BETTER AG

Spitzenqualität zu Herstellerpreisen

Bioteke

COVID-19 Schnelltest-Kit

Für die Eigenanwendung

BIOTEKE 1er

Verpackung

1 Test pro Box

KARTON	800 tests pro Karton

BIOTEKE 5er

Verpackung

5 Tests pro Box

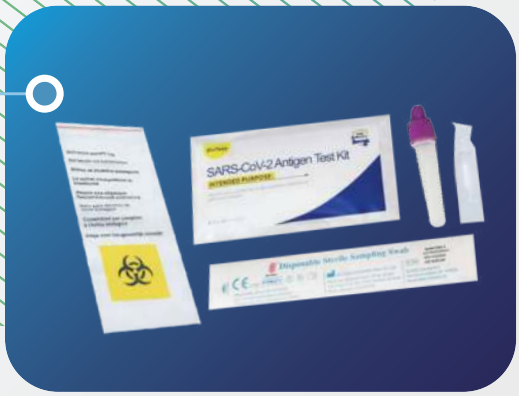
KARTON	1000 tests pro Karton

Einzelheiten

Hersteller steht auf der "EU common list" - Generaldirektion für Gesundheit und Lebensmittelsicherheit

Klicken Sie hier, um die Gültigkeit des CE-Zertifikats zu überprüfen

PROBEENTNAHME	Nasenabstrich
SENSIBILITÄT	96,36 %
SPEZIFIKATION	100 %
ERGEBNIS	10-15 Minuten
CE-ZERTIFIKAT NR.	CE 1434

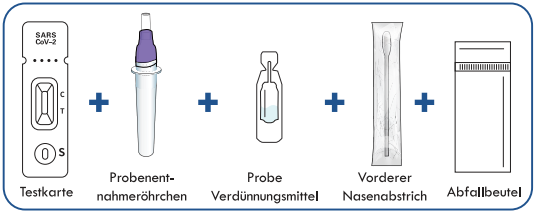


SARS-COV-2-ANTIGEN-TESTSATZ

BioTeke
GEBRAUCHSANWEISUNG

-1. Lesen Sie diese Anleitung sorgfältig durch.
-2. Legen Sie eine Uhr (oder einen Wecker), Taschentücher und entweder Handdesinfektionsmittel oder Seife und warmes Wasser bereit.
-3. Überprüfen Sie den Inhalt des Testkits. Vergewissern Sie sich, dass nichts beschädigt oder zerbrochen ist.

-Für vordere Nasenabstriche.
-Bitte lesen Sie die Anweisungen sorgfältig durch, bevor Sie mit dem Test beginnen.



- Hinweis: Bei niedriger Temperatur aufbewahrte Testkarten sollten vor dem Öffnen wieder auf Raumtemperatur gebracht werden, um eine Feuchtigkeitsaufnahme zu vermeiden.
- Hinweis: Nicht gestellte benötigte Materialien
  (1) Uhr (oder eine Wecker/Timer),
  (2) Taschentücher,
  (3) Handdesinfektionsmittel/Seife.

1

Waschen Sie sich vor dem Test mindestens 20 Sekunden lang gründlich die Hände.

2

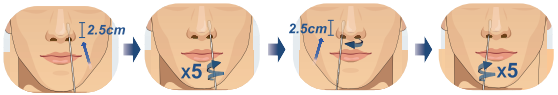
Setzen Sie das Röhrchen in die Halterung der Kitbox, bevor Sie mit dem Röhrchen fortfahren. Geben Sie das gesamte Probenverdünnungsmittel senkrecht in das Probenextraktionsröhrchen.

3

HINWEIS: Bitte putzen Sie sich vor dem Sammeln die Nase.
Nehmen Sie den Tupfer aus der Verpackung und fassen Sie ihn am Griff an. Achten Sie darauf, dass Sie die Stoffspitze des Tupfers nicht mit den Händen berühren.

4

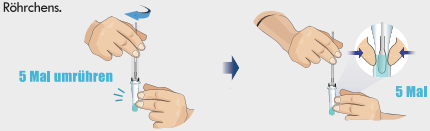
Führen Sie den Tupfer vorsichtig weniger als einen inch (etwa 2,5 cm) in Ihr Nasenloch ein. Reiben Sie den Tupfer langsam an allen Innenwänden Ihres Nasenlochs. Machen Sie mindestens 5 große Kreise. Drehen Sie den Stäbchen nicht einfach. Wiederholen Sie diesen Schritt in Ihrem anderen Nasenloch mit demselben Tupfer.



HINWEIS: Bei Kindern kann die maximale Tiefe des Einführens in das Nasenloch weniger als 3/4 Zoll betragen (etwa 1,9 cm).

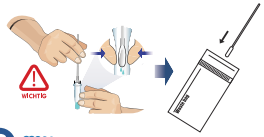
5

Führen Sie den Tupfer in das Probenröhrchen ein. Berühren Sie den Boden des Probenröhrchens mit der Tupferspitze und rühren Sie mindestens 5 Mal um. Drücken Sie den Tupfer im Röhrchen mit dem Finger 5 Mal durch die Außenwand des Röhrchens.



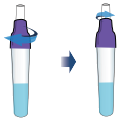
6

Entfernen Sie den Tupfer durch Drehen gegen das Probenröhrchen, während Sie die Seiten des Röhrchens zusammendrücken, um die Flüssigkeit aus dem Tupfer zu lösen. Entfernen Sie den Tupfer und werfen Sie ihn in den mitgelieferten Abfallbeutel.



7

Schrauben Sie den violetten Röhrchenverschluss auf das Probenröhrchen und schrauben Sie dann den oberen weißen Verschluss ab.



8

Öffnen Sie den Beutel und nehmen Sie die Testkarte heraus. Legen Sie sie auf eine flache, trockene und saubere Oberfläche. Drehen Sie die in das Röhrchen integrierte Tropfkappe auf den Kopf und drücken Sie langsam 3 Tropfen in die Probenvertiefung der Testkarte.

9 Interpretation der Ergebnisse

WICHTIG

HINWEIS:
Die Testergebnisse sollten nicht nach 20 Minuten abgelesen werden.

COVID-19 nachgewiesen (positiv)

Ein positives Testergebnis bedeutet, dass Antigene von COVID-19 nachgewiesen wurden und der Patient mit hoher Wahrscheinlichkeit mit dem Virus infiziert ist und vermutlich ansteckend ist. Die Testergebnisse sollten immer im Zusammenhang mit klinischen Beobachtungen und epidemiologischen Daten betrachtet werden, um eine endgültige Diagnose zu stellen und Entscheidungen über die Behandlung des Patienten zu treffen. Wenden Sie sich unverzüglich an Ihren Arzt/Hausarzt oder an das örtliche Gesundheitsamt. Halten Sie sich an die örtlichen Richtlinien zur Selbstisolierung. Führen Sie einen PCR-Bestätigungstest durch.

COVID-19 nicht nachgewiesen (negativ)

Ein negatives Testergebnis bedeutet, dass in der Probe keine Antigene von COVID-19 nachgewiesen wurden. Ein negatives Ergebnis schließt COVID-19 jedoch nicht aus und sollte nicht als alleinige Grundlage für Entscheidungen über die Behandlung oder das Patientenmanagement, einschließlich Entscheidungen zur Infektionskontrolle, verwendet werden. Negative Ergebnisse sollten im Zusammenhang mit den jüngsten Expositionen einer Person, der Vorgeschichte und dem Vorhandensein klinischer Anzeichen und Symptome, die mit COVID19 übereinstimmen, betrachtet und gegebenenfalls mit einem molekularen Test für die Patientenbehandlung bestätigt werden.

Ungültig

Ungültiger Barcode oder Fehlen eines violetten Strichs neben dem "C". Ein erneuter Test mit einem COVID-19-Test kann erforderlich sein. Ein ungültiges Testergebnis bedeutet, dass Ihr Test einen Fehler hatte und das Ergebnis nicht interpretieren kann. Sie müssen den Test dann mit einem neuen Test wiederholen. Wenn das Testergebnis weiterhin ungültig ist, wenden Sie sich an Ihren Arzt oder das COVID-19-Testzentrum.

10

Alle gebrauchten Testkomponenten sollten in dem mitgelieferten Abfallbeutel entsorgt werden. Nach Abschluss aller Schritte die Hände waschen oder ein Händedesinfektionsmittel verwenden.

BioTeke

GEBRAUCHSANWEISUNG

Für vordere Nasenabstriche, für Selbsttests

SARS-COV-2-ANTIGEN-TESTSATZ

PRODUKTNAME

SARS-CoV-2-Antigen-Testkit

PAKETSPEZIFIKATION

1 Test/Kit (REF#,TC1002ST1);
3 Tests/Kit (REF#,TC1002ST3);
5 Tests/Kit (REF#,TC1002ST5)

VERWENDUNGSZWECK

Bei diesem Kit handelt es sich um einen Lateral-Flow-Immunoassay für den qualitativen In-vitro-Nachweis von SARS-CoV-2-Nukleokapsidprotein-Antigen aus menschlichen vorderen Nasenabstrichen von Personen, bei denen innerhalb der ersten 7 Tage nach Auftreten der Symptome der Verdacht auf eine COVID-19-Infektion besteht. Dieses Kit ist für die manuelle Anwendung durch ungeschulte Laien (Selbsttest) im privaten Rahmen zur Unterstützung der Diagnose einer aktiven SARS-CoV-2-Infektion bestimmt. Dieses Produkt ist für Benutzer über 1 Jahr geeignet. Kinder zwischen 1-14 Jahren sollten von einem Erwachsenen unterstützt werden.

TEST-PRINZIP

Das Kit ist immunochromatographisch und verwendet die Doppelantikörper-Sandwich-Methode zum Nachweis des SARS-CoV-2-Antigens. Während des Nachweises werden die behandelten Proben in die Probenvertiefungen der Testkarte gegeben. Wenn die Konzentration des SARS-CoV-2-Antigens in der Probe über der Mindestnachweisgrenze liegt, bildet das virale Antigen zunächst Komplexe mit markierten Antikörpern. Bei der Chromatographie bewegen sich die Komplexe entlang der Nitrocellulosemembran vorwärts, bis sie von dem vorbeschichteten monoklonalen Antikörper gegen SARS-CoV-2 in der Nachweiszone auf dem Nitrocellulosefilm (T) eingefangen werden und eine rosa/violette Reaktionslinie in der Nachweiszone bilden; an diesem Punkt ist das Ergebnis positiv. Unabhängig davon, ob die Probe virale Antigene enthält oder nicht, erscheint in der Qualitätskontrollzone (C) eine rosafarbene/violette Reaktionslinie; die rosafarbene/violette Reaktionslinie, die in der Qualitätskontrollzone (C) erscheint, ist das Kriterium für die Feststellung, ob der Chromatographieprozess normal verläuft.

HAUPTBESTANDTEILE

Komponenten	Hauptbestandteile	Lademenge (Spezifikation)		
		1 Test/Kit	3 Tests/Kit	5 Tests/Kit
Testkarte	Teststreifen mit monoklonalem SARS-CoV-2-Antikörper, polyklonalem Anti-Maus-IgG-Antikörper	1 Stück	3 Stück	5 Stück
Probe Verdünnungsmittel		0.5mL	0.5mL*3	0.5mL*5
Probenentnahmeröhrchen		1 Stück	3 Stück	5 Stück
Anteriorer Nasenabstrich		1 Stück	3 Stück	5 Stück
Abfallsack		1 Stück	3 Stück	5 Stück

Anmerkung:
1. Die Testkarten sind zusammen mit Trockenmittel in einem Beutel aus Aluminiumfolie eingeschweißt.
2. Verwenden Sie keine unterschiedlichen Chargen von Testkarten und Probenverdünner.

LAGERBEDINGUNGEN UND HALTBARKEIT

Die Testkarte und das Probenverdünnungsmittel sollten bei 2°C~30°C gelagert werden und sind 18 Monate lang gültig. Die Testkarten sollten so schnell wie möglich innerhalb von 1 Stunde nach Öffnen des Folienbeutels verwendet werden.
Herstellungs- und Verfallsdatum: Siehe Verpackungsetikett für Details.

PROBENANFORDERUNGEN

Direkte Abstrichproben sollten sofort nach der Entnahme getestet werden.

EINSCHRÄNKUNGEN DES TESTS

1. Die Genauigkeit des Tests hängt von der Qualität der Probe ab.
2. Unsachgemäße Probenahme oder Kontamination, Lagerung, Transport und Verarbeitung sowie niedrige Virustiter in der Probe können zu falsch negativen Ergebnissen führen.
3. Entfernen Sie den Tupfer, indem Sie ihn gegen das Probenröhrchen drehen, während Sie die Seiten des Röhrchens zusammendrücken. Dies ist wichtig, und ein unsachgemäßes Vorgehen kann zu falsch negativen Ergebnissen führen.
4. Die Testergebnisse können auch durch Temperatur und Luftfeuchtigkeit beeinflusst werden. Der Test sollte bei einer Umgebungstemperatur von 10-30°C und einer Luftfeuchtigkeit von 30-75% durchgeführt werden.
5. Negative Ergebnisse können auf eine niedrige Konzentration von SARS-CoV-2-Antigenen in der Probe zurückzuführen sein, so dass eine Infektion nicht vollständig ausgeschlossen werden kann.
6. Einige Medikamente (z. B. hohe Konzentrationen von rezeptfreien oder verschreibungspflichtigen Medikamenten wie Nasenspray) in den entnommenen Proben können das Testergebnis beeinträchtigen. Bitte führen Sie den Test erneut durch, wenn das Ergebnis zweifelhaft ist.
7. Dieses Produkt ist nur für qualitative Tests geeignet. Die spezifische Konzentration der einzelnen Indikatoren muss mit anderen quantitativen Methoden gemessen werden.
8. Die Ergebnisse dieses Tests dienen nur als klinische Referenz und sollten nicht die einzige Grundlage für die Diagnose sein. Die Ergebnisse sollten in Kombination mit klinischen Beobachtungen und anderen Testmethoden verwendet werden.

LEISTUNGSMERKMALE

1. Die Breite des Membranstreifens dieses Kits beträgt nicht weniger als 2,5 mm, und die Geschwindigkeit der Flüssigkeitsmigration beträgt nicht weniger als 10 mm/min.
2. Negative/positive Referenz-Koinzidenzrate
Alle positiven Referenzen sind positiv für die entsprechenden Krankheitserreger, was mit den bekannten Ergebnissen der Referenz übereinstimmt; alle negativen Referenzen sind negativ für den entsprechenden Krankheitserreger.
3. Wiederholbarkeit
Wiederholte Tests wurden für nationale oder unternehmensinterne wiederholbare Referenzprodukte 10 Mal durchgeführt. Die Testergebnisse stimmten mit den bekannten Ergebnissen der Referenzprodukte überein und waren einheitlich in der Farbe.
4. Nachweisgrenze (LoD)
Die Nachweisgrenze (LoD) des SARS-CoV-2-Antigen-Testkits beträgt 1,25x10^{1} TCID$_{50}$ /mL.
5. Klinische Leistung
1) Empfindlichkeit und Spezifität
Das SARS-CoV-2-Antigen-Testkit wurde mit der PCR-Vergleichsmethode an anterioren Nasenabstrichproben verglichen.

Bioteke-Reagenz	PCR-Reagenz		Insgesamt
	Positiv	Negativ	
Positiv	106	0	106
Negativ	4	456	460
Insgesamt	110	456	566

Klinische Sensitivität = 96.36% (95% CI: 90.95%~99.00%)
Klinische Spezifität = 100.00% (95% CI: 99.19%~100.00%)
Genauigkeit =99.29% (95% CI: 98.20%~99.81%);
Kappa-Wert = 0.9771

2) Studie zur Kreuzreaktivität und mikrobiellen Interferenz
Es besteht keine Kreuzreaktivität und mikrobielle Interferenz mit den folgenden Krankheitserregern:

Nein.	Name des Virus/ Bakteriums/Parasiten	Nein.	Name des Virus/ Bakteriums/Parasiten
1	Coronavirus HKU1	26	Masern-Virus
2	Coronavirus OC43	27	Menschliches Zytomegalievirus
3	Coronavirus NL63	28	Rotavirus
4	Coronavirus 229E	29	Norovirus
5	Influenza A virus 2009H1N1	30	Mumps-Virus
6	Influenza A virus der Saison H1N1	31	Varicella zoster virus
7	Influenza A virus H3N2	32	Menschliches Parainfluenza-Virus 1
8	Influenza A virus H5N1	33	Menschliches Parainfluenza-Virus 2
9	Influenza A virus H7N9	34	Menschliches Parainfluenza-Virus 3
10	Influenza B virus Yamagata	35	Menschliches Parainfluenza-Virus 4a
11	Influenza-B-Virus Victoria	36	Menschliches Parainfluenzavirus 4b
12	Respiratorisches Syncytialvirus A	37	MERS-Koronavirus
13	Rhinovirus (Gruppe A)	38	Menschliches Metapneumovirus (hMPV)
14	Rhinovirus (Gruppe B)	39	Mykoplasma a pneumoniae
15	Respiratorisches Adenovirus Typ 1	40	Chlamydia pneumoniae
16	Respiratorisches Adenovirus Typ 2	41	Hämophilus influenzae
17	Respiratorisches Adenovirus Typ 3	42	Streptokokkus pneumoniae
18	Respiratorisches Adenovirus Typ 4	43	Streptokokkus pyogenes
19	Respiratorisches Adenovirus Typ 5	44	Gepoolte menschliche Nasenwässer
20	Respiratorisches Adenovirus Typ 7	45	Bordetella pertussis
21	Respiratorisches Adenovirus Typ 55	46	Legionella pnuemophila
22	Enterovirus (CA16)	47	Staphylococcus aureus
23	Enterovirus (Echo)	48	Staphylococcus epidermidis
24	Enterovirus (EV71)	49	Candida albicans
25	Epstein-Barr-Virus-Kapsid-Antigen		

3) Störende Substanz: Die folgenden störenden Substanzen beeinträchtigen die Ergebnisse des Kits ebenfalls nicht:

Nein.	Potenziell störende Substanzen	Aktiver Inhaltsstoff	Nein.	Potenziell störende Substanzen	Aktiver Inhaltsstoff
1	Antivirales Medikament	α-Interferon	23	Nasale Kortikosteroide	Triamcinolon-Acetonid
2		Zanamivir	24		Budesonid
3		Ribavirin	25		Mometason
4		Oseltamivir	26		Fluticason
5		Peramivir	27	Medikament zur Linderung von Allergiesymptomen	Histamin-Hydrochlorid
6		Lopinavir			
7		Ritonavir			
8		Arbidol	28	Halstabletten, orale Anästhetika und Analgetika	Menthol
9	Antibiotikum	Levofloxacin			
10		Azithromycin			
11		Ceftriaxon	29		Ethyl-4-aminobenzoat
12		Meropenem			
13	Systemische antibakterielle Medikamente	Tobramycin			
14	Mucin	Mucin-Protein, Typ I-S	30	Zicam Erkältungssprüpareat Nasal Gel	Schwefel
15	Menschliches Blut		31	Antibiotika, Nasensalbe	Mupirocin
16	Nasenspray	Epinephrin (Phenylephrin)			
17		Oxymetazolin	32	Naso Gel (NeilMed)	Kochsalzlösung
18		Natriumchlorid (mit Konservierungsstoffen)			
19		Cromolyn-Natrium	33	Alkalol	Galphimia glauca, Luffa operculata, Sabadilla
20	Nasale Kortikosteroide	Beclomethason			
21		Dexamethason	34	Sore Throat Phenol Spray	Phenol
22		Flunisolid			

4) Hakeneffekt: Bei Tests bis zu einer Konzentration von 2,5 x 10^{6} TCID$_{50}$ /mL wurde kein hochdosierter Hook-Effekt beobachtet.
5) Studie zur Benutzerfreundlichkeit

		PCR-Ergebnisse		Insgesamt
		Positiv	Negativ	
Ergebnisse des Selbsttests	Positiv	50	0	50
	Negativ	10	40	50
Insgesamt		60	40	100

Statistik	Wert	95% CI
Empfindlichkeit	83.33%	83.33% (71.48%~91.71%)
Spezifität	100.00%	100.00% (91.19%~100.00%)
Gesamtgenauigkeit	90.00%	90.00% (82.38%~95.10%)

VORSICHTSMASSNAHMEN

1. Dies ist ein In-vitro-Diagnosereagenz zum einmaligen Gebrauch, nicht wiederverwenden und keine abgelaufenen Produkte verwenden.
2. Entsorgen Sie alle Proben, Reaktionskits und potenziell kontaminierten Materialien (z. B. Tupfer, Röhrchen, Testkarte) in dem dafür vorgesehenen Beutel.
3. Verwenden Sie den Alufolienbeutel nicht, wenn er beschädigt ist.
4. Öffnen Sie den versiegelten Folienbeutel nicht vor dem Gebrauch und verwenden Sie ihn so schnell wie möglich nach dem Öffnen des Aluminiumfolienbeutels.
5. Frische Proben für den Test verwenden, keine wiederholten Gefrier-Auftau-Proben verwenden.
6. Arbeiten Sie bei Raumtemperatur. Bei niedriger Temperatur aufbewahrte Testkarten sollten vor dem Öffnen wieder auf Raumtemperatur gebracht werden, um eine Feuchtigkeitsaufnahme zu vermeiden.
7. Verwenden Sie keine Reagenzienkits mit offensichtlichen Schäden oder Testkarten mit beschädigter oder abgelaufener Verpackung.
8. Der Alufolienbeutel enthält Trocknungsmittel und darf nicht oral eingenommen werden.
9. Entfernen Sie den Tupfer, indem Sie ihn gegen das Probenröhrchen drehen, während Sie die Seiten des Röhrchens zusammendrücken. Dies ist wichtig, und ein unsachgemäßes Vorgehen kann zu falsch negativen Ergebnissen führen.
10. Eine unsachgemäße Probenentnahme oder -verarbeitung kann zu falsch-negativen Ergebnissen führen.
11. Fällt das erste Screening positiv aus, wenden Sie sich an Ihre örtliche Gesundheitsbehörde.
12. Wie bei den verwendeten Diagnosereagenzien sollte die endgültige Diagnose von einem Arzt gestellt werden, der die verschiedenen Testparameter und die klinischen Symptome kombiniert.
13. Wenn Sie Fragen oder Anregungen zur Verwendung dieses Kits haben, wenden Sie sich bitte an den Hersteller.
14. Waschmittel, Parfüm und andere Substanzen können ähnliche desinfizierende Bestandteile enthalten. Wenn sie mit den entnommenen Proben in Berührung kommen, können sie zu falsch negativen Ergebnissen führen. Die Hände sollten vor der Probenahme gründlich gereinigt werden.
15. Lange gelagerte Proben können zu einem Rückgang des Virusgehalts führen. Dies kann zu falsch negativen Ergebnissen führen. Bitte testen Sie sofort nach der Probenahme.

REFERENZEN

1.LY Wang, PR Chen, G W Zheng, et al. Research progress on novel coronavirus test methods. Modern Medicine and Clinic, 2020, 35(3): 411-416.
2. K Tugba, W Ralph,L Hakho. Molecular and Immunological Diagnostic Tests of COVID-19: Current Status and Challenges.
Science, 2020, 23(8): Doi:10.1016/j.isci.2020.101406

SYMBOLE

Datum der Herstellung
Hersteller
Nicht wiederverwenden
in-vitro-Diagnostikum
Haltbarkeitsdatum
Chargencode
CE-Kennzeichnung
1434
Vom Sonnenlicht fernhalten
Trocken halten
Temperaturgrenze
Enthält ausreichend für <n> Test
Gebrauchsanweisung beachten
Nicht verwenden, wenn die Verpackung beschädigt ist

Importer: Better AG
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Tel: +49 30 62 93 34 20 • +41 71 58 80 248
E-Mail: infoa@OdemShop.de
Shop: www.OdemShop.de

SUNGO Europe B.V.
Olympisch Stadion 24,1076DE
Amsterdam, Niederlande

BioTeke Corporation Wuxi Co., Ltd
4th Floor, D562nd Floor, D3 & 1st and 2nd Floor,
D16, No.1719, Huishan Avenue, Wuxi, Jiangsu, CN 214174.

● Datum der Überarbeitung: 13. Juli , 2022
Ausgabe: V2.2

Bioteke Corporation(wuxi) Co.,Ltd
Address: 4th floor, D5, No.1719,Huishan Avenue,Wuxi,China

BioTeke

Manufacturer's Declaration

To whom it may concerns,

Product name: SARS-CoV-2 Antigen Test Kit (colloidal gold method)

Country of Origin: China

We, Bioteke Corporation(wuxi) Co., Ltd, headquartered in, 4th floor, D5, No.1719, Huishan Avenue, Wuxi, China, do hereby declare "Better AG" located in General-Guisan-Str. 8, 6300 Zug, Switzerland, is authorized to import, sell, distribute the "Bioteke" branded in Europe and Africa.

We hereby confirm the authenticity of the SARS-CoV-2 Antigen Test Kit (colloidal gold method) sold by this distributor

Bioteke Corporation(wuxi) Co., Ltd
June 28, 2022

Declaration of Conformity

Manufacturer:	BioTeke Corporation (Wuxi) Co., Ltd.
Address:	4th Floor, D5&2nd Floor, D3 & 1st and 2nd Floor, D16, No.1719, Huishan Avenue, Wuxi, Jiangsu, CN 214174.
whose single Authorized	
EU-*Representative:*	*SUNGO Europe B.V.*
Address:	Olympisch Stadion 24,1076DE Amsterdam, Netherlands

Product Name: BioTeke SARS-CoV-2 Antigen Test Kit
1 Test/Kit (REF#, TC1002ST1);
3 Tests/Kit (REF#, TC1002ST3);
5 Tests/Kit (REF#,TC1002ST5).

Classification: Device for self-testing

Conformity Assessment Route: Annex III of 98/79/EC （Section 6）

We declare under our sole responsibility 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 13612:2002, EN 13641: 2002, EN 13975: 2003, EN ISO 14971:2012, EN ISO 15223-1: 2016, EN ISO18113-1:2011, EN ISO18113-4:2011, EN ISO 23640:2015，EN 13532:2002，EN 62366:2008

Notified Body: POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A. (PCBC)
ul. Klobucka 23A
02-699 Warszawa
Poland
CE 1434

Signature:
Name: Zhou Zhitu
Title: GM
Position: 4th Floor, D5 & 2nd Floor, D3 & 1st and 2nd Floor, D16, No.1719, Huishan Avenue, Wuxi, Jiangsu, CN 214174.

CERTIFICATE

EC Certificate No. 1434-IVDD-190/2022

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

Polish Centre for Testing and Certification certifies
that manufactured by:

BioTeke Corporation (Wuxi) Co., Ltd.

**4th Floor, D5&2nd Floor, D3 & 1st and 2nd Floor, D16,
No.1719, Huishan Avenue, Wuxi, Jiangsu,
CN 214174, China**

in vitro diagnostic medical devices
for self-testing

BioTeke SARS-CoV-2 Antigen Test Kit

1 Test/Kit (REF#, TC1002ST1)
3 Tests/Kit (REF#, TC1002ST3)
5 Tests/Kit (REF#,TC1002ST5)

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 24.05.2022 to 27.05.2025

The date of issue of the Certificate: 24.05.2022

The date of the first issue of the Certificate: 24.05.2022

CE 1434

Issued under the Contract No. MD-178/2021
Application No: 531/2021
Certificate bears the qualified signature.
Warsaw, 24/05/2022
Module A1

Director
Medical Device Certification
Department

CENTRALNE LABORATORIUM KLINICZNE
UNIWERSYTECKIE CENTRUM KLINICZNE
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Usability Research Report

Product Name	SARS-CoV-2 Antigen Test Kit
Report Revision	Ver 1.1
Main Investigator	Ewa Czajkowska MSc, Pawel Chrzan PhD
Clinical Trial Unit	Centralne Laboratorium Kliniczne Uniwersyteckie Centrum Kliniczne (University Clinical Center)
Sponsor	BIOTEKE CORPORATION(WUXI)CO., LTD.

Study site and personnel

Research unit: Centralne Laboratorium Kliniczne Uniwersyteckie Centrum Kliniczne, 80-214 Gdańsk, ul. Mariana Smoluchowskiego 17 (University Clinical Center, 80-214 Gdansk Mariana Smoluchowskiego 17 street)

Person in charge of statistics and unit: Pawel Chrzan PhD

Test date: From 2022-02-17 To 2022-03-27

Contact person: Paweł Chrzan

Contact number: +48 585844380

Original data storage location: Centralne Laboratorium Kliniczne Uniwersyteckie Centrum Kliniczne, 80-214 Gdańsk, ul. Mariana Smoluchowskiego 17 (University Clinical Center, 80-214 Gdansk Mariana Smoluchowskiego 17 street)

Institutions and researchers involved in Usability Research:

Researchers	Job title	Take responsibility
Ewa Czajkowska MSc	Laboratory technician	Test implementation, collect samples, report drafting
Pawel Chrzan PhD	Observer	Monitor the entire research process. Will not interfere with the test, but will prevent any potential harm caused by improper operation of participants, appraised the task performance of the participant, report reviewing and approval

Contents

1. Purpose

To evaluate the usability of the SARS-CoV-2 Antigen Test Kit (hereinafter candidate kit) in participant by the means of the accuracy of result interpretation supervised, the diagnostic sensitivity non-supervised, and the diagnostic specificity non-supervised.

2. Participant research program

A person who has certain symptoms during the examination, such as: fever, disturbances of smell or taste, cough, short breath, chest pain, pathological fatigue, muscle pain, headache, sore throat, or without symptoms, will be referred for a PCR test to detect the SARS-CoV-2 virus. Referrals can be received during the visit or during telephone consultation if symptoms match COVID-19. The patient receives an SMS code with the referral number and the proposed place, date and time of the test. He/she arrives at the test center where his/her identity and correctness of referral are checked. After all formalities are met, a team of medical professional takes a nasopharyngeal swab. A person will as participant who meets the appropriate criteria for participation in a clinical trial is offered an antigen test. He/she receives a full set of information on what the test will involve together with an information leaflet. If such a person agrees, he/she receives an informed consent form to take part in the trial to be read and completed. After the consent is obtained, the test is carried out. First, tests are performed by the patient after reading the instructions provided by the manufacturer of a given testing kit. This process is observed by a medical professional and is assessed on Appendix C Observer checklist. Before starting the test, the patient fills in the "Appendix A Pre-test user questionnaire", then within due time after the test, he/she completes the "Appendix B Post-test user questionnaire". Then, the test is repeated by a professional to compare the effectiveness. Participants do not receive remuneration for their participation in the trial.

3. The location/testing space

The summative usability test was performed at the premises of Gdańsk (Uniwersyteckie Centrum Kliniczne w Gdańsku). The tests took place at the test lab or other rooms.

We choose a regular office or neutral room condition as test environment, because this is closest to the most common application environment for self-testing.

The interviews and moderations were given by a laboratory technician sitting opposite to the test user.

4. Research acceptance criteria

4.1 In supervised results interpretation experimental research

Non-professionals read over 90% of the specified response results.

The consistency between non-professional reading and professional reading test results reaches more than 90%.

Participants able to understand the instructions for use are over 90% of all participants.

4.2 In unsupervised laboratory research on diagnostic sensitivity and diagnostic specificity

Calculate the consistency of non-professional test results with professional tests.

5. Participant research criteria

Before participating in the test, the laboratory technician will know relevant background information in advance, such as age, occupation, education level, etc. Then select suitable volunteers to participate in the test.

The ages of these participants in the test are naturally distributed in various age groups. The number of genders is balanced. Their academic qualifications and educational backgrounds are different. They come from different industries and are engaged in different professions, but none of them have medical backgrounds.

6. Supervised results interpretation research

6.1 Result interpretation supervised subject screening criteria. (Hereinafter referred to as "Read the test results& understand the instructions for use" studies)

(1) Inclusion criteria

① Participants ≥ 15 years old

② European population

(2) Exclusion criteria

① The participants who objectively cannot operate autonomously (such as hand disabilities, etc.) when their legal agents are not present;

② The participants who have difficulty in autonomous reading and comprehension (such as illiterate, etc.) when their legal agents are not present;

③ The participants under the age of 18 when their legal agents are not present;

④ The person with experience in medical-related industries.

(3) Elimination criteria

① Samples that fail to complete the test due to sample contamination caused by anthropogenic factors, man-made operational mistakes in the test, or instrumental factors or human factors;

② Samples with reagent's quality problems: for example, reagents are expired or not kept as

required;

3 Before the statistics, it was found that the information required for the original record of any clinical trial was missing or did not meet the selection criteria/exclusion criteria;

4 The same case has supplied multiple samples which are selected for testing, and then the test results of subsequent selected samples will be excluded.

6.2 Research procedure

100 participants have 10-15 minutes to read the instruction for use, and the cards are shown to all participants in the order 3-2-1-4, participants start to read and judge the carefully designed test results, and complete the Appendix A Pre-test user questionnaire. The results of the statistical data are presented in the following content in the section 6.3.

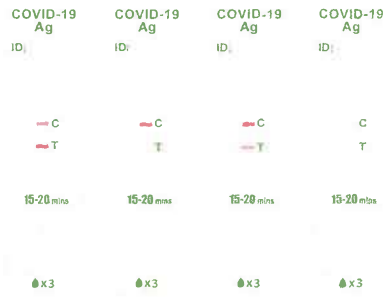

Table 1 The results read by the laboratory technician are:

	3	2	1	4
Professional interpretation	B. Positive (weak reactive)	C. Negative	A. Positive (reactive)	D. invalid

Each participant is required to read the test, and the laboratory technician needs to determine the participants to read the results and the professional results of consistency.

6.3 Questionnaire survey

Table 2 Age range

Age Range (Years)	Amounts
15-34	41
35-64	50
≥65	9
Total	100

Table 3 Education background

Education	Amounts
Basic education	4
Middle education	27
Higher education	66
Others	3
Total	100

Table 4 Occupation background

Profession	Amounts
Staff	51
Government employee	7
Teacher	4
Student	8
Worker	12
Retiree	4
Unemployed	0
Others	14
Total	100

Table 5 Gender

	Amounts
Female	49
Male	51
Total	100

Table 6 Instructions for use are clearly described

	Very clear	Clear	Fuzzy	Very fuzzy	Total
Amounts	60	40	0	0	100

Table 7 Difficulty of this test

	Very simple	Simple	Difficult	Very difficult	Total
Amounts	60	40	0	0	100

Table 8 Participants read and interpret the artificial test results as shown in the table below:

	Amounts			
Professional interpretation	3-B. Positive (weak reactive)	2-C. Negative	1-A. Positive (reactive)	4-D. invalid
Lay users read the result is correct	100	100	100	100
Lay users read the result is wrong	0	0	0	0
Total	100	100	100	100

Result: 100.00%

Conclusion: Passed.

Table 9 Participants are able to understand test result is positive.

How do you know if the test result is positive?				
Both the C and T line color appear.	Only the C line color appear.	The C line is colorless.	Don't know	Total
100	0	0	0	100

Result: 100.00 %

Conclusion: Passed.

Table 10 Participants are able to understand test result is negative.

How do you know if the test result is negative?				
Both the C and T line color appear.	Only the C line color appear.	The C line is colorless.	Don't know	Total
0	100	0	0	100

Result: 100.00 %

Conclusion: Passed.

Table 11 Participants are able to understand test result is invalid.

How do you know if the test result is invalid?				
Both the C and T line color appear.	Only the C line color appear.	The C line is colorless.	Don't know	Total
0	0	100	0	100

Result: 100.00 %

Conclusion: Passed.

Table 12 What the participant should do when the test result is positive.

If your test shows a positive result. What should you do?			
May be infected with COVID-19 and should stay away from others. Strictly abide by the government's instructions "Instructions for self-test users", now you need to contact your family doctor/health department for PCR testing to confirm.	Do nothing, behave in the same way as before.	Don't know	Total
100	0	0	100

Result: 100.00 %

Conclusion: Passed.

Table 13 What the participant should do when the test result is negative.

If your test shows a negative result. What should you do?			
It is unlikely to suffer from COVID-19, follow the government's instructions to "self-test user information". If necessary, contact a doctor for a PCR test for confirmation.	Do nothing, behave in the same way as before.	Don't know	Total

100	0	0	100

Result: 100.00 %

Conclusion: Passed.

Table 14 What the participant should do when the test result is invalid.

If your test shows invalid result. What should you do?			
Read the instructions carefully and retest. If the test results are still invalid, contact your doctor or COVID-19 testing center.	Do nothing, behave in the same way as before.	Don't know	Total
100	0	0	100

Result: 100.00 %

Conclusion: Passed.

6.4 Conclusion

100 participants completed the interpretation of test cards with different results.

100 % of the participants read the test card results completely consistent with the professional reading results.

100% of the participants able to understand the instructions for use, and interpret what's a positive/negative/invalid test result

100% of the participants able to understand the instructions for use, and correctly interpret what to do in case of a positive/negative/invalid test result.

In short, participants only need to follow the operation steps described on the IFU for testing, and the probability of making mistakes is very small.

7. Diagnostic sensitivity non-supervised and diagnostic specificity non-supervised researches

7. 1 Diagnostic sensitivity non-supervised subject screening criteria. (Hereinafter referred to as "Known positive" studies)

(1) Inclusion criteria

① At least 30 participants (approximately ≤7 days after the onset of symptoms and individuals without symptoms)

② Each participant was sampled by laboratory technician in a separate laboratory before the self-examination, and tested positive for the antigen.

③ Participants ≥ 15 years old

④ European population

(2) Exclusion criteria

① The participants who objectively cannot operate autonomously (such as hand disabilities, etc.)

when their legal agents are not present;

2 The participants who have difficulty in autonomous reading and comprehension (such as illiterate, etc.) when their legal agents are not present;

3 The participants under the age of 18 when their legal agents are not present;

4 The person with experience in medical-related industries.

(3) Elimination criteria

1 Samples that fail to complete the test due to sample contamination caused by anthropogenic factors, man-made operational mistakes in the test or instrumental factors or human factors;

2 Samples with reagent's quality problems: for example, reagents are expired or not kept as required;

3 Before the statistics, it was found that the information required for the original record of any clinical trial was missing or did not meet the selection criteria/exclusion criteria;

4 The same case has supplied multiple samples which are selected for testing, and then the test results of subsequent selected samples will be excluded.

7.2 Diagnostic specificity non-supervised subject screening criteria. (Hereinafter referred to as "Unknown status" studies)

(1) Inclusion Criteria

1 At least 70 participants who don't know their status

2 Participants ≥ 15 years old

3 European population

(2) Exclusion criteria

1 The participants who objectively cannot operate autonomously (such as hand disabilities, etc.) when their legal agents are not present;

2 The participants who have difficulty in autonomous reading and comprehension (such as illiterate, etc.) when their legal agents are not present;

3 The participants under the age of 18 when their legal agents are not present;

4 The person with experience in medical-related industries.

(3) Elimination criteria

1 Samples that fail to complete the test due to sample contamination caused by anthropogenic factors, man-made operational mistakes in the test, or instrumental factors or human factors;

2 Samples with reagent's quality problems: for example, reagents are expired or not kept as required;

3 Before the statistics, it was found that the information required for the original record of any clinical trial was missing or did not meet the selection criteria/exclusion criteria;

4 The same case has supplied multiple samples which are selected for testing, and then the test results of subsequent selected samples will be excluded.

7.3 Product information

Table 15: Information on candidate kit

Candidate Kit	SARS-CoV-2 Antigen Test Kit		
IFU Version	A9-Special		
Specification	1 Test/kit	Lot NO.:	TC10022022F1502
Expiration Date	14082023	Storage:	2°C-30°C
Manufacturer	BIOTEKE CORPORATION(WUXI)CO., LTD.		

Table 16: Information of PCR contrast reagent

Reference Kit	Vitassay qPCR SARS-CoV-2		
IFU Version	IU_046 Ed05 Ene21		
Specification	96 Tests/Box	Lot No.	3046-592
Expiration Date	2023-11-30	Storage	Store at -20±5°C, keep away from light
Manufacturer	Vitassay Healthcare S. L.U. (Spain)		
Regulatory Status	CE Marked		

7.4 Research sample type

Candidate kit: anterior nasal swab

Reference RT-PCR kit: nasopharyngeal swab

7.5 Participant research program

30 participants (participant status was known positive and approximately ≤7 days after the onset of symptoms and individuals without symptoms, lay users that are known antigen positive), each participant will collect two samples by a laboratory technician in a separate laboratory before self-examination. The anterior nasal swab sample was provided for laboratory technicians to confirm that the participant was antigen positive using the candidate kit, and that the participant meets the recruitment criteria. Another nasopharyngeal sample was used as a verification comparison by RT-PCR. Participants performed self-tests of self-collection and sample processing (swabs, buffer extraction, etc.) until the questionnaire was completed. After the test, participants must wear mask and be isolated and treated in accordance with local requirements. The laboratory technician disinfected and cleaned the laboratory.

70 participants (participant status was unknown and approximately ≤7 days after the onset of symptoms and individuals without symptoms) who don't know their status (individuals do not know the professional diagnosis results before self-test, and perform the entire test procedure from specimen collection and specimen pretreatment (swabs, buffer extraction, etc.) until the questionnaire is completed. The laboratory

technician collected two samples from each participant, one anterior nasal sample is used for the professional test results of the candidate kit, another nasopharyngeal sample is used for the RT-PCR test of Vitassay qPCR SARS-CoV-2 (hereinafter reference kit) to verify the final result.

7.6 Research procedure

7.6.1 Sampling and testing procedures

The sampling and testing process is described in detail in IFU. All participants participating in the experiment are asked to read the IFU at least once. Each participant needs to complete a self-sampling and test. The laboratory technician needs to collect two samples from the participant, one is the anterior nasal swab sample for professional test results, and the other is the nasopharyngeal swab for comparison and verification with RT-PCR. The sampling and testing process are shown in the chapters below:

1. Wash Your hands thoroughly for at least 20 seconds before the test.

2.Put the tube into the kit box holder before proceeding to the tube. Add all of sample diluent vertically to the sample extraction tube.

3. NOTE: please blow your nose before collection.

Remove the swab from its wrapper and take out swab by holding the handle. Being careful not to touch the fabric tip of the swab with your hands.

4. Gently insert the swab into your nostril less than one inch (about 2.5cm). Slowly rub the swab against all of the inside walls of your nostril. Make at least 5 big circles. Do not just spin the swab. Repeat this step in your other nostril using the same swab.

NOTE: With children, the maximum depth of insertion into the nostril may be less than 3/4 of an inch.

5. Insert the swab into the tube. Touch the bottom of the tube with the swab tip, and stir at least 5 times. Squeeze the swab in the tube through the outer wall of the tube by finger 5 times.

6. Remove the swab by rotating against the sample tube while squeezing the sides of the tube to release the liquid from the swab. Remove and discard the swab into waste bag provided.

7. Screw on the purple cap and unscrew the top white cap.

8. Open the pouch and take out the Test Card. Place it on a flat, dry and clean surface. Turn the tube integrated dropper cap upside down and slowly squeeze 3 drops onto the sample well of the Test Card.

9. Results Interpretation (IMPORTANT)

NOTE:The test results should not be read after 20 minutes.

10. All used test components should be disposed of in your household waste. After completing all steps, wash hands or use hand sanitizer.

7.6.2 Handling of abnormal conditions

When the test results of a participant are inconsistent with those of laboratory technician. Laboratory technician needs to record the test results and analyze the possible reasons. These reasons may include:

1) Participants did not completely follow the sampling and testing procedures to complete the test, resulting in deviations in the results;

2) Operation errors of laboratory technician;

3) Participants make mistakes in the interpretation of the results;

4) Laboratory technician make mistakes in the interpretation of the results;

5) The test results of the antigen test kit have false positives or false negatives;

6) Influence caused by other objective factors.

When an abnormal situation occurs, the test should be performed again. The participant and laboratory technician should do it at the same time. If inconsistent results still occur, the observer needs to record this situation and count the number of abnormal situations.

In the study, if there are any use errors or operation difficulty, the root cause analysis of each event should be carried out. The number of test users who have made safety-related use errors corresponds to the use errors identified in the risk assessment and carries out corresponding risk control.

7.6.3 Statistics of test results

After the participants complete the test, they need to fill out an Appendix B Post-test user questionnaire. Observers need to fill in Appendix C Observer checklist to record the problems and test results during the test.

Laboratory technicians need to perform data statistics on the checklist and participant questionnaires, and conduct risk analysis and assessment of user errors and operating difficulties in the checklist.

The results of all statistical data are given in the section 7.7.

7.7 Questionnaire survey

During the study, participants will receive a test kit and a questionnaire. After the test, each participant needs to fill out a questionnaire (Appendix B Post-test user questionnaire).

Observers need to fill in the checklist and collect participant questionnaires and perform statistical data to evaluate product safety, and the consistency of test results between participants and laboratory technicians.

The research questionnaire data statistics are as follows:

Table 17: Age range

Age Range (Years)	Amounts	
	Known positive	Unknown status
15-34	11	30
35-64	16	34
≥65	3	6

Total	30	70

Table 18: Gender

Gender	Known positive	Unknown status
Female	14	35
Male	16	35
Total	30	70

Table 19. Education background

Education	Amounts	
	Known positive	Unknown status
Basic education	1	3
Middle education	7	20
Higher education	22	44
Others	0	3
Total	30	70

Table 20. Occupation background

Profession	Amounts	
	Known positive	Unknown status
Staff	15	36
Government employee	4	3
Teacher	1	3
Student	3	5
Worker	2	10
Retiree	1	3
Unemployed	0	0
Others	4	10
Total	30	70

Table 21 Symptom of participants

Symptom	Amounts	
	Known positive	Unknown status
Stuffy nose, runny nose	2	2
Sore throat, muscle aches	1	1
Diarrhea and nausea	0	1
Loss of taste	0	0
Loss of smell	0	0
Mild fever, low fever around 38℃	0	1
Dry cough	1	1
High fever, above 38.5℃	0	0
Others	0	0

No symptom	1	17
Two or more above mentioned symptoms	25	47
Total	30	70

Table 22 Date of symptom onset

Symptom	Amounts	
	Known positive	Unknown status
1 day	7	9
2 days	11	13
3 days	4	14
4 days	2	9
5 days	3	3
6 days	1	2
7 days	1	3
Above 7 days	0	0
No symptom	1	17
Total	30	70

Table 23. Read the result time

	10-15 minutes	15-20 minutes	20- minutes	After 20 minutes	Total
Known positive	0	30	0	0	30
Unknown status	0	70	0	0	70

Table 24. Difficulty of sampling

	Very simple	Simple	Difficult	Very difficult	Total
Known positive	22	8	0	0	30
Unknown status	45	24	1	0	70

Table 25. Difficulty of read results

	Very simple	Simple	Difficult	Very difficult	Total
Known positive	23	6	1	0	30
Unknown status	48	20	2	0	70

Table 26 Difficulty of test

	Very simple	Simple	Difficult	Very difficult	Total
Known positive	22	8	0	0	30
Unknown status	49	20	1	0	70

Table 27. Used similar products before

	Amounts	
	Known positive	Unknown status
Yes	15	27
No	15	43
Total	30	70

Table 28. Product are using is within the validity period

	Amounts	
	Known positive	Unknown status
Yes	30	70
No	0	0
Total	30	70

Table 29. Product is reused

	Amounts	
	Known positive	Unknown status
Yes	0	0
No	30	70
Total	30	70

Table 30. Known positive result judgment coincidence rate

	Professional results	Self-test results	PCR results	Concordance rate
Negative	0	0	0	100%
Positive	30	30	30	

Table 31. Unknown status result judgment coincidence rate

	Self-test results	Professional results	PCR results	Concordance rate
Negative	50	50	40	85.71 %
Positive	20	20	30	

		PCR results		Total
		Positive	**Negative**	
Self-test results	**Positive**	50		50
	Negative	10	40	50
Total		60	40	100

Calculation and analysis of the sensitivity, specificity, total accuracy.

Sensitivity=[a/(a+c)] ×100%

Specificity=[d/(b+d)] ×100%

Total accuracy = [(a+d)/(a+b+c+d)] ×100%

Statistic	Value	95% CI
Sensitivity	83.33%	(71.48% ~ 91.71%)
Specificity	100.00%	(91.19% ~ 100.00%)
Total accuracy	90.00%	(82.38% ~ 95.10%)

Table 32. Status before test

	Amounts	
	Known positive	Unknown status
Positive	30	0
Negative	0	0
Unknown	0	70
Total	30	70

Table 33 Encountered an abnormal result

	Amounts	
	Known positive	Unknown status
Re-test with new test reagents	0	0
Use new methods for testing	0	0
Call the manufacturer	0	0
No abnormal results encountered	30	70
Total	30	70

Observer checklist

Table 34 Known positive observer checklist

	Question	Yes	No	Notes
1	Participant is user?	30		
2	Hands Cleaned?	30		
3	Swab unpacked?	30		
4	Swab tip not touched?	30		
5	Swab rotated enough?	30		
6	Swab into the nostril distance appropriate?	30		
7	Reagent opened?	30		
8	Is there buffer in the test tube (or is the test tube filled with the correct amount of buffer)?	30		
9	Swab immersed in extraction tube with sample processing solution?	30		
10	Swab rotated in the tube enough times?	30		
11	Swab wiped off during removal?	30		
12	Tube closed with lid?	30		
13	Test cassette removed from foil bag?	30		
14	Test cassette placed on an even ground?	30		
15	Sample drop was enough yet?	30		
16	Results interpreted on time?	30		
17	Interpret the results correctly?	30		

18	After the test properly discarded trash?	30		
19	Test completed correctly?	30		
20	Participant test result consistent with the professional test result?	30		
21	Participant test result consistent with RT-PCR result?	30		

Table 35: Unknown status checklist

	Question	Yes	No	Notes
1	Participant is user?	70		
2	Hands Cleaned?	70		
3	Swab unpacked?	70		
4	Swab tip not touched?	70		
5	Swab rotated enough?	70		
6	Swab into the nostril distance appropriate?	70		
7	Reagent opened?	70		
8	Is there buffer in the test tube (or is the test tube filled with the correct amount of buffer)?	70		
9	Swab immersed in extraction tube with sample processing solution?	70		
10	Swab rotated in the tube enough times?	70		
11	Swab wiped off during removal?	70		
12	Tube closed with lid?	70		
13	Test cassette removed from foil bag?	70		
14	Test cassette placed on an even ground?	70		
15	Sample drop was enough yet?	70		
16	Results interpreted on time?	70		
17	Interpret the results correctly?	70		
18	After the test properly discarded trash?	70		
19	Test completed correctly?	70		
20	Participant test result consistent with the professional test result?	70		
21	Participant test result consistent with RT-PCR result?	60	10	

7.8 Risk assessment

In the study of diagnostic sensitivity, because the participants did not fully follow the instructions in the experiment and did not collect enough samples, leaded to false negative results.

90.00% (90 /100) of the participants in this study did not experience any error or difficulty in operation, thus verifying that the SARS-CoV-2 Antigen Test Kit and safety-related availability are presumed to be usable.

7.9 Conclusion

During the testing of these 100 participants, comparing the results of these participants with the results of RT-PCR, the test results are 90.00% (90/100) of participants are highly consistent with those of laboratory technician. This shows that the product has better usability and higher consistency, thus verifying that the SARS-CoV-2 Antigen Test Kit is presumed to be usable.

Table 36 Participants (100) test results

Status	Sample No	Age (years)	Gender	Self-test results	Professional results	PCR results
Unknown	1	48	F	Negative	Negative	Negative
Known	2	28	M	Positive	Positive	Positive
Known	3	44	M	Positive	Positive	Positive
Unknown	4	46	M	Negative	Negative	Negative
Unknown	5	24	F	Positive	Positive	Positive
Known	6	54	F	Positive	Positive	Positive
Unknown	7	19	M	Negative	Negative	Negative
Unknown	8	80	F	Negative	Negative	Negative
Known	9	47	M	Positive	Positive	Positive
Unknown	10	20	F	Negative	Negative	Positive
Unknown	11	41	F	Negative	Negative	Negative
Unknown	12	56	M	Positive	Positive	Positive
Unknown	13	24	M	Negative	Negative	Negative
Unknown	14	36	M	Negative	Negative	Negative
Unknown	15	25	F	Negative	Negative	Positive
Unknown	16	24	M	Negative	Negative	Negative
Unknown	17	48	M	Positive	Positive	Positive
Unknown	18	43	M	Positive	Positive	Positive
Known	19	42	F	Positive	Positive	Positive
Known	20	60	M	Positive	Positive	Positive
Unknown	21	42	F	Negative	Negative	Negative
Unknown	22	37	F	Negative	Negative	Negative
Unknown	23	24	F	Negative	Negative	Negative
Unknown	24	35	F	Positive	Positive	Positive
Unknown	25	40	M	Positive	Positive	Positive
Known	26	66	F	Positive	Positive	Positive
Known	27	43	F	Positive	Positive	Positive
Unknown	28	24	M	Positive	Positive	Positive
Unknown	29	50	F	Positive	Positive	Positive
Known	30	37	F	Positive	Positive	Positive
Known	31	24	F	Positive	Positive	Positive
Unknown	32	26	F	Negative	Negative	Negative
Known	33	27	M	Positive	Positive	Positive
Known	34	19	M	Positive	Positive	Positive

Known	35	54	M	Positive	Positive	Positive
Unknown	36	67	F	Positive	Positive	Positive
Unknown	37	43	M	Negative	Negative	Negative
Unknown	38	60	F	Negative	Negative	Negative
Unknown	39	34	M	Negative	Negative	Negative
Unknown	40	62	M	Negative	Negative	Positive
Unknown	41	18	M	Negative	Negative	Negative
Unknown	42	53	M	Negative	Negative	Negative
Known	43	37	M	Positive	Positive	Positive
Known	44	37	M	Positive	Positive	Positive
Unknown	45	59	F	Positive	Positive	Positive
Unknown	46	37	M	Negative	Negative	Positive
Unknown	47	32	M	Negative	Negative	Negative
Known	48	20	F	Positive	Positive	Positive
Known	49	43	F	Positive	Positive	Positive
Unknown	50	30	F	Positive	Positive	Positive
Unknown	51	58	F	Negative	Negative	Positive
Known	52	27	F	Positive	Positive	Positive
Unknown	53	29	F	Negative	Negative	Negative
Unknown	54	30	M	Positive	Positive	Positive
Known	55	25	M	Positive	Positive	Positive
Known	56	40	F	Positive	Positive	Positive
Unknown	57	26	M	Positive	Positive	Positive
Unknown	58	36	M	Negative	Negative	Negative
Unknown	59	52	M	Negative	Negative	Negative
Unknown	60	23	M	Positive	Positive	Positive
Known	61	27	M	Positive	Positive	Positive
Known	62	25	M	Positive	Positive	Positive
Known	63	41	M	Positive	Positive	Positive
Unknown	64	36	F	Positive	Positive	Positive
Unknown	65	30	M	Negative	Negative	Negative
Unknown	66	47	M	Positive	Positive	Positive
Unknown	67	29	M	Negative	Negative	Negative
Unknown	68	40	M	Negative	Negative	Positive
Unknown	69	21	F	Negative	Negative	Negative
Unknown	70	29	M	Negative	Negative	Negative
Known	71	58	M	Positive	Positive	Positive

Unknown	72	27	M	Negative	Negative	Positive
Unknown	73	23	F	Positive	Positive	Positive
Unknown	74	27	M	Negative	Negative	Negative
Unknown	75	44	F	Negative	Negative	Negative
Unknown	76	18	F	Negative	Negative	Negative
Unknown	77	46	M	Negative	Negative	Positive
Known	78	35	F	Positive	Positive	Positive
Unknown	79	53	M	Negative	Negative	Positive
Unknown	80	25	F	Negative	Negative	Negative
Unknown	81	34	F	Negative	Negative	Negative
Unknown	82	66	M	Negative	Negative	Positive
Known	83	34	M	Positive	Positive	Positive
Unknown	84	18	F	Negative	Negative	Negative
Unknown	85	29	F	Negative	Negative	Negative
Unknown	86	31	F	Negative	Negative	Negative
Unknown	87	46	M	Positive	Positive	Positive
Known	88	23	M	Positive	Positive	Positive
Known	89	66	F	Positive	Positive	Positive
Unknown	90	46	F	Negative	Negative	Negative
Unknown	91	66	F	Positive	Positive	Positive
Unknown	92	58	F	Negative	Negative	Negative
Unknown	93	69	M	Positive	Positive	Positive
Known	94	70	F	Positive	Positive	Positive
Unknown	95	36	F	Negative	Negative	Negative
Unknown	96	36	M	Negative	Negative	Negative
Unknown	97	69	F	Negative	Negative	Negative
Unknown	98	42	F	Negative	Negative	Negative
Known	99	45	F	Positive	Positive	Positive
Unknown	100	49	F	Negativ	Negative	Negative

8. References

MDCG 2021-21 & Rev.1: Guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical devices.

9. Signature

Laboratory technician	mgr Ewa Czajkowska DIAGNOSTA LABORATORYJNY specjalista laboratoryjnej transfuzjologii medycznej	26.04.2022
Observer	01232 0989 dr n. med. Paweł Chrzan DIAGNOSTA LABORATORYJNY	26.04.2022

Version	Detail	Date
Ver 1.0	First signed	2022-04-11
Ver 1.1	Supplemental Product Information	2022-04-26

Appendix A

A User questionnaire (anonymised patient number)

BEFORE THE EXAMINATION

GENERAL INFORMATION

1.1 Your age: _____			
1.2 Your gender: □Female □Male			
1.3 Your education:			
□Basic education	□Middle education	□Higher education	□ Others
1.4 Your occupation?			
□Staff □Government employee □Teacher □Student			
□Worker □Retiree □Unemployed □Others			
QUESTIONS			
2.1 What is your symptom? (Multiple choice)			
□Stuffy nose, runny nose □Sore throat, muscle aches □Diarrhea and nausea □Loss of taste ☐Loss of smell □Mild fever, low fever around 38℃ □Dry cough □High fever, above 38.5℃ □Others( ) ☐No symptom			
2.2 Date of symptom onset?			
□ 1 day □ 2 days ☐ 3 days □4 days ☐ 5 days □6 days □7 days □ Above 7 days □ No symptom			
2.3 Do you think the instructions for use are clearly described?			
□Very clear	□Clear	□Fuzzy	□Very fuzzy
2.4 Please rate the difficulty of this test?			
□Very simple	□Simple	□Difficult	□Very difficult
2.5 Observe 4 different test results pictures. Which result is the card that selects [corresponding number]? A. Positive (reactive) B. Positive (weak reactive) C. Negative D. invalid			
3	2	1	4
2.6 How do you know if the test result is positive?			
□ Both the C and T line color appear.	□ Only the C line color appear.	□ The C line is colorless.	□ Don't know
2.7 How do you know if the test result is negative?			

□ Both the C and T line color appear.	□ Only the C line color appear.	□ The C line is colorless.	□ Don't know
2.8 How do you know if the test result is invalid?			
□ Both the C and T line color appear.	□ Only the C line color appear.	□ The C line is colorless.	□ Don't know
2.9 If your test shows a positive result. What should you do?			
□ May be infected with COVID-19 and should stay away from others. Strictly abide by the government's instructions "Instructions for self-test users", now you need to contact your family doctor/health department for PCR testing to confirm.	□ Do nothing, behave in the same way as before.	□ Don't know	
2.10 If your test shows a negative result. What should you do?			
□ It is unlikely to suffer from COVID-19, follow the government's instructions to "self-test user information". If necessary, contact a doctor for a PCR test for confirmation	□ Do nothing, behave in the same way as before.	□ Don't know	
2.11 If your test shows invalid result. What should you do?			
□ Read the instructions carefully and retest. If the test results are still invalid, contact your doctor or COVID-19 testing center.	□ Do nothing, behave in the same way as before.	□ Don't know	

Appendix B

B User questionnaire (anonymised patient number)

After the test

3.1 The result of your test?

□Positive □Negative □ Invalid

3.2 The time you read the results?

□10-15 minutes □15-20 minutes □20 minutes □ After 20minutes

3.3 Please rate the difficulty of sampling?

□Very simple □Simple □Difficult □Very difficult

3.4 Please rate the difficulty of read the results?

□Very simple □Simple □Difficult □Very difficult

3.5 Please rate the difficulty of this test?

□Very simple □Simple □Difficult □Very difficult

3.6 Did you know your health condition before performing the test? (result of the PCR test before the antigen test)

□Positive □Negative □ Do not know

3.7 Have you used similar products before?

□Yes □No

3.8 Whether the product you are using is within the validity period?

□Yes □No

3.9 Whether the product you use is reused?

□Yes □No

3.10 What measures did you take when you encountered an abnormal result?

□Re-test with new test reagents

□Use new methods for testing

□Call the manufacturer

□No abnormal results encountered

Appendix C

C Observer Record (anonymised patient number)

Observer Check List

	Question	Yes	No	Notes
1	Participant is user?			
2	Hands Cleaned?			
3	Swab unpacked?			
4	Swab tip not touched?			
5	Swab rotated enough?			
6	Swab into the nostril distance appropriate?			
7	Reagent opened?			
8	Is there buffer in the test tube (or is the test tube filled with the correct amount of buffer)?			
9	Swab immersed in extraction tube with sample processing solution?			
10	Swab rotated in the tube enough times?			
11	Swab wiped off during removal?			
12	Tube closed with lid?			
13	Test cassette removed from foil bag?			
14	Test cassette placed on an even ground?			
15	Sample drop was enough yet?			
16	Results interpreted on time?			
17	Interpret the results correctly?			
18	After the test properly discarded trash?			
19	Test completed correctly?			
20	Participant test result consistent with the professional test result?			
21	Participant test result consistent with RT-PCR result?			