Locus Medicus Medical SA

Clinical Performance Study Report

EZER COVID-19 Antigen Rapid Test

REF：P213104 (1Test/Kit), P213105 (5Tests/Kit), P213108 (20Tests/Kit)

Analytical／Diagnostic specificity
Diagnostic sensitivity

Sponsor：

Hangzhou Genesis Biodetection and Biocontrol Co., Ltd.

ADD：No.139, 10th Street (East), Hangzhou Economic &
Technological Development Zone, Hangzhou, China, 310018

Web：https://www.genesis-ivd.com

Content

1. Purpose of the Study

The objective of this performance study is to establish the sensitivity and specificity of the EZER COVID-19 Antigen Rapid Test (hereinafter referred to as EZER COVID-19 Ag) (REF: P213104, P213105, P213108) in order to meet the "Guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical devices" of the MDCG dated August 2021.

2. Sponsor - investigation - study coordination

2.1 Sponsor:

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2.3 Study Coordination:

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Researchers	Title	Take responsibility
Dr. Georgios Georgoulias	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

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.

4. Test principle

The EZER COVID-19 Ag is an immunochromatographic assay for the qualitative detection of SARS-CoV-2 antigens.

The EZER COVID-19 Ag 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 EZER COVID-19 Ag 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.

The objective of this performance study was to establish the diagnostic sensitivity and diagnostic and analytical specificity of the EZER COVID-19 Ag in order to meet the "Guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical devices" of the MDCG dated August 2021.

5.2 Samples included:

5.2.1 The overall study size should not be less than 550 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.
— 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.
— Consideration of genetic variants, for the purpose of evaluation, at least 3 samples should be represented for each genetic variant.

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 EZER COVID-19 Ag, and the nasopharyngeal swab will be tested with RT-PCR assay for detection of SARS-CoV-2. The sensitivity and specificity of EZER COVID-19 Ag relative to the RT-PCR test will be calculated.

The genetic variants of samples would be examined as well and applied to evaluate the detection sensitivity of EZER COVID-19 Ag on genetic variants.

The diagnostic specificity of EZER COVID-19 Ag 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

The assays clinical performance is considered acceptable if the following requirements 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-C0V-2-rapid antigen test.

Diagnostic specificity:
Method: Examinations of at least 300 asymptomatic persons without a concrete risk of exposure in the rapid SARS-C0V2 antigen test; clarification of any reactive samples by means of PCR.
Criterion: Specificity >98%.

5.5 Reference Test

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

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. Duration

Starting date: 4th of December, 2021
End-date: 14th of January, 2022

7. Description Device

7.1 Identification
EZER COVID-19 Antigen Rapid Test

7.2 Manufacturer
Hangzhou Genesis Biodetection and Biocontrol Co., Ltd.

7.3 Intended purpose
The EZER COVID-19 Ag is a rapid, lateral flow immunochromatography assay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swab specimens directly from individuals within 7 days of symptom onset or without symptoms or other epidemiological reasons to suspect COVID-19 infection.

This test is for laymen with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older, or adult collected anterior nasal swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

7.4 Analyte or marker
SARS-CoV-2 nucleocapsid protein antigen

7.5 Specimen Type
Anterior nasal swab

7.6 Metrological Traceability
Not applicable.

7.7 Technical and Functional Features
The EZER COVID-19 Ag an immunochromatographic assay for the qualitative detection of 2019 Novel Coronavirus antigens. The EZER COVID-19 Ag has two letters on the surface of the test device 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, with a high accuracy.

8. Study Design

8.1 Materials Supplied by the manufacturer.

8.1.1 Test Kits and Instructions for Use
Sufficient kits of the EZER COVID-19 Ag together with the Instructions for Use have been supplied free of charge to carry out the entire evaluation.

8.1.2 Instrument
Not applicable.

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.

EZER COVID-19 Antigen Rapid Test used:
Lot number: LB21110202 Expiry date: 2023-11-27

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 from cell-free body fluids.
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

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 EZER COVID-19 Ag 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 EZER COVID-19 Ag 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 filtered 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 Georgoulias, 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 Rapid SARS-C0V-2 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^{TM} 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 Hospital and Therapeftirio Ayhinon Hospital, Greece were collected and then tested with EZER COVID-19 Ag 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 EZER COVID-19 Ag for potentially interfering and cross-reactive substances.

(2) The specimens were collected and tested with EZER COVID-19 Ag 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 EZER COVID-19 Ag.

(2) Stock SARS-CoV-2 variants, including alpha, beta, gamma, 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 EZER COVID-19 Ag 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 EZER COVID-19 Ag 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 EZER COVID-19 Ag 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

<u>True positive sample</u>: sample that was determined positive both using the EZER COVID-19 Ag and by RT-PCR.

<u>False positive sample</u>: sample that was determined positive using the EZER COVID-19 Ag, but negative by RT-PCR.

<u>True negative sample</u>: sample that was determined negative both using the EZER COVID-19 Ag and by RT-PCR.

<u>False negative sample</u>: sample that was determined negative using the EZER COVID-19 Ag, but positive by RT-PCR.

<u>Sensitivity (Positive Percent Agreement)</u>: True Positives/True Positives + False Negatives

<u>Specificity (Negative Percent Agreement)</u>: True Negatives/True Negatives + False Positives

<u>Positive Predictive Value</u>: True Positives/Positive

<u>Negative Predictive Value</u>: True Negatives/Negative

<u>Coincidence rate (Overall Percent Agreement)</u>: True Positives + True Negatives/Total Samples

<u>C.I.</u>: Confidence Interval

10. Results

10.1 Diagnostic sensitivity and Diagnostic specificity

10.1.1 Demographics of subjects:

All the 450 clinical samples were from outpatients and covered different ages. 221 specimens (49.1%) were collected from male, and the remaining 229 were from female (50.9%). Table 10.1.1(a) and 10.1.1(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	
SARS-CoV-2 RT-PCR result	Positive	Negative	Positive	Negative
Quantity (%)	78(33.8%)	153(66.2%)	71(30.6%)	161(69.4%)
TOTAL	231(49.1%)		232(50.9%)	

Table 10.1.1(b). Test result broken down by age

Age group (Year)	SARS-CoV-2 RT-PCR result		Total
	Positive	Negative	
0~20	47 (31.5%)	27 (8.6%)	74(16.0%)
21~40	47 (31.5%)	100 (31.8%)	147(31.7%)
41~60	50 (33.6%)	152 (48.4%)	202(43.6%)
61~80	4 (2.7%)	33 (10.5%)	37(8.0%)
>80	1 (0.7%)	2 (0.6%)	3(0.7%)
Total	149	314	463

10.1.2 Sensitivity of COVID-19 Antigen Rapid Test

(1) EZER COVID-19 Ag result for 149 confirmed SARS-CoV-2 RT-PCR positive specimens. Detailed test results are presented in **Annex 1.** Clinical Test Data for Positive Sample.

EZER COVID-19 Ag reveals a sensitivity of 98.0% for SARS-CoV-2 RT-PCR confirmed positive samples with Ct-value of up to 33.6. Samples with a higher Ct-value detected by real-time RT-PCR refers to less viral RNA copies as well as viral antigen in the samples, which result in a little bit lower detection rate for the EZER COVID-19 Ag. This is in line with the expectations regarding viral detection by antigen rapid testing comparing to PCR analysis. The statistical results are shown in the table below,

Ct-value	Number of Samples	Number of true positive Rapid Test Samples	Number of false negative Rapid Test Samples	Sensitivity of EZER COVID-19 Ag
≤20	121	121	0	100 %
≤25	140	140	0	100 %
≤30	145	144	1	99.3 %
<35	149	146	3	98.0%

(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)	44	5	2	4	55
1	28	6	1	0	35
2	20	0	1	0	21
3	29	8	1	0	38
TOTAL	121	19	5	4	149

(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, 12 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	182667	MALE	31	Positive	18.0	Positive	passed
2	182683	MALE	47	Positive	16.0	Positive	passed
3	182687	MALE	42	Positive	13.0	Positive	passed
4	182698	FEMALE	30	Positive	14.0	Positive	passed
5	182703	FEMALE	40	Positive	16.0	Positive	passed
6	182774	MALE	28	Positive	9.4	Positive	passed

7	184993	MALE	57	Positive	12.4	Positive	passed
8	184994	MALE	28	Positive	13.6	Positive	passed
9	188559	MALE	34	Positive	20.0	Positive	passed
10	188560	FEMALE	7	Positive	17.0	Positive	passed
11	188661	MALE	35	Positive	22.0	Positive	passed
12	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 Diagnostic specificity

EZER COVID-19 Ag result for 314 confirmed SARS-CoV-2 RT-PCR negative specimens, detailed test results are presented in **Annex 2.** Clinical Test Data for Negative Sample from non-infected individuals

Number of Samples	Number of true neg. Rapid Test Samples	Number of false positive Rapid Test Samples	Specificity of EZER COVID-19 Antigen Rapid Test
314	312	2	99.4%

Diagnostic Specificity of EZER COVID-19 Ag: 100% (100/100).

10.1.4 Analytical Results of COVID-19 Antigen Rapid Tests

A total of 463 clinical specimens were collected from individual symptomatic patients in the Locus Medicus Medical SA, Greece. Among the 463 specimens, 149 were confirmed positive by Sacace[TM] SARS-CoV-2 RT-PCR, EZER COVID-19 Antigen Rapid Test detects 146 positive out of the 149 specimens, and the sensitivity of EZER COVID-19 Antigen Rapid Test is 98.0%. 314 were confirmed negative by Sacace[TM] SARS-CoV-2 RT-PCR, EZER COVID-19 Antigen Rapid Test detects 312 out of the 314 specimens, and the specificity of EZER COVID-19 Antigen Rapid Test is 99.4%. The accuracy rate is 98.9%; Kappa value: 0.9752 indicates good consistency. The analysis results are as below：

		RT-PCR		
		Positive	Negative	Total
COVID-19 Antigen Self-Test	Positive	146	2	148
	Negative	3	312	315
	Total	149	314	463

Statistics	Numerical ratio	Percentage（95% C.I.）
Sensitivity	146/149	98.0% (94.2%~99.6%)
Specificity	312/314	99.4% (97.7%~99.9%)
Positive Predictive Value	146/148	98.7% (95.2%~99.8%)
Negative Predictive Value	312/315	99.1% (97.2%~99.8%)
Accuracy	458/463	98.9% (97.5%~99.7%)
Kappa value: 0.9752		

10.2 Diagnostic specificity 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 EZER COVID-19 Ag 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 10.2(a) and Table 10.2(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 3* Test results on 106 negative samples from hospitalized cases.

Table 10.2(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 10.2(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

10.3 Diagnostic specificity form potentially interfering and cross-reactive samples

Nasal swab specimens from 66 patients with respiratory symptoms and confirmed with SARS-CoV-2 RT-PCR negative result were tested with EZER COVID-19 Ag. The Kit reveals negative results for all the 66 specimens and the consistency rate is 100%. Detailed test results are presented in *Annex 4*. Cross-reactivity test results on 66 samples containing other respiratory pathogens.

Table 10.3(a) and Table 10.3(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[TM] 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 10.3(c) Cross-reactivity test result.

Table 10.3(a). Samples broken down by gender

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

Table 10.3(b). Samples broken down by age

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

Table 10.3(c). Cross-reactivity test result

Strains	Quantity	EZER 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
Streptococcus pneumoniae	2	100% (2/2)
Staphylococci	2	100% (2/2)

11. Conclusion

The specificity and sensitivity of the EZER COVID-19 Ag was evaluated in this study with 463 nasal swab samples. All samples were tested in parallel with the EZER COVID-19 Ag and a SARS-CoV-2 RT-PCR assay. The correlation between the EZER COVID-19 Ag result and RT-PCR Ct values was further analyzed.

All samples were tested in parallel with the EZER COVID-19 Ag and a SARS-CoV-2 RT-PCR assay. The correlation between the EZER COVID-19 Ag test result and RT-PCR Ct values was further analyzed. In this study, EZER COVID-19 Ag demonstrated a high specificity of 99.4%

(312/314), and a great sensitivity of 98.0 % for Ct-value up to 33.6.　Among 149 samples with Ct-value up to 33.6, COVID-19 Antigen Rapid Test detected 146.

66 nasal specimens collected from patients with respiratory symptoms and confirmed with SARS-CoV-2 RT-PCR negative results were tested with EZER COVID-19 Ag. The specimens were also tested for diagnosing pathogens that lead to the patient respiratory symptoms. All the 66 specimens were detected negative by EZER COVID-19 Ag, and the result demonstrated that EZER COVID-19 Ag has no cross-reactivity with the microbial diagnosed from the 66 clinical specimens.

To understand the performance of COVID-19 Ag on SARS-CoV-2 variants, 48 specimens tested with variants of SARS-CoV-2 by RT-PCR, including Delta (12) and Omicron (36), were retrospectively collected and tested with COVID-19 Antigen Rapid Test. All the 48 specimens were detected positive with COVID-19 Antigen Rapid Test.

In conclusion, this study demonstrated that the EZER COVID-19 Ag is a reliable diagnostic tool for the qualitative detection of SARS-CoV-2 antigen 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 Positive Sample
Annex 2. Clinical Test Data for Negative Sample from non-infected individuals
Annex 3. Test results on 106 negative samples from hospitalized cases
Annex 4. Cross-reactivity test results on 66 samples containing other respiratory pathogens

14. Approval

Reviewer

Locus Medicus Medical SA
Name : Dr. Harilaos P. Kavvadas
Function : Report Reviewing
Date: February 20, 2022   Signature :

Approval

Locus Medicus Medical SA
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 Positive Sample

No.	Sample ID	Gender	Age (Years)	Days of symp. onset	Test date	EZER COVID-19 Ag result	SARS-CoV-2 RT-PCR result	Ct Value	Variant	Comment
1	182667	MALE	31	1	2021/12/10	POSITIVE	POSITIVE	18.0	Delta	Passed
2	182683	MALE	47	0	2021/12/10	POSITIVE	POSITIVE	16.0	Delta	Passed
3	182687	MALE	42	1	2021/12/10	POSITIVE	POSITIVE	13.0	Delta	Passed
4	182698	FEMALE	30	0	2021/12/10	POSITIVE	POSITIVE	14.0	Delta	Passed
5	182703	FEMALE	40	3	2021/12/10	POSITIVE	POSITIVE	16.0	Delta	Passed
6	182774	MALE	28	3	2021/12/11	POSITIVE	POSITIVE	9.4	Delta	Passed
7	182794	MALE	44	3	2021/12/11	POSITIVE	POSITIVE	17.2	—	Passed
8	182795	MALE	7	1	2021/12/11	POSITIVE	POSITIVE	26.0	—	Passed
9	182935	FEMALE	18	3	2021/12/13	POSITIVE	POSITIVE	18.0	—	Passed
10	183203	FEMALE	42	1	2021/12/15	POSITIVE	POSITIVE	24.0	—	Passed
11	183223	FEMALE	4	3	2021/12/15	POSITIVE	POSITIVE	21.0	—	Passed
12	183224	MALE	40	3	2021/12/15	POSITIVE	POSITIVE	8.0	—	Passed
13	183234	FEMALE	61	3	2021/12/15	POSITIVE	POSITIVE	20.0	—	Passed
14	183238	MALE	37	0	2021/12/15	POSITIVE	POSITIVE	20.0	—	Passed
15	183239	FEMALE	4	3	2021/12/15	POSITIVE	POSITIVE	19.0	—	Passed
16	183242	MALE	8	1	2021/12/15	POSITIVE	POSITIVE	20.0	—	Passed
17	183243	FEMALE	31	3	2021/12/15	POSITIVE	POSITIVE	14.0	—	Passed
18	183252	MALE	60	2	2021/12/15	POSITIVE	POSITIVE	17.0	—	Passed
19	183337	MALE	55	3	2021/12/16	POSITIVE	POSITIVE	12.0	—	Passed
20	183448	FEMALE	47	2	2021/12/16	POSITIVE	POSITIVE	13.0	—	Passed
21	183659	MALE	50	1	2021/12/17	POSITIVE	POSITIVE	22.0	—	Passed
22	183668	MALE	20	0	2021/12/17	POSITIVE	POSITIVE	19.0	—	Passed
23	183736	FEMALE	27	3	2021/12/17	POSITIVE	POSITIVE	12.5	—	Passed
24	183804	MALE	64	1	2021/12/18	POSITIVE	POSITIVE	23.1	—	Passed
25	183805	FEMALE	47	0	2021/12/18	POSITIVE	POSITIVE	14.3	—	Passed
26	183806	FEMALE	9	1	2021/12/18	POSITIVE	POSITIVE	12.7	—	Passed
27	183822	MALE	20	0	2021/12/18	POSITIVE	POSITIVE	15.7	—	Passed
28	183824	FEMALE	41	0	2021/12/18	POSITIVE	POSITIVE	16.3	—	Passed
29	183829	MALE	22	0	2021/12/18	NEGATIVE	POSITIVE	33.6	—	Not Passed
30	183836	FEMALE	44	3	2021/12/18	POSITIVE	POSITIVE	17.2	—	Passed
31	183849	MALE	8	3	2021/12/19	POSITIVE	POSITIVE	12.5	—	Passed
32	183850	MALE	11	2	2021/12/19	POSITIVE	POSITIVE	13.4	—	Passed
33	183872	MALE	27	0	2021/12/20	POSITIVE	POSITIVE	30.4	—	Passed
34	184023	MALE	54	0	2021/12/21	POSITIVE	POSITIVE	14.0	—	Passed
35	184052	FEMALE	35	3	2021/12/21	POSITIVE	POSITIVE	14.0	—	Passed
36	184053	FEMALE	6	2	2021/12/21	POSITIVE	POSITIVE	20.0	—	Passed
37	184145	FEMALE	94	0	2021/12/21	POSITIVE	POSITIVE	15.0	—	Passed
38	184147	FEMALE	65	0	2021/12/21	POSITIVE	POSITIVE	11.0	—	Passed
39	184148	FEMALE	46	3	2021/12/21	POSITIVE	POSITIVE	22.0	—	Passed
40	184213	FEMALE	13	3	2021/12/21	POSITIVE	POSITIVE	25.0	—	Passed
41	184214	FEMALE	9	3	2021/12/21	POSITIVE	POSITIVE	12.0	—	Passed
42	184291	MALE	56	2	2021/12/22	POSITIVE	POSITIVE	14.0	—	Passed
43	184321	MALE	22	0	2021/12/22	POSITIVE	POSITIVE	15.0	—	Passed
44	184335	FEMALE	15	3	2021/12/22	POSITIVE	POSITIVE	27.0	—	Passed
45	184336	FEMALE	27	0	2021/12/22	POSITIVE	SPOSITIVE	25.0	—	Passed
46	184353	FEMALE	53	0	2021/12/22	POSITIVE	POSITIVE	11.0	—	Passed

No.	Sample ID	Gender	Age (Years)	Days of symp. onset	Test date	EZER COVID-19 Ag result	SARS-CoV-2 RT-PCR result	Ct Value	Variant	Comment
47	184502	MALE	21	0	2021/12/23	POSITIVE	POSITIVE	31.0	—	Passed
48	184531	FEMALE	45	1	2021/12/23	POSITIVE	POSITIVE	15.0	—	Passed
49	184730	FEMALE	45	1	2021/12/24	POSITIVE	POSITIVE	15.0	—	Passed
50	184731	MALE	50	1	2021/12/24	POSITIVE	POSITIVE	15.0	—	Passed
51	184774	MALE	48	3	2021/12/24	POSITIVE	POSITIVE	13.0	—	Passed
52	184792	MALE	25	0	2021/12/24	NEGATIVE	POSITIVE	32	—	Not Passed
53	184796	MALE	50	1	2021/12/24	POSITIVE	POSITIVE	18.0	—	Passed
54	184797	MALE	19	0	2021/12/24	POSITIVE	POSITIVE	15	—	Passed
55	184824	FEMALE	46	1	2021/12/24	POSITIVE	POSITIVE	13	—	Passed
56	184875	FEMALE	10	3	2021/12/24	POSITIVE	POSITIVE	18.0	—	Passed
57	184894	FEMALE	52	0	2021/12/24	POSITIVE	POSITIVE	15.0	—	Passed
58	184919	FEMALE	31	2	2021/12/24	POSITIVE	POSITIVE	17.0	—	Passed
59	184926	FEMALE	30	1	2021/12/24	POSITIVE	POSITIVE	10	—	Passed
60	184945	FEMALE	35	0	2021/12/27	NEGATIVE	POSITIVE	30.0	—	Not Passed
61	184962	FEMALE	12	1	2021/12/24	POSITIVE	POSITIVE	20	—	Passed
62	184977	MALE	15	2	2021/12/24	POSITIVE	POSITIVE	17	—	Passed
63	184986	FEMALE	11	1	2021/12/27	POSITIVE	POSITIVE	14.0	Omicron	Passed
64	184989	MALE	50	0	2021/12/27	POSITIVE	POSITIVE	15.1	—	Passed
65	184990	FEMALE	16	0	2021/12/27	POSITIVE	POSITIVE	17.4	—	Passed
66	184992	MALE	13	3	2021/12/27	POSITIVE	POSITIVE	16.6	—	Passed
67	184993	MALE	57	2	2021/12/27	POSITIVE	POSITIVE	12.4	Delta	Passed
68	184994	MALE	28	0	2021/12/27	POSITIVE	POSITIVE	13.6	Delta	Passed
69	185005	MALE	8	1	2021/12/27	POSITIVE	POSITIVE	18.6	—	Passed
70	185037	FEMALE	41	0	2021/12/27	POSITIVE	POSITIVE	16.1	—	Passed
71	185045	MALE	19	0	2021/12/27	POSITIVE	POSITIVE	20.7	—	Passed
72	185092	MALE	43	2	2021/12/27	POSITIVE	POSITIVE	17.9	—	Passed
73	185106	FEMALE	29	1	2021/12/27	POSITIVE	POSITIVE	17.6	—	Passed
74	185120	FEMALE	9	1	2021/12/27	POSITIVE	POSITIVE	16.2	—	Passed
75	185122	FEMALE	20	2	2021/12/27	POSITIVE	POSITIVE	14.1	—	Passed
76	185124	MALE	7	2	2021/12/27	POSITIVE	POSITIVE	17.7	—	Passed
77	185131	MALE	57	1	2021/12/27	POSITIVE	POSITIVE	12.1	—	Passed
78	185137	MALE	31	0	2021/12/27	POSITIVE	POSITIVE	12.0	—	Passed
79	185139	FEMALE	37	1	2021/12/27	POSITIVE	POSITIVE	25.0	—	Passed
80	185140	MALE	15	1	2021/12/27	POSITIVE	POSITIVE	13.5	—	Passed
81	185144	MALE	27	1	2021/12/27	POSITIVE	POSITIVE	16.0	—	Passed
82	185147	MALE	6	3	2021/12/27	POSITIVE	POSITIVE	11.4	—	Passed
83	185165	FEMALE	57	3	2021/12/27	POSITIVE	POSITIVE	12.9	—	Passed
84	185167	MALE	22	0	2021/12/27	POSITIVE	POSITIVE	16.8	—	Passed
85	185168	FEMALE	9	0	2021/12/27	POSITIVE	POSITIVE	16.8	—	Passed
86	185169	FEMALE	31	1	2021/12/27	POSITIVE	POSITIVE	20.1	—	Passed
87	185181	FEMALE	46	0	2021/12/27	POSITIVE	POSITIVE	13.5	—	Passed
88	185185	MALE	10	2	2021/12/27	POSITIVE	POSITIVE	13.1	—	Passed
89	185197	FEMALE	21	1	2021/12/27	POSITIVE	POSITIVE	18.9	—	Passed
90	185203	MALE	33	1	2021/12/27	POSITIVE	POSITIVE	13.8	—	Passed
91	185205	MALE	44	1	2021/12/27	POSITIVE	SPOSITIVE	17.1	—	Passed
92	185211	MALE	25	2	2021/12/27	COSITIVE	POSITIVE	17.1	—	Passed
93	185223	FEMALE	58	3	2021/12/27	POSITIVE	POSITIVE	13.9	—	Passed
94	185225	MALE	9	0	2021/12/27	POSITIVE	POSITIVE	17.6	—	Passed

No.	Sample ID	Gender	Age (Years)	Days of symp. onset	Test date	EZER COVID-19 Ag result	SARS-CoV-2 RT-PCR result	Ct Value	Variant	Comment
95	185239	FEMALE	28	3	2021/12/27	POSITIVE	POSITIVE	13.0	—	Passed
96	185254	MALE	15	0	2021/12/27	POSITIVE	POSITIVE	9.5	—	Passed
97	185259	FEMALE	39	0	2021/12/27	POSITIVE	POSITIVE	20.5	—	Passed
98	185266	MALE	19	1	2021/12/27	POSITIVE	POSITIVE	14.0	—	Passed
99	185267	MALE	26	0	2021/12/27	POSITIVE	POSITIVE	18.5	—	Passed
100	185271	MALE	19	2	2021/12/27	POSITIVE	POSITIVE	12.1	—	Passed
101	185272	FEMALE	60	3	2021/12/27	POSITIVE	POSITIVE	20.3	—	Passed
102	185297	MALE	44	3	2021/12/28	POSITIVE	POSITIVE	21.2	—	Passed
103	185312	FEMALE	17	2	2021/12/28	POSITIVE	POSITIVE	13.8	—	Passed
104	185316	MALE	13	3	2021/12/28	POSITIVE	POSITIVE	12.9	—	Passed
105	185321	FEMALE	26	0	2021/12/28	POSITIVE	POSITIVE	18.3	—	Passed
106	185341	FEMALE	19	3	2021/12/28	POSITIVE	POSITIVE	16.5	—	Passed
107	185355	FEMALE	40	3	2021/12/28	POSITIVE	POSITIVE	19.0	—	Passed
108	185392	MALE	19	3	2021/12/28	POSITIVE	POSITIVE	9.2	—	Passed
109	185403	FEMALE	21	3	2021/12/28	POSITIVE	POSITIVE	17.2	—	Passed
110	185425	FEMALE	42	0	2021/12/28	POSITIVE	POSITIVE	24.4	—	Passed
111	188081	MALE	25	0	2022/1/7	POSITIVE	POSITIVE	11.7	Omicron	Passed
112	188099	MALE	45	0	2022/1/7	POSITIVE	POSITIVE	25.8	Omicron	Passed
113	188102	MALE	46	0	2022/1/7	POSITIVE	POSITIVE	17	Omicron	Passed
114	188107	MALE	12	0	2022/1/7	POSITIVE	POSITIVE	21	Omicron	Passed
115	188109	MALE	45	1	2022/1/7	POSITIVE	POSITIVE	22.0	Omicron	Passed
116	188110	MALE	9	3	2022/1/7	POSITIVE	POSITIVE	11.8	Omicron	Passed
117	188111	FEMALE	11	0	2022/1/7	POSITIVE	POSITIVE	12.8	Omicron	Passed
118	188114	MALE	24	0	2022/1/7	POSITIVE	POSITIVE	12.9	Omicron	Passed
119	188115	MALE	39	2	2022/1/7	POSITIVE	POSITIVE	25.3	Omicron	Passed
120	188173	MALE	51	0	2022/1/7	POSITIVE	POSITIVE	11.5	Omicron	Passed
121	188522	FEMALE	27	0	2022/1/8	POSITIVE	POSITIVE	16	Omicron	Passed
122	188555	FEMALE	37	0	2022/1/8	POSITIVE	POSITIVE	19.0	Omicron	Passed
123	188556	FEMALE	43	2	2022/1/8	POSIITVE	POSITIVE	17.0	Omicron	Passed
124	188559	MALE	34	1	2022/1/8	POSITIVE	POSITIVE	20.0	Delta	Passed
125	188560	FEMALE	7	1	2022/1/8	POSITIVE	POSITIVE	17.0	Delta	Passed
126	188561	FEMALE	75	3	2022/1/8	POSITIVE	POSITIVE	16.0	Omicron	Passed
127	188626	FEMALE	43	0	2022/1/10	POSITIVE	POSITIVE	16.0	Omicron	Passed
128	188627	MALE	11	1	2022/1/10	POSITIVE	POSITIVE	19.0	Omicron	Passed
129	188641	MALE	40	2	2022/1/10	POSITIVE	POSITIVE	15.0	Omicron	Passed
130	188646	MALE	36	2	2022/1/10	POSITIVE	POSITIVE	16.0	Omicron	Passed
131	188661	MALE	35	3	2022/1/10	POSITIVE	POSITIVE	22.0	Delta	Passed
132	188664	MALE	44	3	2022/1/10	POSITIVE	POSITIVE	24.0	Omicron	Passed
133	188674	FEMALE	12	0	2022/1/10	POSITIVE	POSITIVE	14.0	Omicron	Passed
134	188675	FEMALE	9	0	2022/1/10	POSITIVE	POSITIVE	18.0	Omicron	Passed
135	188706	FEMALE	5	3	2022/1/10	POSITIVE	POSITIVE	22.0	Omicron	Passed
136	188713	FEMALE	38	3	2022/1/10	POSITIVE	POSITIVE	20.0	Omicron	Passed
137	188717	MALE	49	2	2022/1/10	POSITIVE	POSITIVE	16.0	Omicron	Passed
138	188732	FEMALE	40	1	2022/1/10	POSITIVE	POSITIVE	16.0	Omicron	Passed
139	188765	MALE	50	1	2022/1/10	POSITIVE	SPOSITIVE	18.0	Omicron	Passed
140	188770	MALE	42	2	2022/1/10	COSITIVE	POSITIVE	15.0	Omicron	Passed
141	188783	MALE	30	0	2022/1/10	POSITIVE	POSITIVE	14.0	Omicron	Passed
142	188784	MALE	44	1	2022/1/10	POSITIVE	POSITIVE	16.0	Omicron	Passed

No.	Sample ID	Gender	Age (Years)	Days of symp. onset	Test date	EZER COVID-19 Ag result	SARS-CoV-2 RT-PCR result	Ct Value	Variant	Comment
143	188842	FEMALE	13	0	2022/1/10	POSITIVE	POSITIVE	10.0	Omicron	Passed
144	188843	MALE	48	0	2022/1/10	POSITIVE	POSITIVE	14.0	Omicron	Passed
145	188855	FEMALE	25	0	2022/1/10	POSITIVE	POSITIVE	17.0	Delta	Passed
146	188872	FEMALE	51	0	2022/1/10	POSITIVE	POSITIVE	13.0	Omicron	Passed
147	188885	MALE	55	0	2022/1/10	POSITIVE	POSITIVE	16.0	Omicron	Passed
148	188896	MALE	47	0	2022/1/10	POSITIVE	POSITIVE	13.0	Omicron	Passed
149	188897	FEMALE	41	0	2022/1/10	POSITIVE	POSITIVE	12.0	Omicron	Passed

Annex 2. Clinical Test Data for Negative Sample from non-infected individuals

No.	Sample ID	Gender	Age (Years)	Test date	EZER COVID-19 Ag result	SARS-CoV-2 RT-PCR result	Ct Value	Comment
1	182863	MALE	41	2021/12/13	Negative	Negative	35.43	Passed
2	182864	FEMALE	67	2021/12/13	Negative	Negative	35.47	Passed
3	182865	FEMALE	60	2021/12/13	Negative	Negative	36.26	Passed
4	182867	MALE	55	2021/12/13	Negative	Negative	36.3	Passed
5	182868	FEMALE	53	2021/12/13	Negative	Negative	37.78	Passed
6	182869	FEMALE	41	2021/12/13	Negative	Negative	37.05	Passed
7	182892	MALE	36	2021/12/13	Negative	Negative	36.64	Passed
8	182901	FEMALE	79	2021/12/13	Negative	Negative	36.52	Passed
9	182902	FEMALE	21	2021/12/13	Negative	Negative	35.73	Passed
10	182906	MALE	55	2021/12/13	Negative	Negative	35.25	Passed
11	182908	MALE	45	2021/12/13	Negative	Negative	37.55	Passed
12	182910	FEMALE	53	2021/12/13	Negative	Negative	35.21	Passed
13	182911	MALE	50	2021/12/13	Negative	Negative	36.13	Passed
14	182912	MALE	45	2021/12/13	Negative	Negative	37.52	Passed
15	182913	MALE	51	2021/12/13	Negative	Negative	37.68	Passed
16	182914	FEMALE	50	2021/12/13	Negative	Negative	36.14	Passed
17	182915	MALE	18	2021/12/13	Negative	Negative	35.04	Passed
18	182917	FEMALE	45	2021/12/13	Negative	Negative	35.88	Passed
19	182919	MALE	52	2021/12/13	Negative	Negative	35.26	Passed
20	182921	MALE	58	2021/12/13	Negative	Negative	36.09	Passed
21	182922	MALE	52	2021/12/13	Negative	Negative	36.55	Passed
22	182925	FEMALE	55	2021/12/13	Negative	Negative	37.71	Passed
23	182926	MALE	75	2021/12/13	Negative	Negative	36.8	Passed
24	182929	FEMALE	48	2021/12/13	Negative	Negative	37.5	Passed
25	182930	MALE	43	2021/12/13	Negative	Negative	36.41	Passed
26	182932	FEMALE	48	2021/12/13	Negative	Negative	36.74	Passed
27	182933	MALE	49	2021/12/13	Negative	Negative	35.64	Passed
28	182936	MALE	10	2021/12/13	Negative	Negative	35.21	Passed
29	182940	FEMALE	32	2021/12/13	Negative	Negative	37.06	Passed
30	182951	MALE	30	2021/12/13	Negative	Negative	35.18	Passed
31	182953	MALE	45	2021/12/13	Negative	Negative	36.76	Passed
32	182961	FEMALE	60	2021/12/13	Negative	Negative	37.3	Passed
33	182968	MALE	32	2021/12/13	Negative	Negative	36.04	Passed
34	182984	FEMALE	37	2021/12/13	Negative	Negative	35.07	Passed
35	182985	FEMALE	66	2021/12/13	Negative	Negative	35.57	Passed
36	182986	FEMALE	57	2021/12/13	Negative	Negative	37.57	Passed
37	182988	MALE	46	2021/12/13	Negative	Negative	37.83	Passed
38	182989	FEMALE	46	2021/12/13	Negative	Negative	35.52	Passed
39	182996	FEMALE	36	2021/12/13	Negative	Negative	35.05	Passed
40	183004	MALE	42	2021/12/13	Negative	Negative	36.48	Passed
41	183014	FEMALE	37	2021/12/13	Negative	Negative	36.46	Passed
42	183019	FEMALE	44	2021/12/13	Negative	Negative	36.92	Passed
43	183027	FEMALE	39	2021/12/13	Negative	Negative	35.68	Passed
44	183324	FEMALE	8	2021/12/14	Negative	Negative	36.04	Passed
45	183325	MALE	47	2021/12/14	Negative	Negative	35.13	Passed
46	183326	FEMALE	65	2021/12/14	Negative	Negative	37.65	Passed
47	183330	FEMALE	74	2021/12/14	Negative	Negative	37.43	Passed

No.	Sample ID	Gender	Age (Years)	Test date	EZER COVID-19 Ag result	SARS-CoV-2 RT-PCR result	Ct Value	Comment
48	183331	FEMALE	26	2021/12/14	Negative	Negative	37.63	Passed
49	183332	FEMALE	43	2021/12/14	Negative	Negative	37.2	Passed
50	183335	MALE	50	2021/12/14	Negative	Negative	37.46	Passed
51	183342	FEMALE	26	2021/12/14	Negative	Negative	35.64	Passed
52	183385	FEMALE	31	2021/12/14	Negative	Negative	35.3	Passed
53	183458	FEMALE	27	2021/12/14	Negative	Negative	36.41	Passed
54	183480	MALE	21	2021/12/14	Negative	Negative	35.31	Passed
55	183484	MALE	51	2021/12/14	Negative	Negative	35.09	Passed
56	183495	MALE	50	2021/12/14	Negative	Negative	35.23	Passed
57	183531	MALE	23	2021/12/14	Negative	Negative	35.06	Passed
58	183540	MALE	7	2021/12/14	Negative	Negative	35.76	Passed
59	183630	MALE	47	2021/12/17	Negative	Negative	36.03	Passed
60	183631	MALE	50	2021/12/17	Negative	Negative	37.45	Passed
61	183632	FEMALE	44	2021/12/17	Negative	Negative	36.26	Passed
62	183633	MALE	44	2021/12/17	Negative	Negative	36.28	Passed
63	183635	FEMALE	49	2021/12/17	Negative	Negative	37.3	Passed
64	183637	FEMALE	43	2021/12/17	Negative	Negative	36.41	Passed
65	183638	FEMALE	52	2021/12/17	Negative	Negative	36.44	Passed
66	183641	FEMALE	26	2021/12/17	Negative	Negative	37.86	Passed
67	183642	FEMALE	39	2021/12/17	Negative	Negative	35.4	Passed
68	183643	MALE	45	2021/12/17	Negative	Negative	37.4	Passed
69	183644	MALE	62	2021/12/17	Negative	Negative	36.71	Passed
70	183645	MALE	24	2021/12/17	Negative	Negative	36.44	Passed
71	183646	FEMALE	53	2021/12/17	Negative	Negative	37.04	Passed
72	183647	FEMALE	30	2021/12/17	Negative	Negative	36.56	Passed
73	183648	MALE	31	2021/12/17	Negative	Negative	36.44	Passed
74	183654	FEMALE	49	2021/12/17	Negative	Negative	36.06	Passed
75	183656	MALE	32	2021/12/17	Negative	Negative	36.11	Passed
76	183658	FEMALE	56	2021/12/17	Negative	Negative	36.39	Passed
77	183660	FEMALE	45	2021/12/17	Negative	Negative	36.56	Passed
78	183661	FEMALE	30	2021/12/17	Negative	Negative	36.47	Passed
79	183662	MALE	62	2021/12/17	Negative	Negative	37.74	Passed
80	184987	FEMALE	36	2021/12/27	Negative	Negative	36.4	Passed
81	185000	MALE	28	2021/12/27	Negative	Negative	37	Passed
82	185001	MALE	38	2021/12/27	Negative	Negative	35.4	Passed
83	185002	FEMALE	26	2021/12/27	Positive	Negative	36.6	Not Passed
84	185010	MALE	63	2021/12/27	Negative	Negative	36.1	Passed
85	185018	MALE	30	2021/12/27	Negative	Negative	36.7	Passed
86	185019	MALE	25	2021/12/27	Negative	Negative	35	Passed
87	185020	MALE	57	2021/12/27	Negative	Negative	35	Passed
88	185022	MALE	46	2021/12/27	Negative	Negative	36.3	Passed
89	185023	MALE	37	2021/12/27	Negative	Negative	36.7	Passed
90	185053	FEMALE	58	2021/12/27	Negative	Negative	35.5	Passed
91	185060	MALE	6	2021/12/27	Negative	Negative	35.5	Passed
92	185061	FEMALE	7	2021/12/27	Negative	Negative	36.4	Passed
93	185063	MALE	44	2021/12/27	Negative	Negative	35	Passed
94	185064	FEMALE	55	2021/12/27	Negative	Negative	36	Passed
95	185072	FEMALE	11	2021/12/27	Negative	Negative	35.5	Passed

No.	Sample ID	Gender	Age (Years)	Test date	EZER COVID-19 Ag result	SARS-CoV-2 RT-PCR result	Ct Value	Comment
96	185125	MALE	14	2021/12/27	Negative	Negative	36.9	Passed
97	185129	FEMALE	27	2021/12/27	Negative	Negative	35.4	Passed
98	185148	MALE	43	2021/12/27	Negative	Negative	35.3	Passed
99	185156	FEMALE	43	2021/12/27	Negative	Negative	35.5	Passed
100	185160	MALE	48	2021/12/27	Negative	Negative	35.5	Passed
101	185181	FEMALE	46	2021/12/27	Negative	Negative	35.8	Passed
102	185183	FEMALE	11	2021/12/27	Negative	Negative	36.5	Passed
103	185191	FEMALE	31	2021/12/27	Negative	Negative	35.2	Passed
104	185202	MALE	28	2021/12/27	Negative	Negative	36	Passed
105	185204	FEMALE	23	2021/12/27	Negative	Negative	35.8	Passed
106	185210	MALE	30	2021/12/27	Negative	Negative	36.4	Passed
107	185227	MALE	38	2021/12/27	Negative	Negative	36.1	Passed
108	185238	MALE	41	2021/12/27	Negative	Negative	35.7	Passed
109	185244	FEMALE	47	2021/12/27	Negative	Negative	36.9	Passed
110	187333	MALE	51	2022/1/4	Negative	Negative	35.27	Passed
111	187334	MALE	51	2022/1/4	Negative	Negative	36.19	Passed
112	187338	FEMALE	62	2022/1/4	Negative	Negative	35.41	Passed
113	187339	FEMALE	69	2022/1/4	Negative	Negative	37.57	Passed
114	187340	FEMALE	53	2022/1/4	Negative	Negative	35.49	Passed
115	187341	MALE	63	2022/1/4	Negative	Negative	37.15	Passed
116	187342	MALE	63	2022/1/4	Negative	Negative	36.42	Passed
117	187350	FEMALE	52	2022/1/4	Negative	Negative	36.83	Passed
118	187354	FEMALE	66	2022/1/4	Negative	Negative	37.86	Passed
119	187357	MALE	57	2022/1/4	Negative	Negative	36.8	Passed
120	187358	FEMALE	18	2022/1/4	Negative	Negative	36.91	Passed
121	187359	FEMALE	44	2022/1/4	Negative	Negative	37.1	Passed
122	187360	MALE	43	2022/1/4	Negative	Negative	35.21	Passed
123	187361	MALE	43	2022/1/4	Negative	Negative	35.41	Passed
124	187364	FEMALE	50	2022/1/4	Negative	Negative	35.56	Passed
125	187365	FEMALE	50	2022/1/4	Negative	Negative	35.05	Passed
126	187369	FEMALE	38	2022/1/4	Negative	Negative	35.73	Passed
127	187371	FEMALE	44	2022/1/4	Negative	Negative	36.08	Passed
128	187372	FEMALE	44	2022/1/4	Negative	Negative	35.49	Passed
129	187380	FEMALE	34	2022/1/4	Negative	Negative	36.38	Passed
130	187382	FEMALE	63	2022/1/4	Negative	Negative	35.31	Passed
131	187383	FEMALE	63	2022/1/4	Negative	Negative	36.55	Passed
132	187384	FEMALE	41	2022/1/4	Negative	Negative	35.28	Passed
133	187385	FEMALE	8	2022/1/4	Negative	Negative	36.07	Passed
134	187386	FEMALE	62	2022/1/4	Negative	Negative	35.78	Passed
135	187387	FEMALE	41	2022/1/4	Negative	Negative	37.53	Passed
136	187388	FEMALE	8	2022/1/4	Negative	Negative	37.9	Passed
137	187389	FEMALE	62	2022/1/4	Negative	Negative	36.55	Passed
138	187393	MALE	62	2022/1/4	Negative	Negative	37.85	Passed
139	187394	MALE	62	2022/1/4	Negative	Negative	35.87	Passed
140	187396	FEMALE	32	2022/1/4	Negative	Negative	35.5	Passed
141	187397	FEMALE	62	2022/1/4	Negative	Negative	35.7	Passed
142	187398	FEMALE	62	2022/1/4	Negative	Negative	35.99	Passed
143	187399	FEMALE	32	2022/1/4	Negative	Negative	37.21	Passed

No.	Sample ID	Gender	Age (Years)	Test date	EZER COVID-19 Ag result	SARS-CoV-2 RT-PCR result	Ct Value	Comment
144	187403	FEMALE	54	2022/1/4	Negative	Negative	36.32	Passed
145	187404	FEMALE	54	2022/1/4	Negative	Negative	35.54	Passed
146	187405	MALE	50	2022/1/4	Negative	Negative	37.85	Passed
147	187406	MALE	50	2022/1/4	Negative	Negative	36.39	Passed
148	187411	MALE	22	2022/1/4	Negative	Negative	36.05	Passed
149	187412	MALE	22	2022/1/4	Negative	Negative	35.21	Passed
150	187418	FEMALE	42	2022/1/4	Negative	Negative	36.05	Passed
151	187419	FEMALE	42	2022/1/4	Negative	Negative	36.79	Passed
152	187423	MALE	46	2022/1/4	Negative	Negative	35.98	Passed
153	187426	MALE	21	2022/1/4	Negative	Negative	36.35	Passed
154	187427	FEMALE	46	2022/1/4	Negative	Negative	35.52	Passed
155	187429	FEMALE	18	2022/1/4	Negative	Negative	36.77	Passed
156	187442	MALE	27	2022/1/4	Negative	Negative	35.51	Passed
157	187443	MALE	27	2022/1/4	Negative	Negative	37.54	Passed
158	187454	MALE	61	2022/1/4	Negative	Negative	37.65	Passed
159	187455	MALE	61	2022/1/4	Negative	Negative	36.95	Passed
160	187467	FEMALE	58	2022/1/4	Negative	Negative	37.05	Passed
161	187468	FEMALE	58	2022/1/4	Negative	Negative	35.76	Passed
162	187537	FEMALE	46	2022/1/4	Negative	Negative	35.58	Passed
163	187538	FEMALE	46	2022/1/4	Negative	Negative	37.22	Passed
164	187541	MALE	50	2022/1/4	Negative	Negative	37.95	Passed
165	187542	MALE	50	2022/1/4	Negative	Negative	37.86	Passed
166	187546	MALE	33	2022/1/4	Negative	Negative	35.54	Passed
167	187547	MALE	33	2022/1/4	Negative	Negative	36.09	Passed
168	187558	FEMALE	60	2022/1/4	Negative	Negative	37.57	Passed
169	187559	FEMALE	60	2022/1/4	Negative	Negative	35.68	Passed
170	187561	FEMALE	47	2022/1/4	Negative	Negative	37.47	Passed
171	187562	FEMALE	47	2022/1/4	Negative	Negative	37.65	Passed
172	187574	MALE	69	2022/1/4	Negative	Negative	36.21	Passed
173	187575	MALE	69	2022/1/4	Negative	Negative	36.71	Passed
174	187581	FEMALE	37	2022/1/4	Negative	Negative	37.4	Passed
175	187601	MALE	43	2022/1/4	Negative	Negative	37.48	Passed
176	187602	MALE	43	2022/1/4	Negative	Negative	36.89	Passed
177	187603	MALE	28	2022/1/4	Negative	Negative	37.69	Passed
178	187631	FEMALE	43	2022/1/4	Negative	Negative	37.61	Passed
179	187632	FEMALE	43	2022/1/4	Negative	Negative	37.14	Passed
180	187641	MALE	45	2022/1/4	Negative	Negative	35.98	Passed
181	187642	MALE	11	2022/1/4	Negative	Negative	35.76	Passed
182	187643	FEMALE	45	2022/1/4	Negative	Negative	36.15	Passed
183	187644	MALE	45	2022/1/4	Negative	Negative	35.49	Passed
184	187645	MALE	11	2022/1/4	Negative	Negative	37.57	Passed
185	187646	FEMALE	45	2022/1/4	Negative	Negative	36.71	Passed
186	187647	MALE	46	2022/1/4	Negative	Negative	36.97	Passed
187	187648	MALE	13	2022/1/4	Negative	Negative	36.42	Passed
188	187649	MALE	46	2022/1/4	Negative	Negative	35.78	Passed
189	187650	MALE	13	2022/1/4	Negative	Negative	37.39	Passed
190	187653	FEMALE	18	2022/1/4	Negative	Negative	37.14	Passed
191	187654	FEMALE	18	2022/1/4	Negative	Negative	37.31	Passed

No.	Sample ID	Gender	Age (Years)	Test date	EZER COVID-19 Ag result	SARS-CoV-2 RT-PCR result	Ct Value	Comment
192	187663	FEMALE	45	2022/1/4	Negative	Negative	35.88	Passed
193	187664	FEMALE	45	2022/1/4	Negative	Negative	37.03	Passed
194	187667	FEMALE	55	2022/1/4	Negative	Negative	35.18	Passed
195	187668	FEMALE	55	2022/1/4	Negative	Negative	35.88	Passed
196	188506	FEMALE	14	2022/1/8	Negative	Negative	37.91	Passed
197	188507	FEMALE	11	2022/1/8	Negative	Negative	36.2	Passed
198	188510	FEMALE	24	2022/1/8	Negative	Negative	35.79	Passed
199	188512	MALE	33	2022/1/8	Negative	Negative	35.62	Passed
200	188514	FEMALE	25	2022/1/8	Negative	Negative	36.31	Passed
201	188516	FEMALE	37	2022/1/8	Negative	Negative	37.19	Passed
202	188517	FEMALE	47	2022/1/8	Negative	Negative	37.42	Passed
203	188521	FEMALE	23	2022/1/8	Negative	Negative	36.42	Passed
204	188526	FEMALE	19	2022/1/8	Negative	Negative	36.67	Passed
205	188527	FEMALE	30	2022/1/8	Negative	Negative	35.21	Passed
206	188528	MALE	39	2022/1/8	Negative	Negative	35.28	Passed
207	188529	FEMALE	24	2022/1/8	Negative	Negative	35.27	Passed
208	188530	MALE	92	2022/1/8	Negative	Negative	36.03	Passed
209	188531	MALE	54	2022/1/8	Negative	Negative	37.76	Passed
210	188532	FEMALE	46	2022/1/8	Negative	Negative	37.91	Passed
211	188533	FEMALE	67	2022/1/8	Negative	Negative	36.95	Passed
212	188534	FEMALE	26	2022/1/8	Negative	Negative	37.17	Passed
213	188535	MALE	50	2022/1/8	Negative	Negative	36.69	Passed
214	188536	FEMALE	36	2022/1/8	Negative	Negative	36.05	Passed
215	188537	FEMALE	48	2022/1/8	Negative	Negative	36.64	Passed
216	188538	FEMALE	55	2022/1/8	Negative	Negative	36	Passed
217	188539	FEMALE	57	2022/1/8	Negative	Negative	35.48	Passed
218	188540	FEMALE	69	2022/1/8	Negative	Negative	36.01	Passed
219	188541	FEMALE	73	2022/1/8	Negative	Negative	35.79	Passed
220	188543	FEMALE	36	2022/1/8	Negative	Negative	37.27	Passed
221	188546	FEMALE	38	2022/1/8	Negative	Negative	36.81	Passed
222	188548	MALE	38	2022/1/8	Negative	Negative	35.77	Passed
223	188554	FEMALE	82	2022/1/8	Negative	Negative	35.16	Passed
224	188557	MALE	65	2022/1/8	Negative	Negative	35.9	Passed
225	188562	FEMALE	36	2022/1/8	Negative	Negative	35.88	Passed
226	188565	FEMALE	11	2022/1/8	Negative	Negative	36.28	Passed
227	188567	FEMALE	44	2022/1/8	Negative	Negative	36.87	Passed
228	188578	FEMALE	36	2022/1/8	Negative	Negative	36.98	Passed
229	188921	FEMALE	42	2022/1/11	Negative	Negative	36.91	Passed
230	188928	FEMALE	44	2022/1/11	Negative	Negative	36.97	Passed
231	188931	FEMALE	26	2022/1/11	Negative	Negative	37.43	Passed
232	188934	FEMALE	41	2022/1/11	Positive	Negative	36.35	Not Passed
233	188935	MALE	46	2022/1/11	Negative	Negative	37.5	Passed
234	188938	MALE	36	2022/1/11	Negative	Negative	35.94	Passed
235	188939	MALE	43	2022/1/11	Negative	Negative	36.75	Passed
236	188940	MALE	29	2022/1/11	Negative	Negative	38	Passed
237	188941	MALE	31	2022/1/11	Negative	Negative	37.79	Passed
238	188943	MALE	28	2022/1/11	Negative	Negative	37.24	Passed
239	188944	MALE	52	2022/1/11	Negative	Negative	35.9	Passed

No.	Sample ID	Gender	Age (Years)	Test date	EZER COVID-19 Ag result	SARS-CoV-2 RT-PCR result	Ct Value	Comment
240	188945	MALE	28	2022/1/11	Negative	Negative	35.82	Passed
241	188946	MALE	45	2022/1/11	Negative	Negative	37.9	Passed
242	188947	MALE	44	2022/1/11	Negative	Negative	36.22	Passed
243	188948	FEMALE	43	2022/1/11	Negative	Negative	35.54	Passed
244	188950	MALE	46	2022/1/11	Negative	Negative	35.28	Passed
245	188951	MALE	46	2022/1/11	Negative	Negative	35.03	Passed
246	188952	MALE	64	2022/1/11	Negative	Negative	37.9	Passed
247	188954	MALE	47	2022/1/11	Negative	Negative	37.34	Passed
248	188955	MALE	38	2022/1/11	Negative	Negative	36.02	Passed
249	188956	MALE	50	2022/1/11	Negative	Negative	35.6	Passed
250	188957	MALE	46	2022/1/11	Negative	Negative	36.86	Passed
251	188958	MALE	56	2022/1/11	Negative	Negative	35.7	Passed
252	188959	MALE	41	2022/1/11	Negative	Negative	37.4	Passed
253	188960	MALE	42	2022/1/11	Negative	Negative	35.13	Passed
254	188962	FEMALE	51	2022/1/11	Negative	Negative	37.83	Passed
255	188963	MALE	57	2022/1/11	Negative	Negative	37.87	Passed
256	188964	FEMALE	38	2022/1/11	Negative	Negative	36.2	Passed
257	188965	FEMALE	41	2022/1/11	Negative	Negative	35.08	Passed
258	188966	FEMALE	40	2022/1/11	Negative	Negative	37.21	Passed
259	188967	MALE	36	2022/1/11	Negative	Negative	35.75	Passed
260	188968	MALE	43	2022/1/11	Negative	Negative	37.87	Passed
261	188969	MALE	49	2022/1/11	Negative	Negative	35.51	Passed
262	188970	MALE	29	2022/1/11	Negative	Negative	37.72	Passed
263	188971	MALE	33	2022/1/11	Negative	Negative	37.37	Passed
264	188972	MALE	36	2022/1/11	Negative	Negative	35.73	Passed
265	188987	MALE	26	2022/1/11	Negative	Negative	35.55	Passed
266	188994	MALE	24	2022/1/11	Negative	Negative	37.32	Passed
267	188999	FEMALE	26	2022/1/11	Negative	Negative	36.32	Passed
268	189024	MALE	29	2022/1/11	Negative	Negative	36.14	Passed
269	189025	MALE	25	2022/1/11	Negative	Negative	37.2	Passed
270	189026	MALE	30	2022/1/11	Negative	Negative	36.85	Passed
271	189027	MALE	28	2022/1/11	Negative	Negative	36.69	Passed
272	189028	FEMALE	34	2022/1/11	Negative	Negative	36.05	Passed
273	189029	MALE	37	2022/1/11	Negative	Negative	37.93	Passed
274	189030	FEMALE	23	2022/1/11	Negative	Negative	36	Passed
275	189031	FEMALE	42	2022/1/11	Negative	Negative	37.23	Passed
276	189032	FEMALE	26	2022/1/11	Negative	Negative	37.54	Passed
277	189033	MALE	37	2022/1/11	Negative	Negative	36.64	Passed
278	189034	MALE	41	2022/1/11	Negative	Negative	35.87	Passed
279	189035	MALE	37	2022/1/11	Negative	Negative	36.98	Passed
280	189036	MALE	36	2022/1/11	Negative	Negative	37.34	Passed
281	189038	MALE	40	2022/1/11	Negative	Negative	36.47	Passed
282	189039	MALE	41	2022/1/11	Negative	Negative	35.07	Passed
283	189040	FEMALE	41	2022/1/11	Negative	Negative	35.01	Passed
284	189041	MALE	29	2022/1/11	Negative	Negative	35.73	Passed
285	189042	FEMALE	42	2022/1/11	Negative	Negative	37.26	Coamssed
286	189043	FEMALE	11	2022/1/11	Negative	Negative	35.21	Passed
287	189044	FEMALE	45	2022/1/11	Negative	Negative	37.03	Passed

No.	Sample ID	Gender	Age (Years)	Test date	EZER COVID-19 Ag result	SARS-CoV-2 RT-PCR result	Ct Value	Comment
288	189048	FEMALE	30	2022/1/11	Negative	Negative	37	Passed
289	189049	FEMALE	43	2022/1/11	Negative	Negative	35.93	Passed
290	189053	MALE	15	2022/1/11	Negative	Negative	37.03	Passed
291	189054	MALE	36	2022/1/11	Negative	Negative	36.11	Passed
292	189058	FEMALE	56	2022/1/11	Negative	Negative	37.29	Passed
293	189066	FEMALE	50	2022/1/11	Negative	Negative	35.59	Passed
294	189067	MALE	50	2022/1/11	Negative	Negative	36.66	Passed
295	189068	MALE	48	2022/1/11	Negative	Negative	37.14	Passed
296	189075	MALE	24	2022/1/11	Negative	Negative	37.6	Passed
297	189176	FEMALE	36	2022/1/12	Negative	Negative	36.13	Passed
298	189181	FEMALE	35	2022/1/12	Negative	Negative	37.13	Passed
299	189185	FEMALE	50	2022/1/12	Negative	Negative	37.41	Passed
300	189197	FEMALE	58	2022/1/12	Negative	Negative	35.67	Passed
301	189199	MALE	47	2022/1/12	Negative	Negative	36.52	Passed
302	189206	MALE	52	2022/1/12	Negative	Negative	36.66	Passed
303	189240	MALE	53	2022/1/12	Negative	Negative	35.75	Passed
304	189242	FEMALE	65	2022/1/12	Negative	Negative	36.39	Passed
305	189246	MALE	51	2022/1/12	Negative	Negative	36.42	Passed
306	189270	FEMALE	43	2022/1/12	Negative	Negative	37.25	Passed
307	189303	MALE	32	2022/1/12	Negative	Negative	37.51	Passed
308	189309	MALE	39	2022/1/12	Negative	Negative	36.74	Passed
309	189319	FEMALE	20	2022/1/12	Negative	Negative	37.93	Passed
310	189323	FEMALE	17	2022/1/12	Negative	Negative	36.51	Passed
311	189328	MALE	40	2022/1/12	Negative	Negative	36.81	Passed
312	189330	MALE	63	2022/1/12	Negative	Negative	35.2	Passed
313	189333	MALE	50	2022/1/12	Negative	Negative	35.13	Passed
314	189335	MALE	42	2022/1/12	Negative	Negative	36.3	Passed

Annex 3. Test results on 106 negative samples from hospitalized cases

※Hospital Source: AO=Leto Hospital; THA= Therapeftirio Ayhinon Hospital

No.	Sample ID	Gender	Age	SARS-CoV-2 RT-PCR result	Ct value	EZER COVID-19 Ag result	Comment	Hospital Source※	Cause Of hospitalization
1	181416	FEMALE	36	Negative	35.94	Negative	passed	AO1	labor
2	181418	FEMALE	27	Negative	35.62	Negative	passed	AO2	caesarean section
3	181505	MALE	86	Negative	37.97	Negative	passed	THA-1	weakness
4	181506	FEMALE	80	Negative	36.21	Negative	passed	THA-2	dementia
5	181507	FEMALE	60	Negative	37.95	Negative	passed	THA-3	chronic kidney failure
6	181508	MALE	89	Negative	37.89	Negative	passed	THA-4	dementia
7	181510	FEMALE	93	Negative	36.65	Negative	passed	THA-5	stroke
8	181512	MALE	69	Negative	37.5	Negative	passed	THA-6	mobility difficulty malfunction
9	181513	MALE	74	Negative	35.5	Negative	passed	THA-7	dementia
10	181514	FEMALE	88	Negative	36.05	Negative	passed	THA-8	dementia
11	181588	FEMALE	40	Negative	37.27	Negative	passed	AO3	caesarean section
12	181589	FEMALE	40	Negative	35.42	Negative	passed	AO4	labor
13	181862	FEMALE	38	Negative	35.4	Negative	passed	AO5	caesarean section
14	182008	FEMALE	36	Negative	36.47	Negative	passed	AO6	caesarean section
15	182010	FEMALE	35	Negative	35.94	Negative	passed	AO7	labor
16	182011	FEMALE	39	Negative	37.12	Negative	passed	AO8	caesarean section
17	182260	FEMALE	96	Negative	37.31	Negative	passed	THA-9	mobility difficulty
18	182261	FEMALE	89	Negative	35.64	Negative	passed	THA-10	chronic kidney failure
19	182262	FEMALE	93	Negative	35.02	Negative	passed	THA-11	fracture spinal cord
20	182263	FEMALE	93	Negative	35.62	Negative	passed	THA-12	cardiac failure
21	182264	FEMALE	75	Negative	37.48	Negative	passed	THA-13	kidney failure
22	182265	FEMALE	89	Negative	37.25	Negative	passed	THA-14	dementia
23	182266	FEMALE	73	Negative	36.98	Negative	passed	THA-15	stroke
24	182267	FEMALE	91	Negative	36.31	Negative	passed	THA-16	cardiac failure
25	182268	FEMALE	93	Negative	35.73	Negative	passed	THA-17	chronic kidney failure
26	182270	FEMALE	92	Negative	37.29	Negative	passed	THA-18	gastric hemorrance
27	182271	FEMALE	75	Negative	35.75	Negative	passed	THA-19	mobility malfunction
28	182272	FEMALE	92	Negative	37.56	Negative	passed	THA-20	dementia
29	182483	FEMALE	39	Negative	36.84	Negative	passed	AO9	labor

No.	Sample ID	Gender	Age	SARS-CoV-2 RT-PCR result	Ct value	EZER COVID-19 Ag result	Comment	Hospital Source※	Cause Of hospitalization
30	182484	FEMALE	50	Negative	37.79	Negative	passed	A10	caesarean section
31	182485	FEMALE	38	Negative	35.02	Negative	passed	A11	caesarean section
32	182734	MALE	82	Negative	35.14	Negative	passed	THA-21	stroke
33	182735	MALE	83	Negative	35.5	Negative	passed	THA-22	ventricular fibrillation
34	182736	FEMALE	85	Negative	37.79	Negative	passed	THA-23	kidney failure
35	182737	FEMALE	74	Negative	35.41	Negative	passed	THA-24	kidney failure
36	182738	FEMALE	83	Negative	35.25	Negative	passed	THA-25	weakness
37	182739	FEMALE	89	Negative	36.16	Negative	passed	THA-26	mobility malfunction
38	182741	MALE	68	Negative	36.74	Negative	passed	THA-27	quadriplegia
39	182659	FEMALE	38	Negative	37.6	Negative	passed	A12	caesarean section
40	182815	FEMALE	38	Negative	37.6	Negative	passed	A13	caesarean section
41	182816	FEMALE	36	Negative	37.27	Negative	passed	A14	caesarean section
42	182817	FEMALE	30	Negative	37.07	Negative	passed	A15	caesarean section
43	182818	FEMALE	37	Negative	36.26	Negative	passed	A16	ovarian cyst endometriosis
44	182819	FEMALE	44	Negative	35.93	Negative	passed	A17	caesarean section
45	182820	FEMALE	46	Negative	35.31	Negative	passed	A18	caesarean section
46	182821	FEMALE	34	Negative	37.41	Negative	passed	A19	caesarean section
47	182955	FEMALE	34	Negative	37.61	Negative	passed	A20	labor
48	182956	FEMALE	40	Negative	36.86	Negative	passed	A21	caesarean section
49	183253	FEMALE	33	Negative	36.79	Negative	passed	A22	labor
50	183489	FEMALE	68	Negative	35.5	Negative	passed	A23	stress urinary incontinence
51	183840	FEMALE	36	Negative	35.19	Negative	passed	A24	labor
52	183938	FEMALE	30	Negative	36.49	Negative	passed	A25	labor
53	183939	FEMALE	74	Negative	37.9	Negative	passed	A26	hysterectomy
54	183940	FEMALE	32	Negative	37.39	Negative	passed	A27	caesarean section
55	185514	FEMALE	86	Negative	36.71	Negative	passed	THA-28	hypotension
56	185515	FEMALE	75	Negative	36.52	Negative	passed	THA-29	kidney failure
57	185516	MALE	93	Negative	37.35	Negative	passed	THA 30	kidney failure
58	185517	FEMALE	83	Negative	36.45	Negative	passed	THA 31	mobility malfunction
59	185518	FEMALE	42	Negative	35.68	Negative	passed	THA 32	mobility malfunction
60	185519	MALE	92	Negative	36.69	Negative	passed	THA 33	dementia
61	185520	MALE	91	Negative	36.3	Negative	passed	THA 34	cardiac failure

No.	Sample ID	Gender	Age	SARS-CoV-2 RT-PCR result	Ct value	EZER COVID-19 Ag result	Comment	Hospital Source※	Cause Of hospitalization
62	185521	FEMALE	93	Negative	36.71	Negative	passed	THA 35	fracture spinal cord
63	185522	FEMALE	89	Negative	37.12	Negative	passed	THA 36	kidney failure
64	185523	FEMALE	93	Negative	35.75	Negative	passed	THA 37	mobility malfunction
65	185524	MALE	86	Negative	37.35	Negative	passed	THA 38	kidney failure
66	185525	FEMALE	55	Negative	36.81	Negative	passed	THA 39	kidney failure
67	185526	MALE	83	Negative	35.25	Negative	passed	THA 40	hepatic fibrosis cirrhosis
68	185527	FEMALE	89	Negative	35.21	Negative	passed	THA 41	lower respiratory infection
69	185783	MALE	74	Negative	37.04	Negative	passed	THA 42	dementia
70	185784	MALE	69	Negative	37.12	Negative	passed	THA 43	mobility malfunction
71	185785	FEMALE	81	Negative	37.52	Negative	passed	THA 44	stroke
72	185786	MALE	82	Negative	37.84	Negative	passed	THA 45	weakness
73	185787	MALE	88	Negative	35.5	Negative	passed	THA 46	generalized malignancy unknown origin
74	185790	MALE	92	Negative	35.33	Negative	passed	THA 47	abdominal pelvic pain
75	185795	FEMALE	60	Negative	36.18	Negative	passed	THA 48	chronic renal failure
76	185796	FEMALE	80	Negative	37.49	Negative	passed	THA 49	dementia
77	185799	FEMALE	88	Negative	37.72	Negative	passed	THA 50	dementia
78	185800	FEMALE	93	Negative	36.7	Negative	passed	THA 51	cardiac failure
79	185801	MALE	91	Negative	36.13	Negative	passed	THA 52	cardiac failure
80	185802	MALE	93	Negative	36.01	Negative	passed	THA 53	renal failure final stage
81	185804	FEMALE	83	Negative	37.1	Negative	passed	THA 54	mobility malfunction
82	185805	FEMALE	75	Negative	35.56	Negative	passed	THA 55	mobility malfunction
83	185807	FEMALE	92	Negative	37.23	Negative	passed	THA 56	dementia
84	185808	FEMALE	89	Negative	36.03	Negative	passed	THA 57	renal failure final stage
85	185811	FEMALE	93	Negative	36.88	Negative	passed	THA 58	fracture spinal cord
86	185814	MALE	86	Negative	36.5	Negative	passed	THA 59	hypotension
87	185815	FEMALE	75	Negative	37.47	Negative	passed	THA 60	renal failure final stage
88	185817	FEMALE	67	Negative	35.45	Negative	passed	THA 61	abdominal pelvic pain
89	185818	FEMALE	74	Negative	35.93	Negative	passed	THA 62	renal failure final stage
90	185819	FEMALE	68	Negative	35.78	Negative	passed	THA 63	tetraplegia
91	185821	FEMALE	82	Negative	37.6	Negative	passed	THA 64	stroke
92	185822	MALE	73	Negative	35.91	Negative	passed	THA 65	lung cancer

No.	Sample ID	Gender	Age	SARS-CoV-2 RT-PCR result	Ct value	EZER COVID-19 Ag result	Comment	Hospital Source※	Cause Of hospitalization
93	185823	FEMALE	90	Negative	35.89	Negative	passed	THA 66	weakness
94	185824	FEMALE	80	Negative	36.92	Negative	passed	THA 67	weakness
95	186236	MALE	86	Negative	37.44	Negative	passed	THA68	hypotension
96	186248	MALE	91	Negative	37.07	Negative	passed	THA69	cardiac failure
97	186249	FEMALE	89	Negative	36.81	Negative	passed	THA70	renal failure final stage
98	186251	FEMALE	92	Negative	35.69	Negative	passed	THA71	abdominal pelvic pain
99	186252	FEMALE	81	Negative	35.74	Negative	passed	THA72	stroke
100	186253	FEMALE	88	Negative	35.04	Negative	passed	THA73	dementia
101	186255	FEMALE	93	Negative	35.94	Negative	passed	THA74	heart failure
102	186256	FEMALE	82	Negative	37.61	Negative	passed	THA75	weakness
103	186258	MALE	82	Negative	37.89	Negative	passed	THA76	stroke
104	186259	FEMALE	89	Negative	35.23	Negative	passed	THA77	lower respiratory infection
105	186260	FEMALE	74	Negative	37.01	Negative	passed	THA78	renal failure final stage
106	186262	MALE	73	Negative	35.94	Negative	passed	THA79	lung cancer

Annex 4 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
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

No.	Pathogen	Age	Gender	SARS-CoV-2 RT-PCR result	EZER COVID-19 Ag result	Comment	Cause Of hospitalization
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	22Y	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