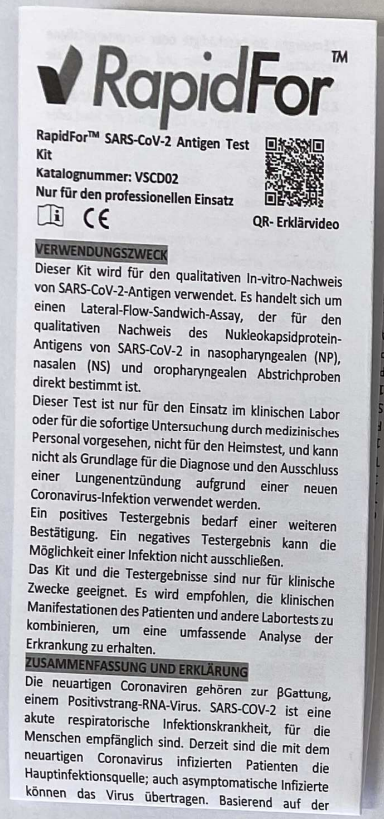

VITROSENS
SCHNELLTEST
NASENABSTRICH
SCHNELLTEST
NASENABSTRICH
-für den professionellen Gebrauch
-einfach
-schmerzfrei
-max 15 minuten
1
Stück
REF VSCD02
IVD
RapidFor™
SARS-CoV-2 Rapid Antigen Test



RapidFor™

RapidFor™ SARS-CoV-2 Antigen Test Kit
Katalognummer: VSCD02
Nur für den professionellen Einsatz

QR- Erklärvideo

VERWENDUNGSZWECK

Dieser Kit wird für den qualitativen In-vitro-Nachweis von SARS-CoV-2-Antigen verwendet. Es handelt sich um einen Lateral-Flow-Sandwich-Assay, der für den qualitativen Nachweis des Nukleokapsidprotein-Antigens von SARS-CoV-2 in nasopharyngealen (NP), nasalen (NS) und oropharyngealen Abstrichproben direkt bestimmt ist.

Dieser Test ist nur für den Einsatz im klinischen Labor oder für die sofortige Untersuchung durch medizinisches Personal vorgesehen, nicht für den Heimstest, und kann nicht als Grundlage für die Diagnose und den Ausschluss einer Lungenentzündung aufgrund einer neuen Coronavirus-Infektion verwendet werden.

Ein positives Testergebnis bedarf einer weiteren Bestätigung. Ein negatives Testergebnis kann die Möglichkeit einer Infektion nicht ausschließen.

Das Kit und die Testergebnisse sind nur für klinische Zwecke geeignet. Es wird empfohlen, die klinischen Manifestationen des Patienten und andere Labortests zu kombinieren, um eine umfassende Analyse der Erkrankung zu erhalten.

ZUSAMMENFASSUNG UND ERKLÄRUNG

Die neuartigen Coronaviren gehören zur βGattung, einem Positivstrang-RNA-Virus. SARS-COV-2 ist eine akute respiratorische Infektionskrankheit, für die Menschen empfänglich sind. Derzeit sind die mit dem neuartigen Coronavirus infizierten Patienten die Hauptinfektionsquelle; auch asymptomatische Infizierte können das Virus übertragen. Basierend auf der

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PRINZIP DES TESTS

Dieses Reagenz verwendet ein Doppel-Antikörper-Sandwich-Verfahren zum legalen Nachweis des Antigens des neuartigen Coronavirus (SARS-CoV-2) in Nasen-, Nasopharyngeal- und Oropharyngeal-Abstrichproben. Während des Nachweises bindet der mit Kolloidal Gold markierte monoklonale Anti-SARS-CoV-2-Antikörper im Markierungskissen an das SARS-CoV-2-Antigen in der Probe, um einen Komplex zu bilden, und der Reaktionskomplex bewegt sich unter der Wirkung der Chromatographie entlang der Nitrocellulose-membran vorwärts, wo er von dem monoklonalen Anti-SARS-CoV-2-Antikörper eingefangen wird, der von der Nachweiszone (T) auf der Nitrocellulose-membran vorbeschichtet ist, und schließlich wird in der T-Zone eine rot gefärbte Reaktionslinie gebildet. Wenn die Probe kein SARS-CoV- 2-Antigen enthält, kann in der T-Zone keine rote Farbreaktionslinie gebildet werden. Unabhängig davon, ob die zu untersuchende Probe SARS-CoV-2-Antigen enthält, bildet sich im Qualitätskontrollbereich (C) immer eine rote Reaktionslinie.

MATERIALIEN UND KOMPONENTEN

Mit den Test Kits mitgelieferte Materialien

KOMPONENT	1 Test/Box	25 Tests /Schachtel
Testgerät	1 Testkassette (1Test/Beutel x 1 Beutel)	25 Testkassette (1Test/Beutel x 25 Beutel)
Puffer	1 Einwegflasche, mit je 500 µL Extraktionspuffer	25 Einwegflaschen, jeweils mit 500 µL Extraktionspuffer
Probenentnahme Tupfer	1 steriler Einweg-Probenentnahme-Tupfer	25 sterile Einweg-Probenentnahme-Tupfer
Packungseinsatz	1 Gebrauchsanweisung	1 Gebrauchsanweisung

Hinweis: Die Komponenten in verschiedenen Chargen des Kits können nicht gemischt werden.

LAGERUNG UND STABILITÄT

1.2°C - 30°C im verschlossenen Beutel bis zum auf der Packung aufgedruckten Verfallsdatum, nicht unter 2°C lagern und abgelaufene Produkte nicht verwenden.

2.Die Testkarte wird innerhalb von 15 Minuten nach Entnahme aus dem Folienumschlag verwendet. Die Pufferlösung wird rechtzeitig nach Gebrauch wieder verschlossen.

3.Das MFG-Datum und das EXP-Datum sind auf dem Etikett angegeben. Das Produkt ist nach 12 Monaten abgelaufen.

TESTVORGANG

Vor dem Test lesen Sie bitte die Gebrauchsanweisung und führen Sie die folgenden 15 Schritte sorgfältig aus. Das Testverfahren beinhaltet folgende Schritte: Probenentnahme, Probenverarbeitung und Testdurchführung.

ANFORDERUNGEN AN DIE PROBENENTNAHME

1. Entnahme aus dem Nasensekret: Führen Sie den sterilen Tupfer an der Stelle ein, an der sich das Nasensekret am meisten befindet, an der vorderen Nase, und drehen Sie den Tupfer 3 Mal nahe an der Innenwand der Nasenhöhle, entfernen Sie den Tupfer.

2.Die Proben sollten so schnell wie möglich nach der Entnahme verwendet werden (innerhalb einer halben Stunde).

3. Die Proben sollten nicht inaktiviert werden.

PROBENVERARBEITUNG

4.500 µl Extraktionspuffer sind im Röhrchen enthalten.

5.Öffnen Sie die Kappe des Extraktionsröhrchens und mischen Sie die Probe mit einem Tupfer.

6. 10-maliges Drehen der Probe gegen die Innenwand des Röhrchens oder 10-maliges Zusammendrücken des Röhrchens zum Eluieren der Probe, um sicherzustellen, dass die Probe auf dem Tupfer vollständig in den Puffer eluiert wird.

7.Drücken Sie den Tupfer Kopf an der Innenwand des Röhrchens entlang, um die Flüssigkeit so weit wie möglich im Röhrchen zu halten.
so dass der untere Teil im Röhrchen bleibt, und schließen Sie die Kappe über dem Tropfkopf, um die Flüssigkeit gründlich zu mischen.

9. Die Proben sollten sofort nach der Entnahme eluiert und verwendet werden; gleichzeitig sollten die Proben nicht inaktiviert, gelagert oder eingefroren und aufgetaut werden.

***Hinweis:** Es wird empfohlen, eine Pipette zum Übertragen der Proben zu verwenden, um Abweichungen zu reduzieren.

TESTBETRIEB

10.Nehmen Sie die erforderlichen Reagenzien und Testkarten, um sie auf Raumtemperatur zu bringen.

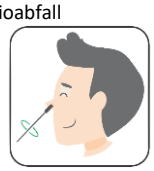
11.Packen Sie den Aluminiumfolienbeutel aus, legen Sie die Reagenzien karte waagerecht auf den Tisch und markieren Sie sie.

12.100µL (3 Tropfen) der verarbeiteten Probe in die Probenvertiefung geben und timen. Es wird empfohlen, eine Pipette zur Entnahme von Puffer/Proben zu verwenden, um Abweichungen zu reduzieren.

13.Wenn der Test zu laufen beginnt, wird die Flüssigkeit, die sich durch das Ergebnisfenster nach oben bewegt, sichtbar.

14.Warten Sie 15 Minuten und lesen Sie die Ergebnisse ab. Lesen Sie die Ergebnisse nicht nach 30 Minuten ab.

15. Entsorgen sie alle während des Tests verwendeten Materialien in den Bioabfall



Probenentnahme

Bearbeitung der Probe

Testbetrieb

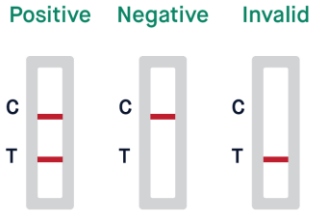
INTERPRETATION DER TESTERGEBNISSE

Dieses Produkt kann nur eine qualitative Analyse des Detektionsobjekts durchführen.

Positives Ergebnis: Wenn sowohl C- als auch T-Linien innerhalb von 15 Minuten sichtbar sind, ist das Testergebnis positiv und gültig.

Negatives Ergebnis: Wenn der Testbereich (T-Linie) keine Farbe aufweist und der Kontrollbereich eine farbige Linie zeigt, ist das Ergebnis negativ und gültig.

Ungültiges Ergebnis: Das Testergebnis ist ungültig, wenn sich im Kontrollbereich keine farbige Linie bildet. Die Probe muss unter Verwendung einer neuen Testkassette erneut getestet werden.



EINSCHRÄNKUNGEN

1.Das Ergebnis des Produkts sollte nicht als bestätigte Diagnose angesehen werden, sondern nur als klinische Referenz. Die Beurteilung sollte zusammen mit RT-PCR-Ergebnissen, klinischen Symptomen, epidemiologischen Informationen und weiteren klinischen Daten erfolgen.

2.Der Inhalt der Kits ist für den qualitativen Nachweis von SARS- CoV-2 Antigenen aus Nasen-, Oropharyngeal- und Nasopharyngealabstrichen bestimmt.

3.Dieser Test detektiert sowohl lebensfähige (lebende) als auch nicht lebensfähige SARS-CoV-2.

4.Die Testleistung hängt von der Virusmenge (Antigen) in der Probe ab und kann mit den Ergebnissen einer Viruskultur, die mit derselben Probe durchgeführt wurde, korrelieren oder nicht.

5.Der Probenpuffer und die Testkarte müssen vor der Verwendung auf Raumtemperatur (18℃~26℃) gebracht werden, sonst können die Ergebnisse falsch sein.

6.Ein negatives Testergebnis kann auftreten, wenn die Antigenkonzentration in einer Probe unter der Nachweisgrenze des Tests liegt oder wenn die Probe unsachgemäß gesammelt oder transportiert wurde.

7.Die Nichtbeachtung des Testverfahrens kann sich negativ auf die Testleistung auswirken und/oder das Testergebnis ungültig machen.

8.Weniger als 10 Minuten ausgewertete Ergebnisse können zu einem falsch negativen Ergebnis oder mehr als 15 Minuten zu einem falsch positiven Ergebnis führen.

9.Ein positives Testergebnis schließt Koinfektionen mit anderen Erregern nicht aus.

10.Negative Testergebnisse schließen andere virale oder bakterielle Infektionen, die nicht SARS sind, nicht aus.

11.Negative Ergebnisse sollten als Vermutung behandelt und mit einem molekularen Assay bestätigt werden.

12.Die klinische Leistung wurde mit gefrorenen Proben evaluiert, die Leistung kann bei frischen Proben anders sein

13.Die Anwender sollten die Proben so schnell wie möglich nach der Probenentnahme testen. Wenn das Probenvolumen nicht ausreichend ist, kann die Chromatographie nicht erfolgreich durchgeführt werden.

14.Bitte beachten Sie die Hinweise auf dem Gerät. Es wird empfohlen, eine Pipette zur Zugabe von Proben zu verwenden.

LEISTUNGSMERKMAL

1.Klinische Verifizierung

Die Leistung des SARS-Cov-2-Schnelltestkits wurde anhand von 630 nasal Abstrichen von symptomatischen Patienten, die innerhalb von 7 Tagen mit Symptomen auftraten, erhoben.

SARS-CoV-2 Rapid Ag Test Kit	RT-PCR-Vergleichstest-Ergebnis		
	Positiv (+)	Negativ (-)	Gesamt
Positiv	613	5	618
Negativ	17	520	537
Gesamt	630	525	1155
Empfindlichkeit : 613/630 97.3%, (95% CI: 95.7, 98.42)			
Spezifität : 520/525 99.0%, (95% CI:97.79, 99.69)			
Genauigkeit: (520+613)/ 1155(613+5+17+520)x100%=98.09%			

Positive Ergebnisse wenige Tage nach dem Auftreten der Symptome:	RT-PCR Positiv (+)	SARS-CoV-2 Rapid Antigen Test Kit	PPA
1	16	16	100%
2	36	36	100%
3	60	60	100%
4	90	90	100%
5	120	120	100%
6	98	98	100%
7	180	164	91.1%
Asymptomatische Patienten	30	29	96.6%

Eine begrenzte Anzahl von Patienten mit Symptomen für mehr als sieben Tage sowie asymptomatische Patienten wurden in die klinische Studie aufgenommen (n = 630). Die Stichprobengröße war relativ signifikant, die positive Zustimmung lag bei 97,3 % (613/630) und die negative Zustimmung bei 99 % (520/525). Der Test ist für den professionellen Einsatz bestimmt.

2.Nachweisgrenze

Bei einer Viruskulturkonzentration von 100 $TCID_{50}$/mL und mehr war der positive Wert größer oder gleich 95%. Bei einer Viruskulturkonzentration von 50 $TCID_{50}$/mL und weniger beträgt der Positivitätsgrad nicht mehr als 95 %, so dass die minimale Nachweisgrenze des SARS-CoV-2 Ag-Schnelltestkits bei 100 $TCID_{50}$/mL liegt.

3. Kreuzreaktivität

Die Kreuzreaktivität des Kits wurde evaluiert. Die Ergebnisse zeigten keine Kreuzreaktivität mit den folgenden Proben.

No.	Exemplar Typ	Resultat
1	HCoV-HKU1	10^5 TCID50/mL
2	Staphylococcus aureus	10^6 CFU /mL
3	Streptococcus pyogenes	10^6 CFU /mL
4	Measles virus	10^5 TCID50/mL
5	Paramyxovirus parotitis	10^5 TCID50/mL
6	Adenovirus 3	10^5 TCID50/mL
7	Mycoplasma pneumoniae	10^6 CFU / mL
8	Parainfluenza virus 2	10^5 TCID50/mL
9	Human Metapneumovirus (hMPV)	10^5TCID50/mL
10	Human coronavirus OC43	10^5 TCID50/mL
11	Human coronavirus NL63	10^5 TCID50/mL
12	Human coronavirus 229E	10^5 TCID50/mL
13	MERS Coronavirus	10^5 TCID50/mL
14	Bordetella parapertussia	10^6 CFU / mL
15	Influenza B (Victoria strain)	10^5 TCID50/mL
16	Influenza B (Ystrain)	10^5 TCID50/mL
17	Influenza A (H1N1 2009)	10^5 TCID50/mL
18	Influenza A (H3N2)	10^5 TCID50/mL
19	Avian influenza virus (H7N9)	10^5 TCID50/mL
20	Avian influenza virus (H5N1)	10^5 TCID50/mL
21	Epstein-Barr virus	10^5 TCID50/mL
22	Enterovirus CA16	10^5 TCID50/mL
23	Human rhinovirus type 1	10^5 TCID50/mL
24	Human rhinovirus type 14	10^5 TCID50/mL
25	Respiratory syncytial virus A	10^5 $TCID_{50}$/mL
26	Respiratory syncytial virus B	10^5 TCID50/mL
27	Streptococcus pneumoniae	10^6 CFU / mL
28	Candida albicans	10^6 CFU / mL
29	Chlamydia pneumoniae	10^6 CFU / mL
30	Bordetella pertussis	10^6 CFU /mL
31	Pneumocystis jirovecii	10^6 CFU /mL
32	Mycobacterium tuberculosis	10^6 CFU / mL
33	Legionella pneumophila	10^6 CFU / mL
34	Human para-flu virus type 1	10^5 $TCID_{50}$/mL
35	Human para-flu virus type 2	10^5 $TCID_{50}$/mL
36	Human para-flu virus type 3	10^5 $TCID_{50}$/mL
37	Human para-flu virus type 4	10^5 $TCID_{50}$/mL
38	Haemophilus influenzae	10^5 TCID50/mL
40	SARS-coronavirus	10^4 TCID50/mL
41	Staphylococcus epidermidis	10^6 CFU /mL

4.Interferenzsubstanzen

Die Testergebnisse werden nicht durch die Substanz in der folgenden Konzentration gestört:

No.	Kontaminanten	Resultat
1	Whole Blood	4%
2	Ibuprofen	1mg / mL
3	Tetracycline	3µg / mL
4	Chloramphenicol	3µg / mL
5	Erythromycin	3µg / mL
6	Tobramycin	5%
7	Throat spray (Menthol)	15%
8	Mupirocine	10mg/mL
9	Throat lozenge (Menthol)	1.5mg/mL
10	Tamiflu (Oseltamivir)	5mg/mL
11	Naphthoxoline hydrochloride nasal drops	15%
12	Mucin	0.50%
13	Fisherman's Friend	1.5mg/mL
14	Compound Benzocain Gel	1.5mg/mL
15	Cromoglycate	15%
16	Sinex (Phenylephrine Hydrochloride)	15%
17	Afrin (Oxymetazoline)	15%
18	Fluticasone propionate spray	15%
19	Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL
20	Naso GEL (NeilMed)	5% v/v
21	CVS Nasal Spray (Cromolyn)	15% v/v
22	Zicam	5% v/v
23	Homeopathic (Alkalol)	%10

5. Präzision

1.10 Replikate von negativen und positiven Proben wurden unter Verwendung der Referenzmaterialien der Unternehmen getestet. Die negative Übereinstimmung und die positive Übereinstimmung lagen bei 100 %.

2.Drei verschiedene Chargen mit positiven und negativen Referenzmaterialien von Unternehmen wurden getestet. Die negativen Ergebnisse und die positiven Ergebnisse lagen bei 100 %.

6. Hakeneffekt

Es wurde kein Hook-Effekt festgestellt, als die Konzentration der inaktivierten Virus-Stammlösung auf $4{,}0\times10^5$ $TCID_{50}$/ml erhöht wurde.

VORSICHTSMASSNAHMEN

1.Für die In-vitro-Diagnostik.

2.Verwenden Sie den Inhalt des Kits nicht nach dem auf der Außenseite der Verpackung aufgedruckten Verfallsdatum.

3.Bei der Entnahme, Handhabung, Lagerung und Entsorgung von Patientenproben und gebrauchtem Kit-Inhalt sind angemessene Vorsichtsmaßnahmen zu beachten.

4.Es wird empfohlen, bei der Handhabung von Patientenproben Nitril-, Latex- (oder gleichwertige) Handschuhe zu verwenden.

5.Die benutzte Testkarte, Reagenzröhrchen oder Tupfer dürfen nicht wiederverwendet werden.

6.Der Benutzer sollte niemals den Folienbeutel der Testkarte öffnen und sie der Umgebung aussetzen, bis die Testkarte für den sofortigen Gebrauch bereit ist.

7.Entsorgen Sie beschädigte oder heruntergefallene Testkarten oder Materialien und verwenden Sie sie nicht.

8.Die Reagenzlösung enthält eine Salzlösung (Kochsalzlösung). Wenn die Lösung mit der Haut oder den Augen in Berührung kommt, spülen Sie sie mit reichlich Wasser aus.

9.Unzureichende oder unsachgemäße Probenentnahme, -lagerung und -transport können zu falschen Testergebnissen führen.

10.Die Verfahren zur Probenentnahme und -handhabung erfordern eine spezielle Schulung und Anleitung.

11.Verwenden Sie die geeignete Festvolumenpipette in Übereinstimmung mit den Testverfahren.

12.Um genaue Ergebnisse zu erhalten, verwenden Sie keine visuell blutigen oder übermäßig viskosen Proben.

13.Schreiben Sie nicht auf den Barcode der Testkarte.

14.Da es sich bei dem Nachweisreagenz um eine fluoreszierende Verbindung handelt, werden keine sichtbaren Ergebnisse auf dem Teststreifen entstehen.

15.Um genaue Ergebnisse zu erhalten, sollte eine geöffnete und freiliegende Testkarte nicht innerhalb einer Laminar-Flow-Haube oder in einem stark belüfteten Bereich verwendet werden.

16.Der Test sollte in einem Bereich mit ausreichender Belüftung durchgeführt werden.

17.Tragen Sie geeignete Schutzkleidung, Handschuhe und einen Augen-/Gesichtsschutz, wenn Sie den Inhalt dieses Kits handhaben.

18.Waschen Sie sich nach der Handhabung gründlich die Hände.

SCHLÜSSEL ZU DEN VERWENDETEN SYMBOLEN

COMPONENT	Enthaltenes Material
TEST CARD	Testkarte
TUBE	Röhrchen
SWAB	Tupfer
IFU	Gebrauchsanweisung
	Gebrauchsanweisung beachten
	Lagern bei 2°C ~ 30°C
	Verfallsdatum
	Hersteller
	Trocken aufbewahren
LOT	Chargennummer
DILUENT	Probenpuffer
	Datum der Herstellung
	Nicht wiederverwenden
REF	Katalognummer
	Von Sonnenlicht fernhalten
	Tests pro Kit
IVD	In-vitro-Diagnostikum Medizinisches Gerät
	Nicht verwenden, wenn die Verpackung beschädigt ist
	Biohazard
CE	Dieses Produkt erfüllt die Anforderungen der Richtlinie 98/79/EG über In-vitro-Diagnostika

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EC REP **HATEX AS GmbH & Co. KG**
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RapidFor™ SARS-CoV-2 Rapid Antigen Test Kit
Catalog Number: VSCD02
For professional use only

INTENDED USE

This kit is used for in vitro qualitative detection of SARS-CoV-2 antigen. It is a lateral flow sandwich assay, intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal (NS) swab specimens directly.
This test is only for clinical laboratory use or for immediate inspection by medical personnel, not for home testing, and cannot be used as the basis for the diagnosis and exclusion of pneumonia caused by new coronavirus infection.
A positive test result needs further confirmation. A negative test result cannot rule out the possibility of infection.
The kit and test results are for clinical reference only. It is recommended to combine the patient's clinical manifestations and other laboratory tests for a comprehensive analysis of the condition.

SUMMARY AND EXPLANATION

The novel coronaviruses belong to the βgenus, a positive strand RNA virus. SARS-COV-2 is an acute respiratory infectious disease which people are susceptible to infection. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be spread the virus. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue, loss of smell and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE OF THE TEST

This reagent uses double-antibody sandwich to legally detect the antigen of novel coronavirus (SARS-CoV-2) in nasal swab samples. During detection, the colloidal gold labeled anti-SARS-CoV-2 monoclonal antibody in the labeling pad binds to the SARS-CoV-2 antigen in the sample to form a complex, and the reaction complex moves forward along the nitrocellulose membrane under the action of chromatography, where it is captured by the anti-SARS-CoV-2 monoclonal antibody pre- coated by the detection zone (T) on the nitrocellulose membrane, and finally a red color reaction line is formed in the T zone. If the sample does not contain SARS-CoV- 2 antigen, are color reaction line cannot be formed in the T zone. Regardless of whether the sample to be tested contains SARS-CoV-2 antigen, a red reaction line will always form in the quality control area (C).

MATERIALS AND COMPONENTS

Materials provided with the test kits

COMPONENT	1 Test /box	25 Tests /box
Test Device	1 Test cassette (1Test/pouch x 1 pouch)	25 Test cassettes (1 Test/pouch x 25 pouches)
Buffer	1 single-use bottle, each with 500 µL extraction buffers	25 single-use bottles, each with 500 µL extraction buffers
Specimen sampling swabs	1 sterile, single use specimen sampling swab	25 sterile, single use specimen sampling swabs
Packing Insert	1 instruction for use	1 instruction for use

Note: The components in different batches of the kit cannot be mixed.

STORAGE AND STABILITY

1.Store at 2°C - 30°C in the sealed pouch up to the expiration date printed on the package, forbidden to store under 2°C and avoid using expired products.
2.The test card is used within 15 minutes after taking out from the foil envelope. Buffer solution are re-capped in time after use.
3.MFG date and EXP date: marked on the label. The product will be expired after 12 months.

TEST PROCEDURE

Before test, please read the instruction manual and apply 15 steps below carefully. Test procedure contains following steps: Sample collection, sample processing and test operation.

SAMPLE COLLECTION REQUIREMENTS

1.Insert the sterile swab into the place where the nasal secretions are the most at the front nose and rotate the swab close to the inner wall of the nasal cavity 3 times, remove the swab.
2.The samples should be used as soon as possible after collected (within half an hour).
3.Samples should not be inactivated.

SAMPLE PROCESSING

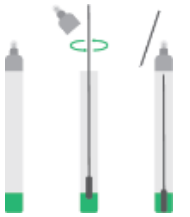
4.The tube contains 500 µl extraction buffer.
5. Open the cap of the extraction tube and mix with sample swab.
6.Rotate the sample against the inner wall of the tube approximately 10 times or squeeze the tube 10 times to elute the sample to ensure that the sample on the swab is fully eluted into the buffer.
7. Squeeze the swab head along the inner wall of the tube to keep the liquid in the tube as much as possible.
8. Break the upper part of the swab from the breaking point so that the lower part remains in the tube and close the cap cover the drip head to mix the liquid thoroughly.
9.Samples should be eluted and used immediately after collection; at the same time, the samples should not be inactivated, stored, or frozen and thawed.

***Note:** Recommend using a pipette to transfer the samples to reduce deviations.

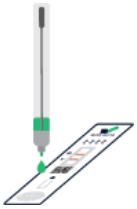
TEST OPERATION

10.Take the required reagents and test cards to equilibrate to room temperature.
11.Unpack the aluminum foil bag, place the reagent card horizontally on the table and mark it.
12.Add 100µL (3 drops) of the processed sample to the sample well, and timed. It is recommended to use a pipette to take buffer/samples to reduce deviations.
13.When the test starts to run, liquid moving up through the result window will be visible.
14.Wait 15 minutes and read the results. Do not read the results after 30 minutes.
15. Dispose all the materials used during the test to biological waste.

Sample collection



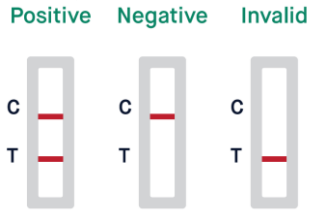
Sample processing



Test operation

INTERPRETATION OF TEST RESULTS

This product can only perform qualitative analysis on the detection object.
Positive Result: If both C and T lines are visible within 15 minutes, the test result is positive and valid.
Negative Result: If test area (T line) has no color and the control area displays a colored line, the result is negative and valid.
Invalid Result: The test result is invalid if a colored line does not form in the control region. The sample must be re-tested, using a new test cassette.



LIMITATIONS

1.The result of the product should not be taken as a confirmed diagnosis, for clinical reference only. Judgement should be made along with RT-PCR results, clinical symptoms, epidemiological information and further clinical data.
2.The contents of this kit are to be used for the qualitative detection of SARS- CoV-2 antigens from nasal swab.
3.This test detects both viable (live) and non-viable, SARS-CoV-2.
4.Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
5.The Sample buffer and test card must be equilibrated to room temperature (18℃~26℃) before used, otherwise the results may be incorrect.
6.A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
7.Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
8.Results interpreted less than 10 minutes may lead a false negative result or more than 15 minutes may lead a false positive result.
9.Positive test results do not rule out co-infections with other pathogens.
10.Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
11.Negative results should be treated as presumptive and confirmed with a molecular assay.
12.Clinical performance was evaluated with frozen samples, and performance may be different with fresh samples.
13.Users should test specimens as quickly as possible after specimen collection. If the sample volume is not enough, the chromatography cannot be carried out successfully.
14. Please pay attention to the prompt information of the instrument. It is recommended to use a pipette to add samples.

PERFORMANCE CHARACTERISTIC

1.Clinical Verification

Performance of the SARS-Cov-2 Rapid Antigen Test Kit was collected using 630 nasal swabs from symptomatic patients who appeared with symptoms within 7 days.

SARS-CoV-2 Rapid Antigen Test Kit	RT-PCR comparative test result		
	Positive (+)	Negative (-)	Total
Positive	613	5	618
Negative	17	520	537
Total	630	525	1155
Sensitivity : 613/630 97.3%, (95% CI: 95.7, 98.42)			
Specificity : 520/525 99.0%, (95% CI:97.79, 99.69)			
Accuracy: (520+613)/ 1155(613+5+17+520) x 100% = 98.09%			

Positive results few days after the onset of symptoms:	RT-PCR Positive (+)	SARS-CoV-2 Rapid Antigen Test Kit	PPA
1	16	16	100%
2	36	36	100%
3	60	60	100%
4	90	90	100%
5	120	120	100%
6	98	98	100%
7	180	164	91.1%
Asymptomatic Patients	30	29	96.6%

A limited number of patients with symptoms for more than seven days as well as asymptomatic patients were included in the clinical study (n = 630). The sample size was relatively significant, positive was 97.3% (613/630) and negative consent was 99% (520/525). The test is intended for professional use.

2.Limit of Detection

At a viral culture concentration of 100 $TCID_{50}$/mL and above, the positive level was greater than or equal to 95%. With a viral culture concentration of 50 $TCID_{50}$/mL and less, the positive level is no more than 95%, so the minimum detection limit of the SARS-CoV-2 Rapid Antigen test kit is 100 $TCID_{50}$/mL.

3.Cross-reactivity

Cross-reactivity of the Kit was evaluated. The results showed no cross reactivity with the following specimen.

No.	Exemplar Typ	Resultat
1	HCoV-HKU1	10^5 TCID50/mL
2	Staphylococcus aureus	10^6 CFU /mL
3	Streptococcus pyogenes	10^6 CFU /mL
4	Measles virus	10^5 TCID50/mL
5	Paramyxovirus parotitis	10^5 TCID50/mL
6	Adenovirus 3	10^5 TCID50/mL
7	Mycoplasma pneumoniae	10^6 CFU / mL
8	Parainfluenza virus 2	10^5 TCID50/mL
9	Human Metapneumovirus (hMPV)	10^5TCID50/mL
10	Human coronavirus OC43	10^5 TCID50/mL
11	Human coronavirus NL63	10^5 TCID50/mL
12	Human coronavirus 229E	10^5 TCID50/mL
13	MERS Coronavirus	10^5 TCID50/mL
14	Bordetella parapertussia	10^6 CFU / mL
15	Influenza B (Victoria strain)	10^5 TCID50/mL
16	Influenza B (Ystrain)	10^5 TCID50/mL
17	Influenza A (H1N1 2009)	10^5 TCID50/mL
18	Influenza A (H3N2)	10^5 TCID50/mL
19	Avian influenza virus (H7N9)	10^5 TCID50/mL
20	Avian influenza virus (H5N1)	10^5 TCID50/mL
21	Epstein-Barr virus	10^5 TCID50/mL
22	Enterovirus CA16	10^5 TCID50/mL
23	Human rhinovirus type 1	10^5 TCID50/mL
24	Human rhinovirus type 14	10^5 TCID50/mL
25	Respiratory syncytial virus A	10^5 $TCID_{50}$/mL
26	Respiratory syncytial virus B	10^5 TCID50/mL
27	Streptococcus pneumoniae	10^6 CFU / mL
28	Candida albicans	10^6 CFU / mL
29	Chlamydia pneumoniae	10^6 CFU / mL
30	Bordetella pertussis	10^6 CFU /mL
31	Pneumocystis jirovecii	10^6 CFU /mL
32	Mycobacterium tuberculosis	10^6 CFU / mL
33	Legionella pneumophila	10^6 CFU / mL
34	Human para-flu virus type 1	10^5 $TCID_{50}$/mL
35	Human para-flu virus type 2	10^5 $TCID_{50}$/mL
36	Human para-flu virus type 3	10^5 $TCID_{50}$/mL
37	Human para-flu virus type 4	10^5 $TCID_{50}$/mL
38	Haemophilus influenzae	10^5 TCID50/mL
40	SARS-coronavirus	10^4 TCID50/mL
41	Staphylococcus epidermidis	10^6 CFU /mL

4.Interference Substances

The test results do not be interfered with the substance at the following concentration:

No.	Kontaminanten	Resultat
1	Whole Blood	4%
2	Ibuprofen	1mg / mL
3	Tetracycline	3µg / mL
4	Chloramphenicol	3µg / mL
5	Erythromycin	3µg / mL
6	Tobramycin	5%
7	Throat spray (Menthol)	15%
8	Mupirocine	10mg/mL
9	Throat lozenge (Menthol)	1.5mg/mL
10	Tamiflu (Oseltamivir)	5mg/mL
11	Naphthoxoline hydrochloride nasal drops	15%
12	Mucin	0.50%
13	Fisherman's Friend	1.5mg/mL
14	Compound Benzocain Gel	1.5mg/mL
15	Cromoglycate	15%
16	Sinex (Phenylephrine Hydrochloride)	15%
17	Afrin (Oxymetazoline)	15%
18	Fluticasone propionate spray	15%
19	Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL
20	Naso GEL (NeilMed)	5% v/v
21	CVS Nasal Spray (Cromolyn)	15% v/v
22	Zicam	5% v/v
23	Homeopathic (Alkalol)	%10

5. Precision

1.10 replicates of negative and positive samples were tested by using the reference materials of enterprises. The negative agreement and the positive agreement were 100%.

2.Three different lots including positive and negative reference materials of enterprises were tested. The negative results and the positive results were 100%

6.Hook Effect

There was no Hook effect detected when the concentration of inactivated virus stock solution raised up to 4.0×10^5 $TCID_{50}$/mL.

PRECAUTIONS

1.For in vitro diagnostic use.

2.Do not use the kit contents beyond the expiration date printed on the outside of the box.

3.Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.

4.Use of Nitrile, Latex (or equivalent) gloves is recommended when handling patient samples.

5.Do not reuse the used Test Card, Reagent Tubes or Swabs.

6.The user should never open the foil pouch of the Test Card exposing it to the ambient environment until the Test Card is ready for immediate use.

7.Discard and do not use any damaged or dropped Test Card or material.

8.The Reagent Solution contains a salt solution (saline). If the solution contacts the skin or eye, flush with copious amounts of water.

9.Inadequate or inappropriate sample collection, storage, and transport may yield false test results.

10.Sample collection and handling procedures require specific training and guidance.

11.Use the appropriate Fixed Volume Pipette in accordance with test procedures.

12.To obtain accurate results, do not use visually bloody or overly viscous samples.

13.Do not write on the barcode of the Test Card.

14.As the detection reagent is a fluorescent compound, no visible results will form on the test strip.

15.To obtain accurate results, an opened and exposed Test Card should not be used inside a laminar flow hood or in a heavily ventilated area.

16.Testing should be performed in an area with adequate ventilation.

17.Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.

18.Wash hands thoroughly after handling.

KEY TO SYMBOLS USED

COMPONENT	Material Included
TEST CARD	Test Card
TUBE	Tube
SWAB	Swab
IFU	Instruction for Use
	Consult Instruction for Use
	Store at 2℃ ~ 30℃
	Expiration Date
	Manufacturer
	Keep Dry
LOT	Lot Number
DILUENT	Sample Buffer
	Date of Manufacture
	Do Not Reuse
REF	Catalogue Number
	Keep Away From Sunlight
Σ	Tests per Kit
IVD	In Vitro Diagnostic Medical Device
	Do not use if the package is damaged
	Biohazard
CE	This product fulfils the requirements of the Directive 98/79/EC on in vitro diagnostic medical device

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CE

Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

05.03.2021

Vergleichende Evaluierung der Sensitivität von SARS-CoV-2 Antigenschnelltests

Ziel

Vergleich verschiedener Antigenschnelltests mit identischem Probenmaterial

Material

Pools von naso- und oropharyngealen Abstrichen.

Trockene Tupfer wurden in PBS aufgenommen, feuchte Tupfer waren bereits in Transportmedium unterschiedlicher Zusammensetzung. Pools sind zufällige Mischungen aus bis zu 10 Proben vergleichbarer CT Werte, die 1:10 in negativen Proben in PBS verdünnt wurden. Die CT Werte eines Pools wurden mit verschiedenen PCR Assays bestimmt und die mutmassliche Anzahl an RNA-Kopien mit Hilfe des INSTAND Standards berechnet. Bei den verwendeten PCRs entspricht ein CT Wert von 25 etwa 10^6 RNA Kopien / mL. Es wurden jeweils 18 Proben mit CT<25, 23 Proben mit CT zwischen 25 und 30 und 9 Proben mit CT>30 analysiert. Vermehrung des Virus in Zellkultur wurde als mögliches Korrelat für Infektiosität als weiteres Merkmal der Proben bestimmt.

Durchführung

Die Pools wurden aliquotiert, eingefroren, versendet, und zur Evaluierung der Tests aufgetaut. Für jeden Test wurden 50µL des Pools mit den vom Test bereitgestellten Komponenten z.B. Tupfer, analysiert. An der vergleichenden Evaluierung beteiligte Labors sind u. a. Robert Koch-Institut, Paul-Ehrlich-Institut, Konsiliarlabor für Coronaviren (Charité), Institut für Mikrobiologie der Bundeswehr.

Zusammenfassung

Diese vergleichende Evaluierung einer großen Anzahl von SARS-CoV-2 Antigenschnelltests (point of care tests; POCT) verschiedenen Designs und verschiedener Hersteller mit demselben Probenset ermöglicht einen Überblick über den derzeitigen Stand der Technik hinsichtlich ihrer Sensitivität. Die Ergebnisse lassen keine Rückschlüsse auf die Spezifität der Tests zu.

Diejenigen POCT, die bislang in die vergleichende Evaluierung eingegangen sind und hier als dem derzeitigen Stand der Technik entsprechend bewertet wurden, sind in der folgenden Tabelle aufgeführt. Weitere Tests, die als nicht dem Stand der Technik entsprechend bewertet wurden, wurden aus der Liste des BfArM entfernt. Die Untersuchungen werden kontinuierlich fortgeführt, die Tabelle entsprechend ergänzt.

Es sei ausdrücklich darauf hingewiesen, dass diese vergleichende Evaluierung nur eine Stichprobe der beim BfArM gelisteten und somit erstattungsfähigen SARS-CoV-2 Antigenschnelltests berücksichtigen kann, und manche Tests bislang (noch) nicht berücksichtigt werden konnten, trotz entsprechendem Interesse seitens Herstellern / Vertreibern.

Kontakt:

E-Mail: sarscov2ivd@pei.de

Stand 05.03.2021

Übersicht SARS-CoV-2 Antigenschnelltests, die als „dem derzeitigen Stand der Technik entsprechend“ bewertet wurden

Testname	Hersteller (Vertrieb)
Panbio™COVID-19 Ag Rapid Test Device (NASOPHARYNGEAL)	Abbott Rapid Diagnostics Jena GmbH
RIDA®QUICK SARS-CoV-2 Antigen	R-Biopharm AG
SARS-CoV-2 Rapid Antigen Test	SD BIOSENSOR (Roche Diagnostics GmbH)
NADAL® COVID-19 Ag Schnelltest	nal von minden gmbh
STANDARD™ F COVID-19 Ag FIA	SD BIOSENSOR
STANDARD™ Q COVID-19 Ag Test	SD BIOSENSOR
BIOSYNEX COVID-19 Ag BSS	BIOSYNEX SWISS SA
MEDsan® SARS-CoV-2 Antigen Rapid Test	MEDsan GmbH
TestNOW® - COVID-19 Antigen	Affimedix
NowCheck® COVID-19 Ag Test	BIONOTE
Coronavirus Ag Rapid Test Cassette (Swab)	Zhejiang Orient Gene Biotech Co.,Ltd
Sofia SARS Antigen FIA	Quidel Corporation
COVID-19 Ag Test Kit	Guangdong Wesail Biotech Co., Ltd.
CLINITEST® Rapid COVID-19 Antigen Test	Siemens Healthineers
ESPLINE® SARS-CoV-2	Fujirebio Inc. (Mast Diagnostica GmbH)
BD Veritor™ System for Rapid Detection of SARS-CoV-2	Becton Dickinson
GenBody COVID-19 Ag	IVC Pragen Healthcare
LumiraDx SARS-CoV-2 Ag Test	LumiraDX
Exdia COVID-19-Ag-Test	Precision Biosensor Inc. (Axon Lab AG)
SARS-CoV-2 Ag Rapid Test (FIA)	Wantai (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.)
SARS-CoV-2 Antigen Schnelltest	Xiamen Boson Biotech Co., Ltd
COVID-19 Antigen Schnelltest (Colloidal Gold)	Joinstar Biomedical Technology Co., Ltd (CIV care impuls Vertrieb)
mö-screen Corona Antigen Test	Mölab GmbH
Rapid SARS-CoV-2 Antigen Test Card	MP Biomedicals Germany GmbH
Lyher Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)	Hangzhou Laihe Biotech Co., Ltd. (Lissner Qi GmbH)
AMP Rapid Test SARS-CoV-2 Ag	Ameda Labordiagnostik GmbH
Clungene COVID-19 Antigen Rapid Test	Hangzhou Clongene Biotech Co., Ltd.
DIA-COVID® COVID-19 Ag Rapid Test Kit	GenSure Biotech Inc.
SARS-CoV-2 Antigen Rapid Test Kit	Beijing Lepu Medical Technology Co., Ltd
Hightop SARS-CoV-2 (Covid-19) Antigen Rapid Test	Qingdao Hightop Biotech Co., Ltd.
Rapid Covid-19 Antigen Test (Colloidal Gold)	Anbio (Xiamen) Biotechnology Co., Ltd
Safecare COVID-19 Ag Rapid Test Kit (Swab)	Safecare Biotech Hangzhou Co., Ltd.
QuickProfile Covid-19 Antigen Test Card	LumiQuick Diagnostics, Inc.

Testname	Hersteller (Vertrieb)
Covid 19 Antigen Schnelltest	BioRepair GmbH
Green Spring SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	Shenzhen Lvshiyuan Biotechnology Co., Ltd.
CAT Antigen Covid Rapid Test	Oncosem Onkolojik Sistemler San. Ve Tic. A.S.
ScheBo SARS-CoV-2 Quick Antigen	ScheBo Biotech AG
Nova Test SARS-CoV-2 Antigen Rapid Test Kit	Atlas Link Technology Co.,Ltd.
Toda Coronadiag Ag	Toda Pharma
Humasis COVID-19 Ag Test	Humasis Co., Ltd.
Novel Coronavirus 2019-nCoV Antigen Test (Colloidal gold)	Beijing Hotgen Biotech Co., Ltd.
COVID-19 Antigen Rapid Test Kit (Colloidal Gold)	AmonMed (Xiamen) Biotechnology Co., Ltd.
Canea COVID-19 Antigen Schnelltest	Core Technology Co., Ltd.
fluorecare COVID-19 SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay)	Shenzhen Microprofit Biotech Co., Ltd
Testsealabs® Rapid Test Kit COVID-19 Antigen Test Cassette	Hangzhou Testsea Biotechnology Co., Ltd
Lysun COVID-19 Antigen Rapid Test Device (Colloidal Gold)	Hangzhou Lysun Biotechnology Co., Ltd.
Wizbiotech SARS-CoV-2 Antigen Rapid Test	Xiamen WIZ Biotech Co., Ltd.
SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromatographic Assay)	PerGrande BioTech Development Co., Ltd.
salocor SARS-CoV-2 Antigen Rapid Test Cassette (Nasopharyngeal swab)	Salofa OY
Genrui SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	Genrui Biotech Inc.
Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method)	Guangzhou Wondfo Biotech Co. Ltd
Aesku Rapid SARS-CoV-2 Rapid Test	Aesku Diagnostics GmbH
Rapid Response COVID-19 Rapid Test Device	BTNX, Inc. (Biotrend Chemikalien Gmbh)
Dia Sure Covid-19 Antigen Rapid Test Device (Nasopharyngeal/Oropharyngeal Swab)	Azure Biotech Inc.
Labnovation SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography)	Labnovation Technologies, Inc.
V-Chek SARS-CoV-2 Rapid Ag Test Kit (Colloidal Gold)	SGA Mühendislik DAN. EG. Icve DIS.Ltd.STI
SGTi-flex COVID-19 Ag	Sugentech, Inc.
softec SARS COV-2 (Covid-19) Antigen Test Kit	Zet Medikal Tekstil Dis Ticaret Ltd. STI.
Genedia W Covid-19 Ag	Green Cross Medical Science Corp. (Weko Pharma GmbH)
COVID-19 (SARS CoV-2) Antigen Test Kit (Colloidal Gold)	Anhui Deepblue Medical Technology Co. , Ltd.
FREND™ COVID-19 Ag	NanoEntek Inc
RapidFor SARS-CoV-2 Rapid Antigen Test Colloidal Gold	Vitrosens Biyoteknoloji Ltd. Sti
COVID-19 (SARS-CoV-2) Antigen Test Kit	Wuhan EasyDiagnosis Diomedicine Co., Ltd
PCL COVID19 Ag Gold Saliva	PCL, Inc.
reOpenTest COVID-19 Antigen Rapid Test (Colloidal Gold)	Zhejiang Anji Saianfu Biotech Co.,Ltd.
IMMUNOBIO SARS-CoV-2 Antigen-Schnelltest (COVID-19 Ag)	Hangzhou Immuno Biotech Co.,Ltd.
Zhenrui COVID-19 (SARS-COV-2) Antigen Test Kits	Shenzhen Zhenrui Biotech co.Ltd.

SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold)	Shenzhen Watmind Medical Co.,Ltd.
2019-nCoV Antigen Test Kit(colloidal gold method)	Guangdong Hecin Scientific,Inc.
Asan Easy Test COVID-19 Ag	ASAN PHARM.CO.,LTD.

VITROSENS
BIOTECHNOLOGY

CE

EU Konformitätserklärung

Date: 18.01.2021

Dieses Konformitätserklärung wird unter der alleinigen Verantwortung des Herstellers ausgestellt.

Hersteller:	Vitrosens Biotechnology Co., Ltd.
Addresse:	Şerifali Mah. Şehit Sok. No:17/1 Ümraniye Istanbul
Produktname:	SARS-CoV-2 Rapid Antigen Test (VSCD02)
	SARS-CoV-2 Saliva Antigen Test (VSCD05)
	SARS-CoV-2 IgG/IgM Test (VSCD01)

Harmonisierte Standards: ISO 9001:2015 & ISO 13485

gemäß der In-vitro-Diagnostika-Richtlinie 98/79/EG für die nachfolgend beschriebenen Produkte erklären wir, dass deren Anforderungen erfüllt sind und übernehmen die Verantwortung.

Der beschriebene Gegenstand der Erklärung/das Produkt entspricht den einschlägigen Harmonisierungsrechtsvorschriften der Union.

Internet: shop.hatex24.de - Schnelltest

Ort der Ausgabe: Istanbul
Datum der Ausgabe: 18.01.2021

VITROSENS
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Datum: 18.01.2021
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VITROSENS
BIOTECHNOLOGY

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EU DECLARATION OF CONFORMITY

Manufacturer: Vitrosens Biotechnology Co., Ltd.
Address: Şerifali Mah. Şehit Sok. No:17/1 Ümraniye/ Istanbul Turkey

In accordance with the In vitro Diagnostic Medical Device Directive Annex I MDD 98/79/EC for the products described below, we declare that their requirements have been done and we take the responsibility.

Products:

SARS-CoV-2 IgG/IgM Test Kit
SARS-CoV-2 Rapid Antigen Test Kit
SARS-CoV-2 Saliva Antigen Test Kit
SARS-CoV-2 & Flu A/B Antigen Combo Test Kit

Model:

RapidFor™

Harmonized Standards: EN ISO 13485:2016
EN ISO 9001:2015 (QMS)

This declaration of conformity is issued under the exclusive responsibility of the manufacturer.

Place of issue: Istanbul
Date of issue: November 20, 2020

Kağan Etka Yörük
General Manager

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RapidFor™

Diagnostic Kit for SARS-CoV-2 Antigen Test Home Testing Evaluation Report

Home Testing Trial Start Date: 08.11.2020

Home Testing Trial Finish Date: 20.01.2021

Statistical Company: Vitrosens Biotechnology Co. Ltd.

Responsible: Furkan Tunç

Report Date: 21.01.2020

VITROSENS BIOTECHNOLOGY

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ABSTRACT

For the personal use detection of the content of SARS-CoV-2 antigen in nasal swab samples RapidFor™ SARS-CoV-2 Rapid Antigen Test Kit (mention as a "Test Kit") that manufacturing by Vitrosens Biotechnology Co. Ltd. was used. A total of 362 nasal swab samples was selected as the study objects, including 162 positive samples and 200 negative samples are use for the quantity control. Bio-Speedy SARS-CoV-2 (2019-nCoV) qPCR Detection Kit (mention as a "Reference Kit") manufacturing by Biokesen was used for reference kit in the study. The test group divided into two groups based on the reference kit result as 2019-nCoV antigen positive and 2019-nCoV antigen negative. Also, samples were tested with the Test Kit, then compared to the Reference Kit and statistically analyzed. All of the results like the negative coincidence rate, positive coincidence rate and total coincidence rate between the Test Kit and the Reference Kit were greater than 90%. It indicates that the Test Kit is suitable for personal use diagnosis.

Home-testing of SARS-CoV-2 virus from nasal samples provides remarkable benefits for people who have symptoms and suspected with COVID-19 disease. Self-testing prevents the spreading of virus by easy and fast testing in addition to self-quarantine of SARS-CoV-2 positive people. Test Kit enables easy and fast testing. The application procedure of the test kit is simple, and the subject can interpret the result within 15 minutes with high confidence. The sample matrix for the test is nasal matrix. For the home-testing, we asked people to take their own nasal samples. As positive control, people were selected with positive nucleic acid test result. After their nucleic acid test result became positive, RapidFor™ SARS-CoV-2 Rapid Test kit was delivered, and they tested themselves. 162 positive people were asked to test themselves from nasal samples.

INTRODUCTION

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

PURPOSE

The clinical performance of the Test Kit will be systematically studied in order to validate its suitability and accuracy in home-testing.

RapidFor™ SARS-CoV-2 Antigen Test Kit were tested with nasal swab samples from the people who diagnosed with COVID-19 with positive PCR test results as 'case' group. Samples from the patients with negative PCR test results were used as 'control group'. The test results were compared with nucleic acid test results. Application of the test procedure was performed by the patient themselves only. Any of the professional do not help or direct the patients about how the sampling should be done. Results of the test results were also reported to test manufacturer Vitrosens Biotechnology Co., Ltd. by the patients themselves.

TEST PROCEDURE

For Clinical Data

The samples were collecting with sterile swab by inserting them the place where the nasal and nasopharyngeal secretions are the most at the front nose and then rotated to the inner wall of the nasal cavity 3 times and then removed. The samples should use as soon as possible after

collection and it should not be inactivated. Then the sample processing step was start. The sample was mix with 500µl extraction buffers. The collected samples should not be stored or frozen and they must be eluted and used immediately after collection. The required reagents and test cards were equilibrated to room temperature before use. Then 100µl of the processed sample added to the sample well and timed. For taking the buffer/sample a pipette is used to reduce deviations. The liquid moving up through the result window when the test starts to run. The results were not read after 30 minutes.

After all clinical samples were tested, results were statistically analyzed to calculate the negative coincidence rate, positive coincidence rate and total coincidence rate.

For Home-Testing

The patients were selected with positive nucleic acid test results. For the nucleic acid tests Bio-Speedy SARS-CoV-2 (2019-nCoV) qPCR Detection Kit by Bioeksen were used. The nucleic acid tests were performed at Private Safa Hospital.

After the samples were taken from the patients and enter the home-quarantine, Test Kits were delivered to the patients after their positive nucleic acid test results were validated.

Patients were asked to test themselves from their nasal sample.

The percentage of successful testing and interpretation were recorded according to data sent from the patients. Patients also filled a survey about the procedure.

Consistency of the Test Kit results with nucleic acid results were compared for the patients and control people who successfully complete the test.

Home-Test Application

The test results from the patients and control group are collected with photo and their comment about how they interpret the results.

The consistency statistics on the test results are analyze the Company's diagnostic sensitivity and specificity according to the Table 1 and listed below.

Table 1: *Compression of reference and test kit results.*

	Test result of reference kit		**Total**
Test Kit	**Positive**	**Negative**	
Positive	True Positive (A)	False Positive (B)	A + B
Negative	False Negative (C)	True Positive (D)	C + D
Total	A + C	B + D	A + B + C + D

The diagnostic sensitivity and specificity formulas made by using Table 4 are given below:

Diagnostic sensitivity = A/(A+C) x 100%

Diagnostic specificity = D/(B+D) x 100%

Total coincidence rate = (A+D)/(A+B+C+D) x 100%

The home-testing and clinical data consistency are calculated by using Table 1.

After the test was complete, a survey is made with the participant about their thoughts, comments, and suggestion for the test. The survey asked participant that the test was easy to apply, comfortable and it can be done by themselves without any help from others. It also includes question about instruction manual that is easy for them to follow up the procedure and interpret the results. The survey asked participant that the results are appear in the time that expected, or it take longer time to appear. The recommendation of the tests was also asked to the participants.

Product Information

Product name for home-testing is RapidFor SARS-CoV-2 Rapid Antigen Test Kit and the specification is 1 test/kit. The Test Kit is manufactured by Vitrosens Biotechnology Co. Ltd. The lot number of is VSCD02003. Test Kit should store at 2°C - 30°C in the sealed pouch up to the expiration date printed on the package, forbidden to store under 2°C and avoid using expired products. The test card is used within 15 minutes after taking out from the foil envelope. Buffer solution are re-capped in time after use. MFG date and EXP date are marked on the label. The product will be expired after 12 months.

The Reference Kit is Bio-Speedy SARS-CoV-2 (2019-nCoV) qPCR Detection Kit manufactured by Bioeksen, its shelf-life is 18 months, refer to the expiration date on the box. Each reagent stored at storage temperature -20°C.

Experiment Design

Sample selection

In order to examine the sensitivity and specificity of the product from a home testing perspective, this home testing trial selected (1) patients diagnosed with pneumonia with positive nucleic acid test results (suspected of SARS-CoV-2 infection) as the "case group"; (2) patients with other diseases or normal persons with negative nucleic acid test results as the "control group". The sample matrix was selected as nasal swap samples.

In this trial, the results of nucleic acid detection of SARS-CoV-2 were selected as a control. The blind method and the comparative test design were used. The tested reagent was used to blindly test the test samples. Test kits were sent to people whose nucleic acid test result became positive. After the patients submit the data to the person in charge of statistics, the person in charge made statistics according to the statistical method in the home testing trial plan and

evaluated the coincidence rate and consistency of the tested reagent and the nucleic acid detection result based on the statistical results.

Sample Size

Patients are diagnosed according to nucleic acid test result with Bio-Speedy SARS-CoV-2 (2019-nCoV) qPCR Detection Kit and rapid antigen tests were investigated with RapidFor™ SARS-CoV-2 Rapid Antigen Test Kit. For nasal swab samples 162 patients and 200 negative people were participated to the trial. The samples for nucleic acid test results was taken one day before the RapidForTM SARS-CoV-2 Rapid Antigen Test kit was performed.

Clinical Evaluation Criteria

The result of the Test Kit and Reference Kit were compared to calculate coincidence rate. The coincidence rates are given in the following parts.

Positive coincidence rate: The ratio of positive results of the Test Kit and Reference Kit should be greater than 90%

Negative coincidence rate: The ratio of negative results of the Test Kit and Reference Kit should be greater than 90%.

Total coincidence rate: The ratio of the same results obtain by Test Kit and Reference Kit should be greater than 90%.

Table 2: *Control and Test System positive and negative results table.*

		Control System		Total
		Positive	**Negative**	
Test System	**Positive**	a	b	a + b
	Negative	c	d	c + d
Total		a + c	b + d	a + b + c + d

From Table 2, the following equations are calculated.

Positive coincidence rate = a/(a+c)*100%

Negative coincidence rate = d//b+d)*100%

Total coincidence rate = (a+d)/(a+b+c+d)*100%

Two methods or products are considered to be equivalent when the positive coincidence rate and negative coincidence are equal; the clinical protocol must be reversed when the difference between the positive coincidence rate and negative coincidence rate is too large.

RESULTS AND ANALYSIS

Clinical Study Results

After all the samples were tested, the analyses are made to calculate the negative coincidence rate, positive coincidence rate and total coincidence rate. For clinical study, 630 nasal swabs collected from symptomatic patients who appeared with symptoms within 7 days. The results were compared with the Reference Kit to calculate specificity, sensitivity and accuracy rates.

Table 3: *Results of SARS-CoV-2 Rapid Antigen Test Kit and RT-PCR comparative test result.*

SARS-CoV-2 Rapid Antigen Test Kit	RT-PCR comparative test result		
	Positive (+)	Negative (-)	Total
Positive	613	5	618
Negative	17	520	537
Total	630	525	1155
Sensitivity : 613/630 97.3%, (95% CI: 95.7, 98.42)			
Specificity : 520/525 99.0%, (95% CI:97.79, 99.69)			
Accuracy: (520+613)/ 1155(613+5+17+520) x 100% = 98.09%			

Positive results few days after the onset of symptoms:	RT-PCR Positive (+)	SARS-CoV-2 Rapid Antigen Test Kit (Colloidal Gold)	PPA
1	16	16	100%
2	36	36	100%
3	60	60	100%
4	90	90	100%
5	120	120	100%
6	98	98	100%
7	180	164	91.1%
Asymptomatic Patients	30	29	96.6%

From Table 3, the sensitivity, specificity and accuracy of the RapidFor™ SARS-CoV-2 Rapid Antigen Test Kit manufactured by Vitrosens Biotechnology Co. Ltd. are given in the above table. It can be seen that the sensitivity of the Test Kit was 97.3% (613/630), the specificity was 99.0% (520/525) and accuracy was 98.09%.

Home Testing Study

362 nasal swabs were selected and tested for home-testing.

The percentage of people who successfully complete the test and consistency with the data they sent, and comment are shown in Table 4.

Table 4: *Percentage of successfully completion and interpretation of results and consistency with nucleic acid results.*

	Nucleic Acid Test Positive Patient	Nucleic Acid Test Negative Patient
Complete the test successfully	98.1% (162/165)	97.5% (196/200)
Interpret the results successfully	97.6% (161/165)	99.0% (198/200)
Consistency with nucleic acid test results	94.5% (156/165)	99.0% (198/200)

Among 162 positive nasal samples, 156 of them were detected as positive and among 200 negative people, 198 of them were detected as negative. The results are given in Table 5.

Table 5: *Results of Reference Kit and Test Kit*

	Positive result of Reference Kit	**Negative result of Reference Kit**	**Total**
Positive result of Test Kit	156	2	158
Negative result of Test Kit	6	198	204
Total	162	200	362

Table 6: *Formulas and results of diagnostic sensitivity, specificity and total coincidence rate.*

Item	**Formula**	**Results**	**95% CI**
Diagnostic sensitivity	A/(A+C) x 100%	96.3%	92.11% to 98.63%
Diagnostic specificity	D/(B+D) x 100%	99.0%	96.43% to 99.88%
Total coincidence rate	(A+D)/(A+B+C+D) x 100%	97.79%	95.69% to 99.04%

From the Table 5 that can be seen that 162 nasal samples in positive group tested with the Test Kit, 156 samples are positive, and 6 samples are negative. Among the 200 samples in the negative group tested with the Test Kit, 198 samples are negative, and 2 samples are positive. As a result of Table 6, the negative coincidence rate, positive coincidence rate and total coincidence rate are larger than 90%. The results indicate that coincidence rates are in good consistency with those of the Reference Kit.

After the study is complete a survey is made with the participant of the study. The asked questions and the answers percentages of the participant are given in Table 7.

***Table** 7: Survey about the home-testing*

	1 (Strong Disagree)	**2 (Disagree)**	**3 (Notr)**	**4 (Agree)**	**5 (Strong Agree)**
Is it easy to take the samples for the test?	-	-	-	1.81%	98,2%
Is the sampling for the test comfortable?	-	-	0.6%	3.6%	95.8%
Is the instructions enough at the IFU to complete the test?	-	-	-	1.2%	98.8%
Is the test results appear as fast as you expect?	-	-	-	0.6%	99.4%
Do you need any assistance during test?	-	3.6%	1.2%	1.2%	95.8%
Is it easy to interpret the results?	-	-		3.0%	97.0%
Do you suggest this test kit to your friend?	-	-	0.6%	0.6%	97%

As a result, the Test Kit can be use easy in the home testing by person who suspected or had infection without any help from others. With the personal use Test Kit the separation of the infection is prevented and the patients' can be isolated themselves from society.

DISCUSSION AND CONCLUSION

DISCUSSION

In this home testing trial with fresh samples, 362 nasal swap samples from RT-PCR positive or negative patients were tested. Among 362 nasal swab 162 of them was "case group" samples and 200 samples of "control group" were determined by nucleic acid detection one day before the patients apply RapidFor™ SARS-CoV-2 Ag Test to themselves. Among patients, 156 positive samples and among 200 control group 198 negative samples were detected by the assessment reagent. The positive coincidence rate of the assessment reagent was 96.3%, and the negative coincidence rate was 99.0% for nasal VSCD02 reference code test kit. At the clinical trials, sensitivity of the test is 97.3% and specificity is 99.0%. The sensitivity of the test results is similar when the people test themselves and the professionals perform the test. It shows that test can be performed at home with high confidence and easy to use.

Test Kit is easy to take samples for the home testing and sampling for the test is comfortable according to participant. The test results appear faster as expected and the interpretation the results were easy. The participant reported that they do not need any assistant during test and the instructions on the IFU is enough to complete the test. Survey also showed that participants are suggest Test Kit to their friend. As a result of the study, the Test Kit is suitable for personal usages.

CONCLUSION

In summary, the detection results of Diagnostic Kit for RapidFor™ SARS-CoV-2 Rapid Antigen Kit (VSCD02) manufactured by Vitrosens Biotechnology Co., Ltd. and the nucleic acid detection results are in good agreement, and the SARS-CoV-2 antigen detection function can meet the needs of home-testing applications.

RapidFor™

Diagnostic Kit for SARS-CoV-2 Rapid Antigen Test Kit

Clinical Evaluation Report

Clinical Trial Start Date: 10.09.2020

Clinical Trial Finish Date: 20.01.2021

Institution for Positive Samples: Bakırköy Dr. Sadi Konuk Research And Training Hospital

Statistical Company: Vitrosens Biotechnology Co. Ltd.

Responsible: Dr. Alim Tunç

Dr. Alim TUNÇ
T.C. Sağlık Bakanlığı
Aile Hekimi Dip No. 736

Report Date: 21.01.21

RapidFor™ Diagnostic Kit for SARS-CoV-2 Antigen Clinical Report

1. Clinical Evaluation Purpose

Testing the nasal (NS) swab samples from patients with pneumonia and positive nucleic acid test results (suspected of SARS-CoV-2 infection). Patients with other diseases or negative persons with negative nucleic acid test results by using Diagnostic Kit: RapidFor™ Coronavirus (SARS-CoV-2) Rapid Antigen Detection Kit, developed by Vitrosens Biotechnology. The test results compared with the nucleic acid test result blindly. The trial purpose is to verify the consistency of the test results of the tested reagents with the nucleic acid test results.

2. Tested Reagents

2.1 Product name: RapidFor™ Coronavirus (SARS-CoV-2) Rapid Antigen Kit
Catalog Number: VSCD02

2.2 Comparison reagent: Bio-Speedy SARS-CoV-2 (2019-nCoV) qPCR Detection Kit by Bioeksen

3. Experiment Design

3.1Sample selection
In order to examine the sensitivity and specificity of the product from a clinical perspective, this clinical trial selected (1) patients diagnosed with pneumonia with positive nucleic acid test results (suspected of SARS-CoV-2 infection) as the "case group"; (2)patients with other diseases or normal persons with negative nucleic acid test results as the "control group". The sample matrix was selected as nasal (NS) swab.

In this trial, the results of nucleic acid detection of SARS-CoV-2 were selected as a control. The blind method and the comparative test design were used. The tested reagent was used to blindly test the test samples, and the complete and real clinical trial data were recorded. After submitting the data to the person in charge of statistics, the person in charge made statistics according to the statistical method in the clinical trial plan and evaluated the coincidence rate and consistency of the tested reagent and the nucleic acid detection result based on the statistical results.

3.2 Sample size

630 PCR positive nasal specimens and 525 PCR negative nasal specimens according to Bio-Speedy SARS-CoV-2 (2019-nCoV) qPCR Detection Kit by Bioeksen were investigated with RapidFor™ Coronavirus (SARS-CoV-2) Rapid Antigen Kit.

3.3 Statistical interpretation

Please refer to 2x2 Contingency Table in EP12-A2 （User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline— Second Edition， 2008） for statistical interpretation.

	qPCR			
RapidFor™ Coronavirus (SARS-CoV-2) Rapid Antigen Kit(VSCD02)		Positive	Negative	Total
	Positive	A True positive	B False positive	A+B
	Negative	C False negative	D True negative	C+D
	Total	A+C	B+D	A+B+C+D

Please refer to computing method in EP12-A2 （User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline— Second Edition， 2008）to calculate negative coincidence rate, positive coincidence rate, and 95% confidence interval for negative coincidence rate and 95% confidence interval for positive coincidence rate.

Statistical interpretation

Clinical Evaluation

With 630 positive samples, 613 samples were detected as positive; With 525 negative samples, 520 samples were detected as negative.

- Sensitivity: 613/630 97.3%, (95% CI: 95.71, 98.42).
- Specificity: 520/525 99.0%, (95% CI:97.79, 99.69).
- Accuracy: (520+613)/ 1155(613+5+17+520) x 100% = 98.09% (95% CI:97.13, 98.80).

	RT-PCR Positive	RT-PCR Negative	Total
Detected Positive	613	5	618
Detected Negative	17	520	537
Total	630	525	1155

Table 1: **Distribution of PCR positive samples according to symptom onset in symptomatic patients and asymptomatic patients.**

Positive results few days after the onset of symptoms:	RT-PCR Positive (+)	SARS-CoV-2 Rapid Antigen Test Kit	PPA
1	16	16	100%
2	36	36	100%
3	60	60	100%
4	90	90	100%
5	120	120	100%
6	98	98	100%
7	180	164	91.1%
Asymptomatic Patients	30	29	96.6%

5. Discussion and Conclusion

5.1 Discussion

In this clinical trial with fresh samples, 1155 samples were taken from RT-PCR positive or negative patients. Among them, 630 cases of "case group" samples and 525 samples of "control group" were determined by nucleic acid detection. example. Among them, 613 positive samples and 520 negative samples were detected by the assessment reagent. The positive coincidence rate of the assessment reagent was 97.3%, and the negative coincidence rate was 99.0%.

5.2 Conclusion

In summary, the detection results of Diagnostic Kit for RapidFor™ Coronavirus (SARS-CoV-2) Rapid Antigen Kit (VSCD02) developed by Vitrosens Biotechnology and the nucleic acid detection results are in good agreement, and the SARS-CoV-2 antigen detection function can meet the needs of clinical application.

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Date of initial registration	**17 December 2020**
Date of this Certificate	**17 December 2020**
Surveillance audit on or before	**16 December 2021**
Recertification Due / Certificate expiry	**16 December 2023**

This Certificate is remains valid subject to satisfactory surveillance audits.

Emmanuel ADEMOSU
Director

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