* 2021.07.13
Reviewer	Shuang Sun	Project manager	孙爽 2021.07.13
Reviewer	Strong Hou	RA manager	*Strong* 2021.07.13
Approver	Angela Liu	General manager	*Angela* 2021.07.13

Change History

Rev.	Change Description	Date Changed
A0	New document	2020.12.08
A1	Add "Annex 1", "Annex 2", "Annex 3", "Annex 4"	2021.07.13

1 Research purpose

COVID-19&FLU A/B Antigen Test Kit (Colloidal Gold) is combined by COVID-19 Antigen Test Kit and FLU A/B Antigen Test Kit, and the detection of both parties is independent of each other. This report summarizes the clinical data of both parties, thus proving the effectiveness and safety of COVID-19 & FLU A/B Antigen Test Kit (Colloidal Gold)

2 Reagent information

Product Name: COVID-19 & FLU A/B Antigen Test Kit (Colloidal Gold)

Manufacturer: Multibrands Trading (Suzhou) Co., Ltd.

3 Product introduction

Both COVID-19 and influenza A/B viruses (Flu A/B) can cause acute respiratory infections, and people are generally susceptible. These three viruses are highly contagious, spread quickly, have a short incubation period, and have a high incidence. The main symptoms are fever, dry cough, fatigue, etc. Therefore, the detection of COVID-19, Flu A/B has relatively Great clinical findings.

4 Intended use

COVID-19 & FLU A/B Antigen Test Kit (Colloidal Gold) is used for in vitro qualitative detection of 2019 Novel Coronavirus antigen and influenza A/B antigen in human nasopharyngeal swab samples.

5 Clinical Trial Center

5.1   Nanjing Baikang Biotechnology Co., LTD.,

5.2   TEODORO MALDONADO CARBO, Hospital in Ecuador

5.3   IESS LOS Ceibos del Norte de Guayaquil, Hospital in Ecuador

5.4   Hospital Arnau, Hospital in Spain

5.5   Laboratory of Multibrands Trading (Suzhou) Co., Ltd.

6   Specimen type

Specimen taken from the human nasopharynx by a nasopharyngeal swab. Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result.

7   Specimen requirements

Each specimen shall contain the following information:

➢   The specimen collection date;

➢   Date of onset of symptoms (if present);

➢   Severity or absence of symptoms;

8   Experiment method

Allow test cassette, specimen, and Antigen extract buffer control to equilibrate to room temperature (15-30°C) prior to testing.

a)   Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.

b)   Place the test device on a clean and level surface.

c)   Ask the patient to remove the secretions on the surface of the anterior nasal cavity, keep the head slightly tilted, and gently and slowly insert the swab through the nasal cavity to the nasopharynx, When resistance is encountered, it will reach the posterior nasopharynx, stay for a few seconds to absorb secretions, and gently rotate to remove the swab.

d)   Place the antigen extraction tube on the workbench. Place the antigen extraction buffer bottle vertically downward, squeeze the bottle to make the buffer drip freely into the extraction tube without touching the edge of the tube, and add 8 drops (about 300ul) to the extraction tube.

e)   Put the swab specimen into the extraction tube pre-added with the antigen extraction buffer, and rotate the swab about 10 times while pressing the swab head against the tube wall to release the antigen in the swab, then let it stand for about 1 minute.

f)   Remove the swab while squeezing the tip of the swab so that as much liquid in the swab can be

discharged as possible. Dispose of used swabs in accordance with biohazard waste disposal methods.

g) Install the dripper on the extraction tube and cap it tightly, and let it stand for about 1 minute.

h) Open the aluminum foil bag and take out the test card, add 3 drops (about 100ul) into the sample hole of the test card (or use a pipette to add 100ul), and start the timer.

i) Wait for the colored line to appear. The result should be read in 15 minutes. Do not interpret the result after 20 minutes.

Note: The detection steps need to be completed under protection against infection.

9   Data summary and analysis

9.1   COVID-19 Antigen：Nov. 09,2020 ~ Nov.23,2020

Method		PCR results		Total
		Positive	Negative	
COVID-19 Test kit	Positive	206	3	209
	Negative	3	306	309
Total		209	309	518
Sensitivity		98.56%	95% confidence interval	95.87%~99.51%
Specificity		99.03%	95% confidence interval	97.18%~99.67%
Accuracy		98.84%	95% confidence interval	97.50%~99.47%

9.1.1 Sensitivity calculation

Sensitivity =206/（206+3）=98.56%

9.1.2 Specificity calculation

Specificity =306/（3+306）=99.03%

9.1.3 Accuracy calculation

Accuracy =（206+306）/518=98.84%

9.1.4 Sensitivity confidence interval calculation

Q1=2*206+1.96^2=415.842

Q2=$1.96\sqrt{1.96^2 + 4*206*3/(206 + 3)}$=7.759

Q3=2*(206+3+1.96^2)=425.683

Sensitivity confidence interval up limit =100%*（415.842-7.759）/425.683=95.87%

Sensitivity confidence interval lower limit =100%*（415.842+7.759）/425.683=99.51%

9.1.5 Specificity confidence interval calculation

$Q1 = 2*306 + 1.96^2 = 615.842$

$Q2 = 1.96\sqrt{1.96^2 + 4*306*3/(306+3)} = 7.772$

$Q3 = 2*(306 + 3 + 1.96^2) = 625.683$

Specificity confidence interval up limit =100%*（615.842-7.772）/625.683=97.18%

Specificity confidence interval lower limit =100%*（615.842+7.772）/625.683=99.67%

9.1.6 Accuracy confidence interval calculation

$Q1 = 2*(206+306) + 1.96^2 = 1027.842$

$Q2 = 1.96\sqrt{1.96^2 + 4*(206+306)*(3+3)/518} = 10.29$

$Q3 = 2*(518 + 1.96^2) = 1043.683$

Accuracy confidence interval up limit =100%*（1027.842-10.29）/1043.683= 97.50%

Accuracy confidence interval lower limit =100%*（1027.842+10.29）/1043.683= 99.47%

9.1.7 Kappa

$PA = \frac{206+306}{518} = 0.9884$

$Pe = \frac{(206+3)(306+3)+(3+306)(3+306)}{518^2} = 0.5931$

$Kappa = \frac{P_A - P_e}{1 - P_e} = \frac{0.9884 - 0.5931}{1 - 0.5931} = 0.9715$

Kappa (k): k>0.75, means good consistency; 0.40<k<0.75, not very consistent; K <0.40, poor consistency.

9.2   FLU A/B Antigen: Nov. 25th,2020 ~ Dec. 4th,2020

Method		Reference Reagent Results			Total
		FLU A Positive	FLU B Positive	Negative	
Test Reagent Results	Positive	89	97	2	188
	Negative	3	2	213	218
Total		92	99	215	406
FLU A Sensitivity		96.74%		90.85%~98.88%	
FLU B Sensitivity		97.98%	95% confidence interval	92.93%~99.44%	
Specificity		99.07%		96.67%~99.74%	
Accuracy		98.28%		96.48%~99.16%	

9.2.1 Sensitivity calculation

FLU A Sensitivity =89/（89+3）=96.74%

FLU B Sensitivity=97/（97+2）=97.08%

9.2.2 Specificity calculation

Specificity =213/（2+213）=99.07%

9.2.3 Accuracy calculation

Accuracy =（89+97+213）/406=98.28%

9.2.4 Sensitivity confidence interval calculation

FLU A:

$Q1=2*89+1.96^2=181.84$

$Q2=1.96\sqrt{1.96^2 + 4*89*3/(89+3)}=7.70$

$Q3=2*(89+3+1.96^2)=191.68$

Sensitivity confidence interval up limit =100%*(181.84-7.70)/191.68=90.85%

Sensitivity confidence interval lower limit =100%*(181.84+7.70)/191.68=98.88%

FLU B:

$Q1=2*97+1.96^2= 197.84$

$Q2=1.96\sqrt{1.96^2 + 4*97*2/(97+2)}=6.70$

$Q3=2*(97+2+1.96^2)= 205.68$

Sensitivity confidence interval up limit =100%*(197.84-6.70)/ 205.68=92.93%

Sensitivity confidence interval lower limit =100%*(197.84+6.70)/ 205.68=99.44%

9.2.5 Specificity confidence interval calculation

$Q1=2*213+1.96^2=429.84$

$Q2=1.96\sqrt{1.96^2 + 4*213*2/(213+2)}=6.72$

$Q3=2*(213+2+1.96^2)= 437.68$

Specificity confidence interval up limit =100%*（429.84-6.72）/437.68 =96.67%

Specificity confidence interval lower limit =100%*(429.84+6.72)/437.68=99.74%

9.2.6 Accuracy confidence interval calculation

$Q1=2(89+97+213)+1.96^2=801.84$

$Q2=1.96\sqrt{1.96^2 + 4*(89+97+213)(3+2+2)/406}=10.98$

$Q3=2(406+1.96^2)= 819.68$

Accuracy confidence interval up limit =100%*(801.84-10.98)/819.68= 96.48%

Accuracy confidence interval lower limit =100%*(801.84+10.98)/819.68= 99.16%

9.2.7 Kappa

$$PA = \frac{89+97+213}{406} = 0.9828$$

$$Pe = \frac{(89+3+97+2)(89+97+2)+(3+213)(3+2+213)}{406^2} = 0.5012$$

$$Kappa = \frac{P_A - P_e}{1 - P_e} = \frac{0.9828 - 0.5012}{1 - 0.5012} = 0.9655$$

Kappa (k): k>0.75, means good consistency; 0.40<k<0.75, not very consistent; K <0.40, poor consistency.

10 Conclusion

COVID-19 antigen：The expected research purpose has been achieved. The total number of samples studied is 518, of which 209 are positive and 309 are negative. Compared with PCR, the sensitivity of the product is 98.56% (confidence interval is 95.87%~99.51%), specificity is 99.03% (confidence interval is 97.18%~99.67%), and accuracy is 98.84% (confidence interval is 97.50%~99.47%). The Kappa is 0.9715, reach" K>0.75", which proves that the results of this study are in good consistency.

FLU A/B antigen：The expected research purpose has been achieved. The total number of samples studied is 406, of which 92 are FLU A positive,99 are FLU B positive and 215 are negative. Compared with reference reagent, the FLU A sensitivity of the product is 96.74% (confidence interval is 90.85%~98.88%), FLU B sensitivity of the product is 97.98% (confidence interval is 92.93%~99.44%), specificity is 99.07% (confidence interval is 96.67%~99.74%), and accuracy is 98.28% (confidence interval is 96.48%~99.16%). The Kappa is 0.9655, reach" K>0.75", which proves that the results of this study are in good consistency.

NO.	Gender	Age	COVID-19 Test kit	RT-PCR	NO.	Gender	Age	COVID-19 Test kit	RT-PCR
1	F	39	Positive	Positive	37	M	44	Positive	Positive
2	F	36	Positive	Positive	38	F	37	Positive	Positive
3	M	50	Positive	Positive	39	M	47	Positive	Positive
4	M	48	Positive	Positive	40	F	81	Positive	Positive
5	M	62	Positive	Positive	41	F	42	Positive	Positive
6	F	87	Positive	Positive	42	M	45	Positive	Positive
7	F	23	Positive	Positive	43	M	60	Positive	Positive
8	M	22	Positive	Positive	44	M	52	Positive	Positive
9	F	38	Positive	Positive	45	F	86	Positive	Positive
10	F	24	Positive	Positive	46	M	63	Positive	Positive
11	M	31	Positive	Positive	47	M	56	Positive	Positive
12	M	63	Positive	Positive	48	M	24	Positive	Positive
13	F	41	Positive	Positive	49	F	34	Positive	Positive
14	M	37	Positive	Positive	50	M	42	Positive	Positive
15	M	28	Positive	Positive	51	M	49	Positive	Positive
16	F	32	Positive	Positive	52	M	52	Positive	Positive
17	F	24	Positive	Positive	53	M	28	Negative	Negative
18	M	49	Positive	Positive	54	F	73	Positive	Positive
19	M	34	Positive	Positive	55	M	48	Negative	Negative
20	F	53	Positive	Positive	56	M	42	Negative	Negative
21	F	25	Positive	Positive	57	M	38	Positive	Positive
22	M	38	Positive	Positive	58	F	44	Positive	Positive
23	F	74	Positive	Positive	59	M	27	Negative	Negative
24	M	33	Positive	Positive	60	F	46	Negative	Negative
25	F	31	Positive	Positive	61	F	33	Negative	Negative
26	F	56	Positive	Positive	62	F	52	Negative	Negative
27	F	34	Positive	Positive	63	F	80	Positive	Positive
28	F	69	Positive	Positive	64	F	24	Positive	Positive
29	F	35	Positive	Positive	65	F	51	Positive	Positive
30	F	28	Positive	Positive	66	M	61	Positive	Positive
31	M	40	Positive	Positive	67	F	52	Positive	Positive
32	M	61	Positive	Positive	68	M	18	Positive	Positive
33	M	29	Positive	Positive	69	F	56	Positive	Positive
34	F	46	Positive	Positive	70	M	52	Positive	Positive
35	F	58	Positive	Positive	71	M	54	Positive	Positive
36	F	58	Positive	Positive	72	F	55	Positive	Positive

NO.	Gender	Age	COVID-19 Test kit	RT-PCR	NO.	Gender	Age	COVID-19 Test kit	RT-PCR
73	M	44	Positive	Positive	110	M	54	Positive	Positive
74	M	48	Positive	Positive	111	M	29	Positive	Positive
75	M	43	Positive	Positive	112	M	50	Positive	Positive
76	M	37	Positive	Positive	113	M	27	Positive	Positive
77	M	42	Positive	Positive	114	M	25	Positive	Positive
78	M	57	Positive	Positive	115	F	35	Positive	Positive
79	M	65	Positive	Positive	116	M	23	Positive	Positive
80	M	41	Positive	Positive	117	M	22	Positive	Positive
81	M	31	Positive	Positive	118	F	51	Positive	Positive
82	M	65	Positive	Positive	119	M	35	Positive	Positive
83	M	59	Positive	Positive	120	F	48	Positive	Positive
84	M	48	Positive	Positive	121	F	35	Positive	Positive
85	M	56	Positive	Positive	122	F	33	Positive	Positive
86	M	63	Positive	Positive	123	M	32	Positive	Positive
87	M	66	Positive	Positive	124	F	42	Positive	Positive
88	M	58	Positive	Positive	125	M	43	Positive	Positive
89	M	42	Positive	Positive	126	F	46	Positive	Positive
90	M	54	Positive	Positive	127	F	73	Positive	Positive
91	M	59	Positive	Positive	128	M	39	Positive	Positive
92	F	43	Positive	Positive	129	F	19	Positive	Positive
93	M	66	Positive	Positive	130	M	20	Positive	Positive
94	M	38	Positive	Positive	131	F	20	Positive	Positive
95	M	33	Positive	Positive	132	F	25	Positive	Positive
96	M	31	Positive	Positive	133	F	63	Positive	Positive
97	M	44	Positive	Positive	134	F	29	Positive	Positive
98	M	59	Positive	Positive	135	F	39	Positive	Positive
99	M	60	Positive	Positive	136	M	77	Positive	Positive
100	M	38	Positive	Positive	137	F	65	Positive	Positive
101	M	63	Positive	Positive	138	M	60	Positive	Positive
102	M	60	Positive	Positive	139	M	44	Positive	Positive
103	F	55	Positive	Positive	140	F	41	Positive	Positive
104	M	33	Positive	Positive	141	M	80	Positive	Positive
105	F	48	Positive	Positive	142	M	42	Positive	Positive
106	F	52	Positive	Positive	143	F	59	Positive	Positive
107	M	54	Positive	Positive	144	M	66	Positive	Positive
108	M	33	Positive	Positive	145	F	64	Positive	Positive
109	M	22	Positive	Positive	146	F	28	Positive	Positive

NO.	Gender	Age	COVID-19 Test kit	RT-PCR	NO.	Gender	Age	COVID-19 Test kit	RT-PCR
147	M	20	Positive	Positive	184	F	67	Positive	Positive
148	F	72	Positive	Positive	185	M	21	Positive	Positive
149	F	47	Positive	Positive	186	M	37	Positive	Positive
150	F	76	Positive	Positive	187	F	54	Positive	Positive
151	M	29	Positive	Positive	188	M	34	Positive	Positive
152	M	47	Positive	Positive	189	M	41	Positive	Positive
153	F	28	Positive	Positive	190	M	30	Positive	Positive
154	F	32	Positive	Positive	191	F	25	Positive	Positive
155	F	30	Positive	Positive	192	M	63	Positive	Positive
156	M	28	Positive	Positive	193	M	46	Positive	Positive
157	M	18	Positive	Positive	194	M	27	Positive	Positive
158	M	21	Positive	Positive	195	F	35	Positive	Positive
159	F	29	Positive	Positive	196	M	22	Positive	Positive
160	F	41	Positive	Positive	197	M	43	Positive	Positive
161	F	59	Positive	Positive	198	M	27	Positive	Positive
162	M	61	Positive	Positive	199	F	92	Positive	Positive
163	F	48	Positive	Positive	200	M	94	Positive	Positive
164	M	41	Positive	Positive	201	M	30	Positive	Positive
165	F	44	Positive	Positive	202	F	34	Positive	Positive
166	M	20	Positive	Positive	203	F	48	Positive	Positive
167	M	56	Positive	Positive	204	M	50	Positive	Positive
168	F	24	Positive	Positive	205	F	42	Positive	Positive
169	M	28	Positive	Positive	206	M	32	Positive	Positive
170	F	49	Positive	Positive	207	F	35	Positive	Positive
171	M	35	Positive	Positive	208	F	60	Positive	Positive
172	F	74	Positive	Positive	209	M	25	Positive	Positive
173	F	29	Positive	Positive	210	M	30	Positive	Positive
174	F	23	Positive	Positive	211	F	44	Positive	Positive
175	M	14	Positive	Positive	212	M	47	Positive	Positive
176	M	51	Negative	Negative	213	M	37	Negative	Positive
177	M	67	Positive	Positive	214	M	51	Positive	Positive
178	F	44	Positive	Positive	215	F	75	Positive	Positive
179	F	26	Negative	Negative	216	F	60	Negative	Negative
180	F	38	Positive	Positive	217	F	75	Negative	Negative
181	M	36	Positive	Positive	218	F	34	Positive	Positive
182	F	35	Negative	Positive	219	M	25	Negative	Positive
183	F	43	Positive	Positive	220	M	75	Positive	Positive

NO.	Gender	Age	COVID-19 Test kit	RT-PCR	NO.	Gender	Age	COVID-19 Test kit	RT-PCR
221	F	32	Negative	Negative	258	M	28	Negative	Negative
222	F	33	Negative	Negative	259	F	24	Negative	Negative
223	F	23	Negative	Negative	260	M	39	Negative	Negative
224	F	35	Negative	Negative	261	F	49	Negative	Negative
225	F	35	Negative	Negative	262	M	31	Negative	Negative
226	M	30	Negative	Negative	263	F	58	Negative	Negative
227	F	39	Negative	Negative	264	M	35	Negative	Negative
228	F	30	Negative	Negative	265	F	40	Negative	Negative
229	F	28	Negative	Negative	266	M	33	Negative	Negative
230	M	28	Negative	Negative	267	M	63	Negative	Negative
231	F	30	Negative	Negative	268	F	33	Negative	Negative
232	F	25	Negative	Negative	269	F	30	Negative	Negative
233	F	44	Negative	Negative	270	F	24	Negative	Negative
234	F	37	Negative	Negative	271	M	34	Negative	Negative
235	F	32	Negative	Negative	272	M	42	Negative	Negative
236	F	38	Negative	Negative	273	F	37	Negative	Negative
237	F	31	Negative	Negative	274	F	39	Negative	Negative
238	M	29	Negative	Negative	275	F	33	Negative	Negative
239	F	31	Negative	Negative	276	F	35	Negative	Negative
240	M	43	Negative	Negative	277	M	26	Negative	Negative
241	M	35	Negative	Negative	278	M	22	Negative	Negative
242	F	31	Negative	Negative	279	M	35	Negative	Negative
243	F	39	Negative	Negative	280	F	28	Negative	Negative
244	F	33	Negative	Negative	281	F	30	Negative	Negative
245	F	50	Negative	Negative	282	F	37	Negative	Negative
246	F	37	Negative	Negative	283	F	37	Negative	Negative
247	F	34	Negative	Negative	284	F	27	Negative	Negative
248	F	32	Negative	Negative	285	M	43	Negative	Negative
249	M	22	Negative	Negative	286	M	37	Negative	Negative
250	F	42	Negative	Negative	287	F	60	Negative	Negative
251	F	58	Negative	Negative	288	M	44	Negative	Negative
252	M	25	Negative	Negative	289	F	37	Negative	Negative
253	M	26	Negative	Negative	290	F	40	Negative	Negative
254	F	37	Negative	Negative	291	F	33	Negative	Negative
255	F	28	Negative	Negative	292	F	30	Negative	Negative
256	F	32	Negative	Negative	293	M	23	Negative	Negative
257	F	37	Negative	Negative	294	F	31	Negative	Negative

NO.	Gender	Age	COVID-19 Test kit	RT-PCR	NO.	Gender	Age	COVID-19 Test kit	RT-PCR
295	M	25	Negative	Negative	332	F	34	Negative	Negative
296	M	27	Negative	Negative	333	F	46	Negative	Negative
297	F	22	Negative	Negative	334	M	33	Negative	Negative
298	F	37	Negative	Negative	335	M	41	Negative	Negative
299	F	35	Negative	Negative	336	F	36	Negative	Negative
300	M	36	Negative	Negative	337	F	31	Negative	Negative
301	M	22	Negative	Negative	338	F	41	Negative	Negative
302	M	30	Negative	Negative	339	F	34	Negative	Negative
303	M	35	Negative	Negative	340	F	33	Negative	Negative
304	M	27	Negative	Negative	341	M	38	Negative	Negative
305	M	45	Negative	Negative	342	M	48	Negative	Negative
306	M	34	Negative	Negative	343	F	35	Negative	Negative
307	M	46	Negative	Negative	344	M	25	Negative	Negative
308	F	20	Negative	Negative	345	M	29	Negative	Negative
309	F	40	Negative	Negative	346	F	37	Negative	Negative
310	M	34	Negative	Negative	347	F	41	Negative	Negative
311	M	28	Negative	Negative	348	F	37	Negative	Negative
312	F	42	Negative	Negative	349	F	30	Negative	Negative
313	F	28	Negative	Negative	350	F	34	Negative	Negative
314	M	29	Negative	Negative	351	F	26	Negative	Negative
315	F	34	Negative	Negative	352	M	38	Negative	Negative
316	M	37	Negative	Negative	353	F	42	Negative	Negative
317	M	35	Negative	Negative	354	F	37	Negative	Negative
318	M	22	Negative	Negative	355	M	45	Negative	Negative
319	M	37	Negative	Negative	356	F	28	Negative	Negative
320	F	39	Negative	Negative	357	F	29	Negative	Negative
321	M	53	Negative	Negative	358	F	27	Negative	Negative
322	M	51	Negative	Negative	359	F	39	Negative	Negative
323	M	24	Negative	Negative	360	F	25	Negative	Negative
324	F	34	Negative	Negative	361	F	33	Negative	Negative
325	F	32	Negative	Negative	362	F	27	Negative	Negative
326	M	22	Negative	Negative	363	F	31	Negative	Negative
327	F	29	Negative	Negative	364	F	32	Negative	Negative
328	M	34	Negative	Negative	365	F	29	Negative	Negative
329	M	41	Negative	Negative	366	F	36	Negative	Negative
330	F	35	Negative	Negative	367	F	35	Negative	Negative
331	F	28	Negative	Negative	368	F	33	Negative	Negative

NO.	Gender	Age	COVID-19 Test kit	RT-PCR	NO.	Gender	Age	COVID-19 Test kit	RT-PCR
369	F	33	Negative	Negative	406	F	23	Negative	Negative
370	F	41	Negative	Negative	407	F	39	Negative	Negative
371	F	36	Negative	Negative	408	F	23	Negative	Negative
372	F	33	Negative	Negative	409	M	30	Negative	Negative
373	F	33	Negative	Negative	410	M	28	Negative	Negative
374	M	24	Negative	Negative	411	M	25	Negative	Negative
375	F	35	Negative	Negative	412	F	38	Negative	Negative
376	M	28	Negative	Negative	413	M	34	Negative	Negative
377	F	29	Negative	Negative	414	M	38	Negative	Negative
378	F	47	Negative	Negative	415	F	24	Positive	Negative
379	M	27	Negative	Negative	416	F	29	Negative	Negative
380	M	31	Negative	Negative	417	F	29	Negative	Negative
381	F	32	Negative	Negative	418	F	30	Negative	Negative
382	M	32	Negative	Negative	419	F	36	Negative	Negative
383	F	32	Negative	Negative	420	M	31	Negative	Negative
384	F	34	Negative	Negative	421	F	59	Negative	Negative
385	M	32	Negative	Negative	422	F	31	Negative	Negative
386	M	22	Negative	Negative	423	M	30	Negative	Negative
387	F	35	Negative	Negative	424	F	43	Negative	Negative
388	M	28	Negative	Negative	425	F	26	Positive	Negative
389	F	38	Negative	Negative	426	F	44	Negative	Negative
390	M	30	Negative	Negative	427	F	39	Negative	Negative
391	M	28	Negative	Negative	428	M	38	Negative	Negative
392	F	37	Negative	Negative	429	M	38	Negative	Negative
393	M	22	Negative	Negative	430	F	28	Negative	Negative
394	F	27	Negative	Negative	431	F	27	Negative	Negative
395	F	33	Negative	Negative	432	F	34	Negative	Negative
396	F	49	Negative	Negative	433	M	23	Negative	Negative
397	F	42	Negative	Negative	434	M	28	Negative	Negative
398	F	27	Positive	Negative	435	M	27	Negative	Negative
399	F	39	Negative	Negative	436	F	22	Negative	Negative
400	M	45	Negative	Negative	437	F	29	Negative	Negative
401	F	35	Negative	Negative	438	F	33	Negative	Negative
402	F	39	Negative	Negative	439	F	22	Negative	Negative
403	F	30	Negative	Negative	440	F	27	Negative	Negative
404	F	29	Negative	Negative	441	M	27	Negative	Negative
405	F	35	Negative	Negative	442	M	25	Negative	Negative

NO.	Gender	Age	COVID-19 Test kit	RT-PCR	NO.	Gender	Age	COVID-19 Test kit	RT-PCR
443	F	41	Negative	Negative	480	F	28	Negative	Negative
444	M	36	Negative	Negative	481	F	33	Negative	Negative
445	M	32	Negative	Negative	482	M	30	Negative	Negative
446	M	37	Negative	Negative	483	F	29	Negative	Negative
447	F	25	Negative	Negative	484	M	38	Negative	Negative
448	M	35	Negative	Negative	485	F	22	Negative	Negative
449	F	34	Negative	Negative	486	F	25	Negative	Negative
450	F	29	Negative	Negative	487	F	30	Negative	Negative
451	M	22	Negative	Negative	488	F	36	Negative	Negative
452	M	23	Negative	Negative	489	M	35	Negative	Negative
453	F	25	Negative	Negative	490	M	30	Negative	Negative
454	M	29	Negative	Negative	491	F	38	Negative	Negative
455	M	27	Negative	Negative	492	F	33	Negative	Negative
456	M	23	Negative	Negative	493	M	36	Negative	Negative
457	M	26	Negative	Negative	494	M	46	Negative	Negative
458	M	27	Negative	Negative	495	M	38	Negative	Negative
459	M	35	Negative	Negative	496	M	42	Negative	Negative
460	F	30	Negative	Negative	497	M	29	Negative	Negative
461	M	34	Negative	Negative	498	M	31	Negative	Negative
462	M	29	Negative	Negative	499	F	31	Negative	Negative
463	M	30	Negative	Negative	500	F	37	Negative	Negative
464	M	28	Negative	Negative	501	M	38	Negative	Negative
465	M	23	Negative	Negative	502	F	29	Negative	Negative
466	F	29	Negative	Negative	503	F	27	Negative	Negative
467	F	32	Negative	Negative	504	M	43	Negative	Negative
468	M	26	Negative	Negative	505	M	31	Negative	Negative
469	M	22	Negative	Negative	506	M	33	Negative	Negative
470	F	28	Negative	Negative	507	M	31	Negative	Negative
471	M	26	Negative	Negative	508	M	32	Negative	Negative
472	M	39	Negative	Negative	509	M	34	Negative	Negative
473	M	23	Negative	Negative	510	F	29	Negative	Negative
474	M	30	Negative	Negative	511	F	26	Negative	Negative
475	F	52	Negative	Negative	512	F	30	Negative	Negative
476	M	29	Negative	Negative	513	F	36	Negative	Negative
477	F	58	Negative	Negative	514	M	37	Negative	Negative
478	F	51	Negative	Negative	515	M	30	Negative	Negative
479	M	28	Negative	Negative	516	F	27	Negative	Negative

NO.	Gender	Age	COVID-19 Test kit	RT-PCR	NO.	Gender	Age	COVID-19 Test kit	RT-PCR
517	F	37	Negative	Negative	518	F	31	Negative	Negative

Annex 2：

NO.	Gender	Age	Test Reagent （FLU A）	Reference Reagent	NO.	Gender	Age	Test Reagent （FLU A）	Reference Reagent
1	F	41	Positive	Positive	47	M	30	Positive	Positive
2	F	35	Positive	Positive	48	F	29	Positive	Positive
3	M	49	Positive	Positive	49	F	37	Positive	Positive
4	F	50	Positive	Positive	50	M	72	Positive	Positive
5	F	74	Positive	Positive	51	F	44	Positive	Positive
6	M	27	Positive	Positive	52	F	24	Positive	Positive
7	F	29	Positive	Positive	53	F	39	Positive	Positive
8	F	36	Positive	Positive	54	M	28	Positive	Positive
9	F	31	Positive	Positive	55	F	69	Positive	Positive
10	F	35	Positive	Positive	56	F	24	Positive	Positive
11	F	43	Positive	Positive	57	F	33	Positive	Positive
12	F	44	Positive	Positive	58	F	33	Positive	Positive
13	M	35	Positive	Positive	59	M	50	Positive	Positive
14	M	34	Positive	Positive	60	M	9	Positive	Positive
15	F	42	Positive	Positive	61	F	41	Positive	Positive
16	M	40	Positive	Positive	62	M	45	Positive	Positive
17	M	27	Negative	Positive	63	F	21	Positive	Positive
18	M	27	Positive	Positive	64	M	22	Positive	Positive
19	F	38	Positive	Positive	65	M	34	Positive	Positive
20	M	25	Positive	Positive	66	M	67	Positive	Positive
21	M	17	Positive	Positive	67	M	32	Positive	Positive
22	F	26	Positive	Positive	68	M	64	Positive	Positive
23	F	22	Positive	Positive	69	F	34	Positive	Positive
24	F	31	Positive	Positive	70	M	45	Positive	Positive
25	F	34	Positive	Positive	71	F	37	Positive	Positive
26	F	27	Positive	Positive	72	F	39	Positive	Positive
27	F	35	Positive	Positive	73	M	39	Positive	Positive
28	M	64	Positive	Positive	74	M	21	Negative	Positive
29	M	7	Positive	Positive	75	M	1	Positive	Positive
30	F	37	Positive	Positive	76	M	22	Positive	Positive
31	M	40	Positive	Positive	77	F	29	Positive	Positive
32	F	60	Positive	Positive	78	F	27	Positive	Positive
33	M	23	Positive	Positive	79	M	39	Positive	Positive
34	F	12	Positive	Positive	80	F	42	Positive	Positive
35	M	30	Negative	Positive	81	M	28	Positive	Positive
36	M	23	Positive	Positive	82	M	36	Positive	Positive

NO.	Gender	Age	Test Reagent （FLU A）	Reference Reagent	NO.	Gender	Age	Test Reagent （FLU A）	Reference Reagent
37	F	50	Positive	Positive	83	F	28	Positive	Positive
38	F	52	Positive	Positive	84	F	37	Positive	Positive
39	M	66	Positive	Positive	85	M	38	Positive	Positive
40	M	40	Positive	Positive	86	M	40	Positive	Positive
41	F	15	Positive	Positive	87	F	25	Positive	Positive
42	M	32	Positive	Positive	88	F	39	Positive	Positive
43	F	50	Positive	Positive	89	M	39	Positive	Positive
44	F	30	Positive	Positive	90	M	33	Positive	Positive
45	F	37	Positive	Positive	91	F	30	Positive	Positive
46	F	23	Positive	Positive	92	M	28	Positive	Positive

Annex 3：

NO.	Gender	Age	Test Reagent（FLU B）	Reference Reagent	NO.	Gender	Age	Test Reagent（FLU B）	Reference Reagent
1	F	14	Positive	Positive	51	F	48	Positive	Positive
2	F	35	Positive	Positive	52	M	36	Positive	Positive
3	M	30	Positive	Positive	53	M	48	Positive	Positive
4	M	29	Positive	Positive	54	F	55	Positive	Positive
5	F	8	Positive	Positive	55	F	56	Positive	Positive
6	M	21	Positive	Positive	56	M	22	Positive	Positive
7	F	43	Positive	Positive	57	F	41	Positive	Positive
8	F	38	Positive	Positive	58	M	62	Positive	Positive
9	M	34	Positive	Positive	59	M	74	Positive	Positive
10	F	33	Negative	Positive	60	M	30	Positive	Positive
11	F	24	Positive	Positive	61	F	58	Positive	Positive
12	F	18	Positive	Positive	62	M	70	Positive	Positive
13	M	26	Positive	Positive	63	M	44	Positive	Positive
14	F	33	Positive	Positive	64	M	35	Positive	Positive
15	F	48	Positive	Positive	65	M	43	Positive	Positive
16	F	50	Positive	Positive	66	F	28	Positive	Positive
17	F	24	Positive	Positive	67	M	25	Positive	Positive
18	F	30	Positive	Positive	68	M	34	Positive	Positive
19	M	31	Positive	Positive	69	M	24	Positive	Positive
20	F	36	Positive	Positive	70	F	30	Positive	Positive
21	M	40	Positive	Positive	71	F	55	Positive	Positive
22	F	31	Positive	Positive	72	M	42	Positive	Positive
23	M	45	Positive	Positive	73	F	40	Positive	Positive
24	M	28	Positive	Positive	74	F	37	Positive	Positive
25	F	36	Positive	Positive	75	M	19	Positive	Positive
26	F	73	Positive	Positive	76	F	25	Positive	Positive
27	F	39	Positive	Positive	77	M	36	Positive	Positive
28	M	27	Positive	Positive	78	M	39	Positive	Positive
29	M	69	Positive	Positive	79	F	20	Positive	Positive
30	F	32	Positive	Positive	80	F	35	Positive	Positive
31	F	45	Positive	Positive	81	M	47	Positive	Positive
32	F	33	Positive	Positive	82	F	32	Positive	Positive
33	M	21	Positive	Positive	83	M	25	Positive	Positive
34	F	36	Positive	Positive	84	F	36	Positive	Positive
35	M	36	Positive	Positive	85	M	41	Positive	Positive
36	F	27	Positive	Positive	86	M	38	Positive	Positive

NO.	Gender	Age	Test Reagent （FLU B）	Reference Reagent	NO.	Gender	Age	Test Reagent （FLU B）	Reference Reagent
37	M	24	Positive	Positive	87	F	32	Positive	Positive
38	M	66	Positive	Positive	88	M	43	Positive	Positive
39	M	35	Positive	Positive	89	M	38	Negative	Positive
40	M	23	Positive	Positive	90	F	15	Positive	Positive
41	M	23	Positive	Positive	91	M	36	Positive	Positive
42	F	37	Positive	Positive	92	F	46	Positive	Positive
43	M	22	Positive	Positive	93	F	30	Positive	Positive
44	F	33	Positive	Positive	94	M	36	Positive	Positive
45	M	46	Positive	Positive	95	F	33	Positive	Positive
46	M	48	Positive	Positive	96	F	18	Positive	Positive
47	M	24	Positive	Positive	97	F	25	Positive	Positive
48	F	34	Positive	Positive	98	F	27	Positive	Positive
49	M	40	Positive	Positive	99	M	32	Positive	Positive
50	M	35	Positive	Positive					

Annex 4:

NO.	Gender	Age	Test Reagent （FLU A/B）	Reference Reagent	NO.	Gender	Age	Test Reagent （FLU A/B	Reference Reagent
1	M	28	Negative	Negative	109	M	24	Negative	Negative
2	F	28	Negative	Negative	110	M	43	Negative	Negative
3	F	28	Negative	Negative	111	F	27	Negative	Negative
4	F	41	Negative	Negative	112	F	23	Negative	Negative
5	F	65	Negative	Negative	113	F	27	Negative	Negative
6	F	50	Negative	Negative	114	F	50	Negative	Negative
7	M	32	Negative	Negative	115	F	39	Negative	Negative
8	M	28	Negative	Negative	116	F	50	Negative	Negative
9	F	27	Negative	Negative	117	M	37	Negative	Negative
10	F	35	Negative	Negative	118	M	33	Negative	Negative
11	F	32	Negative	Negative	119	M	45	Negative	Negative
12	F	32	Negative	Negative	120	M	35	Negative	Negative
13	F	63	Negative	Negative	121	M	64	Negative	Negative
14	M	30	Negative	Negative	122	M	51	Negative	Negative
15	F	47	Negative	Negative	123	M	28	Negative	Negative
16	F	39	Negative	Negative	124	M	31	Negative	Negative
17	M	40	Negative	Negative	125	F	49	Negative	Negative
18	F	37	Negative	Negative	126	F	30	Negative	Negative
19	F	31	Negative	Negative	127	F	39	Negative	Negative
20	F	52	Negative	Negative	128	F	27	Negative	Negative
21	F	27	Negative	Negative	129	F	56	Negative	Negative
22	M	29	Negative	Negative	130	F	30	Negative	Negative
23	M	54	Negative	Negative	131	M	27	Negative	Negative
24	M	29	Negative	Negative	132	F	37	Negative	Negative
25	F	47	Negative	Negative	133	M	38	Negative	Negative
26	F	33	Negative	Negative	134	F	29	Negative	Negative
27	M	41	Negative	Negative	135	F	36	Negative	Negative
28	M	46	Negative	Negative	136	M	48	Negative	Negative
29	M	32	Negative	Negative	137	M	26	Negative	Negative
30	M	42	Negative	Negative	138	F	36	Negative	Negative
31	F	30	Negative	Negative	139	F	29	Negative	Negative
32	M	53	Negative	Negative	140	F	28	Negative	Negative
33	F	24	Negative	Negative	141	F	29	Negative	Negative
34	M	65	Negative	Negative	142	F	20	Negative	Negative
35	F	33	Negative	Negative	143	F	41	Negative	Negative
36	M	30	Negative	Negative	144	F	31	Negative	Negative

NO.	Gender	Age	Test Reagent （FLU A/B）	Reference Reagent	NO.	Gender	Age	Test Reagent （FLU A/B	Reference Reagent
37	M	32	Negative	Negative	145	F	24	Negative	Negative
38	M	22	Negative	Negative	146	F	27	Negative	Negative
39	F	36	Negative	Negative	147	F	49	Negative	Negative
40	M	29	Negative	Negative	148	F	42	Negative	Negative
41	M	34	Negative	Negative	149	M	29	Negative	Negative
42	M	8	Negative	Negative	150	F	61	Negative	Negative
43	M	35	Negative	Negative	151	F	74	Negative	Negative
44	M	38	Negative	Negative	152	F	31	Negative	Negative
45	F	52	Negative	Negative	153	M	35	Negative	Negative
46	F	29	Negative	Negative	154	M	37	Negative	Negative
47	M	50	Negative	Negative	155	F	27	Negative	Negative
48	F	16	Negative	Negative	156	F	47	Negative	Negative
49	M	33	Negative	Negative	157	F	71	Negative	Negative
50	M	33	Negative	Negative	158	M	41	Negative	Negative
51	F	41	Negative	Negative	159	F	35	Negative	Negative
52	M	28	Negative	Negative	160	F	13	Negative	Negative
53	F	57	Negative	Negative	161	F	33	Negative	Negative
54	M	35	Negative	Negative	162	F	35	Negative	Negative
55	M	52	Negative	Negative	163	M	66	Negative	Negative
56	F	17	Negative	Negative	164	F	78	Negative	Negative
57	M	22	Negative	Negative	165	M	30	Negative	Negative
58	M	67	Negative	Negative	166	F	39	Negative	Negative
59	F	39	Negative	Negative	167	M	22	Negative	Negative
60	M	57	Negative	Negative	168	F	34	Negative	Negative
61	M	23	Negative	Negative	169	M	41	Negative	Negative
62	F	30	Negative	Negative	170	F	58	Negative	Negative
63	F	48	Negative	Negative	171	F	37	Negative	Negative
64	M	44	Negative	Negative	172	F	59	Negative	Negative
65	M	38	FLU A Positive	Negative	173	M	36	Negative	Negative
66	F	45	Negative	Negative	174	M	33	Negative	Negative
67	F	38	Negative	Negative	175	F	41	Negative	Negative
68	M	59	Negative	Negative	176	F	65	Negative	Negative
69	F	58	Negative	Negative	177	M	37	Negative	Negative
70	F	37	Negative	Negative	178	F	37	Negative	Negative
71	F	31	Negative	Negative	179	M	50	Negative	Negative
72	M	34	Negative	Negative	180	M	43	Negative	Negative

NO.	Gender	Age	Test Reagent（FLU A/B）	Reference Reagent	NO.	Gender	Age	Test Reagent（FLU A/B	Reference Reagent
73	M	39	Negative	Negative	181	F	39	FLU B Positive	Negative
74	M	44	Negative	Negative	182	M	25	Negative	Negative
75	M	45	Negative	Negative	183	F	33	Negative	Negative
76	M	24	Negative	Negative	184	F	27	Negative	Negative
77	M	25	Negative	Negative	185	F	35	Negative	Negative
78	M	28	Negative	Negative	186	F	40	Negative	Negative
79	F	33	Negative	Negative	187	F	23	Negative	Negative
80	F	51	Negative	Negative	188	F	16	Negative	Negative
81	F	39	Negative	Negative	189	M	45	Negative	Negative
82	M	37	Negative	Negative	190	F	26	Negative	Negative
83	F	27	Negative	Negative	191	F	37	Negative	Negative
84	F	33	Negative	Negative	192	M	47	Negative	Negative
85	F	9	Negative	Negative	193	F	30	Negative	Negative
86	M	58	Negative	Negative	194	M	40	Negative	Negative
87	M	24	Negative	Negative	195	F	15	Negative	Negative
88	F	43	Negative	Negative	196	F	33	Negative	Negative
89	F	24	Negative	Negative	197	F	24	Negative	Negative
90	M	28	Negative	Negative	198	F	35	Negative	Negative
91	F	33	Negative	Negative	199	F	23	Negative	Negative
92	M	44	Negative	Negative	200	M	18	Negative	Negative
93	M	34	Negative	Negative	201	F	39	Negative	Negative
94	M	15	Negative	Negative	202	F	10	Negative	Negative
95	F	50	Negative	Negative	203	M	57	Negative	Negative
96	M	10	Negative	Negative	204	F	46	Negative	Negative
97	M	36	Negative	Negative	205	F	17	Negative	Negative
98	M	28	Negative	Negative	206	F	38	Negative	Negative
99	F	33	Negative	Negative	207	F	41	Negative	Negative
100	M	22	Negative	Negative	208	F	36	Negative	Negative
101	F	40	Negative	Negative	209	M	44	Negative	Negative
102	M	18	Negative	Negative	210	F	49	Negative	Negative
103	M	57	Negative	Negative	211	F	28	Negative	Negative
104	F	35	Negative	Negative	212	F	48	Negative	Negative
105	M	21	Negative	Negative	213	F	19	Negative	Negative
106	M	53	Negative	Negative	214	M	34	Negative	Negative
107	F	35	Negative	Negative	215	M	25	Negative	Negative
108	F	48	Negative	Negative					