RAPIDAN TESTER COVID-19 Ag HOMETEST

CE1434 CORONA-HEIMTEST ZUR EIGENANWENDUNG IM VORDEREN NASENBEREICH

LOD 21.8 TCID50/ml

BfArM & PEI gelistet

BfArM-Test-ID: AT1222/21

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RAPIDAN TESTER COVID-19 Ag HOMETEST

PRODUKTBESCHREIBUNG

Der Türklab RAPIDAN TESTER COVID-19 Ag Home Test ist ein CE-zertizifierter Heimtest für die Eigenanwendung durch Laien.

Die Probenentnahme erfolgt durch einen Abstrich im vorderen Teil der Nase und ist demnach schmerzfrei und angenehm durchzuführen.

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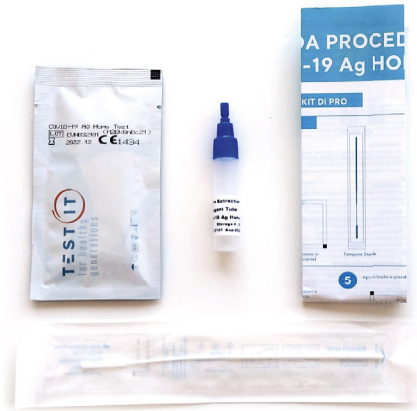
RAPIDAN TESTER COVID-19 Ag HOMETEST



VERPACKUNGSINHALT

1x Vorgefüllte Pufferlösung mit abbrechbarer Spitze
1x Testkassette
1x Probenentnahme-Tupfer
1x Anleitung in Deutsch und Englisch

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RAPIDAN TESTER COVID-19 Ag HOMETEST

DIE WICHTIGSTEN VORTEILE AUF EINEN BLICK

- Top Preis
- CE1434- zertifizierter Laientest in 1er-VPE
- Einer der besten LOD-Werte auf dem Test-Markt (LOD 21.8 TCID50/ml)
- BfArM + Paul Ehrlich-Listung
- Dauerhaft lieferfähig durch EU-nahes Produktionsland! Die Ware kommt mit dem LKW!

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RAPIDAN TESTER COVID-19 Ag HOMETEST

KLINISCHE PERFORMANCE

Analyse der Koinzidenzrate von COVID-19 Ag Home Test und RT-PCR Test in Nasenproben:

Sensitivität: 92,77% (*95% CI: 89,34% - 95,36%)
Spezifität: 99,61% (95% CI: 98,85% - 99,92%)
Genauigkeit: 97,59% (95% CI: 96,49% - 98,42%)

Analyse der Koinzidenzrate von COVID-19 Ag Home Test in nasalen Proben und RT-PCR-Test aus nasopharyngealen Proben:

Sensitivität: 92,65% (95% CI: 88,87% - 95,45%)
Spezifität: 99,38% (95% CI: 97,79% - 99,93%)
Genauigkeit: 96,31% (95% CI: 94,47% - 97,68%)

*95% Konfidenzintervall

Gesamtanalyse der Koinzidenzrate des COVID-19 Ag Home Tests:

Sensitivität: 92,71% (95% CI: 90,31% - 94,68%)
Spezifität: 99,54% (95% CI: 98,93% - 99,85%)
Genauigkeit: 97,14% (95% CI: 96,22% - 97,88%)

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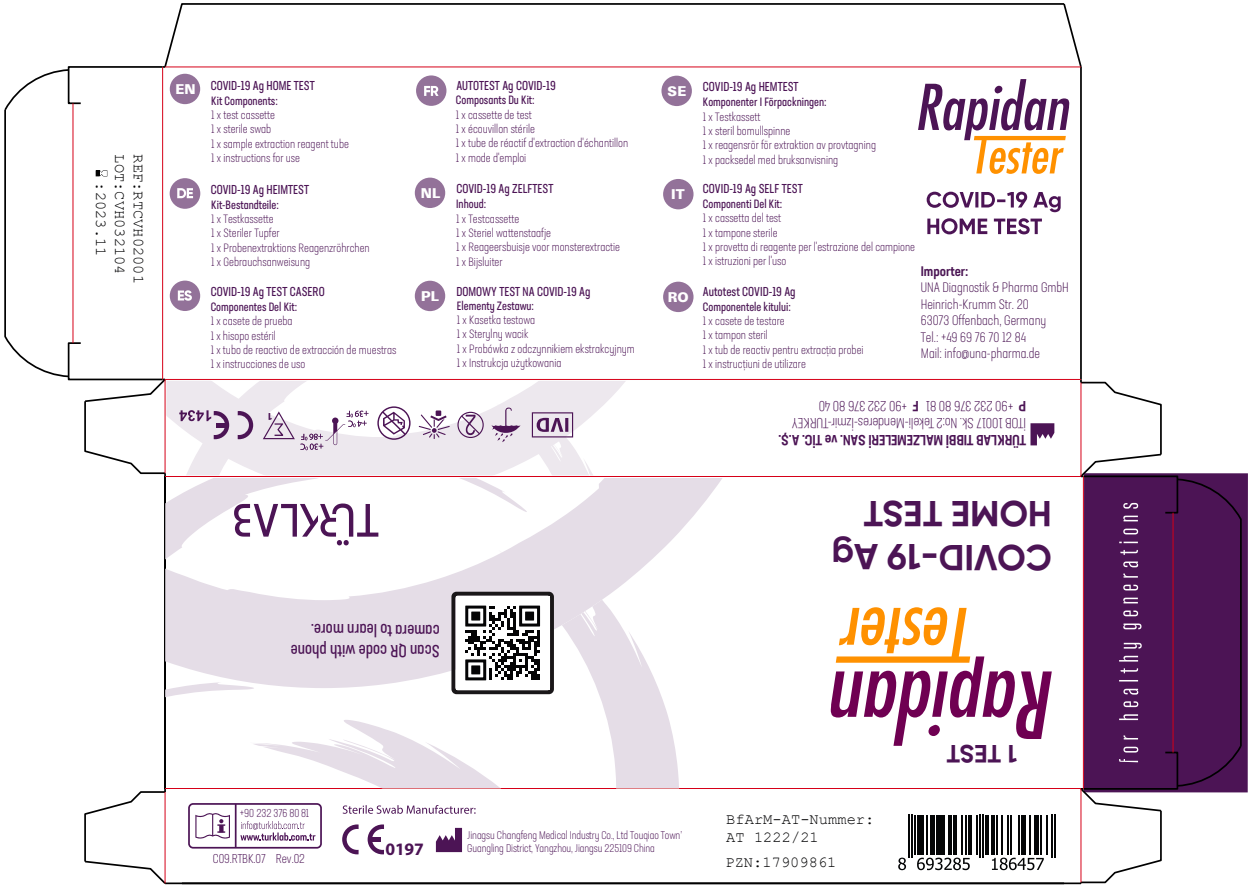
RAPIDAN TESTER COVID-19 Ag HOMETEST



1er-VERPACKUNG

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RAPIDAN TESTER COVID-19 Ag HOMETEST

Bundesinstitut für Arzneimittel und Medizinprodukte

Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2

Impressum | Administration

Suchen: Alle Textspalten | Los | Aktionen | Zurücksetzen

			Hersteller		Europäischer Bevollmächtigter			Sensitivität		Spezifität		
Test-ID	Name des Tests	Evaluier... PEI	Name	Land	Name	Land	Probennah...	%	95%iges Vertrauensi...	%	95%iges Vertrauensi...	Gebrauch...
AT1217/21	SARS-CoV-2 Antigen Rapid Test(Self-testing)	Ja	ACON Biotech(Hangzhou) Co., Ltd	CN	MedNet GmbH	DE	nasal	97,10	93,1 - 98,9	99,50	98,2 - 99,9	Link ...
AT1190/21	COVID-19 (SARS-CoV-2) Antigentestkit (kolloidales Gold)	Ja	ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.	CN	Luxus Lebenswelt GmbH	DE	nasal	96,40	90,8 - 98,2	99,80	94,4 - 99,9	Link ...
AT1236/21	Coronavirus (2019-nCoV)-Antigentest-	Ja	Beijing Hotgen Biotech Co., Ltd.	CN	MedNet GmbH	DE	nasal	96,95	92,4 - 99,2	98,88	96,8 - 99,8	Link ...
AT1265/21	WANTAI SARS-CoV-2 Ag Schnelltest (Kolloidales Gold)	Nein	Beijing WANTAI Biological Pharmacy Enterprise Co.,...	CN	Qarad BV	BE	Speichel / na...	89,76	85,42 - 92,92	99,61	98,58 - 99,89	Link ...
AT1189/21	Dräger COVID-19 Home Test	Ja	Dräger Safety AG & Co KGaA	DE			nasal	87,50	81,3 - 91,9	99,30	97,6 - 99,8	Link ...
AT1200/21	SARS-CoV-2 Antigen Test Kit (Kolloidales Gold)	Ja	Genrui Biotech Inc.	CN	Lotus NL B.V.	NL	nasal	98,13	93,0 - 99,0	100,00	96,0 - 100,0	Link ...
AT1158/21	COVID-19 Ag Test	Ja	Guangdong Wesail	CN	Lotus NL B.V.	NL	nasal	82,40	74,68 - 88,15	99,70	98,24 - 99,99	Link ...
AT1172/21	SARS-CoV-2 Antigen Schnelltest (Nasenabstrich)for self testing	Ja	Hangzhou AllTest Biotech Co., Ltd.	CN	MedNet GmbH	DE	nasal	95,40	92,6 - 97,3	99,40	98,3 - 99,9	Link ...
AT1117/21	COVID-19 Antigen Rapid Test (Oral Fluid) for self testing	Ja	Hangzhou AllTest Biotech Co., Ltd.	CN	MedNet GmbH	DE	Speichel	90,10	82,50 - 95,10	99,30	97,70 - 99,90	
AT1228/21	Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) for self-testing	Ja	Hangzhou Laihe Biotech Co., Ltd	CN	SUNGO Europe B.V.	NL	nasal	95,00	90,39 - 97,82	99,60	97,80 - 99,99	Link ...
AT1259/21	COVID-19 Test Kit (Colloidal Gold Method)	Nein	Hangzhou Singclean Medical Products Co., Ltd.	CN	SUNGO Europe B.V.	NL	nasal	97,99	94,25 - 99,31	99,71	98,40 - 99,95	Link ...
AT1234/21	ZuhauseTEST Corona	Nein	NanoRepro AG	DE			Speichel	94,29	87,98 - 97,87	99,00	97,46 - 99,73	Link ...
AT1155/21	NanoRepro SARS-CoV-2 Antigen Schnelltest (Viromed)	Ja	NanoRepro AG	DE			nasal	97,33	93,31 - 99,27	99,33	96,34 - 99,98	Link ...
AT1210/21	COVID-19 Antigen-Nachweis-Kit – Nasenabstrich	Nein	New Gene (Hangzhou) Bioengineering Co., Ltd.	CN	SUNGO Europe B.V.	NL	nasal	97,11	93,38 - 99,06	99,24	97,29 - 99,90	Link ...
AT1154/21	SARS-CoV-2 Antigen Self Test Nasal	Ja	SD Biosensor Inc.	KR	MT Promedt Consulting GmbH	DE	nasal	86,40	78,50 - 92,20	99,60	97,9- 100,00	Link ...
AT1222/21	TEST IT COVID-19 Ag Home Test | RAPIDAN TESTER COVID-19 Ag Home Test | ...	Ja	TÜRKLAB TIBBI MALZEMELER SAN. ve TIC. A.S.	TR			nasal	92,65	88,87 - 95,45	99,38	97,79 - 99,93	Link ...
AT1165/21	Rapid SARS-CoV-2 Antigen Test Card	Ja	Xiamen Boson Biotech Co., Ltd.	CN	Lotus NL B.V.	NL	nasal	96,19	92,53 - 99,85	99,20	97,64 - 99,99	Link ...

1 Zeilen ausgewählt

1 - 17 von 17

letzte Änderung: 09.11.2021 16:08

BFARM-LISTUNG BfArM-Test-ID: AT1222/21

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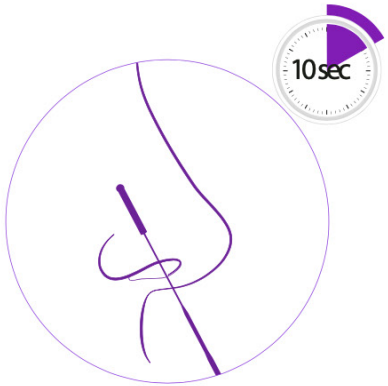
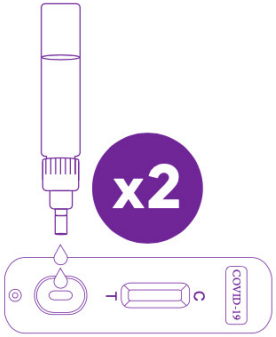
RAPIDAN TESTER COVID-19 Ag HOMETEST

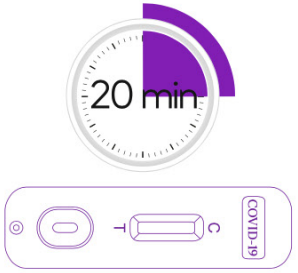


Nasale Probenentnahme

Probenstäbchen in Pufferlösung



Probenabgabe in Testkassette



Ergebnis nach max. 20 Min ablesen

ANWENDUNG - KURZFORM

CE 1434 TÜRKLAB

RAPIDAN TESTER COVID-19 Ag HOMETEST

CERTIFICATE

EC Certificate No. 1434-IVDD-446/2021
EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
ITOB 10017 Sokak No: 2, Tekeli – Menderes Izmir, Turkey

in vitro diagnostic medical devices
for self-testing

COVID-19 Ag Home Test
The list of medical devices covered by this certificate is provided in the annex 1

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 30.07.2021 to 27.05.2024

The date of issue of the Certificate: 30.07.2021

The date of the first issue of the Certificate: 30.07.2021

CE 1434

Issued under the Contract No. MD-74/2021
Application No: 114/2021
Certificate bears the qualified signature.
Warsaw, 30.07.2021
Module A1

Anna Małgorzata Wyroba
Vice-President

POLISH CENTRE FOR TESTING AND CERTIFICATION 02-844 Warsaw, 469 Puławska Street, tel. +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-446/2021

List of medical devices covered by the certificate:

Serial No.	Brand/Trademark	REF. No.	Product Name
1	Rapidan® Tester	RTCVH02001	COVID-19 Ag Home Test
2	Toyo®	TCVH02001	COVID-19 Ag Home Test
3	Info®	ICVH02001	COVID-19 Ag Home Test
4	Test It	TICVH02001	COVID-19 Ag Home Test
5	Rapidan® Tester	RTCVH02005	COVID-19 Ag Home Test
6	Toyo®	TCVH02005	COVID-19 Ag Home Test
7	Info®	ICVH02005	COVID-19 Ag Home Test
8	Test It	TICVH02005	COVID-19 Ag Home Test

CE 1434

Issued under the Contract No. MD-74/2021
Application No: 114/2021
Certificate bears the qualified signature.
Warsaw, 30/07/2021

Anna Małgorzata Wyroba
Vice - President

POLISH CENTRE FOR TESTING AND CERTIFICATION 02-844 Warsaw, 469 Puławska Street, tel. +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

EC DECLARATION OF CONFORMITY

In vitro Diagnostic Medical Devices in accordance with Directive 98/79/EC

Manufacturer:	Türklab Tibbi Mal. San. ve Tic. A.Ş.
Headquarters / Manufacturing Side:	ITOB 10017 Sokak No: 2 Tekeli - Menderes / Izmir - Turkey
Product:	COVID-19 Ag HOME TEST
Brand:	Rapidan® Tester, Toyo®, Info®, Test It
Classification:	Self-Test, 98/79/EC
Conformity Assessment Route:	Self-Test, Annex III, Section 9

We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for In-Vitro Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied:	EN ISO 13485:2016 EN ISO 14971:2019 EN ISO 15223:2016 EN ISO 18113-4:2011 EN ISO 18113-5:2011 EN ISO 23640:2015 EN 13532:2002 EN 13612:2002
Notified Body:	Polish Centre for Testing and Certification (PCBC), ul. Puławska 469 02-844 Warszawa Poland (Notified Body # 1434)
Start of CE Marking:	30.07.2021
Revision No:	0
Place, Date of Issue:	Izmir, 04.08.2021
Signature	Kartal Yağdiere General Manager

TÜRKLAB TIBBİ MAL. SAN. VE TİC. A.Ş.

CE 1434

ZERTIFIKATE

CE 1434 TÜRKLAB

IMPORTEUR:

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D-63073 Offenbach am Main

Tel.: +49 69 7670 1284
Email: info@una-pharma.de

DISTRIBUTEUR:

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Südstrand 2b
26382 Wilhelmshaven

Tel.: +49 (0)4421-1812509
Email: s.scheller@scheller-pl.com

KONTAKTE

CE 1434 TÜRKLAB