FISA TEHNICA PRODUS

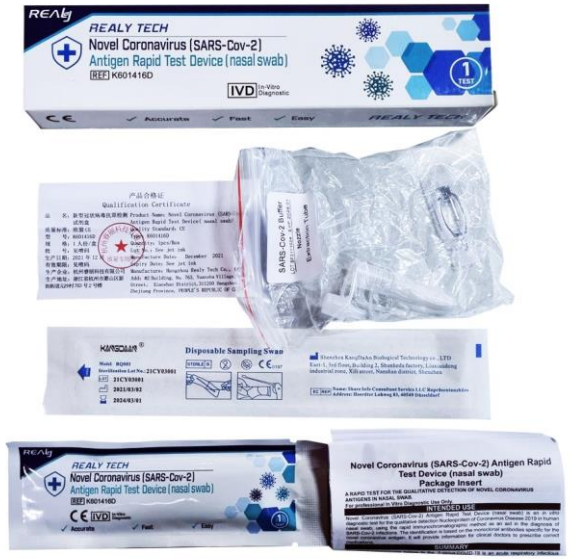
Denumire Produs: Test Rapid Antigen SARS-CoV-2 Realy Tech Lateral Nazal 1 Buc

Producator: Hangzhou Realy Tech Co., Ltd.

1. DESCRIERE

Test Rapid Antigen COVID Lateral Nazal (1 buc)

Dispozitiv de testare rapida cu antigen pentru noul coronavirus (SARS-CoV-2) (tampon nazal) este un test de diagnosticare *in vitro* pentru detectarea calitativa a nucleoproteinei bolii Coronavirus in tamponul nazal uman, utilizand metoda imunocromatografica rapida ca ajutor in diagnosticarea infectiilor cu SARS-CoV-2. Identificarea se bazeaza pe anticoprii monoclonali specifici pentru antigenul noului coronavirus.
Testul este destinat uzului profesional (cadre medicale).



Continut pachet:
•1 x Dispozitiv de testare
•1 x Tampon sterilizat
•1 x eprubeta de extractie
•1 x Duza
•1 x Solutie tampon de extractie a probei
•1 x Prospect
•1 x Suport pentru eprubeta

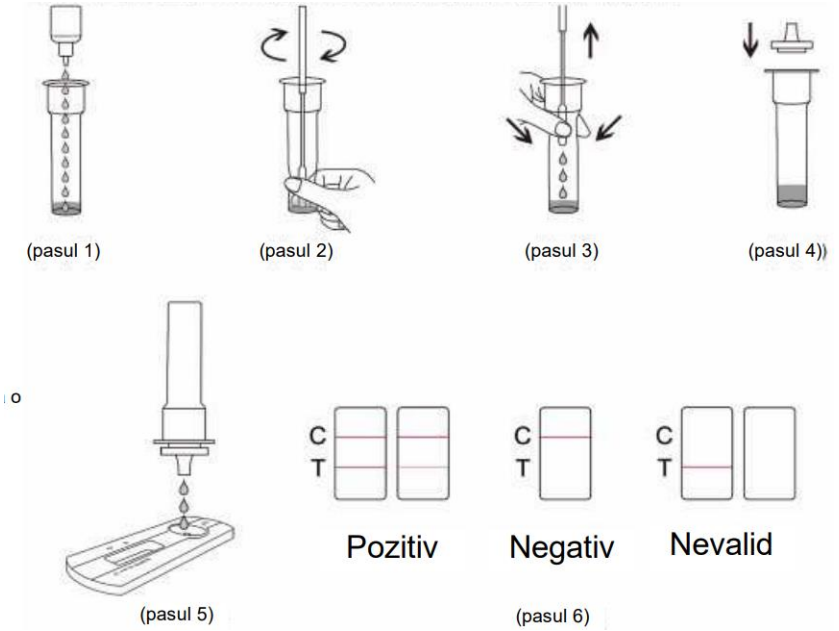
Performante testare:
•Sensibilitate=95,38%
•Specificitate= 99.9%
•Precizie=98,56%.

Alte avantaje:
•Tipuri de testare: tampon nazofaringian
•Test rapid. Rezultatul poate fi citit în decurs de 10-20 min
•Poate indica infectia in faza acuta a bolii
•Poate indica infectia și la persoane care nu prezinta simptome, daca infectia este activa

Instructiuni de utilizare:

Lăsați testul, specimenul, tamponul de extracție să se echilibreze la temperatura camerei (15-30°C) înainte de testare.

- Deșurubați întregul capac al eprubetei de recoltare a specimenului, adăugați 10 picături de soluție tampon de extracție în eprubeta de extracție.
- Amplasați specimenul de tampon sterilizat în soluția tampon de extracție a probei. Rotiți tamponul timp de aproximativ 10 secunde în timp ce apăsați capacul pe interiorul eprubetei pentru a elibera antigenul în tampon.
- Îndepărtați tamponul sterilizat în timp ce strângeți capul tamponului sterilizat pe interiorul tamponului în timp ce îl îndepărtați pentru a elimina cât mai mult lichid posibil din tampon. Aruncați tamponul sterilizat în conformitate cu protocolul privind eliminarea deșeurilor cu risc biologic.
- Înșurubați și strângeți capacul pe eprubeta de recoltare a specimenului, apoi agitați puternic eprubeta de recoltare a specimenului pentru a amesteca specimenul și soluția tampon de extracție a probei. Consultați ilustrația 4.
- Aplicați 3 picături de soluție (aprox. 80 ul) în godeul pentru probă și apoi porniți temporizatorul.



Precautii:

- Numai pentru utilizare in cadrul diagnosticarii in vitro
- Nu utilizati dupa data de expirare
- Asigurati-va ca folia protectoare care contine dispozitivul de testare nu este deteriorata inainte de a o deschide pentru utilizare
- Efectuati testul la temperatura camerei intre 15 si 30°C
- Purtati manusi atunci cand prelevati probe, evitati atingerea membranei de reactiv si a ferestrei de proba
- Toate probele si accesoriile utilizate trebuie tratate ca infectioase si eliminate in conformitate cu reglementarile locale
- Evitati utilizarea cu probe de sange

Declaration of Conformity

in accordance with Directive 98/79/EC

Manufacturer:

Name: *Hangzhou Realy Tech Co., Ltd.*
Address: #2 Building, No. 763, Yuansha Village, Xinjie Street, Xiaoshan District, 311200 Hangzhou City, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

Product/s	*Catalogue number*
Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab)	K601416D

Category: Other Devices (All devices except Annex II and self-testing devices)

Conformity assessment route: Annex III (except Point 6) of the Directive

Applicable Standards: EN ISO 13485:2016; EN ISO 15223-1:2016; EN ISO 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 23640:2015; EN ISO 13641:2002; EN ISO 14971:2019, EN 62366-1:2015.

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint Luxus Lebenswelt GmbH, located at Kochstr.1,47877, Willich, Germany to act as our European Authorised Representative as defined in the aforementioned Directive.

Hang Zhou 2021.3.2 — Dean

(Place and date of issue) (Signature and position)

Signed for and on behalf of the manufacturer

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für In-vitro-Diagnostika / Form for In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority			
	Code **DE/CA20**		
	Bezeichnung / Name **Bezirksregierung Düsseldorf, Dezernat 24**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Düsseldorf**		Postleitzahl / Postal code **40474**
	Straße, Haus-Nr. / Street, house no. **Cecilienallee 2**		
	Telefon / Phone **+49-211-4750**		Telefax / Fax **+49-211-4752671**
	E-Mail / E-mail **dez24.mpg@brd.nrw.de**		

Anlage 2
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00160722

Anzeige / Notification			
	Registrierdatum bei der zuständigen Behörde Registration date at competent authority **15.03.2021**		Registriernummer / Registration number **DE/CA20/01-IVD-Luxuslebenswelt-18/21**
	Rechtsgrundlage / Legacy basis ☒ Medizinprodukte (98/79/EG) / German Medical Device Act (98/79/EG) ☐ Verordnung (EU) 2017/746 (IVDR) / Regulation (EU) 2017/746 (IVDR)		
	Typ der Anzeige / Notification type ☒ Erstanzeige / Initial notification ☐ Änderungsanzeige / Notification of change ☐ Widerrufsanzeige / Notification of withdrawal		
	Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn		
	Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG ☐ Hersteller / Manufacturer ☒ Bevollmächtigter / Authorised Representative ☐ Einführer / Importer ☐ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG ☐ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV ☐ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG		

Anzeigender / Reporting organisation (person)			
	Code **DE/0000047791**		
	Bezeichnung / Name **Luxus Lebenswelt GmbH**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Willich**		Postleitzahl / Postal code **47877**
	Straße, Haus-Nr. / Street, house no. **Kochstr. 1**		
	Telefon / Phone **0049-1715605732**		Telefax / Fax
	E-Mail / E-mail **info.m@luxuslw.de**		

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office@medplaza.ro
medplaza
www.medplaza.ro
0316.30.66.90

Hersteller / Manufacturer

Bezeichnung / Name
Hangzhou Realy Tech Co.,Ltd.

Staat / State
CN

Ort / City
Hangzhou

Postleitzahl / Postal code
311200

Straße, Haus-Nr. / Street, house no.
#2 Building, No. 763, Yuansha Village, Xinjie Street, Xiaoshan District, Hangzhou City, Zhejiang Province

Telefon / Phone
0086-571-56050793

Telefax / Fax
0086-571-56050794

E-Mail / E-mail
ryy@realytech.com

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9)
Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG

Bezeichnung / Name
Lin Sun

Staat / State
Deutschland

Land / Federal state
Nordrhein-Westfalen

Ort / City
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Vertreter / Deputy (optional)

Bezeichnung / Name

Telefon / Phone

Telefax / Fax

E-Mail / E-mail

☒ Erstanzeige / Initial notification
☐ Änderungsanzeige / Notification of change

Anlage 2
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00160722

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort / City: **Willich**
Datum / Date: **2021-01-21**
Name: **Lin Sun**
Unterschrift / Signature

Bearbeitungsvermerke / Processing notes
Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority

Bearbeiter / Person responsible: **Frau Nadine Schlingmeier**
Telefon / Phone: **0211-475-3853**

Anlage 2
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00160722

In-vitro-Diagnostikum / In vitro diagnostic medical device

Klassifizierung / Classification
☐ Produkt der Liste A, Anhang II / Device of List A, Annex II
☐ Produkt der Liste B, Anhang II / Device of List B, Annex II
☐ Produkt zur Eigenanwendung / Device for self-testing
☒ Sonstiges Produkt / Other device (all devices except Annex II and self-testing devices)

App (Software auf mobilen Endgeräten) ☐ ja / yes ☒ nein / no

Anzeige nach § 25 Abs. 3 Nummer 3 MPG
Notification pursuant to § 25 (3) number 3 Medical Devices Act, MPG
☐ "Neues In-vitro-Diagnostikum / New in vitro diagnostic medical device"

Handelsname des Produktes / Trade name of the device
Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab)

Produktbezeichnung / Name of device
Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab)

Angabe der benutzten Nomenklatur / Nomenclature used
☒ EDMS-Klassifikation / EDMS Classification
☐ GMDN

Nomenklaturcode / Nomenclature code
15-70-90-90-00

Nomenklaturbezeichnung / Nomenclature term
OTHER OTHER VIROLOGY RAPID TESTS

Kurzbeschreibung / Short description
In Deutsch / In German
Das Coronavirus (SARS-Cov-2) -Antigen-Schnelltestgerät (Nasentupfer) ist ein In-vitro-Diagnosetest zum qualitativen Nachweis des Nucleoproteins der Coronavirus-Krankheit 2019 im menschlichen Nasentupfer unter Verwendung der schnellen immunochromatographischen Methode als Hilfe bei der Diagnose von SARS -Cov-2-Infektionen. Die Identifizierung basiert auf den monoklonalen Antikörpern, die für das neue Coronavirus-Antigen spezifisch sind. Es wird Informationen für klinische Ärzte bereitstellen, um korrekte Medikamente zu verschreiben.

In Englisch / In English
The Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab) is an in vitro diagnostic test for the qualitative detection Nucleoprotein of Coronavirus Disease 2019 in human nasal swab, using the rapid immunochromatographic method as an aid in the diagnosis of SARS-Cov-2 infections. The identification is based on the monoclonal antibodies specific for the novel coronavirus antigen. It will provide information for clinical doctors to prescribe correct medications.

Zusätzliche Angaben im Falle der In-vitro-Diagnostika gemäß Anhang II und der In-vitro-Diagnostika zur Eigenanwendung / Addtional information for Annex II and self-testing in vitro diagnostic medical devices

Nummer(n) der Bescheinigung(en) / Certificate number(s)

☐ In übereinstimmung mit den Gemeinsamen Technischen Spezifikationen (für Produkte gem. Anhang II, Liste A)
In conformity with Common Technical Specifications (for Annex II List A devices)

Ergebnisse der Leistungsbewertung
Outcome of performance evaluation

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medplaza

Digitally signed by BERNARDINI SERGIO

UNIVERSITA' DEGLI STUDI DI ROMA "TOR VERGATA"

DIPARTIMENTO DI MEDICINA SPERIMENTALE
Cattedra di Biochimica Clinica e Biologia Molecolare Clinica
(Direttore Prof. Sergio Bernardini)

Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test cassette (swab)

Clinical Evaluation Report

Introduction

SARS-CoV-2 is the causative agent of coronavirus disease 2019 (COVID-19), whose principal clinical manifestation is a bilateral pneumonia. The novel coronavirus belongs to the *Coronaviridae* family, genus Betacoronavirus, subgenus Sarbecovirus. Due to the efficient human-to-human transmission, the virus spread rapidly all over the world and on 11 March 2020, WHO declared COVID-19 as a pandemic. To date, SARS-CoV-2 infected more than one-hundred million people and caused the death of more than 3 million people.
The virus can be isolated from both the upper and lower respiratory tract. Real-time PCR is considered the gold standard for the detection of SARS-CoV-2; however, it requires skilled personnel, is time consuming and suffer of reagents shortage. On the other hand, antigen testing is quick and can identify infectious individuals, which are those that carry a high viral load in their upper respiratory tract. Although, less sensitive than molecular test, antigen test is useful for identifying infected individuals in the first days of infection when the viral load in the upper respiratory tract is highest.
Here, we tested the sensitivity and specificity of the Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test using nasal swabs already tested by real-time PCR with the Allplex™-SARS-CoV-2 assay (Seegene, Seoul, South Korea).

Material and methods

Sample size

Two hundred nasal swabs collected at the COVID center of the University Hospital Tor Vergata and tested for the presence of SARS-CoV-2 by real-time PCR were included in the study. The selected samples included 100 samples positive for SARS-CoV-2 and 100 samples negative to SARS-CoV-2. All positive selected samples were amplified at a Ct value ≤ 25. Samples were collected on May 2021.

SARS-CoV-2 real-time PCR

Nasal swabs were tested by Allplex™-SARS-CoV-2 assay (Seegene, Seoul, South Korea). The assay detects the E gene, common to the Sarbecovirus subgenus, and three specific SARS-CoV-2 genes: N, RdRp and S.

Antigen test

Samples selected on the basis of real-time PCR results were subsequently tested by Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test cassette (Hangzhou Realy Tech Co.,Ltd., China). Eighty µl of nasal swab dispersed in universal transport medium (UTM) were mixed with 80 µl of extraction buffer of the Antigen assay. Then, 80 µl were loaded on the cassette according to the manufacturer's instruction. The appearance of control and antigen lines was checked after 1520 min as indicated by the manufacturer.

Results

Of the one-hundred positive samples with a Ct value ≤ 25, 96 tested positive also with the Antigen assay, while 4 were negative, Table 1. The four negative samples had a mean Ct value of 22.5. The 100 negative samples by real-time PCR were all confirmed negative by the Antigen assay with a specificity of 100%, Table 2.

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Conclusions

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test showed 96% sensitivity (considering only RTPCR positive sample with a cycle threshold ≤ 25) and 100% specificity .
Based on these results, it can be stated that the Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test is suitable for the diagnosis of SARS-CoV-2 infection with a Detection Limit corresponding to or less than 25 CT at the molecular test (RTPCR).

Table 1. Demographics of 100 SARS-CoV-2 positive patients detected by real-time PCR (Allplex™ SARS-CoV-2 assay, Seegene) carried out on nasal swabs collected on May 2021.

NO.	Gender	Age	Experimental reagent Assessment test results		PCR test results		
			Sample type	Determination	Sample type	Determination	Ct value
1	M	18	nasal swab	Positive	nasal swab	Positive	20
2	F	57	nasal swab	Negative	nasal swab	Positive	22
3	M	18	nasal swab	Positive	nasal swab	Positive	21
4	M	20	nasal swab	Positive	nasal swab	Positive	16
5	F	18	nasal swab	Positive	nasal swab	Positive	13
6	M	26	nasal swab	Positive	nasal swab	Positive	21
7	M	80	nasal swab	Positive	nasal swab	Positive	20
8	M	37	nasal swab	Positive	nasal swab	Positive	19
9	M	26	nasal swab	Positive	nasal swab	Positive	18
10	M	17	nasal swab	Positive	nasal swab	Positive	16
11	M	41	nasal swab	Positive	nasal swab	Positive	22
12	M	45	nasal swab	Positive	nasal swab	Positive	19
13	F	46	nasal swab	Positive	nasal swab	Positive	21
14	M	38	nasal swab	Positive	nasal swab	Positive	21
15	F	37	nasal swab	Positive	nasal swab	Positive	25
16	M	37	nasal swab	Positive	nasal swab	Positive	23
17	M	68	nasal swab	Positive	nasal swab	Positive	21
18	M	43	nasal swab	Positive	nasal swab	Positive	23
19	M	56	nasal swab	Negative	nasal swab	Positive	23
20	F	48	nasal swab	Positive	nasal swab	Positive	18
21	M	19	nasal swab	Positive	nasal swab	Positive	21
22	M	46	nasal swab	Positive	nasal swab	Positive	20
23	F	51	nasal swab	Positive	nasal swab	Positive	18
24	M	72	nasal swab	Positive	nasal swab	Positive	18
25	M	14	nasal swab	Positive	nasal swab	Positive	17
26	M	34	nasal swab	Positive	nasal swab	Positive	22
27	M	61	nasal swab	Positive	nasal swab	Positive	22
28	F	33	nasal swab	Positive	nasal swab	Positive	24
29	M	19	nasal swab	Positive	nasal swab	Positive	19
30	M	51	nasal swab	Positive	nasal swab	Positive	18
31	F	46	nasal swab	Positive	nasal swab	Positive	19
32	F	78	nasal swab	Positive	nasal swab	Positive	24

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Va multumim!

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