

EC DECLARATION OF CONFORMITY

Manufacturer: CORDX, INC.
9540 Waples St Unit C, San Diego, CA 92121, USA

European Representative: Luxus Lebenswelt GmbH
Kochstr. 1, 47877, Willich, Germany

Manufacturing Site: Core Technology Co., Ltd.
Room 100 C Building No. 29 Life Park Rd, Changping District, Beijing
102206, P. R. China

Trade Name: Influenza A/B+COVID- 19/RSV Combo Ag Test

Product Model(s): See the Attachment I

Classification: **for self-testing of IVDD**

Conformity Assessment Route: **IVDD Annex III - Section 6**

We herewith declare that the above mentioned products meet the transposition into European regulations, the provisions of the following EC Council Directives and Standards. The declaration of conformity is exclusively under the sole responsibility of CorDx, Inc. (Manufacturer).

General applicable directives:

In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Notified Body:

CeCert Sp. z o.o.(CE 2934)

EC Certificate No . CeCert/064/W/E.3

Validity date: 02.05.2022 – 26.05.2025

Edition issue date: 16.12.2022

Harmonized standards:

EN ISO 13485:2016, EN ISO 18113-1:2011, EN ISO 18113-4:2011, EN 13612:2002,
EN ISO 15223-1:2016, EN ISO 14971:2019, EN ISO 23640:2015,
EN 13641:2002, EN 13532:2002, EN 62366-1:2015.

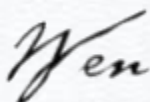
Date: Dec 16, 2022

Name: Amber Wen

Title: Regulatory Affairs Manager

Position: San Diego, USA

Signature:



Attachment I: Product Name and Model(s)

Product Name	Brand	Packaging Specification	Catalogue Number
Influenza A/B+COVID- 19/RSV Combo Ag Test	Coretests	1 test/box	BP292-01
		2 tests/box	BP292-02
		1 test/soft pack	BP292-04
		5 tests/box	BP292-05
		25 tests/box	BP292-25
	CorDx	1 test/box	BC292-01
		2 tests/box	BC292-02
		5 tests/box	BC292-05
		25 tests/box	BC292-25
	HW	1 test/box	HWP292-01
		5 tests/box	HWP292-05
		25 tests/box	HWP292-25
	TGS Velox Ag	1 test/box	TGS-01
		5 tests/box	TGS-05
		25 tests/box	TGS-25
	Diather	1 test/box	DP292-01
	Milapharm	1 test/box	MP292-01
	MyBio	1 test/box	MY-01
		2 tests/box	MY-02
		5 tests/box	MY-05
		25 tests/box	MY-25
	Accufast	1 test/box	AF-01
		2 tests/box	AF-02
		5 tests/box	AF-05
		25 tests/box	AF-25
	RapiChek	1 test/box	RC292-01
		2 tests/box	RC292-02
		5 tests/box	RC292-05

-END-

CERTIFICATE

DIRECTIVE 98/79/EC
EC DESIGN-EXAMINATION

CeCert Sp. z o.o. hereby confirms that manufactured by

CorDx, Inc.

9540 Waples St Unit C, San Diego, CA 92121, USA

in vitro diagnostic medical device for self-testing

The list of devices covered by the scope
of this Certificate is included in Annex 1

in term of the design conforms to the requirements of Annex III
section 6 to Directive 98/79/EC (as amended) implemented into Polish
Law, as evidenced by the assessment conducted
by CeCert Sp. z o.o.

CE 2934

Validity date: 02.05.2022 – 26.05.2025

Edition issue date: 15.09.2022

Check it



CeCert Sp. z o.o.
ul. Warecka 11A
00-034 Warszawa

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device
Certification Department

ANNEX 1

TO THE CERTIFICATE NO. CECERT/064/W/E.2

List of *in vitro* diagnostic medical devices covered by the scope
of the Certificate No. CeCert/064/W/E.2:

Device Name	Brand	Catalogue Number
Influenza A/B+COVID-19/RSV Combo Ag Test	Coretests	BP292-01
		BP292-02
		BP292-04
		BP292-05
		BP292-25
	CorDx	BC292-01
		BC292-02
		BC292-05
		BC292-25
	HW	HWP292-01
		HWP292-05
		HWP292-25
	TGS Velox Ag	TGS-01
		TGS-05
		TGS-25

Check it



CeCert Sp. z o.o.
ul. Warecka 11A
00-034 Warszawa

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device
Certification Department

CE Technicaal File	File No: CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

Analytical Performance Study Report

Prepared by:	Weina Cui	Date:	2022.04.15
Review by:	Qiyong Lu	Date:	2022.04.15
Approved by:	Huijun Shi	Date:	2022.04.15

Revision History

Rev. No.	Description	Approved By	Effective Date
1.0	Firstly Prepared	Huijun Shi	2022.01.03
1.1	Add research content	Huijun Shi	2022.04.15

CorDx, Inc.

CE Technical File	File No: CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

1. Purpose and content of the study

1.1 Purpose of the study

The purpose of this study was to evaluate the analytical performance of the Influenza A/B+COVID-19/RSV Combo Ag Test.

1.2 Contents

This report includes:

- 1) Limit of Detection (LoD) study
- 2) Precision study
- 3) Hook Effect study
- 4) Interference Testing
- 5) Cross-reactivity Testing

2. Test materials and test requirements

2.1 Test kits

2.2 Test requirements

- 1) Laboratory staff should be familiar with the operation of instruments, testing procedures and be able to handle samples correctly.
- 2) All samples used in the laboratory shall be considered as infectious materials and shall be handled in accordance with the laboratory safety management regulations.

2.3 Location and time of the experiment

3. Analytical performance assessment

3.1 Limit of Detection (LoD) Study

3.1.1 Determine the Limit of Detection (LoD)

3.1.1.1 Source of viral culture stock solution: Inactivated virus

3.1.1.2 Pretest: determine the scope initially

3.1.1.2.1 Test sample preparation

The concentration of the purchased inactivated virus is too high for the product's limit of detection determination study, so first use the negative sample matrix to dilute the virus 100 times, and then prepare the positive samples for validation of the lowest detection limit according to the following table:

Table 1-1 Pretest sample preparation for Influenza A

No.	Dilution rate (Culture:buffer)	Upper level of sample (μL)	Negative sample matrix(μL)	Volume (mL)	Concentration (TCID ₅₀ /mL)
Stock solution	/	/	/	/	4.8×10 ⁷
AS1	1:100	20	1980	2	4.8×10 ⁵
AS2	1:200	1000	1000	2	2.4×10 ⁵
AS3	1:400	1000	1000	2	1.2×10 ⁵

CE Technicaal File			File No: CorDx-CE-Flu A+B&COVID-19+RSV-7		
Influenza A/B+COVID-19/RSV Combo Ag Test					
AS4	1:800	1000	1000	2	6.0×10 ⁴
AS5	1:1600	1000	1000	2	3.0×10 ⁴
AS6	1:3200	1000	1000	2	1.5×10 ⁴
AS7	1:6400	1000	1000	2	7.5×10 ³

Table 1-2 Pretest sample preparation for Influenza B

No.	Dilution rate (Culture:buffer)	Upper level of sample (μ L)	Negative sample matrix(μ L)	Volume (mL)	Concentration (TCID ₅₀ /mL)
Stock solution	/	/	/	/	4.8×10^8
BS1	1:100	20	1980	2	4.8×10^6
BS2	1:200	1000	1000	2	2.4×10^6
BS3	1:400	1000	1000	2	1.2×10^6
BS4	1:800	1000	1000	2	6.0×10^5
BS5	1:1600	1000	1000	2	3.0×10^5
BS6	1:3200	1000	1000	2	1.5×10^5
BS7	1:6400	1000	1000	2	7.5×10^4

Table 1-3 Pretest sample preparation for COVID-19

No.	Dilution rate (Culture:buffer)	Upper level of sample (μ L)	Negative sample matrix(μ L)	Volume (mL)	Concentration (TCID ₅₀ /mL)
Stock solution	/	/	/	/	1.6×10^6
CS1	1:100	20	1980	2	1.6×10^4
CS2	1:1000	200	1800	2	1.6×10^3
CS3	1:2000	1000	1000	2	800
CS4	1:4000	1000	1000	2	400
CS5	1:8000	1000	1000	2	200
CS6	1:16000	1000	1000	2	100
CS7	1:32000	1000	1000	2	50

Table 1-4 Pretest sample preparation for RSV

No.	Dilution rate (Culture:buffer)	Upper level of sample (μ L)	Negative sample matrix(μ L)	Volume (mL)	Concentration (TCID ₅₀ /mL)
Stock solution	/	/	/	/	3.2×10^7
RS1	1:100	20	1980	2	3.2×10^5
RS2	1:200	1000	1000	2	1.6×10^5
RS3	1:400	1000	1000	2	8.0×10^4
RS4	1:800	1000	1000	2	4.0×10^4
RS5	1:1600	1000	1000	2	2.0×10^4
RS6	1:3200	1000	1000	2	1.0×10^4
RS7	1:6400	1000	1000	2	5.0×10^3

3.1.1.2.2 Test method

3.1.1.2.3 Acceptance criteria

CE Technical File	File No: CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

The concentration corresponding to a positive test result at the negative-positive junction is the critical concentration.

3.1.1.2.4 Data processing

Based on the color band of the test line, it is possible to determine whether the color is consistent and whether the result is negative or positive, see Figure 1 for a diagram of the standard color card.

It should be noted that the result record corresponding to the standard color card is only for the evaluation of internal laboratory content and is not applicable to the self-test consumer population. The interpretation of the results in the instruction for use is only positive, negative and invalid.

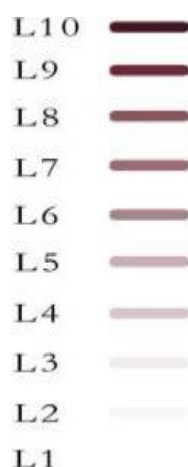


Figure 1: Standard color card

Note: L1-L10 indicates the color of the reaction band, L1/L2 represents negative "-", L3/L4 represents positive "+", L5~L7 represents positive "++", L8~L10 represents positive "+++". For the color band that does not reach the next level should all belong to the previous level results. For example, if a color band is darker than L2 but lighter than L3, then it should be recorded as L2.

3.1.1.2.5 Results and analysis

Results: Pretest results are shown in Table 2

Table 2-1 Pretest results of Influenza A

Pretest- Limit of Detection							
No.	Concentration (TCID ₅₀ /mL)	Number of tests					
		1		2		3	
		T1	T2	T1	T2	T1	T2
AS0: Stock solution	4.8×10 ⁷	/	/	/	/	/	/
AS1	4.8×10 ⁵	+++	-	+++	-	+++	-
AS2	2.4×10 ⁵	+++	-	+++	-	+++	-
AS3	1.2×10 ⁵	+++	-	+++	-	+++	-
AS4	6.0×10 ⁴	+++	-	+++	-	+++	-
AS5	3.0×10 ⁴	++	-	++	-	++	-

CE Technicaal File			File No: CorDx-CE-Flu A+B&COVID-19+RSV-7				
Influenza A/B+COVID-19/RSV Combo Ag Test							
AS6	1.5×10 ⁴	+	-	+	-	+	-
AS7	7.5×10 ³	-	-	-	-	-	-
Critical concentration	1.5×10 ⁴ TCID ₅₀ /mL						

Table 2-2 Pretest results of Influenza B

Pretest- Limit of Detection							
No.	Concentration (TCID ₅₀ /mL)	Number of tests					
		1		2		3	
		T1	T2	T1	T2	T1	T2
BS0: Stock solution	4.8×10^8	/	/	/	/	/	/
BS1	4.8×10^6	-	+++	-	+++	-	+++
BS2	2.4×10^6	-	+++	-	+++	-	+++
BS3	1.2×10^6	-	+++	-	+++	-	+++
BS4	6.0×10^5	-	+++	-	+++	-	+++
BS5	3.0×10^5	-	++	-	++	-	++
BS6	1.5×10^5	-	+	-	+	-	+
BS7	7.5×10^4	-	-	-	-	-	-
Critical concentration	1.5×10^5 TCID ₅₀ /mL						

Table 2-3 Pretest results of COVID-19

Pretest- Limit of Detection							
No.	Concentration (TCID ₅₀ /mL)	Number of tests					
		1		2		3	
		T1	T2	T1	T2	T1	T2
CS0: Stock solution	1.6×10^6	/	/	/	/	/	/
CS1	1.6×10^4	-	+++	-	+++	-	+++
CS2	1.6×10^3	-	+++	-	+++	-	+++
CS3	800	-	+++	-	+++	-	+++
CS4	400	-	++	-	++	-	++
CS5	200	-	+	-	+	-	+
CS6	100	-	-	-	-	-	-
CS7	50	-	-	-	-	-	-
Critical concentration	200 TCID ₅₀ /mL						

Table 2-4 Pretest results of RSV

Pretest- Limit of Detection							
Number of tests							

CE Technicaal File			File No: CorDx-CE-Flu A+B&COVID-19+RSV-7				
Influenza A/B+COVID-19/RSV Combo Ag Test							
No.	Concentration (TCID ₅₀ /mL)	1		2		3	
		T1	T2	T1	T2	T1	T2
RS0: Stock solution	3.2×10 ⁷	/	/	/	/	/	/
RS1	3.2×10 ⁵	+++	-	+++	-	+++	-
RS2	1.6×10 ⁵	+++	-	+++	-	+++	-
RS3	8.0×10 ⁴	+++	-	+++	-	+++	-
RS4	4.0×10 ⁴	+++	-	+++	-	+++	-
RS5	2.0×10 ⁴	++	-	++	-	++	-
RS6	1.0×10 ⁴	+	-	+	-	+	-
RS7	5.0×10 ³	-	-	-	-	-	-
Critical concentration	1.0×10 ⁴ TCID ₅₀ /mL						

Analysis: The limit of detection (LoD) for the Influenza A/B+COVID-19/RSV Combo Ag Test was established using limiting dilutions of inactivated viral stocks. Those materials were supplied at a concentration and diluted in confirmed-negative matrix derived from nasal swab specimens that had been expressed in viral transport media. This study was designed to estimate the LoD of the assay using a direct nasal swab, the tentative LoD was identified as the below table.

Virus Type	Concentration(TCID ₅₀ /mL)
Influenza A	1.5×10 ⁴
Influenza B	1.5×10 ⁵
COVID-19	200
RSV	1.0×10 ⁴

3.1.1.3 Determine the Limit of Detection

3.1.1.3.1 Test sample preparation

The viral culture stock solution was diluted close to critical concentration using negative sample matrix and 3 test samples were prepared in triplicate for each of the following concentration gradients: critical concentration, supra-critical concentration (high pool) and sub-critical concentration (low pool), as detailed in Table 3.

Table 3-1 Test sample preparation for influenza A- Determine the LoD

No.	Stock solution(μL)	Negative sample matrix(μL)	Volume (mL)	Concentration (TCID ₅₀ /mL)
AS4- 1	7.5	5992.5	6	6.0×10 ⁴
AS4-2	7.5	5992.5	6	
AS4-3	7.5	5992.5	6	
AS5-1	3.75	5996.25	6	3.0×10 ⁴
AS5-2	3.75	5996.25	6	

CE Technicaal File		File No: CorDx-CE-Flu A+B&COVID-19+RSV-7		
Influenza A/B+COVID-19/RSV Combo Ag Test				
AS5-3	3.75	5996.25	6	1.5×10 ⁴
AS6-1	1.875	5998.125	6	
AS6-2	1.875	5998.125	6	
AS6-3	1.875	5998.125	6	

Table 3-2 Test sample preparation for influenza B- Determine the LoD

No.	Stock solution(μL)	Negative sample matrix(μL)	Volume (mL)	Concentration (TCID ₅₀ /mL)
BS4- 1	7.5	5992.5	6	6.0×10 ⁵
BS4-2	7.5	5992.5	6	
BS4-3	7.5	5992.5	6	
BS5-1	3.75	5996.25	6	3.0×10 ⁵
BS5-2	3.75	5996.25	6	
BS5-3	3.75	5996.25	6	
BS6-1	1.875	5998.125	6	1.5×10 ⁵
BS6-2	1.875	5998.125	6	
BS6-3	1.875	5998.125	6	

Table 3-3 Test sample preparation for COVID-19- Determine the LoD

No.	Stock solution(μL)	Negative sample matrix(μL)	Volume (mL)	Concentration (TCID ₅₀ /mL)
CS3- 1	3	5997	6	800
CS3-2	3	5997	6	
CS3-3	3	5997	6	
CS4-1	1.5	5998.5	6	400
CS4-2	1.5	5998.5	6	
CS4-3	1.5	5998.5	6	
CS5-1	0.75	5999.25	6	200
CS5-2	0.75	5999.25	6	
CS5-3	0.75	5999.25	6	

Table 3-4 Test sample preparation for RSV- Determine the LoD

No.	Stock solution(μL)	Negative sample matrix(μL)	Volume (mL)	Concentration (TCID ₅₀ /mL)
RS4- 1	7.5	5992.5	6	4.0×10 ⁴
RS4-2	7.5	5992.5	6	
RS4-3	7.5	5992.5	6	
RS5-1	3.75	5996.25	6	2.0×10 ⁴
RS5-2	3.75	5996.25	6	
RS5-3	3.75	5996.25	6	
RS6-1	1.875	5998.125	6	1.0×10 ⁴
RS6-2	1.875	5998.125	6	

CE Technicaal File		File No: CorDx-CE-Flu A+B&COVID-19+RSV-7		
Influenza A/B+COVID-19/RSV Combo Ag Test				
RS6-3	1.875	5998.125	6	

3.1.1.3.2 Test method

Each sample was tested 20 times repeatedly using 3 batches of test kits separately and the results were recorded.

3.1.1.3.3 Acceptance criteria

A virus concentration level with a positive detection rate of 95% or more is used as the Limit of Detection.

3.1.1.3.4 Data processing

60 results were counted for each of the 3 concentrations and the positive detection rate was calculated using the formula.

Positive detection rate % = number of positive results / 60 x 100%

3.1.1.3.5 Results and analysis

Results: The results of LoD determination test are shown in Table 4.

Table 4-1 LoD determination test results of Influenza A

Lot	20200601																	
Number of times	Test Results																	
	AS4- 1		AS4-2		AS4-3		AS5- 1		AS5-2		AS5-3		AS6- 1		AS6-2		AS6-3	
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
1	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
2	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
3	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
4	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
5	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
6	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
7	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
8	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
9	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
10	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
11	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
12	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
13	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
14	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
15	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
16	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
17	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
18	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
19	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	-	-	+	-
20	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-

CE Technicaal File								File No: CorDx-CE-Flu A+B&COVID-19+RSV-7										
Influenza A/B+COVID-19/RSV Combo Ag Test																		
Positive detection rate	100%						100%						98.3%					
Lot	20200602																	
Number of times	Test Results																	
	AS4- 1		AS4-2		AS4-3		AS5- 1		AS5-2		AS5-3		AS6- 1		AS6-2		AS6-3	
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
1	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
2	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
3	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
4	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
5	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
6	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
7	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
8	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
9	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
10	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
11	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
12	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
13	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
14	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
15	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
16	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
17	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
18	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
19	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
20	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
Positive detection rate	100%						100%						100%					
Lot	20200603																	
Number of times	Test Results																	
	AS4- 1		AS4-2		AS4-3		AS5- 1		AS5-2		AS5-3		AS6- 1		AS6-2		AS6-3	
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
1	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
2	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
3	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
4	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
5	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
6	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-

CE Technicaal File								File No: CorDx-CE-Flu A+B&COVID-19+RSV-7											
Influenza A/B+COVID-19/RSV Combo Ag Test																			
7	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-	
8	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-	
9	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-	
10	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-	
11	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-	
12	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-	
13	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-	
14	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-	
15	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-	
16	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-	
17	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-	
18	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-	
19	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-	
20	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-	
Positive detection rate	100%						100%						100%						

Table 4-2 LoD determination test results of Influenza B

Lot	20200601																	
Number of times	Test Results																	
	BS4- 1		BS4-2		BS4-3		BS5- 1		BS5-2		BS5-3		BS6- 1		BS6-2		BS6-3	
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
1	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
2	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
3	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
4	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
5	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
6	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
7	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
8	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
9	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
10	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
11	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
12	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
13	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
14	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
15	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
16	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
17	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+

CE Technicaal File							File No: CorDx-CE-Flu A+B&COVID-19+RSV-7												
Influenza A/B+COVID-19/RSV Combo Ag Test																			
	18	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
	19	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
	20	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
Positive detection rate	100%							100%						100%					
Lot	20200602																		
Number of times	Test Results																		
	BS4- 1		BS4-2		BS4-3		BS5- 1		BS5-2		BS5-3		BS6- 1		BS6-2		BS6-3		
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	
	1	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
	2	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
	3	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
	4	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
	5	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
	6	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
	7	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
	8	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
	9	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
	10	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
	11	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
	12	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
	13	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
	14	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
	15	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
	16	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
	17	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
	18	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
	19	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
	20	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
Positive detection rate	100%							100%						100%					
Lot	20200603																		
Number of times	Test Results																		
	BS4- 1		BS4-2		BS4-3		BS5- 1		BS5-2		BS5-3		BS6- 1		BS6-2		BS6-3		
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	
	1	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
	2	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
	3	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+

CE Technicaal File								File No: CorDx-CE-Flu A+B&COVID-19+RSV-7											
Influenza A/B+COVID-19/RSV Combo Ag Test																			
4	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	
5	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	
6	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	
7	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	
8	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	
9	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	
10	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	
11	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	
12	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	
13	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	
14	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	
15	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	
16	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	
17	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	
18	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	
19	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	
20	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	
Positive detection rate	100%						100%						100%						

Table 4-3 LoD determination test results of COVID-19

Lot	20200601																	
Number of times	Test Results																	
	CS3- 1		CS3-2		CS3-3		CS4- 1		CS4-2		CS4-3		CS5- 1		CS5-2		CS5-3	
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
1	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
2	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
3	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
4	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
5	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
6	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
7	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
8	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
9	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
10	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
11	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
12	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
13	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
14	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+

CE Technicaal File								File No: CorDx-CE-Flu A+B&COVID-19+RSV-7										
Influenza A/B+COVID-19/RSV Combo Ag Test																		
15	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
16	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
17	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
18	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
19	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
20	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
Positive detection rate	100%						100%						100%					
Lot	20200602																	
Number of times	Test Results																	
	CS3- 1		CS3-2		CS3-3		CS4- 1		CS4-2		CS4-3		CS5- 1		CS5-2		CS5-3	
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
1	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
2	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
3	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
4	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
5	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
6	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
7	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
8	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
9	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
10	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
11	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
12	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
13	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
14	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
15	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
16	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
17	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
18	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
19	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
20	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
Positive detection rate	100%						100%						100%					
Lot	20200603																	
Number of times	Test Results																	
	CS3- 1		CS3-2		CS3-3		CS4- 1		CS4-2		CS4-3		CS5- 1		CS5-2		CS5-3	
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2

CE Technicaal File								File No: CorDx-CE-Flu A+B&COVID-19+RSV-7												
Influenza A/B+COVID-19/RSV Combo Ag Test																				
1	-	+++	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
2	-	+++	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
3	-	+++	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
4	-	+++	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
5	-	+++	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
6	-	+++	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
7	-	+++	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
8	-	+++	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
9	-	+++	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
10	-	+++	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
11	-	+++	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
12	-	+++	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
13	-	+++	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
14	-	+++	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
15	-	+++	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
16	-	+++	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
17	-	+++	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
18	-	+++	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
19	-	+++	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
20	-	+++	-	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+
Positive detection rate	100%								100%						100%					

Table 4-4 LoD determination test results of RSV

Lot	20200601																	
Number of times	Test Results																	
	RS4- 1		RS4-2		RS4-3		RS5- 1		RS5-2		RS5-3		RS6- 1		RS6-2		RS6-3	
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
1	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
2	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
3	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
4	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
5	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
6	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
7	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
8	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
9	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
10	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
11	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-

CE Technicaal File								File No: CorDx-CE-Flu A+B&COVID-19+RSV-7										
Influenza A/B+COVID-19/RSV Combo Ag Test																		
12	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
13	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
14	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
15	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
16	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
17	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
18	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
19	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
20	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
Positive detection rate	100%						100%						100%					
Lot	20200602																	
Number of times	Test Results																	
	RS4- 1		RS4-2		RS4-3		RS5- 1		RS5-2		RS5-3		RS6- 1		RS6-2		RS6-3	
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
1	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
2	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
3	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
4	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
5	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
6	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
7	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
8	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
9	+++	-	+++	-	+++	-	++	-	++	-	++	-	-	-	+	-	+	-
10	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
11	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
12	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
13	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
14	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
15	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
16	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
17	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
18	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
19	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
20	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
Positive detection rate	100%						100%						98.3%					
Lot	20200603																	

CE Technicaal File								File No: CorDx-CE-Flu A+B&COVID-19+RSV-7										
Influenza A/B+COVID-19/RSV Combo Ag Test																		
Number of times	Test Results																	
	RS4- 1		RS4-2		RS4-3		RS5- 1		RS5-2		RS5-3		RS6- 1		RS6-2		RS6-3	
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
1	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
2	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
3	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
4	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
5	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
6	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
7	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
8	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
9	+++	-	+++	-	+++	-	++	-	++	-	++	-	-	-	+	-	+	-
10	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
11	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
12	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
13	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
14	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
15	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
16	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
17	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
18	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
19	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
20	+++	-	+++	-	+++	-	++	-	++	-	++	-	+	-	+	-	+	-
Positive detection rate	100%						100%						98.3%					

Analysis: The analytical results is shown in Table 5

Table 5-1 Analysis of Influenza A test Results

Test kit Lot Concentration Positive detection rate	20200601	20200602	20200603
6.0×10 ⁴ TCID ₅₀ /mL	100%	100%	100%
3.0×10 ⁴ TCID ₅₀ /mL	100%	100%	100%
1.5×10 ⁴ TCID ₅₀ /mL	98.3%	100%	100%

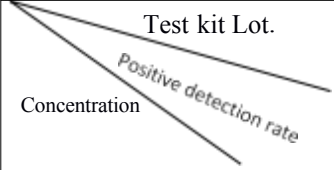
The test results of 3 batches of test kits showed a positive detection rate of over 95% at Influenza A virus concentration of 1.5×10⁴ TCID₅₀/mL.

Table 5-2 Analysis of Influenza B test Results

CE Technicaal File		File No: CorDx-CE-Flu A+B&COVID-19+RSV-7	
Influenza A/B+COVID-19/RSV Combo Ag Test			
Test kit Lot Concentration Positive detection rate	20200601	20200602	20200603
6.0×10 ⁵ TCID ₅₀ /mL	100%	100%	100%
3.0×10 ⁵ TCID ₅₀ /mL	100%	100%	100%
1.5×10 ⁵ TCID ₅₀ /mL	100%	100%	100%

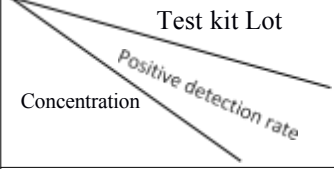
The test results of 3 batches of test kits showed a positive detection rate of over 95% at Influenza B virus concentration of 1.5×10^5 TCID₅₀/mL.

Table 5-3 Analysis of COVID-19 test Results

	20200601	20200602	20200603
800TCID ₅₀ /mL	100%	100%	100%
400 TCID ₅₀ /mL	100%	100%	100%
200TCID ₅₀ /mL	100%	100%	100%

The test results of 3 batches of test kits showed a positive detection rate of over 95% at SARS-CoV-2 virus concentration of 200TCID₅₀/mL.

Table 5-4 Analysis of RSV test Results

	20200601	20200602	20200603
4.0×10^4 TCID ₅₀ /mL	100%	100%	100%
2.0×10^4 TCID ₅₀ /mL	100%	100%	100%
1.0×10^4 TCID ₅₀ /mL	100%	98.3%	98.3%

The test results of 3 batches of test kits showed a positive detection rate of over 95% at RSV concentration of 1.0×10^4 TCID₅₀/mL.

3.1.2 Validation of LoD

3.1.2.1 Source of viral culture stock solution: Inactivated virus

Influenza A : AS10: 3.02×10^7 TCID₅₀/mL; AS11: 2.96×10^7 TCID₅₀/mL; AS12: 3.06×10^7 TCID₅₀/mL;

Influenza B: BS10: 2.98×10^8 TCID₅₀/mL; BS11: 3.04×10^8 TCID₅₀/mL; BS12: 3.00×10^8 TCID₅₀/mL;

COVID-19: CS10: 1.12×10^6 TCID₅₀/mL; CS11: 1.07×10^6 TCID₅₀/mL; CS12: 1.09×10^6 TCID₅₀/mL;

RSV: RS10: 2.02×10^7 TCID₅₀/mL; RS11: 2.06×10^7 TCID₅₀/mL; RS12: 1.96×10^7 TCID₅₀/mL.

3.1.2.2 Test sample preparation

CE Technical File	File No: CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

The above 3 isolated strains, which were cultured from positive samples, were diluted to LoD using negative sample matrix. The preparation method is shown in Table 6. Using 3 batches of test kits to test each sample 20 times repeatedly and record the results.

Table 6-1 Test sample preparation for Influenza A

No.	Stock solution (mL)	Upper level of sample (mL)	Negative sample matrix (mL)	Volume (mL)	Test concentration (TCID ₅₀ /mL)
AS10-1	0.02	/	1.98	2	3.02×10 ⁵
AS10-2	/	0.9	8.1	9	3.02×10 ⁴
AS10-3	/	3	3	6	1.51×10 ⁴
AS11-1	0.02	/	1.98	2	2.96×10 ⁵
AS11-2	/	0.9	8.1	9	2.96×10 ⁴
AS11-3	/	3	3	6	1.48×10 ⁴
AS12-1	0.02	/	1.98	2	3.06×10 ⁵
AS12-2	/	0.9	8.1	9	3.06×10 ⁴
AS12-3		3	3	6	1.53×10 ⁴

Table 6-2 Test sample preparation for Influenza B

No.	Stock solution (mL)	Upper level of sample (mL)	Negative sample matrix (mL)	Volume (mL)	Test concentration (TCID ₅₀ /mL)
BS10-1	0.02	/	1.98	2	2.98×10 ⁶
BS10-2	/	0.9	8.1	9	2.98×10 ⁵
BS10-3	/	3	3	6	1.49×10 ⁵
BS11-1	0.02	/	1.98	2	3.04×10 ⁶
BS11-2	/	0.9	8.1	9	3.04×10 ⁵
BS11-3	/	3	3	6	1.52×10 ⁵
BS12-1	0.02	/	1.98	2	3.00×10 ⁶
BS12-2	/	0.9	8.1	9	3.00×10 ⁵
BS12-3		3	3	6	1.50×10 ⁵

Table 6-3 Test sample preparation for COVID-19

No.	Stock solution (mL)	Upper level of sample (mL)	Negative sample matrix (mL)	Volume (mL)	Test concentration (TCID ₅₀ /mL)
CS10-1	0.02	/	1.98	2	1.12×10 ⁴
CS10-2	/	0.9	8.1	9	1.12×10 ³
CS10-3	/	1.11	4.89	6	207.2
CS11-1	0.02	/	1.98	2	1.07×10 ⁴
CS11-2	/	0.9	8.1	9	1.07×10 ³
CS11-3	/	1.11	4.89	6	198
CS12-1	0.02	/	1.98	2	1.09×10 ⁴
CS12-2	/	0.9	8.1	9	1.09×10 ³
CS12-3		1.11	4.89	6	201.7

Table 6-4 Test sample preparation for RSV

No.	Stock solution (mL)	Upper level of sample (mL)	Negative sample matrix (mL)	Volume (mL)	Test concentration (TCID ₅₀ /mL)
RS10-1	0.02	/	1.98	2	2.02×10 ⁵

CE Technicaal File			File No: CorDx-CE-Flu A+B&COVID-19+RSV-7		
Influenza A/B+COVID-19/RSV Combo Ag Test					
RS10-2	/	0.9	8.1	9	2.02×10 ⁴
RS10-3	/	3	3	6	1.01×10 ⁴
RS11-1	0.02	/	1.98	2	2.06×10 ⁵
RS11-2	/	0.9	8.1	9	2.06×10 ⁴
RS11-3	/	3	3	6	1.03×10 ⁴
RS12-1	0.02	/	1.98	2	1.96×10 ⁵
RS12-2	/	0.9	8.1	9	1.96×10 ⁴
RS12-3		3	3	6	0.98×10 ⁴

3.1.2.3 Test method

Samples (S10-3, S11-3 and S12-3) were tested using 3 batches of test kits, each sample was tested 20 times, repeatedly and the results were recorded.

3.1.2.4 Acceptance criteria

A positive detection rate of $\geq 95\%$ is required for all 3 batches of test kits.

3.1.2.5 Data processing

20 results from each batch of test kits testing each sample were counted separately and the positive detection rate was calculated using the formula.

Positive detection rate % = number of positive results / 20 x 100%

3.1.2.6 Results and analysis

Results: The results of LoD determination test are shown in Table 7.

Table 7-1 LoD determination test results of Influenza A

No.	AS10-3		AS11-3		AS12-3	
Concentration	1.51×10 ⁴ TCID ₅₀ /mL		1.48×10 ⁴ TCID ₅₀ /mL		1.53×10 ⁴ TCID ₅₀ /mL	
Lot	20200601					
Number of times	Results					
	T1	T2	T1	T2	T1	T2
1	+	-	+	-	+	-
2	+	-	+	-	+	-
3	+	-	+	-	+	-
4	+	-	+	-	+	-
5	+	-	+	-	+	-
6	+	-	+	-	+	-
7	+	-	+	-	+	-
8	+	-	+	-	+	-
9	+	-	+	-	+	-
10	+	-	+	-	+	-
11	+	-	+	-	+	-
12	+	-	-	-	+	-
13	+	-	+	-	+	-
14	+	-	+	-	+	-

CE Technicaal File			File No: CorDx-CE-Flu A+B&COVID-19+RSV-7			
Influenza A/B+COVID-19/RSV Combo Ag Test						
15	+	-	+	-	+	-
16	+	-	+	-	+	-
17	+	-	+	-	+	-
18	+	-	+	-	+	-
19	+	-	+	-	+	-
20	+	-	+	-	+	-
Detection rate	100%	/	95%	/	100%	/
Lot	20200602					
Number of times	Results					
	T1	T2	T1	T2	T1	T2
1	+	-	+	-	+	-
2	+	-	+	-	+	-
3	+	-	+	-	+	-
4	+	-	+	-	+	-
5	+	-	+	-	+	-
6	+	-	+	-	+	-
7	+	-	+	-	+	-
8	+	-	+	-	+	-
9	+	-	+	-	+	-
10	+	-	+	-	+	-
11	+	-	+	-	+	-
12	+	-	+	-	+	-
13	+	-	+	-	+	-
14	+	-	+	-	+	-
15	+	-	+	-	+	-
16	+	-	+	-	+	-
17	+	-	+	-	+	-
18	+	-	+	-	+	-
19	+	-	+	-	+	-
20	+	-	+	-	+	-
Detection rate	100%	/	100%	/	100%	/
Lot	20200603					
Number of times	Results					
	T1	T2	T1	T2	T1	T2
1	+	-	+	-	+	-
2	+	-	+	-	+	-
3	+	-	+	-	+	-
4	+	-	+	-	+	-

CE Technicaal File			File No: CorDx-CE-Flu A+B&COVID-19+RSV-7			
Influenza A/B+COVID-19/RSV Combo Ag Test						
5	+	-	+	-	+	-
6	+	-	+	-	+	-
7	+	-	+	-	+	-
8	+	-	+	-	+	-
9	+	-	+	-	+	-
10	+	-	+	-	+	-
11	+	-	+	-	+	-
12	+	-	+	-	+	-
13	+	-	+	-	+	-
14	+	-	+	-	+	-
15	+	-	+	-	+	-
16	+	-	+	-	+	-
17	+	-	+	-	+	-
18	+	-	+	-	+	-
19	+	-	+	-	+	-
20	+	-	-	-	+	-
Detection rate	100%	/	95%	/	100%	/

Table 7-2 LoD determination test results of Infuenza B

No.	BS10-3		BS11-3		BS12-3	
Concentration	1.49×10 ⁵ TCID ₅₀ /mL		1.52×10 ⁵ TCID ₅₀ /mL		1.50×10 ⁵ TCID ₅₀ /mL	
Lot	20200601					
Number of times	Results					
	T1	T2	T1	T2	T1	T2
1	-	+	-	+	-	+
2	-	+	-	+	-	+
3	-	+	-	+	-	+
4	-	+	-	+	-	+
5	-	+	-	+	-	+
6	-	+	-	+	-	+
7	-	+	-	+	-	+
8	-	+	-	+	-	+
9	-	+	-	+	-	+
10	-	+	-	+	-	+
11	-	+	-	+	-	+
12	-	+	-	+	-	+
13	-	+	-	+	-	+
14	-	+	-	+	-	+
15	-	+	-	+	-	+

CE Technicaal File			File No: CorDx-CE-Flu A+B&COVID-19+RSV-7			
Influenza A/B+COVID-19/RSV Combo Ag Test						
16	-	+	-	+	-	+
17	-	+	-	+	-	+
18	-	+	-	+	-	+
19	-	+	-	+	-	+
20	-	+	-	+	-	+
Detection rate	/	100%	/	100%	/	100%
Lot	20200602					
Number of times	Results					
	T1	T2	T1	T2	T1	T2
1	-	+	-	+	-	+
2	-	+	-	+	-	+
3	-	+	-	+	-	+
4	-	+	-	+	-	+
5	-	+	-	+	-	+
6	-	+	-	+	-	+
7	-	+	-	+	-	+
8	-	+	-	+	-	+
9	-	+	-	+	-	+
10	-	+	-	+	-	+
11	-	+	-	+	-	+
12	-	+	-	+	-	+
13	-	+	-	+	-	+
14	-	+	-	+	-	+
15	-	+	-	+	-	+
16	-	+	-	+	-	+
17	-	+	-	+	-	+
18	-	+	-	+	-	+
19	-	+	-	+	-	+
20	-	+	-	+	-	+
Detection rate	/	100%	/	100%	/	100%
Lot	20200603					
Number of times	Results					
	T1	T2	T1	T2	T1	T2
1	-	+	-	+	-	+
2	-	+	-	+	-	+
3	-	+	-	+	-	+
4	-	+	-	+	-	+
5	-	+	-	+	-	+

CE Technicaal File			File No: CorDx-CE-Flu A+B&COVID-19+RSV-7			
Influenza A/B+COVID-19/RSV Combo Ag Test						
6	-	+	-	+	-	+
7	-	+	-	+	-	+
8	-	+	-	+	-	+
9	-	+	-	+	-	+
10	-	+	-	+	-	+
11	-	+	-	+	-	+
12	-	+	-	+	-	+
13	-	+	-	+	-	+
14	-	+	-	+	-	+
15	-	+	-	+	-	+
16	-	+	-	+	-	+
17	-	+	-	+	-	+
18	-	+	-	+	-	+
19	-	+	-	+	-	+
20	-	+	-	+	-	+
Detection rate	/	100%	/	100%	/	100%

Table 7-3 LoD determination test results of COVID-19

No.	CS10-3		CS11-3		CS12-3	
Concentration	207.2 TCID ₅₀ /mL		198 TCID ₅₀ /mL		201.7 TCID ₅₀ /mL	
Lot	20200601					
Number of times	Results					
	T1	T2	T1	T2	T1	T2
1	-	+	-	+	-	+
2	-	+	-	+	-	+
3	-	+	-	+	-	+
4	-	+	-	+	-	+
5	-	+	-	+	-	+
6	-	+	-	+	-	+
7	-	+	-	+	-	+
8	-	+	-	+	-	+
9	-	+	-	+	-	+
10	-	+	-	+	-	+
11	-	+	-	+	-	+
12	-	+	-	+	-	+
13	-	+	-	+	-	+
14	-	+	-	+	-	+
15	-	+	-	+	-	+
16	-	+	-	+	-	+

CE Technicaal File			File No: CorDx-CE-Flu A+B&COVID-19+RSV-7			
Influenza A/B+COVID-19/RSV Combo Ag Test						
17	-	+	-	+	-	+
18	-	+	-	+	-	+
19	-	+	-	+	-	+
20	-	+	-	+	-	+
Detection rate	/	100%	/	100%	/	100%
Lot	20200602					
Number of times	Results					
	T1	T2	T1	T2	T1	T2
1	-	+	-	+	-	+
2	-	+	-	+	-	+
3	-	+	-	+	-	+
4	-	+	-	+	-	+
5	-	+	-	+	-	+
6	-	+	-	+	-	+
7	-	+	-	+	-	+
8	-	+	-	+	-	+
9	-	+	-	+	-	+
10	-	+	-	+	-	+
11	-	+	-	+	-	+
12	-	+	-	+	-	+
13	-	+	-	+	-	+
14	-	+	-	+	-	+
15	-	+	-	+	-	+
16	-	+	-	+	-	+
17	-	+	-	+	-	+
18	-	+	-	+	-	+
19	-	+	-	+	-	+
20	-	+	-	+	-	+
Detection rate	100%	/	100%	/	100%	/
Lot	20200603					
Number of times	Results					
	T1	T2	T1	T2	T1	T2
1	-	+	-	+	-	+
2	-	+	-	+	-	+
3	-	+	-	+	-	+
4	-	+	-	+	-	+
5	-	+	-	+	-	+
6	-	+	-	+	-	+
7	-	+	-	+	-	+

CE Technicaal File			File No: CorDx-CE-Flu A+B&COVID-19+RSV-7			
Influenza A/B+COVID-19/RSV Combo Ag Test						
8	-	+	-	+	-	+
9	-	+	-	+	-	+
10	-	+	-	+	-	+
11	-	+	-	+	-	+
12	-	+	-	+	-	+
13	-	+	-	+	-	+
14	-	+	-	+	-	+
15	-	+	-	+	-	+
16	-	+	-	+	-	+
17	-	+	-	+	-	+
18	-	+	-	+	-	+
19	-	+	-	+	-	+
20	-	+	-	+	-	+
Detection rate	100%	/	100%	/	100%	/

Table 7-4 LoD determination test results of RSV

No.	RS10-3		RS11-3		RS12-3	
Concentration	1.01×10 ⁴ TCID ₅₀ /mL		1.03×10 ⁴ TCID ₅₀ /mL		0.98×10 ⁴ TCID ₅₀ /mL	
Lot	20200601					
Number of times	Results					
	T1	T2	T1	T2	T1	T2
1	+	-	+	-	+	-
2	+	-	+	-	+	-
3	+	-	+	-	+	-
4	+	-	+	-	+	-
5	+	-	+	-	+	-
6	+	-	+	-	+	-
7	+	-	+	-	+	-
8	+	-	+	-	+	-
9	+	-	+	-	+	-
10	+	-	+	-	+	-
11	+	-	+	-	+	-
12	+	-	+	-	+	-
13	+	-	+	-	+	-
14	+	-	+	-	+	-
15	+	-	+	-	+	-
16	+	-	+	-	+	-
17	+	-	+	-	+	-
18	+	-	+	-	+	-

CE Technicaal File			File No: CorDx-CE-Flu A+B&COVID-19+RSV-7			
Influenza A/B+COVID-19/RSV Combo Ag Test						
19	+	-	+	-	+	-
20	+	-	+	-	+	-
Detection rate	100%	/	100%	/	100%	/
Lot	20200602					
Number of times	Results					
	T1	T2	T1	T2	T1	T2
1	+	-	+	-	+	-
2	+	-	+	-	+	-
3	+	-	+	-	+	-
4	+	-	+	-	+	-
5	+	-	+	-	+	-
6	+	-	+	-	+	-
7	+	-	+	-	+	-
8	+	-	+	-	+	-
9	+	-	+	-	+	-
10	+	-	+	-	+	-
11	+	-	+	-	+	-
12	+	-	+	-	+	-
13	+	-	+	-	+	-
14	+	-	+	-	+	-
15	+	-	+	-	+	-
16	+	-	+	-	+	-
17	+	-	+	-	+	-
18	+	-	+	-	+	-
19	+	-	+	-	+	-
20	+	-	+	-	+	-
Detection rate	100%	/	100%	/	100%	/
Lot	20200603					
Number of times	Results					
	T1	T2	T1	T2	T1	T2
1	+	-	+	-	+	-
2	+	-	+	-	+	-
3	+	-	+	-	+	-
4	+	-	+	-	+	-
5	+	-	+	-	-	-
6	+	-	+	-	+	-
7	+	-	+	-	+	-
8	+	-	+	-	+	-

CE Technicaal File			File No: CorDx-CE-Flu A+B&COVID-19+RSV-7			
Influenza A/B+COVID-19/RSV Combo Ag Test						
9	+	-	+	-	+	-
10	+	-	+	-	+	-
11	+	-	+	-	+	-
12	+	-	+	-	+	-
13	+	-	+	-	+	-
14	+	-	+	-	+	-
15	+	-	+	-	+	-
16	+	-	+	-	+	-
17	+	-	+	-	+	-
18	+	-	+	-	+	-
19	+	-	+	-	+	-
20	+	-	+	-	+	-
Detection rate	100%	/	100%	/	95%	/

Analysis: The results analysis is shown in Table 8

Table 8-1 Analysis of Influenza A test Results

NO. \ Lot		20200601	20200602	20200603
AS10-3		100%	95%	100%
AS11-3		100%	100%	100%
AS12-3		100%	95%	100%

The results of the 3 batches of test kits showed that the positive detection rate was above 95% at Influenza A virus concentration 1.5×10^4 TCID₅₀/mL.

Table 8-2 Analysis of Influenza B test Results

NO. \ Lot		20200601	20200602	20200603
BS10-3		100%	100%	100%
BS11-3		100%	100%	100%
BS12-3		100%	100%	100%

The results of the 3 batches of test kits showed that the positive detection rate was above 95% at Influenza B virus concentration 1.5×10^5 TCID₅₀/mL

Table 8-3 Analysis of COVID-19 test Results

NO. \ Lot		20200601	20200602	20200603
CS10-3		100%	100%	100%
CS11-3		100%	100%	100%
CS12-3		100%	100%	100%

The results of the 3 batches of test kits showed that the positive detection rate was above 95% at SARS-CoV-2 virus concentration 200 TCID₅₀/mL

CE Technicaal File	File No: CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

Table 8-4 Analysis of RSV test Results

NO. \ Lot	20200601	20200602	20200603
RS10-3	100%	100%	100%
RS11-3	100%	100%	100%
RS12-3	100%	100%	95%

The results of the 3 batches of test kits showed that the positive detection rate was above 95% at RSV virus concentration 1.0×10^4 TCID₅₀/mL

3.1.3 Conclusion

Based on the determination and validation of the 3 batches of test kits for LoD study, the LoD of Influenza A for this kit was 1.5×10^4 TCID₅₀/mL, the LOD of Influenza B for this kit was 1.5×10^5 TCID₅₀/mL, the LOD of COVID-19 for this kit was 200 TCID₅₀/mL and the LOD of RSV for this kit was 1.0×10^4 TCID₅₀/mL.

3.2 Precision Study

3.2.1 Test sample preparation

Precision tests were performed with viral cultures, sample preparation information is given in Table 9, test concentration included.

Table 9-1 Precision sample preparation-Info of Influenza A

No.	Stock solution (μL)	Upper level of sample (mL)	Negative sample matrix (mL)	Volume (mL)	Test concentration (TCID ₅₀ /mL)	T1 Result	T2 Result
Stock solution	/	/	/	/	4.8×10^7	/	/
AS3	50	/	19.95	20	1.2×10^5	+++	-
AR3	/	7.5	22.5	30	3.0×10^4	++	-
AR2	/	15	15	30	1.5×10^4	+	-
AR1	/	10	10	20	7.5×10^3	-	-

Table 9-2 Precision sample preparation-Info of Influenza B

No.	Stock solution (μL)	Upper level of sample (mL)	Negative sample matrix (mL)	Volume (mL)	Test concentration (TCID ₅₀ /mL)	T1 Result	T2 Result
Stock solution	/	/	/	/	4.8×10^8	/	/
BS3	50	/	19.95	20	1.2×10^6	-	+++
BR3	/	7.5	22.5	30	3.0×10^5	-	++
BR2	/	15	15	30	1.5×10^5	-	+
BR1	/	10	10	20	7.5×10^4	-	-

CE Technicaal File	File No: CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

Table 9-3 Precision sample preparation-Info of COVID-19

No.	Stock solution (μL)	Upper level of sample (mL)	Negative sample matrix (mL)	Volume (mL)	Test concentration (TCID ₅₀ /mL)	T1 Result	T2 Result
Stock solution	/	/	/	/	1.6×10 ⁶	/	/
CS2	20	/	19.98	20	1.6×10 ³	-	+++
CR3	/	7.5	22.5	30	400	-	++
CR2		15	15	30	200	-	+
CR1	/	10	10	20	100	-	-

Table 9-4 Precision sample preparation-Info of RSV

No.	Stock solution (μL)	Upper level of sample (mL)	Negative sample matrix (mL)	Volume (mL)	Test concentration (TCID ₅₀ /mL)	T1 Result	T2 Result
Stock solution	/	/	/	/	3.2×10 ⁷	/	/
RS3	50	/	19.95	20	8.0×10 ⁴	+++	-
RR3	/	7.5	22.5	30	2.0×10 ⁴	++	-
RR2		15	15	30	1.0×10 ⁴	+	-
RR1	/	10	10	20	5.0×10 ³	-	-

3.2.2 Test method

Samples (R3, R2 and R1) were tested using 3 batches of test kits, each sample was tested 2 times, by each operator, each day and each site. It has total 3 sites, 5 days and 2 operators which one is professional person and the other is lay person, repeatedly and the results were recorded.

3.2.3 Acceptance criteria

Based on the test results, the results were observed for repeatability (Within-Run), between-run precision, between-day precision, within-lab precision, between-lot precision, between-lab precision and reproducibility was constructed incorporating all of the above precision factors.

Precision result requirements: negative sample R1 remains negative, the test line is always L1~L2 and no color band appears; test line of low positive sample R2 is L3~L4, test line of moderately positive sample R3 is L5~L7, positive result shows uniform color rendering. As the test kit is a qualitative product, all of the above precision requirements can be met so long as the same sample is tested consistently.

3.2.4 Results and analysis

Results: The results are shown in Table 10.

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

Table 10-1 Precision results of Influenza A

Sites	Lot	Days	Runs	Replicates	AR1				AR2				AR3			
					T1		T2		T1		T2		T1		T2	
					Test line colour	Results	Test line colour	Results	Test line colour	Results	Test line colour	Results	Test line colour	Results	Test line colour	Results
1	20200601	1	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L5	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		2	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L7	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		3	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		4	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		5	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
	20200602	1	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		2	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		3	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

		4	1	2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		5	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
	20200603	1	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L5	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L3	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		2	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		3	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		4	1	1	L1	-	L1	-	L3	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		5	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		1	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		2	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

2	20200601	3	2	2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		4	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		5	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
	20200602	1	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L5	++	L1	-
		2	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L3	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L5	++	L1	-
		3	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		4	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L3	+	L1	-	L6	++	L1	-
		5	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L5	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		1	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L5	++	L1	-
		2	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

	20200603		1	2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		2	2	1	L1	-	L1	-	L4	+	L1	-	L7	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		1	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		2	2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		1	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
	20200601	1	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L5	++	L1	-
		2	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L5	++	L1	-
		3	1	1	L1	-	L1	-	L3	+	L1	-	L5	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		4	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		5	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		1	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		2	2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

3	20200602	2	2	2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		3	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		4	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		5	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L3	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L5	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
	20200603	1	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		2	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		3	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		4	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		5	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-

Table 10-2 Precision results of Influenza B

Sites	Lot	Days	Runs	Replicates	BR1			BR2			BR3		
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CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

					T1		T2		T1		T2		T1		T2	
					Test line colour	Results	Test line colour	Results	Test line colour	Results	Test line colour	Results	Test line colour	Results	Test line colour	Results
1	20200601	1	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		2	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		3	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L5	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		4	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		5	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
	20200602	1	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L7	++
		2	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L3	+	L1	-	L6	++
		3	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

	20200603	4	2	1	L1	-	L1	-	L1	-	L3	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		5	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L5	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		1	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L5	++
		2	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		3	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L7	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		4	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L3	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		5	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
	20200601	1	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		2	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		3	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

2		4	1	1	L1	-	L1	-	L1	-	L3	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		5	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
	20200602	1	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		2	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L3	+	L1	-	L6	++
		3	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		4	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		5	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L5	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		1	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L3	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L5	++
		2	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

	20200603	3	2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		4	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		5	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L5	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
	20200601	1	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L5	++
		2	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		3	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		4	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L7	++
		5	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		1	1	1	L1	-	L1	-	L1	-	L3	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		2	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L3	+	L1	-	L6	++

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

3	20200602	3	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		4	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		20200603	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L5	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			3	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			4	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			5	1	L1	-	L1	-	L1	-	L4	+	L1	-	L5	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
Table 10 -3 Precision results of COVID-	Lot	Days	Runs	Replicates	CR1				CR2				CR3			
					T1		T2		T1		T2		T1		T2	
					Test line colour	Results	Test line colour	Results	Test line colour	Results	Test line colour	Results	Test line colour	Results	Test line colour	Results

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

19Sites																
1	20200601	1	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		2	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		3	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L5	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		4	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		5	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
	20200602	1	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L7	++
		2	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L3	+	L1	-	L6	++
		3	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		4	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L3	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

	20200603	5	2	2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				1	L1	-	L1	-	L1	-	L4	+	L1	-	L5	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		1	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L5	++
		2	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		3	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L7	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		4	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L3	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		5	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
	20200601	1	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		2	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		3	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		4	1	1	L1	-	L1	-	L1	-	L3	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

2	20200602	5	1	2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		1	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L3	+	L1	-	L6	++
			3	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		4	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		5	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L5	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
	20200603	1	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L3	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L5	++
		2	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		3	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

		4	2	2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		5	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L5	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
3	20200601	1	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		2	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		3	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		4	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L7	++
		5	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
	20200602	1	1	1	L1	-	L1	-	L1	-	L3	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		2	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L3	+	L1	-	L6	++
		3	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

	20200603	4	1	2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		5	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
	20200603	1	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		2	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		3	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		4	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
		5	1	1	L1	-	L1	-	L1	-	L4	+	L1	-	L5	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
			2	1	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++
				2	L1	-	L1	-	L1	-	L4	+	L1	-	L6	++

Table 10-4 Precision results of RSV

Sites	Lot	Days	Runs	Replicates	RR1				RR2				RR3			
					T1		T2		T1		T2		T1		T2	
					Test line colour	Results	Test line colour	Results	Test line colour	Results	Test line colour	Results	Test line colour	Results	Test line colour	Results
			1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

1	20200601	1	2	2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		2	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L3	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		3	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L5	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		4	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		5	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L3	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
	20200602	1	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		2	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		3	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		4	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
	5	1	2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		2	2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

	20200603		1	2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				1	L1	-	L1	-	L3	+	L1	-	L6	++	L1	-
		2	1	2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		3	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		4	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		5	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
	20200601	1	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L3	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		2	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L5	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		3	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		4	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

2	20200602	5	2	2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		1	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		2	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L5	++	L1	-
		3	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		4	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		5	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L5	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
	20200603	1	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L5	++	L1	-
		2	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		3	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		4	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		5	1	1	L1	-	L1	-	L4	+	L1	-	L5	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L3	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
3	20200601	1	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L5	++	L1	-
		2	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		3	1	1	L1	-	L1	-	L4	+	L1	-	L5	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		4	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		5	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
	20200602	1	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L3	+	L1	-	L6	++	L1	-
		2	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		3	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-

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		4	2	2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		5	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L5	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
	20200603	1	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L3	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L5	++	L1	-
		2	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		3	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L3	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L7	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		4	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
		5	1	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
			2	1	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-
				2	L1	-	L1	-	L4	+	L1	-	L6	++	L1	-

Analysis: The results analysis is shown in Table 11.

Table 11 Precision results analysis

No.	Number of results (pcs)	Chromaticity	Results
R1	90	L1-L2	-
R2	90	L3-L4	+
R3	90	L5-L7	++

In the results, tested in different sites, by different operators, with different batches and in different number of test runs, the result of R1 was always L1 or L2 with a negative result. The result of R2 was always L3 or L4 with consistent color and a low positive result, while the result of R3 was always L5 or L6 or L7 with consistent color and a moderately positive result. The results show that the requirements for repeatability and reproducibility are met.

3.2.5 Conclusion

3 batches of test kits were used for precision study and it was concluded that the kit met the requirements for repeatability, reproducibility and precision.

3.3 Hook effect Study

3.3.1 Test sample preparation

The viral culture stock solution was diluted through a concentration gradient and then tested starting from low to high concentrations, with 3 samples prepared for each concentration. The preparation method is shown in Table 12.

Table 12-1 Test sample preparation for Influenza A

No.1	Stock solution (mL)	Upper level of sample(mL)	Negative sample matrix(mL)	Volume (mL)	Concentration (TCID ₅₀ /mL)
AS0- 1	/	/	/	/	4.8×10^7
AS1- 1	0.2	/	1.8	2	4.8×10^6
AS2- 1	/	0.2	1.8	2	4.8×10^5
AS3- 1	/	0.2	1.8	2	4.8×10^4
AS4- 1	/	1	1	2	2.4×10^4
AS5- 1	/	1	1	2	1.2×10^4
No.2	Stock solution (mL)	Upper level of sample(mL)	Negative sample matrix(mL)	Volume (mL)	Concentration (TCID ₅₀ /mL)
AS0-2	/	/	/	/	3.06×10^7
AS1-2	0.2	/	1.8	2	3.06×10^6
AS2-2	/	0.2	1.8	2	3.06×10^5
AS3-2	/	0.2	1.8	2	3.06×10^4
AS4-2	/	1	1	2	1.53×10^4
AS5-2	/	1	1	2	7.65×10^3
No.3	Stock solution (mL)	Upper level of sample(mL)	Negative sample matrix(mL)	Volume (mL)	Concentration (TCID ₅₀ /mL)
AS0-3	/	/	/	/	2.96×10^7
AS1-3	0.2	/	1.8	2	2.96×10^6

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AS2-3	/	0.2	1.8	2	2.96×10^5
AS3-3	/	0.2	1.8	2	2.96×10^4
AS4-3	/	1	1	2	1.48×10^4
AS5-3	/	1	1	2	7.6×10^3

Table 12-2 Test sample preparation for Influenza B

No.1	Stock solution (mL)	Upper level of sample(mL)	Negative sample matrix(mL)	Volume (mL)	Concentration (TCID ₅₀ /mL)
BS0- 1	/	/	/	/	4.8×10^8
BS1- 1	0.2	/	1.8	2	4.8×10^7
BS2- 1	/	0.2	1.8	2	4.8×10^6
BS3- 1	/	0.2	1.8	2	4.8×10^5
BS4- 1	/	1	1	2	2.4×10^5
BS5- 1	/	1	1	2	1.2×10^5
No.2	Stock solution (mL)	Upper level of sample(mL)	Negative sample matrix(mL)	Volume (mL)	Concentration (TCID ₅₀ /mL)
BS0-2	/	/	/	/	3.0×10^8
BS1-2	0.2	/	1.8	2	3.0×10^7
BS2-2	/	0.2	1.8	2	3.0×10^6
BS3-2	/	0.2	1.8	2	3.0×10^5
BS4-2	/	1	1	2	1.5×10^5
BS5-2	/	1	1	2	7.5×10^4
No.3	Stock solution (mL)	Upper level of sample(mL)	Negative sample matrix(mL)	Volume (mL)	Concentration (TCID ₅₀ /mL)
BS0-3	/	/	/	/	2.98×10^8
BS1-3	0.2	/	1.8	2	2.98×10^7
BS2-3	/	0.2	1.8	2	2.98×10^6
BS3-3	/	0.2	1.8	2	2.98×10^5
BS4-3	/	1	1	2	1.49×10^5
BS5-3	/	1	1	2	7.45×10^4

Table 12-3 Test sample preparation for COVID-19

No.1	Stock solution (mL)	Upper level of sample(mL)	Negative sample matrix(mL)	Volume (mL)	Concentration (TCID ₅₀ /mL)
CS0- 1	/	/	/	/	1.6×10^6
CS1- 1	0.02	/	1.98	2	1.6×10^4
CS2- 1	/	0.2	1.8	2	1.6×10^3
CS3- 1	/	0.5	1.5	2	400
CS4- 1	/	1	1	2	200
CS5- 1	/	1	1	2	100
No.2	Stock solution (mL)	Upper level of sample(mL)	Negative sample matrix(mL)	Volume (mL)	Concentration (TCID ₅₀ /mL)
CS0-2	/	/	/	/	1.7×10^6
CS1-2	0.02	/	1.98	2	1.7×10^4
CS2-2	/	0.2	1.8	2	1.7×10^3
CS3-2	/	0.5	1.5	2	425

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CS4-2	/	1	1	2	212.5
CS5-2	/	1	1	2	106.25
No.3	Stock solution (mL)	Upper level of sample(mL)	Negative sample matrix(mL)	Volume (mL)	Concentration (TCID ₅₀ /mL)
CS0-3	/	/	/	/	1.8×10 ⁶
CS1-3	0.02	/	1.98	2	1.8×10 ⁴
CS2-3	/	0.2	1.8	2	1.8×10 ³
CS3-3	/	0.5	1.5	2	450
CS4-3	/	1	1	2	225
CS5-3	/	1	1	2	112.5

Table 12-4 Test sample preparation for RSV

No.1	Stock solution (mL)	Upper level of sample(mL)	Negative sample matrix(mL)	Volume (mL)	Concentration (TCID ₅₀ /mL)
RS0- 1	/	/	/	/	2.02×10 ⁷
RS1- 1	0.2	/	1.8	2	2.02×10 ⁶
RS2- 1	/	0.2	1.8	2	2.02×10 ⁵
RS3- 1	/	0.2	1.8	2	2.02×10 ⁴
RS4- 1	/	1	1	2	1.01×10 ⁴
RS5- 1	/	1	1	2	5.05×10 ³
No.2	Stock solution (mL)	Upper level of sample(mL)	Negative sample matrix(mL)	Volume (mL)	Concentration (TCID ₅₀ /mL)
RS0-2	/	/	/	/	3.2×10 ⁷
RS1-2	0.2	/	1.8	2	3.2×10 ⁶
RS2-2	/	0.2	1.8	2	3.2×10 ⁵
RS3-2	/	0.2	1.8	2	3.2×10 ⁴
RS4-2	/	1	1	2	1.6×10 ⁴
RS5-2	/	1	1	2	8.0×10 ³
No.3	Stock solution (mL)	Upper level of sample(mL)	Negative sample matrix(mL)	Volume (mL)	Concentration (TCID ₅₀ /mL)
RS0-3	/	/	/	/	1.96×10 ⁷
RS1-3	0.2	/	1.8	2	1.96×10 ⁶
RS2-3	/	0.2	1.8	2	1.96×10 ⁵
RS3-3	/	0.2	1.8	2	1.96×10 ⁴
RS4-3	/	1	1	2	9.8×10 ³
RS5-3	/	1	1	2	4.9×10 ³

3.3.2 Test method

The test was performed separately using 3 batches of test kits and each sample testing was repeated 3 times.

3.3.3 Acceptance criteria

According to the color band of the test line, the last concentration at which the color band becomes lighter with increasing concentration is the critical concentration of Hook.

3.3.4 Data processing

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The last concentration at which the color band becomes lighter as the concentration increases is the critical concentration of Hook. This is the scenario when the color becomes lighter as the concentration increases. A diagram of the standard color card is shown in Figure 1 in 3.1.1.2.4

3.3.5 Results and analysis

Results: The results are shown in Table 13.

Table 13-1 Hook effect test results of Influenza A

Lot	20200601											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
AS0- 1	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
AS1- 1	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
AS2- 1	L9	+++	L1	-	L9	+++	L1	-	L8	+++	L1	-
AS3- 1	L6	++	L1	-	L6	++	L1	-	L6	++	L1	-
AS4- 1	L3	+	L1	-	L3	+	L1	-	L4	+	L1	-
AS5- 1	L1	-	L1	-	L1	-	L1	-	L1	-	L1	-
Hook critical concentration sample	NO.1											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
AS0- 2	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
AS1- 2	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
AS2- 2	L9	+++	L1	-	L9	+++	L1	-	L9	+++	L1	-
AS3- 2	L6	++	L1	-	L6	++	L1	-	L6	++	L1	-
AS4- 2	L4	+	L1	-	L4	+	L1	-	L3	+	L1	-
AS5- 2	L1	-	L1	-	L1	-	L1	-	L2	-	L1	-
Hook critical concentration sample	NO.2											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
AS0- 3	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
AS1- 3	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
AS2- 3	L9	+++	L1	-	L9	+++	L1	-	L8	+++	L1	-
AS3- 3	L6	++	L1	-	L6	++	L1	-	L6	++	L1	-
AS4- 3	L3	+	L1	-	L4	+	L1	-	L3	+	L1	-
AS5- 3	L2	-	L1	-	L1	-	L1	-	L1	-	L1	-
Hook critical concentration sample	NO.3											
Lot	20200602											

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Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
AS0- 1	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
AS1- 1	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
AS2- 1	L9	+++	L1	-	L9	+++	L1	-	L9	+++	L1	-
AS3- 1	L5	++	L1	-	L7	++	L1	-	L6	++	L1	-
AS4- 1	L3	+	L1	-	L4	+	L1	-	L3	+	L1	-
AS5- 1	L1	-	L1	-	L1	-	L1	-	L1	-	L1	-
Hook critical concentration sample	NO.1											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
AS0- 2	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
AS1- 2	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
AS2- 2	L9	+++	L1	-	L9	+++	L1	-	L9	+++	L1	-
AS3- 2	L6	++	L1	-	L5	++	L1	-	L6	++	L1	-
AS4- 2	L4	+	L1	-	L4	+	L1	-	L4	+	L1	-
AS5- 2	L2	-	L1	-	L1	-	L1	-	L1	-	L1	-
Hook critical concentration sample	NO.2											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
AS0- 3	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
AS1- 3	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
AS2- 3	L9	+++	L1	-	L9	+++	L1	-	L9	+++	L1	-
AS3- 3	L6	++	L1	-	L6	++	L1	-	L6	++	L1	-
AS4- 3	L4	+	L1	-	L3	+	L1	-	L4	+	L1	-
AS5- 3	L1	-	L1	-	L1	-	L1	-	L1	-	L1	-
Hook critical concentration sample	NO.3											
Lot	20200603											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
AS0- 1	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
AS1- 1	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
AS2- 1	L9	+++	L1	-	L9	+++	L1	-	L10	+++	L1	-
AS3- 1	L5	++	L1	-	L7	++	L1	-	L6	++	L1	-
AS4- 1	L3	+	L1	-	L4	+	L1	-	L3	+	L1	-
AS5- 1	L1	-	L1	-	L2	-	L1	-	L1	-	L1	-
Hook critical	NO.1											

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concentration sample												
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
AS0- 2	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
AS1- 2	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
AS2- 2	L8	+++	L1	-	L9	+++	L1	-	L9	+++	L1	-
AS3- 2	L6	++	L1	-	L5	++	L1	-	L6	++	L1	-
AS4- 2	L4	+	L1	-	L4	+	L1	-	L3	+	L1	-
AS5- 2	L2	-	L1	-	L1	-	L1	-	L1	-	L1	-
Hook critical concentration sample	NO.2											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
AS0- 3	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
AS1- 3	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
AS2- 3	L9	+++	L1	-	L9	+++	L1	-	L9	+++	L1	-
AS3- 3	L6	++	L1	-	L6	++	L1	-	L6	++	L1	-
AS4- 3	L3	+	L1	-	L4	+	L1	-	L4	+	L1	-
AS5- 3	L1	-	L1	-	L1	-	L1	-	L1	-	L1	-
Hook critical concentration sample	NO.3											

Table 13-2 Hook effect test results of Influenza B

Lot	20200601											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
BS0- 1	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
BS1- 1	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
BS2- 1	L1	-	L9	+++	L1	-	L9	+++	L1	-	L8	+++
BS3- 1	L1	-	L6	++	L1	-	L6	++	L1	-	L6	++
BS4- 1	L1	-	L3	+	L1	-	L3	+	L1	-	L4	+
BS5- 1	L1	-	L1	-	L1	-	L1	-	L1	-	L1	-
Hook critical concentration sample	NO.1											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
BS0- 2	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
BS1- 2	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
BS2- 2	L1	-	L8	+++	L1	-	L9	+++	L1	-	L9	+++

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

BS3- 2	L1	-	L6	++	L1	-	L6	++	L1	-	L5	++
BS4- 2	L1	-	L4	+	L1	-	L4	+	L1	-	L4	+
BS5- 2	L1	-	L1	-	L1	-	L2	-	L1	-	L1	-
Hook critical concentration sample	NO.2											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
BS0- 3	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
BS1- 3	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
BS2- 3	L1	-	L9	+++	L1	-	L9	+++	L1	-	L8	+++
BS3- 3	L1	-	L6	++	L1	-	L5	++	L1	-	L6	++
BS4- 3	L1	-	L4	+	L1	-	L3	+	L1	-	L4	+
BS5- 3	L1	-	L1	-	L1	-	L1	-	L1	-	L1	-
Hook critical concentration sample	NO.3											
Lot	20200602											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
BS0- 1	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
BS1- 1	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
BS2- 1	L1	-	L9	+++	L1	-	L8	+++	L1	-	L8	+++
BS3- 1	L1	-	L7	++	L1	-	L6	++	L1	-	L6	++
BS4- 1	L1	-	L4	+	L1	-	L3	+	L1	-	L4	+
BS5- 1	L1	-	L1	-	L1	-	L1	-	L1	-	L1	-
Hook critical concentration sample	NO.1											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
BS0- 2	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
BS1- 2	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
BS2- 2	L1	-	L9	+++	L1	-	L9	+++	L1	-	L9	+++
BS3- 2	L1	-	L6	++	L1	-	L6	++	L1	-	L6	++
BS4- 2	L1	-	L4	+	L1	-	L4	+	L1	-	L4	+
BS5- 2	L1	-	L1	-	L1	-	L1	-	L1	-	L1	-
Hook critical concentration sample	NO.2											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
BS0- 3	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

BS1- 3	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
BS2- 3	L1	-	L9	+++	L1	-	L9	+++	L1	-	L9	+++
BS3- 3	L1	-	L6	++	L1	-	L7	++	L1	-	L6	++
BS4- 3	L1	-	L4	+	L1	-	L4	+	L1	-	L4	+
BS5- 3	L1	-	L2	-	L1	-	L1	-	L1	-	L1	-
Hook critical concentration sample	NO.3											
Lot	20200603											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
BS0- 1	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
BS1- 1	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
BS2- 1	L1	-	L9	+++	L1	-	L9	+++	L1	-	L9	+++
BS3- 1	L1	-	L6	++	L1	-	L6	++	L1	-	L6	++
BS4- 1	L1	-	L4	+	L1	-	L3	+	L1	-	L4	+
BS5- 1	L1	-	L1	-	L1	-	L1	-	L1	-	L1	-
Hook critical concentration sample	NO.1											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
BS0- 2	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
BS1- 2	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
BS2- 2	L1	-	L9	+++	L1	-	L9	+++	L1	-	L9	+++
BS3- 2	L1	-	L6	++	L1	-	L6	++	L1	-	L6	++
BS4- 2	L1	-	L4	+	L1	-	L4	+	L1	-	L3	+
BS5- 2	L1	-	L2	-	L1	-	L1	-	L1	-	L1	-
Hook critical concentration sample	NO.2											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
BS0- 3	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
BS1- 3	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
BS2- 3	L1	-	L9	+++	L1	-	L9	+++	L1	-	L8	+++
BS3- 3	L1	-	L6	++	L1	-	L7	++	L1	-	L6	++
BS4- 3	L1	-	L4	+	L1	-	L4	+	L1	-	L4	+
BS5- 3	L1	-	L1	-	L1	-	L1	-	L1	-	L1	-
Hook critical concentration sample	NO.3											

Table 13-3 Hook effect test results of COVID-19

Lot	20200601
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CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
CS0- 1	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
CS1- 1	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
CS2- 1	L1	-	L9	+++	L1	-	L8	+++	L1	-	L9	+++
CS3- 1	L1	-	L6	++	L1	-	L7	++	L1	-	L6	++
CS4- 1	L1	-	L3	+	L1	-	L4	+	L1	-	L4	+
CS5- 1	L1	-	L2	-	L1	-	L1	-	L1	-	L1	-
Hook critical concentration sample	NO.1											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
CS0- 2	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
CS1- 2	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
CS2- 2	L1	-	L9	+++	L1	-	L9	+++	L1	-	L9	+++
CS3- 2	L1	-	L6	++	L1	-	L6	++	L1	-	L5	++
CS4- 2	L1	-	L4	+	L1	-	L4	+	L1	-	L4	+
CS5- 2	L1	-	L1	-	L1	-	L1	-	L1	-	L2	-
Hook critical concentration sample	NO.2											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
CS0- 3	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
CS1- 3	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
CS2- 3	L1	-	L9	+++	L1	-	L9	+++	L1	-	L8	+++
CS3- 3	L1	-	L6	++	L1	-	L7	++	L1	-	L6	++
CS4- 3	L1	-	L4	+	L1	-	L4	+	L1	-	L4	+
CS5- 3	L1	-	L1	-	L1	-	L2	-	L1	-	L1	-
Hook critical concentration sample	NO.3											
Lot	20200602											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
CS0- 1	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
CS1- 1	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
CS2- 1	L1	-	L9	+++	L1	-	L8	+++	L1	-	L9	+++
CS3- 1	L1	-	L6	++	L1	-	L7	++	L1	-	L6	++
CS4- 1	L1	-	L3	+	L1	-	L4	+	L1	-	L4	+
CS5- 1	L1	-	L1	-	L1	-	L1	-	L1	-	L1	-
Hook critical	NO.1											

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

concentration sample												
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
CS0- 2	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
CS1- 2	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
CS2- 2	L1	-	L9	+++	L1	-	L8	+++	L1	-	L9	+++
CS3- 2	L1	-	L6	++	L1	-	L6	++	L1	-	L5	++
CS4- 2	L1	-	L4	+	L1	-	L4	+	L1	-	L4	+
CS5- 2	L1	-	L1	-	L1	-	L1	-	L1	-	L2	-
Hook critical concentration sample	NO.2											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
CS0- 3	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
CS1- 3	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
CS2- 3	L1	-	L9	+++	L1	-	L9	+++	L1	-	L8	+++
CS3- 3	L1	-	L5	++	L1	-	L7	++	L1	-	L6	++
CS4- 3	L1	-	L4	+	L1	-	L4	+	L1	-	L4	+
CS5- 3	L1	-	L1	-	L1	-	L2	-	L1	-	L1	-
Hook critical concentration sample	NO.3											
Lot	20200603											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
CS0- 1	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
CS1- 1	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
CS2- 1	L1	-	L9	+++	L1	-	L9	+++	L1	-	L9	+++
CS3- 1	L1	-	L6	++	L1	-	L5	++	L1	-	L6	++
CS4- 1	L1	-	L3	+	L1	-	L4	+	L1	-	L4	+
CS5- 1	L1	-	L1	-	L1	-	L1	-	L1	-	L1	-
Hook critical concentration sample	NO.1											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
CS0- 2	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
CS1- 2	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
CS2- 2	L1	-	L9	+++	L1	-	L9	+++	L1	-	L9	+++
CS3- 2	L1	-	L6	++	L1	-	L6	++	L1	-	L6	++
CS4- 2	L1	-	L4	+	L1	-	L4	+	L1	-	L4	+

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

CS5- 2	L1	-	L1	-	L1	-	L1	-	L1	-	L2	-
Hook critical concentration sample	NO.2											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
CS0- 3	L1	-	L10	+++	L1	-	L10	+++	L1	-	L10	+++
CS1- 3	L1	-	L10	+++	L1	-	L9	+++	L1	-	L10	+++
CS2- 3	L1	-	L8	+++	L1	-	L9	+++	L1	-	L8	+++
CS3- 3	L1	-	L6	++	L1	-	L5	++	L1	-	L6	++
CS4- 3	L1	-	L4	+	L1	-	L4	+	L1	-	L3	+
CS5- 3	L1	-	L1	-	L1	-	L2	-	L1	-	L1	-
Hook critical concentration sample	NO.3											

Table 13-4 Hook effect test results of RSV

Lot	20200601											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
RS0- 1	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
RS1- 1	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
RS2- 1	L9	+++	L1	-	L9	+++	L1	-	L8	+++	L1	-
RS3- 1	L5	++	L1	-	L7	++	L1	-	L6	++	L1	-
RS4- 1	L3	+	L1	-	L4	+	L1	-	L3	+	L1	-
RS5- 1	L1	-	L1	-	L1	-	L1	-	L1	-	L1	-
Hook critical concentration sample	NO.1											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
RS0- 2	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
RS1- 2	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
RS2- 2	L9	+++	L1	-	L9	+++	L1	-	L9	+++	L1	-
RS3- 2	L6	++	L1	-	L6	++	L1	-	L7	++	L1	-
RS4- 2	L4	+	L1	-	L4	+	L1	-	L3	+	L1	-
RS5- 2	L2	-	L1	-	L1	-	L1	-	L1	-	L1	-
Hook critical concentration sample	NO.2											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
RS0- 3	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

RS1- 3	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
RS2- 3	L8	+++	L1	-	L9	+++	L1	-	L9	+++	L1	-
RS3- 3	L6	++	L1	-	L5	++	L1	-	L6	++	L1	-
RS4- 3	L4	+	L1	-	L4	+	L1	-	L4	+	L1	-
RS5- 3	L1	-	L1	-	L1	-	L1	-	L1	-	L1	-
Hook critical concentration sample	NO.3											
Lot	20200602											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
RS0- 1	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
RS1- 1	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
RS2- 1	L9	+++	L1	-	L9	+++	L1	-	L9	+++	L1	-
RS3- 1	L6	++	L1	-	L7	++	L1	-	L6	++	L1	-
RS4- 1	L3	+	L1	-	L4	+	L1	-	L4	+	L1	-
RS5- 1	L1	-	L1	-	L1	-	L1	-	L1	-	L1	-
Hook critical concentration sample	NO.1											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
RS0- 2	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
RS1- 2	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
RS2- 2	L8	+++	L1	-	L9	+++	L1	-	L9	+++	L1	-
RS3- 2	L6	++	L1	-	L5	++	L1	-	L7	++	L1	-
RS4- 2	L4	+	L1	-	L4	+	L1	-	L4	+	L1	-
RS5- 2	L1	-	L1	-	L1	-	L1	-	L1	-	L1	-
Hook critical concentration sample	NO.2											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
RS0- 3	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
RS1- 3	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
RS2- 3	L9	+++	L1	-	L9	+++	L1	-	L9	+++	L1	-
RS3- 3	L6	++	L1	-	L7	++	L1	-	L6	++	L1	-
RS4- 3	L4	+	L1	-	L3	+	L1	-	L4	+	L1	-
RS5- 3	L1	-	L1	-	L1	-	L1	-	L1	-	L1	-
Hook critical concentration sample	NO.3											
Lot	20200603											
	1				2				3			

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

Sample No.	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
RS0- 1	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
RS1- 1	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
RS2- 1	L9	+++	L1	-	L9	+++	L1	-	L8	+++	L1	-
RS3- 1	L5	++	L1	-	L6	++	L1	-	L6	++	L1	-
RS4- 1	L4	+	L1	-	L4	+	L1	-	L4	+	L1	-
RS5- 1	L1	-	L1	-	L1	-	L1	-	L1	-	L1	-
Hook critical concentration sample	NO.1											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
RS0- 2	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
RS1- 2	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
RS2- 2	L9	+++	L1	-	L9	+++	L1	-	L9	+++	L1	-
RS3- 2	L6	++	L1	-	L6	++	L1	-	L5	++	L1	-
RS4- 2	L3	+	L1	-	L4	+	L1	-	L4	+	L1	-
RS5- 2	L1	-	L1	-	L1	-	L1	-	L1	-	L1	-
Hook critical concentration sample	NO.2											
Sample No.	1				2				3			
	T1		T2		T1		T2		T1		T2	
	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results	Chrom aticity	Results
RS0- 3	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
RS1- 3	L10	+++	L1	-	L10	+++	L1	-	L10	+++	L1	-
RS2- 3	L9	+++	L1	-	L9	+++	L1	-	L9	+++	L1	-
RS3- 3	L5	++	L1	-	L6	++	L1	-	L6	++	L1	-
RS4- 3	L4	+	L1	-	L4	+	L1	-	L4	+	L1	-
RS5- 3	L1	-	L1	-	L1	-	L1	-	L1	-	L1	-
Hook critical concentration sample	NO.3											

Analysis: The results analysis is shown in Table 14

Table 14-1 Influnza A testing Results analysis

Lot	Hook critical concentration sample No.			Hook critical concentration (TCID ₅₀ /mL)
20200601	AS0- 1	AS0-2	AS0-3	4.8×10 ⁷
20200602	AS0- 1	AS0-2	AS0-3	4.8×10 ⁷
20200603	AS0- 1	AS0-2	AS0-3	4.8×10 ⁷

Table 14-2 Influnza B testing Results analysis

Lot	Hook critical concentration sample No.			Hook critical concentration (TCID ₅₀ /mL)
20200601	BS0- 1	BS0-2	BS0-3	4.8×10 ⁸

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

20200602	BS0- 1	BS0-2	BS0-3	4.8×10^8
20200603	BS0- 1	BS0-2	BS0-3	4.8×10^8

Table 14-3 COVID-19 testing Results analysis

Lot	Hook critical concentration sample No.			Hook critical concentration (TCID ₅₀ /mL)
20200601	CS0- 1	CS0-2	CS0-3	1.8×10^6
20200602	CS0- 1	CS0-2	CS0-3	1.8×10^6
20200603	CS0- 1	CS0-2	CS0-3	1.8×10^6

Table 14-4 RSV testing Results analysis

Lot	Hook critical concentration sample No.			Hook critical concentration (TCID ₅₀ /mL)
20200601	RS0- 1	RS0-2	RS0-3	3.2×10^7
20200602	RS0- 1	RS0-2	RS0-3	3.2×10^7
20200603	RS0- 1	RS0-2	RS0-3	3.2×10^7

3.3.6 Conclusion

A high-dose hook effect was not detected in the Influenza A/B+COVID-19/RSV Combo Ag Test, for the Influenza A and B, COVID-19 and RSV viral strains at the concentration listed below.

Virus Type	Concentration Tested (TCID ₅₀ /mL)
Influenza A	4.8×10^7
Influenza B	4.8×10^8
COVID-19	1.8×10^6
RSV	3.2×10^7

3.4 Cross-reactivity Testing

Cross-reactivity of the Influenza A/B+COVID-19/RSV Combo Ag Test was evaluated by testing the related pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in clinical specimens and could potentially cross-react with the Influenza A/B+COVID-19/RSV Combo Ag Test including bacteria, viruses, and negative matrix. Each organism and virus were tested in the absence or presence of heat inactivated Influenza A and B, COVID-19 and RSV at $2 \times \text{LoD}$. No cross-reactivity was seen with the listed microorganisms when tested at the concentration presented in the Table 15.

Table 15-1 Cross-Reactivity-Influenza A/B

NO.	Potential Cross-reactant	Concentration
1	Human Adenovirus B	$1.0 \times 10^5 \text{ TCID}_{50}/\text{mL}$
2	Human Rhinovirus 2	$1.0 \times 10^5 \text{ PFU}/\text{mL}$
3	Human Adenovirus C	$1.0 \times 10^5 \text{ TCID}_{50}/\text{mL}$
4	Human Rhinovirus 14	$1.0 \times 10^5 \text{ TCID}_{50}/\text{mL}$
5	Human Adenovirus type 10	$1.0 \times 10^5 \text{ TCID}_{50}/\text{mL}$
6	Human Rhinovirus 16	$1.0 \times 10^5 \text{ TCID}_{50}/\text{mL}$
7	Adenovirus type 18	$1.0 \times 10^2 \text{ TCID}_{50}/\text{mL}$

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

8	Measles	1.0 x 10 ⁵ TCID ₅₀ /mL
9	Human coronavirus OC43	1.0 × 10 ⁵ TCID ₅₀ /mL
10	Mumps	1.0 x 10 ⁵ TCID ₅₀ /mL
11	Human Coxsackievirus A9	1.0 x 10 ⁵ TCID ₅₀ /mL
12	sendai virus	1.0 x 10 ⁵ TCID ₅₀ /mL
13	Coxsackievirus B5	1.0 x 10 ⁵ TCID ₅₀ /mL
14	Parainfluenza virus 2	1.0 x 10 ⁵ TCID ₅₀ /mL
15	Human herpesvirus 2	1.0 x 10 ⁵ TCID ₅₀ /mL
16	Parainfluenza virus 3	1.0 x 10 ² TCID ₅₀ /mL
17	Acinetobacter calcoaceticus	1.0 x 10 ⁷ org/mL
18	Bacteroides fragilis	1.0 x 10 ⁷ org/mL
19	Neisseria gonorrhoeae	1.0 x 10 ⁷ org/mL
20	Neisseria meningitidis	1.0 x 10 ⁷ org/mL
21	Pseudomonas aeruginosa	1.0 x 10 ⁷ org/mL
22	Staphylococcus aureus	1.0 x 10 ⁷ org/mL
23	Streptococcus pneumoniae	1.0 x 10 ⁷ cells/mL
24	Streptococcus sanguis	1.0 x 10 ⁷ org/mL
25	Proteus vulgaris	1.0 x 10 ⁷ org/mL
26	Streptococcus sp. Gp.B	1.0 x 10 ⁷ org/mL
27	Streptococcus sp.Gp.C	1.0 x 10 ⁷ org/mL
28	Streptococcus sp. Gp.G	1.0 x 10 ⁷ org/mL
29	Mycobacterium tuberculosis	1.0 x 10 ⁷ cells/mL
30	Mycoplasma orale	1.0 x 10 ⁷ org/mL
31	Influenza B	1.0 x 10 ⁵ TCID ₅₀ /mL
32	Influenza A	1.0 x 10 ⁵ TCID ₅₀ /mL
33	Human respiratory syncytial virus A	1.0 x 10 ⁵ TCID ₅₀ /mL
34	Human respiratory syncytial virus B	1.0 x 10 ⁵ TCID ₅₀ /mL
35	SARS-COV-2	1.0 x 10 ⁵ TCID ₅₀ /mL
36	Pooled human nasal wash	N/A

Table 15-2 Cross-Reactivity-COVID-19/RSV

No.	Potential Cross-reactant	Concentration
1	Adenovirus	1.0 × 10 ⁵ TCID ₅₀ /mL
2	Human metapneumovirus (hMPV)	1.0 × 10 ⁵ TCID ₅₀ /mL
3	Rhinovirus	1.0 × 10 ⁵ TCID ₅₀ /mL
4	Enterovirus/Coxsackievirus B4	1.0 × 10 ⁵ TCID ₅₀ /mL
5	Human coronavirus OC43	1.0 × 10 ⁵ TCID ₅₀ /mL
6	Human coronavirus 229E	1.0 × 10 ⁵ TCID ₅₀ /mL
7	Human coronavirus NL63	1.0 × 10 ⁵ TCID ₅₀ /mL

No.	Potential Cross-reactant	Concentration
8	Human coronavirus HKU1	1.0×10^5 TCID ₅₀ /mL
9	Human parainfluenza virus 1	1.0×10^5 TCID ₅₀ /mL
10	Human parainfluenza virus 2	1.0×10^5 TCID ₅₀ /mL
11	Human parainfluenza virus 3	1.0×10^5 TCID ₅₀ /mL
12	Human parainfluenza virus 4	1.0×10^5 TCID ₅₀ /mL
13	Influenza A H3N2	1.0×10^5 TCID ₅₀ /mL
14	Influenza A H1N1	1.0×10^5 TCID ₅₀ /mL
15	Influenza A H5N1	1.0×10^5 TCID ₅₀ /mL
16	Influenza A H7N9	1.0×10^5 TCID ₅₀ /mL
17	Influenza B Yamagata	1.0×10^5 TCID ₅₀ /mL
18	Influenza B Guangdong/120/00	1.0×10^5 TCID ₅₀ /mL
19	Respiratory Syncytial Virus A	1.0×10^5 TCID ₅₀ /mL
20	Respiratory Syncytial Virus B	1.0×10^5 TCID ₅₀ /mL
21	MERS-CoV	1.0×10^5 TCID ₅₀ /mL
22	Bordetella pertussis	1.0×10^6 cells/mL
23	Chlamydia pneumoniae	1.0×10^6 IFU/mL
24	Haemophilus influenzae	1.0×10^6 cells/mL
25	Legionella pneumophila	1.0×10^6 cells/mL
26	Mycoplasma pneumoniae	1.0×10^6 PFU/mL
27	Streptococcus pneumoniae	1.0×10^6 cells/mL
28	Streptococcus pyogenes (group A)	1.0×10^6 cells/mL
29	Mycobacterium tuberculosis	1.0×10^6 cells/mL
30	Staphylococcus aureus	1.0×10^6 org/mL
31	Staphylococcus epidermidis	1.0×10^6 org/mL
32	Candida albicans	1.0×10^5 TCID ₅₀ /mL
33	SARS-COV-2	1.0×10^5 TCID ₅₀ /mL
34	Pooled human nasal wash	N/A

3.4.1 Test sample preparation

3.4.1.1 Potential Cross-Reactant Sources

The colony count, TCID₅₀ determination and other methods are used to confirm the concentration of the bacterial solution.

3.4.1.2 Test sample preparation

Test sample concentration requirements for potential cross-reactant.

According to requirements for antigen reagents, the potential cross-reactant concentration is set as shown in Table 15.

3.4.1.3 Preparation for potential cross-reactant test

The cross-reactant stock solution was diluted to the concentrations in Table 15 using negative sample matrix, prepared as shown in Table 16 and Table 17.

Table 16-1 Sample preparation for potential interference test of Influenza A/B

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

No.	Negative sample matrix (μL)	Stock solution(μL)	Volume(μL)	Concentration
1	1800	200	2000	1.0 x 10 ⁵ TCID ₅₀ /mL
2	1800	200	2000	1.0 x 10 ⁵ PFU/mL
3	1800	200	2000	1.0 x 10 ⁵ TCID ₅₀ /mL
4	1800	200	2000	1.0 x 10 ⁵ TCID ₅₀ /mL
5	1800	200	2000	1.0 x 10 ⁵ TCID ₅₀ /mL
6	1800	200	2000	1.0 x 10 ⁵ TCID ₅₀ /mL
7	1800	200	2000	1.0 x 10 ² TCID ₅₀ /mL
8	1800	200	2000	1.0 x 10 ⁵ TCID ₅₀ /mL
9	1800	200	2000	1.0 × 10 ⁵ TCID ₅₀ /mL
10	1800	200	2000	1.0 x 10 ⁵ TCID ₅₀ /mL
11	1800	200	2000	1.0 x 10 ⁵ TCID ₅₀ /mL
12	1800	200	2000	1.0 x 10 ⁵ TCID ₅₀ /mL
13	1800	200	2000	1.0 x 10 ⁵ TCID ₅₀ /mL
14	1800	200	2000	1.0 x 10 ⁵ TCID ₅₀ /mL
15	1800	200	2000	1.0 x 10 ⁵ TCID ₅₀ /mL
16	1800	200	2000	1.0 x 10 ² TCID ₅₀ /mL
17	1800	200	2000	1.0 x 10 ⁷ org/mL
18	1800	200	2000	1.0 x 10 ⁷ org/mL
19	1800	200	2000	1.0 x 10 ⁷ org/mL
20	1800	200	2000	1.0 x 10 ⁷ org/mL
21	1800	200	2000	1.0 x 10 ⁷ org/mL
22	1800	200	2000	1.0 x 10 ⁷ org/mL
23	1800	200	2000	1.0 x 10 ⁷ cells/mL
24	1800	200	2000	1.0 x 10 ⁷ org/mL
25	1800	200	2000	1.0 x 10 ⁷ org/mL
26	1800	200	2000	1.0 x 10 ⁷ org/mL
27	1800	200	2000	1.0 x 10 ⁷ org/mL
28	1800	200	2000	1.0 x 10 ⁷ org/mL
29	1800	200	2000	1.0 x 10 ⁷ cellsg/mL
30	1800	200	2000	1.0 x 10 ⁷ org/mL
31	1800	200	2000	1.0 x 10 ⁵ TCID ₅₀ /mL
32	1800	200	2000	1.0 x 10 ⁵ TCID ₅₀ /mL
33	1800	200	2000	1.0 x 10 ⁵ TCID ₅₀ /mL
34	1800	200	2000	1.0 x 10 ⁵ TCID ₅₀ /mL
35	1800	200	2000	1.0 x 10 ⁵ TCID ₅₀ /mL
36	1800	200	2000	N/A

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

Table 16-2 Sample preparation for potential interference test of COVID-19/RSV

No.	Negative sample matrix (μL)	Stock solution(μL)	Volume(μL)	Concentration
1	1800	200	2000	1.0×10^5 TCID ₅₀ /mL
2	1800	200	2000	1.0×10^5 TCID ₅₀ /mL
3	1800	200	2000	1.0×10^5 TCID ₅₀ /mL
4	1800	200	2000	1.0×10^5 TCID ₅₀ /mL
5	1800	200	2000	1.0×10^5 TCID ₅₀ /mL
6	1800	200	2000	1.0×10^5 TCID ₅₀ /mL
7	1800	200	2000	1.0×10^5 TCID ₅₀ /mL
8	1800	200	2000	1.0×10^5 TCID ₅₀ /mL
9	1800	200	2000	1.0×10^5 TCID ₅₀ /mL
10	1800	200	2000	1.0×10^5 TCID ₅₀ /mL
11	1800	200	2000	1.0×10^5 TCID ₅₀ /mL
12	1800	200	2000	1.0×10^5 TCID ₅₀ /mL
13	1800	200	2000	1.0×10^5 TCID ₅₀ /mL
14	1800	200	2000	1.0×10^5 TCID ₅₀ /mL
15	1800	200	2000	1.0×10^5 TCID ₅₀ /mL
16	1800	200	2000	1.0×10^5 TCID ₅₀ /mL
17	1800	200	2000	1.0×10^5 TCID ₅₀ /mL
18	1800	200	2000	1.0×10^5 TCID ₅₀ /mL
19	1800	200	2000	1.0×10^5 TCID ₅₀ /mL
20	1800	200	2000	1.0×10^5 TCID ₅₀ /mL
21	1800	200	2000	1.0×10^5 TCID ₅₀ /mL
22	1800	200	2000	1.0×10^6 cells/mL
23	1800	200	2000	1.0×10^6 IFU/mL
24	1800	200	2000	1.0×10^6 cells/mL
25	1800	200	2000	1.0×10^6 cells/mL
26	1800	200	2000	1.0×10^6 PFU/mL
27	1800	200	2000	1.0×10^6 cells/mL
28	1800	200	2000	1.0×10^6 cells/mL
29	1800	200	2000	1.0×10^6 cells/mL
30	1800	200	2000	1.0×10^6 org/mL
31	1800	200	2000	1.0×10^6 org/mL
32	1800	200	2000	1.0×10^5 TCID ₅₀ /mL
33	1800	200	2000	1.0×10^5 TCID ₅₀ /mL
34	1800	200	2000	N/A

Table 17-1 Influenza A-test sample preparation

No.	Volume of Negative Sample Matrix(μL)	Volume of Influenza A (μL)	CONC of Influenza A (TCID ₅₀ /mL)	Volume of culture liquid(μL)	Concentration
1	858	6	3.0×10^4	96	1.0×10^5 TCID ₅₀ /mL
2	858	6	3.0×10^4	96	1.0×10^5 PFU/mL
3	858	6	3.0×10^4	96	1.0×10^5 TCID ₅₀ /mL

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

4	858	6	3.0×10 ⁴	96	1.0 x 10 ⁵ TCID ₅₀ /mL
5	858	6	3.0×10 ⁴	96	1.0 x 10 ⁵ TCID ₅₀ /mL
6	858	6	3.0×10 ⁴	96	1.0 x 10 ⁵ TCID ₅₀ /mL
7	858	6	3.0×10 ⁴	96	1.0 x 10 ² TCID ₅₀ /mL
8	858	6	3.0×10 ⁴	96	1.0 x 10 ⁵ TCID ₅₀ /mL
9	858	6	3.0×10 ⁴	96	1.0 × 10 ⁵ TCID ₅₀ /mL
10	858	6	3.0×10 ⁴	96	1.0 x 10 ⁵ TCID ₅₀ /mL
11	858	6	3.0×10 ⁴	96	1.0 x 10 ⁵ TCID ₅₀ /mL
12	858	6	3.0×10 ⁴	96	1.0 x 10 ⁵ TCID ₅₀ /mL
13	858	6	3.0×10 ⁴	96	1.0 x 10 ⁵ TCID ₅₀ /mL
14	858	6	3.0×10 ⁴	96	1.0 x 10 ⁵ TCID ₅₀ /mL
15	858	6	3.0×10 ⁴	96	1.0 x 10 ⁵ TCID ₅₀ /mL
16	858	6	3.0×10 ⁴	96	1.0 x 10 ² TCID ₅₀ /mL
17	858	6	3.0×10 ⁴	96	1.0 x 10 ⁷ org/mL
18	858	6	3.0×10 ⁴	96	1.0 x 10 ⁷ org/mL
19	858	6	3.0×10 ⁴	96	1.0 x 10 ⁷ org/mL
20	858	6	3.0×10 ⁴	96	1.0 x 10 ⁷ org/mL
21	858	6	3.0×10 ⁴	96	1.0 x 10 ⁷ org/mL
22	858	6	3.0×10 ⁴	96	1.0 x 10 ⁷ org/mL
23	858	6	3.0×10 ⁴	96	1.0 x 10 ⁷ cells/mL
24	858	6	3.0×10 ⁴	96	1.0 x 10 ⁷ org/mL
25	858	6	3.0×10 ⁴	96	1.0 x 10 ⁷ org/mL
26	858	6	3.0×10 ⁴	96	1.0 x 10 ⁷ org/mL
27	858	6	3.0×10 ⁴	96	1.0 x 10 ⁷ org/mL
28	858	6	3.0×10 ⁴	96	1.0 x 10 ⁷ org/mL
29	858	6	3.0×10 ⁴	96	1.0 x 10 ⁷ cells/mL
30	858	6	3.0×10 ⁴	96	1.0 x 10 ⁷ org/mL
31	858	6	3.0×10 ⁴	96	1.0 x 10 ⁵ TCID ₅₀ /mL
32	858	6	3.0×10 ⁴	96	1.0 x 10 ⁵ TCID ₅₀ /mL
33	858	6	3.0×10 ⁴	96	1.0 x 10 ⁵ TCID ₅₀ /mL
34	858	6	3.0×10 ⁴	96	1.0 x 10 ⁵ TCID ₅₀ /mL
35	858	6	3.0×10 ⁴	96	1.0 x 10 ⁵ TCID ₅₀ /mL
36	858	6	3.0×10 ⁴	96	N/A

Table 17-2 Influenza B-test sample preparation

No.	Volume of Negative Sample Matrix (μL)	Volume of Influenza B (μL)	CONC of Influenza B (TCID ₅₀ /mL)	Volume of culture liquid (μL)	Concentration
1	858	6	3.0×10 ⁵	96	1.0 x 10 ⁵ TCID ₅₀ /mL
2	858	6	3.0×10 ⁵	96	1.0 x 10 ⁵ PFU/mL

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

3	858	6	3.0×10 ⁵	96	1.0 x 10 ⁵ TCID ₅₀ /mL
4	858	6	3.0×10 ⁵	96	1.0 x 10 ⁵ TCID ₅₀ /mL
5	858	6	3.0×10 ⁵	96	1.0 x 10 ⁵ TCID ₅₀ /mL
6	858	6	3.0×10 ⁵	96	1.0 x 10 ⁵ TCID ₅₀ /mL
7	858	6	3.0×10 ⁵	96	1.0 x 10 ² TCID ₅₀ /mL
8	858	6	3.0×10 ⁵	96	1.0 x 10 ⁵ TCID ₅₀ /mL
9	858	6	3.0×10 ⁵	96	1.0 x 10 ⁵ TCID ₅₀ /mL
10	858	6	3.0×10 ⁵	96	1.0 x 10 ⁵ TCID ₅₀ /mL
11	858	6	3.0×10 ⁵	96	1.0 x 10 ⁵ TCID ₅₀ /mL
12	858	6	3.0×10 ⁵	96	1.0 x 10 ⁵ TCID ₅₀ /mL
13	858	6	3.0×10 ⁵	96	1.0 x 10 ⁵ TCID ₅₀ /mL
14	858	6	3.0×10 ⁵	96	1.0 x 10 ⁵ TCID ₅₀ /mL
15	858	6	3.0×10 ⁵	96	1.0 x 10 ⁵ TCID ₅₀ /mL
16	858	6	3.0×10 ⁵	96	1.0 x 10 ² TCID ₅₀ /mL
17	858	6	3.0×10 ⁵	96	1.0 x 10 ⁷ org/mL
18	858	6	3.0×10 ⁵	96	1.0 x 10 ⁷ org/mL
19	858	6	3.0×10 ⁵	96	1.0 x 10 ⁷ org/mL
20	858	6	3.0×10 ⁵	96	1.0 x 10 ⁷ org/mL
21	858	6	3.0×10 ⁵	96	1.0 x 10 ⁷ org/mL
22	858	6	3.0×10 ⁵	96	1.0 x 10 ⁷ org/mL
23	858	6	3.0×10 ⁵	96	1.0 x 10 ⁷ cells/mL
24	858	6	3.0×10 ⁵	96	1.0 x 10 ⁷ org/mL
25	858	6	3.0×10 ⁵	96	1.0 x 10 ⁷ org/mL
26	858	6	3.0×10 ⁵	96	1.0 x 10 ⁷ org/mL
27	858	6	3.0×10 ⁵	96	1.0 x 10 ⁷ org/mL
28	858	6	3.0×10 ⁵	96	1.0 x 10 ⁷ org/mL
29	858	6	3.0×10 ⁵	96	1.0 x 10 ⁷ cells/mL
30	858	6	3.0×10 ⁵	96	1.0 x 10 ⁷ org/mL
31	858	6	3.0×10 ⁵	96	1.0 x 10 ⁵ TCID ₅₀ /mL
32	858	6	3.0×10 ⁵	96	1.0 x 10 ⁵ TCID ₅₀ /mL
33	858	6	3.0×10 ⁵	96	1.0 x 10 ⁵ TCID ₅₀ /mL
34	858	6	3.0×10 ⁵	96	1.0 x 10 ⁵ TCID ₅₀ /mL
35	858	6	3.0×10 ⁵	96	1.0 x 10 ⁵ TCID ₅₀ /mL
36	858	6	3.0×10 ⁵	96	N/A

Table 17-3 COVID-19-test sample preparation

No.	Volume of Negative Sample Matrix (μL)	Volume of COVID-19 (μL)	CONC of COVID-19 (TCID ₅₀ /mL)	Volume of culture liquid (μL)	Concentration
1	861.6	2.4	400	96	1.0 × 10 ⁵ TCID ₅₀ /mL

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

2	861.6	2.4	400	96	1.0×10^5 TCID ₅₀ /mL
3	861.6	2.4	400	96	1.0×10^5 TCID ₅₀ /mL
4	861.6	2.4	400	96	1.0×10^5 TCID ₅₀ /mL
5	861.6	2.4	400	96	1.0×10^5 TCID ₅₀ /mL
6	861.6	2.4	400	96	1.0×10^5 TCID ₅₀ /mL
7	861.6	2.4	400	96	1.0×10^5 TCID ₅₀ /mL
8	861.6	2.4	400	96	1.0×10^5 TCID ₅₀ /mL
9	861.6	2.4	400	96	1.0×10^5 TCID ₅₀ /mL
10	861.6	2.4	400	96	1.0×10^5 TCID ₅₀ /mL
11	861.6	2.4	400	96	1.0×10^5 TCID ₅₀ /mL
12	861.6	2.4	400	96	1.0×10^5 TCID ₅₀ /mL
13	861.6	2.4	400	96	1.0×10^5 TCID ₅₀ /mL
14	861.6	2.4	400	96	1.0×10^5 TCID ₅₀ /mL
15	861.6	2.4	400	96	1.0×10^5 TCID ₅₀ /mL
16	861.6	2.4	400	96	1.0×10^5 TCID ₅₀ /mL
17	861.6	2.4	400	96	1.0×10^5 TCID ₅₀ /mL
18	861.6	2.4	400	96	1.0×10^5 TCID ₅₀ /mL
19	861.6	2.4	400	96	1.0×10^5 TCID ₅₀ /mL
20	861.6	2.4	400	96	1.0×10^5 TCID ₅₀ /mL
21	861.6	2.4	400	96	1.0×10^5 TCID ₅₀ /mL
22	861.6	2.4	400	96	1.0×10^6 cells/mL
23	861.6	2.4	400	96	1.0×10^6 IFU/mL
24	861.6	2.4	400	96	1.0×10^6 cells/mL
25	861.6	2.4	400	96	1.0×10^6 cells/mL
26	861.6	2.4	400	96	1.0×10^6 PFU/mL
27	861.6	2.4	400	96	1.0×10^6 cells/mL
28	861.6	2.4	400	96	1.0×10^6 cells/mL
29	861.6	2.4	400	96	1.0×10^6 cells/mL
30	861.6	2.4	400	96	1.0×10^6 org/mL
31	861.6	2.4	400	96	1.0×10^6 org/mL
32	861.6	2.4	400	96	1.0×10^5 TCID ₅₀ /mL
33	861.6	2.4	400	96	1.0×10^5 TCID ₅₀ /mL
34	861.6	2.4	400	96	N/A

Table 17-4 RSV-test sample preparation

No.	Volume of Negative Sample Matrix (μL)	Volume of RSV (μL)	CONC of RSV (TCID ₅₀ /mL)	Volume of culture liquid (μL)	Concentration
1	858	6	2.0×10^4	96	1.0×10^5 TCID ₅₀ /mL
2	858	6	2.0×10^4	96	1.0×10^5 TCID ₅₀ /mL
3	858	6	2.0×10^4	96	1.0×10^5 TCID ₅₀ /mL

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

4	858	6	2.0×10^4	96	1.0×10^5 TCID ₅₀ /mL
5	858	6	2.0×10^4	96	1.0×10^5 TCID ₅₀ /mL
6	858	6	2.0×10^4	96	1.0×10^5 TCID ₅₀ /mL
7	858	6	2.0×10^4	96	1.0×10^5 TCID ₅₀ /mL
8	858	6	2.0×10^4	96	1.0×10^5 TCID ₅₀ /mL
9	858	6	2.0×10^4	96	1.0×10^5 TCID ₅₀ /mL
10	858	6	2.0×10^4	96	1.0×10^5 TCID ₅₀ /mL
11	858	6	2.0×10^4	96	1.0×10^5 TCID ₅₀ /mL
12	858	6	2.0×10^4	96	1.0×10^5 TCID ₅₀ /mL
13	858	6	2.0×10^4	96	1.0×10^5 TCID ₅₀ /mL
14	858	6	2.0×10^4	96	1.0×10^5 TCID ₅₀ /mL
15	858	6	2.0×10^4	96	1.0×10^5 TCID ₅₀ /mL
16	858	6	2.0×10^4	96	1.0×10^5 TCID ₅₀ /mL
17	858	6	2.0×10^4	96	1.0×10^5 TCID ₅₀ /mL
18	858	6	2.0×10^4	96	1.0×10^5 TCID ₅₀ /mL
19	858	6	2.0×10^4	96	1.0×10^5 TCID ₅₀ /mL
20	858	6	2.0×10^4	96	1.0×10^5 TCID ₅₀ /mL
21	858	6	2.0×10^4	96	1.0×10^5 TCID ₅₀ /mL
22	858	6	2.0×10^4	96	1.0×10^6 cells/mL
23	858	6	2.0×10^4	96	1.0×10^6 IFU/mL
24	858	6	2.0×10^4	96	1.0×10^6 cells/mL
25	858	6	2.0×10^4	96	1.0×10^6 cells/mL
26	858	6	2.0×10^4	96	1.0×10^6 PFU/mL
27	858	6	2.0×10^4	96	1.0×10^6 cells/mL
28	858	6	2.0×10^4	96	1.0×10^6 cells/mL
29	858	6	2.0×10^4	96	1.0×10^6 cells/mL
30	858	6	2.0×10^4	96	1.0×10^6 org/mL
31	858	6	2.0×10^4	96	1.0×10^6 org/mL
32	858	6	2.0×10^4	96	1.0×10^5 TCID ₅₀ /mL
33	858	6	2.0×10^4	96	1.0×10^5 TCID ₅₀ /mL
34	858	6	2.0×10^4	96	N/A

3.4.2 Test method

The samples prepared above were tested by using 3 batches of test kits with each tested repeatedly 3 times.

3.4.3 Acceptance criteria

All test results were negative and consistent with the control group, demonstrating that this potential cross-reactant does not cross-react with the test kit at this concentration.

3.4.4 Results

Influenza A/B Results: Test results of negative samples and positive samples are shown in Table 18.

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

Table 18-1 Test result of negative samples-Influenza A+B

No. of Matrix	Lot																	
	20200601						20200602						20200603					
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
24	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
32	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
33	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

36	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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Table 18-2 Test result of influenza A positive samples

No. of Matrix	Lot																	
	20200601						20200602						20200603					
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
1	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
2	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
3	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
4	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
5	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
6	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
7	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
8	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
9	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
10	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
11	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
12	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
13	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
14	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
15	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
16	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
17	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
18	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
19	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
20	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
21	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
22	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
23	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
24	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
25	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
26	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
27	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
28	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
29	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
30	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
31	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
32	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
33	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
34	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-

35	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
36	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-

Table 18-3 Test result of influenza B positive samples

No. of Matrix	Lot																	
	20200601						20200602						20200603					
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
1	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
2	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
3	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
4	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
5	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
6	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
7	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
8	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
9	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
10	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
11	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
12	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
13	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
14	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
15	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
16	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
17	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
18	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
19	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
20	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
21	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
22	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
23	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
24	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
25	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
26	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
27	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
28	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
29	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
30	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
31	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
32	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
33	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+

34	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
35	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
36	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+

The COVID-19/RSV Results: Test results of negative samples and positive samples are shown in Table 19.

Table 19-1 Test result of negative samples

No. of Matrix	Lot																	
	20200601						20200602						20200603					
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
20	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
21	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
24	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

29	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
34	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Table 19-2 Test result of COVID-19 positive samples

No. of Matrix	Lot																	
	20200601						20200602						20200603					
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
1	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
2	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
3	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
4	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
5	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
6	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
7	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
8	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
9	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
10	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
11	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
12	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
13	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
14	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
15	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
16	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
17	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
18	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
19	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
20	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
21	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
22	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
23	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
24	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
25	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
26	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
27	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
28	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
29	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+

30	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
31	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
32	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
33	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
34	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+

Table 19-3 Test result of RSV positive samples

No. of Matrix	Lot																	
	20200601						20200602						20200603					
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
1	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
2	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
3	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
4	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
5	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
6	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
7	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
8	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
9	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
10	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
11	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
12	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
13	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
14	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
15	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
16	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
17	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
18	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
19	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
20	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
21	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
22	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
23	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
24	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
25	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
26	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
27	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
28	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
29	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
30	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-

CE Technical File									File No:CorDx-CE-Flu A+B&COVID-19+RSV-7									
Influenza A/B+COVID-19/RSV Combo Ag Test																		
31	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
32	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
33	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
34	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-

3.4.5 Conclusion

The results are below the corresponding concentration of the substances, which has no effect on the negative and positive test results of this reagent, and there is no cross-reaction.

3.5 Interference testing

3.5.1 Sample preparation for microbiological testing

3.5.1.1 Source of microbiological test sample

Table 20-1 Potential interfering substances of Influenza A/B

NO.	Substance	Concentration
1	Whole blood	2.5% v/v
2	OTC MouthWash 1	25% v/v
3	OTC MouthWash 2	25% v/v
4	OTC MouthWash 3	25% v/v
5	OTC Nasal Spray 1	10% v/v
6	OTC Nasal Spray 2	10% v/v
7	OTC Nasal Spray 3	10% v/v
8	4-Acetamidophenol	10mg/mL
9	Acetylsalicylic Acid	20mg/mL
10	Chlorpheniramine	5mg/mL
11	Dextromethorphan	10mg/mL
12	Diphenhydramine	5mg/mL
13	Ephedrine	20mg/mL
14	Guaiacol glyceryl ether	20mg/mL
15	Oxymetazolin	10mg/mL
16	Phenylephrine	100mg/mL
17	Phenylpropanolamine	20mg/mL

Table 20-2 Potential interfering substances of COVID-19/RSV

NO.	Substance	Concentration
1	Whole blood	2.5% v/v
2	Mucin	2% v/v
3	Phenylephrine	15% v/v
4	Sodium Chloride	5% w/v
5	Cromolyn	15% v/v
6	Oxymetazoline	15% v/v
7	Fluconazole	5% w/v

8	Benzocaine	0.15% w/v
9	Veratramine	20% v/v
10	Zincum gluconium	5% w/v
11	Alkalol	10% v/v
12	Fluticasone Propionate	5% w/v
13	Phenol	15% w/v
14	Tamiflu (Oseltamivir hosphate)	0.5% w/v
15	Mupirocin	0.25% w/v
16	Tobramycin	0.0004% w/v

3.5.2 Experiment method

3.5.2.1 Sample preparation

3.5.2.2 Negative sample preparation

In this experiment, the mixture of negative sample matrix and interfering substances in Table 20 was used as the negative sample.

3.5.2.2.1 Positive sample preparation

The mixture of interfering substances in Table 20 with the 2×LOD virus solution was used as the positive sample this experiment. Please refer to Table 21:

Table 21-1 Influenza A testing sample preparation

No. of Interference	Volume of Influenza A (μL)	CONC of Influenza A (TCID ₅₀ /mL)	Volume of Interference (μL)	CONC of Interference
1	5	3.0×10 ⁴	795	2.5% v/v
2	5	3.0×10 ⁴	795	25% v/v
3	5	3.0×10 ⁴	795	25% v/v
4	5	3.0×10 ⁴	795	25% v/v
5	5	3.0×10 ⁴	795	10% v/v
6	5	3.0×10 ⁴	795	10% v/v
7	5	3.0×10 ⁴	795	10% v/v
8	5	3.0×10 ⁴	795	10mg/mL
9	5	3.0×10 ⁴	795	20mg/mL
10	5	3.0×10 ⁴	795	5mg/mL
11	5	3.0×10 ⁴	795	10mg/mL
12	5	3.0×10 ⁴	795	5mg/mL
13	5	3.0×10 ⁴	795	20mg/mL
14	5	3.0×10 ⁴	795	20mg/mL
15	5	3.0×10 ⁴	795	10mg/mL
16	5	3.0×10 ⁴	795	100mg/mL
17	5	3.0×10 ⁴	795	20mg/mL

Table 21-2 Influenza B testing sample preparation

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

No. of Interference	Volume of Influenza B (μL)	CONC of Influenza B (TCID ₅₀ /mL)	Volume of Interference (μL)	CONC of Interference
1	5	3.0×10 ⁵	795	2.5% v/v
2	5	3.0×10 ⁵	795	25% v/v
3	5	3.0×10 ⁵	795	25% v/v
4	5	3.0×10 ⁵	795	25% v/v
5	5	3.0×10 ⁵	795	10% v/v
6	5	3.0×10 ⁵	795	10% v/v
7	5	3.0×10 ⁵	795	10% v/v
8	5	3.0×10 ⁵	795	10mg/mL
9	5	3.0×10 ⁵	795	20mg/mL
10	5	3.0×10 ⁵	795	5mg/mL
11	5	3.0×10 ⁵	795	10mg/mL
12	5	3.0×10 ⁵	795	5mg/mL
13	5	3.0×10 ⁵	795	20mg/mL
14	5	3.0×10 ⁵	795	20mg/mL
15	5	3.0×10 ⁵	795	10mg/mL
16	5	3.0×10 ⁵	795	100mg/mL
17	5	3.0×10 ⁵	795	20mg/mL

Table 21-3 COVID-19 testing sample preparation

No. of Interference	Volume of SARS-COV-2 (μL)	CONC of SARS-COV-2 (TCID ₅₀ /mL)	Volume of Interference (μL)	CONC of Interference
1	2	400	798	2% w/v
2	2	400	798	2.5% v/v
3	2	400	798	15% v/v
4	2	400	798	5% v/v
5	2	400	798	15% v/v
6	2	400	798	15% v/v
7	2	400	798	5% w/v
8	2	400	798	0.15% w/v
9	2	400	798	20% v/v
10	2	400	798	5% w/v
11	2	400	798	10% v/v
12	2	400	798	5% v/v
13	2	400	798	15% v/v
14	2	400	798	0.5% w/v
15	2	400	798	0.25% w/v
16	2	400	798	0.0004% w/v

Table 21-4 RSV testing sample preparation

No. of Interference	Volume of RSV (μL)	CONC of RSV (TCID ₅₀ /mL)	Volume of Interference (μL)	CONC of Interference
1	5	2.0×10 ⁴	795	2% w/v
2	5	2.0×10 ⁴	795	2.5% v/v
3	5	2.0×10 ⁴	795	15% v/v
4	5	2.0×10 ⁴	795	5% v/v
5	5	2.0×10 ⁴	795	15% v/v
6	5	2.0×10 ⁴	795	15% v/v
7	5	2.0×10 ⁴	795	5% w/v
8	5	2.0×10 ⁴	795	0.15% w/v
9	5	2.0×10 ⁴	795	20% v/v
10	5	2.0×10 ⁴	795	5% w/v
11	5	2.0×10 ⁴	795	10% v/v
12	5	2.0×10 ⁴	795	5% v/v
13	5	2.0×10 ⁴	795	15% v/v
14	5	2.0×10 ⁴	795	0.5% w/v
15	5	2.0×10 ⁴	795	0.25% w/v
16	5	2.0×10 ⁴	795	0.0004% w/v

3.5.2.2.2 Experimental procedures

- 1) Use 3 different batches of products to test the samples prepared.
- 2) Each sample is tested 3 times.
- 3) Test operation:
 - Transfer the sample into sample well and start timer.
 - Read the result at 15 minutes.
 - Refer to IFU of this product.

4. Results

4.1 Test result of negative matrix:

Tests using the Influenza A/B+COVID-19/RSV Combo Ag Test device to detect samples containing potential interference substances without influenza A/B or COVID-19/RSV antigens confirmed that 100% of samples had no detectable antigen. See Table 22 for detailed results. There was no interference between the interfering substances and the device in testing.

Table 22-1 Results of the Influenza A/B

No. of matrix	Lot																	
	20200601						20200602						20200603					
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Table 22-2 Results of the COVID-19/RSV

No. of matrix	Lot																	
	20200601						20200602						20200603					
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

16	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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4.2 Test result of positive matrix

Tests using the Influenza A/B+COVID-19/RSV Combo Ag Test device to detect samples containing potential interference substances with the Influenza A/B or COVID-19/RSV antigens confirmed that 100% of samples had antigen present. See Table 23 for detailed results. There was no interference between the interfering substances and the device in testing.

Table 23-1 Results of Influenza A

No. of matrix	Lot																	
	20200601						20200602						20200603					
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
1	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
2	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
3	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
4	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
5	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
6	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
7	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
8	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
9	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
10	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
11	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
12	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
13	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
14	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
15	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
16	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
17	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-

Table 23-2 Results of Influenza B

No. of matrix	Lot																	
	20200601						20200602						20200603					
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
1	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
2	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
3	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+

CE Technical File	File No:CorDx-CE-Flu A+B&COVID-19+RSV-7
Influenza A/B+COVID-19/RSV Combo Ag Test	

4	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
5	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
6	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
7	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
8	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
9	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
10	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
11	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
12	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
13	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
14	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
15	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
16	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
17	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+

Table 23-3 Results of COVID-19

No. of matrix	Lot																	
	20200601						20200602						20200603					
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
1	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
2	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
3	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
4	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
5	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
6	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
7	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
8	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
9	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
10	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
11	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
12	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
13	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
14	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
15	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
16	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+

Table 23-4 Results of RSV

No. of matrix	Lot																	
	20200601						20200602						20200603					
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
1	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
2	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
3	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
4	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
5	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
6	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
7	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
8	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
9	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
10	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
11	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
12	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
13	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
14	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
15	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
16	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-

5. Conclusions

It can be concluded from the test results that there was no interference that would cause false positive results between the device and the potential interference substances listed in Table 20 when detecting Influenza A/B or COVID-19/RSV antigens, and there was no interference that would create false negative results between the device and the potential interference substances listed in Table 20 when detecting Influenza A/B or COVID-19/RSV antigens.

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

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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°C , 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°C~8°C for 72 hours, and it needs to be frozen at -20°C 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
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				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%
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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>

Compiled by : Xu Junyue

Date: 2022-03-22

Reviewed by: Li Yi

Date: 2022-03-22

The seal is read Beijing Electric Power Hospital.