浙江世佳生物医疗有限公司
Sejoy Biomedical Co., Ltd.

Clinical Validation Report

of SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette (Nasopharyngeal /Oropharyngeal)

Report No.: NHSY210722001

Version: A/2

Editor/Date: H a o Wu/2023.09.20

Reviewer/Date: Gang Qian/2023.09.20

1. Purpose

Supplement clinical validation to validate whether the SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette product meets the intended use of the product using nasopharyngeal swab.

2. Summary

The SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette produced by our company consists of three parts (a plastic box and a verified SARS-CoV-2 Antigen Rapid Test Casette, a verified Influenza A+B Antigen Rapid Test Casette). The performance of the internal test paper is the same as COVG-602 and Flu-602. The two test items are added samples separately, and the results do not interfere with each other, so the clinical

verification that have done before will not be verified again. Please refer to Annex A and Annex B for verification content.

Annex A

Clinical Validation Report

of SARS-CoV-2 Antigen Rapid Test Cassette (Nasopharyngeal /Oropharyngeal)

Report No.: NHSY210313001

Version: A/2

Editor/Date: Hao Wu/2023.09.20

Reviewer/Date: Gang Qian/2023.09.20

Content

1. Purpose

The purpose of this performance study was to establish the diagnostic sensitivity and diagnostic and analytical specificity of the Sejoy SARS-CoV-2 Antigen Rapid Test Cassette in order to validate whether the COVG product meets the intended use of the product using nasopharyngeal swab.

2. Information

2.1 Product information

	Lot	Expiry date
COVG-602	COVG200901	2022.09

2.2 RT-PCR information

Name: Thermo Fisher Scientific Inc TaqPath® COVID-19 CE-IVD RT-PCR Kit

Manufacturer: Thermofisher

PCR tests performed on Step One Plus Real-Time PCR System

2.3 Experimental location

Source of clinical samples: Prince Hamzah Hospital located at Fakhr Ad Din Ar Razi 12, Amman, Jordan;

2.4 Required patient information

-Age
-Gender
-Specimen type
-Symptoms
-Days from onset to sample collection
-Sample Collection Date

2.5 Timelines

2020.7.1- 2021.2.28

3. Validation plan

Method: Collect two nasopharyngeal swab samples from the same person. Collect one swab and wait for 15-30 minutes before collecting another swab. one of which was tested with the Sejoy SARS-CoV-2 Antigen Rapid Test Cassette, another sample is used for PCR testing to obtain reference results. Because the experimental mechanism of the test kits is different, the results of the Sejoy SARS-CoV-2 Antigen Rapid Test Cassette appear earlier than the PCR kits. After the PCR results were obtained, they were compared with the results obtained by the Sejoy SARS-CoV-2 Antigen Rapid Test Cassette. All samples tested shall have no less than 100 positive samples and no less than 200 negative samples. The results of Sejoy SARS-CoV-2 Antigen Rapid Test Cassette were interpreted and recorded within 10 minutes and the results were invalid after 30 minutes.

The swabs for the positive samples have been collected during the infectious phase of COVID-19 infected patients, the swabs of the negative samples have been collected from donors not infected with COVID-19. All swabs were collected from nasopharyngeal.

4. Sample selection

The samples selected included samples of patients of different ages, different genders. The samples of symptomatic patients included samples of patients with different symptoms, include cough, fatigue, fever,

headache, sore throat ect. The collection time of symptomatic clinical samples was after the onset of symptoms within seven days (including seven days).

5. Reference Test

An analysis has been performed of the correlation between the antigen -positive/PCR -positive and the antigen-negative/PCR -negative samples with the Ct-values of the PCR. The detection rate of the antigen test (e.g. detection rate >90%) should be observed in relation to the Ct-value. However, it should be noted that the Ct-values vary between PCR tests in the case of a given concentration of the target RNA.

6. Expected Risk & benefits

The patient's sample was prospectively assessed, and PCR testing was performed concurrently, so there was no risk to the patient. The results obtained in this study will not be used for patient care decisions.

The risks related to the user have been reduced as far as possible by providing detailed instructions for use with the kits, including warning and precautions for the users and known limitations of the device. Furthermore, the study will be performed by professionals who are qualified and trained for conducting the clinical performance study.

7. Test procedure

Throughout the evaluation, all samples swabs were extracted in the Sejoy SARS-CoV-2 Antigen Rapid Test Cassette extraction buffer as described in the IFU of the rapid test. 2 drops of the treated sample (approximately go 65uL) were applied to the sample well of the test cassette. Results obtained with the rapid test device were visually read-out by the operator between10-30 minutes after the sample had been applied onto the test cassette.

8. Data analysis

The following analyses have been performed:

The diagnostic sensitivity of the Sejoy SARS-CoV-2 Antigen Rapid Test Cassette was calculated as the number of identified positive samples compared to the total number of positive samples tested in parallel on the reference RT-PCR-assay in correlation to the Ct-value.

The diagnostic specificity of the Sejoy SARS-CoV-2 Antigen Rapid Test Cassette was calculated as the number of negative samples on the total number of negative samples tested with the RT-PCR- test.

The diagnostic sensitivities and specificities of different populations reported together with the 95% confidence interval.

The diagnostic sensitivities and specificities are reported together with the 95% confidence interval.

9. Validation results

True positive sample: sample that was determined positive both using the Sejoy SARS-CoV-2 Antigen Rapid Test Cassette and by RT-PCR.

False positive sample: sample that was determined positive using the Sejoy SARS-CoV-2 Antigen Rapid Test Cassette, but negative by RT-PCR.

True negative sample: sample that was determined negative both using the Sejoy SARS-CoV-2 Antigen Rapid Test Cassette and by RT-PCR.

False negative sample: sample that was determined negative using the Sejoy SARS-CoV-2 Antigen Rapid Test Cassette but positive by RT-PCR.

A total of 330 samples were detected by the Sejoy SARS-CoV-2 Antigen Rapid Test Cassette, of which 113 were positive and 212 were negative. Compared with the PCR test results, 3 cases were false negative and 2 cases were false positive.

Compare the PCR results to analyze the detection results of the Sejoy SARS-CoV-2 Antigen Rapid Test Cassette.

9.1 Diagnostic sensitivity

Analytical Results with correlation to Ct-values of the positive samples:

Ct-value	Number of Samples	Number of correct result	Number of wrong results	Sensitivity of Sejoy SARS-CoV-2 Antigen Rapid Test Cassette
≤25	79	79	0	100.00%(95.36%-100.00%)
≤30	94	93	1	98.94%(94.22%-99.81%)
≤32	100	98	2	98.00%(93.00%-99.45%)
≤34	102	100	2	98.04%(93.13%-99.46%)
≤36	116	113	3	97.41%(92.67%-99.12%)

The correlation between the Ct-values of the analyzed samples and the sensitivity reveals a sensitivity of 100.00% for samples with a Ct-value of up to 25. There is still a very good sensitivity of 97.41% up to a Ct-value of 36. This is in line with expectations regarding viral detection by antigen rapid testing compared to PCR analysis.

9.2 Diagnostic specificity

Analytical Results with correlation to Ct-values of the negative samples:

Number of Samples	Number of correct result	Number of wrong results	Sensitivity of Sejoy SARS-CoV-2 Antigen Rapid Test Cassette
214	212	2	99.07% (96.66%-99.74%)

Diagnostic Specificity of Sejoy SARS-CoV-2 Antigen Rapid Test Cassette: 99.07% (212/214), 95%CI: 96.66%-99.74%.

9.3 Total accuracy

Product		PCR		Total Results
		Positive	Negative	
COVG-602	Positive	113	2	115
	Negative	3	212	215
Total Results		116	214	330

Relative Specificity: 212/214*100%=99.07% (95%CI*:96.66%-99.74%)

Relative Sensitivity: 113/116*100%=97.41% (95%CI*:92.67%-99.12%)

Total accuracy: (113+212)/(116+214)*100%=98.48% (95%CI*:96.50%-99.35%)

10. Conclusion

From the above results, it can be concluded that the COVG product meets the intended use.

The specificity and sensitivity of the Sejoy SARS-CoV-2 Antigen Rapid Test Cassette was evaluated in this study with 330 samples collected nasopharyngeal swab. All samples were tested in parallel with the Sejoy SARS-CoV-2 Antigen Rapid Test Cassette and a real-time RT-PCR assay.

The specificity of the Sejoy SARS-CoV-2 Antigen Rapid Test Cassette calculated from results of all samples was 99.07%, the sensitivity calculated from results of samples with a Ct-value up to 25 (79 samples) was 100.00% (95% CI: 95.36%- 100.00%). Also up to a Ct value of 36 the sensitivity was very good with 97.41% (95% CI: 92.67%-99. 12%) with only 3 negatives out of 116 samples.

In conclusion, the results from this study confirm that the Sejoy SARS-CoV-2 Antigen Rapid Test Cassette can be used for the qualitative detection of antigen from SARS-CoV-2 in human nasopharyngeal swab with a very high sensitivity and specificity.

11. Revision history

Revision history			
Version	Revision content	Revision date	Remarks
A/0	First edition	2021.03.13	New release
A/1	Sensitivity was recalculated according to the CT values	2021.9.20	Revise
A/2	Change the name of the company	2023.9.20	Revise

12. Appendices

Appendix 1: Clinical Samples Information

Appendix 2: Clinical samples Information Sheet of SARS-CoV-2 Antigen Rapid Test Cassette

Appendix 1: Clinical Samples Information

I hereby certify that the samples collected below have not been diluted and are not adulterated with other substances.

Source of clinical samples: Prince Hamzah Hospital located at Fakhr Ad Din Ar Razi 12, Amman, Jordan;

Clinical sample collection time: 2020.7.1- 2021.2.28

Method for confirming clinical sample results: After sampling the patient through nasopharyngeal sampling, with the gold standard Real-time PCR test (Thermo Fisher Scientific Inc TaqPath® COVID- 19 Combo Kit CE-IVD RT-PCR) SARS-CoV-2 Test Kit,to determine the sensitivity and specificity over a range of viral loads as determined by the Ct values.

Selection of clinical samples:

The samples selected included samples of patients of different ages, different genders. The samples of symptomatic patients included samples of patients with different symptoms, include cough, fatigue, fever, headache, sore throat, ect. The collection time of symptomatic clinical samples was after the onset of symptoms within seven days (including seven days).

Number of clinical samples:

116 positive samples, 214 negative samples. All the samples confirmed by RT-PCR.

For details of the clinical sample information, please refer to the appendix 2"Clinical samples Information Sheet of SARS-CoV-2 Antigen Rapid Test Cassette"

The form contains the basic information, symptoms, sample type, RT-PCR test results and ct value of the clinical sample provider, date of onset, sample collection date, test date, and test results of verification reagents, etc.

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Appendix 2: Clinical samples Information Sheet of SARS-CoV-2 Antigen Rapid Test Cassette

Sample	Gender	Age	RT-PCR	CT-Value	symptom	Date of onset	Sample collection date	Days from onset to sample collection	Test date	Sejoy
Nasopharyngeal swab	F	50	Positive	35.6	headache	2020/7/21	2020/7/22	2	2021/1/13	Negative
Nasopharyngeal swab	F	18	Positive	29.2	FatigueFever	2020/7/29	2020/7/29	1	2021/1/13	Positive
Nasopharyngeal swab	F	23	Positive	2.2	Fever headache	2020/8/29	2020/9/3	6	2021/1/13	Positive
Nasopharyngeal swab	F	35	Positive	23.7	headache	2020/9/19	2020/9/24	6	2021/1/13	Positive
Nasopharyngeal swab	M	39	Positive	23	Fever	2020/10/19	2020/10/20	2	2021/1/13	Positive
Nasopharyngeal swab	F	70	Positive	35.3	Fever Cough	2020/7/21	2020/7/23	3	2021/1/13	Positive
Nasopharyngeal swab	F	19	Positive	17.2	fever	2020/11/16	2020/11/18	3	2021/1/13	Positive
Nasopharyngeal swab	M	38	Positive	5.7	FatigueFever	2020/11/23	2020/11/28	6	2021/1/13	Positive
Nasopharyngeal swab	M	12	Positive	26.2	Sore throat	2020/8/9	2020/8/10	2	2021/1/13	Positive
Nasopharyngeal swab	M	67	Positive	21.4	headache	2020/11/3	2020/11/5	3	2021/1/13	Positive
Nasopharyngeal swab	M	45	Positive	34.6	Sore throat headache	2020/12/5	2020/12/7	3	2021/1/13	Positive
Nasopharyngeal swab	F	48	Positive	13.1	Fever Sore throat	2020/9/10	2020/9/16	7	2021/1/13	Positive
Nasopharyngeal swab	F	36	Positive	24.1	Fever	2020/9/15	2020/9/16	2	2021/1/13	Positive
Nasopharyngeal swab	M	30	Positive	20.6	Sore throat headache	2020/9/30	2020/9/30	1	2021/1/13	Positive
Nasopharyngeal swab	M	18	Positive	15.5	Fever Cough	2020/8/16	2020/8/16	1	2021/1/13	Positive
Nasopharyngeal swab	M	68	Positive	25.3	Fever Sore throat	2020/9/16	2020/9/21	6	2021/1/13	Positive
Nasopharyngeal swab	F	54	Positive	6.1	headache	2020/9/26	2020/9/30	5	2021/1/13	Positive
Nasopharyngeal swab	F	75	Positive	34.8	Sore throat headache	2020/9/8	2020/9/14	7	2021/1/13	Positive
Nasopharyngeal swab	F	45	Positive	10.9	Sore throat	2020/7/18	2020/7/20	3	2021/1/13	Positive
Nasopharyngeal swab	M	36	Positive	6.8	Sore throat headache	2020/9/12	2020/9/17	6	2021/1/13	Positive
Nasopharyngeal swab	F	52	Positive	29.3	Cough	2020/8/17	2020/8/17	1	2021/1/13	Positive
Nasopharyngeal swab	F	23	Positive	17.9	headache	2020/8/11	2020/8/16	6	2021/1/13	Positive
Nasopharyngeal swab	M	46	Positive	25.2	Absence of symptoms	/	2020/8/4	/	2021/1/13	Positive

Nasopharyngeal swab	M	19	Positive	4.7	Sore throat	2020/9/17	2020/9/17	1	2021/1/13	Positive
Nasopharyngeal swab	M	53	Positive	32	Fever Sore throat	2020/8/11	2020/8/16	6	2021/1/13	Positive
Nasopharyngeal swab	F	28	Positive	35.3	Cough	2020/7/19	2020/7/22	4	2021/1/13	Positive
Nasopharyngeal swab	F	48	Positive	10.7	Fever	2020/8/19	2020/8/20	2	2021/1/13	Positive
Nasopharyngeal swab	M	68	Positive	5.2	Fever Sore throat	2020/7/18	2020/7/23	6	2021/1/13	Positive
Nasopharyngeal swab	M	36	Positive	35.6	headache	2020/7/22	2020/7/22	1	2021/1/13	Positive
Nasopharyngeal swab	F	39	Positive	1.8	Fever	2020/7/17	2020/7/20	4	2021/1/13	Positive
Nasopharyngeal swab	F	52	Positive	30.7	Fever Sore throat	2020/9/22	2020/9/25	4	2021/1/13	Positive
Nasopharyngeal swab	F	25	Positive	30.2	Fatigue	2020/8/19	2020/8/19	1	2021/1/13	Positive
Nasopharyngeal swab	F	59	Positive	35.2	Fever Cough	2021/1/2	2021/1/7	6	2021/1/13	Positive
Nasopharyngeal swab	F	42	Positive	19.9	Cough	2020/9/4	2020/9/7	4	2021/1/13	Positive
Nasopharyngeal swab	M	30	Positive	35.4	Cough	2020/12/8	2020/12/10	3	2021/1/13	Positive
Nasopharyngeal swab	M	35	Positive	23.3	Fatigue	2020/9/28	2020/9/30	3	2021/1/13	Positive
Nasopharyngeal swab	F	48	Positive	5.3	Fever	2020/8/29	2020/9/1	4	2021/1/13	Positive
Nasopharyngeal swab	F	63	Positive	3.1	headache	2021/1/1	2021/1/7	7	2021/1/13	Positive
Nasopharyngeal swab	M	56	Positive	31.8	Fatigue	2020/8/7	2020/8/11	5	2021/1/13	Negative
Nasopharyngeal swab	F	29	Positive	3.2	Sore throat	2020/11/10	2020/11/12	3	2021/1/13	Positive
Nasopharyngeal swab	M	38	Positive	10.6	Fatigue	2020/9/21	2020/9/23	3	2021/1/13	Positive
Nasopharyngeal swab	M	60	Positive	25.1	Fatigue	2020/9/18	2020/9/20	3	2021/1/13	Positive
Nasopharyngeal swab	F	48	Positive	25.7	Sore throat headache	2020/11/4	2020/11/6	3	2021/1/13	Positive
Nasopharyngeal swab	M	35	Positive	25.9	headache	2020/9/16	2020/9/22	7	2021/1/13	Positive
Nasopharyngeal swab	M	38	Positive	8.2	Fever Cough	2020/8/11	2020/8/15	5	2021/1/13	Positive
Nasopharyngeal swab	F	68	Positive	29.6	Fever Cough	2020/8/22	2020/8/28	7	2021/1/13	Positive
Nasopharyngeal swab	F	52	Positive	20.4	Fever	2020/10/15	2020/10/20	6	2021/1/13	Positive
Nasopharyngeal swab	F	39	Positive	21.6	Fatigue	2020/11/14	2020/11/16	3	2021/1/13	Positive
Nasopharyngeal swab	M	48	Positive	17.3	Fever Cough	2020/7/24	2020/7/28	5	2021/1/13	Positive
Nasopharyngeal swab	M	45	Positive	18.8	Cough	2020/11/2	2020/11/5	4	2021/1/13	Positive
Nasopharyngeal swab	M	15	Positive	16.4	Fatigue	2020/7/21	2020/7/23	3	2021/1/13	Positive

Nasopharyngeal swab	M	25	Positive	23	fever	2020/12/17	2020/12/18	2	2021/1/13	Positive
Nasopharyngeal swab	M	35	Positive	10.7	headache	2020/10/24	2020/10/29	6	2021/1/13	Positive
Nasopharyngeal swab	F	61	Positive	11.9	Fatigue	2020/11/18	2020/11/20	3	2021/1/13	Positive
Nasopharyngeal swab	F	25	Positive	30.4	Fatigue	2020/9/27	2020/9/29	3	2021/1/13	Positive
Nasopharyngeal swab	F	37	Positive	31.6	Fever	2020/8/15	2020/8/18	4	2021/1/13	Positive
Nasopharyngeal swab	F	26	Positive	16.8	Fatigue	2020/9/18	2020/9/20	3	2021/1/13	Positive
Nasopharyngeal swab	F	25	Positive	1.6	Cough	2020/9/22	2020/9/25	4	2021/1/14	Positive
Nasopharyngeal swab	M	38	Positive	20.6	Fatigue	2020/9/4	2020/9/4	1	2021/1/14	Positive
Nasopharyngeal swab	M	26	Positive	9.1	Fever Cough	2020/7/27	2020/7/29	3	2021/1/14	Positive
Nasopharyngeal swab	F	59	Positive	2.6	Fever Cough	2020/7/10	2020/7/14	5	2021/1/14	Positive
Nasopharyngeal swab	M	61	Positive	9.6	Fatigue	2020/7/15	2020/7/17	3	2021/1/14	Positive
Nasopharyngeal swab	M	45	Positive	20.6	headache	2020/11/11	2020/11/13	3	2021/1/14	Positive
Nasopharyngeal swab	F	28	Positive	11.1	headache	2020/8/6	2020/8/7	2	2021/1/14	Positive
Nasopharyngeal swab	F	20	Positive	6.7	fever	2021/1/3	2021/1/8	6	2021/1/14	Positive
Nasopharyngeal swab	F	53	Positive	10.2	Fever headache	2020/10/20	2020/10/21	2	2021/1/14	Positive
Nasopharyngeal swab	F	24	Positive	20.8	Cough	2020/11/1	2020/11/4	4	2021/1/14	Positive
Nasopharyngeal swab	M	37	Positive	9.6	Fever Cough	2020/12/6	2020/12/7	2	2021/1/14	Positive
Nasopharyngeal swab	F	65	Positive	4.5	Fever Cough	2020/11/26	2020/11/28	3	2021/1/14	Positive
Nasopharyngeal swab	M	36	Positive	29.5	Fever Sore throat	2020/8/10	2020/8/11	2	2021/1/14	Positive
Nasopharyngeal swab	F	48	Positive	6.9	Fever	2020/10/12	2020/10/13	2	2021/1/14	Positive
Nasopharyngeal swab	M	68	Positive	23.2	Fever Cough	2020/11/26	2020/11/27	2	2021/1/14	Positive
Nasopharyngeal swab	M	52	Positive	20.4	Absence of symptoms	/	2020/8/13	/	2021/1/14	Positive
Nasopharyngeal swab	F	29	Positive	2.3	Fever headache	2020/10/24	2020/10/30	7	2021/1/14	Positive
Nasopharyngeal swab	M	48	Positive	22.7	Fever Sore throat	2020/8/15	2020/8/16	2	2021/1/14	Positive
Nasopharyngeal swab	M	29	Positive	29.6	headache	2020/10/1	2020/10/7	7	2021/1/14	Negative
Nasopharyngeal swab	F	38	Positive	5.7	Sore throat	2020/8/27	2020/8/31	5	2021/1/14	Positive
Nasopharyngeal swab	F	68	Positive	2.1	Sore throat	2020/9/3	2020/9/6	4	2021/1/14	Positive
Nasopharyngeal swab	F	48	Positive	5.5	Fever headache	2020/7/18	2020/7/23	6	2021/1/14	Positive

Nasopharyngeal swab	F	26	Positive	23.1	Absence of symptoms	/	2020/7/16	/	2021/1/14	Positive
Nasopharyngeal swab	M	46	Positive	15.7	headache	2020/12/19	2020/12/23	5	2021/1/14	Positive
Nasopharyngeal swab	F	53	Positive	21.2	Sore throat headache	2020/10/19	2020/10/22	4	2021/1/14	Positive
Nasopharyngeal swab	F	56	Positive	8.5	Fatigue	2020/10/22	2020/10/23	2	2021/1/14	Positive
Nasopharyngeal swab	M	62	Positive	12	headache	2020/7/18	2020/7/23	6	2021/1/14	Positive
Nasopharyngeal swab	M	29	Positive	16.5	Absence of symptoms	/	2020/9/8	/	2021/1/14	Positive
Nasopharyngeal swab	M	24	Positive	34.4	Fever headache	2020/8/4	2020/8/6	3	2021/1/14	Positive
Nasopharyngeal swab	M	21	Positive	35.5	Sore throat	2020/8/8	2020/8/10	3	2021/1/14	Positive
Nasopharyngeal swab	F	21	Positive	7.3	Fever	2020/8/8	2020/8/13	6	2021/1/14	Positive
Nasopharyngeal swab	M	50	Positive	34.9	Fever headache	2020/10/29	2020/10/30	2	2021/1/14	Positive
Nasopharyngeal swab	F	45	Positive	20.1	Sore throat	2020/7/20	2020/7/21	2	2021/1/14	Positive
Nasopharyngeal swab	M	46	Positive	21.9	Fever Cough	2020/8/9	2020/8/14	6	2021/1/14	Positive
Nasopharyngeal swab	F	23	Positive	5.8	Fever Cough	2020/8/4	2020/8/7	4	2021/1/14	Positive
Nasopharyngeal swab	F	46	Positive	10.2	Fever Sore throat	2020/7/21	2020/7/22	2	2021/1/14	Positive
Nasopharyngeal swab	F	59	Positive	33.5	headache	2020/12/1	2020/12/1	1	2021/1/14	Positive
Nasopharyngeal swab	M	60	Positive	17.9	Sore throat headache	2020/7/16	2020/7/20	5	2021/1/14	Positive
Nasopharyngeal swab	M	65	Positive	1.9	Fever Cough	2020/9/11	2020/9/16	6	2021/1/14	Positive
Nasopharyngeal swab	F	31	Positive	24.4	Fever Cough	2020/7/14	2020/7/15	2	2021/1/14	Positive
Nasopharyngeal swab	M	49	Positive	5.6	Absence of symptoms	/	2020/7/24	/	2021/1/14	Positive
Nasopharyngeal swab	F	47	Positive	26.4	Sore throat	2020/8/29	2020/9/3	6	2021/1/14	Positive
Nasopharyngeal swab	M	54	Positive	14.5	Fever Sore throat	2020/8/7	2020/8/10	4	2021/1/14	Positive
Nasopharyngeal swab	M	58	Positive	21	Sore throat	2020/11/21	2020/11/25	5	2021/1/14	Positive
Nasopharyngeal swab	F	46	Positive	27.8	Cough	2020/7/10	2020/7/13	4	2021/1/14	Positive
Nasopharyngeal swab	F	60	Positive	10.4	Fatigue	2020/8/6	2020/8/7	2	2021/1/14	Positive
Nasopharyngeal swab	M	46	Positive	29.1	Fever Cough	2020/8/9	2020/8/12	4	2021/1/14	Positive
Nasopharyngeal swab	F	26	Positive	7.8	Fever Sore throat	2020/11/17	2020/11/20	4	2021/1/14	Positive
Nasopharyngeal swab	M	59	Positive	11.9	headache	2020/7/31	2020/8/6	7	2021/1/14	Positive
Nasopharyngeal swab	F	27	Positive	5.4	Sore throat headache	2020/9/16	2020/9/18	3	2021/1/14	Positive

Nasopharyngeal swab	M	32	Positive	19.3	Absence of symptoms	/	2020/9/29	/	2021/1/14	Positive
Nasopharyngeal swab	F	25	Positive	32.1	Fever headache	2021/1/1	2021/1/5	5	2021/1/14	Positive
Nasopharyngeal swab	F	36	Positive	35.3	FatigueFever	2020/8/6	2020/8/10	5	2021/1/14	Positive
Nasopharyngeal swab	F	57	Positive	9.3	FatigueFever	2020/7/15	2020/7/17	3	2021/1/14	Positive
Nasopharyngeal swab	M	60	Positive	17.5	Absence of symptoms	/	2020/10/26	/	2021/1/14	Positive
Nasopharyngeal swab	M	52	Positive	21.6	Fatigue	2020/7/21	2020/7/24	4	2021/1/14	Positive
Nasopharyngeal swab	F	62	Positive	29	Fatigue	2020/10/22	2020/10/27	6	2021/1/14	Positive
Nasopharyngeal swab	F	50	Positive	35.6	Absence of symptoms	/	2020/7/24	/	2021/1/14	Positive
Nasopharyngeal swab	F	50	Positive	35.6	headache	2020/10/5	2020/10/8	4	2021/1/14	Positive

Annex B

Clinical Validation Report

of Influenza A+B Antigen Rapid Test Cassette (Nasopharyngeal/oropharyngeal)

Report No.: NHSY210319001

Version: A/1

Editor/Date: Hao Wu/2023.09.20

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Content

13. Purpose

The purpose of this performance study was to establish the diagnostic sensitivity and diagnostic and analytical specificity of the Sejoy Influenza A+B Antigen Rapid Test Cassette in order to validate whether the FLU-602 product meets the intended use of the product using nasopharyngeal swab.

14. Information

2.6 Product information

FLU-602	Lot	Expiry date
	FLU201001	2022.09

2.7 RT-PCR information

Name: Thermo Fisher Scientific Inc TaqPath® Influenza A and Influenza B CE-IVD RT-PCR Kit

Manufacturer: Thermofisher

PCR tests performed on Step One Plus Real-Time PCR System

2.8 Experimental location

Source of clinical samples: Prince Hamzah Hospital located at Fakhr Ad Din Ar Razi 12, Amman, Jordan;

2.9 Required patient information

-Age
-Gender
-Specimen type
-Symptoms
-Days from onset to sample collection
-Sample Collection Date

2.10 Timelines

2020.10.01- 2021.3.10

15. Validation plan

Method: Collect two nasopharyngeal swab samples from the same person. Collect one swab and wait for 15-30 minutes before collecting another swab. one of which was tested with the Sejoy Influenza A+B Antigen Rapid Test Cassette, another sample is used for PCR testing to obtain reference results. Because the experimental mechanism of the test kits is different, the results of the Sejoy Influenza A+B Antigen Rapid Test Cassette appear earlier than the PCR kits. After the PCR results were obtained, they were compared with the results obtained by the Sejoy Influenza A+B Antigen Rapid Test Cassette. All samples tested shall have no less than 50 positive samples and no less than 150 negative samples. The results of Sejoy Influenza A+B Antigen Rapid Test Cassette were interpreted and recorded within 10 minutes and the results were invalid after 30 minutes.

The swabs for the positive samples have been collected during the infectious phase of Influenza A+B infected patients, the swabs of the negative samples have been collected from donors not infected with Influenza A+B. All swabs were collected from nasopharyngeal.

16. Sample selection

The samples selected included samples of patients of different ages, different genders. The samples of symptomatic patients included samples of patients with different symptoms, include cough, fatigue, fever,

headache, sore throat ect. The collection time of symptomatic clinical samples was after the onset of symptoms within seven days (including seven days).

17. Reference Test

An analysis has been performed of the correlation between the antigen -positive/PCR -positive and the antigen-negative/PCR -negative samples with the result of PCR. The detection rate of the antigen test (e.g. detection rate >90%) should be observed in relation to the result of PCR. However, it should be noted that the result vary between PCR tests in the case of a given concentration of the target RNA.

18. Expected Risk & benefits

The patient's sample was prospectively assessed, and PCR testing was performed concurrently, so there was no risk to the patient. The results obtained in this study will not be used for patient care decisions.

The risks related to the user have been reduced as far as possible by providing detailed instructions for use with the kits, including warning and precautions for the users and known limitations of the device. Furthermore, the study will be performed by professionals who are qualified and trained for conducting the clinical performance study.

19. Test procedure

Throughout the evaluation, all samples swabs were extracted in the Sejoy Influenza A+B Antigen Rapid Test Cassette extraction buffer as described in the IFU of the rapid test. 2 drops of the treated sample (approximately go 65uL) were applied to the sample well of the test cassette. Results obtained with the rapid test device were visually read-out by the operator between10-30 minutes after the sample had been applied onto the test cassette.

20. Data analysis

The following analyses have been performed:

The diagnostic sensitivity of the Sejoy Influenza A+B Antigen Rapid Test Cassette was calculated as the number of identified positive samples compared to the total number of positive samples tested in parallel on the reference RT-PCR-assay in correlation to the Ct-value.

The diagnostic specificity of the Sejoy Influenza A+B Antigen Rapid Test Cassette was calculated as the number of negative samples on the total number of negative samples tested with the RT-PCR- test.

The diagnostic sensitivities and specificities of different populations reported together with the 95% confidence interval.

The diagnostic sensitivities and specificities are reported together with the 95% confidence interval.

21. Validation results

True positive sample: sample that was determined positive both using the Sejoy Influenza A+B Antigen Rapid Test Cassette and by RT-PCR.

False positive sample: sample that was determined positive using the Sejoy Influenza A+B Antigen Rapid Test Cassette, but negative by RT-PCR.

True negative sample: sample that was determined negative both using the Sejoy Influenza A+B Antigen Rapid Test Cassette and by RT-PCR.

False negative sample: sample that was determined negative using the Sejoy Influenza A+B Antigen Rapid Test Cassette but positive by RT-PCR.

A total of 283 Influenza A samples were detected by the Sejoy Influenza A+B Antigen Rapid Test Cassette, of which 100 were positive and 180 were negative. Compared with the PCR test results, 1 cases were false negative and 2 cases were false positive;

A total of 289 Influenza B samples were detected by the Sejoy Influenza A+B Antigen Rapid Test Cassette, of which 85 were positive and 200 were negative. Compared with the PCR test results, 2 cases were false negative and 2 cases were false positive;

Compare the PCR results to analyze the detection results of the Sejoy Influenza A+B Antigen Rapid Test Cassette.

9.4 Diagnostic sensitivity

Analytical Results with correlation to PCR of the positive samples:

For Influenza A

Number of Samples	Number of correct result	Number of wrong results	Sensitivity of Sejoy Influenza A+B Antigen Rapid Test Cassette
101	100	1	99.00% (95%CI*: 94.6%-99.8%)

The correlation between the Sejoy Influenza A+B Antigen Rapid Test Cassette of the analyzed samples and the sensitivity reveals a sensitivity of 99.00% for samples with PCR. This is in line with expectations regarding viral detection by antigen rapid testing compared to PCR analysis.

For Influenza B

Number of Samples	Number of correct result	Number of wrong results	Sensitivity of Sejoy Influenza A+B Antigen Rapid Test Cassette
87	85	2	97.70%(95%CI*:92.0%-99.4%)

The correlation between the Sejoy Influenza A+B Antigen Rapid Test Cassette of the analyzed samples and the sensitivity reveals a sensitivity of 97.70% for samples with PCR. This is in line with expectations regarding viral detection by antigen rapid testing compared to PCR analysis.

9.5 Diagnostic specificity

Analytical Results with correlation to PCR of the negative samples:

For For Influenza A

Number of Samples	Number of correct result	Number of wrong results	Sensitivity of Sejoy SARS-CoV-2 Antigen Rapid Test Cassette
182	180	2	98.90%(95%CI*:96. 1%-99.7%)

Diagnostic Specificity of Sejoy Influenza A+B Antigen Rapid Test Cassette: 98.90% (180/182), 95%CI: 96.0%-99.7%.

For For Influenza B

Number of Samples	Number of correct result	Number of wrong results	Sensitivity of Sejoy SARS-CoV-2 Antigen Rapid Test Cassette
202	200	2	99.0%(95%CI*:96.5%-99.7%)

Diagnostic Specificity of Sejoy Influenza A+B Antigen Rapid Test Cassette: 99.0% (200/202), 95%CI: 96.5%-99.7%.

9.6 Total accuracy

		Type A			Type B		
		RT-PCR		Total	RT-PCR		Total
		Positive	Negative		Positive	Negative	
Influenza A+B Rapid	Positive	100	2	102	85	2	87
	Negative	1	180	181	2	200	202
Total		101	182	283	87	202	289
Relative Sensitivity		99.0% (95%CI*: 94.6%-99.8%)			97.7%(95%CI*:92.0%-99.4%)		
Relative Specificity		98.9%(95%CI*:96. 1%-99.7%)			99.0%(95%CI*:96.5%-99.7%)		
Accuracy		98.9% (95%CI*: 96.9%-99.6%)			98.6%(95%CI*:96.5%-99.5%)		

22. Conclusion

From the above results, it can be concluded that the FLU-602 product meets the intended use.

The specificity and sensitivity of the Sejoy Influenza A+B Antigen Rapid Test Cassette was evaluated in this study with 283 Influenza A and 289 Influenza B samples collected nasopharyngeal swab. All samples were tested in parallel with the Sejoy Influenza A+B Antigen Rapid Test Cassette and a real-time RT-PCR assay.

The specificity of the Sejoy Influenza A calculated from results of all samples was 98.9%, the sensitivity calculated from results of samples was 99.0% (95%CI*: 94.6%-99.8%) with only 1 negatives out of 101 samples.

The specificity of the Sejoy Influenza B calculated from results of all samples was 99.0%, the sensitivity calculated from results of samples was 97.7% (95%CI*:92.0%-99.4%) with only 2 negatives out of 87 samples

In conclusion, the results from this study confirm that the Sejoy Influenza A+B Antigen Rapid Test Cassette can be used for the qualitative detection of antigen from Influenza A+B in human nasopharyngeal swab with a very high sensitivity and specificity.

23. Revision history

Revision history			
Version	Revision content	Revision date	Remarks
A/0	First edition	2021.03.19	New release
A/1	Change the name of the company	2023.9.20	Revise

24. Appendices

Appendix 1: Clinical Samples Information

Appendix 2: Clinical samples Information Sheet of Influenza A+B Antigen Rapid Test Cassette

Appendix 1: Clinical Samples Information

I hereby certify that the samples collected below have not been diluted and are not adulterated with other substances.

Source of clinical samples: Prince Hamzah Hospital located at Fakhr Ad Din Ar Razi 12, Amman, Jordan;

Clinical sample collection time: 2020.10.01- 2021.3.10

Method for confirming clinical sample results: After sampling the patient through nasopharyngeal sampling, with the gold standard Real-time PCR test (Thermo Fisher Scientific Inc TaqPath® COVID- 19 Combo Kit CE-IVD RT-PCR) SARS-CoV-2 Test Kit,to determine the sensitivity and specificity over a range of viral loads as determined by the Ct values.

Selection of clinical samples:

The samples selected included samples of patients of different ages, different genders. The samples of symptomatic patients included samples of patients with different symptoms, include cough, fatigue, fever, headache, sore throat, ect. The collection time of symptomatic clinical samples was after the onset of symptoms within seven days (including seven days).

Number of clinical samples:

101 Influenza A and 87 Influenza B positive samples, 182 Influenza A and 202 Influenza B negative samples. All the samples confirmed by RT-PCR.

For details of the clinical sample information, please refer to the appendix 2"Clinical samples Information Sheet of Influenza A+B Antigen Rapid Test Cassette"

The form contains the basic information, symptoms, sample type, RT-PCR test results and ct value of the clinical sample provider, date of onset, sample collection date, test date, and test results of verification reagents, etc.

Appendix 2: Clinical samples Information Sheet of Influenza A+B Antigen Rapid Test Cassette

NO	Samples type	Gender	Age	PCR-A	PCR-B	Influenza A Rapid Test	Influenza B Rapid Test
1	nasopharyngeal swab	Female	33	Negative	Negative	Negative	Negative
2	nasopharyngeal swab	Male	36	Positive	Negative	Positive	Negative
3	nasopharyngeal swab	Female	22	Negative	Negative	Negative	Negative
4	nasopharyngeal swab	Female	62	Negative	Negative	Negative	Negative
5	nasopharyngeal swab	Male	47	Negative	Negative	Negative	Negative
6	nasopharyngeal swab	Male	43	Negative	Negative	Negative	Negative
7	nasopharyngeal swab	Male	15	Positive	Positive	Positive	Positive
8	nasopharyngeal swab	Female	39	Negative	Negative	Negative	Negative
9	nasopharyngeal swab	Female	45	Negative	Negative	Negative	Negative
10	nasopharyngeal swab	Female	19	Positive	Negative	Positive	Negative
11	nasopharyngeal swab	Female	49	Negative	Negative	Negative	Negative
12	nasopharyngeal swab	Female	24	Negative	Negative	Negative	Negative
13	nasopharyngeal swab	Male	54	Negative	Negative	Negative	Negative
14	nasopharyngeal swab	Male	37	Negative	Negative	Negative	Negative
15	nasopharyngeal swab	Female	25	Negative	Negative	Negative	Negative
16	nasopharyngeal swab	Male	43	Negative	Negative	Negative	Negative
17	nasopharyngeal swab	Male	45	Positive	Positive	Positive	Positive
18	nasopharyngeal swab	Female	16	Positive	Negative	Positive	Negative
19	nasopharyngeal swab	Female	41	Positive	Positive	Positive	Positive
20	nasopharyngeal swab	Male	56	Positive	Negative	Positive	Negative
21	nasopharyngeal swab	Female	21	Negative	Positive	Negative	Positive
22	nasopharyngeal swab	Female	36	Positive	Negative	Positive	Negative
23	nasopharyngeal swab	Male	40	Negative	Negative	Negative	Negative
24	nasopharyngeal swab	Male	29	Negative	Positive	Negative	Positive
25	nasopharyngeal swab	Female	36	Negative	Negative	Negative	Negative
26	nasopharyngeal swab	Female	51	Negative	Negative	Negative	Negative
27	nasopharyngeal swab	Male	18	Positive	Negative	Positive	Negative
28	nasopharyngeal swab	Female	65	Negative	Positive	Negative	Positive
29	nasopharyngeal swab	Male	48	Negative	Negative	Negative	Negative
30	nasopharyngeal swab	Male	48	Negative	Negative	Negative	Negative
31	nasopharyngeal swab	Female	24	Positive	Negative	Positive	Negative
32	nasopharyngeal swab	Male	47	Negative	Positive	Negative	Positive
33	nasopharyngeal swab	Female	60	Positive	Positive	Positive	Positive
34	nasopharyngeal swab	Female	31	Negative	Positive	Negative	Positive
35	nasopharyngeal swab	Female	40	Negative	Positive	Negative	Positive
36	nasopharyngeal swab	Female	59	Positive	Negative	Positive	Negative
37	nasopharyngeal swab	Female	21	Negative	Positive	Negative	Positive
38	nasopharyngeal swab	Male	43	Negative	Negative	Negative	Negative

39	nasopharyngeal swab	Male	21	Positive	Negative	Positive	Negative
40	nasopharyngeal swab	Male	36	Negative	Negative	Negative	Negative
41	nasopharyngeal swab	Female	37	Negative	Negative	Negative	Negative
42	nasopharyngeal swab	Male	31	Negative	Positive	Negative	Negative
43	nasopharyngeal swab	Male	44	Negative	Negative	Negative	Negative
44	nasopharyngeal swab	Male	26	Negative	Negative	Negative	Negative
45	nasopharyngeal swab	Male	47	Negative	Negative	Negative	Negative
46	nasopharyngeal swab	Female	65	Negative	Negative	Negative	Negative
47	nasopharyngeal swab	Female	55	Negative	Positive	Negative	Positive
48	nasopharyngeal swab	Male	21	Negative	Negative	Negative	Negative
49	nasopharyngeal swab	Female	52	Negative	Negative	Negative	Negative
50	nasopharyngeal swab	Female	37	Positive	Negative	Positive	Negative
51	nasopharyngeal swab	Female	39	Negative	Negative	Negative	Negative
52	nasopharyngeal swab	Female	58	Positive	Negative	Positive	Negative
53	nasopharyngeal swab	Female	42	Positive	Negative	Positive	Negative
54	nasopharyngeal swab	Male	42	Positive	Negative	Positive	Negative
55	nasopharyngeal swab	Female	58	Negative	Negative	Negative	Negative
56	nasopharyngeal swab	Female	36	Positive	Positive	Positive	Positive
57	nasopharyngeal swab	Male	33	Positive	Negative	Positive	Negative
58	nasopharyngeal swab	Male	59	Negative	Negative	Negative	Negative
59	nasopharyngeal swab	Female	34	Positive	Positive	Positive	Positive
60	nasopharyngeal swab	Male	64	Negative	Negative	Negative	Negative
61	nasopharyngeal swab	Male	31	Positive	Positive	Positive	Positive
62	nasopharyngeal swab	Female	46	Negative	Negative	Negative	Negative
63	nasopharyngeal swab	Male	52	Negative	Negative	Negative	Negative
64	nasopharyngeal swab	Male	25	Negative	Negative	Negative	Negative
65	nasopharyngeal swab	Male	40	Negative	Negative	Negative	Negative
66	nasopharyngeal swab	Male	22	Negative	Positive	Negative	Positive
67	nasopharyngeal swab	Female	29	Negative	Negative	Negative	Negative
68	nasopharyngeal swab	Female	21	Negative	Negative	Negative	Negative
69	nasopharyngeal swab	Male	42	Positive	Positive	Positive	Positive
70	nasopharyngeal swab	Male	36	Negative	Positive	Negative	Positive
71	nasopharyngeal swab	Male	44	Positive	Negative	Positive	Negative
72	nasopharyngeal swab	Female	38	Negative	Negative	Negative	Negative
73	nasopharyngeal swab	Male	41	Negative	Negative	Negative	Negative
74	nasopharyngeal swab	Female	15	Negative	Positive	Negative	Positive
75	nasopharyngeal swab	Male	48	Negative	Positive	Negative	Positive
76	nasopharyngeal swab	Male	48	Positive	Negative	Positive	Negative
77	nasopharyngeal swab	Male	37	Negative	Negative	Negative	Negative
78	nasopharyngeal swab	Female	37	Negative	Negative	Negative	Negative
79	nasopharyngeal swab	Female	40	Negative	Negative	Negative	Negative
80	nasopharyngeal swab	Female	18	Positive	Negative	Positive	Negative
81	nasopharyngeal swab	Male	37	Negative	Negative	Negative	Negative

82	nasopharyngeal swab	Male	50	Negative	Negative	Negative	Negative
83	nasopharyngeal swab	Male	35	Positive	Negative	Positive	Negative
84	nasopharyngeal swab	Female	57	Positive	Negative	Positive	Negative
85	nasopharyngeal swab	Female	34	Positive	Positive	Positive	Positive
86	nasopharyngeal swab	Female	31	Negative	Negative	Negative	Negative
87	nasopharyngeal swab	Male	54	Negative	Positive	Negative	Positive
88	nasopharyngeal swab	Female	48	Positive	Positive	Positive	Positive
89	nasopharyngeal swab	Male	60	Negative	Negative	Negative	Negative
90	nasopharyngeal swab	Male	41	Negative	Negative	Negative	Negative
91	nasopharyngeal swab	Male	47	Positive	Negative	Positive	Negative
92	nasopharyngeal swab	Female	25	Negative	Negative	Negative	Negative
93	nasopharyngeal swab	Male	54	Positive	Positive	Positive	Positive
94	nasopharyngeal swab	Male	21	Negative	Positive	Negative	Positive
95	nasopharyngeal swab	Male	29	Positive	Negative	Positive	Negative
96	nasopharyngeal swab	Male	19	Positive	Negative	Positive	Negative
97	nasopharyngeal swab	Male	64	Negative	Negative	Negative	Negative
98	nasopharyngeal swab	Male	25	Negative	Positive	Negative	Positive
99	nasopharyngeal swab	Female	51	Negative	Positive	Negative	Positive
100	nasopharyngeal swab	Male	20	Positive	Negative	Positive	Negative
101	nasopharyngeal swab	Male	50	Negative	Positive	Negative	Positive
102	nasopharyngeal swab	Male	32	Positive	Negative	Positive	Negative
103	nasopharyngeal swab	Male	22	Negative	Negative	Negative	Negative
104	nasopharyngeal swab	Male	52	Positive	Positive	Positive	Positive
105	nasopharyngeal swab	Male	32	Negative	Negative	Negative	Negative
106	nasopharyngeal swab	Female	19	Negative	Negative	Negative	Negative
107	nasopharyngeal swab	Male	35	Negative	Positive	Negative	Positive
108	nasopharyngeal swab	Female	35	Positive	Negative	Positive	Negative
109	nasopharyngeal swab	Male	42	Negative	Negative	Negative	Negative
110	nasopharyngeal swab	Male	45	Positive	Negative	Positive	Negative
111	nasopharyngeal swab	Male	29	Positive	Negative	Positive	Negative
112	nasopharyngeal swab	Male	61	Positive	Negative	Positive	Negative
113	nasopharyngeal swab	Female	49	Negative	Negative	Negative	Negative
114	nasopharyngeal swab	Female	30	Positive	Positive	Positive	Positive
115	nasopharyngeal swab	Female	54	Negative	Positive	Negative	Positive
116	nasopharyngeal swab	Male	46	Negative	Negative	Negative	Negative
117	nasopharyngeal swab	Female	30	Negative	Negative	Negative	Negative
118	nasopharyngeal swab	Male	39	Positive	Negative	Positive	Negative
119	nasopharyngeal swab	Female	18	Positive	Negative	Positive	Negative
120	nasopharyngeal swab	Male	54	Negative	Negative	Negative	Negative
121	nasopharyngeal swab	Female	33	Positive	Negative	Positive	Negative
122	nasopharyngeal swab	Male	41	Positive	Negative	Positive	Negative
123	nasopharyngeal swab	Female	61	Positive	Positive	Positive	Positive
124	nasopharyngeal swab	Male	20	Negative	Negative	Negative	Negative

125	nasopharyngeal swab	Female	32	Negative	Negative	Negative	Negative
126	nasopharyngeal swab	Female	32	Negative	Positive	Negative	Positive
127	nasopharyngeal swab	Female	34	Positive	Negative	Positive	Negative
128	nasopharyngeal swab	Female	26	Positive	Negative	Positive	Negative
129	nasopharyngeal swab	Female	49	Negative	Negative	Negative	Negative
130	nasopharyngeal swab	Male	29	Negative	Positive	Negative	Positive
131	nasopharyngeal swab	Female	59	Positive	Negative	Positive	Negative
132	nasopharyngeal swab	Male	44	Negative	Positive	Negative	Positive
133	nasopharyngeal swab	Male	34	Negative	Negative	Negative	Negative
134	nasopharyngeal swab	Female	41	Positive	Negative	Positive	Negative
135	nasopharyngeal swab	Male	52	Negative	Positive	Negative	Positive
136	nasopharyngeal swab	Female	21	Negative	Negative	Negative	Negative
137	nasopharyngeal swab	Male	50	Positive	Negative	Positive	Negative
138	nasopharyngeal swab	Male	30	Positive	Positive	Positive	Positive
139	nasopharyngeal swab	Female	54	Negative	Negative	Negative	Negative
140	nasopharyngeal swab	Male	45	Negative	Negative	Negative	Negative
141	nasopharyngeal swab	Female	19	Negative	Negative	Negative	Negative
142	nasopharyngeal swab	Male	30	Negative	Negative	Negative	Negative
143	nasopharyngeal swab	Male	51	Negative	Negative	Negative	Negative
144	nasopharyngeal swab	Male	32	Negative	Positive	Negative	Positive
145	nasopharyngeal swab	Female	25	Positive	Positive	Positive	Positive
146	nasopharyngeal swab	Female	35	Negative	Positive	Negative	Positive
147	nasopharyngeal swab	Male	52	Negative	Positive	Positive	Positive
148	nasopharyngeal swab	Female	39	Negative	Positive	Negative	Positive
149	nasopharyngeal swab	Female	25	Negative	Negative	Negative	Negative
150	nasopharyngeal swab	Male	32	Negative	Positive	Negative	Positive
151	nasopharyngeal swab	Female	49	Negative	Negative	Negative	Negative
152	nasopharyngeal swab	Female	36	Negative	Negative	Negative	Negative
153	nasopharyngeal swab	Male	37	Negative	Negative	Negative	Negative
154	nasopharyngeal swab	Female	31	Positive	Negative	Positive	Negative
155	nasopharyngeal swab	Female	28	Negative	Negative	Negative	Negative
156	nasopharyngeal swab	Male	51	Negative	Negative	Negative	Negative
157	nasopharyngeal swab	Female	54	Negative	Positive	Negative	Positive
158	nasopharyngeal swab	Male	35	Negative	Negative	Negative	Negative
159	nasopharyngeal swab	Female	21	Negative	Negative	Negative	Negative
160	nasopharyngeal swab	Female	62	Positive	Negative	Positive	Negative
161	nasopharyngeal swab	Female	20	Negative	Negative	Negative	Negative
162	nasopharyngeal swab	Female	29	Positive	Negative	Positive	Negative
163	nasopharyngeal swab	Male	18	Negative	Negative	Negative	Negative
164	nasopharyngeal swab	Female	20	Positive	Positive	Positive	Positive
165	nasopharyngeal swab	Male	31	Negative	Negative	Negative	Negative
166	nasopharyngeal swab	Male	33	Negative	Positive	Negative	Positive
167	nasopharyngeal swab	Female	19	Positive	Negative	Positive	Negative

168	nasopharyngeal swab	Male	46	Positive	Negative	Positive	Negative
169	nasopharyngeal swab	Male	32	Negative	Negative	Negative	Negative
170	nasopharyngeal swab	Female	41	Negative	Negative	Negative	Negative
171	nasopharyngeal swab	Male	40	Negative	Negative	Negative	Negative
172	nasopharyngeal swab	Male	29	Negative	Negative	Negative	Negative
173	nasopharyngeal swab	Female	54	Negative	Negative	Negative	Negative
174	nasopharyngeal swab	Male	24	Negative	Positive	Negative	Positive
175	nasopharyngeal swab	Male	42	Positive	Positive	Positive	Positive
176	nasopharyngeal swab	Female	62	Negative	Negative	Positive	Negative
177	nasopharyngeal swab	Female	17	Negative	Negative	Negative	Positive
178	nasopharyngeal swab	Male	62	Negative	Positive	Negative	Positive
179	nasopharyngeal swab	Female	42	Negative	Negative	Negative	Negative
180	nasopharyngeal swab	Female	46	Positive	Positive	Positive	Positive
181	nasopharyngeal swab	Female	41	Positive	Negative	Positive	Negative
182	nasopharyngeal swab	Male	20	Negative	Positive	Negative	Positive
183	nasopharyngeal swab	Male	52	Negative	Negative	Negative	Negative
184	nasopharyngeal swab	Male	27	Negative	Negative	Negative	Negative
185	nasopharyngeal swab	Female	62	Negative	Negative	Negative	Negative
186	nasopharyngeal swab	Male	40	Negative	Positive	Negative	Positive
187	nasopharyngeal swab	Male	39	Positive	Negative	Positive	Negative
188	nasopharyngeal swab	Female	31	Negative	Negative	Negative	Negative
189	nasopharyngeal swab	Female	20	Negative	Negative	Negative	Negative
190	nasopharyngeal swab	Female	17	Positive	Negative	Negative	Negative
191	nasopharyngeal swab	Female	33	Negative	Negative	Negative	Negative
192	nasopharyngeal swab	Female	40	Positive	Negative	Positive	Negative
193	nasopharyngeal swab	Female	44	Positive	Negative	Positive	Negative
194	nasopharyngeal swab	Male	58	Negative	Negative	Negative	Negative
195	nasopharyngeal swab	Female	49	Negative	Positive	Negative	Positive
196	nasopharyngeal swab	Female	45	Negative	Positive	Negative	Positive
197	nasopharyngeal swab	Male	27	Positive	Positive	Positive	Positive
198	nasopharyngeal swab	Male	44	Positive	Negative	Positive	Negative
199	nasopharyngeal swab	Male	24	Negative	Negative	Negative	Negative
200	nasopharyngeal swab	Female	39	Negative	Negative	Negative	Negative
201	nasopharyngeal swab	Female	43	Negative	Negative	Negative	Negative
202	nasopharyngeal swab	Female	58	Negative	Negative	Negative	Negative
203	nasopharyngeal swab	Male	31	Negative	Positive	Negative	Positive
204	nasopharyngeal swab	Female	29	Negative	Negative	Negative	Negative
205	nasopharyngeal swab	Male	35	Negative	Negative	Negative	Negative
206	nasopharyngeal swab	Male	17	Positive	Negative	Positive	Negative
207	nasopharyngeal swab	Male	54	Negative	Negative	Negative	Negative
208	nasopharyngeal swab	Female	16	Negative	Negative	Negative	Negative
209	nasopharyngeal swab	Female	46	Negative	Positive	Negative	Positive
210	nasopharyngeal swab	Female	59	Positive	Negative	Positive	Negative

211	nasopharyngeal swab	Male	56	Negative	Negative	Negative	Positive
212	nasopharyngeal swab	Male	32	Negative	Positive	Negative	Negative
213	nasopharyngeal swab	Male	15	Positive	Positive	Positive	Positive
214	nasopharyngeal swab	Female	40	Negative	Negative	Negative	Negative
215	nasopharyngeal swab	Female	55	Positive	Negative	Positive	Negative
216	nasopharyngeal swab	Female	65	Positive	Positive	Positive	Positive
217	nasopharyngeal swab	Male	46	Positive	Negative	Positive	Negative
218	nasopharyngeal swab	Male	22	Negative	Negative	Negative	Negative
219	nasopharyngeal swab	Male	42	Positive	Positive	Positive	Positive
220	nasopharyngeal swab	Male	15	Negative	Negative	Negative	Negative
221	nasopharyngeal swab	Male	60	Positive	Negative	Positive	Negative
222	nasopharyngeal swab	Female	33	Positive	Positive	Positive	Positive
223	nasopharyngeal swab	Male	30	Negative	Positive	Negative	Positive
224	nasopharyngeal swab	Female	23	Positive	Negative	Positive	Negative
225	nasopharyngeal swab	Male	22	Negative	Positive	Negative	Positive
226	nasopharyngeal swab	Female	45	Negative	Negative	Negative	Negative
227	nasopharyngeal swab	Male	32	Positive	Negative	Positive	Negative
228	nasopharyngeal swab	Male	65	Negative	Negative	Negative	Negative
229	nasopharyngeal swab	Female	19	Negative	Negative	Negative	Negative
230	nasopharyngeal swab	Female	57	Negative	Negative	Negative	Negative
231	nasopharyngeal swab	Male	21	Positive	Negative	Positive	Negative
232	nasopharyngeal swab	Male	40	Negative	Positive	Negative	Positive
233	nasopharyngeal swab	Female	42	Positive	Negative	Positive	Negative
234	nasopharyngeal swab	Female	37	Positive	Negative	Positive	Negative
235	nasopharyngeal swab	Male	63	Positive	Negative	Positive	Negative
236	nasopharyngeal swab	Female	62	Positive	Negative	Positive	Negative
237	nasopharyngeal swab	Male	23	Negative	Positive	Negative	Positive
238	nasopharyngeal swab	Female	61	Positive	Negative	Positive	Negative
239	nasopharyngeal swab	Female	41	Negative	Negative	Negative	Negative
240	nasopharyngeal swab	Male	31	Negative	Negative	Negative	Negative
241	nasopharyngeal swab	Male	43	Negative	Negative	Negative	Negative
242	nasopharyngeal swab	Male	64	Negative	Negative	Negative	Negative
243	nasopharyngeal swab	Female	40	Negative	Negative	Negative	Negative
244	nasopharyngeal swab	Female	28	Positive	Positive	Positive	Positive
245	nasopharyngeal swab	Male	24	Negative	Negative	Negative	Negative
246	nasopharyngeal swab	Female	18	Negative	Positive	Negative	Positive
247	nasopharyngeal swab	Male	30	Positive	Negative	Positive	Negative
248	nasopharyngeal swab	Female	23	Positive	Positive	Positive	Positive
249	nasopharyngeal swab	Male	35	Negative	Positive	Negative	Positive
250	nasopharyngeal swab	Female	31	Positive	Negative	Positive	Negative
251	nasopharyngeal swab	Female	44	Positive	Positive	Positive	Positive
252	nasopharyngeal swab	Female	24	Negative	Positive	Negative	Positive
253	nasopharyngeal swab	Male	46	Positive	Negative	Positive	Negative

254	nasopharyngeal swab	Male	16	Positive	Negative	Positive	Negative
255	nasopharyngeal swab	Male	62	Negative	Positive	Negative	Positive
256	nasopharyngeal swab	Male	49	Negative	Positive	Negative	Positive
257	nasopharyngeal swab	Female	37	Negative	Positive	Negative	Positive
258	nasopharyngeal swab	Female	41	Negative	Negative	Negative	Negative
259	nasopharyngeal swab	Female	19	Negative	Negative	Negative	Negative
260	nasopharyngeal swab	Male	34	Positive	Negative	Positive	Negative
261	nasopharyngeal swab	Female	44	Positive	Negative	Positive	Negative
262	nasopharyngeal swab	Female	51	Negative	Negative	Negative	Negative
263	nasopharyngeal swab	Female	51	Negative	Negative	Negative	Negative
264	nasopharyngeal swab	Female	27	Negative	Negative	Negative	Negative
265	nasopharyngeal swab	Male	29	Positive	Negative	Positive	Negative
266	nasopharyngeal swab	Female	43	Positive	Negative	Positive	Negative
267	nasopharyngeal swab	Female	30	Negative	Positive	Negative	Positive
268	nasopharyngeal swab	Male	49	Negative	Positive	Negative	Positive
269	nasopharyngeal swab	Male	45	Negative	Negative	Negative	Negative
270	nasopharyngeal swab	Male	37	Negative	Negative	Negative	Negative
271	nasopharyngeal swab	Male	56	Positive	Negative	Positive	Negative
272	nasopharyngeal swab	Male	29	Positive	Negative	Positive	Negative
273	nasopharyngeal swab	Female	15	Negative	Positive	Negative	Positive
274	nasopharyngeal swab	Male	43	Negative	Negative	Negative	Negative
275	nasopharyngeal swab	Female	38	Negative	Positive	Negative	Positive
276	nasopharyngeal swab	Female	36	Positive	Negative	Positive	Negative
277	nasopharyngeal swab	Male	37	Negative	Negative	Negative	Negative
278	nasopharyngeal swab	Female	60	Positive	Negative	Positive	Negative
279	nasopharyngeal swab	Female	65	Positive	Positive	Positive	Positive
280	nasopharyngeal swab	Male	51	Negative	Negative	Negative	Negative
281	nasopharyngeal swab	Female	53	Negative	Positive	Negative	Positive
282	nasopharyngeal swab	Male	19	Negative	Negative	Negative	Negative
283	nasopharyngeal swab	Female	17	Negative	Negative	Negative	Negative
284	nasopharyngeal swab	Male	28	/	Negative	/	Negative
285	nasopharyngeal swab	Female	19	/	Positive	/	Positive
286	nasopharyngeal swab	Male	26	/	Positive	/	Positive
287	nasopharyngeal swab	Male	49	/	Positive	/	Positive
288	nasopharyngeal swab	Female	53	/	Negative	/	Negative
289	nasopharyngeal swab	Female	16	/	Positive	/	Positive

Revision history			
Version	Revision content	Revision date	Remarks
A/0	First edition	2021.07.22	New release
A/1	Add some new part of the flu	2022.09.20	