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ABT

2019-nCoV

ANTIGEN RAPID TEST CASSETTE

INTENDED USE

The 2019-nCoV Antigen Rapid Test Cassette is a lateral flow immunoassay intended for the qualitative detection 2019-nCoV nucleocapsid antigens in anterior nasal swab. This test cassette can be used for self-testing.

medical diagnoable healthy

BENEFITS

- Rapid testing for SARS-CoV-2 antigen within 15 minutes
- Facilitates patient treatment decisions quickly
- Anterior nasal swab, time-saving procedure
- All necessary reagents provided & no equipment needed
- High sensitivity and specificity

Applicable Samples: anterior nasal swab.

Packing Specification

1 tests/kit	5 tests/kit	10 tests/kit	20 tests/kit	30 tests/kit

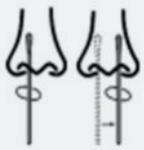
Main components

Test Cassette	Sterilized Swab	Positive Control（If required）
Extraction Tube	Extraction Reagent	Negative control（If required）

Test Method

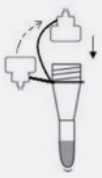
◎ Please open the extraction reagent and drop all the liquid into the extraction tube.

◎ Put the swab into one nostril. The swab tip should be inserted no less than 2.5 cm (1 inch) from the edge of the nostril. Roll swab at least 3 times along the mucosa inside the nostril. Leave swab in the nostril for several seconds. Using the same swab, repeat this process for the other nostril. Withdraw swab from the nasal cavity. Caution: This may feel uncomfortable. Do not insert the swab any deeper if you feel strong resistance or pain.



◎ Insert the swab into the extraction tube which contains the extraction reagent. Rotate the swab inside the tube using a circular motion to roll the side of the extraction tube so that the solution is expressed and reabsorbed from the swab. Pinch the extraction tube with fingers and elute the liquid on the swab as far as possible into the extraction reagent, then pull out the swab. The extracted solution will be used as test specimen.

◎ Buckle the dripper



◎ Reverse the specimen extraction tube, holding the specimen extraction tube upright，add 3 drops (about 90μL) of the sample to be tested into the sample hole. Wait for colored lined to appear

◎ Wait for colored lines to appear. Interpret the test results at 15 minutes. Do not read results after 20 minutes.

Beijing Applied Biological Technologies Co.,LTD.
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No.33 Kexueyuan Road, Changping District,
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STATEMENT ON THE OMICRON VARIANT

We have been continuously monitoring the emergence of **SARS-CoV-2** variants and the Omicron variant is no exception.

The Omicron variant is notable for the significant number of mutations in the Spike protein. Those mutations are not relevant to the **SARS-CoV-2 Antigen Rapid Test Cassette,**which detects the SARS-CoV-2 Nucleocapsid protein.

According to the GISAID analysis and the pairwise sequence alignment comparison of the Nucleocapsid protein from all of the tested variants (B.1.351, B.1.1.7, P.1, and Delta variant B.1.617.2), there is a high likelihood that the SARS-CoV-2 Omicron variant (lineage B.1.1.529) is detectable by the **SARS-CoV-2 Antigen Rapid Test Cassette.**

We anticipate testing virus samples, once they become available to us, to further verify the performance of our test in detecting the Omicron variant.

Furthermore, X-ABT will continue to monitor the evolution of **SARS-CoV-2** variants in circulation worldwide and evaluate the performance of our assays against Omicron and future variants to maintain the high level of product performance our customers have come to rely upon.

Beijing Applied Biological Technologies Co., Ltd.

December 16, 2021

Building 5 C101, Building 6 504, Building 7 304, No. 97, Changping Road, Shahe Town, 102206 Beijing, P.R.China
Tel:+86-10-81937999

Declaration of Conformity

Manufacturer:	Beijing Applied Biological Technologies Co., Ltd. Room C 101, Building 1, 37 Science Park Road, Changping District, 102206 Beijing, P.R.China
Manufacturer Address:	Building 5 C101, Building 6 504, Building 7 304, No. 97, Changping Road, Shahe Town, 102206 Beijing, P.R.China
whose single Authorized **EU**-*Representative:*	Luxus Lebenswelt GmbH Kochstr.1, 47877, Willich, Germany E-mail: info.m@luxuslw.de
Product Name:	SARS-CoV-2 Antigen Rapid Test Cassette
Reference Numbers:	CG9011(S)-1T-AN,CG9011(S)-5T-AN,CG9011(S)-10T-AN,CG9011(S)-20T-AN,CG9011(S)-30T-AN

EDMA CODE:	15.04.09.01
Notify Body:	POLISH CENTRE FOR TESTING AND CERTIFICATION
EC Certificate No:	1434-IVDD-511/2021
Classification:	**Self-testing**
Conformity Assessment Route:	**Annex III - section 6**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:

In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Harmonized standards:

EN ISO 13485:2016
EN ISO 15223-1:2016
EN ISO 14971:2012
EN 13975:2003
EN ISO 18113-1:2011
EN ISO 18113-4:2011
EN 13612:2002
EN ISO 17511:2003
EN ISO 23640:2015
EN 13641:2002
EN 62366-1:2015
EN ISO 13532:2002

Signature: Zhang Zhiqiang

Date: 2021-08-15
Title: General manager
Position: Beijing, China

CERTIFICATE

EC Certificate No. 1434-IVDD-511/2021

EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

Beijing Applied Biological Technologies Co., Ltd.
Room C 101, Building 1, 37 Science Park Road, Changping District, 102206 Beijing, P.R.China

in vitro diagnostic medical devices
for self-testing

SARS-CoV-2 Antigen Rapid Test Cassette

CG9011(S)-1T-AN, CG9011(S)-5T-AN, CG9011(S)-10T-AN, CG9011(S)-20T-AN, CG9011(S)-30T-AN

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC
Validity of the Certificate: from 26.11.2021 to 27.05.2024

The date of issue of the Certificate: 26.11.2021

The date of the first issue of the Certificate: 26.11.2021

CE 1434

Issued under the Contract No. **MD-126/2021**
Application No: **241/2021**
Certificate bears the qualified signature.
Warsaw, 24/11/2021
Module A1

Vice-President

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 093143 0002 Rev. 02

Holder of Certificate: **Beijing Applied Biological Technologies Co., Ltd.**
Room A204, B304, D203, D203-1
No. 29 Shengmingyuan Road, Science Park, Changping District
102206 Beijing
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production, Distribution and Sales of Real-Time PCR Diagnostic Kits, Colloidal *Gold Method Diagnostic Kits*.**
Design and Development, Production, Distribution, Sales and Service of Automatic Nucleic Acid Extractor.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:Q5 093143 0002 Rev. 02

Report No.: BJ21099901

Valid from: 2021-10-21
Valid until: 2023-10-18

Date, 2021-10-21

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany
TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ СЕРТИФИКАТ ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 093143 0002 Rev. 02

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Beijing Applied Biological Technologies Co., Ltd.
Room A204, B304, D203, D203-1, No. 29 Shengmingyuan Road, Science Park, Changping District, 102206 Beijing, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production, Distribution and Sales of Real-Time PCR Diagnostic Kits.

Beijing Applied Biological Technologies Co., Ltd.
Building 5 C101, Building 6 504, Building 7 304, No.97 Changping Road, Shahe Town, Changping District, 102206 Beijing, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production, Distribution and Sales of Real-Time PCR Diagnostic Kits, Colloidal Gold Method Diagnostic Kits.
Design and Development, Production, Distribution, Sales and Service of Automatic Nucleic Acid Extractor.

TÜV®

Bundesinstitut
für Arzneimittel
und Medizinprodukte

Antigen-Tests zum direkten Erregernachweis des Coronavirus

Impressum Administration

Suchen: Alle Textspalten Los Aktionen

Nach 'x-abt' suchen

			Hersteller		Europäischer Bevollmächtigter		
Test-ID	**Name des Tests**	**Evaluieru... PEI**	**Name**	**Land**	**Name**	**Land**	**Probennahme**
AT1322/21	SARS-CoV-2 Antigen Rapid Test ...	Nein	Beijing Applied Biological Techn...	CN	Luxus Lebenswelt GmbH	DE	nasal

letzte Änderung: 23.12.2021 18:21

Release 1.0

Bundesinstitut für Arzneimittel und Medizinprodukte

Antigen-Tests zum direkten Erregernachweis des Coronavirus

Impressum Administration

Sonderzulassung ist eine positive Evaluierung des PEI eine zwingende Voraussetzung.

Hinweis: Eine aktuelle Übersicht der SARS-CoV-2-Tests, die von den europäischen Mitgliedsstaaten gegenseitig für COVID-19-Testergebnisbescheinigungen anerkannt werden und damit für das „EU Digital COVID-19 Certificate" berücksichtigt werden können, finden Sie im entsprechenden Dokument der Europäischen Kommission: Link zum Dokument

x-abt Los Aktionen

Nach 'x-abt' suchen

			Hersteller			Europäischer Bevollmächtigter			
Test-ID	**Handelsname**	**Evaluieru... PEI**	**Name**	**Stadt**	**Land**	**Name**	**Stadt**	**Land**	**Testo...**
AT927/21	2019-nCoV Antigen Rapid Test Cassette	Nein	Beijing Applied Biological Technologies Co., Ltd.	Beijing	CN	CMC MEDICAL DEVICES & DRUGS S.L.	Málaga	ES	POC (ohne Gerät)
AT926/21	2019-nCoV Antigen Rapid Test Cassette	Nein	Beijing Applied Biological Technologies Co., Ltd.	Beijing	CN	CMC MEDICAL DEVICES & DRUGS S.L.	Málaga	ES	POC (ohne Gerät)

letzte Änderung: 23.12.2021 18:21 * POC = Point of Care

Release 1.0

UCK Uniwersyteckie Centrum Kliniczne

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REGON 000288640, NIP 957 07 30 409

Supplement Clinical Evaluation Report for SARS-CoV-2 Antigen Rapid Test Cassette Anterior Nasal Swab

(Original name: 2019-nCoV Antigen Rapid Test Cassette Anterior Nasal Swab)

Company: Beijing Applied Biological Technologies Co., Ltd

Researchers	Title	Take responsibility
Ewelina Szpak mgr	Operator:	Test implementation, collect samples， report drafting
Paweł Chrzan PhD	Reviewer:	Report reviewing and approval

1. Summary

This trial is as the additional test for the first submission after the regulation updated and supply for the supplement request.

The first trial was conducted by Centralne Laboratorium Kliniczne Uniwersyteckie Centrum Kliniczne (University Clinical Center) from 2021-06-24 to 2021-07-06. In the first trial, anterior nasal swab samples from confirmed or suspected cases of viral pneumonia were enrolled for study, and a total of 440 valid samples were tested.

The second trial was conducted by Centralne Laboratorium Kliniczne Uniwersyteckie Centrum Kliniczne (University Clinical Center) from 2021-08-10 to 2021-09-20. In the second trial, anterior nasal swab samples from confirmed or suspected cases of viral pneumonia were enrolled for study, and a additional 270 valid samples were tested.

During the two trials, total of 710 samples were tested.

A total of 710 subjects were enrolled in this trial, including 347 males and 363 females, a total of 710 samples were detected in this trial. 240 cases were positive and 470 cases were negative. The positive consistent rate is 95.83%(Detection of >80%) and the negative consistent rate is 100.00%(Specificity >98%). Total consistent rate is 98.59 %.

2. Propose :

In first submission(Attachment 1), we completed total 220 positive and 220 negative samples. According to the new regulation MDCG 2021-21, which issued on August 2021, the new regulation increased the negative from total 220 to total 450 negative samples, include 300 non-infected individuals, 100 hospitalised patients and 50 potentially interfering and cross-reactive samples: including virus-positive samples of endemic human coronaviruses 229E, OC43, NL63, HKU1; influenza A, B, RSV, and other pathogens of respiratory diseases, eligible for differential diagnosis; including bacteria present in the sampling area.

To satisfy the new regulation, we provide additional total 250 negative samples, include 100 non-infected individuals, 100 hospitalised patients and 50 potentially interfering and cross-reactive samples.

And also, to monitor new emerging mutants of the virus, we tested additional 20 positive for the delta subtype samples to obtain the test result. Please check the Table 1 for more information.

Table 1: Summary of the count samples for the first submission and second submission

Requirement	Provide
100 Positive specimens	First submission ： 220 positive Second submission： 20 positive（delta） Total： 240 positive
300 Negative specimens from non-infected individuals	First submission ： 220 negative specimens from non-infected individuals Second submission： 100 negative specimens from non-infected individuals Total： 320 negative
100 Negative specimens from hospitalised patients	Second submission： 100 Negative specimens from hospitalised patients

50 Negative specimens Potentially interfering and cross-reactive samples	Second submission: 50 Negative specimens potentially interfering and cross-reactive samples

3. Materials for the Study

Investigational reagent: 2019-nCoV Antigen Rapid Test Cassette Anterior Nasal Swab
Manufacture: Beijing Applied Biological Technologies Co., Ltd.
Comparison reagent: Vitassay qPCR SARS-CoV-2 CE-approved
Manufacturer: Vitassay Healthcare S.L.U.

Product name	Manufacturer	Lot No.	Expiry date
2019-nCoV Antigen Rapid Test Cassette Anterior Nasal Swab	XABT	E20210821	2023-08-14
Vitassay qPCR SARS-CoV-2	Vitassay Healthcare S.L.U.	11046-448	2023-05-31
Nucleic acid extraction Kit	GeneProof crobee 201A	2027617	2022-03

4. Clinical Results and Analysis

4.1 Basic characteristics of subjects

A total of 710 subjects were enrolled in the two trials, including 347males and 363 females. The result for the investigational reagents shows total 230 positive and 480 negative in these two trails. The specific results are shown in below table.

Table 2 Basic information of subjects

Observation indicators	**Amount**	**Positive Numbers**	**Negative Numbers**
Gender	710	230	480
Male	347	115	232
Female	363	115	248
Age, (Years old)	**Amount**	**Positive Numbers**	**Negative Numbers**
< 1Y	7	0	7
1-10Y (including 10)	58	4	54
11-20Y (including 20)	95	11	84
21-30Y (including 30)	96	44	52
31-40Y (including 40)	88	43	45
41-50Y (including 50)	117	50	67
51-60Y (including 60)	79	31	48
61-70Y (including 70)	101	31	70
71-80Y (including 80)	40	7	33
81 -90Y (including 90)	27	7	20

>90Y	2	2	0
Minimum - maximum	0-94 years old		

710	230	480

4.2 Clinical evaluation results

Requirement	Acceptance criteria
Positive specimens	Detection of >80% (rapid tests);
Negative specimens	Specificity >98% (rapid tests)

Refer to: MDCG 2021-21 Guidance on performance evaluation of SARS-CoV-2 invitro diagnostic medical(Page 11)

Total 710 samples were tested. The result showed in below table.

The positive consistent rate is 95.83%(Detection of >80%) and the negative consistent rate is 100.00%(Specificity >98%). Total consistent rate is 98.59 %.

Table 3: Test Group Divided by Ct Value

Group	Ct of ORF gene	Amounts of samples
High/Medium Positive	Ct<25	167
Medium/Low Positive	25<Ct<30	51
Low Positive	Ct>30	22
Negative	Not detected.	470

Table 4: Result Analysis

Investigational Reagent		Comparison reagent		total
		Positive	Negative	
2019-nCoV Antigen Rapid Test Cassette Anterior Nasal Swab	Positive	230	0	230
	Negative	10	470	480
total		240	470	710

The evaluated reagent detection results are as follows:

Positive consistent rate = 95.83% (92.47%～97.98%)*

Negative consistent rate = 100.00% (99.22%～100.00%)*

Total consistent rate = 98.59% (97.43%～99.32%)*

*95% Confidence Interval

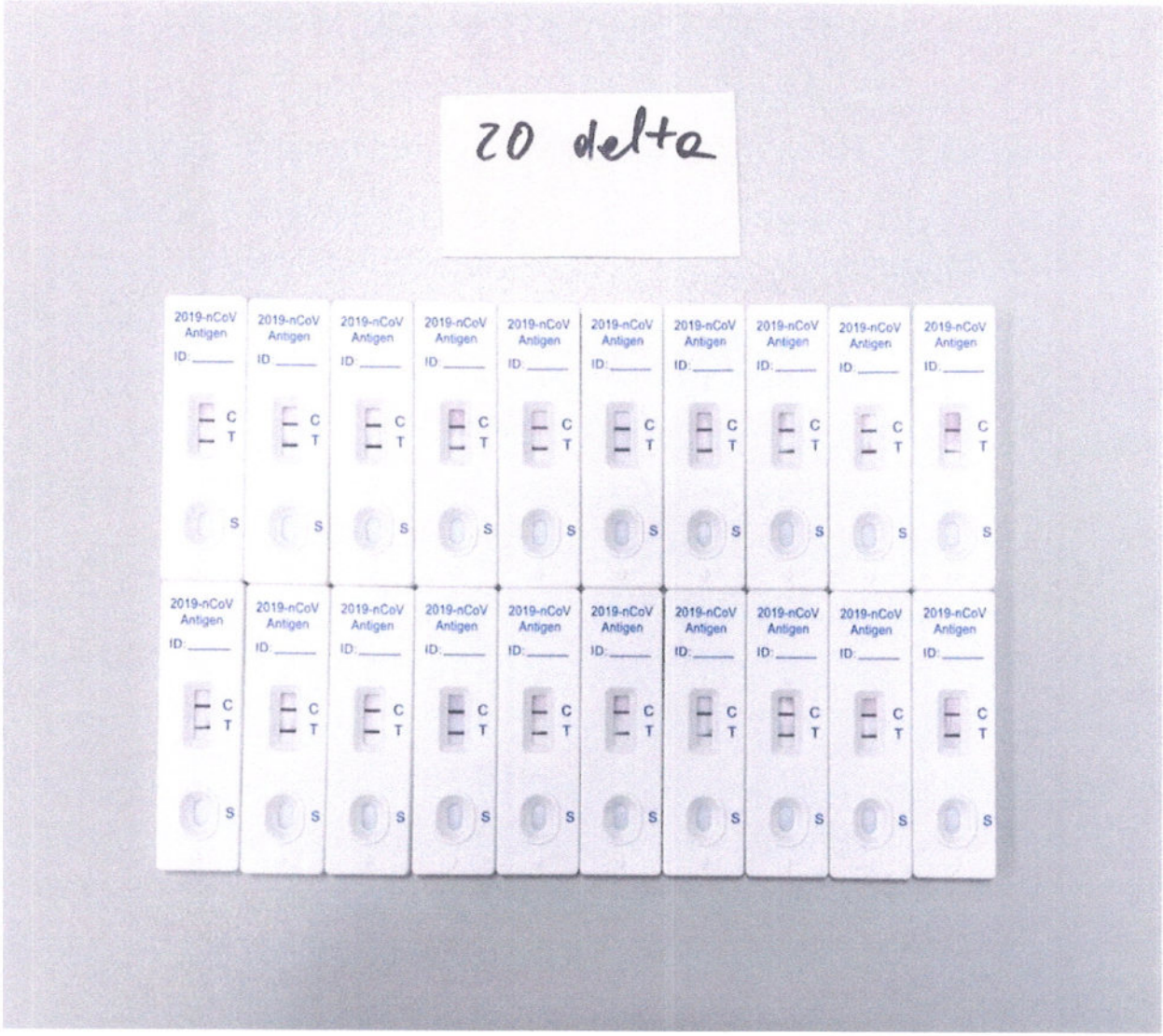
Kappa value = 0.968, indicating that the evaluated reagent detection results and the comparison results were in good consistency.

5. Study Conclusion

In summary, the 2019-nCoV Antigen Rapid Test Cassette Anterior Nasal Swab has shown satisfying sensitivity, specificity, and total accuracy in the present evaluation. It can be used as a rapid tool to assist the early diagnosis of COVID-19 cases.

6. Appendix

1. Positive patients (delta) 20 cases



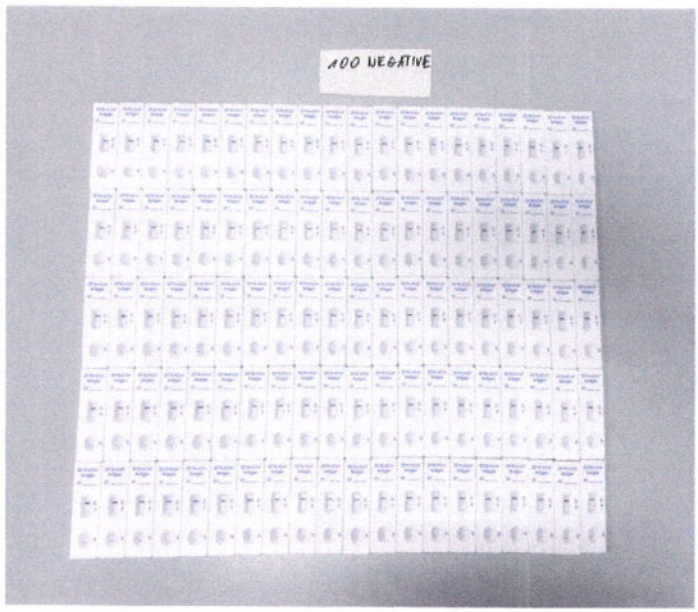
	Gender	Age	PCR result	Ct	Ag result	Line intensity	Comment
1.	M	44	positive	20,97	positive	(+++)	passed
2.	F	18	positive	34,38	positive	(++)	passed
3.	M	68	positive	23,28	positive	(+++)	passed
4.	M	35	positive	21,33	positive	(+++)	passed
5.	F	30	positive	24,43	positive	(+++)	passed
6.	F	34	positive	27,66	positive	(++)	passed
7.	M	69	positive	24,31	positive	(+++)	passed

8.	M	35	positive	18,99	positive	(+++)	passed
9.	F	69	positive	25,87	positive	(+++)	passed
10.	F	40	positive	29,15	positive	(+++)	passed
11.	F	58	positive	20,63	positive	(+++)	passed
12.	F	23	positive	36,98	positive	(+++)	passed
13.	F	42	positive	27,11	positive	(+++)	passed
14.	F	30	positive	18,52	positive	(+++)	passed
15.	M	44	positive	23,02	positive	(++)	passed
16.	M	11	positive	19,8	positive	(++)	passed
17.	M	35	positive	21,18	positive	(+++)	passed
18.	M	41	positive	18,09	positive	(+++)	passed
19.	M	42	positive	17,33	positive	(+++)	passed
20.	F	41	positive	18,76	positive	(+++)	passed

2. Negative patients 250 cases

Specimen type	Amount of the specimens
2.1 Non-infected individuals	100 Negative specimens from non-infected individuals
2.2 Hospitalised patients	100 Negative specimens from hospitalised patients
2.3 Potentially interfering and cross-reactive samples	50 Negative specimens potentially interfering and cross-reactive samples

2.1 Non-infected individuals



	Gender	Age	PCR result	Ct	Ag result	Line intensity	Comment
1	F	63	negative	ND	negative	(-)	passed
2	F	20	negative	ND	negative	(-)	passed
3	M	63	negative	ND	negative	(-)	passed
4	F	61	negative	ND	negative	(-)	passed
5	F	58	negative	ND	negative	(-)	passed
6	M	49	negative	ND	negative	(-)	passed
7	M	46	negative	ND	negative	(-)	passed
8	M	41	negative	ND	negative	(-)	passed
9	F	78	negative	ND	negative	(-)	passed
10	M	67	negative	ND	negative	(-)	passed
11	F	26	negative	ND	negative	(-)	passed
12	M	38	negative	ND	negative	(-)	passed
13	F	56	negative	ND	negative	(-)	passed
14	F	66	negative	ND	negative	(-)	passed
15	F	35	negative	ND	negative	(-)	passed
16	M	18	negative	ND	negative	(-)	passed
17	F	30	negative	ND	negative	(-)	passed
18	M	23	negative	ND	negative	(-)	passed
19	M	46	negative	ND	negative	(-)	passed
20	F	70	negative	ND	negative	(-)	passed
21	F	41	negative	ND	negative	(-)	passed
22	M	87	negative	ND	negative	(-)	passed
23	F	45	negative	ND	negative	(-)	passed
24	M	48	negative	ND	negative	(-)	passed
25	F	37	negative	ND	negative	(-)	passed
26	M	45	negative	ND	negative	(-)	passed
27	M	14	negative	ND	negative	(-)	passed
28	M	39	negative	ND	negative	(-)	passed
29	F	22	negative	ND	negative	(-)	passed
30	F	31	negative	ND	negative	(-)	passed
31	M	33	negative	ND	negative	(-)	passed
32	F	69	negative	ND	negative	(-)	passed
33	M	67	negative	ND	negative	(-)	passed
34	F	54	negative	ND	negative	(-)	passed
35	M	19	negative	ND	negative	(-)	passed
36	F	20	negative	ND	negative	(-)	passed
37	M	21	negative	ND	negative	(-)	passed
38	M	80	negative	ND	negative	(-)	passed

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info@uck.gda.pl
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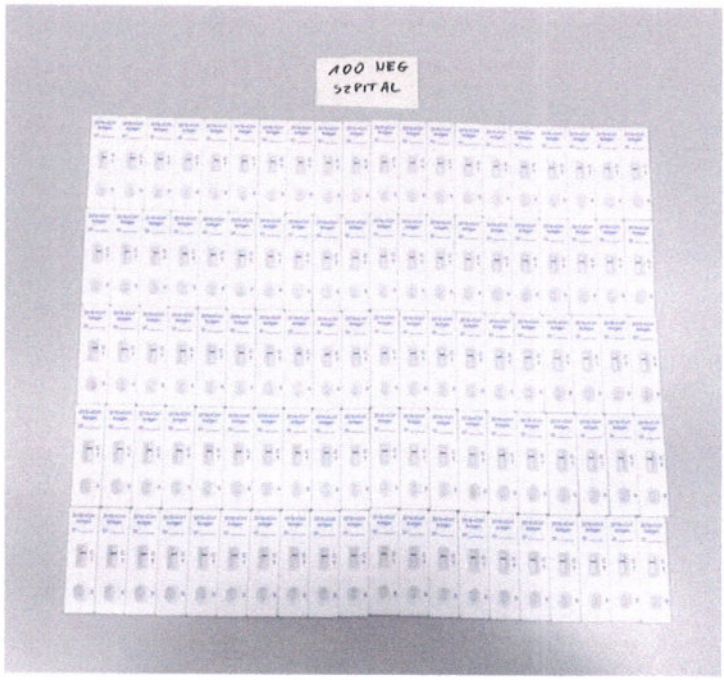
39	M	47	negative	ND	negative	(-)	passed
40	F	67	negative	ND	negative	(-)	passed
41	F	46	negative	ND	negative	(-)	passed
42	M	29	negative	ND	negative	(-)	passed
43	F	24	negative	ND	negative	(-)	passed
44	M	20	negative	ND	negative	(-)	passed
45	M	48	negative	ND	negative	(-)	passed
46	F	57	negative	ND	negative	(-)	passed
47	F	48	negative	ND	negative	(-)	passed
48	F	69	negative	ND	negative	(-)	passed
49	F	13	negative	ND	negative	(-)	passed
50	M	20	negative	ND	negative	(-)	passed
51	M	65	negative	ND	negative	(-)	passed
52	F	67	negative	ND	negative	(-)	passed
53	M	65	negative	ND	negative	(-)	passed
54	M	24	negative	ND	negative	(-)	passed
55	F	32	negative	ND	negative	(-)	passed
56	F	68	negative	ND	negative	(-)	passed
57	F	33	negative	ND	negative	(-)	passed
58	M	15	negative	ND	negative	(-)	passed
59	F	63	negative	ND	negative	(-)	passed
60	M	49	negative	ND	negative	(-)	passed
61	F	20	negative	ND	negative	(-)	passed
62	M	14	negative	ND	negative	(-)	passed
63	M	28	negative	ND	negative	(-)	passed
64	M	64	negative	ND	negative	(-)	passed
65	F	53	negative	ND	negative	(-)	passed
66	F	29	negative	ND	negative	(-)	passed
67	M	10	negative	ND	negative	(-)	passed
68	F	47	negative	ND	negative	(-)	passed
69	M	63	negative	ND	negative	(-)	passed
70	F	63	negative	ND	negative	(-)	passed
71	M	53	negative	ND	negative	(-)	passed
72	F	28	negative	ND	negative	(-)	passed
73	M	64	negative	ND	negative	(-)	passed
74	M	36	negative	ND	negative	(-)	passed
75	F	19	negative	ND	negative	(-)	passed
76	M	48	negative	ND	negative	(-)	passed
77	M	30	negative	ND	negative	(-)	passed
78	M	37	negative	ND	negative	(-)	passed

79	F	48	negative	ND	negative	(-)	passed
80	F	67	negative	ND	negative	(-)	passed
81	M	65	negative	ND	negative	(-)	passed
82	F	49	negative	ND	negative	(-)	passed
83	F	30	negative	ND	negative	(-)	passed
84	M	48	negative	ND	negative	(-)	passed
85	F	64	negative	ND	negative	(-)	passed
86	F	20	negative	ND	negative	(-)	passed
87	F	39	negative	ND	negative	(-)	passed
88	F	40	negative	ND	negative	(-)	passed
89	M	27	negative	ND	negative	(-)	passed
90	F	40	negative	ND	negative	(-)	passed
91	M	37	negative	ND	negative	(-)	passed
92	M	64	negative	ND	negative	(-)	passed
93	M	50	negative	ND	negative	(-)	passed
94	F	45	negative	ND	negative	(-)	passed
95	M	28	negative	ND	negative	(-)	passed
96	F	10	negative	ND	negative	(-)	passed
97	M	47	negative	ND	negative	(-)	passed
98	M	39	negative	ND	negative	(-)	passed
99	M	43	negative	ND	negative	(-)	passed
100	F	56	negative	ND	negative	(-)	passed

2.2 Hospitalised patients



	Gender	Age	PCR result	Ct	Ag result	Line intensity	comment	ICD 10*
1	M	9	negative	ND	negative	(-)	passed	C49.8
2	M	72	negative	ND	negative	(-)	passed	I62.0
3	F	11	negative	ND	negative	(-)	passed	E10.9
4	M	45	negative	ND	negative	(-)	passed	I63.3
5	F	64	negative	ND	negative	(-)	passed	I20.8
6	M	46	negative	ND	negative	(-)	passed	dializa
7	M	61	negative	ND	negative	(-)	passed	G00.1
8	M	42	negative	ND	negative	(-)	passed	D11.0
9	M	60	negative	ND	negative	(-)	passed	C34.1
10	M	17	negative	ND	negative	(-)	passed	dializa
11	F	40	negative	ND	negative	(-)	passed	G40.9
12	F	36	negative	ND	negative	(-)	passed	D63.0
13	M	4	negative	ND	negative	(-)	passed	C91.0
14	M	9	negative	ND	negative	(-)	passed	N18.8
15	M	89	negative	ND	negative	(-)	passed	S06.5
16	M	25	negative	ND	negative	(-)	passed	T24.3
17	M	60	negative	ND	negative	(-)	passed	C32.0
18	F	31	negative	ND	negative	(-)	passed	Z94.8
19	F	78	negative	ND	negative	(-)	passed	I25.0
20	F	27	negative	ND	negative	(-)	passed	J38.2
21	M	38	negative	ND	negative	(-)	passed	I60.2
22	M	60	negative	ND	negative	(-)	passed	C49.0
23	M	56	negative	ND	negative	(-)	passed	K25.2
24	F	67	negative	ND	negative	(-)	passed	C67.2
25	M	5	negative	ND	negative	(-)	passed	Z51.1
26	M	17	negative	ND	negative	(-)	passed	D69.3
27	M	7 days	negative	ND	negative	(-)	passed	P52.8
28	M	11 days	negative	ND	negative	(-)	passed	Q21.0
29	M	24	negative	ND	negative	(-)	passed	C62.9
30	M	77	negative	ND	negative	(-)	passed	C67.9
31	F	15	negative	ND	negative	(-)	passed	Z51.1
32	F	25	negative	ND	negative	(-)	passed	K58.0
33	M	4	negative	ND	negative	(-)	passed	C91.0
34	M	11	negative	ND	negative	(-)	passed	L20.9
35	M	66	negative	ND	negative	(-)	passed	R57.8
36	M	28	negative	ND	negative	(-)	passed	J96.0
37	M	34	negative	ND	negative	(-)	passed	S35.8

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38	F	46	negative	ND	negative	(-)	passed	Z51.0
39	F	80	negative	ND	negative	(-)	passed	I25.0
40	M	8	negative	ND	negative	(-)	passed	D46.2
41	F	57	negative	ND	negative	(-)	passed	D13.6
42	M	61	negative	ND	negative	(-)	passed	M48.8
43	F	86	negative	ND	negative	(-)	passed	I71.4
44	F	41	negative	ND	negative	(-)	passed	I60.1
45	F	64	negative	ND	negative	(-)	passed	A04.7
46	F	9	negative	ND	negative	(-)	passed	G40.8
47	F	50	negative	ND	negative	(-)	passed	Z51.0
48	F	12	negative	ND	negative	(-)	passed	Wydanie karty
49	M	72	negative	ND	negative	(-)	passed	C34.8
50	M	10	negative	ND	negative	(-)	passed	C91.0
51	M	10	negative	ND	negative	(-)	passed	C71.6
52	M	11	negative	ND	negative	(-)	passed	C49.4
53	M	6	negative	ND	negative	(-)	passed	C91.0
54	M	41	negative	ND	negative	(-)	passed	S21.1
55	M	28	negative	ND	negative	(-)	passed	J96.0
56	M	35	negative	ND	negative	(-)	passed	T06.8
57	M	67	negative	ND	negative	(-)	passed	R57.8
58	F	79	negative	ND	negative	(-)	passed	R57.8
59	M	27	negative	ND	negative	(-)	passed	I34.0
60	M	63	negative	ND	negative	(-)	passed	Z51.0
61	F	36	negative	ND	negative	(-)	passed	A15.0
62	M	65	negative	ND	negative	(-)	passed	J16.8
63	M	38	negative	ND	negative	(-)	passed	I61.0
64	F	81	negative	ND	negative	(-)	passed	Z51.0
65	M	60	negative	ND	negative	(-)	passed	T22.3
66	F	6	negative	ND	negative	(-)	passed	D70
67	M	49	negative	ND	negative	(-)	passed	J96.0
68	F	13 weeks	negative	ND	negative	(-)	passed	Q24.5
69	M	59	negative	ND	negative	(-)	passed	C77.0
70	M	60	negative	ND	negative	(-)	passed	J96.0
71	F	12	negative	ND	negative	(-)	passed	N18.0
72	F	12	negative	ND	negative	(-)	passed	C91.0
73	M	72	negative	ND	negative	(-)	passed	I63.9
74	M	17	negative	ND	negative	(-)	passed	D38.3
75	F	82	negative	ND	negative	(-)	passed	I63.9
76	F	15	negative	ND	negative	(-)	passed	N18.0

77	M	67	negative	ND	negative	(-)	passed	I70.2
78	M	56	negative	ND	negative	(-)	passed	Z51.0
79	F	11	negative	ND	negative	(-)	passed	N39.1
80	M	68	negative	ND	negative	(-)	passed	Z51.0
81	M	29	negative	ND	negative	(-)	passed	I73.1
82	F	3	negative	ND	negative	(-)	passed	G40.1
83	F	5 days	negative	ND	negative	(-)	passed	P61.8
84	F	6,5 weeks	negative	ND	negative	(-)	passed	BD
85	M	2	negative	ND	negative	(-)	passed	D16.4
86	M	3	negative	ND	negative	(-)	passed	Q21.3
87	M	65	negative	ND	negative	(-)	passed	I25.0
88	M	76	negative	ND	negative	(-)	passed	I35.0
89	F	64	negative	ND	negative	(-)	passed	I35.1
90	M	11	negative	ND	negative	(-)	passed	N18.8
91	F	49	negative	ND	negative	(-)	passed	J85.3
92	F	17	negative	ND	negative	(-)	passed	D44.1
93	F	84	negative	ND	negative	(-)	passed	I35.0
94	M	8	negative	ND	negative	(-)	passed	D46.9
95	M	31	negative	ND	negative	(-)	passed	Z51.1
96	M	2	negative	ND	negative	(-)	passed	C92.0
97	M	5	negative	ND	negative	(-)	passed	C74.9
98	M	53	negative	ND	negative	(-)	passed	BD
99	F	74	negative	ND	negative	(-)	passed	C34.3
100	F	19	negative	ND	negative	(-)	passed	E66.0

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C49.8 Malignant neoplasm of other connective and soft tissue Overlapping lesion of connective and soft tissue

I62.0Nontraumatic subdural haemorrhage

E10.9 Family history of diabetes mellitus

Conditions classifiable to E10-E14, O24

I63.3 Cerebral infarction due to thrombosis of cerebral arteries

I20.8 Other forms of angina pectoris

G00.1 Pneumococcal meningitis

D11.0 Benign neoplasm of major salivary glands, Parotid gland

C34.1 Malignant. Upper lobe, bronchus or lung

G40.9 Epilepsy, unspecified

D63.0*Anaemia in neoplastic disease

C91.0 Acute lymphoblastic leukaemia [ALL]

N18.8 Chronic kidney disease

S06.5 Traumatic subdural haemorrhage

T91.8 Sequelae of other specified injuries of neck and trunk

Sequelae of injury classifiable to S13.-, S14.2-S14.6, S15-S18, S19.7-S19.8, S23.-, S24.2-S24.6, S25.-, S28.-, S29.0-S29.8, S33.-, S34.2-S34.8, S35.-, S38.-, S39.0-S39.8, T09.2 and T09.4 -T09.8

C32.0 Malignant neoplasm of larynx Glottis

Z95.8 Presence of other cardiac and vascular implants and grafts

I25.0 Atherosclerotic cardiovascular disease, so described

J38.2 Nodules of vocal cords

I60.2 Subarachnoid haemorrhage from anterior communicating artery

C49.0 Connective and soft tissue of head, face and neck

K25.2 Gastric ulcer : acute with both haemorrhage and perforation

C67.2 Lateral wall of bladder

Z51.1 Chemotherapy session for neoplasm

D69.3 Idiopathic thrombocytopenic purpura

P52.8 Other intracranial (nontraumatic) haemorrhages of fetus and newborn

Q21.0 Ventricular septal defect

C62.9 Malignant Testis, unspecified

C67.9 Malignant Bladder, unspecified

K58.0 Irritable bowel syndrome

C91.0Acute lymphoblastic leukaemia [ALL]

L20.9Atopic dermatitis, unspecified

R57.8Other shock

J96.0Acute respiratory failure

S35.8Injury of other blood vessels at abdomen, lower back and pelvis level

Z51.0Radiotherapy session

I25.0Atherosclerotic cardiovascular disease, so described

D46.2Refractory anaemia with excess of blasts [RAEB]

D13 Benign neoplasm of other and ill-defined parts of digestive system, Pancreas

M48.8Other specified spondylopathies

I71.4Abdominal aortic aneurysm, without mention of rupture

I60.1Subarachnoid haemorrhage from middle cerebral artery

A04.7Enterocolitis due to Clostridium difficile

G40.8Other epilepsy

Z51.0Radiotherapy session

Wydanie karty – release documentation

C34.8Overlapping lesion of bronchus and lung

C91.0Acute lymphoblastic leukaemia [ALL]

C71.6 Malignant neoplasm of brain, Cerebrum

C49.4 Malignant neoplasm Connective and soft tissue of abdomen

C91.0Acute lymphoblastic leukaemia [ALL]

S21.1Open wound of front wall of thorax

J96.0Acute respiratory failure

T06.8Other specified injuries involving multiple body regions

R57.8Other shock, endotoxic

R57.8Other shock, endotoxic

I34.0Mitral (valve) insufficiency

Z51.0Radiotherapy session

T95.2Sequelae of burn, corrosion and frostbite of upper limb (Sequelae of injury classifiable to T22-T23, T33.4-T33.5, T34.4-T34.5 and T35.4)

D70Agranulocytosis

J96.0Acute respiratory failure

N18.0 Chronic kidney disease,

C91.0Acute lymphoblastic leukaemia [ALL]

I63.9Cerebral infarction, unspecified

D38.3 Neoplasm of uncertain or unknown behaviour of middle ear and respiratory and intrathoracic organs Mediastinum

I63.9Cerebral infarction, unspecified

N18.0 Chronic kidney disease

I70.2Atherosclerosis of arteries of extremities

Z51.0Radiotherapy session

N39.1Persistent proteinuria, unspecified

Z51.0Radiotherapy session

I73.1Thromboangiitis obliterans [Buerger]

G40.1Localization-related (focal)(partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures

P61.8Other specified perinatal haematological disorders

BD – missing data

D16.4 Benign neoplasm of bone and articular cartilage Bones of skull and face

Q21.3Tetralogy of Fallot

I25.0Atherosclerotic cardiovascular disease, so described

I35.0Aortic (valve) stenosis

I35.1Aortic (valve) insufficiency

N18.8 Chronic kidney disease, stage 5

J85.3Abscess of mediastinum

D44.1 Neoplasm of uncertain or unknown behaviour of endocrine glands Adrenal gland

I35.0Aortic (valve) stenosis

D46.9Myelodysplastic syndrome, unspecified

Z51.1Chemotherapy session for neoplasm

C92.0Acute myeloblastic leukaemia [AML]

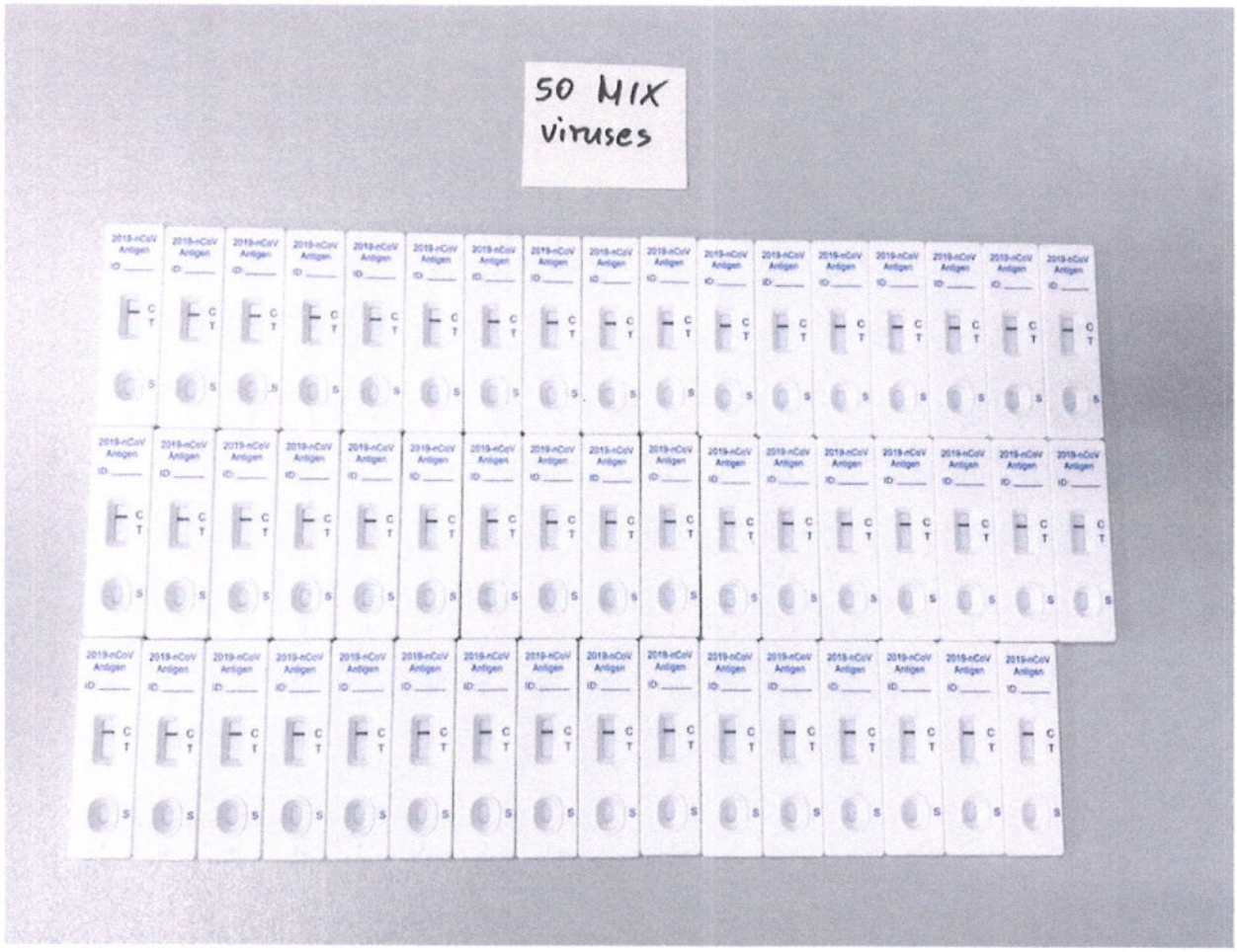
C74.9 Malignant neoplasm of adrenal gland Adrenal gland, unspecified

BD – missing data

C34.3 Malignant neoplasm of bronchus and lung Lower lobe, bronchus or lung

E66.0Obesity due to excess calories

2.3 Potentially interfering and cross-reactive samples



	nr lab	Patogen	Gender	Age	PCR result	Ct	Ag result	Line intensity	comment
1	5171872	NL63	F	11	negative	ND	negative	(-)	passed
2	5215292	NL63	M	17	negative	ND	negative	(-)	passed
3	5228407	HKU1	F	7	negative	ND	negative	(-)	passed
4	5244476	RSV	M	5	negative	ND	negative	(-)	passed
5	5247406	HKU1, adenovirus	F	3	negative	ND	negative	(-)	passed
6	1059703	RSV	M	3	negative	ND	negative	(-)	passed
7	5255243	HKU1	F	11	negative	ND	negative	(-)	passed
8	5256629	influenza A H3	M	19	negative	ND	negative	(-)	passed
9	5260436	HKU1	F	19	negative	ND	negative	(-)	passed

10	5264495	NL63	M	4	negative	ND	negative	(-)	passed
11	5272088	RSV	F	5	negative	ND	negative	(-)	passed
12	5284511	influenza A H3	F	3	negative	ND	negative	(-)	passed
13	5289286	NL63	F	5	negative	ND	negative	(-)	passed
14	5291030	NL63 A H3 parainfluenza	M	14	negative	ND	negative	(-)	passed
15	5292773	Influenza A H1	F	8	negative	ND	negative	(-)	passed
16	5295879	NL63	M	7	negative	ND	negative	(-)	passed
17	5296524	influenza A, Rhinovirus/Enterovirus	F	7	negative	ND	negative	(-)	passed
18	5297685	OC43	F	7	negative	ND	negative	(-)	passed
19	5302419	influenza A H3, adenovirus	F	3	negative	ND	negative	(-)	passed
20	530338	influenza A H3	M	16	negative	ND	negative	(-)	passed
21	5304989	influenza A H3	M	11	negative	ND	negative	(-)	passed
22	5308155	NL63	M	44	negative	ND	negative	(-)	passed
23	5308575	OC43, influenza A H3	F	4	negative	ND	negative	(-)	passed
24	5319051	influenza A H3	M	67	negative	ND	negative	(-)	passed
25	1101539	NL63	F	6	negative	ND	negative	(-)	passed
26	5322663	RSV	F	19	negative	ND	negative	(-)	passed
27	5323316	NL63	F	5	negative	ND	negative	(-)	passed
28	5323345	NL63	M	54	negative	ND	negative	(-)	passed
29	1106073	HKU1, influenza A H1	M	57	negative	ND	negative	(-)	passed
30	5330451	NL63	F	71	negative	ND	negative	(-)	passed
31	5332412	HKU1	M	58	negative	ND	negative	(-)	passed
32	5332711	RSV	M	59	negative	ND	negative	(-)	passed
33	5337443	Rhinovirus/Enterovirus	F	5	negative	ND	negative	(-)	passed
34	5338410	RSV	M	48	negative	ND	negative	(-)	passed
35	5351266	HKU1	M	58	negative	ND	negative	(-)	passed
36	5820324	229E	F	22	negative	ND	negative	(-)	passed
37	5824791	OC43	M	4	negative	ND	negative	(-)	passed
38	5860690	OC43	M	5 weeks	negative	ND	negative	(-)	passed
39	5904033	OC43	F	19	negative	ND	negative	(-)	passed
40	5903901	OC43	M	9	negative	ND	negative	(-)	passed
41	5944153	adenovirus, parainfluenza	F	5	negative	ND	negative	(-)	passed
42	5948147	OC43	M	4 months	negative	ND	negative	(-)	passed

43	5949604	OC43, adenovirus	F	5	negative	ND	negative	(-)	passed
44	5951500	NL63	F	12	negative	ND	negative	(-)	passed
45	6083654	RSV	F	5	negative	ND	negative	(-)	passed
46	6094665	229E, infuenza B	F	58	negative	ND	negative	(-)	passed
47	6094912	229E	F	23	negative	ND	negative	(-)	passed
48	5965022	Rhinovirus/Enterovirus	F	10	negative	ND	negative	(-)	passed
49	5988784	Parainfluenza 4	F	1	negative	ND	negative	(-)	passed
50	6082515	Influenza B	M	57	negative	ND	negative	(-)	passed

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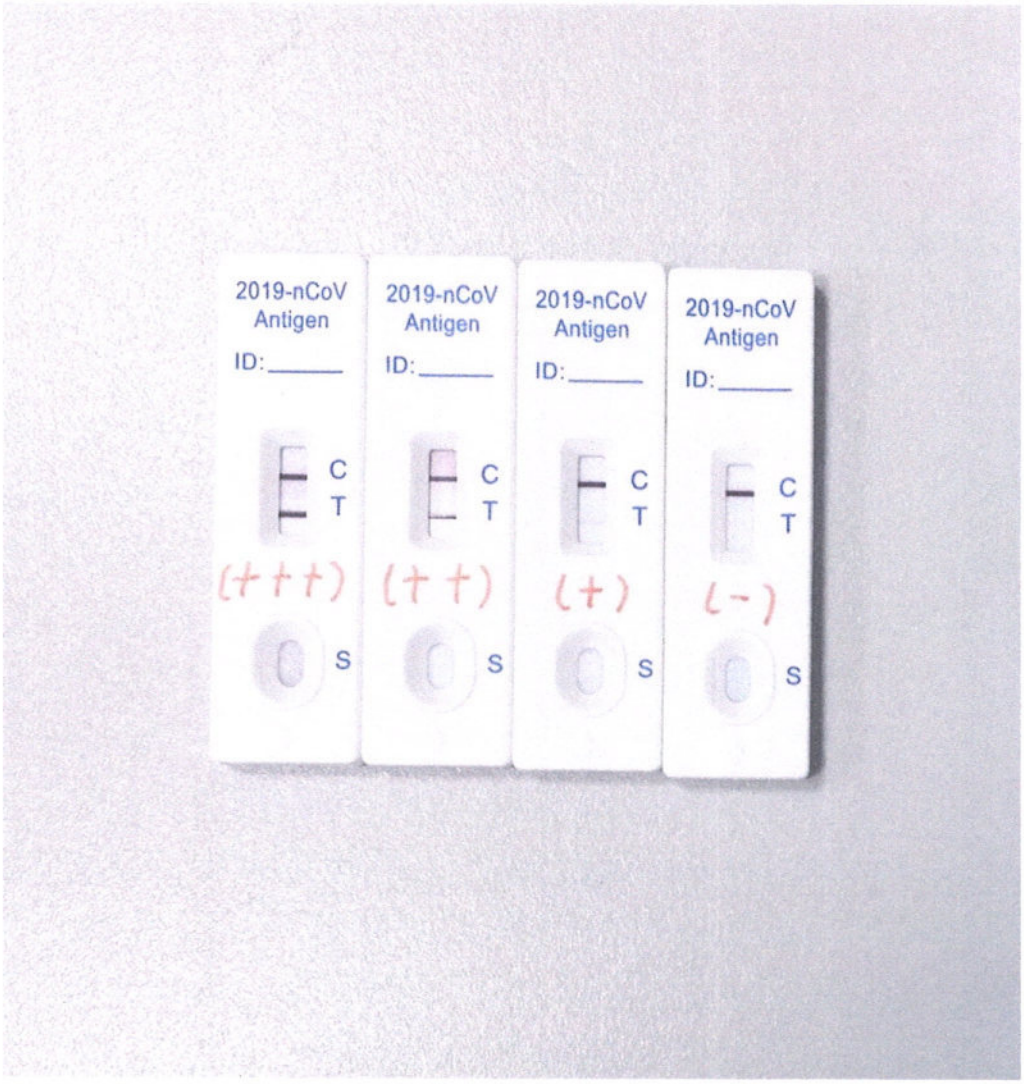
Product photos

3.1

Package

3.2 Test Cassette



Signatures

Operator: mgr Ewelina Szpak 10708 DIAGNOSTA LABORATORYJNY Ewelina Szpak Date: 30.09.2021

Reviewer: dr n. med. Paweł Chrzan 09893 DIAGNOSTA LABORATORYJNY Date: 30.09.2021

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2019-nCoV Antigen Rapid Test Cassette

Anterior Nasal Swab

Clinical Evaluation Report

Company: Beijing Applied Biological Technologies Co., Ltd

Start date of the Clinical Trial: 2021-06-24

End date of the Clinical Trial: 2021-07-13

Report prepared by: Paweł Chrzan PhD **Date: 2021-07-14**
Report checked by: Aneta Gołaszewska MS **Date: 2021-07-16**
Report approved by: Paweł Chrzan PhD **Date: 2021-07-16**

Name of the Lab(stamp)
Centralne Laboratorium Kliniczne Uniwersyteckie Centrum Kliniczne (University Clinical Center)
ul. Mariana Smoluchowskiego 17, 80-214 Gdansk

Table of Contents

Abstract

1. Summary

2019-nCoV Antigen Rapid Test Cassette Anterior Nasal Swab produced by Beijing Applied Biological Technologies Co., Ltd. as the investigational reagent, The trial was conductedCentralne Laboratorium Kliniczne Uniwersyteckie Centrum Kliniczne (University Clinical Center) from2021-06-24 to 2021-07-06. In this trial, anterior nasal swab samples from confirmed or suspected cases of viral pneumonia were enrolled for study, and a total of 440 valid samples were tested.

A total of 440 subjects were enrolled in this trial, including 203 males and 237 females, a total of 440 samples were detected in this trial. 220 cases were positive and 220 cases were negative.

Results: the 440 samples included 220 of positive samples, and 220 negative samples. Statistical analysis: the sensitivity of the investigational reagent detection results was 95.45% (91.80%-97.80%), the clinical specificity was 100.00% (98.34%-100.00%), and the total coincidence rate was 97.73% (95.86%-98.90%), that is, the investigational reagent detection results and the comparison results were in good consistency.

2. Main researchers

Clinical trial personnel	Institution	Responsibilities
Paweł Chrzan PhD	University Clinical Center	Clinical trial report writer, principal investigator, and person in charge of statistics
Michał Makowiecki MSc	University Clinical Center	Overall coordination
Paweł Chrzan PhD	University Clinical Center	Sample management
Aneta Gołaszewska MSc	University Clinical Center	Experimental operation

3. Abbreviations

Abbreviations	Full name
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
2019-nCoV	2019 novel coronavirus
PCR	Polymerase chain reaction

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1.Product Information

1.1 Intended Use

2019-nCoV nucleocapsid antigen is generally detectable in anterior nasal swab during the acute phase of infection(within seven days after symptoms appeared). Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses.

Negative results do not rule out 2019-nCoV infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with 2019-nCoV, the test results of this kit are only for clinical reference.The 2019-nCoV Antigen Rapid Test Cassette is only used as an auxiliary diagnosis, not as a basis for clinical diagnosis.

1.2 Test Principle

The test is based on the specific antibody-antigen reaction and immunoanalysis technology to detect 2019-nCoV antigen from anterior nasal swab specimens. During testing, a specimen migrates upward by capillary action. The 2019-nCoV antigens if present in the specimen will bind to the antibody conjugates. The immune complex is then captured on the membrane by the pre-coated 2019-nCoV nuclenocapsid protein monoclonal antibody, and a visible colored line will show up in the test line region indicating a positive result. In the absence of 2019-nCoV antigens, a colored line will not form in the test line region indicating a negative result.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane siphoning has occurred.

1.3 Product Storage

Storage conditions and expiration date: The kit should be stored at 2-30℃, and is valid provisionally for 24 months. Once open the pouch, the test should be used within 30min.

2.Study Objective

The objective of the study is to evaluate the consistency of the 2019-nCoV Antigen Rapid Test Cassette Anterior Nasal Swab produced by Beijing Applied Biological Technologies Co., Ltd (hereinafter referred to as XABT) with the comparison reagent.

3.Trial management

Before assessment, the technical staff of XABT and the researchers made discussions together to formulate the clinical study protocol, implemented in strict accordance with the study protocol, and agreed to clarify the objectives, contents and duties of both parties.

The researchers participating in the assessment had received technical training, and they were scientific researchers with high qualifications and rich experience.

The assessment samples and related data were managed by designated personnel. The data were archived in a computer in multiple copies.

Any other situation not specified in the protocol and occurring during the assessment was resolved by the two parties after consultation.

4.Study Design

4.1 Overall trial design and protocol

This clinical trial was designed to compare with the comparison reagent to evaluate the consistency. The anterior nasal swab specimens will be included in the trial， both

the samples will be tested by the two methods and analysis the test data to evaluate the consistency.

4.2 Sample Group

The samples are classified into two groups which are positive group and the negative group. Meanwhile, the samples shall be tested via the investigational reagent, and then compare the test results of the product with the comparison method and perform statistical analysis.The study was expected to test a total 440 samples.

4.3 Sample inclusion criteria, exclusion criteria, and rejection criteria

1） Inclusion criteria

①Samples from confirmed or suspected cases of novel coronavirus pneumonia, or with pneumonia, close contact, fever and other relevant symptoms;

②Samples from confirmed cases and released/discharged cases with previously negative result in SARS-CoV-2 detection;

③Interfering samples (such as samples from patients carrying influenza virus, respiratorysyncytial virus, rhinovirus, etc.);

④At all ages, male or female (try to cover all age groups);

2）Exclusion criteria

①Sample collection, shipment and storage do not meet relevant requirements;

②Samples contaminated or with an insufficient size;

③Other nonconforming samples considered by the principal investigator.

3） Rejection criteria:

①Sample collection, shipment and storage do not meet the requirements; the trial cannot be completed due to various reasons.

②Abnormal experimental results occur for unexpected reasons , such as the test cassette failure and operating errors.

③The concentration of interfering substances in the sample is beyond the product requirements, leading to abnormal clinical data.

④Other factors recognized by the principal investigator.

4.4 Sample collection, sample handling and preservation

Sample collection:

Put the swab into one nostril. The swab tip should be inserted no less than 2.5 cm (1 inch) from the edge of the nostril. Roll swab at least 3 times along the mucosa inside the nostril. Leave swab in the nostril for several seconds. Using the same swab, repeat this process for the other nostril. Withdraw swab from the nasal cavity.(Caution: This may feel uncomfortable. Do not insert the swab any deeper if you feel strong resistance or pain.)

Sample handling:

Insert the swab into the extraction tube which contains the extraction reagent. Rotate the swab inside the tube using a circular motion to roll the side of the extraction tube so that the solution is expressed and reabsorbed from the swab. Pinch the extraction tube with fingers and elute the liquid on the swab as far as possible into the extraction reagent, then pull out the swab. The extracted solution will be used as test specimen.

4.5 Experiment method

To test the clinical samples using both investigational reagent and the comparison reagent, record the test result. To evaluate the consistency of the test results between the investigational reagent and the comparison method.

The test operation is carried out in strict accordance with the respective instructions.

4.6 Quality control method

Laboratory quality control shall follow the quality control requirements of clinical institutions and departments to ensure the standardization of the clinical trial process.

Quality control before analysis: Check whether the sample collection and processing meet requirements and whether the sample information is complete and traceable.

Quality control should be performed in accordance with the requirements of the instructions of the evaluated reagent and Predicate device to ensure that the reagents

are under effective quality control and ensure the accuracy and repeatability of the test data.

4.7 Statistical analysis methods for clinical trial data

Statistical methods: the positive coincidence rate, negative coincidence rate, clinical sensitivity, clinical specificity, overall coincidence rate and 95% confidence interval of the qualitative detection results of the evaluated reagent were summarized in the form of four-grid table, the qualitative detection results of the two methods were summarized in the form of four-grid table, and Kappa test (consistency test) was performed on the qualitative results to verify the consistency of the qualitative results of the consistency with the clinical diagnosis/exclusion results.

Four-grid table statistics

Fill in the test results in the form of the following four-grid table, calculate the positive coincidence rate, negative coincidence rate, overall coincidence rate and 95% confidence interval of the results of the evaluated reagent and the Predicate device, and calculate the clinical sensitivity, clinical specificity and 95% confidence interval of the evaluated reagent detection result and clinical diagnosis/exclusion result, expressed using the following formula:

Investigational Reagent	**Comparison Result**		
	Positive	Negative	Total
Positive	a	b	a+b
Negative	c	d	c+d
Total	a+c	b+d	n (a+b+c+d)

a is true positive, b is false positive, c is false negative, and d is true negative

Positive coincidence rate / clinical sensitivity = a/(a+c)×100% (95%CI)

Negative coincidence rate / clinical specificity = d/(b+d)×100%(95%CI)

Overall coincidence rate = (a+d)/(a+b+c+d)×100%(95%CI)

Kappa test (consistency test)

To test whether there are consistency, equivalence or difference among evaluated reagent and the comparison method, the evaluated reagent and clinical diagnosis/exclusion result have consistency, equivalence or difference in the test result for a same sample, a statistical software will be used to calculate the Kappa value to make statistical analysis of the test result, and it will be significant for determining the consistency only when the Kappa value is 0-1. The higher the Kappa value, the better the consistency. It is generally considered that when the Kappa value is ≥0.75, they are highly consistent, and the two reagent systems are equivalent. If the Kappa value is <0.4, the two reagent systems are considered to be inconsistent, and further clinical validation is required.

2. Materials for the Study

Investigational reagent: 2019-nCoV Antigen Rapid Test Cassette Anterior Nasal Swab

Manufacturer: Beijing Applied Biological Technologies Co., Ltd.

Comparison reagent: Vitassay qPCR SARS-CoV-2 CE-approved

Manufacturer: Vitassay Healthcare S.L.U.

Table 1 Materials for the study

Product name	Manufacturer	**Lot No.**	**Expiry date**
2019-nCoV Antigen Rapid Test Cassette Anterior Nasal Swab	XABT	E20210608	2023-06-01
Vitassay qPCR SARS-CoV-2	Vitassay Healthcare S.L.U.	11046-416	2023-02-28
Nucleic acid extraction Kit	GeneProof crobee 201A	2027617	2022-03

6.Clinical Results and Analysis

6.1 Basic characteristics of subjects

A total of 440 subjects were enrolled in this trial, including 203 males and 237females. The specific results are shown in below table.

Table 2 Basic information of subjects

Observation indicators	Amount	Positive Numbers	Negative Numbers
Gender	440	210	230
Male	203	105	98
Female	237	105	132
Age,（Years old）	Amount	Positive Numbers	Negative Numbers
1-10Y (including 10)	15	4	11
11-20Y (including 20)	54	9	45
21-30Y (including 30)	68	41	27
31-40Y (including 40)	59	38	21
41-50Y (including 50)	78	44	34
51-60Y (including 60)	54	30	24
61-70Y (including 70)	61	28	33
71-80Y (including 80)	28	7	21
81-90Y (including 90)	21	7	14
>90Y	2	2	0
Minimum - maximum	1-94 years old		

6.2 Clinical evaluation results

Total 220 positive and 220 negative samples were tested. The result showed in below table.

The positive consistent rate is 95.45% (91.80%-97.80%) and the negative consistent rate is 100.00% (98.34% -100.00%). Total consistent rate is 97.73 % (95.86% -98.90%)。

Table 3: Test Group Divided by Ct Value

Group	Ct of ORF gene	Amounts of samples
High/Medium Positive	Ct≤ 25	153
Medium/Low Positive	25<Ct≤30	47
Low Positive	Ct>30	20
Negative	Not detected.	220

Table 4: Result Analysis

Investigational Reagent		Comparison reagent		total
		Positive	Negative	
2019-nCoV Antigen Rapid Test Cassette Anterior Nasal Swab	Positive	210	0	210
	Negative	10	220	230
total		220	220	440

The evaluated reagent detection results are as follows:

Positive consistent rate = 95.45% (91.80%-97.80%)*

Negative consistent rate = 100.00% (98.34% -100.00%)*

Total consistent rate =97.73 % (95.86% -98.90%)*

*95% Confidence Interval

Kappa value = 0.955, indicating that the evaluated reagent detection results and the comparison results were in good consistency.

7.Study Conclusion

The comparison study was conducted using 2019-nCoV Antigen Rapid Test Cassette Anterior Nasal Swab and the Vitassay qPCR SARS-CoV-2 RT-PCR, the results : the positive consistent rate is 95.45% (91.80%-97.80%)and the negative consistent rate is 100.00% (98.34% -100.00%),total consistent rate is 97.73 % (95.86% -98.90%).

Indicating a good consistency with the comparison product. Shows that the 2019-nCoV Antigen Rapid Test Cassette Anterior Nasal Swab can meet the clinical needs.

8.References

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

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

9.Appendix

Test Result Forms

	Gender	age	onset time (day)	PCR Results	CT ORF1 ab	Ag result	line intensity	comment
1.	M	63	3	positive	15,45	positive	(+)	passed
2.	M	28	5	positive	15,69	positive	(+)	passed
3.	M	37	3	positive	16,2	positive	(+)	passed
4.	M	37	4	positive	16,29	positive	(+)	passed
5.	F	61	2	positive	16,45	positive	(+)	passed
6.	M	81	2	positive	16,53	positive	(+)	passed
7.	M	56	2	positive	16,89	positive	(+)	passed
8.	F	37	2	positive	17,12	positive	(+)	passed
9.	M	61	2	positive	17,2	positive	(+)	passed
10.	F	67	1	positive	17,26	positive	(+)	passed
11.	F	61	2	positive	17,29	positive	(+)	passed
12.	F	10	2	positive	17,34	positive	(+)	passed
13.	F	48	2	positive	17,34	positive	(+)	passed
14.	M	57	2	positive	17,5	positive	(+)	passed
15.	F	50	1	positive	17,53	positive	(+)	passed
16.	M	65	5	positive	17,54	positive	(+)	passed
17.	M	35	2	positive	17,58	positive	(+)	passed
18.	M	46	2	positive	17,58	positive	(+)	passed
19.	F	42	2	positive	17,64	positive	(+)	passed
20.	F	37	1	positive	17,65	positive	(+)	passed
21.	F	65	2	positive	17,8	positive	(+)	passed
22.	F	94	3	positive	17,8	positive	(+)	passed
23.	M	10	2	positive	17,85	positive	(+)	passed
24.	M	34	1	positive	17,96	positive	(+)	passed
25.	F	42	2	positive	18,15	positive	(+)	passed

26.	M	63	2	positive	18,22	positive	(+)	passed
27.	M	61	3	positive	18,34	positive	(+)	passed
28.	F	64	2	positive	18,45	positive	(+)	passed
29.	F	60	2	positive	18,45	positive	(+)	passed
30.	F	66	2	positive	18,46	positive	(+)	passed
31.	F	48	2	positive	18,56	positive	(+)	passed
32.	M	45	2	positive	18,56	positive	(+)	passed
33.	M	27	5	positive	18,64	positive	(+)	passed
34.	M	46	1	positive	18,8	positive	(+)	passed
35.	F	26	3	positive	18,82	positive	(+)	passed
36.	F	54	2	positive	19	positive	(+)	passed
37.	F	45	4	positive	19	positive	(+)	passed
38.	F	41	1	positive	19,02	positive	(+)	passed
39.	M	25	2	positive	19,07	positive	(+)	passed
40.	M	46	1	positive	19,24	positive	(+)	passed
41.	F	27	2	positive	19,3	positive	(+)	passed
42.	F	38	1	positive	19,31	positive	(+)	passed
43.	M	50	5	positive	19,32	positive	(+)	passed
44.	M	34	2	positive	19,34	positive	(+)	passed
45.	M	23	4	positive	19,45	positive	(+)	passed
46.	F	15	3	positive	19,53	positive	(+)	passed
47.	F	58	2	positive	19,54	positive	(+)	passed
48.	M	56	2	positive	19,54	positive	(+)	passed
49.	F	45	1	positive	19,56	positive	(+)	passed
50.	M	60	1	positive	19,58	positive	(+)	passed
51.	F	53	1	positive	19,59	positive	(+)	passed
52.	M	31	2	positive	19,68	positive	(+)	passed
53.	F	1	1	positive	19,75	positive	(+)	passed
54.	F	25	4	positive	19,79	positive	(+)	passed
55.	M	84	2	positive	19,8	positive	(+)	passed
56.	F	38	2	positive	19,85	positive	(+)	passed
57.	F	66	2	positive	19,9	positive	(+)	passed

58.	M	31	2	positive	19,9	positive	(+)	passed
59.	F	44	3	positive	19,94	positive	(+)	passed
60.	F	27	2	positive	20	positive	(+)	passed
61.	M	34	1	positive	20,05	positive	(+)	passed
62.	M	32	2	positive	20,07	positive	(+)	passed
63.	F	45	3	positive	20,1	positive	(+)	passed
64.	M	23	1	positive	20,1	positive	(+)	passed
65.	F	45	1	positive	20,17	positive	(+)	passed
66.	M	26	3	positive	20,42	positive	(+)	passed
67.	F	61	2	positive	20,46	positive	(+)	passed
68.	F	73	2	positive	20,49	positive	(+)	passed
69.	M	12	1	positive	20,57	positive	(+)	passed
70.	M	39	2	positive	20,61	positive	(+)	passed
71.	F	56	3	positive	20,7	positive	(+)	passed
72.	M	46	2	positive	20,7	positive	(+)	passed
73.	M	32	2	positive	20,8	positive	(+)	passed
74.	F	56	2	positive	20,81	positive	(+)	passed
75.	F	42	4	positive	20,9	positive	(+)	passed
76.	F	15	2	positive	20,93	positive	(+)	passed
77.	F	62	2	positive	20,95	positive	(+)	passed
78.	F	45	2	positive	21,02	positive	(+)	passed
79.	F	25	1	positive	21,04	positive	(+)	passed
80.	M	15	2	positive	21,09	positive	(+)	passed
81.	M	42	4	positive	21,2	positive	(+)	passed
82.	F	50	2	positive	21,23	positive	(+)	passed
83.	F	52	4	positive	21,24	positive	(+)	passed
84.	M	24	1	positive	21,28	positive	(+)	passed
85.	M	54	2	positive	21,32	positive	(+)	passed
86.	M	67	3	positive	21,35	positive	(+)	passed
87.	F	57	1	positive	21,45	positive	(+)	passed
88.	M	25	3	positive	21,56	positive	(+)	passed
89.	F	47	2	positive	21,57	positive	(+)	passed

90.	M	47	2	positive	21,64	positive	(+)	passed
91.	M	31	1	positive	22,02	positive	(+)	passed
92.	F	61	1	positive	22,1	positive	(+)	passed
93.	M	62	3	positive	22,14	positive	(+)	passed
94.	F	45	1	positive	22,17	positive	(+)	passed
95.	F	25	6	positive	22,27	positive	(+)	passed
96.	F	43	2	positive	22,46	positive	(+)	passed
97.	M	23	1	positive	22,6	positive	(+)	passed
98.	M	35	2	positive	22,78	positive	(+)	passed
99.	M	58	1	positive	22,8	positive	(+)	passed
100.	F	9	2	positive	22,97	positive	(+)	passed
101.	F	78	4	positive	23	positive	(+)	passed
102.	M	47	2	positive	23	positive	(+)	passed
103.	M	81	2	positive	23	positive	(+)	passed
104.	M	24	2	positive	23,06	positive	(+)	passed
105.	F	31	2	positive	23,09	positive	(+)	passed
106.	F	24	2	positive	23,1	positive	(+)	passed
107.	F	43	1	positive	23,1	positive	(+)	passed
108.	M	27	2	positive	23,1	positive	(+)	passed
109.	M	26	1	positive	23,12	positive	(+)	passed
110.	F	35	2	positive	23,14	positive	(+)	passed
111.	F	32	2	positive	23,17	positive	(+)	passed
112.	F	56	3	positive	23,2	positive	(+)	passed
113.	F	42	4	positive	23,28	positive	(+)	passed
114.	F	31	2	positive	23,31	positive	(+)	passed
115.	M	45	2	positive	23,35	positive	(+)	passed
116.	M	39	2	positive	23,41	positive	(+)	passed
117.	F	26	2	positive	23,55	positive	(+)	passed
118.	F	48	4	positive	23,57	positive	(+)	passed
119.	M	57	2	positive	23,57	positive	(+)	passed
120.	F	31	1	positive	23,6	positive	(+)	passed
121.	F	60	2	positive	23,68	positive	(+)	passed

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122.	M	30	5	positive	23,7	positive	(+)	passed
123.	F	25	3	positive	23,72	positive	(+)	passed
124.	F	47	5	positive	23,78	positive	(+)	passed
125.	M	32	2	positive	23,78	positive	(+)	passed
126.	M	53	3	positive	23,85	positive	(+)	passed
127.	M	62	1	positive	23,92	positive	(+)	passed
128.	M	61	2	positive	24,08	positive	(+)	passed
129.	M	45	3	positive	24,12	positive	(+)	passed
130.	M	80	1	positive	24,14	positive	(+)	passed
131.	M	38	4	positive	24,16	positive	(+)	passed
132.	M	61	3	positive	24,21	positive	(+)	passed
133.	F	24	3	positive	24,23	positive	(+)	passed
134.	F	59	2	positive	24,26	positive	(+)	passed
135.	M	61	2	positive	24,28	positive	(+)	passed
136.	M	41	2	positive	24,31	positive	(+)	passed
137.	F	34	2	positive	24,32	positive	(+)	passed
138.	F	84	3	positive	24,34	positive	(+)	passed
139.	F	67	3	positive	24,45	positive	(+)	passed
140.	F	15	3	positive	24,48	positive	(+)	passed
141.	M	23	1	positive	24,51	positive	(+)	passed
142.	F	24	3	positive	24,52	positive	(+)	passed
143.	F	28	2	positive	24,56	positive	(+)	passed
144.	F	52	2	positive	24,57	positive	(+)	passed
145.	F	18	1	positive	24,61	positive	(+)	passed
146.	M	52	1	positive	24,61	positive	(+)	passed
147.	F	26	2	positive	24,62	positive	(+)	passed
148.	M	62	2	positive	24,73	positive	(+)	passed
149.	M	73	2	positive	24,73	positive	(+)	passed
150.	F	38	2	positive	24,74	positive	(+)	passed
151.	F	84	3	positive	24,78	positive	(+)	passed
152.	F	34	1	positive	24,86	positive	(+)	passed
153.	M	27	4	positive	24,86	positive	(+)	passed

154.	M	64	2	positive	25,14	positive	(+)	passed
155.	F	38	2	positive	25,15	positive	(+)	passed
156.	M	80	2	positive	25,34	positive	(+)	passed
157.	M	84	2	positive	25,35	positive	(+)	passed
158.	F	44	3	positive	25,42	positive	(+)	passed
159.	F	52	2	positive	25,57	positive	(+)	passed
160.	F	67	2	positive	25,57	positive	(+)	passed
161.	M	54	3	positive	25,7	positive	(+)	passed
162.	F	26	4	positive	25,77	positive	(+)	passed
163.	F	34	2	positive	25,97	positive	(+)	passed
164.	F	59	3	positive	26	positive	(+)	passed
165.	F	45	3	positive	26,04	positive	(+)	passed
166.	F	61	5	positive	26,12	positive	(+)	passed
167.	M	54	4	positive	26,19	positive	(+)	passed
168.	M	32	2	positive	26,41	positive	(+)	passed
169.	M	24	2	positive	26,42	positive	(+)	passed
170.	F	32	3	positive	26,43	positive	(+)	passed
171.	F	50	2	positive	26,45	positive	(+)	passed
172.	M	34	1	positive	26,45	positive	(+)	passed
173.	M	34	2	positive	26,56	positive	(+)	passed
174.	M	44	1	positive	26,8	positive	(+)	passed
175.	F	38	3	positive	26,9	positive	(+)	passed
176.	M	23	2	positive	27	positive	(+)	passed
177.	F	26	4	positive	27,2	positive	(+)	passed
178.	M	35	3	positive	27,41	positive	(+)	passed
179.	M	25	2	positive	27,45	positive	(+)	passed
180.	M	42	2	positive	27,5	positive	(+)	passed
181.	M	44	5	positive	27,62	positive	(+)	passed
182.	M	23	2	positive	27,64	positive	(+)	passed
183.	M	52	2	positive	27,64	positive	(+)	passed
184.	M	15	2	positive	27,65	positive	(+)	passed
185.	F	25	1	positive	28,02	positive	(+)	passed

186.	F	60	2	positive	28,1	positive	(+)	passed
187.	F	50	3	positive	28,16	positive	(+)	passed
188.	M	27	2	positive	28,16	positive	(+)	passed
189.	F	50	3	positive	28,34	positive	(+)	passed
190.	M	56	2	positive	28,34	positive	(+)	passed
191.	M	94	1	positive	28,34	positive	(+)	passed
192.	F	19	2	positive	28,46	positive	(+)	passed
193.	F	57	3	positive	28,46	positive	(+)	passed
194.	M	78	3	positive	28,46	positive	(+)	passed
195.	M	48	2	positive	28,92	negative	(-)	failed
196.	F	74	3	positive	29,1	positive	(+)	passed
197.	M	15	2	positive	29,12	positive	(+)	passed
198.	M	30	1	positive	29,12	positive	(+)	passed
199.	M	26	3	positive	29,13	positive	(+)	passed
200.	F	52	2	positive	29,6	negative	(-)	failed
201.	M	45	3	positive	30,41	positive	(+)	passed
202.	F	41	3	positive	30,43	positive	(+)	passed
203.	F	58	3	positive	30,51	negative	(-)	failed
204.	F	35	4	positive	30,78	negative	(-)	failed
205.	F	45	2	positive	31,25	positive	(+)	passed
206.	M	21	3	positive	31,29	positive	(+)	passed
207.	M	35	2	positive	31,56	positive	(+)	passed
208.	M	56	1	positive	31,83	positive	(+)	passed
209.	F	27	2	positive	32,41	negative	(-)	failed
210.	M	29	3	positive	32,81	negative	(-)	failed
211.	F	29	2	positive	33,1	positive	(+)	passed
212.	F	82	3	positive	33,1	positive	(+)	passed
213.	M	68	1	positive	33,4	positive	(+)	passed
214.	F	19	2	positive	33,7	negative	(-)	failed
215.	F	73	1	positive	33,7	negative	(-)	failed
216.	M	34	5	positive	33,8	positive	(+)	passed
217.	M	64	2	positive	34,1	positive	(+)	passed

218.	F	59	3	positive	34,2	negative	(-)	failed
219.	M	24	2	positive	34,5	positive	(+)	passed
220.	M	45	4	positive	34,7	negative	(-)	failed
	NEGATIVE PCR RESULTS (CT value >37)							
221.	M	7	1	negative	ND	negative	(-)	passed
222.	F	8	1	negative	ND	negative	(-)	passed
223.	M	8	1	negative	ND	negative	(-)	passed
224.	F	10	1	negative	ND	negative	(-)	passed
225.	M	10	1	negative	ND	negative	(-)	passed
226.	F	10	1	negative	ND	negative	(-)	passed
227.	F	10	1	negative	ND	negative	(-)	passed
228.	F	11	1	negative	ND	negative	(-)	passed
229.	F	12	1	negative	ND	negative	(-)	passed
230.	M	13	1	negative	ND	negative	(-)	passed
231.	F	13	1	negative	ND	negative	(-)	passed
232.	M	14	1	negative	ND	negative	(-)	passed
233.	M	16	1	negative	ND	negative	(-)	passed
234.	M	18	1	negative	ND	negative	(-)	passed
235.	F	22	1	negative	ND	negative	(-)	passed
236.	M	22	1	negative	ND	negative	(-)	passed
237.	M	23	1	negative	ND	negative	(-)	passed
238.	M	23	1	negative	ND	negative	(-)	passed
239.	F	23	1	negative	ND	negative	(-)	passed
240.	M	23	1	negative	ND	negative	(-)	passed
241.	F	24	1	negative	ND	negative	(-)	passed
242.	F	24	1	negative	ND	negative	(-)	passed
243.	M	24	1	negative	ND	negative	(-)	passed
244.	F	29	1	negative	ND	negative	(-)	passed
245.	F	32	1	negative	ND	negative	(-)	passed
246.	M	35	1	negative	ND	negative	(-)	passed
247.	F	38	1	negative	ND	negative	(-)	passed
248.	F	46	1	negative	ND	negative	(-)	passed

249.	M	46	1	negative	ND	negative	(-)	passed
250.	M	49	1	negative	ND	negative	(-)	passed
251.	F	50	1	negative	ND	negative	(-)	passed
252.	M	51	1	negative	ND	negative	(-)	passed
253.	F	56	1	negative	ND	negative	(-)	passed
254.	F	56	1	negative	ND	negative	(-)	passed
255.	M	57	1	negative	ND	negative	(-)	passed
256.	F	57	1	negative	ND	negative	(-)	passed
257.	M	58	1	negative	ND	negative	(-)	passed
258.	M	60	1	negative	ND	negative	(-)	passed
259.	F	61	1	negative	ND	negative	(-)	passed
260.	M	64	1	negative	ND	negative	(-)	passed
261.	M	67	1	negative	ND	negative	(-)	passed
262.	F	67	1	negative	ND	negative	(-)	passed
263.	M	68	1	negative	ND	negative	(-)	passed
264.	M	68	1	negative	ND	negative	(-)	passed
265.	M	68	1	negative	ND	negative	(-)	passed
266.	M	69	1	negative	ND	negative	(-)	passed
267.	M	69	1	negative	ND	negative	(-)	passed
268.	M	70	1	negative	ND	negative	(-)	passed
269.	M	71	1	negative	ND	negative	(-)	passed
270.	F	74	1	negative	ND	negative	(-)	passed
271.	F	75	1	negative	ND	negative	(-)	passed
272.	M	79	1	negative	ND	negative	(-)	passed
273.	F	80	1	negative	ND	negative	(-)	passed
274.	F	81	1	negative	ND	negative	(-)	passed
275.	F	82	1	negative	ND	negative	(-)	passed
276.	F	82	1	negative	ND	negative	(-)	passed
277.	F	10	2	negative	ND	negative	(-)	passed
278.	F	10	2	negative	ND	negative	(-)	passed
279.	F	10	2	negative	ND	negative	(-)	passed
280.	M	12	2	negative	ND	negative	(-)	passed

281.	M	12	2	negative	ND	negative	(-)	passed
282.	F	13	2	negative	ND	negative	(-)	passed
283.	M	13	2	negative	ND	negative	(-)	passed
284.	F	13	2	negative	ND	negative	(-)	passed
285.	F	14	2	negative	ND	negative	(-)	passed
286.	M	14	2	negative	ND	negative	(-)	passed
287.	M	15	2	negative	ND	negative	(-)	passed
288.	F	16	2	negative	ND	negative	(-)	passed
289.	F	16	2	negative	ND	negative	(-)	passed
290.	M	16	2	negative	ND	negative	(-)	passed
291.	F	16	2	negative	ND	negative	(-)	passed
292.	F	17	2	negative	ND	negative	(-)	passed
293.	M	17	2	negative	ND	negative	(-)	passed
294.	M	17	2	negative	ND	negative	(-)	passed
295.	F	17	2	negative	ND	negative	(-)	passed
296.	F	18	2	negative	ND	negative	(-)	passed
297.	M	18	2	negative	ND	negative	(-)	passed
298.	M	19	2	negative	ND	negative	(-)	passed
299.	F	19	2	negative	ND	negative	(-)	passed
300.	M	20	2	negative	ND	negative	(-)	passed
301.	F	20	2	negative	ND	negative	(-)	passed
302.	F	20	2	negative	ND	negative	(-)	passed
303.	M	21	2	negative	ND	negative	(-)	passed
304.	F	22	2	negative	ND	negative	(-)	passed
305.	M	23	2	negative	ND	negative	(-)	passed
306.	F	23	2	negative	ND	negative	(-)	passed
307.	M	23	2	negative	ND	negative	(-)	passed
308.	M	24	2	negative	ND	negative	(-)	passed
309.	M	24	2	negative	ND	negative	(-)	passed
310.	F	26	2	negative	ND	negative	(-)	passed
311.	F	28	2	negative	ND	negative	(-)	passed
312.	F	29	2	negative	ND	negative	(-)	passed

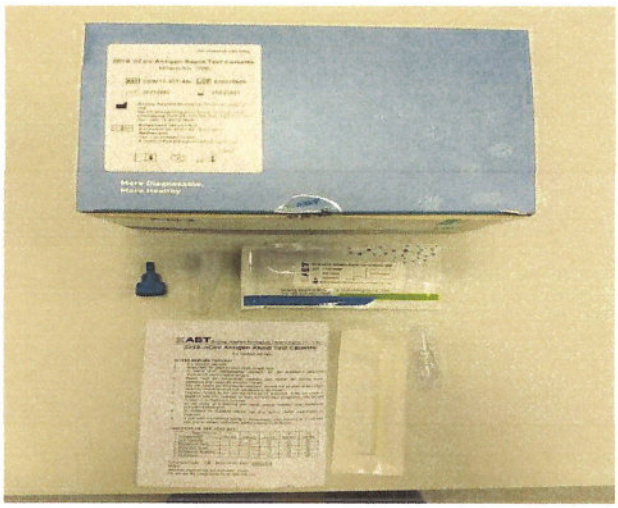
313.	M	31	2	negative	ND	negative	(-)	passed
314.	M	35	2	negative	ND	negative	(-)	passed
315.	F	46	2	negative	ND	negative	(-)	passed
316.	F	46	2	negative	ND	negative	(-)	passed
317.	F	46	2	negative	ND	negative	(-)	passed
318.	F	46	2	negative	ND	negative	(-)	passed
319.	M	47	2	negative	ND	negative	(-)	passed
320.	F	47	2	negative	ND	negative	(-)	passed
321.	F	50	2	negative	ND	negative	(-)	passed
322.	F	51	2	negative	ND	negative	(-)	passed
323.	F	54	2	negative	ND	negative	(-)	passed
324.	F	54	2	negative	ND	negative	(-)	passed
325.	F	57	2	negative	ND	negative	(-)	passed
326.	M	58	2	negative	ND	negative	(-)	passed
327.	F	58	2	negative	ND	negative	(-)	passed
328.	F	59	2	negative	ND	negative	(-)	passed
329.	F	60	2	negative	ND	negative	(-)	passed
330.	F	63	2	negative	ND	negative	(-)	passed
331.	F	66	2	negative	ND	negative	(-)	passed
332.	F	67	2	negative	ND	negative	(-)	passed
333.	M	67	2	negative	ND	negative	(-)	passed
334.	M	68	2	negative	ND	negative	(-)	passed
335.	M	68	2	negative	ND	negative	(-)	passed
336.	F	68	2	negative	ND	negative	(-)	passed
337.	M	69	2	negative	ND	negative	(-)	passed
338.	F	69	2	negative	ND	negative	(-)	passed
339.	M	69	2	negative	ND	negative	(-)	passed
340.	M	69	2	negative	ND	negative	(-)	passed
341.	M	69	2	negative	ND	negative	(-)	passed
342.	M	70	2	negative	ND	negative	(-)	passed
343.	F	70	2	negative	ND	negative	(-)	passed
344.	F	70	2	negative	ND	negative	(-)	passed

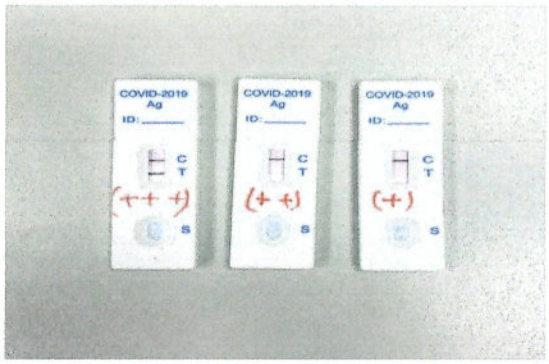
345.	M	71	2	negative	ND	negative	(-)	passed
346.	M	71	2	negative	ND	negative	(-)	passed
347.	F	71	2	negative	ND	negative	(-)	passed
348.	F	74	2	negative	ND	negative	(-)	passed
349.	F	74	2	negative	ND	negative	(-)	passed
350.	M	75	2	negative	ND	negative	(-)	passed
351.	F	75	2	negative	ND	negative	(-)	passed
352.	M	77	2	negative	ND	negative	(-)	passed
353.	F	78	2	negative	ND	negative	(-)	passed
354.	F	78	2	negative	ND	negative	(-)	passed
355.	M	80	2	negative	ND	negative	(-)	passed
356.	M	80	2	negative	ND	negative	(-)	passed
357.	M	80	2	negative	ND	negative	(-)	passed
358.	M	80	2	negative	ND	negative	(-)	passed
359.	F	80	2	negative	ND	negative	(-)	passed
360.	F	81	2	negative	ND	negative	(-)	passed
361.	F	83	2	negative	ND	negative	(-)	passed
362.	M	84	2	negative	ND	negative	(-)	passed
363.	F	85	2	negative	ND	negative	(-)	passed
364.	F	85	2	negative	ND	negative	(-)	passed
365.	F	85	2	negative	ND	negative	(-)	passed
366.	F	86	2	negative	ND	negative	(-)	passed
367.	F	89	2	negative	ND	negative	(-)	passed
368.	M	89	2	negative	ND	negative	(-)	passed
369.	M	9	3	negative	ND	negative	(-)	passed
370.	F	12	3	negative	ND	negative	(-)	passed
371.	F	12	3	negative	ND	negative	(-)	passed
372.	M	13	3	negative	ND	negative	(-)	passed
373.	M	13	3	negative	ND	negative	(-)	passed
374.	F	13	3	negative	ND	negative	(-)	passed
375.	M	14	3	negative	ND	negative	(-)	passed
376.	F	18	3	negative	ND	negative	(-)	passed

377.	M	18	3	negative	ND	negative	(-)	passed
378.	F	18	3	negative	ND	negative	(-)	passed
379.	F	19	3	negative	ND	negative	(-)	passed
380.	M	20	3	negative	ND	negative	(-)	passed
381.	F	23	3	negative	ND	negative	(-)	passed
382.	F	24	3	negative	ND	negative	(-)	passed
383.	M	25	3	negative	ND	negative	(-)	passed
384.	M	27	3	negative	ND	negative	(-)	passed
385.	M	32	3	negative	ND	negative	(-)	passed
386.	F	34	3	negative	ND	negative	(-)	passed
387.	F	34	3	negative	ND	negative	(-)	passed
388.	F	36	3	negative	ND	negative	(-)	passed
389.	M	46	3	negative	ND	negative	(-)	passed
390.	M	46	3	negative	ND	negative	(-)	passed
391.	F	46	3	negative	ND	negative	(-)	passed
392.	F	46	3	negative	ND	negative	(-)	passed
393.	F	46	3	negative	ND	negative	(-)	passed
394.	M	46	3	negative	ND	negative	(-)	passed
395.	F	48	3	negative	ND	negative	(-)	passed
396.	F	50	3	negative	ND	negative	(-)	passed
397.	F	50	3	negative	ND	negative	(-)	passed
398.	M	52	3	negative	ND	negative	(-)	passed
399.	F	56	3	negative	ND	negative	(-)	passed
400.	F	56	3	negative	ND	negative	(-)	passed
401.	F	59	3	negative	ND	negative	(-)	passed
402.	F	59	3	negative	ND	negative	(-)	passed
403.	F	64	3	negative	ND	negative	(-)	passed
404.	F	65	3	negative	ND	negative	(-)	passed
405.	F	68	3	negative	ND	negative	(-)	passed
406.	F	69	3	negative	ND	negative	(-)	passed
407.	F	70	3	negative	ND	negative	(-)	passed
408.	F	70	3	negative	ND	negative	(-)	passed

409.	M	88	3	negative	ND	negative	(-)	passed
410.	F	12	4	negative	ND	negative	(-)	passed
411.	F	21	4	negative	ND	negative	(-)	passed
412.	M	37	4	negative	ND	negative	(-)	passed
413.	F	46	4	negative	ND	negative	(-)	passed
414.	F	49	4	negative	ND	negative	(-)	passed
415.	M	84	4	negative	ND	negative	(-)	passed
416.	F	11	5	negative	ND	negative	(-)	passed
417.	M	20	5	negative	ND	negative	(-)	passed
418.	F	54	5	negative	ND	negative	(-)	passed
419.	M	61	5	negative	ND	negative	(-)	passed
420.	F	68	5	negative	ND	negative	(-)	passed
421.	F	47	3	negative	ND	negative	(-)	passed
422.	M	32	3	negative	ND	negative	(-)	passed
423.	F	46	3	negative	ND	negative	(-)	passed
424.	F	45	3	negative	ND	negative	(-)	passed
425.	F	44	5	negative	ND	negative	(-)	passed
426.	M	33	5	negative	ND	negative	(-)	passed
427.	M	31	4	negative	ND	negative	(-)	passed
428.	F	39	4	negative	ND	negative	(-)	passed
429.	M	40	2	negative	ND	negative	(-)	passed
430.	F	45	3	negative	ND	negative	(-)	passed
431.	M	37	2	negative	ND	negative	(-)	passed
432.	F	33	2	negative	ND	negative	(-)	passed
433.	F	43	2	negative	ND	negative	(-)	passed
434.	M	46	5	negative	ND	negative	(-)	passed
435.	M	47	5	negative	ND	negative	(-)	passed
436.	F	47	2	negative	ND	negative	(-)	passed
437.	M	37	5	negative	ND	negative	(-)	passed
438.	F	39	3	negative	ND	negative	(-)	passed
439.	M	48	4	negative	ND	negative	(-)	passed
440.	M	38	3	negative	ND	negative	(-)	passed

Test photos





Report approved by: Pawel Chrzan PhD **Date: 2021-07-16**

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