



Locus Medicus Medical SA

Clinical Performance Study Report

KaiBiLi Flu & COVID-19 Antigen Duo Rapid Test

REF : P211137

Sponsor :

Hangzhou Genesis Biodetection and Biocontrol Co., Ltd.

**ADD : No.139, 10th Street (East), Hangzhou Economic &
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1. Purpose of the Study

The rationale of this study is to evaluate the sensitivity and specificity of KaiBiLi Flu & COVID-19 Antigen Duo Rapid Test Kit (Hereinafter referred to as KaiBiLi Flu & COVID-19 Ag Duo) (REF: P211137) to meet "Guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical devices" of MDCG dated August 2021.

2. Collaborations

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Hangzhou Genesis Biodetection and Biocontrol Co., Ltd.

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2.2 Investigation:

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2.3 Study Coordination:

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Original data storage location: 246 Mesogeion Ave.155 61 Holargos, Athens, Greece

Researchers	Title	Take responsibility
Dr. Georgios Georgoulas	Operator	Test implementation, collect samples, report drafting
Dr. Vassiliki Michou	Operator	Test implementation, Head of Molecular Department
Dr. Harilaos P. Kavvadas	Reviewer	Report reviewing and approval

3. Background

Influenza is a highly contagious acute viral infection of the respiratory tract. It is a communicable disease easily transmitted from person to person through aerosol droplets excreted when sneezing and coughing. Common symptoms include high fever, chills, headache, cough, sore throat and malaise. The type A influenza virus is more prevalent and is the primary pathogen associated with serious epidemics. The type B virus causes a disease that is generally not as severe as that caused by the type A virus. An accurate diagnosis of influenza based on clinical symptoms is difficult because the initial symptoms of influenza are similar to those of numerous other illnesses.

The novel coronavirus belongs to the β genus. SARS-CoV-2 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia, and diarrhea are found in a few cases.

COVID-19 has demonstrated the capability of spreading rapidly, leading to significant impacts on the healthcare system and causing societal disruption. To respond effectively to the COVID-19 outbreak, rapid detection of cases, stringent performance assessment, and increase in the current diagnostic capacity are still urgently needed. The symptoms of COVID-19 are similar to those of other viral respiratory disease and include fever or chills, cough, shortness of breath or difficulty of breathing, fatigue, muscle or body aches, headache, the new loss of taste or smell, sore throat, congested or runny nose, nausea or vomiting or diarrhea, etc. As the early symptoms of COVID-19 are similar to those of seasonal Influenza A or B, a rapid detection test to specifically diagnose symptomatic patients is urgently needed.

4. Test principle

The KaiBiLi Flu & COVID-19 Ag Duo composed of one test strip for Flu Antigen and another for COVID-19 Antigen, is an immunochromatographic assay for qualitative detection of 2019 Novel Coronavirus, influenza A and B antigens.

The Flu Antigen Rapid Test has three letters on the surface of the strips indicating test line (A) , (B) and control line (C). Test line and control line in the result window are not visible before applying any samples. The control line is a reference line which indicates the test is performing properly. The control line must appear every time when the test is performed.

When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If influenza A presents in the sample, a complex formed between the anti-influenza A conjugate and the virus will be captured by the specific anti-influenza A monoclonal antibodies coated on the A region (A). If the sample contains influenza B, a complex formed between the anti-influenza B conjugate and the virus will be captured by the specific anti-influenza B monoclonal antibodies coated on the B region (B). Results appear at 15 minutes in the form of a red line in the A region (A) or B region (B) that develops on the membrane.

The COVID-19 Antigen Rapid Test has two letters on the surface of the strips indicating test line (T) and control line (C). Test line and control line in the result window are not visible before applying any samples. The control line is a reference line which indicates the test is performing properly. The control line must appear every time when the test is performed. If SARS CoV-2 is present in the sample, the test line would appear. The highly selective antibodies to SARS CoV-2 are used as capture and detector in the assay. These antibodies can detect SARS CoV-2 antigens directly

5. Scope

5.1 Objectives

The objective of this study is to compare the performance of KaiBiLi Flu & COVID-19 Ag Duo manufactured by Hangzhou Genesis Biodetection and Biocontrol Co., Ltd. with Sacace™ SARS-CoV-2 Real-time PCR kit manufactured by Sacace Biotechnologies Srl which meets EU CE standards, to evaluate the ability for detecting variants, as well as the effectiveness, and analytical specificity of the kit.

This study performed according to MDCG-2021 Guidelines & Requirements.

Provided that the KaiBiLi Flu & COVID-19 Ag Duo is shown to have sufficient sensitivity and specificity, then this device could contribute to overall COVID-19 testing capacity, offering advantages in terms of shorter turnaround times and reduced costs.

5.2 Sample Types

5.2.1 The overall study samples shall not be less than 750 individuals (all positive and negative), in which:

- At least 100 RT-PCR positive specimens, collected from symptomatic individuals who were tested within 0~7 days of the onset of symptoms.
- Consideration of genetic variants, for the purpose of evaluation.
- At least 300 RT-PCR negative specimens, from non-infected individuals.
- At least 100 negative samples from hospitalized patients.
- At least 50 negative samples from potentially interfering and cross-reactive samples: including virus-positive samples of endemic human coronaviruses ; influenza A, B, RSV, and other pathogens of respiratory diseases, eligible for differential diagnosis; including bacteria¹⁰) present in the sampling area.
- With inability to obtain of fresh clinical Influenza A/B positive specimens, specimens stored/frozen in viral transport media (VTM) confirmed positive by real-time PCR were used instead. The source of the sample is provided by Leto hospital, there are a total of 54 influenza A positive sample and 51 influenza B positive sample were analyzed.

5.2.2 Inclusion criteria

- Symptomatic individuals (within 7 days of symptom onset) who were suspected of COVID-19
- Asymptomatic individuals without a known SARS-CoV-2 exposure
- Written informed consent of the participant; for children under 18 years of age, informed consent of the parents or legal guardians.

5.2.3 Exclusion Criteria:

- Symptoms have been present for more than seven days
- Prone to nosebleeds
- Unable to provide informed consent due to mental or cognitive disabilities
- Individuals duplicate enrolment

5.3 Method

Subjects will be prospectively enrolled and tested sequentially and blindly. Both nasal and nasopharyngeal swabs will be collected from each participant by medical professionals. The nasal swab will be tested directly with KaiBiLi Flu & COVID-19 Ag Duo, and the nasopharyngeal

swab will be tested with RT-PCR assay for detection of SARS-CoV-2. The sensitivity and specificity of KaiBiLi Flu & COVID-19 Ag Duo relative to the RT-PCR test will be calculated. The SARS-CoV-2 genetic variants of samples would be examined as well and applied to evaluate the detection sensitivity of KaiBiLi Flu & COVID-19 Ag Duo on SARS-CoV-2 genetic variants.

The diagnostic specificity of KaiBiLi Flu & COVID-19 Ag Duo would be evaluated by performing the test with negative samples with organisms or reagent which might lead to potential cross reactivity.

5.4 Current state of the art

Performance of the Kit is considered acceptable if the following criteria are met:

Diagnostic sensitivity:

Method: Parallel examination of diagnostic PCR tests and antigen tests in at least 100 persons with COVID-19 symptoms within seven days after onset of symptoms.

Criterion: >80% of at least 100 unselected PCR-positive samples, positive in the SARS-CoV-2-rapid antigen test.

Diagnostic specificity:

Method: Examinations of at least 300 asymptomatic persons without a concrete risk of exposure in the rapid SARS-CoV2 antigen test; clarification of any reactive samples by means of PCR.

Criterion: Specificity >98%.

5.5 Gold Standard

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.

5.6 Expected Risk & benefits

A nasal specimen collection has few risks. Subjects may feel tension and uncomfortable. If there is a tendency to nosebleeds, the sampling may cause nosebleeds. Therefore, subjects with a tendency to nosebleeds are not allowed according to the exclusion criteria.

The benefit of participating and helping to bring this test to market is that the test can help reduce further transmission through early detection of highly infectious cases, enabling a rapid start of contact tracing. The test can contribute to overall COVID-19 testing capacity, as the test is very simple to perform and the turnaround time for result is typically < 30 minutes.

5.7 Informed consent

Each subject will be verbally informed about the trial, in terms of the processes, duration, potential risks and benefits. If there are no further questions by the subject, then each should sign an informed consent.

6. Sample Collection Period

Starting date: November 24th, 2021

End-date: January 28th, 2022

7. Description Device

7.1 Identification

KaiBiLi Flu & COVID-19 Antigen Duo Rapid Test

7.2 Manufacturer

Hangzhou Genesis Biodetection and Biocontrol Co., Ltd.

7.3 Intended purpose

The KaiBiLi Flu & COVID-19 Ag Duo is a lateral flow immunoassay intended for the in vitro rapid, simultaneous qualitative detection and differentiation of nucleocapsid antigen from SARS-CoV-2, influenza A and influenza B directly from nasal swab specimens obtained from individuals, who are suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider, within the first five days of onset of symptoms. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

Results are for the simultaneous identification of nucleocapsid antigens of SARS-CoV-2, influenza A and influenza B

7.4 Specimen

Nasal swab

8. Material and Method

8.1 Materials Supplied by the manufacturer.

8.1.1 Test Kits and Instructions for Use

Sufficient kits of the KaiBiLi Flu & COVID-19 Ag Duo together with the Instructions for Use have been supplied free of charge to carry out the entire evaluation.

8.2 Materials Supplied by the Investigator

8.2.1 Standard laboratory reagents and disposables.

These are supplied by the Investigator and must meet the specifications required to correctly carry out the test procedure.

KaiBiLi Flu & COVID-19 Antigen Duo Rapid Test

Lot number: LE2106030202 Exp. Date: 2023-06-14

8.2.2 Equipment / instrumentation

Sacace™ SaCycler-96 Real Time PCR System (Como, Italy)

8.2.3 PCR Kit

(1) QIAGEN QIAamp Viral RNA Kits, for viral RNA isolation.

Exp. Date: 2022-12

(2) Sacace™ SARS-CoV-2 Real-time PCR kit (REF: V435- 100FRT) (Como, Italy), for the qualitative detection of SARS-CoV-2 (COVID-19 virus, 2019-nCoV) RNA in clinical samples. It detects 2 different specific genes of the SARS-Cov-2 virus genome, E-gene and N-gene. Lot number: F1512S-2-S

(3) Sacace™ ARVI Screen Real-TM PCR kit (REF: V57-100FRT) (Como, Italy), for multiplex detection of respiratory viruses ARVI Screen Real-TM PCR kit is an in vitro nucleic acid amplification test for multiplex detection and identification of specific nucleic acid fragments of pathogens that cause acute respiratory viral infections – human Respiratory Syncytial virus (hRSV) RNA; human Metapneumovirus (hMpv) RNA; human Parainfluenza virus-1-4 (hPiv) RNA; OC43, E229, NL63, and HKU 1 human Coronavirus (hCov) RNA; human Rhinovirus (hRv) RNA; human B, C, and E Adenovirus (hAdv) DNA; and human Bocavirus (hBov) DNA

Lot number: 01I21.K790 Exp. Date: 2022-08-30

(4) Immundiagnostik AG, MutaPLEX® CoV-2 MUT 3 Real-Time-RT-PCR-Kit (REF: KG193396)

(Bensheim, Germany), For the identification of the SARS-CoV-2 variants Delta and Omicron

Lot number: MPlexCMUT3-091221 Exp. Date: 2023-12-08

- (5) QIAGEN artus Infl. A/B/H1 QS-RGQ Kit CE (REF : 4523005), for the separate qualitative detection and identification of influenza A and/or B virus RNA and influenza A-H1 Pandemic 2009 strain (H1pdm2009)
Exp. Date: 2022-06

8.3 Evaluation Sampling

8.3.1 Sampling

Subjects were recruited into the evaluation based on the MDCG 2021-21 Guidance with written informed consent. Two swab specimens in total (one nasal swab and one nasopharyngeal) were collected from the subjects by medical professionals follow.

8.3.2 KaiBiLi Flu & COVID-19 Ag Duo sample collection

- (1) Remove the swab from the pouch, being careful not to touch the swab head.
- (2) Insert nasal swab into one nostril, and the tip should be inserted up to 3/4 inch from the edge of the nostril. Be sure to rub BOTH nostrils with the SAME SWAB.
- (3) Gently insert the entire absorbent tip of the swab head into 1 nostril resistance is felt. Then firmly rub the swab in a circular motion around the inside wall of the nostril at least 5 times. Take approximately 15 seconds to collect the specimen.
- (4) Remove swab from nostril. Using the same swab, repeat step (3) in your other nostril.

8.3.3 KaiBiLi Flu & COVID-19 Ag Duo test procedure

Reagents, specimens and devices must be at room temperature (15–30 °C) for testing. Please read the instruction completely before beginning to test specimens.

- (1) Sample Extraction: insert swab with collected sample into extraction tube containing 0.5 ml of sample extraction buffer. Squeeze the swab several times by compressing the outside walls of the tube end against the swab to mix well. Finally squeeze the swab to make most of the solution stays in the extraction tube and remove the swab. Use extraction solution as test sample.
- (2) Remove test device from sealed foil pouch prior to testing and lay flat on work bench.
- (3) Insert nozzle into the extraction tube with test sample.
- (4) Invert the extraction tube and add 3 drops of test sample into sample well by gently squeezing the extraction tube.
- (5) Read results at 15 minutes and disregard after 30 minutes. A positive result may be visible at 3 minutes. However, the complete reaction time of 15 minutes is required to confirm a negative result.

8.4 Operator and site

Study Sites Info: Locus Medicus Medical SA, 246 Mesogeion Ave.155 61 Holargos, Athens, Greece

Operators: Dr. Georgios Georgoulis, Dr. Vassiliki Michou

Hospitals for negative samples: Leto Hospital and Therapeftirio Ayhinon Hospital

8.5 Trial Subject enrollment

According to MDCG 2021-21 Guidance, the following sample size need to be tested for evaluating a COVID-19 Antigen Tests

8.6 Diagnostics Sensitivity and specificity

- (1) Two clinical swab specimens (one nasal and one nasopharyngeal) from over 400 outpatients respectively with respiratory symptoms were collected by medical professionals.
- (2) The nasal swab specimens were applied for COVID-19 Antigen rapid test immediately after sample collection.
- (3) The nasopharyngeal swab were then delivered to Locus Medicus Medical SA, Greece for Sacace™ SARS-CoV-2 Real-Time PCR testing.
- (4) Professional lab techs were randomly assigned to perform the test of COVID-19 Antigen Rapid Self-Test or RT-PCR assay for the specimens. The lab techs who performs the antigen rapid test should be blinded to the RT-PCR test result, and vice versa.
- (5) The diagnostics sensitivity of COVID-19 Antigen rapid test was evaluated based on the test result comparing to the RT-PCR result.

Diagnostic sensitivity:

Criterion antigen test: >80% of at least 100 unselected PCR-positive samples, positive in the COVID-19 Antigen Rapid Test.

Diagnostic specificity:

Examinations of at least 300 asymptomatic persons without a concrete risk of exposure in the COVID-19 Antigen Rapid Test; clarification of any reactive samples by means of PCR Devices shall have a specificity of > 98 %.

Required patient information:

- Collection date of swab
- Gender
- Age,
- Date of onset of symptoms (Expressed as 1~7) or Asymptomatic (Expressed as 0)

8.7 Diagnostic specificity from hospitalized patients

- (1) Nasal swab specimens from over 100 inpatients respectively without SARS-CoV-2 infection from Leto and Therapeftirio Ayhinon Hospital, Greece were collected and then tested with COVID-19 Antigen Self-Test by medical professionals.
- (2) The diagnostic specificity were then evaluated based on the test result comparing to the well-known negative specimen data.

8.8 Diagnostic specificity form potentially interfering and cross-reactive samples

- (1) Nasal swab specimens collected from patients with respiratory symptoms but confirmed with SARS-CoV-2 negative were used to evaluate the performance of COVID-19 Antigen Test for potentially interfering and cross-reactive substances.
- (2) The specimens were collected and tested with COVID-19 Antigen Rapid Test by medical professionals in Locus Medicus Medical SA laboratory, Greece
- (3) The potential virus and bacteria that may cause potential cross reactivity including endemic human coronaviruses 229E, OC43, NL63, HKU1; Influenza A virus, Influenza B virus, Adenovirus, Respiratory syncytial virus(RSV), Metapneumovirus, Rotavirus, Human Parainfluenza virus, Streptococcus pneumoniae, Streptococcus group A were covered in the evaluation.

8.9 Detect variants of SARS-CoV-2

- (1) SARS-CoV-2 Variants were applied to evaluate the performance of Nasal swab specimens collected from patients with respiratory symptoms but confirmed with SARS-CoV-2 negative

were used to evaluate the performance of COVID-19 Antigen Rapid Test for potentially interfering and cross-reactive substances.

- (2) Stock SARS-CoV-2 variants, including delta, and omicron, were collected and applied for this retrospective study. For each genetic variant, at least 3 individual samples should be included for the evaluation.

9. Data management

Data management entails the planning for the creation, identification, verification, storage, transfer and archiving of data pertinent to the study, by means of the format of the study records, as well as associated responsibilities.

9.1 Data and results recording

The sample information and reference results of the samples are recorded in the Study Record Forms (SRFs) in excel.

To protect the subject or patient's privacy, no personal data shall appear anywhere on the SRF. All data will be filed both as a hard copy and in electronic files by Locus Medicus Medical SA laboratory.

The KaiBiLi Flu & COVID-19 Ag Duo results are for performance evaluation only and must not be used for diagnostic purposes.

9.2 Data analysis

The following analyses have been performed:

The diagnostic sensitivity of the COVID-19 Antigen Rapid Test 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 COVID-19 Antigen Rapid Test 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 are reported together with a 2-sided 95% confidence interval.

The consistency analysis is conducted between the test results of assessing reagent and the test results of comparator, and the test level is $\alpha = 0.05$.

The reference evaluation principles for Kappa values are as follows: In case of $0.75 < K \leq 1$, the consistency is good; In case of $0.4 < K \leq 0.75$, the consistency is general; In case of $0 \leq K \leq 0.4$, the consistency is poor.

The confidence interval and significance levels can quantify this statistical uncertainty in estimates due to the subject/sample selection process. The 95% confidence intervals were calculated in order to assess the level of uncertainty introduced by sample size, using the Wilson's score method.

9.3 Definitions

True positive sample: sample that was determined positive both using the KaiBiLi Flu & COVID-19 Ag Duo and by RT-PCR.

False positive sample: sample that was determined positive using the KaiBiLi Flu & COVID-19 Ag Duo, but negative by RT-PCR.

True negative sample: sample that was determined negative both using the KaiBiLi Flu & COVID-19 Ag Duo and by RT-PCR.

False negative sample: sample that was determined negative using the KaiBiLi Flu & COVID-19 Ag Duo, but positive by RT-PCR.

Sensitivity (Positive Percent Agreement): True Positives/True Positives + False Negatives
Specificity (Negative Percent Agreement): True Negatives/True Negatives + False Positives
Positive Predictive Value: True Positives/Positive
Negative Predictive Value: True Negatives/Negative
Coincidence rate (Overall Percent Agreement): True Positives + True Negatives/Total Samples
C.I.: Confidence Interval

10. Results

10.1 Diagnostic sensitivity and Diagnostic specificity

Among the 502 specimens, 178 positive results and 324 negative results were detected by SACACE™ SARS-CoV-2 RT-PCR, Influenza RT-qPCR were all negative. With difficulty to obtain of fresh clinical Influenza A/B positive specimens, specimens stored/frozen in viral transport media (VTM) confirmed positive by real-time PCR were used instead. 54 influenza A positive samples and 51 influenza B positive samples were analyzed. Refer to 10.2 Diagnostic sensitivity of Flu Antigen Rapid Test for test results.

10.1.1 Demographics of subjects:

All the 502 clinical samples were from outpatients and covered different ages. 256 specimens (51.0%) were collected from male, and the remaining 246 were from female (49.0%). Detailed test results are presented in **Annex 1**. Clinical Test Data for SARS-CoV-2 Positive sample. Table 10.1.1(a) and 10.1.2(b) shows the positive results broken down by gender and age of the subjects:

Table 10.1.1(a). Test result broken down by gender

Gender	MALE		FEMALE	
	Positive	Negative	Positive	Negative
SARS-CoV-2 RT-PCR result				
Quantity (%)	95(37.1%)	161(62.9%)	83(33.7%)	163(66.3%)
TOTAL	256(51.0%)		246(49.0%)	

Table 10.1.2(b). Test result broken down by age

Age group (Year)	SARS-CoV-2 RT-PCR result		Total
	Positive	Negative	
0~20	53 (29.8%)	27 (8.3%)	80(15.9%)
21~40	65 (36.5%)	106 (32.7%)	171(34.1%)
41~60	53 (29.8%)	156 (48.1%)	209(41.6%)
60~80	6 (3.4%)	33 (10.2%)	39(7.8%)
>80	1 (0.6%)	2 (0.6%)	3(0.6%)
Total	178	324	502

10.1.2 Sensitivity of COVID-19 Antigen Rapid Test

(1) COVID-19 Antigen Rapid Test result for 178 confirmed SARS-CoV-2 RT-PCR positive specimens

Ct-value	Number of Samples	Number of true positive Rapid Test Samples	Number of false negative Rapid Test Samples	Sensitivity of KaiBiLi COVID-19 Ag
≤20	141	141	0	100 %
≤25	163	163	0	100 %
≤30	173	171	2	98.8 %
<35	178	173	5	97.2%

COVID-19 Antigen Rapid Test reveals a sensitivity of 97.2% for positive samples confirmed by SARS-CoV-2 RT-PCR with Ct-value up to 33.6. Samples with higher Ct-value indicate less viral RNA copies as well as viral antigen in the samples, which result in slightly lower detection rate for the COVID-19 Antigen Rapid Test. This is in line with the expectations regarding viral detection by antigen rapid testing comparing to PCR analysis.

(2) The test result broken down by SARS-CoV-2 RT-PCR Ct value and the days of symptom onset of the participants enrolled.

Days of symp. onset	Ct values of the PCR				Total
	≤20	>20~25	>25~30	>30	
0 (Asymptomatic)	49	5	3	4	61
1	32	7	4	0	43
2	28	1	2	1	32
3	32	9	1	0	42
TOTAL	141	22	10	5	178

(3) Positive samples containing Delta viral variants

Delta viral mutants (Pango lineage B.1.617.2) was first documented in October 2020, and listed as variants of concern (VOC) on 4th April 2021. This mutant is adaptive and spread fast all over the world because of its outstanding infectivity and capability of immune evasion.

In the current study, 36 samples tested by MutaPLEX® CoV-2 MUT 3 Real-Time-RT-PCR-Kit were confirmed to be Delta variants, showing the COVID-19 Antigen Rapid Test has the ability to detect mutations of Delta variants.

No.	Sample ID	Gender	Age (years)	PCR Results	Ct value	COVID-19 Ag results	Comment
1	181691	FEMALE	23	Positive	27.0	Positive	passed
2	181697	MALE	32	Positive	12.0	Positive	passed
3	181725	FEMALE	16	Positive	12.0	Positive	passed
4	181727	MALE	22	Positive	17.0	Positive	passed
5	181745	FEMALE	14	Positive	12.6	Positive	passed
6	181746	FEMALE	45	Positive	13.4	Positive	passed
7	181797	FEMALE	12	Positive	10.3	Positive	passed
8	181812	MALE	46	Positive	17.0	Positive	passed
9	181817	FEMALE	23	Positive	19.0	Positive	passed

10	181818	MALE	11	Positive	27.0	Positive	passed
11	181820	MALE	10	Positive	17.0	Positive	passed
12	181941	MALE	34	Positive	20.6	Positive	passed
13	181948	MALE	37	Positive	14.9	Positive	passed
14	181970	MALE	67	Positive	11.0	Positive	passed
15	182017	MALE	37	Positive	13.7	Positive	passed
16	182019	FEMALE	22	Positive	16.2	Positive	passed
17	182023	FEMALE	45	Positive	14.5	Positive	passed
18	182031	MALE	11	Positive	18.0	Positive	passed
19	182129	MALE	27	Positive	20.0	Positive	passed
20	182135	FEMALE	23	Positive	15.9	Positive	passed
21	182286	MALE	25	Positive	16.0	Positive	passed
22	182467	MALE	28	Positive	14.0	Positive	passed
23	182502	FEMALE	29	Positive	21.7	Positive	passed
24	182590	FEMALE	32	Positive	14.0	Positive	passed
25	182667	MALE	31	Positive	18.0	Positive	passed
26	182683	MALE	47	Positive	16.0	Positive	passed
27	182687	MALE	42	Positive	13.0	Positive	passed
28	182698	FEMALE	30	Positive	14.0	Positive	passed
29	182703	FEMALE	40	Positive	16.0	Positive	passed
30	182774	MALE	28	Positive	9.4	Positive	passed
31	184993	MALE	57	Positive	12.4	Positive	passed
32	184994	MALE	28	Positive	13.6	Positive	passed
33	188559	MALE	34	Positive	20.0	Positive	passed
34	188560	FEMALE	7	Positive	17.0	Positive	passed
35	188661	MALE	35	Positive	22.0	Positive	passed
36	188855	FEMALE	25	Positive	17.0	Positive	passed

(4) Positive samples containing Omicron viral variants

On November 24, 2021, South Africa reported the identification of a new SARS-CoV-2 variant, B.1.1.529, to the World Health Organization (WHO). B.1.1.529 was first detected in specimens collected on November 11, 2021 in Botswana and on November 14, 2021 in South Africa.

In the current study, 36 samples tested by MutaPLEX® CoV-2 MUT 3 Real-Time-RT-PCR-Kit were confirmed to be Omicron variants, showing the COVID-19 Antigen Rapid Test has the ability to detect mutations of Omicron variants.

No.	Sample ID	Gender	Age (years)	PCR Results	Ct value	COVID-19 Ag results	Comment
1	184986	FEMALE	11	Positive	14.0	Positive	passed
2	188081	MALE	25	Positive	11.7	Positive	passed
3	188099	MALE	45	Positive	25.8	Positive	passed

4	188102	MALE	46	Positive	17	Positive	passed
5	188107	MALE	12	Positive	21	Positive	passed
6	188109	MALE	45	Positive	22.0	Positive	passed
7	188110	MALE	9	Positive	11.8	Positive	passed
8	188111	FEMALE	11	Positive	12.8	Positive	passed
9	188114	MALE	24	Positive	12.9	Positive	passed
10	188115	MALE	39	Positive	25.3	Positive	passed
11	188173	MALE	51	Positive	11.5	Positive	passed
12	188522	FEMALE	27	Positive	16	Positive	passed
13	188555	FEMALE	37	Positive	19.0	Positive	passed
14	188556	FEMALE	43	Positive	17.0	Positive	passed
15	188561	FEMALE	75	Positive	16.0	Positive	passed
16	188626	FEMALE	43	Positive	16.0	Positive	passed
17	188627	MALE	11	Positive	19.0	Positive	passed
18	188641	MALE	40	Positive	15.0	Positive	passed
19	188646	MALE	36	Positive	16.0	Positive	passed
20	188664	MALE	44	Positive	24.0	Positive	passed
21	188674	FEMALE	12	Positive	14.0	Positive	passed
22	188675	FEMALE	9	Positive	18.0	Positive	passed
23	188706	FEMALE	5	Positive	22.0	Positive	passed
24	188713	FEMALE	38	Positive	20.0	Positive	passed
25	188717	MALE	49	Positive	16.0	Positive	passed
26	188732	FEMALE	40	Positive	16.0	Positive	passed
27	188765	MALE	50	Positive	18.0	Positive	passed
28	188770	MALE	42	Positive	15.0	Positive	passed
29	188783	MALE	30	Positive	14.0	Positive	passed
30	188784	MALE	44	Positive	16.0	Positive	passed
31	188842	FEMALE	13	Positive	10.0	Positive	passed
32	188843	MALE	48	Positive	14.0	Positive	passed
33	188872	FEMALE	51	Positive	13.0	Positive	passed
34	188885	MALE	55	Positive	16.0	Positive	passed
35	188896	MALE	47	Positive	13.0	Positive	passed
36	188897	FEMALE	41	Positive	12.0	Positive	passed

10.1.3 Specificity of COVID-19 Antigen Rapid Test

COVID-19 Antigen Rapid Test result for 324 confirmed SARS-CoV-2 RT-PCR negative specimens

Detailed test results are presented in **Annex 2**. Clinical Test Data for Negative Sample

Number of Samples	Number of true neg. Rapid Test Samples	Number of false positive Rapid Test Samples	Specificity of KaiBiLi COVID-19 Antigen Rapid Test
324	322	2	99.4 %

Diagnostic Specificity of COVID-19 Antigen Rapid Test: 99.4% (322/324).

10.1.4 Analytical Results of COVID-19 Antigen Rapid Test

A total of 502 clinical specimens were collected from individual symptomatic patients in the Locus Medicus Medical SA, Greece. Among the 502 specimens, 178 were confirmed positive by Sacace™ SARS-CoV-2 RT-PCR, COVID-19 Antigen Rapid Test detects 173 positive out of the 178 specimens, and the sensitivity of COVID-19 Antigen Rapid Test is 97.2%. 324 were confirmed negative by Sacace™ SARS-CoV-2 RT-PCR, COVID-19 Antigen Rapid Test detects 322 out of the 324 specimens, and the specificity of COVID-19 Antigen Rapid Test is 99.4%. The accuracy rate is 98.6%; Kappa value: 0.9694 indicates good consistency. The analysis results are as below:

		SARS-CoV-2 RT-PCR		
		Positive	Negative	Total
KaiBiLi Flu & COVID-19 Antigen Duo (COVID-19 Antigen)	Positive	173	2	175
	Negative	5	322	327
	Total	178	324	502

Statistics	Numerical ratio	Percentage(95% C.I.)
Sensitivity	173/178	97.2% (93.6%~99.1%)
Specificity	322/324	99.4% (97.8%~99.9%)
Positive Predictive Value	173/175	98.9% (95.9%~99.9%)
Negative Predictive Value	322/327	98.5% (96.5%~99.5%)
Accuracy	495/502	98.6% (97.2%~99.4%)
Kappa value: 0.9694		

10.1.5 Analytical Results of Influenza Antigen Rapid Test

A total of 502 clinical specimens were collected from individual symptomatic patients in the Locus Medicus Medical SA, Greece.

Among the 502 specimens, by using QIAGEN artus Infl. A/B/H1 QS-RGQ Kit (RT-qPCR), it was confirmed that either Influenza A or Influenza B were negative.

However, 2 Influenza A and 3 Influenza B samples were tested positive by Flu Antigen rapid test. Thus, QIAGEN artus Infl. A/B/H1 QS-RGQ Kit (RT-qPCR) was used again to verify and confirm abovementioned 5 samples were negative. The specificity of Influenza A Antigen rapid test is 99.6%, and Influenza B Antigen rapid test is 99.4%. The analysis results are as below:

		Influenza RT-qPCR (Influenza A)		
		Positive	Negative	Total
KaiBiLi Flu & COVID-19 Antigen Duo (Flu A Antigen)	Positive	0	2	2
	Negative	0	500	500
	Total	0	502	502

Diagnostic Specificity of Flu A Antigen Rapid Test: 99.6% (500/502).

		Influenza RT-qPCR (Influenza B)		
		Positive	Negative	Total
KaiBiLi Flu & COVID-19 Antigen Duo (Flu B Antigen)	Positive	0	3	3
	Negative	0	499	499
	Total	0	502	502

Diagnostic Specificity of Flu B Antigen Rapid Test: 99.4% (499/502).

10.2 Diagnostic sensitivity of Influenza Antigen Rapid Test

With difficulty to obtain of fresh clinical Influenza A/B positive specimens, specimens stored/frozen in viral transport media (VTM) confirmed positive by Influenza RT-qPCR were used instead. Overall, 54 influenza A positive samples and 51 influenza B positive samples were analyzed.

52 and 47 out of 54 specimens were detected by KaiBiLi Flu A Antigen Rapid Test and KaiBiLi Flu B Antigen Rapid Test, respectively. The sensitivity of the test is 96.3% for KaiBiLi Flu A Antigen Rapid Test and 92.2% for KaiBiLi Flu B Antigen Rapid Test. 105 samples of Influenza positive (54 influenza A+51 influenza B) tested by KaiBiLi COVID-19 Antigen Rapid Test were 100% negative. The analysis results are as below :

Detailed test results are presented in **Annex 3**. Clinical Test Data for Influenza Positive Sample.

- (1) 54 were confirmed positive by influenza A RT-qPCR, among which, Flu A Antigen Rapid Test detects 52 positive samples out of 54 specimens, the sensitivity of Flu A Antigen Rapid Test is 96.3%.

The analysis results are as below:

		Influenza RT-qPCR (Influenza A)		
		Positive	Negative	Total
KaiBiLi Flu & COVID-19 Antigen Duo (Flu A Antigen)	Positive	52	0	52
	Negative	2	0	2
	Total	54	0	54

- (2) 51 were confirmed positive by influenza B RT-qPCR, among which, Flu B Antigen Rapid Test detects 47 positive samples out of the 51 specimens, the sensitivity of Flu B Antigen Rapid Test is 92.2%.

The analysis results are as below:

		Influenza RT-qPCR (Influenza A)		
		Positive	Negative	Total
KaiBiLi Flu & COVID-19 Antigen Duo (Flu B Antigen)	Positive	47	0	47
	Negative	4	0	4
	Total	51	0	51

10.3 Diagnostic specificity of COVID-19 Antigen Rapid Test from hospitalized patients

106 nasal swab sample were collected from SARS-CoV-2 RT-PCR negative inpatient from 2021/12/2 to 2021/12/30 for COVID-19 Antigen Rapid Test testing. The COVID-19 Antigen Rapid Test has the same test results as the SARS-CoV-2 RT-PCR on 106 negative samples from hospitalized cases, suggesting good specificity of the COVID-19 Antigen Rapid Test.

All the 106 specimen were collected in Leto Hospital and Therapeftirio Ayhinon Hospital. Among the 106 specimens, 25 were from male patients (23.6%), and 81 were from female patients (76.4%). No specimen was from age below 20, and 53 specimens were form age over 80. Table 10.3(a) and Table 10.3(b) shows the sample broken down by gender and age of the SARS-CoV-2 RT-PCR negative inpatient:

Detailed test results are presented in **Annex 4** Test results on 106 negative samples from hospitalized cases.

Table 10.3(a) Samples broken down by gender (SARS-CoV-2 RT-PCR negative inpatient)

Gender	MALE	FEMALE	Total
Quantity (%)	25 (23.6%)	81 (76.4%)	106

Table 10.3(b) Samples broken down by age (SARS-CoV-2 RT-PCR negative inpatient)

Age group	0~20	21~40	41~60	60~80	>80	Total
Quantity	0	22	7	24	53	106

10.4 Cross reaction evaluation of COVID-19 Antigen Rapid Test

Nasal swab specimens from 66 patients with respiratory symptoms and confirmed with SARS-CoV-2 RT-PCR negative result were tested with COVID-19 Antigen Rapid Tests. The Kit reveals negative results for all the 66 specimens and the consistency rate is 100%. Detailed test results are presented in **Annex 5** Cross-reactivity test results on 66 samples containing other respiratory pathogens.

Table 10.4(a) and Table 10.4(b) shows the specimen broken down by gender and age of the patient for the 66 specimens with potential microbial interference. Among the 66 specimens, 26 were from male patients (39.4%), and 40 were from female patients (60.6%). No specimen were from age over 80.

The 66 patients with respiratory symptoms and confirmed as SARS-CoV-2 RT-PCR negative were further diagnosed by Sacace™ ARVI Screen Real-TM PCR kit, for multiplex detection of respiratory viruses for the pathogens. Among the 66 patients, 5 were confirmed to be infected with Influenza A, 5 with Influenza B, 14 with Adenovirus (2 co-infected with Parainfluenza type 3, and 2 co-infected with coronavirus NL-63 and coronavirus 229E), 16 with RSV (2 co-infected with Parainfluenza type3 coinfection, 6 with Coronavirus(NL-63, 229E) (2 co-infected with Adenovirus), 2 with *Streptococcus pneumoniae*, and 2 with *Staphylococcus* Details please refer

to Table 10.4(c) Cross-reactivity test result.

Table 10.4(a). Samples broken down by gender

Gender	MALE	FEMALE	Total
Quantity (%)	26 (39.4)	40 (60.6%)	66

Table 10.4(b). Samples broken down by age

Age group	0~20	21~40	41~60	60~80	>80
Quantity	17	14	15	6	0

Table 10.4(c) Cross-reactivity test result

Strains	Quantity	COVID-19 Antigen Rapid Test Negative Result %
Influenza A Virus	5	100% (5/5)
Influenza B Virus	5	100% (5/5)
Adenovirus	12	100% (12/12)
Adenovirus and Parainfluenza virus-3 coinfection	2	100% (2/2)
Adenovirus and coronavirus (NL-63, 229E) coinfection	2	100% (2/2)
Respiratory syncytial virus, RSV	14	100% (14/14)
RSV and Parainfluenza virus-3 coinfection	2	100% (2/2)
Metapneumovirus	2	100% (2/2)
Rotavirus	16	100% (16/16)
coronavirus (NL-63, 229E)	4	100% (4/4)
coronavirus (HKU-1, OC43)	0	N/A
<i>Streptococcus pneumoniae</i>	2	100% (2/2)
<i>Staphylococci</i>	2	100% (2/2)

11. Conclusion

Number of 502 nasal swab samples and 105 viral transport media tubes (retrospective performance evaluation) of Flu Antigen Rapid Test were used to test the specificity and sensitivity of the KaiBiLi Flu & COVID-19 Ag Duo in the performance study

11.1 COVID-19 Antigen Rapid Test performance study

All samples were tested in parallel with the KaiBiLi Flu & COVID-19 Ag Duo and a SARS-CoV-2 RT-PCR assay. The correlation between the COVID-19 Antigen Rapid Test result and RT-PCR Ct values was further analyzed. In this study, KaiBiLi Flu & COVID-19 Ag Duo demonstrated a high specificity of 99.4% (322/324), and a great sensitivity of 97.2 % for Ct-value up to 34. Among 178 samples with Ct-value up to 34, COVID-19 Antigen Rapid Test detected 173.

66 nasal specimens collected from patients with respiratory symptoms and confirmed with SARS-CoV-2 RT-PCR negative results were tested with COVID-19 Antigen Rapid Tests. The specimens were also tested for diagnosing pathogens that lead to the patient respiratory symptoms. All the 66 specimens were detected negative by COVID-19 Antigen Rapid Tests,

and the result demonstrated that COVID-19 Antigen Rapid Tests has no cross-reactivity with the microbial diagnosed from the 66 clinical specimens.

To understand the performance of COVID-19 Antigen Rapid Test on SARS-CoV-2 variants, 72 specimens tested with variants of SARS-CoV-2 by RT-PCR, including Delta (36) and Omicron (36), were retrospectively collected and tested with COVID-19 Antigen Rapid Test. All the 72 specimens were detected positive with COVID-19 Antigen Rapid Test.

1 1.2 Flu Antigen Rapid Test performance study

During the study, with inability to obtain fresh positive influenza samples, retrospective method was used to evaluate the performance of the kit. Specimens stored/frozen in viral transport media (VTM) confirmed positive by RT-qPCR were used. In this study, Flu A Antigen rapid test demonstrated a high sensitivity of 96.3% (52/54), and Flu B Antigen rapid test demonstrated a high sensitivity of 92.2% (47/51).

In conclusion, this study demonstrated that the KaiBiLi Flu & COVID-19 Ag Duo is a reliable diagnostic tool for the qualitative detection of SARS-CoV-2 antigen and influenza A and influenza B from human nasal swab with great sensitivity and specificity.

12. Bibliography

MDCG 2021-21, Guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical devices, August 2021

13. Annexes

Annex 1. Clinical Test Data for SARS-CoV-2 Positive Sample

Annex 2. Clinical Test Data for Negative Sample

Annex 3. Clinical Test Data for Influenza Positive Sample

Annex 4. Test results on 106 negative samples from hospitalized cases

Annex 5. *Cross-reactivity test results on 66 samples containing other respiratory pathogens*

14. Approval

Reviewer

Locus Medicus Medical SA. Laboratory

Name : Dr. Harilaos P. Kavvadas

Function : Report Reviewing

Date : February 20,2022

Signature :



Approval

Locus Medicus Medical SA. Laboratory

Name : Nikolaos G. Manias

Function : Project Lead

Date : February 20,2022

Signature :



Locus Medicus Medical SA. Laboratory

Name : Vassilis Tsilivakos, MD, Ph.D

Function : CEO

Date : February 20,2022

Signature :



Annex 1. Clinical Test Data for SARS-CoV-2 Positive Sample

No.	Sample ID	Gender	Age (Years)	Days of symp. onset	Test date	SARS-CoV-2 RT-PCR			Influenza A RT-qPCR		Influenza B RT-qPCR		KaIBiLi Flu & COVID-19 Antigen Duo result			Comment
						Result	Ct Value	VARIANT	Result	Ct Value	Result	Ct Value	COVID-19	Flu A	Flu B	
1	180822	FEMALE	23	2	2021/12/1	Positive	33.3	—	Negative	36.2	Negative	36.2	Negative	Negative	Negative	Not Passed
2	180829	MALE	25	2	2021/12/1	Positive	26.8	—	Negative	35.8	Negative	35.8	Positive	Negative	Negative	Passed
3	180999	MALE	27	2	2021/12/1	Positive	24.0	—	Negative	35.9	Negative	35.9	Positive	Negative	Negative	Passed
4	181691	FEMALE	23	0	2021/12/4	Positive	27.0	Delta	Negative	35.6	Negative	37.1	Positive	Negative	Negative	Passed
5	181697	MALE	32	2	2021/12/4	Positive	12.0	Delta	Negative	35.3	Negative	37.4	Positive	Negative	Negative	Passed
6	181725	FEMALE	16	0	2021/12/4	Positive	12.0	Delta	Negative	36.5	Negative	35.6	Positive	Negative	Negative	Passed
7	181727	MALE	22	2	2021/12/4	Positive	17.0	Delta	Negative	35.1	Negative	36.1	Positive	Negative	Negative	Passed
8	181745	FEMALE	14	2	2021/12/6	Positive	12.6	Delta	Negative	37.6	Negative	35.9	Positive	Negative	Negative	Passed
9	181746	FEMALE	45	2	2021/12/6	Positive	13.4	Delta	Negative	37.2	Negative	35.6	Positive	Negative	Negative	Passed
10	181797	FEMALE	12	0	2021/12/6	Positive	10.3	Delta	Negative	36.7	Negative	36.7	Positive	Negative	Negative	Passed
11	181812	MALE	46	2	2021/12/6	Positive	17.0	Delta	Negative	36.9	Negative	36.3	Positive	Negative	Negative	Passed
12	181817	FEMALE	23	2	2021/12/6	Positive	19.0	Delta	Negative	35.6	Negative	35.6	Positive	Negative	Negative	Passed
13	181818	MALE	11	1	2021/12/6	Positive	27.0	Delta	Negative	37	Negative	37.6	Positive	Negative	Negative	Passed
14	181820	MALE	10	1	2021/12/6	Positive	17.0	Delta	Negative	37.4	Negative	37.6	Positive	Negative	Negative	Passed
15	181941	MALE	34	1	2021/12/7	Positive	20.6	Delta	Negative	35.3	Negative	35	Positive	Negative	Negative	Passed
16	181948	MALE	37	2	2021/12/7	Positive	14.9	Delta	Negative	35.9	Negative	35.9	Positive	Negative	Negative	Passed
17	181970	MALE	67	1	2021/12/7	Positive	11.0	Delta	Negative	35.8	Negative	36.9	Positive	Negative	Negative	Passed
18	181980	MALE	27	1	2021/12/7	Positive	28.0	—	Negative	37.1	Negative	37.1	Positive	Negative	Negative	Passed
19	182017	MALE	37	0	2021/12/7	Positive	13.7	Delta	Negative	37.6	Negative	35.4	Positive	Negative	Negative	Passed
20	182019	FEMALE	22	1	2021/12/7	Positive	16.2	Delta	Negative	37.7	Negative	36.6	Positive	Negative	Negative	Passed
21	182020	MALE	67	1	2021/12/7	Positive	28.0	—	Negative	36.3	Negative	36.3	Negative	Negative	Negative	Not Passed
22	182023	FEMALE	45	0	2021/12/7	Positive	14.5	Delta	Negative	35.3	Negative	37.4	Positive	Negative	Negative	Passed
23	182031	MALE	11	3	2021/12/7	Positive	18.0	Delta	Negative	35.3	Negative	37.3	Positive	Negative	Negative	Passed
24	182129	MALE	27	2	2021/12/8	Positive	20.0	Delta	Negative	37.3	Negative	37	Positive	Negative	Negative	Passed
25	182135	FEMALE	23	1	2021/12/8	Positive	15.9	Delta	Negative	36.6	Negative	37.1	Positive	Negative	Negative	Passed
26	182286	MALE	25	0	2021/12/8	Positive	16.0	Delta	Negative	36	Negative	37.4	Positive	Negative	Negative	Passed
28	182502	FEMALE	29	3	2021/12/9	Positive	21.7	Delta	Negative	35.8	Negative	37.1	Positive	Negative	Negative	Passed
29	182590	FEMALE	32	3	2021/12/9	Positive	14.0	Delta	Negative	36.2	Negative	36.8	Positive	Negative	Negative	Passed
30	182667	MALE	31	1	2021/12/10	Positive	18.0	Delta	Negative	36	Negative	35	Positive	Negative	Negative	Passed
31	182683	MALE	47	0	2021/12/10	Positive	16.0	Delta	Negative	37.1	Negative	35.5	Positive	Negative	Negative	Passed
32	182687	MALE	42	1	2021/12/10	Positive	13.0	Delta	Negative	35.5	Negative	35.9	Positive	Negative	Negative	Passed
33	182698	FEMALE	30	0	2021/12/10	Positive	14.0	Delta	Negative	35.6	Negative	35.1	Positive	Negative	Negative	Passed

No.	Sample ID	Gender	Age (Years)	Days of symp. onset	Test date	SARS-CoV-2 RT-PCR			Influenza A RT-qPCR		Influenza B RT-qPCR		KaiBiLi Flu & COVID-19 Antigen Duo result			Comment
						Result	Ct Value	VARIANT	Result	Ct Value	Result	Ct Value	COVID-19	Flu A	Flu B	
34	182703	FEMALE	40	3	2021/12/10	Positive	16.0	Delta	Negative	36.2	Negative	37.6	Positive	Negative	Negative	Passed
35	182774	MALE	28	3	2021/12/11	Positive	9.4	Delta	Negative	37.9	Negative	37.1	Positive	Negative	Negative	Passed
36	182794	MALE	44	3	2021/12/11	Positive	17.2	—	Negative	35.7	Negative	35.7	Positive	Negative	Negative	Passed
37	182795	MALE	7	1	2021/12/11	Positive	26.0	—	Negative	35.7	Negative	35.7	Positive	Negative	Negative	Passed
38	182935	FEMALE	18	3	2021/12/13	Positive	18.0	—	Negative	37.88	Negative	36.62	Positive	Negative	Negative	Passed
39	183203	FEMALE	42	1	2021/12/15	Positive	24.0	—	Negative	36.6	Negative	35.22	Positive	Negative	Negative	Passed
40	183223	FEMALE	4	3	2021/12/15	Positive	21.0	—	Negative	36.43	Negative	36.92	Positive	Negative	Negative	Passed
41	183224	MALE	40	3	2021/12/15	Positive	8.0	—	Negative	37.03	Negative	35.55	Positive	Negative	Negative	Passed
42	183234	FEMALE	61	3	2021/12/15	Positive	20.0	—	Negative	36.24	Negative	35.84	Positive	Negative	Negative	Passed
43	183238	MALE	37	0	2021/12/15	Positive	20.0	—	Negative	35.96	Negative	37.78	Positive	Negative	Negative	Passed
44	183239	FEMALE	4	3	2021/12/15	Positive	19.0	—	Negative	35.39	Negative	35.71	Positive	Negative	Negative	Passed
45	183242	MALE	8	1	2021/12/15	Positive	20.0	—	Negative	35.7	Negative	36.03	Positive	Negative	Negative	Passed
46	183243	FEMALE	31	3	2021/12/15	Positive	14.0	—	Negative	37.07	Negative	36.57	Positive	Negative	Negative	Passed
47	183252	MALE	60	2	2021/12/15	Positive	17.0	—	Negative	37.58	Negative	36.6	Positive	Negative	Negative	Passed
48	183337	MALE	55	3	2021/12/16	Positive	12.0	—	Negative	35.64	Negative	36.24	Positive	Negative	Negative	Passed
49	183448	FEMALE	47	2	2021/12/16	Positive	13.0	—	Negative	36.79	Negative	35.52	Positive	Negative	Negative	Passed
50	183659	MALE	50	1	2021/12/17	Positive	22.0	—	Negative	36.03	Negative	36.23	Positive	Negative	Negative	Passed
51	183668	MALE	20	0	2021/12/17	Positive	19.0	—	Negative	36.06	Negative	37.35	Positive	Negative	Negative	Passed
52	183736	FEMALE	27	3	2021/12/17	Positive	12.5	—	Negative	35.13	Negative	35.55	Positive	Negative	Negative	Passed
53	183804	MALE	64	1	2021/12/18	Positive	23.1	—	Negative	35.83	Negative	36.65	Positive	Negative	Negative	Passed
54	183805	FEMALE	47	0	2021/12/18	Positive	14.3	—	Negative	36.96	Negative	37.29	Positive	Negative	Negative	Passed
55	183806	FEMALE	9	1	2021/12/18	Positive	12.7	—	Negative	35.41	Negative	36.73	Positive	Negative	Negative	Passed
56	183822	MALE	20	0	2021/12/18	Positive	15.7	—	Negative	36.48	Negative	36.59	Positive	Negative	Negative	Passed
57	183824	FEMALE	41	0	2021/12/18	Positive	16.3	—	Negative	35.63	Negative	35.4	Positive	Negative	Negative	Passed
58	183829	MALE	22	0	2021/12/18	Positive	33.6	—	Negative	36.4	Negative	36.4	Negative	Negative	Negative	Not Passed
59	183836	FEMALE	44	3	2021/12/18	Positive	17.2	—	Negative	36.4	Negative	36.4	Positive	Negative	Negative	Passed
60	183849	MALE	8	3	2021/12/19	Positive	12.5	—	Negative	36.59	Negative	37.84	Positive	Negative	Negative	Passed
61	183850	MALE	11	2	2021/12/19	Positive	13.4	—	Negative	37.29	Negative	36.88	Positive	Negative	Negative	Passed
62	183872	MALE	27	0	2021/12/20	Positive	30.4	—	Negative	37.3	Negative	37.3	Positive	Negative	Negative	Passed
63	184023	MALE	54	0	2021/12/21	Positive	14.0	—	Negative	36.14	Negative	35.26	Positive	Negative	Negative	Passed
64	184052	FEMALE	35	3	2021/12/21	Positive	14.0	—	Negative	37.54	Negative	37.89	Positive	Negative	Negative	Passed
65	184053	FEMALE	6	2	2021/12/21	Positive	20.0	—	Negative	36.14	Negative	36.38	Positive	Negative	Negative	Passed
66	184145	FEMALE	94	0	2021/12/21	Positive	15.0	—	Negative	37.72	Negative	37.46	Positive	Negative	Negative	Passed
67	184147	FEMALE	65	0	2021/12/21	Positive	11.0	—	Negative	36.59	Negative	37.38	Positive	Negative	Negative	Passed

No.	Sample ID	Gender	Age (Years)	Days of symp. onset	Test date	SARS-CoV-2 RT-PCR			Influenza A RT-qPCR		Influenza B RT-qPCR		KaiBiLi Flu & COVID-19 Antigen Duo result			Comment
						Result	Ct Value	VARIANT	Result	Ct Value	Result	Ct Value	COVID-19	Flu A	Flu B	
68	184148	FEMALE	46	3	2021/12/21	Positive	22.0	—	Negative	37.58	Negative	37.52	Positive	Negative	Negative	Passed
69	184213	FEMALE	13	3	2021/12/21	Positive	25.0	—	Negative	37.7	Negative	35.47	Positive	Negative	Negative	Passed
70	184214	FEMALE	9	3	2021/12/21	Positive	12.0	—	Negative	37.84	Negative	35.69	Positive	Negative	Negative	Passed
71	184291	MALE	56	2	2021/12/22	Positive	14.0	—	Negative	36.23	Negative	37.14	Positive	Negative	Negative	Passed
72	184321	MALE	22	0	2021/12/22	Positive	15.0	—	Negative	36.12	Negative	35.4	Positive	Negative	Negative	Passed
73	184335	FEMALE	15	3	2021/12/22	Positive	27.0	—	Negative	36.74	Negative	37.12	Positive	Negative	Negative	Passed
74	184336	FEMALE	27	0	2021/12/22	Positive	25.0	—	Negative	35.01	Negative	35.37	Positive	Negative	Negative	Passed
75	184353	FEMALE	53	0	2021/12/22	Positive	11.0	—	Negative	36.32	Negative	37	Positive	Negative	Negative	Passed
76	184502	MALE	21	0	2021/12/23	Positive	31.0	—	Negative	36.5	Negative	36.5	Positive	Negative	Negative	Passed
77	184531	FEMALE	45	1	2021/12/23	Positive	15.0	—	Negative	35.23	Negative	36.41	Positive	Negative	Negative	Passed
78	184730	FEMALE	45	1	2021/12/24	Positive	15.0	—	Negative	36.51	Negative	36.52	Positive	Negative	Negative	Passed
79	184731	MALE	50	1	2021/12/24	Positive	15.0	—	Negative	35.35	Negative	36.55	Positive	Negative	Negative	Passed
80	184774	MALE	48	3	2021/12/24	Positive	13.0	—	Negative	36.22	Negative	37.47	Positive	Negative	Negative	Passed
81	184792	MALE	25	0	2021/12/24	Positive	32	—	Negative	35.3	Negative	35.3	Negative	Negative	Negative	Not Passed
82	184796	MALE	50	1	2021/12/24	Positive	18.0	—	Negative	35.27	Negative	35.43	Positive	Negative	Negative	Passed
83	184797	MALE	19	0	2021/12/24	Positive	15	—	Negative	35.83	Negative	35.7	Positive	Negative	Negative	Passed
84	184824	FEMALE	46	1	2021/12/24	Positive	13	—	Negative	36.1	Negative	36.72	Positive	Negative	Negative	Passed
85	184875	FEMALE	10	3	2021/12/24	Positive	18.0	—	Negative	37.18	Negative	36.9	Positive	Negative	Negative	Passed
86	184894	FEMALE	52	0	2021/12/24	Positive	15.0	—	Negative	36.28	Negative	35.86	Positive	Negative	Negative	Passed
87	184919	FEMALE	31	2	2021/12/24	Positive	17.0	—	Negative	35.21	Negative	35.86	Positive	Negative	Negative	Passed
88	184926	FEMALE	30	1	2021/12/24	Positive	10	—	Negative	35.99	Negative	37.79	Positive	Negative	Negative	Passed
89	184945	FEMALE	35	0	2021/12/27	Positive	30.00	—	Negative	35.7	Negative	35.7	Negative	Negative	Negative	Not Passed
90	184962	FEMALE	12	1	2021/12/24	Positive	20	—	Negative	35.23	Negative	37.91	Positive	Negative	Negative	Passed
91	184977	MALE	15	2	2021/12/24	Positive	17	—	Negative	37.9	Negative	35.97	Positive	Negative	Negative	Passed
92	184986	FEMALE	11	1	2021/12/27	Positive	14.0	Omicron	Negative	36.67	Negative	36.11	Positive	Negative	Negative	Passed
93	184989	MALE	50	0	2021/12/27	Positive	15.1	—	Negative	36.31	Negative	36.92	Positive	Negative	Negative	Passed
94	184990	FEMALE	16	0	2021/12/27	Positive	17.4	—	Negative	35.16	Negative	36.99	Positive	Negative	Negative	Passed
95	184992	MALE	13	3	2021/12/27	Positive	16.6	—	Negative	35.66	Negative	36.31	Positive	Negative	Negative	Passed
96	184993	MALE	57	2	2021/12/27	Positive	12.4	Delta	Negative	36.15	Negative	37.21	Positive	Negative	Negative	Passed
97	184994	MALE	28	0	2021/12/27	Positive	13.6	Delta	Negative	35.02	Negative	36.66	Positive	Negative	Negative	Passed
98	185005	MALE	8	1	2021/12/27	Positive	18.6	—	Negative	36.51	Negative	35.9	Positive	Negative	Negative	Passed
99	185037	FEMALE	41	0	2021/12/27	Positive	16.1	—	Negative	35.85	Negative	37.94	Positive	Negative	Negative	Passed
100	185045	MALE	19	0	2021/12/27	Positive	20.7	—	Negative	37.59	Negative	37.94	Positive	Negative	Negative	Passed
101	185092	MALE	43	2	2021/12/27	Positive	17.9	—	Negative	37.43	Negative	35.68	Positive	Negative	Negative	Passed

No.	Sample ID	Gender	Age (Years)	Days of symp. onset	Test date	SARS-CoV-2 RT-PCR			Influenza A RT-qPCR		Influenza B RT-qPCR		KaiBiLi Flu & COVID-19 Antigen Duo result			Comment
						Result	Ct Value	VARIANT	Result	Ct Value	Result	Ct Value	COVID-19	Flu A	Flu B	
102	185106	FEMALE	29	1	2021/12/27	Positive	17.6	—	Negative	37.43	Negative	36.69	Positive	Negative	Negative	Passed
103	185120	FEMALE	9	1	2021/12/27	Positive	16.2	—	Negative	37.71	Negative	37.42	Positive	Negative	Negative	Passed
104	185122	FEMALE	20	2	2021/12/27	Positive	14.1	—	Negative	36.15	Negative	36.9	Positive	Negative	Negative	Passed
105	185124	MALE	7	2	2021/12/27	Positive	17.7	—	Negative	36.87	Negative	35.57	Positive	Negative	Negative	Passed
106	185131	MALE	57	1	2021/12/27	Positive	12.1	—	Negative	37.32	Negative	35.71	Positive	Negative	Negative	Passed
107	185137	MALE	31	0	2021/12/27	Positive	12.0	—	Negative	37.79	Negative	37.41	Positive	Negative	Negative	Passed
108	185139	FEMALE	37	1	2021/12/27	Positive	25.0	—	Negative	37.61	Negative	36.02	Positive	Negative	Negative	Passed
109	185140	MALE	15	1	2021/12/27	Positive	13.5	—	Negative	37.63	Negative	36.38	Positive	Negative	Negative	Passed
110	185144	MALE	27	1	2021/12/27	Positive	16.0	—	Negative	35.26	Negative	35.19	Positive	Negative	Negative	Passed
111	185147	MALE	6	3	2021/12/27	Positive	11.4	—	Negative	35.27	Negative	37.14	Positive	Negative	Negative	Passed
112	185165	FEMALE	57	3	2021/12/27	Positive	12.9	—	Negative	37.18	Negative	36.96	Positive	Negative	Negative	Passed
113	185167	MALE	22	0	2021/12/27	Positive	16.8	—	Negative	35.21	Negative	37.09	Positive	Negative	Negative	Passed
114	185168	FEMALE	9	0	2021/12/27	Positive	16.8	—	Negative	36.4	Negative	35.68	Positive	Negative	Negative	Passed
115	185169	FEMALE	31	1	2021/12/27	Positive	20.1	—	Negative	35.99	Negative	35.69	Positive	Negative	Negative	Passed
116	185181	FEMALE	46	0	2021/12/27	Positive	13.5	—	Negative	36.12	Negative	36.33	Positive	Negative	Negative	Passed
117	185185	MALE	10	2	2021/12/27	Positive	13.1	—	Negative	37.33	Negative	37.93	Positive	Negative	Negative	Passed
118	185197	FEMALE	21	1	2021/12/27	Positive	18.9	—	Negative	35.69	Negative	37.42	Positive	Negative	Negative	Passed
119	185203	MALE	33	1	2021/12/27	Positive	13.8	—	Negative	35.83	Negative	37.63	Positive	Negative	Negative	Passed
120	185205	MALE	44	1	2021/12/27	Positive	17.1	—	Negative	37.49	Negative	35.39	Positive	Negative	Negative	Passed
121	185211	MALE	25	2	2021/12/27	Positive	17.1	—	Negative	35.59	Negative	37.7	Positive	Negative	Negative	Passed
122	185223	FEMALE	58	3	2021/12/27	Positive	13.9	—	Negative	37.16	Negative	37.7	Positive	Negative	Negative	Passed
123	185225	MALE	9	0	2021/12/27	Positive	17.6	—	Negative	37.14	Negative	37.52	Positive	Negative	Negative	Passed
124	185239	FEMALE	28	3	2021/12/27	Positive	13.0	—	Negative	35.27	Negative	35.86	Positive	Negative	Negative	Passed
125	185254	MALE	15	0	2021/12/27	Positive	9.5	—	Negative	37.7	Negative	36.46	Positive	Negative	Negative	Passed
126	185259	FEMALE	39	0	2021/12/27	Positive	20.5	—	Negative	36.88	Negative	37.12	Positive	Negative	Negative	Passed
127	185266	MALE	19	1	2021/12/27	Positive	14.0	—	Negative	36.59	Negative	37.53	Positive	Negative	Negative	Passed
128	185267	MALE	26	0	2021/12/27	Positive	18.5	—	Negative	35.12	Negative	36.82	Positive	Negative	Negative	Passed
129	185271	MALE	19	2	2021/12/27	Positive	12.1	—	Negative	36.11	Negative	35.3	Positive	Negative	Negative	Passed
130	185272	FEMALE	60	3	2021/12/27	Positive	20.3	—	Negative	37.67	Negative	37.13	Positive	Negative	Negative	Passed
131	185297	MALE	44	3	2021/12/28	Positive	21.2	—	Negative	37.12	Negative	36.04	Positive	Negative	Negative	Passed
132	185312	FEMALE	17	2	2021/12/28	Positive	13.8	—	Negative	37.1	Negative	35.8	Positive	Negative	Negative	Passed
133	185316	MALE	13	3	2021/12/28	Positive	12.9	—	Negative	37.22	Negative	36.84	Positive	Negative	Negative	Passed
134	185321	FEMALE	26	0	2021/12/28	Positive	18.3	—	Negative	37.77	Negative	37.55	Positive	Negative	Negative	Passed
135	185341	FEMALE	19	3	2021/12/28	Positive	16.5	—	Negative	36.02	Negative	35.26	Positive	Negative	Negative	Passed

No.	Sample ID	Gender	Age (Years)	Days of symp. onset	Test date	SARS-CoV-2 RT-PCR			Influenza A RT-qPCR		Influenza B RT-qPCR		KaiBiLi Flu & COVID-19 Antigen Duo result			Comment
						Result	Ct Value	VARIANT	Result	Ct Value	Result	Ct Value	COVID-19	Flu A	Flu B	
136	185355	FEMALE	40	3	2021/12/28	Positive	19.0	—	Negative	37.19	Negative	36.91	Positive	Negative	Negative	Passed
137	185392	MALE	19	3	2021/12/28	Positive	9.2	—	Negative	37.87	Negative	35.11	Positive	Negative	Negative	Passed
138	185403	FEMALE	21	3	2021/12/28	Positive	17.2	—	Negative	37.47	Negative	37.04	Positive	Negative	Negative	Passed
139	185425	FEMALE	42	0	2021/12/28	Positive	24.4	—	Negative	35.18	Negative	37.7	Positive	Negative	Negative	Passed
140	188081	MALE	25	0	2022/1/7	Positive	11.7	Omicron	Negative	37.49	Negative	38	Positive	Negative	Negative	Passed
141	188099	MALE	45	0	2022/1/7	Positive	25.8	Omicron	Negative	37.9	Negative	37.42	Positive	Negative	Negative	Passed
142	188102	MALE	46	0	2022/1/7	Positive	17	Omicron	Negative	37.25	Negative	37.14	Positive	Negative	Negative	Passed
143	188107	MALE	12	0	2022/1/7	Positive	21	Omicron	Negative	37.33	Negative	37.21	Positive	Negative	Negative	Passed
144	188109	MALE	45	1	2022/1/7	Positive	22.0	Omicron	Negative	37.1	Negative	36.66	Positive	Negative	Negative	Passed
145	188110	MALE	9	3	2022/1/7	Positive	11.8	Omicron	Negative	36.41	Negative	36.67	Positive	Negative	Negative	Passed
146	188111	FEMALE	11	0	2022/1/7	Positive	12.8	Omicron	Negative	37.25	Negative	37.42	Positive	Negative	Negative	Passed
147	188114	MALE	24	0	2022/1/7	Positive	12.9	Omicron	Negative	37.29	Negative	37.55	Positive	Negative	Negative	Passed
148	188115	MALE	39	2	2022/1/7	Positive	25.3	Omicron	Negative	35.49	Negative	37.41	Positive	Negative	Negative	Passed
149	188173	MALE	51	0	2022/1/7	Positive	11.5	Omicron	Negative	36.78	Negative	37.52	Positive	Negative	Negative	Passed
150	188522	FEMALE	27	0	2022/1/8	Positive	16	Omicron	Negative	37.89	Negative	37.12	Positive	Negative	Negative	Passed
151	188555	FEMALE	37	0	2022/1/8	Positive	19.0	Omicron	Negative	36.19	Negative	36.02	Positive	Negative	Negative	Passed
152	188556	FEMALE	43	2	2022/1/8	Positive	17.0	Omicron	Negative	37.61	Negative	35.51	Positive	Negative	Negative	Passed
153	188559	MALE	34	1	2022/1/8	Positive	20.0	Delta	Negative	35.53	Negative	37.32	Positive	Negative	Negative	Passed
154	188560	FEMALE	7	1	2022/1/8	Positive	17.0	Delta	Negative	35.36	Negative	35.52	Positive	Negative	Negative	Passed
155	188561	FEMALE	75	3	2022/1/8	Positive	16.0	Omicron	Negative	36.72	Negative	35.38	Positive	Negative	Negative	Passed
156	188626	FEMALE	43	0	2022/1/10	Positive	16.0	Omicron	Negative	36.03	Negative	36.2	Positive	Negative	Negative	Passed
157	188627	MALE	11	1	2022/1/10	Positive	19.0	Omicron	Negative	36.54	Negative	38	Positive	Negative	Negative	Passed
158	188641	MALE	40	2	2022/1/10	Positive	15.0	Omicron	Negative	36.41	Negative	37.2	Positive	Negative	Negative	Passed
159	188646	MALE	36	2	2022/1/10	Positive	16.0	Omicron	Negative	36.96	Negative	36.8	Positive	Negative	Negative	Passed
160	188661	MALE	35	3	2022/1/10	Positive	22.0	Delta	Negative	35.85	Negative	35.99	Positive	Negative	Negative	Passed
161	188664	MALE	44	3	2022/1/10	Positive	24.0	Omicron	Negative	35.72	Negative	36.39	Positive	Negative	Negative	Passed
162	188674	FEMALE	12	0	2022/1/10	Positive	14.0	Omicron	Negative	35.92	Negative	36.77	Positive	Negative	Negative	Passed
163	188675	FEMALE	9	0	2022/1/10	Positive	18.0	Omicron	Negative	36.43	Negative	36.46	Positive	Negative	Negative	Passed
164	188706	FEMALE	5	3	2022/1/10	Positive	22.0	Omicron	Negative	36.62	Negative	36.04	Positive	Negative	Negative	Passed
165	188713	FEMALE	38	3	2022/1/10	Positive	20.0	Omicron	Negative	35.83	Negative	37.14	Positive	Negative	Negative	Passed
166	188717	MALE	49	2	2022/1/10	Positive	16.0	Omicron	Negative	36.35	Negative	37.66	Positive	Negative	Negative	Passed
167	188732	FEMALE	40	1	2022/1/10	Positive	16.0	Omicron	Negative	37.9	Negative	36.9	Positive	Negative	Negative	Passed
168	188765	MALE	50	1	2022/1/10	Positive	18.0	Omicron	Negative	37.74	Negative	37.49	Positive	Negative	Negative	Passed
169	188770	MALE	42	2	2022/1/10	Positive	15.0	Omicron	Negative	37.95	Negative	36.16	Positive	Negative	Negative	Passed

No.	Sample ID	Gender	Age (Years)	Days of symp. onset	Test date	SARS-CoV-2 RT-PCR			Influenza A RT-qPCR		Influenza B RT-qPCR		KaiBiLi Flu & COVID-19 Antigen Duo result			Comment
						Result	Ct Value	VARIANT	Result	Ct Value	Result	Ct Value	COVID-19	Flu A	Flu B	
170	188783	MALE	30	0	2022/1/10	Positive	14.0	Omicron	Negative	36.28	Negative	36.72	Positive	Negative	Negative	Passed
171	188784	MALE	44	1	2022/1/10	Positive	16.0	Omicron	Negative	35.06	Negative	37.38	Positive	Negative	Negative	Passed
172	188842	FEMALE	13	0	2022/1/10	Positive	10.0	Omicron	Negative	37.44	Negative	35.21	Positive	Negative	Negative	Passed
173	188843	MALE	48	0	2022/1/10	Positive	14.0	Omicron	Negative	35.21	Negative	36.37	Positive	Negative	Negative	Passed
174	188855	FEMALE	25	0	2022/1/10	Positive	17.0	Delta	Negative	37.25	Negative	37.21	Positive	Negative	Negative	Passed
175	188872	FEMALE	51	0	2022/1/10	Positive	13.0	Omicron	Negative	35.67	Negative	36.95	Positive	Negative	Negative	Passed
176	188885	MALE	55	0	2022/1/10	Positive	16.0	Omicron	Negative	35.77	Negative	36.64	Positive	Negative	Negative	Passed
177	188896	MALE	47	0	2022/1/10	Positive	13.0	Omicron	Negative	36.98	Negative	35.36	Positive	Negative	Negative	Passed
178	188897	FEMALE	41	0	2022/1/10	Positive	12.0	Omicron	Negative	35.63	Negative	35.98	Positive	Negative	Negative	Passed

Annex 2. Clinical Test Data for Negative Sample

No.	Sample ID	Gender	Age (Years)	Test date	SARS-CoV-2 RT-PCR		Influenza A RT-qPCR		Influenza B RT-qPCR		KaiBiLi Flu & COVID-19 Antigen Duo result			Comment
					Result	Ct Value	Result	Ct Value	Result	Ct Value	COVID-19	Flu A	Flu B	
1	180291	MALE	25	2021/11/24	Negative	35.47	Negative	36.5	Negative	37.41	Negative	Negative	Negative	Passed
2	180295	FEMALE	27	2021/11/24	Negative	35.66	Negative	35.28	Negative	36.59	Negative	Negative	Negative	Passed
3	180301	MALE	27	2021/11/24	Negative	35.91	Negative	36.49	Negative	36.64	Negative	Negative	Negative	Passed
4	180313	MALE	41	2021/11/24	Negative	37.47	Negative	37.97	Negative	36.53	Negative	Negative	Negative	Passed
5	180314	MALE	42	2021/11/24	Negative	36.68	Negative	35.96	Negative	37.92	Negative	Negative	Negative	Passed
6	180315	FEMALE	44	2021/11/24	Negative	37.15	Negative	36.49	Negative	35.5	Negative	Negative	Negative	Passed
7	180321	MALE	26	2021/11/24	Negative	36.74	Negative	37.78	Negative	36.94	Negative	Negative	Negative	Passed
8	180327	MALE	26	2021/11/24	Negative	36.86	Negative	37.89	Negative	35.51	Negative	Negative	Negative	Passed
9	180364	MALE	42	2021/11/24	Negative	35.9	Negative	36.92	Negative	37.54	Negative	Negative	Negative	Passed
10	180375	MALE	34	2021/11/24	Negative	37.54	Negative	36.11	Negative	37.94	Negative	Negative	Negative	Passed
11	182863	MALE	41	2021/12/13	Negative	35.43	Negative	37.91	Negative	37.45	Negative	Negative	Negative	Passed
12	182864	FEMALE	67	2021/12/13	Negative	35.47	Negative	37.9	Negative	37.09	Negative	Negative	Negative	Passed
13	182865	FEMALE	60	2021/12/13	Negative	36.26	Negative	36.44	Negative	37.62	Negative	Negative	Negative	Passed
14	182867	MALE	55	2021/12/13	Negative	36.3	Negative	36.03	Negative	36.95	Negative	Negative	Negative	Passed
15	182868	FEMALE	53	2021/12/13	Negative	37.78	Negative	36.61	Negative	37.86	Negative	Negative	Negative	Passed
16	182869	FEMALE	41	2021/12/13	Negative	37.05	Negative	37.6	Negative	37.48	Negative	Negative	Negative	Passed
17	182892	MALE	36	2021/12/13	Negative	36.64	Negative	36.15	Negative	37.04	Negative	Negative	Negative	Passed
18	182901	FEMALE	79	2021/12/13	Negative	36.52	Negative	36.42	Negative	36.47	Negative	Negative	Negative	Passed
19	182902	FEMALE	21	2021/12/13	Negative	35.73	Negative	36.43	Negative	37.98	Negative	Negative	Negative	Passed
20	182906	MALE	55	2021/12/13	Negative	35.25	Negative	37.98	Negative	35.14	Negative	Negative	Negative	Passed
21	182908	MALE	45	2021/12/13	Negative	37.55	Negative	36.46	Negative	37.81	Negative	Negative	Negative	Passed
22	182910	FEMALE	53	2021/12/13	Negative	35.21	Negative	35.07	Negative	37.53	Negative	Negative	Negative	Passed
23	182911	MALE	50	2021/12/13	Negative	36.13	Negative	36	Negative	35.75	Negative	Negative	Negative	Passed
24	182912	MALE	45	2021/12/13	Negative	37.52	Negative	37.7	Negative	36.67	Negative	Negative	Negative	Passed
25	182913	MALE	51	2021/12/13	Negative	37.68	Negative	36.01	Negative	37.09	Negative	Negative	Negative	Passed
26	182914	FEMALE	50	2021/12/13	Negative	36.14	Negative	35.85	Negative	37.65	Negative	Negative	Negative	Passed
27	182915	MALE	18	2021/12/13	Negative	35.04	Negative	35.57	Negative	36.03	Negative	Negative	Negative	Passed
28	182917	FEMALE	45	2021/12/13	Negative	35.88	Negative	37.16	Negative	35.69	Negative	Negative	Negative	Passed
29	182919	MALE	52	2021/12/13	Negative	35.26	Negative	37.17	Negative	35.8	Negative	Negative	Negative	Passed
30	182921	MALE	58	2021/12/13	Negative	36.09	Negative	35.75	Negative	35.85	Negative	Negative	Negative	Passed
31	182922	MALE	52	2021/12/13	Negative	36.55	Negative	36.25	Negative	36.78	Negative	Negative	Negative	Passed
32	182925	FEMALE	55	2021/12/13	Negative	37.71	Negative	35.2	Negative	37.3	Negative	Negative	Negative	Passed
33	182926	MALE	75	2021/12/13	Negative	36.8	Negative	35.83	Negative	36.31	Negative	Negative	Negative	Passed

No.	Sample ID	Gender	Age (Years)	Test date	SARS-CoV-2 RT-PCR		Influenza A RT-qPCR		Influenza B RT-qPCR		KaiBili Flu & COVID-19 Antigen Duo result			Comment
					Result	Ct Value	Result	Ct Value	Result	Ct Value	COVID-19	Flu A	Flu B	
34	182929	FEMALE	48	2021/12/13	Negative	37.5	Negative	36.49	Negative	37.66	Negative	Negative	Negative	Passed
35	182930	MALE	43	2021/12/13	Negative	36.41	Negative	36.01	Negative	35.39	Negative	Negative	Negative	Passed
36	182932	FEMALE	48	2021/12/13	Negative	36.74	Negative	36.98	Negative	35.9	Negative	Negative	Negative	Passed
37	182933	MALE	49	2021/12/13	Negative	35.64	Negative	35.19	Negative	37.64	Negative	Negative	Negative	Passed
38	182936	MALE	10	2021/12/13	Negative	35.21	Negative	35.27	Negative	37.47	Negative	Negative	Negative	Passed
39	182940	FEMALE	32	2021/12/13	Negative	37.06	Negative	37.09	Negative	35.68	Negative	Negative	Negative	Passed
40	182951	MALE	30	2021/12/13	Negative	35.18	Negative	37.01	Negative	35.8	Negative	Negative	Negative	Passed
41	182953	MALE	45	2021/12/13	Negative	36.76	Negative	35.48	Negative	37.19	Negative	Negative	Negative	Passed
42	182961	FEMALE	60	2021/12/13	Negative	37.3	Negative	35.82	Negative	37.88	Negative	Negative	Negative	Passed
43	182968	MALE	32	2021/12/13	Negative	36.04	Negative	35.72	Negative	35.08	Negative	Negative	Negative	Passed
44	182984	FEMALE	37	2021/12/13	Negative	35.07	Negative	35.07	Negative	36.41	Negative	Negative	Negative	Passed
45	182985	FEMALE	66	2021/12/13	Negative	35.57	Negative	35.45	Negative	36.13	Negative	Positive	Negative	Not Passed
46	182986	FEMALE	57	2021/12/13	Negative	37.57	Negative	36.21	Negative	37.02	Negative	Negative	Negative	Passed
47	182988	MALE	46	2021/12/13	Negative	37.83	Negative	37.83	Negative	37.41	Negative	Negative	Negative	Passed
48	182989	FEMALE	46	2021/12/13	Negative	35.52	Negative	35.47	Negative	36.67	Negative	Negative	Negative	Passed
49	182996	FEMALE	36	2021/12/13	Negative	35.05	Negative	35.32	Negative	36.1	Negative	Negative	Negative	Passed
50	183004	MALE	42	2021/12/13	Negative	36.48	Negative	35.24	Negative	37.5	Negative	Negative	Negative	Passed
51	183014	FEMALE	37	2021/12/13	Negative	36.46	Negative	37.96	Negative	36.12	Negative	Negative	Negative	Passed
52	183019	FEMALE	44	2021/12/13	Negative	36.92	Negative	35.4	Negative	36.17	Negative	Negative	Negative	Passed
53	183027	FEMALE	39	2021/12/13	Negative	35.68	Negative	35.17	Negative	35.17	Negative	Negative	Negative	Passed
54	183324	FEMALE	8	2021/12/14	Negative	36.04	Negative	36.02	Negative	37	Negative	Negative	Negative	Passed
55	183325	MALE	47	2021/12/14	Negative	35.13	Negative	36.2	Negative	36.25	Negative	Negative	Negative	Passed
56	183326	FEMALE	65	2021/12/14	Negative	37.65	Negative	37.95	Negative	35.44	Negative	Negative	Negative	Passed
57	183330	FEMALE	74	2021/12/14	Negative	37.43	Negative	36.5	Negative	35.1	Negative	Negative	Negative	Passed
58	183331	FEMALE	26	2021/12/14	Negative	37.63	Negative	35.31	Negative	36.06	Negative	Negative	Negative	Passed
59	183332	FEMALE	43	2021/12/14	Negative	37.2	Negative	35	Negative	37.61	Negative	Negative	Negative	Passed
60	183335	MALE	50	2021/12/14	Negative	37.46	Negative	37.8	Negative	37.56	Negative	Negative	Negative	Passed
61	183342	FEMALE	26	2021/12/14	Negative	35.64	Negative	36	Negative	35.31	Negative	Negative	Negative	Passed
62	183385	FEMALE	31	2021/12/14	Negative	35.3	Negative	37.69	Negative	35.85	Negative	Negative	Negative	Passed
63	183458	FEMALE	27	2021/12/14	Negative	36.41	Negative	37.13	Negative	36.36	Negative	Negative	Negative	Passed
64	183480	MALE	21	2021/12/14	Negative	35.31	Negative	36.35	Negative	37.76	Negative	Negative	Negative	Passed
65	183484	MALE	51	2021/12/14	Negative	35.09	Negative	35.01	Negative	36.11	Negative	Negative	Negative	Passed
66	183495	MALE	50	2021/12/14	Negative	35.23	Negative	35.47	Negative	37.07	Negative	Negative	Negative	Passed
67	183531	MALE	23	2021/12/14	Negative	35.06	Negative	37.8	Negative	36.95	Negative	Negative	Negative	Passed

No.	Sample ID	Gender	Age (Years)	Test date	SARS-CoV-2 RT-PCR		Influenza A RT-qPCR		Influenza B RT-qPCR		KaiBili Flu & COVID-19 Antigen Duo result			Comment
					Result	Ct Value	Result	Ct Value	Result	Ct Value	COVID-19	Flu A	Flu B	
68	183540	MALE	7	2021/12/14	Negative	35.76	Negative	35.66	Negative	36.85	Negative	Negative	Negative	Passed
69	183630	MALE	47	2021/12/17	Negative	36.03	Negative	36.94	Negative	35.7	Negative	Negative	Negative	Passed
70	183631	MALE	50	2021/12/17	Negative	37.45	Negative	36.69	Negative	37.93	Negative	Negative	Negative	Passed
71	183632	FEMALE	44	2021/12/17	Negative	36.26	Negative	37.97	Negative	36.53	Negative	Negative	Negative	Passed
72	183633	MALE	44	2021/12/17	Negative	36.28	Negative	37.79	Negative	36.7	Negative	Negative	Negative	Passed
73	183635	FEMALE	49	2021/12/17	Negative	37.3	Negative	37.05	Negative	37.82	Negative	Negative	Negative	Passed
74	183637	FEMALE	43	2021/12/17	Negative	36.41	Negative	36.02	Negative	36.03	Negative	Negative	Negative	Passed
75	183638	FEMALE	52	2021/12/17	Negative	36.44	Negative	35.6	Negative	37.24	Negative	Negative	Negative	Passed
76	183641	FEMALE	26	2021/12/17	Negative	37.86	Negative	35.37	Negative	37.34	Negative	Negative	Negative	Passed
77	183642	FEMALE	39	2021/12/17	Negative	35.4	Negative	36.83	Negative	37.77	Negative	Negative	Negative	Passed
78	183643	MALE	45	2021/12/17	Negative	37.4	Negative	37.24	Negative	35.26	Negative	Negative	Negative	Passed
79	183644	MALE	62	2021/12/17	Negative	36.71	Negative	35.61	Negative	37.17	Negative	Negative	Negative	Passed
80	183645	MALE	24	2021/12/17	Negative	36.44	Negative	35.7	Negative	35.14	Negative	Negative	Negative	Passed
81	183646	FEMALE	53	2021/12/17	Negative	37.04	Negative	35.44	Negative	37.32	Negative	Negative	Negative	Passed
82	183647	FEMALE	30	2021/12/17	Negative	36.56	Negative	37.35	Negative	36.55	Negative	Negative	Negative	Passed
83	183648	MALE	31	2021/12/17	Negative	36.44	Negative	36.52	Negative	36.65	Negative	Negative	Negative	Passed
84	183654	FEMALE	49	2021/12/17	Negative	36.06	Negative	37.88	Negative	35.23	Negative	Negative	Negative	Passed
85	183656	MALE	32	2021/12/17	Negative	36.11	Negative	35.29	Negative	37.41	Negative	Negative	Negative	Passed
86	183658	FEMALE	56	2021/12/17	Negative	36.39	Negative	37.36	Negative	37.08	Negative	Negative	Negative	Passed
87	183660	FEMALE	45	2021/12/17	Negative	36.56	Negative	35.24	Negative	36.59	Negative	Negative	Negative	Passed
88	183661	FEMALE	30	2021/12/17	Negative	36.47	Negative	36.16	Negative	36.92	Negative	Negative	Negative	Passed
89	183662	MALE	62	2021/12/17	Negative	37.74	Negative	36.16	Negative	36.39	Negative	Negative	Negative	Passed
90	184987	FEMALE	36	2021/12/27	Negative	36.4	Negative	35.8	Negative	35.4	Negative	Negative	Negative	Passed
91	185000	MALE	28	2021/12/27	Negative	37	Negative	36.2	Negative	35.2	Negative	Negative	Negative	Passed
92	185001	MALE	38	2021/12/27	Negative	35.4	Negative	35.9	Negative	36.1	Negative	Negative	Negative	Passed
93	185002	FEMALE	26	2021/12/27	Negative	36.6	Negative	36.3	Negative	35	Positive	Negative	Negative	Not Passed
94	185010	MALE	63	2021/12/27	Negative	36.1	Negative	36.3	Negative	35.2	Negative	Negative	Negative	Passed
95	185018	MALE	30	2021/12/27	Negative	36.7	Negative	37	Negative	35.4	Negative	Negative	Negative	Passed
96	185019	MALE	25	2021/12/27	Negative	35	Negative	36.7	Negative	36.1	Negative	Negative	Negative	Passed
97	185020	MALE	57	2021/12/27	Negative	35	Negative	37	Negative	35.4	Negative	Negative	Negative	Passed
98	185022	MALE	46	2021/12/27	Negative	36.3	Negative	36.5	Negative	35.3	Negative	Negative	Negative	Passed
99	185023	MALE	37	2021/12/27	Negative	36.7	Negative	35.8	Negative	35.6	Negative	Negative	Negative	Passed
100	185053	FEMALE	58	2021/12/27	Negative	35.5	Negative	36.4	Negative	36.7	Negative	Negative	Negative	Passed
101	185060	MALE	6	2021/12/27	Negative	35.5	Negative	37	Negative	37	Negative	Negative	Negative	Passed

No.	Sample ID	Gender	Age (Years)	Test date	SARS-CoV-2 RT-PCR		Influenza A RT-qPCR		Influenza B RT-qPCR		KaiBili Flu & COVID-19 Antigen Duo result			Comment
					Result	Ct Value	Result	Ct Value	Result	Ct Value	COVID-19	Flu A	Flu B	
102	185061	FEMALE	7	2021/12/27	Negative	36.4	Negative	35.9	Negative	36	Negative	Negative	Negative	Passed
103	185063	MALE	44	2021/12/27	Negative	35	Negative	36	Negative	36.9	Negative	Negative	Negative	Passed
104	185064	FEMALE	55	2021/12/27	Negative	36	Negative	35	Negative	36.2	Negative	Negative	Negative	Passed
105	185072	FEMALE	11	2021/12/27	Negative	35.5	Negative	36.1	Negative	35.9	Negative	Negative	Negative	Passed
106	185125	MALE	14	2021/12/27	Negative	36.9	Negative	35.1	Negative	36.1	Negative	Negative	Negative	Passed
107	185129	FEMALE	27	2021/12/27	Negative	35.4	Negative	35	Negative	36.5	Negative	Negative	Negative	Passed
108	185148	MALE	43	2021/12/27	Negative	35.3	Negative	36.6	Negative	36.8	Negative	Negative	Negative	Passed
109	185156	FEMALE	43	2021/12/27	Negative	35.5	Negative	35.2	Negative	36.3	Negative	Negative	Negative	Passed
110	185160	MALE	48	2021/12/27	Negative	35.5	Negative	36.9	Negative	36.8	Negative	Negative	Negative	Passed
111	185181	FEMALE	46	2021/12/27	Negative	35.8	Negative	35.5	Negative	35.4	Negative	Negative	Negative	Passed
112	185183	FEMALE	11	2021/12/27	Negative	36.5	Negative	35.1	Negative	35.8	Negative	Negative	Negative	Passed
113	185191	FEMALE	31	2021/12/27	Negative	35.2	Negative	35.4	Negative	35.9	Negative	Negative	Negative	Passed
114	185202	MALE	28	2021/12/27	Negative	36	Negative	36.3	Negative	35.8	Negative	Negative	Negative	Passed
115	185204	FEMALE	23	2021/12/27	Negative	35.8	Negative	35.9	Negative	35	Negative	Negative	Negative	Passed
116	185210	MALE	30	2021/12/27	Negative	36.4	Negative	37	Negative	35.7	Negative	Negative	Negative	Passed
117	185227	MALE	38	2021/12/27	Negative	36.1	Negative	36	Negative	37	Negative	Negative	Negative	Passed
118	185238	MALE	41	2021/12/27	Negative	35.7	Negative	35.3	Negative	37	Negative	Negative	Negative	Passed
119	185244	FEMALE	47	2021/12/27	Negative	36.9	Negative	36.5	Negative	36.8	Negative	Negative	Negative	Passed
120	187333	MALE	51	2022/1/4	Negative	35.27	Negative	37.82	Negative	36.72	Negative	Negative	Negative	Passed
121	187334	MALE	51	2022/1/4	Negative	36.19	Negative	36.22	Negative	36.03	Negative	Negative	Negative	Passed
122	187338	FEMALE	62	2022/1/4	Negative	35.41	Negative	36.26	Negative	35.4	Negative	Negative	Negative	Passed
123	187339	FEMALE	69	2022/1/4	Negative	37.57	Negative	37.31	Negative	35.84	Negative	Negative	Negative	Passed
124	187340	FEMALE	53	2022/1/4	Negative	35.49	Negative	36.92	Negative	36.02	Negative	Negative	Negative	Passed
125	187341	MALE	63	2022/1/4	Negative	37.15	Negative	36.25	Negative	36.37	Negative	Negative	Negative	Passed
126	187342	MALE	63	2022/1/4	Negative	36.42	Negative	36.34	Negative	35.71	Negative	Negative	Negative	Passed
127	187350	FEMALE	52	2022/1/4	Negative	36.83	Negative	37.3	Negative	35.48	Negative	Negative	Negative	Passed
128	187354	FEMALE	66	2022/1/4	Negative	37.86	Negative	37.8	Negative	36.37	Negative	Negative	Negative	Passed
129	187357	MALE	57	2022/1/4	Negative	36.8	Negative	36.32	Negative	35.16	Negative	Negative	Positive	Not Passed
130	187358	FEMALE	18	2022/1/4	Negative	36.91	Negative	35.66	Negative	36.6	Negative	Negative	Negative	Passed
131	187359	FEMALE	44	2022/1/4	Negative	37.1	Negative	35.62	Negative	37.63	Negative	Negative	Negative	Passed
132	187360	MALE	43	2022/1/4	Negative	35.21	Negative	37.76	Negative	35.15	Negative	Negative	Negative	Passed
133	187361	MALE	43	2022/1/4	Negative	35.41	Negative	35.54	Negative	35.32	Negative	Negative	Negative	Passed
134	187364	FEMALE	50	2022/1/4	Negative	35.56	Negative	36.29	Negative	36.19	Negative	Negative	Negative	Passed
135	187365	FEMALE	50	2022/1/4	Negative	35.05	Negative	36.74	Negative	36.16	Negative	Negative	Negative	Passed

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					Result	Ct Value	Result	Ct Value	Result	Ct Value	COVID-19	Flu A	Flu B	
136	187369	FEMALE	38	2022/1/4	Negative	35.73	Negative	36.47	Negative	37.79	Negative	Negative	Negative	Passed
137	187371	FEMALE	44	2022/1/4	Negative	36.08	Negative	36.32	Negative	37.77	Negative	Negative	Negative	Passed
138	187372	FEMALE	44	2022/1/4	Negative	35.49	Negative	37.66	Negative	36.01	Negative	Negative	Negative	Passed
139	187380	FEMALE	34	2022/1/4	Negative	36.38	Negative	35.05	Negative	35.47	Negative	Negative	Negative	Passed
140	187382	FEMALE	63	2022/1/4	Negative	35.31	Negative	36.61	Negative	35.09	Negative	Negative	Negative	Passed
141	187383	FEMALE	63	2022/1/4	Negative	36.55	Negative	35.48	Negative	35.42	Negative	Negative	Negative	Passed
142	187384	FEMALE	41	2022/1/4	Negative	35.28	Negative	36.71	Negative	35.61	Negative	Negative	Negative	Passed
143	187385	FEMALE	8	2022/1/4	Negative	36.07	Negative	37.53	Negative	36.24	Negative	Negative	Negative	Passed
144	187386	FEMALE	62	2022/1/4	Negative	35.78	Negative	37.06	Negative	36.15	Negative	Positive	Negative	Not Passed
145	187387	FEMALE	41	2022/1/4	Negative	37.53	Negative	37.59	Negative	35.5	Negative	Negative	Negative	Passed
146	187388	FEMALE	8	2022/1/4	Negative	37.9	Negative	37.22	Negative	36.9	Negative	Negative	Negative	Passed
147	187389	FEMALE	62	2022/1/4	Negative	36.55	Negative	35.93	Negative	36.75	Negative	Negative	Negative	Passed
148	187393	MALE	62	2022/1/4	Negative	37.85	Negative	35.82	Negative	37.78	Negative	Negative	Negative	Passed
149	187394	MALE	62	2022/1/4	Negative	35.87	Negative	36.22	Negative	37.99	Negative	Negative	Negative	Passed
150	187396	FEMALE	32	2022/1/4	Negative	35.5	Negative	35.93	Negative	37.73	Negative	Negative	Negative	Passed
151	187397	FEMALE	62	2022/1/4	Negative	35.7	Negative	37.22	Negative	37.5	Negative	Negative	Negative	Passed
152	187398	FEMALE	62	2022/1/4	Negative	35.99	Negative	37.55	Negative	36.43	Negative	Negative	Negative	Passed
153	187399	FEMALE	32	2022/1/4	Negative	37.21	Negative	36.6	Negative	37.48	Negative	Negative	Negative	Passed
154	187403	FEMALE	54	2022/1/4	Negative	36.32	Negative	36.7	Negative	37.76	Negative	Negative	Negative	Passed
155	187404	FEMALE	54	2022/1/4	Negative	35.54	Negative	36.14	Negative	35.87	Negative	Negative	Negative	Passed
156	187405	MALE	50	2022/1/4	Negative	37.85	Negative	37.94	Negative	36.71	Negative	Negative	Negative	Passed
157	187406	MALE	50	2022/1/4	Negative	36.39	Negative	36.52	Negative	36.26	Negative	Negative	Negative	Passed
158	187411	MALE	22	2022/1/4	Negative	36.05	Negative	35.62	Negative	36.52	Negative	Negative	Negative	Passed
159	187412	MALE	22	2022/1/4	Negative	35.21	Negative	37.13	Negative	36.91	Negative	Negative	Negative	Passed
160	187418	FEMALE	42	2022/1/4	Negative	36.05	Negative	37.75	Negative	35.88	Negative	Negative	Negative	Passed
161	187419	FEMALE	42	2022/1/4	Negative	36.79	Negative	36.72	Negative	36.35	Negative	Negative	Negative	Passed
162	187423	MALE	46	2022/1/4	Negative	35.98	Negative	35.54	Negative	37.78	Negative	Negative	Negative	Passed
163	187426	MALE	21	2022/1/4	Negative	36.35	Negative	35.9	Negative	36.1	Negative	Negative	Negative	Passed
164	187427	FEMALE	46	2022/1/4	Negative	35.52	Negative	36.3	Negative	36.07	Negative	Negative	Negative	Passed
165	187429	FEMALE	18	2022/1/4	Negative	36.77	Negative	35.5	Negative	36.44	Negative	Negative	Negative	Passed
166	187442	MALE	27	2022/1/4	Negative	35.51	Negative	37.18	Negative	35.82	Negative	Negative	Negative	Passed
167	187443	MALE	27	2022/1/4	Negative	37.54	Negative	36	Negative	35.25	Negative	Negative	Negative	Passed
168	187454	MALE	61	2022/1/4	Negative	37.65	Negative	35.71	Negative	37.25	Negative	Negative	Negative	Passed
169	187455	MALE	61	2022/1/4	Negative	36.95	Negative	35.91	Negative	37.77	Negative	Negative	Negative	Passed

No.	Sample ID	Gender	Age (Years)	Test date	SARS-CoV-2 RT-PCR		Influenza A RT-qPCR		Influenza B RT-qPCR		KaiBili Flu & COVID-19 Antigen Duo result			Comment
					Result	Ct Value	Result	Ct Value	Result	Ct Value	COVID-19	Flu A	Flu B	
170	187467	FEMALE	58	2022/1/4	Negative	37.05	Negative	35.1	Negative	37.2	Negative	Negative	Negative	Passed
171	187468	FEMALE	58	2022/1/4	Negative	35.76	Negative	37.13	Negative	36.85	Negative	Negative	Negative	Passed
172	187537	FEMALE	46	2022/1/4	Negative	35.58	Negative	35.83	Negative	35.07	Negative	Negative	Negative	Passed
173	187538	FEMALE	46	2022/1/4	Negative	37.22	Negative	37.2	Negative	37.81	Negative	Negative	Negative	Passed
174	187541	MALE	50	2022/1/4	Negative	37.95	Negative	35.78	Negative	35.8	Negative	Negative	Negative	Passed
175	187542	MALE	50	2022/1/4	Negative	37.86	Negative	37.35	Negative	36.84	Negative	Negative	Negative	Passed
176	187546	MALE	33	2022/1/4	Negative	35.54	Negative	35.86	Negative	37.71	Negative	Negative	Negative	Passed
177	187547	MALE	33	2022/1/4	Negative	36.09	Negative	35.68	Negative	36.7	Negative	Negative	Negative	Passed
178	187558	FEMALE	60	2022/1/4	Negative	37.57	Negative	37.04	Negative	37.23	Negative	Negative	Negative	Passed
179	187559	FEMALE	60	2022/1/4	Negative	35.68	Negative	35.45	Negative	35.04	Negative	Negative	Negative	Passed
180	187561	FEMALE	47	2022/1/4	Negative	37.47	Negative	35.22	Negative	35.22	Negative	Negative	Negative	Passed
181	187562	FEMALE	47	2022/1/4	Negative	37.65	Negative	37.11	Negative	36.95	Negative	Negative	Negative	Passed
182	187574	MALE	69	2022/1/4	Negative	36.21	Negative	36.2	Negative	36.73	Negative	Negative	Negative	Passed
183	187575	MALE	69	2022/1/4	Negative	36.71	Negative	37.84	Negative	37.82	Negative	Negative	Negative	Passed
184	187581	FEMALE	37	2022/1/4	Negative	37.4	Negative	37.59	Negative	37.65	Negative	Negative	Negative	Passed
185	187601	MALE	43	2022/1/4	Negative	37.48	Negative	37.71	Negative	37.44	Negative	Negative	Negative	Passed
186	187602	MALE	43	2022/1/4	Negative	36.89	Negative	35.1	Negative	38	Negative	Negative	Negative	Passed
187	187603	MALE	28	2022/1/4	Negative	37.69	Negative	37.32	Negative	36.98	Negative	Negative	Negative	Passed
188	187631	FEMALE	43	2022/1/4	Negative	37.61	Negative	37.39	Negative	36.81	Negative	Negative	Negative	Passed
189	187632	FEMALE	43	2022/1/4	Negative	37.14	Negative	35.96	Negative	37.6	Negative	Negative	Negative	Passed
190	187641	MALE	45	2022/1/4	Negative	35.98	Negative	35.43	Negative	35.37	Negative	Negative	Negative	Passed
191	187642	MALE	11	2022/1/4	Negative	35.76	Negative	36.53	Negative	35.41	Negative	Negative	Negative	Passed
192	187643	FEMALE	45	2022/1/4	Negative	36.15	Negative	36.53	Negative	37.86	Negative	Negative	Negative	Passed
193	187644	MALE	45	2022/1/4	Negative	35.49	Negative	35.98	Negative	36.62	Negative	Negative	Negative	Passed
194	187645	MALE	11	2022/1/4	Negative	37.57	Negative	36.76	Negative	37.59	Negative	Negative	Negative	Passed
195	187646	FEMALE	45	2022/1/4	Negative	36.71	Negative	35.29	Negative	35.94	Negative	Negative	Negative	Passed
196	187647	MALE	46	2022/1/4	Negative	36.97	Negative	35.3	Negative	35.66	Negative	Negative	Negative	Passed
197	187648	MALE	13	2022/1/4	Negative	36.42	Negative	36.63	Negative	36.9	Negative	Negative	Negative	Passed
198	187649	MALE	46	2022/1/4	Negative	35.78	Negative	37.4	Negative	35.22	Negative	Negative	Negative	Passed
199	187650	MALE	13	2022/1/4	Negative	37.39	Negative	36.5	Negative	35.2	Negative	Negative	Positive	Not Passed
200	187653	FEMALE	18	2022/1/4	Negative	37.14	Negative	35.28	Negative	37.64	Negative	Negative	Negative	Passed
201	187654	FEMALE	18	2022/1/4	Negative	37.31	Negative	36.27	Negative	35.71	Negative	Negative	Negative	Passed
202	187663	FEMALE	45	2022/1/4	Negative	35.88	Negative	37.85	Negative	36.67	Negative	Negative	Negative	Passed
203	187664	FEMALE	45	2022/1/4	Negative	37.03	Negative	36.98	Negative	36.99	Negative	Negative	Negative	Passed

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					Result	Ct Value	Result	Ct Value	Result	Ct Value	COVID-19	Flu A	Flu B	
204	187667	FEMALE	55	2022/1/4	Negative	35.18	Negative	37.21	Negative	37.98	Negative	Negative	Negative	Passed
205	187668	FEMALE	55	2022/1/4	Negative	35.88	Negative	35.8	Negative	37.1	Negative	Negative	Negative	Passed
206	188506	FEMALE	14	2022/1/8	Negative	37.91	Negative	36.41	Negative	35.86	Negative	Negative	Negative	Passed
207	188507	FEMALE	11	2022/1/8	Negative	36.2	Negative	35.02	Negative	36.02	Negative	Negative	Negative	Passed
208	188510	FEMALE	24	2022/1/8	Negative	35.79	Negative	35	Negative	37.87	Negative	Negative	Negative	Passed
209	188512	MALE	33	2022/1/8	Negative	35.62	Negative	36.37	Negative	36.34	Negative	Negative	Negative	Passed
210	188514	FEMALE	25	2022/1/8	Negative	36.31	Negative	37.41	Negative	36.23	Negative	Negative	Negative	Passed
211	188516	FEMALE	37	2022/1/8	Negative	37.19	Negative	36.26	Negative	35.36	Negative	Negative	Negative	Passed
212	188517	FEMALE	47	2022/1/8	Negative	37.42	Negative	36.27	Negative	37.39	Negative	Negative	Negative	Passed
213	188521	FEMALE	23	2022/1/8	Negative	36.42	Negative	36.3	Negative	36.15	Negative	Negative	Negative	Passed
214	188526	FEMALE	19	2022/1/8	Negative	36.67	Negative	35.55	Negative	36.2	Negative	Negative	Negative	Passed
215	188527	FEMALE	30	2022/1/8	Negative	35.21	Negative	35.95	Negative	36.88	Negative	Negative	Negative	Passed
216	188528	MALE	39	2022/1/8	Negative	35.28	Negative	37.62	Negative	35.48	Negative	Negative	Negative	Passed
217	188529	FEMALE	24	2022/1/8	Negative	35.27	Negative	36.35	Negative	36.29	Negative	Negative	Negative	Passed
218	188530	MALE	92	2022/1/8	Negative	36.03	Negative	35.37	Negative	36.81	Negative	Negative	Negative	Passed
219	188531	MALE	54	2022/1/8	Negative	37.76	Negative	35.63	Negative	37.79	Negative	Negative	Negative	Passed
220	188532	FEMALE	46	2022/1/8	Negative	37.91	Negative	35.23	Negative	37.19	Negative	Negative	Negative	Passed
221	188533	FEMALE	67	2022/1/8	Negative	36.95	Negative	37.44	Negative	35.37	Negative	Negative	Negative	Passed
222	188534	FEMALE	26	2022/1/8	Negative	37.17	Negative	35.62	Negative	35.19	Negative	Negative	Negative	Passed
223	188535	MALE	50	2022/1/8	Negative	36.69	Negative	35.92	Negative	35.35	Negative	Negative	Negative	Passed
224	188536	FEMALE	36	2022/1/8	Negative	36.05	Negative	35.56	Negative	35.13	Negative	Negative	Negative	Passed
225	188537	FEMALE	48	2022/1/8	Negative	36.64	Negative	36.32	Negative	37.1	Negative	Negative	Negative	Passed
226	188538	FEMALE	55	2022/1/8	Negative	36	Negative	37.77	Negative	35.31	Negative	Negative	Negative	Passed
227	188539	FEMALE	57	2022/1/8	Negative	35.48	Negative	37.37	Negative	36.68	Negative	Negative	Negative	Passed
228	188540	FEMALE	69	2022/1/8	Negative	36.01	Negative	37.71	Negative	35.66	Negative	Negative	Negative	Passed
229	188541	FEMALE	73	2022/1/8	Negative	35.79	Negative	35.74	Negative	35.67	Negative	Negative	Negative	Passed
230	188543	FEMALE	36	2022/1/8	Negative	37.27	Negative	35.86	Negative	37.94	Negative	Negative	Negative	Passed
231	188546	FEMALE	38	2022/1/8	Negative	36.81	Negative	37.85	Negative	37.03	Negative	Negative	Negative	Passed
232	188548	MALE	38	2022/1/8	Negative	35.77	Negative	36.12	Negative	36.7	Negative	Negative	Negative	Passed
233	188554	FEMALE	82	2022/1/8	Negative	35.16	Negative	37.32	Negative	35.5	Negative	Negative	Negative	Passed
234	188557	MALE	65	2022/1/8	Negative	35.9	Negative	36.39	Negative	37	Negative	Negative	Negative	Passed
235	188562	FEMALE	36	2022/1/8	Negative	35.88	Negative	35.17	Negative	36.07	Negative	Negative	Negative	Passed
236	188565	FEMALE	11	2022/1/8	Negative	36.28	Negative	36.95	Negative	37.51	Negative	Negative	Negative	Passed
237	188567	FEMALE	44	2022/1/8	Negative	36.87	Negative	35.5	Negative	36.06	Negative	Negative	Negative	Passed

No.	Sample ID	Gender	Age (Years)	Test date	SARS-CoV-2 RT-PCR		Influenza A RT-qPCR		Influenza B RT-qPCR		KaiBili Flu & COVID-19 Antigen Duo result			Comment
					Result	Ct Value	Result	Ct Value	Result	Ct Value	COVID-19	Flu A	Flu B	
238	188578	FEMALE	36	2022/1/8	Negative	36.98	Negative	35.88	Negative	37.79	Negative	Negative	Negative	Passed
239	188921	FEMALE	42	2022/1/11	Negative	36.91	Negative	35.45	Negative	35.81	Negative	Negative	Negative	Passed
240	188928	FEMALE	44	2022/1/11	Negative	36.97	Negative	35.65	Negative	37.22	Negative	Negative	Negative	Passed
241	188931	FEMALE	26	2022/1/11	Negative	37.43	Negative	36	Negative	35.42	Negative	Negative	Negative	Passed
242	188934	FEMALE	41	2022/1/11	Negative	36.35	Negative	35.55	Negative	37.32	Positive	Negative	Negative	Not Passed
243	188935	MALE	46	2022/1/11	Negative	37.5	Negative	36.28	Negative	35.09	Negative	Negative	Negative	Passed
244	188938	MALE	36	2022/1/11	Negative	35.94	Negative	37.6	Negative	36.53	Negative	Negative	Negative	Passed
245	188939	MALE	43	2022/1/11	Negative	36.75	Negative	36.34	Negative	36.01	Negative	Negative	Negative	Passed
246	188940	MALE	29	2022/1/11	Negative	38	Negative	36.89	Negative	36.01	Negative	Negative	Negative	Passed
247	188941	MALE	31	2022/1/11	Negative	37.79	Negative	37.29	Negative	37.04	Negative	Negative	Negative	Passed
248	188943	MALE	28	2022/1/11	Negative	37.24	Negative	35.41	Negative	36.6	Negative	Negative	Positive	Not Passed
249	188944	MALE	52	2022/1/11	Negative	35.9	Negative	35.92	Negative	35.97	Negative	Negative	Negative	Passed
250	188945	MALE	28	2022/1/11	Negative	35.82	Negative	35.91	Negative	35.72	Negative	Negative	Negative	Passed
251	188946	MALE	45	2022/1/11	Negative	37.9	Negative	37.95	Negative	37.48	Negative	Negative	Negative	Passed
252	188947	MALE	44	2022/1/11	Negative	36.22	Negative	35.05	Negative	36.27	Negative	Negative	Negative	Passed
253	188948	FEMALE	43	2022/1/11	Negative	35.54	Negative	36.31	Negative	36.02	Negative	Negative	Negative	Passed
254	188950	MALE	46	2022/1/11	Negative	35.28	Negative	37.01	Negative	35.05	Negative	Negative	Negative	Passed
255	188951	MALE	46	2022/1/11	Negative	35.03	Negative	35.9	Negative	35.74	Negative	Negative	Negative	Passed
256	188952	MALE	64	2022/1/11	Negative	37.9	Negative	37.42	Negative	36.17	Negative	Negative	Negative	Passed
257	188954	MALE	47	2022/1/11	Negative	37.34	Negative	37.41	Negative	37.22	Negative	Negative	Negative	Passed
258	188955	MALE	38	2022/1/11	Negative	36.02	Negative	37.25	Negative	36.04	Negative	Negative	Negative	Passed
259	188956	MALE	50	2022/1/11	Negative	35.6	Negative	35.67	Negative	37.58	Negative	Negative	Negative	Passed
260	188957	MALE	46	2022/1/11	Negative	36.86	Negative	37.51	Negative	35.97	Negative	Negative	Negative	Passed
261	188958	MALE	56	2022/1/11	Negative	35.7	Negative	37.77	Negative	36.69	Negative	Negative	Negative	Passed
262	188959	MALE	41	2022/1/11	Negative	37.4	Negative	37.69	Negative	37.39	Negative	Negative	Negative	Passed
263	188960	MALE	42	2022/1/11	Negative	35.13	Negative	35.47	Negative	35.09	Negative	Negative	Negative	Passed
264	188962	FEMALE	51	2022/1/11	Negative	37.83	Negative	36.99	Negative	36.62	Negative	Negative	Negative	Passed
265	188963	MALE	57	2022/1/11	Negative	37.87	Negative	37.18	Negative	37.69	Negative	Negative	Negative	Passed
266	188964	FEMALE	38	2022/1/11	Negative	36.2	Negative	37.37	Negative	36.53	Negative	Negative	Negative	Passed
267	188965	FEMALE	41	2022/1/11	Negative	35.08	Negative	35.79	Negative	35.35	Negative	Negative	Negative	Passed
268	188966	FEMALE	40	2022/1/11	Negative	37.21	Negative	36.29	Negative	36.69	Negative	Negative	Negative	Passed
269	188967	MALE	36	2022/1/11	Negative	35.75	Negative	37.19	Negative	35.73	Negative	Negative	Negative	Passed
270	188968	MALE	43	2022/1/11	Negative	37.87	Negative	35.63	Negative	36.62	Negative	Negative	Negative	Passed
271	188969	MALE	49	2022/1/11	Negative	35.51	Negative	36.11	Negative	37.09	Negative	Negative	Negative	Passed

No.	Sample ID	Gender	Age (Years)	Test date	SARS-CoV-2 RT-PCR		Influenza A RT-qPCR		Influenza B RT-qPCR		KaiBiLi Flu & COVID-19 Antigen Duo result			Comment
					Result	Ct Value	Result	Ct Value	Result	Ct Value	COVID-19	Flu A	Flu B	
272	188970	MALE	29	2022/1/11	Negative	37.72	Negative	36.02	Negative	36.9	Negative	Negative	Negative	Passed
273	188971	MALE	33	2022/1/11	Negative	37.37	Negative	37.67	Negative	36	Negative	Negative	Negative	Passed
274	188972	MALE	36	2022/1/11	Negative	35.73	Negative	37.6	Negative	37.34	Negative	Negative	Negative	Passed
275	188987	MALE	26	2022/1/11	Negative	35.55	Negative	36.51	Negative	37.61	Negative	Negative	Negative	Passed
276	188994	MALE	24	2022/1/11	Negative	37.32	Negative	36.19	Negative	37.04	Negative	Negative	Negative	Passed
277	188999	FEMALE	26	2022/1/11	Negative	36.32	Negative	35.72	Negative	37.91	Negative	Negative	Negative	Passed
278	189024	MALE	29	2022/1/11	Negative	36.14	Negative	36.93	Negative	35.21	Negative	Negative	Negative	Passed
279	189025	MALE	25	2022/1/11	Negative	37.2	Negative	35.56	Negative	36.9	Negative	Negative	Negative	Passed
280	189026	MALE	30	2022/1/11	Negative	36.85	Negative	35.55	Negative	35.43	Negative	Negative	Negative	Passed
281	189027	MALE	28	2022/1/11	Negative	36.69	Negative	37.37	Negative	36.97	Negative	Negative	Negative	Passed
282	189028	FEMALE	34	2022/1/11	Negative	36.05	Negative	36.04	Negative	36.11	Negative	Negative	Negative	Passed
283	189029	MALE	37	2022/1/11	Negative	37.93	Negative	35	Negative	35.89	Negative	Negative	Negative	Passed
284	189030	FEMALE	23	2022/1/11	Negative	36	Negative	35.33	Negative	37.08	Negative	Negative	Negative	Passed
285	189031	FEMALE	42	2022/1/11	Negative	37.23	Negative	35.83	Negative	36.64	Negative	Negative	Negative	Passed
286	189032	FEMALE	26	2022/1/11	Negative	37.54	Negative	37.6	Negative	37.82	Negative	Negative	Negative	Passed
287	189033	MALE	37	2022/1/11	Negative	36.64	Negative	36.66	Negative	35.36	Negative	Negative	Negative	Passed
288	189034	MALE	41	2022/1/11	Negative	35.87	Negative	37.39	Negative	37.75	Negative	Negative	Negative	Passed
289	189035	MALE	37	2022/1/11	Negative	36.98	Negative	35.43	Negative	36.8	Negative	Negative	Negative	Passed
290	189036	MALE	36	2022/1/11	Negative	37.34	Negative	36.68	Negative	37.13	Negative	Negative	Negative	Passed
291	189038	MALE	40	2022/1/11	Negative	36.47	Negative	36.47	Negative	36.2	Negative	Negative	Negative	Passed
292	189039	MALE	41	2022/1/11	Negative	35.07	Negative	37.28	Negative	36.44	Negative	Negative	Negative	Passed
293	189040	FEMALE	41	2022/1/11	Negative	35.01	Negative	36.03	Negative	37.23	Negative	Negative	Negative	Passed
294	189041	MALE	29	2022/1/11	Negative	35.73	Negative	35.94	Negative	36.4	Negative	Negative	Negative	Passed
295	189042	FEMALE	42	2022/1/11	Negative	37.26	Negative	35	Negative	37.22	Negative	Negative	Negative	Passed
296	189043	FEMALE	11	2022/1/11	Negative	35.21	Negative	37.87	Negative	37.44	Negative	Negative	Negative	Passed
297	189044	FEMALE	45	2022/1/11	Negative	37.03	Negative	35.99	Negative	36.29	Negative	Negative	Negative	Passed
298	189048	FEMALE	30	2022/1/11	Negative	37	Negative	37.8	Negative	35.33	Negative	Negative	Negative	Passed
299	189049	FEMALE	43	2022/1/11	Negative	35.93	Negative	36.47	Negative	37.46	Negative	Negative	Negative	Passed
300	189053	MALE	15	2022/1/11	Negative	37.03	Negative	35.53	Negative	36.76	Negative	Negative	Negative	Passed
301	189054	MALE	36	2022/1/11	Negative	36.11	Negative	36.58	Negative	36.81	Negative	Negative	Negative	Passed
302	189058	FEMALE	56	2022/1/11	Negative	37.29	Negative	35.05	Negative	37.94	Negative	Negative	Negative	Passed
303	189066	FEMALE	50	2022/1/11	Negative	35.59	Negative	35.46	Negative	36.02	Negative	Negative	Negative	Passed
304	189067	MALE	50	2022/1/11	Negative	36.66	Negative	36.26	Negative	37.13	Negative	Negative	Negative	Passed
305	189068	MALE	48	2022/1/11	Negative	37.14	Negative	36.42	Negative	37.32	Negative	Negative	Negative	Passed

No.	Sample ID	Gender	Age (Years)	Test date	SARS-CoV-2 RT-PCR		Influenza A RT-qPCR		Influenza B RT-qPCR		KaiBiLi Flu & COVID-19 Antigen Duo result			Comment
					Result	Ct Value	Result	Ct Value	Result	Ct Value	COVID-19	Flu A	Flu B	
306	189075	MALE	24	2022/1/11	Negative	37.6	Negative	35.7	Negative	35.35	Negative	Negative	Negative	Passed
307	189176	FEMALE	36	2022/1/12	Negative	36.13	Negative	35.16	Negative	35.7	Negative	Negative	Negative	Passed
308	189181	FEMALE	35	2022/1/12	Negative	37.13	Negative	35.32	Negative	35.67	Negative	Negative	Negative	Passed
309	189185	FEMALE	50	2022/1/12	Negative	37.41	Negative	35.56	Negative	37.26	Negative	Negative	Negative	Passed
310	189197	FEMALE	58	2022/1/12	Negative	35.67	Negative	36.66	Negative	37.11	Negative	Negative	Negative	Passed
311	189199	MALE	47	2022/1/12	Negative	36.52	Negative	35.22	Negative	36.21	Negative	Negative	Negative	Passed
312	189206	MALE	52	2022/1/12	Negative	36.66	Negative	35.37	Negative	35.73	Negative	Negative	Negative	Passed
313	189240	MALE	53	2022/1/12	Negative	35.75	Negative	37.06	Negative	36.12	Negative	Negative	Negative	Passed
314	189242	FEMALE	65	2022/1/12	Negative	36.39	Negative	35.09	Negative	35.93	Negative	Negative	Negative	Passed
315	189246	MALE	51	2022/1/12	Negative	36.42	Negative	35.06	Negative	37.06	Negative	Negative	Negative	Passed
316	189270	FEMALE	43	2022/1/12	Negative	37.25	Negative	36.14	Negative	35.68	Negative	Negative	Negative	Passed
317	189303	MALE	32	2022/1/12	Negative	37.51	Negative	36.31	Negative	37.01	Negative	Negative	Negative	Passed
318	189309	MALE	39	2022/1/12	Negative	36.74	Negative	37.27	Negative	36.12	Negative	Negative	Negative	Passed
319	189319	FEMALE	20	2022/1/12	Negative	37.93	Negative	35.65	Negative	37.8	Negative	Negative	Negative	Passed
320	189323	FEMALE	17	2022/1/12	Negative	36.51	Negative	37.29	Negative	37.91	Negative	Negative	Negative	Passed
321	189328	MALE	40	2022/1/12	Negative	36.81	Negative	36.16	Negative	37.81	Negative	Negative	Negative	Passed
322	189330	MALE	63	2022/1/12	Negative	35.2	Negative	37.04	Negative	36.76	Negative	Negative	Negative	Passed
323	189333	MALE	50	2022/1/12	Negative	35.13	Negative	37.5	Negative	36.08	Negative	Negative	Negative	Passed
324	189335	MALE	42	2022/1/12	Negative	36.3	Negative	36.87	Negative	38	Negative	Negative	Negative	Passed

Annex 3. Clinical Test Data for Influenza Positive Sample

No.	Original Sample No.	Gender	Age	Influenza RT-qPCR		KaiBili Flu & COVID-19 Antigen Duo result			Comment
				result	Ct value	Flu A	Flu B	COVID-19	
1	13325613	MALE	32	Influenza A	24.4	Positive	Negative	Negative	Passed
2	13325614	FEMALE	31	Influenza A	24.3	Positive	Negative	Negative	Passed
3	13325615	FEMALE	51	Influenza A	25	Positive	Negative	Negative	Passed
4	13325616	FEMALE	40	Influenza A	25	Positive	Negative	Negative	Passed
5	13325617	MALE	32	Influenza A	21.3	Positive	Negative	Negative	Passed
6	13325621	FEMALE	49	Influenza A	24.7	Positive	Negative	Negative	Passed
7	13325623	MALE	25	Influenza A	25.1	Positive	Negative	Negative	Passed
8	13325624	FEMALE	38	Influenza A	24.3	Positive	Negative	Negative	Passed
9	13325627	FEMALE	26	Influenza A	24	Positive	Negative	Negative	Passed
10	13325632	FEMALE	49	Influenza A	24.6	Positive	Negative	Negative	Passed
11	13325633	FEMALE	23	Influenza A	24.4	Positive	Negative	Negative	Passed
12	13325634	FEMALE	53	Influenza A	24.8	Positive	Negative	Negative	Passed
13	13325635	FEMALE	48	Influenza A	24.9	Positive	Negative	Negative	Passed
14	13325638	FEMALE	53	Influenza A	24.2	Negative	Negative	Negative	Not Passed
15	13325639	FEMALE	23	Influenza A	24.4	Positive	Negative	Negative	Passed
16	13325641	MALE	34	Influenza A	20.9	Positive	Negative	Negative	Passed
17	13325643	FEMALE	52	Influenza A	24.6	Positive	Negative	Negative	Passed
18	13325644	FEMALE	34	Influenza A	24	Positive	Negative	Negative	Passed
19	13325645	MALE	51	Influenza A	24.5	Positive	Negative	Negative	Passed
20	13325646	MALE	31	Influenza A	24.3	Positive	Negative	Negative	Passed
21	13325648	FEMALE	29	Influenza A	24.9	Positive	Negative	Negative	Passed
22	13325650	MALE	34	Influenza A	24.4	Positive	Negative	Negative	Passed
23	13325652	MALE	36	Influenza A	24.8	Positive	Negative	Negative	Passed
24	13325659	FEMALE	46	Influenza A	24.7	Positive	Negative	Negative	Passed
25	13325660	MALE	28	Influenza A	24.7	Positive	Negative	Negative	Passed
26	13325661	MALE	19	Influenza A	24	Positive	Negative	Negative	Passed
27	13325667	FEMALE	43	Influenza A	25.1	Positive	Negative	Negative	Passed
28	13325668	FEMALE	30	Influenza A	24.2	Positive	Negative	Negative	Passed
29	13325670	FEMALE	37	Influenza A	21.3	Positive	Negative	Negative	Passed
30	13325671	FEMALE	25	Influenza A	24.8	Positive	Negative	Negative	Passed
31	13325673	FEMALE	36	Influenza A	25.1	Positive	Negative	Negative	Passed
32	13325674	MALE	20	Influenza A	24.2	Positive	Negative	Negative	Passed
33	13325675	FEMALE	28	Influenza A	24.4	Positive	Negative	Negative	Passed
34	13325676	FEMALE	26	Influenza A	25	Positive	Negative	Negative	Passed
35	13325678	FEMALE	38	Influenza A	25.1	Positive	Negative	Negative	Passed
36	13325679	MALE	35	Influenza A	24.8	Positive	Negative	Negative	Passed
37	13325680	FEMALE	19	Influenza A	24.6	Positive	Negative	Negative	Passed
38	13325681	FEMALE	29	Influenza A	24.9	Positive	Negative	Negative	Passed
39	13325682	FEMALE	35	Influenza A	24.9	Positive	Negative	Negative	Passed
40	13325683	MALE	44	Influenza A	24.5	Negative	Negative	Negative	Not Passed
41	13325685	MALE	29	Influenza A	24.7	Positive	Negative	Negative	Passed
42	13325688	MALE	53	Influenza A	24.7	Positive	Negative	Negative	Passed
43	13325689	FEMALE	32	Influenza A	24.8	Positive	Negative	Negative	Passed
44	13325691	MALE	39	Influenza A	24.4	Positive	Negative	Negative	Passed
45	13325696	MALE	53	Influenza A	24.8	Positive	Negative	Negative	Passed
46	13325701	FEMALE	48	Influenza A	24.7	Positive	Negative	Negative	Passed

No.	Original Sample No.	Gender	Age	Influenza RT-qPCR		KaiBiLi Flu & COVID-19 Antigen Duo result			Comment
				result	Ct value	Flu A	Flu B	COVID-19	
47	13325702	FEMALE	36	Influenza A	24.2	Positive	Negative	Negative	Passed
48	13325703	MALE	46	Influenza A	24.8	Positive	Negative	Negative	Passed
49	13325705	FEMALE	53	Influenza A	24.7	Positive	Negative	Negative	Passed
50	13325707	FEMALE	43	Influenza A	25	Positive	Negative	Negative	Passed
51	13325708	FEMALE	26	Influenza A	24.5	Positive	Negative	Negative	Passed
52	13325709	MALE	52	Influenza A	24.3	Positive	Negative	Negative	Passed
53	13325710	FEMALE	40	Influenza A	24.1	Positive	Negative	Negative	Passed
54	13325711	FEMALE	42	Influenza A	24.7	Positive	Negative	Negative	Passed
55	13325712	FEMALE	37	Influenza B	24.7	Negative	Positive	Negative	Passed
56	13325713	FEMALE	52	Influenza B	24.1	Negative	Positive	Negative	Passed
57	13325714	FEMALE	48	Influenza B	24.2	Negative	Positive	Negative	Passed
58	13325715	FEMALE	40	Influenza B	24.1	Negative	Positive	Negative	Passed
59	13325716	MALE	24	Influenza B	21.1	Negative	Positive	Negative	Passed
60	13325719	FEMALE	52	Influenza B	24.9	Negative	Negative	Negative	Not Passed
61	13325722	FEMALE	37	Influenza B	24.8	Negative	Positive	Negative	Passed
62	13325723	MALE	51	Influenza B	24.5	Negative	Positive	Negative	Passed
63	13325724	FEMALE	35	Influenza B	24.1	Negative	Positive	Negative	Passed
64	13325727	MALE	34	Influenza B	21.2	Negative	Positive	Negative	Passed
65	13325730	FEMALE	21	Influenza B	24.5	Negative	Positive	Negative	Passed
66	13325731	MALE	50	Influenza B	24.1	Negative	Positive	Negative	Passed
67	13325732	MALE	21	Influenza B	24.7	Negative	Positive	Negative	Passed
68	13325733	FEMALE	43	Influenza B	20.9	Negative	Positive	Negative	Passed
69	13325738	MALE	54	Influenza B	24.8	Negative	Positive	Negative	Passed
70	13325740	FEMALE	24	Influenza B	24.5	Negative	Positive	Negative	Passed
71	13325741	MALE	33	Influenza B	24.6	Negative	Positive	Negative	Passed
72	13325742	MALE	25	Influenza B	24.1	Negative	Positive	Negative	Passed
73	13325743	FEMALE	43	Influenza B	24.4	Negative	Positive	Negative	Passed
74	13325744	MALE	28	Influenza B	24.9	Negative	Positive	Negative	Passed
75	13325747	MALE	22	Influenza B	24.6	Negative	Positive	Negative	Passed
76	13325750	FEMALE	38	Influenza B	24.2	Negative	Positive	Negative	Passed
77	13325751	FEMALE	43	Influenza B	24.5	Negative	Negative	Negative	Not Passed
78	13325752	FEMALE	30	Influenza B	25.1	Negative	Positive	Negative	Passed
79	13325755	MALE	31	Influenza B	24	Negative	Positive	Negative	Passed
80	13325756	FEMALE	43	Influenza B	24.5	Negative	Positive	Negative	Passed
81	13325759	FEMALE	21	Influenza B	24.6	Negative	Positive	Negative	Passed
82	13325761	FEMALE	31	Influenza B	24.4	Negative	Positive	Negative	Passed
83	13325762	FEMALE	37	Influenza B	25	Negative	Positive	Negative	Passed
84	13325771	FEMALE	29	Influenza B	24.9	Negative	Positive	Negative	Passed
85	13325772	MALE	25	Influenza B	24.4	Negative	Positive	Negative	Passed
86	13325775	FEMALE	47	Influenza B	24.4	Negative	Positive	Negative	Passed
87	13325776	MALE	19	Influenza B	24.6	Negative	Positive	Negative	Passed
88	13325777	MALE	55	Influenza B	24.7	Negative	Positive	Negative	Passed
89	13325780	FEMALE	35	Influenza B	24.1	Negative	Positive	Negative	Passed
90	13325783	FEMALE	21	Influenza B	24.4	Negative	Positive	Negative	Passed
91	13325784	MALE	43	Influenza B	25	Negative	Positive	Negative	Passed
92	13325786	FEMALE	29	Influenza B	25.1	Negative	Negative	Negative	Not Passed
93	13325788	FEMALE	53	Influenza B	24.8	Negative	Positive	Negative	Passed
94	13325789	FEMALE	50	Influenza B	25.1	Negative	Positive	Negative	Passed

No.	Original Sample No.	Gender	Age	Influenza RT-qPCR		KaiBiLi Flu & COVID-19 Antigen Duo result			Comment
				result	Ct value	Flu A	Flu B	COVID-19	
95	13325790	MALE	43	Influenza B	24	Negative	Positive	Negative	Passed
96	13325793	FEMALE	27	Influenza B	24.3	Negative	Positive	Negative	Passed
97	13325796	MALE	30	Influenza B	24.6	Negative	Positive	Negative	Passed
98	13325798	FEMALE	20	Influenza B	24.5	Negative	Positive	Negative	Passed
99	13325799	FEMALE	23	Influenza B	25	Negative	Positive	Negative	Passed
100	13325800	FEMALE	27	Influenza B	24.2	Negative	Negative	Negative	Not Passed
101	13325803	FEMALE	49	Influenza B	24.1	Negative	Positive	Negative	Passed
102	13325804	MALE	45	Influenza B	24.2	Negative	Positive	Negative	Passed
103	13325807	FEMALE	45	Influenza B	24.8	Negative	Positive	Negative	Passed
104	13325808	MALE	46	Influenza B	24.6	Negative	Positive	Negative	Passed
105	13325811	MALE	55	Influenza B	24.2	Negative	Positive	Negative	Passed

Annex 4. Test results on 106 negative samples from hospitalized cases

No.	Sample ID	Hospital Source	Gender	Age (Years)	Test date	SARS-CoV-2 RT-PCR		Influenza A RT-qPCR		Influenza B RT-qPCR		KaiBiLi Flu & COVID-19 Antigen Duo result			Comment	Cause Of hospitalization
						Result	Ct Value	Result	Ct Value	Result	Ct Value	COVID-19	Flu A	Flu B		
1	181416	AO1	FEMALE	36	2021/12/2	Negative	35.94	Negative	35.3	Negative	35.52	Negative	Negative	Negative	Passed	labor
2	181418	AO2	FEMALE	27	2021/12/2	Negative	35.62	Negative	35.97	Negative	36.99	Negative	Negative	Negative	Passed	cesarean section
3	181505	THA-1	MALE	86	2021/12/2	Negative	37.97	Negative	37.19	Negative	37.58	Negative	Negative	Negative	Passed	weakness
4	181506	THA-2	FEMALE	80	2021/12/2	Negative	36.21	Negative	36.86	Negative	37.52	Negative	Negative	Negative	Passed	dementia
5	181507	THA-3	FEMALE	60	2021/12/2	Negative	37.95	Negative	36.74	Negative	36.32	Negative	Negative	Negative	Passed	chronic kidney failure
6	181508	THA-4	MALE	89	2021/12/2	Negative	37.89	Negative	35.12	Negative	36.87	Negative	Negative	Negative	Passed	dementia
7	181510	THA-5	FEMALE	93	2021/12/2	Negative	36.65	Negative	36.92	Negative	38	Negative	Negative	Negative	Passed	stroke
8	181512	THA-6	MALE	69	2021/12/2	Negative	37.5	Negative	36.2	Negative	36.36	Negative	Negative	Negative	Passed	mobility difficulty malfunction
9	181513	THA-7	MALE	74	2021/12/2	Negative	35.2	Negative	37.81	Negative	36.07	Negative	Negative	Negative	Passed	dementia
10	181514	THA-8	FEMALE	88	2021/12/2	Negative	36.05	Negative	37.82	Negative	35.36	Negative	Negative	Negative	Passed	dementia
11	181588	AO3	FEMALE	40	2021/12/3	Negative	37.27	Negative	36.54	Negative	35.17	Negative	Negative	Negative	Passed	cesarean section
12	181589	AO4	FEMALE	40	2021/12/3	Negative	35.42	Negative	37.6	Negative	36.22	Negative	Negative	Negative	Passed	labor
13	181862	AO5	FEMALE	38	2021/12/6	Negative	35.4	Negative	35.26	Negative	36.82	Negative	Negative	Negative	Passed	cesarean section
14	182008	AO6	FEMALE	36	2021/12/7	Negative	36.47	Negative	36.24	Negative	36.49	Negative	Negative	Negative	Passed	cesarean section
15	182010	AO7	FEMALE	35	2021/12/7	Negative	35.94	Negative	37.49	Negative	36.35	Negative	Negative	Negative	Passed	labor
16	182011	AO8	FEMALE	39	2021/12/7	Negative	37.12	Negative	36.25	Negative	36.84	Negative	Negative	Negative	Passed	cesarean section
17	182260	THA-9	FEMALE	96	2021/12/8	Negative	37.31	Negative	36.99	Negative	35.01	Negative	Negative	Negative	Passed	mobility difficulty
18	182261	THA-10	FEMALE	89	2021/12/8	Negative	35.64	Negative	37.37	Negative	35.52	Negative	Negative	Negative	Passed	chronic kidney failure
19	182262	THA-11	FEMALE	93	2021/12/8	Negative	35.02	Negative	36.8	Negative	36.78	Negative	Negative	Negative	Passed	fracture spinal cord
20	182263	THA-12	FEMALE	93	2021/12/8	Negative	35.62	Negative	37.96	Negative	36.79	Negative	Negative	Negative	Passed	cardiac failure

No.	Sample ID	Hospital Source	Gender	Age (Years)	Test date	SARS-CoV-2 RT-PCR		Influenza A RT-qPCR		Influenza B RT-qPCR		KaiBiLi Flu & COVID-19 Antigen Duo result			Comment	Cause Of hospitalization
						Result	Ct Value	Result	Ct Value	Result	Ct Value	COVID-19	Flu A	Flu B		
21	182264	THA-13	FEMALE	75	2021/12/8	Negative	37.48	Negative	36.06	Negative	35.69	Negative	Negative	Negative	Passed	kidney failure
22	182265	THA-14	FEMALE	89	2021/12/8	Negative	37.25	Negative	36.79	Negative	37.89	Negative	Negative	Negative	Passed	dementia
23	182266	THA-15	FEMALE	73	2021/12/8	Negative	36.98	Negative	35.5	Negative	37.15	Negative	Negative	Negative	Passed	stroke
24	182267	THA-16	FEMALE	91	2021/12/8	Negative	36.31	Negative	35.32	Negative	37.94	Negative	Negative	Negative	Passed	cardiac failure
25	182268	THA-17	FEMALE	93	2021/12/8	Negative	35.73	Negative	35.02	Negative	36.65	Negative	Negative	Negative	Passed	chronic kidney failure
26	182270	THA-18	FEMALE	92	2021/12/8	Negative	37.29	Negative	37.2	Negative	36	Negative	Negative	Negative	Passed	gastric hemorrhage
27	182271	THA-19	FEMALE	75	2021/12/8	Negative	35.75	Negative	37.24	Negative	36.18	Negative	Negative	Negative	Passed	mobility malfunction
28	182272	THA-20	FEMALE	92	2021/12/8	Negative	37.56	Negative	35.65	Negative	36.69	Negative	Negative	Negative	Passed	dementia
29	182483	AO9	FEMALE	39	2021/12/9	Negative	36.84	Negative	36.83	Negative	37.87	Negative	Negative	Negative	Passed	labor
30	182484	A10	FEMALE	50	2021/12/9	Negative	37.79	Negative	37.6	Negative	37.58	Negative	Negative	Negative	Passed	cesarean section
31	182485	A11	FEMALE	38	2021/12/10	Negative	35.22	Negative	36.61	Negative	35.1	Negative	Negative	Negative	Passed	cesarean section
39	182659	A12	FEMALE	38	2021/12/11	Negative	37.6	Negative	36.89	Negative	35.36	Negative	Negative	Negative	Passed	cesarean section
32	182734	THA-21	MALE	82	2021/12/10	Negative	35.14	Negative	37.98	Negative	35.32	Negative	Negative	Negative	Passed	stroke
33	182735	THA-22	MALE	83	2021/12/10	Negative	35.2	Negative	36.35	Negative	36.73	Negative	Negative	Negative	Passed	ventricular fibrillation
34	182736	THA-23	FEMALE	85	2021/12/10	Negative	37.79	Negative	36.36	Negative	36.65	Negative	Negative	Negative	Passed	kidney failure
35	182737	THA-24	FEMALE	74	2021/12/10	Negative	35.41	Negative	35.27	Negative	37.54	Negative	Negative	Negative	Passed	kidney failure
36	182738	THA-25	FEMALE	83	2021/12/10	Negative	35.25	Negative	35.06	Negative	36.96	Negative	Negative	Negative	Passed	weakness
37	182739	THA-26	FEMALE	89	2021/12/10	Negative	36.16	Negative	36.18	Negative	35.01	Negative	Negative	Negative	Passed	mobility malfunction
38	182741	THA-27	MALE	68	2021/12/10	Negative	36.74	Negative	37.63	Negative	35.44	Negative	Negative	Negative	Passed	quadriplegia
40	182815	A13	FEMALE	38	2021/12/11	Negative	37.6	Negative	37.7	Negative	35.12	Negative	Negative	Negative	Passed	cesarean section
41	182816	A14	FEMALE	36	2021/12/11	Negative	37.27	Negative	36.31	Negative	37.1	Negative	Negative	Negative	Passed	cesarean section
42	182817	A15	FEMALE	30	2021/12/11	Negative	37.07	Negative	37.64	Negative	37.63	Negative	Negative	Negative	Passed	cesarean section

No.	Sample ID	Hospital Source	Gender	Age (Years)	Test date	SARS-CoV-2 RT-PCR		Influenza A RT-qPCR		Influenza B RT-qPCR		KaiBiLi Flu & COVID-19 Antigen Duo result			Comment	Cause Of hospitalization
						Result	Ct Value	Result	Ct Value	Result	Ct Value	COVID-19	Flu A	Flu B		
43	182818	A16	FEMALE	37	2021/12/11	Negative	36.26	Negative	36.25	Negative	37.54	Negative	Negative	Negative	Passed	ovarian cyst endometriosis
44	182819	A17	FEMALE	44	2021/12/11	Negative	35.93	Negative	36.1	Negative	37.87	Negative	Negative	Negative	Passed	ceaserean section
45	182820	A18	FEMALE	46	2021/12/11	Negative	35.31	Negative	36.15	Negative	35.49	Negative	Negative	Negative	Passed	ceaserean section
46	182821	A19	FEMALE	34	2021/12/11	Negative	37.41	Negative	37.82	Negative	37.22	Negative	Negative	Negative	Passed	ceaserean section
47	182955	A20	FEMALE	34	2021/12/13	Negative	37.61	Negative	36.82	Negative	36.51	Negative	Negative	Negative	Passed	labor
48	182956	A21	FEMALE	40	2021/12/13	Negative	36.86	Negative	37.94	Negative	35.2	Negative	Negative	Negative	Passed	ceaserean section
49	183253	A22	FEMALE	33	2021/12/15	Negative	36.79	Negative	36.12	Negative	36.44	Negative	Negative	Negative	Passed	labor
50	183489	A23	FEMALE	68	2021/12/16	Negative	35.1	Negative	37.73	Negative	36.79	Negative	Negative	Negative	Passed	stress urinary incontineuse
51	183840	A24	FEMALE	36	2021/12/18	Negative	35.19	Negative	36.07	Negative	36.94	Negative	Negative	Negative	Passed	labor
52	183938	A25	FEMALE	30	2021/12/20	Negative	36.49	Negative	36.68	Negative	37	Negative	Negative	Negative	Passed	labor
53	183939	A26	FEMALE	74	2021/12/20	Negative	37.9	Negative	35.05	Negative	37	Negative	Negative	Negative	Passed	hysterectomy
54	183940	A27	FEMALE	32	2021/12/20	Negative	37.39	Negative	37.66	Negative	37.32	Negative	Negative	Negative	Passed	ceaserean section
55	185514	THA-28	FEMALE	86	2021/12/28	Negative	36.71	Negative	37.01	Negative	36.27	Negative	Negative	Negative	Passed	hypotension
56	185515	THA-29	FEMALE	75	2021/12/28	Negative	36.52	Negative	36.96	Negative	35.01	Negative	Negative	Negative	Passed	kidney failure
57	185516	THA 30	MALE	93	2021/12/28	Negative	37.35	Negative	37.28	Negative	36.8	Negative	Negative	Negative	Passed	kidney failure
58	185517	THA 31	FEMALE	83	2021/12/28	Negative	36.45	Negative	36.96	Negative	37.1	Negative	Negative	Negative	Passed	mobility malfuntion
59	185518	THA 32	FEMALE	42	2021/12/28	Negative	35.68	Negative	36.55	Negative	37.03	Negative	Negative	Negative	Passed	mobility malfuntion
60	185519	THA 33	MALE	92	2021/12/28	Negative	36.69	Negative	36.09	Negative	36.06	Negative	Negative	Negative	Passed	dementia
61	185520	THA 34	MALE	91	2021/12/28	Negative	36.3	Negative	36.47	Negative	35.45	Negative	Negative	Negative	Passed	cardiac failure
62	185521	THA 35	FEMALE	93	2021/12/28	Negative	36.71	Negative	35.13	Negative	35.84	Negative	Negative	Negative	Passed	fracture spinal cord
63	185522	THA 36	FEMALE	89	2021/12/28	Negative	37.12	Negative	36.29	Negative	35.01	Negative	Negative	Negative	Passed	kidney failure
64	185523	THA 37	FEMALE	93	2021/12/28	Negative	35.75	Negative	37.04	Negative	35.65	Negative	Negative	Negative	Passed	mobility malfuntion
65	185524	THA 38	MALE	86	2021/12/28	Negative	37.35	Negative	37.23	Negative	37.44	Negative	Negative	Negative	Passed	kidney failure

No.	Sample ID	Hospital Source	Gender	Age (Years)	Test date	SARS-CoV-2 RT-PCR		Influenza A RT-qPCR		Influenza B RT-qPCR		KaiBiLi Flu & COVID-19 Antigen Duo result			Comment	Cause Of hospitalization
						Result	Ct Value	Result	Ct Value	Result	Ct Value	COVID-19	Flu A	Flu B		
66	185525	THA 39	FEMALE	55	2021/12/28	Negative	36.81	Negative	37.62	Negative	36.21	Negative	Negative	Negative	Passed	kidney failure
67	185526	THA 40	MALE	83	2021/12/28	Negative	35.25	Negative	37.8	Negative	37.14	Negative	Negative	Negative	Passed	hepatic fibrosis kirrrosis
68	185527	THA 41	FEMALE	89	2021/12/28	Negative	35.21	Negative	36.7	Negative	35.12	Negative	Negative	Negative	Passed	lower respiratory infection
69	185783	THA 42	MALE	74	2021/12/29	Negative	37.04	Negative	36.14	Negative	35.16	Negative	Negative	Negative	Passed	dementia
70	185784	THA 43	MALE	69	2021/12/29	Negative	37.12	Negative	35.9	Negative	35.94	Negative	Negative	Negative	Passed	mobility malfuntion
71	185785	THA 44	FEMALE	81	2021/12/29	Negative	37.52	Negative	36.6	Negative	36.13	Negative	Negative	Negative	Passed	stroke
72	185786	THA 45	MALE	82	2021/12/29	Negative	37.84	Negative	37.3	Negative	36.85	Negative	Negative	Negative	Passed	weakness
73	185787	THA 46	MALE	88	2021/12/29	Negative	35.5	Negative	36.26	Negative	37.94	Negative	Negative	Negative	Passed	generaized malignancy unknown origin
74	185790	THA 47	MALE	92	2021/12/29	Negative	35.33	Negative	36.32	Negative	37.01	Negative	Negative	Negative	Passed	adbominal pelvic pain
75	185795	THA 48	FEMALE	60	2021/12/29	Negative	36.18	Negative	37.31	Negative	35.23	Negative	Negative	Negative	Passed	chronic renal failure
76	185796	THA 49	FEMALE	80	2021/12/29	Negative	37.49	Negative	35.37	Negative	37.64	Negative	Negative	Negative	Passed	dementia
77	185799	THA 50	FEMALE	88	2021/12/29	Negative	37.72	Negative	36.8	Negative	35.26	Negative	Negative	Negative	Passed	dementia
78	185800	THA 51	FEMALE	93	2021/12/29	Negative	36.7	Negative	36.16	Negative	35.47	Negative	Negative	Negative	Passed	cardiac failure
79	185801	THA 52	MALE	91	2021/12/29	Negative	36.13	Negative	35.09	Negative	36.19	Negative	Negative	Negative	Passed	cardiac failure
80	185802	THA 53	MALE	93	2021/12/29	Negative	36.01	Negative	36.3	Negative	36.18	Negative	Negative	Negative	Passed	renal failure final stage
81	185804	THA 54	FEMALE	83	2021/12/29	Negative	37.1	Negative	37.55	Negative	37.1	Negative	Negative	Negative	Passed	mobility malfuntion
82	185805	THA 55	FEMALE	75	2021/12/29	Negative	35.56	Negative	36.98	Negative	35.08	Negative	Negative	Negative	Passed	mobility malfuntion
83	185807	THA 56	FEMALE	92	2021/12/29	Negative	37.23	Negative	37.59	Negative	36.68	Negative	Negative	Negative	Passed	dementia
84	185808	THA 57	FEMALE	89	2021/12/29	Negative	36.03	Negative	36.34	Negative	37.85	Negative	Negative	Negative	Passed	renal failure final stage
85	185811	THA 58	FEMALE	93	2021/12/29	Negative	36.88	Negative	37.18	Negative	35.43	Negative	Negative	Negative	Passed	fracture spinal cord
86	185814	THA 59	MALE	86	2021/12/29	Negative	36.5	Negative	37.43	Negative	36.09	Negative	Negative	Negative	Passed	hypotension

No.	Sample ID	Hospital Source	Gender	Age (Years)	Test date	SARS-CoV-2 RT-PCR		Influenza A RT-qPCR		Influenza B RT-qPCR		KaiBiLi Flu & COVID-19 Antigen Duo result			Comment	Cause Of hospitalization
						Result	Ct Value	Result	Ct Value	Result	Ct Value	COVID-19	Flu A	Flu B		
87	185815	THA 60	FEMALE	75	2021/12/29	Negative	37.47	Negative	36.89	Negative	35.64	Negative	Negative	Negative	Passed	renal failure final stage
88	185817	THA 61	FEMALE	67	2021/12/29	Negative	35.45	Negative	37.59	Negative	35.39	Negative	Negative	Negative	Passed	abdominal pelvic pain
89	185818	THA 62	FEMALE	74	2021/12/29	Negative	35.93	Negative	37.37	Negative	35.94	Negative	Negative	Negative	Passed	renal failure final stage
90	185819	THA 63	FEMALE	68	2021/12/29	Negative	35.78	Negative	37.26	Negative	36.41	Negative	Negative	Negative	Passed	tetraplegia
91	185821	THA 64	FEMALE	82	2021/12/29	Negative	37.6	Negative	37.17	Negative	35.97	Negative	Negative	Negative	Passed	stroke
92	185822	THA 65	MALE	73	2021/12/29	Negative	35.91	Negative	36.33	Negative	36.9	Negative	Negative	Negative	Passed	lung cancer
93	185823	THA 66	FEMALE	90	2021/12/29	Negative	35.89	Negative	37.83	Negative	37.75	Negative	Negative	Negative	Passed	weakness
94	185824	THA 67	FEMALE	80	2021/12/29	Negative	36.92	Negative	35.01	Negative	35.59	Negative	Negative	Negative	Passed	weakness
95	186236	THA68	MALE	86	2021/12/30	Negative	37.44	Negative	36.43	Negative	35.93	Negative	Negative	Negative	Passed	hypotension
96	186248	THA69	MALE	91	2021/12/30	Negative	37.07	Negative	37.66	Negative	36.98	Negative	Negative	Negative	Passed	cardiac failure
97	186249	THA70	FEMALE	89	2021/12/30	Negative	36.81	Negative	35.14	Negative	35.99	Negative	Negative	Negative	Passed	renal failure final stage
98	186251	THA71	FEMALE	92	2021/12/30	Negative	35.69	Negative	36.89	Negative	37.64	Negative	Negative	Negative	Passed	abdominal pelvic pain
99	186252	THA72	FEMALE	81	2021/12/30	Negative	35.74	Negative	37.16	Negative	37.45	Negative	Negative	Negative	Passed	stroke
100	186253	THA73	FEMALE	88	2021/12/30	Negative	35.04	Negative	36.65	Negative	37.01	Negative	Negative	Negative	Passed	dementia
101	186255	THA74	FEMALE	93	2021/12/30	Negative	35.94	Negative	35.1	Negative	35.27	Negative	Negative	Negative	Passed	heart failure
102	186256	THA75	FEMALE	82	2021/12/30	Negative	37.61	Negative	36.67	Negative	37.32	Negative	Negative	Negative	Passed	weakness
103	186258	THA76	MALE	82	2021/12/30	Negative	37.89	Negative	36.24	Negative	37.65	Negative	Negative	Negative	Passed	stroke
104	186259	THA77	FEMALE	89	2021/12/30	Negative	35.23	Negative	35.5	Negative	36.67	Negative	Negative	Negative	Passed	lower respiratory infection
105	186260	THA78	FEMALE	74	2021/12/30	Negative	37.01	Negative	37.41	Negative	37.47	Negative	Negative	Negative	Passed	renal failure final stage
106	186262	THA79	MALE	73	2021/12/30	Negative	36.94	Negative	35.8	Negative	35.92	Negative	Negative	Negative	Passed	lung cancer

Annex 5. Cross-reactivity test results on 66 samples containing other respiratory pathogens

No.	Pathogen	Age	Gender	SARS-CoV-2 RT-PCR result	COVID-19 Antigen result	Comment	Cause Of hospitalization
1	RSV & HPIV-3	30 Y	FEMALE	Negative	Negative	Passed	throat pain, low fever
2	Adenovirus	20 M	FEMALE	Negative	Negative	Passed	respiratory infection, Rhinitis, 4 day fever
3	RSV	10 M	MALE	Negative	Negative	Passed	Rhinitis, 3 day fever
4	Adenovirus & HPIV-3	42 Y	FEMALE	Negative	Negative	Passed	throat pain, low fever, cough
5	Rotavirus	43 Y	FEMALE	Negative	Negative	Passed	fever (38), nose flow
6	Coronavirus (NL-63, 229E)	80 Y	MALE	Negative	Negative	Passed	Fever, congestion, throat pain
7	Rotavirus	61 Y	MALE	Negative	Negative	Passed	Congestion, throat pain
8	Rotavirus	54 Y	MALE	Negative	Negative	Passed	nose flow, cough
9	Rotavirus	37 Y	FEMALE	Negative	Negative	Passed	Cough, fever (39.3)
10	Coronavirus (NL-63, 229E)	44 Y	MALE	Negative	Negative	Passed	nose flow
11	Adenovirus	17.5 M	FEMALE	Negative	Negative	Passed	3 day fever 38.5, cough, Rhinitis
12	RSV	6 M	FEMALE	Negative	Negative	Passed	fever (38.4), Rhinitis, Vronghites
13	RSV	3 Y	MALE	Negative	Negative	Passed	Respiratory ionization, fever 24h, Rhinitis- Vronghites
14	Adenovirus & Coronavirus (NL-63, 229E)	8 Y	FEMALE	Negative	Negative	Passed	low fever, cough
15	Rotavirus	20 Y	MALE	Negative	Negative	Passed	cough
16	Adenovirus	56 Y	MALE	Negative	Negative	Passed	Head pain, fever (38)
17	RSV	18 Y	FEMALE	Negative	Negative	Passed	lower respiratory infection, congestion, nose flow, cough
18	RSV	67 Y	MALE	Negative	Negative	Passed	Fever, congestion
19	Adenovirus	40 Y	FEMALE	Negative	Negative	Passed	throat pain, cough
20	RSV	52 Y	FEMALE	Negative	Negative	Passed	unknown
21	Adenovirus	20 Y	FEMALE	Negative	Negative	Passed	Cough, congestion
22	Rotavirus	29 Y	MALE	Negative	Negative	Passed	unknown
23	Metapneumovirus	33 Y	MALE	Negative	Negative	Passed	unknown
24	Rotavirus	42 Y	FEMALE	Negative	Negative	Passed	unknown
25	RSV	42 Y	FEMALE	Negative	Negative	Passed	Congestion, cough
26	Rotavirus	50 Y	MALE	Negative	Negative	Passed	Congestion, throat pain
27	RSV & HPIV-3	33 Y	FEMALE	Negative	Negative	Passed	throat pain
28	Adenovirus	18 M	FEMALE	Negative	Negative	Passed	Rhinitis
29	RSV	10 Y	MALE	Negative	Negative	Passed	3 day fever
30	Adenovirus & HPIV-3	46 Y	FEMALE	Negative	Negative	Passed	cough
31	Rotavirus	33 Y	FEMALE	Negative	Negative	Passed	fever (39)
32	Coronavirus (NL-63, 229E)	68 Y	MALE	Negative	Negative	Passed	fever
33	Rotavirus	63 Y	MALE	Negative	Negative	Passed	throat pain
34	Rotavirus	55 Y	MALE	Negative	Negative	Passed	cough
35	Rotavirus	39 Y	FEMALE	Negative	Negative	Passed	cough

No.	Pathogen	Age	Gender	SARS-CoV-2 RT-PCR result	COVID-19 Antigen result	Comment	Cause Of hospitalization
36	Coronavirus (NL-63, 229E)	24 Y	FEMALE	Negative	Negative	Passed	cough
37	Adenovirus	11 Y	MALE	Negative	Negative	Passed	respiratory infection
38	RSV	16 Y	MALE	Negative	Negative	Passed	respiratory infection
39	RSV	13 Y	FEMALE	Negative	Negative	Passed	respiratory infection
40	Adenovirus & Coronavirus (NL-63, 229E)	18 Y	FEMALE	Negative	Negative	Passed	low fever
41	Rotavirus	29 Y	FEMALE	Negative	Negative	Passed	cough
42	Adenovirus	68 Y	FEMALE	Negative	Negative	Passed	fever (38)
43	RSV	18 Y	FEMALE	Negative	Negative	Passed	fever
44	RSV	22 Y	FEMALE	Negative	Negative	Passed	fever
45	Adenovirus	32 Y	FEMALE	Negative	Negative	Passed	cough
46	RSV	52 Y	FEMALE	Negative	Negative	Passed	cough
47	Adenovirus	20 Y	FEMALE	Negative	Negative	Passed	cough
48	Rotavirus	28 Y	MALE	Negative	Negative	Passed	congestion
49	Metapneumovirus	33 Y	FEMALE	Negative	Negative	Passed	congestion
50	Rotavirus	45 Y	FEMALE	Negative	Negative	Passed	cough
51	RSV	42 Y	FEMALE	Negative	Negative	Passed	congestion
52	Rotavirus	50 Y	MALE	Negative	Negative	Passed	Congestion, throat pain
53	Influenza B	22 Y	MALE	Negative	Negative	Passed	fever
54	Influenza A	32 Y	FEMALE	Negative	Negative	Passed	fever
55	Influenza A	21 Y	FEMALE	Negative	Negative	Passed	fever
56	Staphylococci	47 Y	MALE	Negative	Negative	Passed	fever
57	Influenza B	54 Y	MALE	Negative	Negative	Passed	fever
58	Influenza A	45 Y	FEMALE	Negative	Negative	Passed	fever
59	Influenza B	47 Y	FEMALE	Negative	Negative	Passed	fever
60	Streptococcus pneumoniae	32 Y	MALE	Negative	Negative	Passed	fever
61	Influenza B	18 Y	FEMALE	Negative	Negative	Passed	fever
62	Staphylococci	18 Y	MALE	Negative	Negative	Passed	fever
63	Influenza A	22 Y	FEMALE	Negative	Negative	Passed	fever
64	Influenza B	27 Y	FEMALE	Negative	Negative	Passed	fever
65	Influenza A	28 Y	MALE	Negative	Negative	Passed	fever
66	Streptococcus pneumoniae	30 Y	FEMALE	Negative	Negative	Passed	fever