Clinical Evaluation Report

Investigation product	Influenza A/B+COVID-19/RSV Combo Ag Test
Brand holder	CorDx, Inc. 9540 Waples St Unit C, San Diego, CA 92121
Study start date	2022.01.20
Study finish date	2022.03.15
Sponsor	Core Technology Co., Ltd. Room 100, C Building, No.29 Life Park Rd., Changping District, Beijing 102206, P.R. China
Principal investigator	Li Yi; Chen Lijuan
Research unit	Beijing Electric Power Hospital Beijing Centre for Disease Prevention and Control
Report date	2022.03.22
Raw data archived	Beijing Electric Power Hospital Beijing Centre for Disease Prevention and Control

Contents

1. Background

Influenza is a highly contagious, acute respiratory disease usually caused by influenza A (Flu A) and influenza B (Flu B) viruses with symptoms such as headache, chills, dry cough, body aches or fever. It is a communicable disease that is easily transmitted through aerosolized droplets containing live virus from coughing and sneezing. Influenza A viruses are typically more prevalent than influenza B viruses and are associated with most sensitive influenza epidemics. Influenza is an important public health issue of global concern.

Respiratory syncytial virus (RSV) is an RNA virus belonging to the paramyxoviridae family. The disease is spread by airborne droplets and close contact. It is more common in newborns and infants less than 6 months old. The incubation period is 3~7 days. When infected with RSV, upper respiratory tract infection is the main symptom in adults and elder children, while infants and young children have more severe symptoms, including high fever, rhinitis, pharyngitis and laryngitis, followed by bronchiolitis and pneumonia. A few sick children can be complicated with otitis media, pleurisy and myocarditis, etc.

To help fight against influenza A, influenza B and respiratory syncytial virus, CorDx, Inc. has developed an over-the-counter at home self-collection lateral flow antigen test for the detection of influenza A, influenza B and respiratory syncytial virus antigen in nasal swab samples. The test detects influenza A, influenza B and respiratory syncytial virus nucleocapsid N protein.

2. Study Overview

This is a multi-site prospective study to evaluate the clinical performance of the investigational test, CorDx Influenza A/B+COVID-19/RSV Combo Ag Test for the detection of the Flu A, Flu B and RSV antigen in nasal swab samples. The investigational test results are compared to results obtained from the CE marked Influenza A/B+COVID-19/RSV Combo Ag Test (reference test) manufactured by Abiores Technology (Beijing) Co., Ltd (Abiores).

The study evaluates the investigational test performance in symptomatic and asymptomatic individuals. A total of 452 subjects who are currently experiencing symptoms associated with Flu A, Flu B or RSV, or asymptomatic subjects are enrolled.

Two nasal swab samples were collected from each enrolled subject, and all samples were randomly blinded. One nasal swab was tested with the investigational test and the other tested with the reference test. Samples with inconsistent test results between the investigational test and the reference test were confirmed by PCR nucleic acid reagent.

3. Study Objective

The objective of this study is to evaluate the clinical performance of the CorDx Influenza A/B+COVID-19/RSV Combo Ag Test for the detection of nucleocapsid protein antigen from influenza A, influenza B and respiratory syncytial virus in nasal swab specimens by comparison testing with the selected CE marked Abiores's Influenza A/B+COVID-19/RSV Combo Ag Test.

4. Study Content

4.1 Study Institutions and Period

Study institutions:

Institution 1: Beijing Centre for Disease Prevention and Control

Address: No. 16, Hepingli Middle Street, Dongcheng District, Beijing, P.R. China

Researcher: Cui Shujuan (associate researcher), Chen Lijuan (chief technician)

Institution 2: Beijing Electric Power Hospital

Address: No. 1, Taiping Bridge Xili A, Fengtai District, Beijing, P.R. China

Researcher: Xu Junyue (deputy chief technician), Li Yi (chief technician)

Study period: 2022/01/20-2022/03/15

4.2 Study Product

Table 1 Investigational Test Info.

Investigational Test	Influenza A/B+COVID-19/RSV Combo Ag Test		
Specification	25 tests /box	Lot No.	20211229
Expiration Date	20231228	Storage	2~30℃
Manufacturer	CorDx, Inc. 9540 Waples St Unit C, San Diego, CA 92121		
Manufacturing site	Core Technology Co., Ltd. Room 100, C Building, No.29 Life Park Rd., Changping District, Beijing 102206, P.R. China		

Table 2 Reference Test Info.

Reference Test	Influenza A/B+COVID-19/RSV Combo Ag Test		
Specification	25 tests/box	Lot No.	20211010
Expiration Date	2023/10/09	Storage	2~30℃
Manufacturer	Abiores Technology (Beijing) Co., Ltd. No. 8 Central Road, Doudian Town, Fangshan District, 102433 Beijing, P.R. China		
Regulatory Status	CE Marked		

Table 3 FLU A/B PCR Confirmation Reagent Info.

Confirmation Reagent	Influenza A Virus and Influenza B Virus RNA Diagnostic Kit (Fluorescence PCR)		
Specification	24 tests /box	Lot No.	20220110
Expiration Date	2022-09-09	Storage	-20 ± 5℃, away from light
Manufacturer	Abiores Technology (Beijing) Co., Ltd. No. 8 Central Road, Doudian Town, Fangshan District, 102433 Beijing, P.R. China		
Regulatory Status	CE Marked		
Applicable instrument	Mx3000P QPCR Systems (Agilent Technologies Inc.)		

Table 4 RSV PCR Confirmation Reagent Info.

Confirmation Reagent	Respiratory Syncytial Virus RNA Diagnostic Kit (Fluorescence PCR)		
Specification	24 tests /box	Lot No.	20211221
Expiration Date	2022-08-20	Storage	Nucleic acid extraction reagent: 2~8℃, away from light
			Amplification reagent: -20 ± 5℃, away from light
Manufacturer	Abiores Technology (Beijing) Co., Ltd. No. 8 Central Road, Doudian Town, Fangshan District, 102433 Beijing, P.R. China		
Regulatory Status	CE Marked		
Applicable instrument	Mx3000P QPCR Systems (Agilent Technologies Inc.)		

4.3 Study Sample Size

Sample type	Positive sample	Negative sample	Cross-reactivity sample
Influenza A	51	200	50
Influenza B	51		
RSV	100		

4.4 Sample Collection and Storage

For each subject, two nasal swab samples were collected. All samples were randomly blinded. One swab sample was collected and tested with the investigational test according to its instructions for use. The other was collected and tested with the reference test according to its instructions for use. Two tests were conducted simultaneously.

For inconsistent nasal swab results, one oropharyngeal swab sample was collected and tested for confirmation with the PCR reagent according to its instructions.

Swab samples shall be extracted and tested as soon as possible. The sample can be stored at 2℃~8℃ for 72 hours, and it needs to be frozen at -20℃ for long-term storage,

avoiding repeated freezing and thawing.

4.5 Sample Inclusion Criteria

(1) Diagnosed Flu A/B and RSV positive samples.

(2) Samples from individuals for whom investigators believe Flu A/B and RSV testing are needed.

4.6 Sample Exclusion Criteria

(1) Extracted samples that have been stored in a liquid format for more than 72 hours before freezing.

(2) Extracted samples that have been repeatedly frozen and thawed more than 3 times.

(3) The remaining sample volume is less than 100μL.

5. Statistical Results of the Clinical Evaluation

Note: “F” indicates female, “M” indicates male

Table 1 Test results of 51 Flu A samples

No.	Subject ID	Gender	Age	CorDx test result	Reference test result	Comment	PCR test result	Sampling date	Clinical diagnosis
				FLU A	FLU A				
1	1718hr1443	F	30	+	+	Consistent	/	2018/3/12	Influenza suspect
2	1718hr0769	F	26	+	+	Consistent	/	2017/12/20	Influenza suspect
3	1718hr0947	M	66	+	+	Consistent	/	2018/1/11	Influenza suspect
4	1718hr1346	F	31	+	+	Consistent	/	2018/2/25	Influenza suspect
5	210429	F	75	+	+	Consistent	/	2022/2/10	Fever
6	1718hr0801	M	35	+	+	Consistent	/	2017/12/25	Influenza suspect
7	1718hr1240	M	39	+	+	Consistent	/	2018/2/6	Influenza suspect
8	1718hr1399	M	45	+	+	Consistent	/	2018/3/6	Influenza suspect
9	210215	M	33	+	-	Inconsistent	CT: 35.09 Positive	2022/2/10	Fever
10	1718hr1408	F	54	+	+	Consistent	/	2018/3/7	Influenza suspect
11	210497	F	69	+	+	Consistent	/	2022/2/10	Fever
12	1718hr0615	M	50	+	+	Consistent	/	2017/12/6	Influenza suspect
13	1718hr1277	F	32	+	+	Consistent	/	2018/2/12	Influenza suspect
14	1718hr0583	F	48	+	+	Consistent	/	2017/12/4	Influenza suspect

No.	Subject ID	Gender	Age	CorDx test result	Reference test result	Comment	PCR test result	Sampling date	Clinical diagnosis
				FLU A	FLU A				
15	1718hr1232	F	30	+	+	Consistent	/	2018/2/5	Influenza suspect
16	1718hr1206	F	34	+	+	Consistent	/	2018/2/1	Influenza suspect
17	210110	M	51	+	+	Consistent	/	2022/2/10	Fever
18	1718hr0450	M	28	+	+	Consistent	/	2017/11/20	Influenza suspect
19	1718hr1448	F	58	+	+	Consistent	/	2018/3/13	Influenza suspect
20	1718hr1230	M	38	+	+	Consistent	/	2018/2/5	Influenza suspect
21	1718hr1559	M	6	+	+	Consistent	/	2018/4/1	Influenza suspect
22	1718hr1195	F	6	+	+	Consistent	/	2018/1/31	Influenza suspect
23	1718hr1381	M	60	+	+	Consistent	/	2018/3/1	Influenza suspect
24	1718hr0432	F	31	+	+	Consistent	/	2017/11/16	Influenza suspect
25	1718hr1259	F	4	+	+	Consistent	/	2018/2/7	Influenza suspect
26	1718hr1201	F	37	+	+	Consistent	/	2018/2/1	Influenza suspect
27	1718hr1219	F	36	+	+	Consistent	/	2018/2/5	Influenza suspect
28	1718hr1202	F	66	+	+	Consistent	/	2018/1/31	Influenza suspect
29	1718hr0646	F	27	+	+	Consistent	/	2017/12/11	Influenza suspect
30	210045	M	44	+	+	Consistent	/	2022/2/10	Fever
31	1718hr1042	M	48	+	+	Consistent	/	2018/1/17	Influenza suspect
32	1718hr1510	M	17	+	+	Consistent	/	2018/3/25	Influenza suspect
33	210176	M	46	+	+	Consistent	/	2022/2/10	Fever
34	1718hr0578	F	33	+	+	Consistent	/	2017/12/4	Influenza suspect
35	1718hr1181	F	48	+	+	Consistent	/	2018/1/31	Influenza suspect
36	1718hr0922	M	31	+	+	Consistent	/	2018/1/9	Influenza suspect
37	210028	M	31	+	+	Consistent	/	2022/2/10	Fever
38	1718hr1246	M	32	+	+	Consistent	/	2018/2/5	Influenza suspect
39	210088	M	54	+	+	Consistent	/	2022/2/10	Fever
40	1718hr1196	F	2	+	+	Consistent	/	2018/1/31	Influenza suspect
41	210308	M	37	+	+	Consistent	/	2022/2/10	Fever

No.	Subject ID	Gender	Age	CorDx test result	Reference test result	Comment	PCR test result	Sampling date	Clinical diagnosis
				FLU A	FLU A				
42	210262	F	30	+	+	Consistent	/	2022/2/10	Fever
43	210217	F	56	+	-	Inconsistent	CT: 35.34 Positive	2022/2/10	Fever
44	1718hr1319	F	29	+	+	Consistent	/	2018/2/21	Influenza suspect
45	1718hr1250	M	37	+	+	Consistent	/	2018/2/6	Influenza suspect
46	1718hr1199	M	4	+	+	Consistent	/	2018/1/31	Influenza suspect
47	1718hr0986	F	15	+	+	Consistent	/	2018/1/15	Influenza suspect
48	1718hr1368	M	82	+	+	Consistent	/	2018/2/26	Influenza suspect
49	1718hr1252	F	31	+	+	Consistent	/	2018/2/6	Influenza suspect
50	1718hr0905	M	12	+	+	Consistent	/	2018/1/8	Influenza suspect
51	1718hr0537	F	22	+	+	Consistent	/	2017/11/30	Influenza suspect

Table 2 Test results of 51 influenza B samples

No.	Subject ID	Gender	Age	CorDx test result	Reference test result	Comment	PCR test result	Sampling date	Clinical diagnosis
				FLU B	FLU B				
1	306510	F	35	-	+	Inconsistent	CT: 35.5 Positive	2022/3/6	Fever
2	307003	M	45	+	+	Consistent	/	2022/3/7	Fever
3	302606	M	29	+	+	Consistent	/	2022/3/2	Fever
4	226307	F	31	+	+	Consistent	/	2022/2/26	Fever
5	304515	M	33	+	-	Inconsistent	CT: 34.57 Positive	2022/3/4	Fever
6	302609	F	31	+	+	Consistent	/	2022/3/2	Fever
7	302622	M	42	+	+	Consistent	/	2022/3/2	Fever
8	306521	M	36	+	+	Consistent	/	2022/3/6	Fever
9	306518	F	29	+	+	Consistent	/	2022/3/6	Fever
10	303511	M	30	+	+	Consistent	/	2022/3/3	Fever
11	228510	M	36	+	+	Consistent	/	2022/2/28	Fever
12	227507	M	30	+	+	Consistent	/	2022/2/27	Fever
13	223504	F	36	+	+	Consistent	/	2022/2/23	Fever
14	303504	F	51	+	+	Consistent	/	2022/3/3	Fever
15	306522	M	31	+	+	Consistent	/	2022/3/6	Fever
16	223503	M	33	+	+	Consistent	/	2022/2/23	Fever
17	303508	M	38	+	+	Consistent	/	2022/3/3	Fever

No.	Subject ID	Gender	Age	CorDx test result	Reference test result	Comment	PCR test result	Sampling date	Clinical diagnosis
				FLU B	FLU B				
18	303505	M	33	+	+	Consistent	/	2022/3/3	Fever
19	303502	F	33	+	+	Consistent	/	2022/3/3	Fever
20	227506	M	15	+	+	Consistent	/	2022/2/27	Fever
21	302604	F	31	+	+	Consistent	/	2022/3/2	Fever
22	306524	F	28	+	+	Consistent	/	2022/3/6	Fever
23	306520	F	33	+	+	Consistent	/	2022/3/6	Fever
24	302602	M	26	+	+	Consistent	/	2022/3/2	Fever
25	301501	F	31	+	+	Consistent	/	2022/3/1	Fever
26	228511	M	38	+	+	Consistent	/	2022/2/28	Fever
27	302603	M	27	+	+	Consistent	/	2022/3/2	Sore throat
28	226309	M	25	+	+	Consistent	/	2022/2/26	Fever
29	306523	M	40	+	+	Consistent	/	2022/3/6	Fever
30	306527	F	35	+	+	Consistent	/	2022/3/6	Fever
31	302614	M	32	+	+	Consistent	/	2022/3/2	Fever
32	228515	M	32	+	+	Consistent	/	2022/2/28	Fever, FLU B Positive
33	227509	F	35	+	+	Consistent	/	2022/2/27	Fever
34	227508	M	56	+	+	Consistent	/	2022/2/27	Fever
35	302607	M	48	+	+	Consistent	/	2022/3/2	Fever
36	226301	M	41	+	+	Consistent	/	2022/2/26	Fever
37	226308	M	26	+	+	Consistent	/	2022/2/26	Fever
38	303510	M	33	+	+	Consistent	/	2022/3/3	Fever
39	303503	F	50	+	+	Consistent	/	2022/3/3	Fever
40	302613	M	30	+	+	Consistent	/	2022/3/2	Fever
41	227504	F	32	+	+	Consistent	/	2022/2/27	Fever
42	306514	F	50	-	+	Inconsistent	CT: 35.71 Positive	2022/3/6	Fever
43	305501	F	32	+	+	Consistent	/	2022/3/5	Fever
44	306505	M	37	+	+	Consistent	/	2022/3/6	Pneumonia
45	227502	F	38	+	+	Consistent	/	2022/2/27	Fever
46	224302	F	29	+	+	Consistent	/	2022/2/24	Fever
47	228514	F	34	+	+	Consistent	/	2022/2/28	Fever
48	302605	M	27	+	+	Consistent	/	2022/3/2	Fever
49	301504	F	28	+	+	Consistent	/	2022/3/1	Fever
50	306526	F	28	+	+	Consistent	/	2022/3/6	Fever
51	307006	F	33	+	+	Consistent	/	2022/3/7	Fever

Table 3 Test results of 100 RSV samples

No.	Subject ID	Gender	Age	CorDx test result	Reference test result	Comment	PCR test result	Sampling date	Clinical diagnosis

				RSV	RSV				
1	120127	M	21	+	+	Consistent	/	2022/1/20	Fever
2	208021	M	58	+	+	Consistent	/	2022/2/8	Fever
3	126055	M	60	+	+	Consistent	/	2022/1/26	Fever
4	128131	M	23	+	+	Consistent	/	2022/1/28	Fever
5	129075	M	54	+	+	Consistent	/	2022/1/29	Fever
6	129241	M	35	+	+	Consistent	/	2022/1/29	Fever
7	128260	F	58	+	+	Consistent	/	2022/1/28	Fever
8	226316	F	35	+	+	Consistent	/	2022/2/26	Sore throat
9	121189	M	23	+	+	Consistent	/	2022/1/21	Fever
10	208206	M	44	+	+	Consistent	/	2022/2/8	Fever
11	207043	M	68	+	+	Consistent	/	2022/2/7	Fever
12	207142	F	51	-	+	Inconsistent	CT: 34.74 Positive	2022/2/7	Fever
13	126032	F	32	+	+	Consistent	/	2022/1/26	Fever
14	208088	M	36	+	+	Consistent	/	2022/2/8	Fever
15	125099	M	24	+	+	Consistent	/	2022/1/25	Fever
16	125118	F	51	+	+	Consistent	/	2022/1/25	Fever
17	208168	M	54	+	+	Consistent	/	2022/2/8	Fever
18	126041	M	20	+	+	Consistent	/	2022/1/26	Fever
19	207008	F	36	+	+	Consistent	/	2022/2/7	Fever
20	125053	F	33	+	+	Consistent	/	2022/1/25	Fever
21	208211	F	51	+	+	Consistent	/	2022/2/8	Fever
22	207048	M	24	+	+	Consistent	/	2022/2/7	Fever
23	122212	F	59	+	+	Consistent	/	2022/1/22	Fever
24	124223	F	56	+	+	Consistent	/	2022/1/24	Fever
25	122074	F	16	+	+	Consistent	/	2022/1/22	Fever
26	121120	M	61	+	+	Consistent	/	2022/1/21	Fever
27	208062	M	68	+	+	Consistent	/	2022/2/8	Fever
28	124065	M	57	+	+	Consistent	/	2022/1/24	Fever
29	124229	F	38	+	+	Consistent	/	2022/1/24	Fever
30	124207	M	70	+	+	Consistent	/	2022/1/24	Fever
31	124125	M	31	+	+	Consistent	/	2022/1/24	Fever
32	208126	F	60	+	+	Consistent	/	2022/2/8	Fever
33	129113	M	38	+	+	Consistent	/	2022/1/29	Fever
34	129092	F	26	+	+	Consistent	/	2022/1/29	Fever
35	19-00-3-124	M	5	+	+	Consistent	/	2019/4/2	Influenza suspect
36	121140	M	53	+	+	Consistent	/	2022/1/21	Fever
37	208245	M	21	+	+	Consistent	/	2022/2/8	Fever
38	208139	M	17	+	+	Consistent	/	2022/2/8	Fever
39	125191	M	30	+	+	Consistent	/	2022/1/25	Fever
40	121073	M	58	+	+	Consistent	/	2022/1/21	Fever

No.	Subject ID	Gender	Age	CorDx test result	Reference test result	Comment	PCR test result	Sampling date	Clinical diagnosis
				RSV	RSV				
41	121134	F	47	+	+	Consistent	/	2022/1/21	Fever
42	122244	F	15	+	+	Consistent	/	2022/1/22	Fever
43	19-01-3-050	M	70	+	+	Consistent	/	2019/4/3	Influenza suspect
44	208179	F	37	+	+	Consistent	/	2022/2/8	Fever
45	208150	F	21	+	+	Consistent	/	2022/2/8	Fever
46	122063	M	43	+	+	Consistent	/	2022/1/22	Fever
47	207029	M	45	+	+	Consistent	/	2022/2/7	Fever
48	208194	F	49	+	+	Consistent	/	2022/2/8	Fever
49	19-03-3-428	F	3	+	+	Consistent	/	2019/4/20	Influenza suspect
50	208040	M	15	+	+	Consistent	/	2022/2/8	Fever
51	129182	M	16	+	+	Consistent	/	2022/1/29	Fever
52	125248	F	45	+	+	Consistent	/	2022/1/25	Fever
53	129171	F	57	+	+	Consistent	/	2022/1/29	Fever
54	126022	M	32	+	+	Consistent	/	2022/1/26	Fever
55	121112	M	69	+	+	Consistent	/	2022/1/21	Fever
56	125087	F	30	+	+	Consistent	/	2022/1/25	Fever
57	128132	M	19	+	+	Consistent	/	2022/1/28	Fever
58	208101	F	29	+	+	Consistent	/	2022/2/8	Fever
59	120143	F	69	+	+	Consistent	/	2022/1/20	Fever
60	129200	M	33	+	+	Consistent	/	2022/1/29	Fever
61	124151	F	19	+	+	Consistent	/	2022/1/24	Fever
62	122123	F	51	+	+	Consistent	/	2022/1/22	Fever
63	122173	M	40	+	+	Consistent	/	2022/1/22	Fever
64	129190	F	17	+	+	Consistent	/	2022/1/29	Fever
65	126252	M	65	+	+	Consistent	/	2022/1/26	Fever
66	122128	M	30	+	+	Consistent	/	2022/1/22	Fever
67	208037	F	31	+	+	Consistent	/	2022/2/8	Fever
68	126066	F	65	+	+	Consistent	/	2022/1/26	Fever
69	122227	M	64	+	+	Consistent	/	2022/1/22	Fever
70	125237	M	21	+	+	Consistent	/	2022/1/25	Fever
71	124176	F	30	+	+	Consistent	/	2022/1/24	Fever
72	19-01-2-144	M	7	+	+	Consistent	/	2019/4/8	Influenza suspect
73	19-00-5-065	F	85	+	+	Consistent	/	2019/4/29	Influenza suspect
74	207175	F	48	+	+	Consistent	/	2022/2/7	Fever
75	124231	F	33	+	+	Consistent	/	2022/1/24	Fever
76	122039	M	49	+	+	Consistent	/	2022/1/22	Fever
77	207009	F	26	+	-	Inconsistent	CT: 35.44 Positive	2022/2/7	Fever

No.	Subject ID	Gender	Age	CorDx test result	Reference test result	Comment	PCR test result	Sampling date	Clinical diagnosis
				RSV	RSV				
78	122153	F	18	+	+	Consistent	/	2022/1/22	Fever
79	129082	M	52	+	+	Consistent	/	2022/1/29	Fever
80	121044	F	56	+	+	Consistent	/	2022/1/21	Fever
81	210356	F	51	+	+	Consistent	/	2022/2/10	Fever
82	121083	M	17	+	+	Consistent	/	2022/1/21	Fever
83	208154	M	15	+	+	Consistent	/	2022/2/8	Fever
84	126215	M	34	+	+	Consistent	/	2022/1/26	Fever
85	208085	M	64	+	+	Consistent	/	2022/2/8	Fever
86	124049	M	43	+	+	Consistent	/	2022/1/24	Fever
87	121254	M	44	+	+	Consistent	/	2022/1/21	Fever
88	208149	M	65	+	+	Consistent	/	2022/2/8	Fever
89	122135	F	16	+	+	Consistent	/	2022/1/22	Fever
90	121070	M	39	+	+	Consistent	/	2022/1/21	Fever
91	124193	F	38	+	+	Consistent	/	2022/1/24	Fever
92	126090	F	70	+	+	Consistent	/	2022/1/26	Fever
93	124017	F	65	+	-	Inconsistent	CT: 35.53 Positive	2022/1/24	Fever
94	208100	M	33	+	+	Consistent	/	2022/2/8	Fever
95	128025	M	53	+	+	Consistent	/	2022/1/28	Fever
96	124195	M	60	+	+	Consistent	/	2022/1/24	Fever
97	122166	M	62	+	+	Consistent	/	2022/1/22	Fever
98	207196	M	65	+	+	Consistent	/	2022/2/7	Fever
99	126158	M	38	+	+	Consistent	/	2022/1/26	Fever
100	225303	F	19	+	+	Consistent	/	2022/2/25	Fever

Table 4 Test results of 200 negative samples

No.	Subject ID	Gender	Age	CorDx test result			Reference test result			Comment	Sampling date	Clinical diagnosis
				FLU A	FLU B	RSV	FLU A	FLU B	RSV			
1	121044	F	58	-	-	-	-	-	-	Consistent	2022/1/21	Fever
2	128302	F	75	-	-	-	-	-	-	Consistent	2022/1/28	Fever
3	125322	F	18	-	-	-	-	-	-	Consistent	2022/1/25	Fever
4	129454	F	63	-	-	-	-	-	-	Consistent	2022/1/29	Fever
5	225311	M	57	-	-	-	-	-	-	Consistent	2022/2/25	Fever
6	227503	F	35	-	-	-	-	-	-	Consistent	2022/2/27	Sore throat
7	129168	F	41	-	-	-	-	-	-	Consistent	2022/1/29	Fever
8	305502	M	30	-	-	-	-	-	-	Consistent	2022/3/5	Fever
9	309009	F	44	-	-	-	-	-	-	Consistent	2022/3/9	Fever
10	211367	M	20	-	-	-	-	-	-	Consistent	2022/2/11	Fever

No.	Subject ID	Gender	Age	CorDx test result			Reference test result			Comment	Sampling date	Clinical diagnosis
				FLU A	FLU B	RSV	FLU A	FLU B	RSV			
11	124159	M	56	-	-	-	-	-	-	Consistent	2022/1/24	Fever
12	211233	M	44	-	-	-	-	-	-	Consistent	2022/2/11	Fever
13	216232	F	28	-	-	-	-	-	-	Consistent	2022/2/16	Fever
14	223506	F	36	-	-	-	-	-	-	Consistent	2022/2/23	Fever
15	211328	M	53	-	-	-	-	-	-	Consistent	2022/2/11	Fever
16	226302	F	34	-	-	-	-	-	-	Consistent	2022/2/26	Fever
17	223501	M	32	-	-	-	-	-	-	Consistent	2022/2/23	Fever
18	125441	M	70	-	-	-	-	-	-	Consistent	2022/1/25	Fever
19	211480	M	36	-	-	-	-	-	-	Consistent	2022/2/11	Fever
20	307001	M	58	-	-	-	-	-	-	Consistent	2022/3/7	Fever
21	212133	M	24	-	-	-	-	-	-	Consistent	2022/2/12	Fever
22	315363	M	15	-	-	-	-	-	-	Consistent	2022/3/15	Fever
23	128425	F	82	-	-	-	-	-	-	Consistent	2022/1/28	Fever
24	306512	F	22	-	-	-	-	-	-	Consistent	2022/3/6	Sore throat
25	222136	M	32	-	-	-	-	-	-	Consistent	2022/2/22	Fever
26	218146	M	45	-	-	-	-	-	-	Consistent	2022/2/18	Fever
27	129334	M	42	-	-	-	-	-	-	Consistent	2022/1/29	Fever
28	125124	M	37	-	-	-	-	-	-	Consistent	2022/1/25	Fever
29	129182	M	71	-	-	-	-	-	-	Consistent	2022/1/29	Fever
30	125287	F	49	-	-	-	-	-	-	Consistent	2022/1/25	Fever
31	127507	F	22	-	-	-	-	-	-	Consistent	2022/1/27	Fever
32	212387	F	48	-	-	-	-	-	-	Consistent	2022/2/12	Fever
33	124384	M	42	-	-	-	-	-	-	Consistent	2022/1/24	Fever
34	128426	M	31	-	-	-	-	-	-	Consistent	2022/1/28	Fever
35	214290	M	36	-	-	-	-	-	-	Consistent	2022/2/14	Fever
36	211389	M	55	-	-	-	-	-	-	Consistent	2022/2/11	Fever
37	211203	F	20	-	-	-	-	-	-	Consistent	2022/2/11	Fever
38	226323	M	19	-	-	-	-	-	-	Consistent	2022/2/26	All negative
39	306503	M	61	-	-	-	-	-	-	Consistent	2022/3/6	Fever
40	212178	M	18	-	-	-	-	-	-	Consistent	2022/2/12	Fever
41	301503	F	25	-	-	-	-	-	-	Consistent	2022/3/1	Fever
42	302615	M	39	-	-	-	-	-	-	Consistent	2022/3/2	Pneumonia
43	207362	F	22	-	-	-	-	-	-	Consistent	2022/2/7	Fever
44	303506	M	25	-	-	-	-	-	-	Consistent	2022/3/3	Fever
45	225315	F	34	-	-	-	-	-	-	Consistent	2022/2/25	Fever
46	212085	F	56	-	-	-	-	-	-	Consistent	2022/2/12	Fever
47	211090	F	24	-	-	-	-	-	-	Consistent	2022/2/11	Fever
48	303509	M	21	-	-	-	-	-	-	Consistent	2022/3/3	Fever
49	221100	M	55	-	-	-	-	-	-	Consistent	2022/2/21	Fever
50	306511	M	15	-	-	-	-	-	-	Consistent	2022/3/6	Fever

No.	Subject ID	Gender	Age	CorDx test result			Reference test result			Comment	Sampling date	Clinical diagnosis
				FLU A	FLU B	RSV	FLU A	FLU B	RSV			
51	301506	F	32	-	-	-	-	-	-	Consistent	2022/3/1	Fever
52	216202	M	27	-	-	-	-	-	-	Consistent	2022/2/16	Fever
53	314319	F	29	-	-	-	-	-	-	Consistent	2022/3/14	Fever
54	314328	M	32	-	-	-	-	-	-	Consistent	2022/3/14	Fever
55	126451	M	60	-	-	-	-	-	-	Consistent	2022/1/26	Fever
56	311003	M	48	-	-	-	-	-	-	Consistent	2022/3/11	Fever
57	121431	M	47	-	-	-	-	-	-	Consistent	2022/1/21	Fever
58	305503	M	42	-	-	-	-	-	-	Consistent	2022/3/5	Fever
59	211009	F	34	-	-	-	-	-	-	Consistent	2022/2/11	Fever
60	121218	M	33	-	-	-	-	-	-	Consistent	2022/1/21	Fever
61	307005	M	35	-	-	-	-	-	-	Consistent	2022/3/7	Fever
62	124137	F	72	-	-	-	-	-	-	Consistent	2022/1/24	Fever
63	217408	F	82	-	-	-	-	-	-	Consistent	2022/2/17	Fever
64	125263	M	29	-	-	-	-	-	-	Consistent	2022/1/25	Fever
65	310014	M	41	-	-	-	-	-	-	Consistent	2022/3/10	Fever
66	125117	F	35	-	-	-	-	-	-	Consistent	2022/1/25	Fever
67	125365	F	67	-	-	-	-	-	-	Consistent	2022/1/25	Fever
68	302618	F	36	-	-	-	-	-	-	Consistent	2022/3/2	咳嗽
69	218304	F	67	-	-	-	-	-	-	Consistent	2022/2/18	Fever
70	207397	M	51	-	-	-	-	-	-	Consistent	2022/2/7	Fever
71	126339	M	27	-	-	-	-	-	-	Consistent	2022/1/26	Fever
72	312001	M	45	-	-	-	-	-	-	Consistent	2022/3/12	Fever
73	127209	F	29	-	-	-	-	-	-	Consistent	2022/1/27	Fever
74	305504	M	31	-	-	-	-	-	-	Consistent	2022/3/6	Fever
75	301507	M	53	-	-	-	-	-	-	Consistent	2022/3/1	Fever
76	128092	M	23	-	-	-	-	-	-	Consistent	2022/1/28	Fever
77	121481	F	45	-	-	-	-	-	-	Consistent	2022/1/21	Fever
78	225308	F	25	-	-	-	-	-	-	Consistent	2022/2/25	Fever
79	125490	F	49	-	-	-	-	-	-	Consistent	2022/1/25	Fever
80	128305	F	67	-	-	-	-	-	-	Consistent	2022/1/28	Fever
81	120040	F	57	-	-	-	-	-	-	Consistent	2022/1/20	Fever
82	122079	F	31	-	-	-	-	-	-	Consistent	2022/1/22	Fever
83	214459	F	42	-	-	-	-	-	-	Consistent	2022/2/14	Fever
84	310005	M	39	-	-	-	-	-	-	Consistent	2022/3/10	Fever
85	223505	M	38	-	-	-	-	-	-	Consistent	2022/2/23	Fever
86	211324	F	75	-	-	-	-	-	-	Consistent	2022/2/11	Fever
87	212390	M	19	-	-	-	-	-	-	Consistent	2022/2/12	Fever
88	216072	M	24	-	-	-	-	-	-	Consistent	2022/2/16	Fever
89	212314	M	45	-	-	-	-	-	-	Consistent	2022/2/12	Fever
90	126306	F	33	-	-	-	-	-	-	Consistent	2022/1/26	Fever

No.	Subject ID	Gender	Age	CorDx test result			Reference test result			Comment	Sampling date	Clinical diagnosis
				FLU A	FLU B	RSV	FLU A	FLU B	RSV			
91	212188	M	24	-	-	-	-	-	-	Consistent	2022/2/12	Fever
92	309010	F	23	-	-	-	-	-	-	Consistent	2022/3/9	Fever
93	127228	M	50	-	-	-	-	-	-	Consistent	2022/1/27	Fever
94	128042	M	80	-	-	-	-	-	-	Consistent	2022/1/28	Fever
95	128496	F	80	-	-	-	-	-	-	Consistent	2022/1/28	Fever
96	127089	F	77	-	-	-	-	-	-	Consistent	2022/1/27	Fever
97	124037	F	68	-	-	-	-	-	-	Consistent	2022/1/24	Fever
98	225312	F	24	-	-	-	-	-	-	Consistent	2022/2/25	Fever
99	126134	F	49	-	-	-	-	-	-	Consistent	2022/1/26	Fever
100	310007	M	45	-	-	-	-	-	-	Consistent	2022/3/10	Fever
101	215355	M	29	-	-	-	-	-	-	Consistent	2022/2/15	Fever
102	217396	M	45	-	-	-	-	-	-	Consistent	2022/2/17	Fever
103	301513	M	31	-	-	-	-	-	-	Consistent	2022/3/1	All negative
104	212158	M	65	-	-	-	-	-	-	Consistent	2022/2/12	Fever
105	306507	M	36	-	-	-	-	-	-	Consistent	2022/3/6	Fever
106	221309	F	60	-	-	-	-	-	-	Consistent	2022/2/21	Fever
107	217138	M	39	-	-	-	-	-	-	Consistent	2022/2/17	Fever
108	225302	F	50	-	-	-	-	-	-	Consistent	2022/2/25	Fever
109	218416	M	39	-	-	-	-	-	-	Consistent	2022/2/18	Fever
110	120041	F	75	-	-	-	-	-	-	Consistent	2022/1/20	Fever
111	310004	M	52	-	-	-	-	-	-	Consistent	2022/3/10	Fever
112	315356	F	55	-	-	-	-	-	-	Consistent	2022/3/15	Fever
113	314329	M	53	-	-	-	-	-	-	Consistent	2022/3/14	Fever
114	218405	M	82	-	-	-	-	-	-	Consistent	2022/2/18	Fever
115	313303	F	17	-	-	-	-	-	-	Consistent	2022/3/13	Fever
116	126065	M	38	-	-	-	-	-	-	Consistent	2022/1/26	Fever
117	120465	M	54	-	-	-	-	-	-	Consistent	2022/1/20	Fever
118	212035	F	34	-	-	-	-	-	-	Consistent	2022/2/12	Fever
119	306508	M	39	-	-	-	-	-	-	Consistent	2022/3/6	Fever
120	121297	M	45	-	-	-	-	-	-	Consistent	2022/1/21	Fever
121	307010	F	29	-	-	-	-	-	-	Consistent	2022/3/7	Fever
122	211252	M	80	-	-	-	-	-	-	Consistent	2022/2/11	Fever
123	314320	M	44	-	-	-	-	-	-	Consistent	2022/3/14	Fever
124	307007	M	24	-	-	-	-	-	-	Consistent	2022/3/7	Fever
125	211122	F	62	-	-	-	-	-	-	Consistent	2022/2/11	Fever
126	226321	M	31	-	-	-	-	-	-	Consistent	2022/2/26	Fever
127	307004	M	26	-	-	-	-	-	-	Consistent	2022/3/7	Fever
128	211458	F	71	-	-	-	-	-	-	Consistent	2022/2/11	Fever
129	215023	F	59	-	-	-	-	-	-	Consistent	2022/2/15	Fever
130	124359	F	67	-	-	-	-	-	-	Consistent	2022/1/24	Fever

No.	Subject ID	Gender	Age	CorDx test result			Reference test result			Comment	Sampling date	Clinical diagnosis
				FLU A	FLU B	RSV	FLU A	FLU B	RSV			
131	125410	F	51	-	-	-	-	-	-	Consistent	2022/1/25	Fever
132	211446	M	36	-	-	-	-	-	-	Consistent	2022/2/11	Fever
133	302616	M	70	-	-	-	-	-	-	Consistent	2022/3/2	Fever
134	306506	M	39	-	-	-	-	-	-	Consistent	2022/3/6	Fever
135	211385	M	67	-	-	-	-	-	-	Consistent	2022/2/11	Fever
136	313302	M	28	-	-	-	-	-	-	Consistent	2022/3/13	Fever
137	222102	M	57	-	-	-	-	-	-	Consistent	2022/2/22	Fever
138	315368	M	37	-	-	-	-	-	-	Consistent	2022/3/15	Fever
139	122506	M	77	-	-	-	-	-	-	Consistent	2022/1/22	Fever
140	126165	F	54	-	-	-	-	-	-	Consistent	2022/1/26	Fever
141	313304	M	32	-	-	-	-	-	-	Consistent	2022/3/13	Fever
142	129358	M	67	-	-	-	-	-	-	Consistent	2022/1/29	Fever
143	306513	F	38	-	-	-	-	-	-	Consistent	2022/3/6	Fever
144	211422	M	25	-	-	-	-	-	-	Consistent	2022/2/11	Fever
145	126081	F	25	-	-	-	-	-	-	Consistent	2022/1/26	Fever
146	216031	M	76	-	-	-	-	-	-	Consistent	2022/2/16	Fever
147	314337	F	34	-	-	-	-	-	-	Consistent	2022/3/14	Fever
148	122266	M	52	-	-	-	-	-	-	Consistent	2022/1/22	Fever
149	124101	F	24	-	-	-	-	-	-	Consistent	2022/1/24	Fever
150	124270	M	23	-	-	-	-	-	-	Consistent	2022/1/24	Fever
151	214103	M	61	-	-	-	-	-	-	Consistent	2022/2/14	Fever
152	224308	M	31	-	-	-	-	-	-	Consistent	2022/2/24	Fever
153	311006	F	15	-	-	-	-	-	-	Consistent	2022/3/11	Fever
154	308011	M	28	-	-	-	-	-	-	Consistent	2022/3/8	Fever
155	211381	F	70	-	-	-	-	-	-	Consistent	2022/2/11	Fever
156	129301	F	75	-	-	-	-	-	-	Consistent	2022/1/29	Fever
157	302611	M	29	-	-	-	-	-	-	Consistent	2022/3/2	Fever
158	309001	F	30	-	-	-	-	-	-	Consistent	2022/3/9	Fever
159	302617	M	23	-	-	-	-	-	-	Consistent	2022/3/2	Fever
160	310008	M	34	-	-	-	-	-	-	Consistent	2022/3/10	Fever
161	312004	M	31	-	-	-	-	-	-	Consistent	2022/3/12	Fever
162	307009	F	29	-	-	-	-	-	-	Consistent	2022/3/7	Fever
163	226313	M	32	-	-	-	-	-	-	Consistent	2022/2/26	Fever
164	121208	M	44	-	-	-	-	-	-	Consistent	2022/1/21	Fever
165	309003	F	66	-	-	-	-	-	-	Consistent	2022/3/9	Fever
166	211437	M	47	-	-	-	-	-	-	Consistent	2022/2/11	Fever
167	314330	M	37	-	-	-	-	-	-	Consistent	2022/3/14	Diarrhea
168	126220	M	42	-	-	-	-	-	-	Consistent	2022/1/26	Fever
169	306517	F	22	-	-	-	-	-	-	Consistent	2022/3/6	Fever
170	125375	F	30	-	-	-	-	-	-	Consistent	2022/1/25	Fever
171	225301	M	44	-	-	-	-	-	-	Consistent	2022/2/25	Fever

No.	Subject ID	Gender	Age	CorDx test result			Reference test result			Comment	Sampling date	Clinical diagnosis
				FLU A	FLU B	RSV	FLU A	FLU B	RSV			
172	125498	F	21	-	-	-	-	-	-	Consistent	2022/1/25	Fever
173	128471	M	37	-	-	-	-	-	-	Consistent	2022/1/28	Fever
174	125343	F	81	-	-	-	-	-	-	Consistent	2022/1/25	Fever
175	214113	F	80	-	-	-	-	-	-	Consistent	2022/2/14	Fever
176	120421	F	60	-	-	-	-	-	-	Consistent	2022/1/20	Fever
177	122070	F	46	-	-	-	-	-	-	Consistent	2022/1/22	Fever
178	226312	F	65	-	-	-	-	-	-	Consistent	2022/2/26	Fever
179	126069	F	75	-	-	-	-	-	-	Consistent	2022/1/26	Fever
180	127404	F	52	-	-	-	-	-	-	Consistent	2022/1/27	Fever
181	310003	M	17	-	-	-	-	-	-	Consistent	2022/3/10	Fever
182	217461	F	75	-	-	-	-	-	-	Consistent	2022/2/17	Fever
183	302619	F	21	-	-	-	-	-	-	Consistent	2022/3/2	Fever
184	314335	F	32	-	-	-	-	-	-	Consistent	2022/3/14	Fever
185	129487	F	69	-	-	-	-	-	-	Consistent	2022/1/29	Fever
186	306516	M	23	-	-	-	-	-	-	Consistent	2022/3/6	Fever
187	121144	F	20	-	-	-	-	-	-	Consistent	2022/1/21	Fever
188	127293	M	34	-	-	-	-	-	-	Consistent	2022/1/27	Fever
189	309011	M	35	-	-	-	-	-	-	Consistent	2022/3/9	Fever
190	303512	F	30	-	-	-	-	-	-	Consistent	2022/3/3	Fever
191	211486	M	43	-	-	-	-	-	-	Consistent	2022/2/11	Fever
192	302601	M	29	-	-	-	-	-	-	Consistent	2022/3/2	Fever
193	302620	M	31	-	-	-	-	-	-	Consistent	2022/3/2	Fever
194	211433	F	31	-	-	-	-	-	-	Consistent	2022/2/11	Fever
195	310002	M	42	-	-	-	-	-	-	Consistent	2022/3/10	Fever
196	121291	M	19	-	-	-	-	-	-	Consistent	2022/1/21	Fever
197	127468	M	57	-	-	-	-	-	-	Consistent	2022/1/27	Fever
198	226320	M	15	-	-	-	-	-	-	Consistent	2022/2/26	Fever
199	301505	F	36	-	-	-	-	-	-	Consistent	2022/3/1	Fever
200	121296	F	63	-	-	-	-	-	-	Consistent	2022/1/21	Fever

Table 5 Test results of 50 cross-reactivity samples

No.	Subject ID	Gender	Age	CorDx test result			Reference test result			Comment	Clinical diagnosis	Sampling date	Pathogens
				FLU A	FLU B	RSV	FLU A	FLU B	RSV				
1	2019-S0006	F	27	-	-	-	-	-	-	Consistent	Fever, Sore throat	2019/3/18	MS
2	2019-R1610-2	M	61	-	-	-	-	-	-	Consistent	Influenza suspect	2019/4/2	hMPV
3	2019-R1801-4	F	9	-	-	-	-	-	-	Consistent	Influenza suspect	2019/4/2	MP

No.	Subject ID	Gender	Age	CorDx test result			Reference test result			Comment	Clinical diagnosis	Sampling date	Pathogens
				FLU A	FLU B	RSV	FLU A	FLU B	RSV				
4	2019-R1652-2	F	96	-	-	-	-	-	-	Consistent	Influenza suspect	2019/4/10	PIV3
5	2019-R1697-1	M	8m	-	-	-	-	-	-	Consistent	Influenza suspect	2019/4/11	Adv
6	2019-R1900-2	M	76	-	-	-	-	-	-	Consistent	Influenza suspect	2019/4/11	SP
7	2019-R1987-1	M	12	-	-	-	-	-	-	Consistent	Influenza suspect	2019/4/20	RV
8	2019-R1853-2	M	48	-	-	-	-	-	-	Consistent	Influenza suspect	2019/4/25	229E
9	2019-R1926-1	M	2	-	-	-	-	-	-	Consistent	Influenza suspect	2019/4/26	PIV1
10	2019-M0012	F	15	-	-	-	-	-	-	Consistent	Fever、出疹	2019/5/28	MV
11	125246	M	37	-	-	-	-	-	-	Consistent	Fever	2022/1/25	MP
12	125187	M	67	-	-	-	-	-	-	Consistent	Fever	2022/1/25	PIV1
13	129258	F	70	-	-	-	-	-	-	Consistent	Fever	2022/1/29	PIV1
14	129033	M	52	-	-	-	-	-	-	Consistent	Fever	2022/1/29	RV
15	208047	F	31	-	-	-	-	-	-	Consistent	Fever	2022/2/8	Adv
16	208121	F	16	-	-	-	-	-	-	Consistent	Fever	2022/2/8	hMPV
17	208011	F	34	-	-	-	-	-	-	Consistent	Fever	2022/2/8	hMPV
18	208010	F	57	-	-	-	-	-	-	Consistent	Fever	2022/2/8	MP
19	208034	M	40	-	-	-	-	-	-	Consistent	Fever	2022/2/8	PIV1
20	208249	M	45	-	-		-	-	-	Consistent	Fever	2022/2/8	PIV1
21	208137	M	48	-	-	-	-	-	-	Consistent	Fever	2022/2/8	PIV1
22	208105	M	57	-	-	-	-	-	-	Consistent	Fever	2022/2/8	PIV3
23	208228	F	35	-	-	-	-	-	-	Consistent	Fever	2022/2/8	PIV3
24	208046	M	55	-	-	-	-	-	-	Consistent	Fever	2022/2/8	PIV3
25	208148	F	50	-	-	-	-	-	-	Consistent	Fever	2022/2/8	PIV3
26	208102	F	19	-	-	-	-	-	-	Consistent	Fever	2022/2/8	PIV3
27	208006	M	37	-	-	-	-	-	-	Consistent	Fever	2022/2/8	PIV3
28	208061	F	31	-	-	-	-	-	-	Consistent	Fever	2022/2/8	RV

No.	Subject ID	Gender	Age	CorDx test result			Reference test result			Comment	Clinical diagnosis	Sampling date	Pathogens
				FLU A	FLU B	RSV	FLU A	FLU B	RSV				
29	208157	M	47	-	-	-	-	-	-	Consistent	Fever	2022/2/8	RV
30	208224	M	50	-	-	-	-	-	-	Consistent	Fever	2022/2/8	RV
31	208095	M	36	-	-	-	-	-	-	Consistent	Fever	2022/2/8	RV
32	208004	M	19	-	-	-	-	-	-	Consistent	Fever	2022/2/8	SP
33	208199	F	25	-	-	-	-	-	-	Consistent	Fever	2022/2/8	SP
34	209086	F	43	-	-	-	-	-	-	Consistent	Fever	2022/2/9	hMPV
35	209089	M	61	-	-	-	-	-	-	Consistent	Fever	2022/2/9	MP
36	209098	F	34	-	-	-	-	-	-	Consistent	Fever	2022/2/9	MP
37	209114	F	70	-	-	-	-	-	-	Consistent	Fever	2022/2/9	MP
38	209028	M	37	-	-	-	-	-	-	Consistent	Fever	2022/2/9	PIV1
39	209042	M	46	-	-	-	-	-	-	Consistent	Fever	2022/2/9	PIV3
40	209243	F	37	-	-	-	-	-	-	Consistent	Fever	2022/2/9	PIV3
41	209188	M	30	-	-	-	-	-	-	Consistent	Fever	2022/2/9	PIV3
42	209094	F	35	-	-	-	-	-	-	Consistent	Fever	2022/2/9	PIV3
43	209236	M	45	-	-	-	-	-	-	Consistent	Fever	2022/2/9	RV
44	209167	F	28	-	-	-	-	-	-	Consistent	Fever	2022/2/9	RV
45	209003	M	29	-	-	-	-	-	-	Consistent	Fever	2022/2/9	SP
46	209203	M	35	-	-	-	-	-	-	Consistent	Fever	2022/2/9	SP
47	209159	M	20	-	-	-	-	-	-	Consistent	Fever	2022/2/9	SP
48	210067	M	24	-	-	-	-	-	-	Consistent	Fever	2022/2/10	MP
49	210079	M	56	-	-	-	-	-	-	Consistent	Fever	2022/2/10	SP
50	2019-09R0070-1	F	60	-	-	-	-	-	-	Consistent	Influenza suspect	2019/04/13	OC43

Table 6 Potential Cross-reactivity Substance

No.	Substance	No.	Substance
1	MV: Mumps	7	OC43: human Coronavirus OC43
2	MS: Measles virus	8	229E: human Coronavirus 229E
3	hMPV: Human Metapneumovirus	9	SP: Streptococcus pneumoniae
4	MP: Mycoplasma pneumoniae	10	Adv: Adenovirus
5	RV: Rhinovirus	11	PIV1: Parainfluenza virus 1
6	PIV3: Parainfluenza virus 3	/	/

6. Statistical Analysis

The statistical analysis is as follows.

Table 7 Statistical analysis of Flu A test result

Flu A test result		Reference test result		Total
		Positive	Negative	
CorDx test result	Positive	49	2	51
	Negative	0	301	301
Total		49	303	352

	Value	95% Confidence Interval
Positive coincidence rate	100.00%	92.73%~100%
Negative coincidence rate	99.34%	97.63%~99.82%
Total coincidence rate	99.43%	97.95%~99.84%

Kappa=0.9767

Table 8 Statistical analysis of Flu B test result

Flu B test result		Reference test result		Total
		Positive	Negative	
CorDx test result	Positive	48	1	49
	Negative	2	301	303
Total		50	302	352

	Value	95% Confidence Interval
Positive coincidence rate	96.00%	86.54%~98.90%
Negative coincidence rate	99.67%	98.15%~99.94%

Total coincidence rate	99.15%	97.52%~99.71%

Kappa=0.9647

Table 9 Statistical analysis of RSV test result

RSV test result		Reference test result		Total
		Positive	Negative	
CorDx test result	Positive	97	2	99
	Negative	1	250	251
Total		98	252	350

	Value	95% Confidence Interval
Positive coincidence rate	98.98%	94.44%~99.82%
Negative coincidence rate	99.21%	97.15%~99.78%
Total coincidence rate	99.14%	97.51%~99.71%

Kappa=0.9798

95% confidence intervals for the positive coincidence rate, the negative coincidence rate and the total coincidence rate were calculated from the binomial distribution. Statistical results show that there is a good consistency between the investigational test and the reference test.

Kappa>0.75, meets the performance requirements of the investigational test the CorDx, Inc. product Influenza A/B+COVID-19/RSV Combo Ag Test, indicating that there is a high consistency between the investigational test and the reference test.

7. Conclusion

A side-by-side comparison test for the detection of nucleocapsid protein antigen from influenza A, influenza B and respiratory syncytial virus in nasal swab specimens between the CorDx, Inc. Influenza A/B+COVID-19/RSV Combo Ag Test and the reference test Abiores Influenza A/B+COVID-19/RSV Combo Ag Test was conducted.

For FLU A antigen detection, the positive coincidence rate is 100.00%, the negative coincidence rate is 99.34%, the total coincidence rate is 99.43%.

For FLU B antigen detection, the positive coincidence rate is 96.00%, the negative coincidence rate is 99.67%, the total coincidence rate is 99.15%.

For RSV antigen detection, the positive coincidence rate is 98.98%, the negative

coincidence rate is 99.21%, the total coincidence rate is 99.14%.

The study showed that there is a high coincidence rate between the CorDx Influenza A/B+COVID-19/RSV Combo Ag Test and the reference test Abiores Influenza A/B+COVID-19/RSV Combo Ag Test. It can be used to assist an early diagnosis of both symptomatic and asymptomatic of influenza A, influenza B and/or respiratory syncytial virus infection.

The samples with inconsistent results of the two tests were tested with the PCR nucleic acid reagent. The test results showed that 2 influenza A samples, 3 influenza B samples and 3 RSV samples were all weak positive samples. Limited by the colloidal gold methodology, both tests missed detection for some low-value samples. In this case, if the patient has symptoms of respiratory tract infection, it is recommended to perform the test again after an interval of 24 hours or go to the hospital to confirm the infection status.

Subject ID	Investigational test result of FLUA	Reference test result of FLUA	RCR test		Comment
			CT	Result	
210215	+	-	35.09	Positive	Reference test missed detection
210217	+	-	35.34	Positive	Reference test missed detection

Subject ID	Investigational test result of FLUB	Reference test result of FLUB	RCR test		Comment
			CT	Result	
304515	+	-	34.57	Positive	Reference test missed detection
306514	-	+	35.71	Positive	Investigational test missed detection
306510	-	+	35.5	Positive	Investigational test missed detection

Subject ID	Investigational test result of RSV	Reference test result of RSV	RCR test		Comment
			CT	Result	
207142	-	+	34.74	Positive	Investigational test missed detection
207009	+	-	35.44	Positive	Reference test missed

					detection
124017	+	-	35.53	Positive	Reference test missed detection

8. References

WHO Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays Interim guidance

https://www.who.int/docs/default-source/coronaviruse/corrigenda-ig-2020-1-antigen-detection-2020-09-11-corr-2020-10-27-en.pdf

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The seal is read Beijing Electric Power Hospital.