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SARS-COV-2 Antigen-Schnelltestsatz

Immunchromatographie mit kolloidalem Gold

Marketing@lepu-medical.com

Produktmerkmale

Nichtinvasiv

Anwenderfreundlich

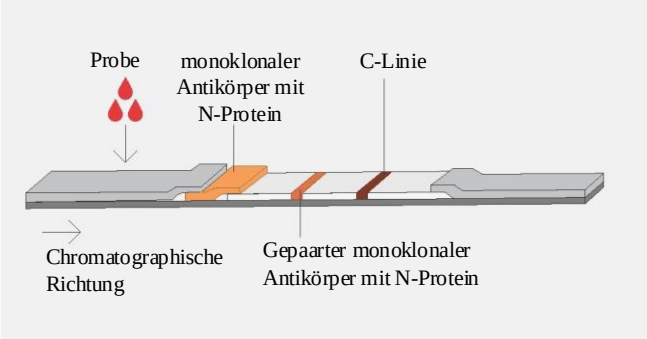
Praktisch, keine Geräte erforderlich

Schnell, Resultate schon nach 15 min

Zuverlässig, sehr präzise

Preiswert, kostengünstig

Auf der Testkarte ist ein goldmarkierter monoklonaler Antikörper auf Basis des N-Proteins von SARS-CoV-2 enthalten, der auf dem Bindungspolster vorbeschichtet ist. Daneben befinden sich ein gepaarter monoklonaler Antikörper, ebenfalls auf Basis des N-Proteins von SARS-CoV-2, der in der Testlinie (T) fixiert ist, und entsprechende Antikörper in der Kontrolllinie (C).



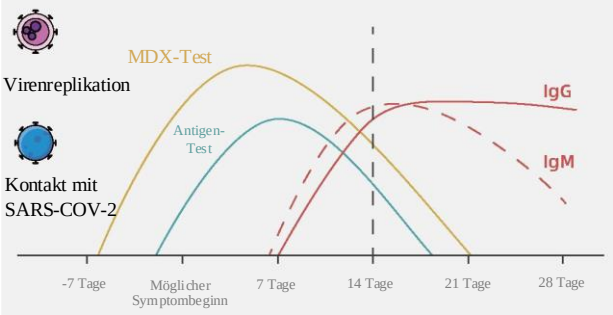
Tupf

Puffe

Der Testsatz für den SARS-COV-2-Antigen-Schnelltest erfasst das Virus von der ersten Infektionsphase (2-3 Tage vor dem möglichen Auftreten von Symptomen) bis zur letzten (7-10 Tage nach dem Auftreten).

Infektionsverlauf

Molekularer Test-wahrscheinlich negativ
Molekularer Test-wahrscheinlich positiv
Antigentest-wahrscheinlich negativ
Antikörpererfassung
Antigentest-wahrscheinlich positiv
Erfassung unwahrscheinlich



Literatur:

Sethuraman N, Jeremiah SS, Ryo A. Interpreting Diagnostic Tests for SARS-CoV-2. JAMA. 9. Juni 2020;323(22):2249-2251. doi: 10,1001/ma.2020.8259 PMID: 32374370

Long QX, Liu BZ, Huang AL. Antibody responses to SARS-CoV-2 in patients with COVID-19. Nat Med. 2020;26(6):845-848. 10,1038/s41591-020-0897-1. Epub 29 Apr. 2020. PMID: 32350462.

„Sowohl Antigentests als auch NAATs funktionieren am besten , wenn die Person unter höchster Viruslast getestet wird"-Interim Guidance for Antigen Testing for SARS-CoV-2, Centers for Disease Control and Prevention

Medizinische Anwendung des Antigen-Testsatzes

---Antigentestalgorithmus empfohlen von CDC

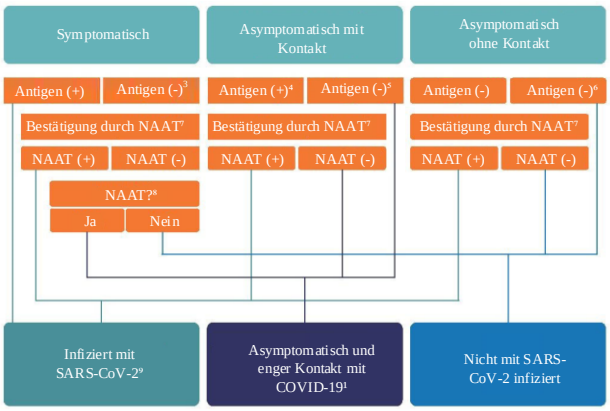
(https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/An-tigen_Testing_Algorithm_2020-12-14_v03_NO_DRAFT_SPW_508.pdf)

• Symptomatisch

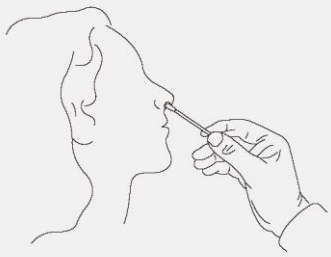
• Asymptomatisch und enger Kontakt mit Covid-19

• Asymptomatisch und kein bekannter Kontakt

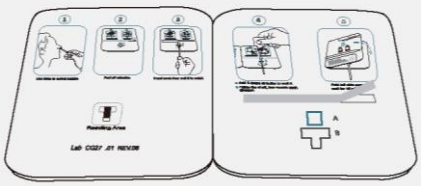
Antigentestalgorithmus



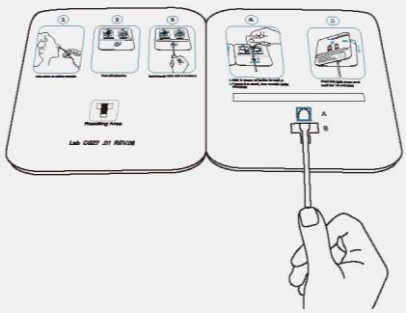
Anleitung



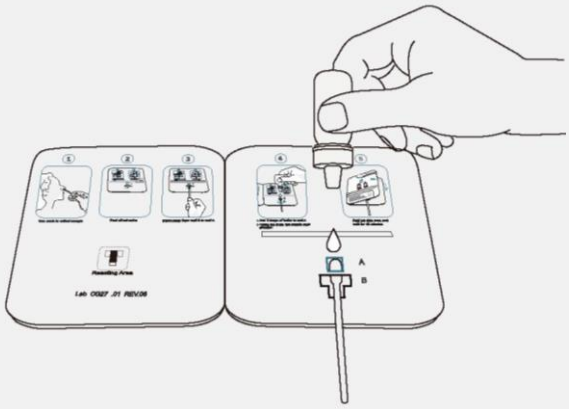
Schritt 1 Tupfer zur Probenentnahme benutzen.



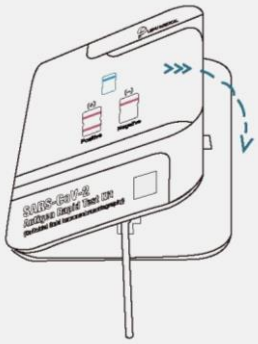
Schritt 2 Kleber abziehen.



Schritt 3 Tupfer von Vertiefung B in Vertiefung A einführen.

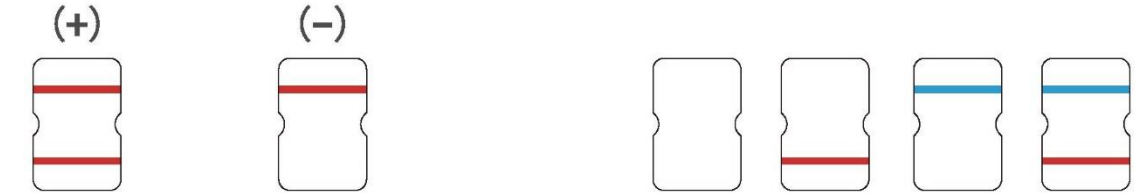


Schritt 4: a. 6 Tropfen Puffer in Vertiefung A geben. b. Tupferschaft in jede Richtung zweimal umdrehen.



Schritt 5 Linke Seite umklappen und 15 Minuten warten.

Auswertung der Ergebnisse



Technische Daten

Klinik | Testzentrum | Flughafen | Bahnhof | Hotel | Gewerbe | Massentest

EU Common List of COVID-19 Rapid Antigen Tests

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health, country knowledge, crisis management
Health Security and Vaccination

EU health preparedness:

A common list of COVID-19 rapid antigen tests, including those whose test results are mutually recognised, and a common standardised set of data to be included in COVID-19 test result certificates

Agreed by the Health Security Committee
on 17 February 2021

III. Rapid antigen tests of which the test results are mutually recognised

As stipulated in point 15 of the Council Recommendation of 21 January 2021, Member States will agree on a selection of rapid antigen tests of which they will mutually recognise the test results for public health measures, based on the information included in the common list (see Annex I).

The Health Security Committee agrees that, for rapid antigen test results to be mutually recognised, at least three Member States should be using a rapid antigen tests in practice. Based on this criterion, Member States agree that the results of the following rapid antigen tests will be mutually recognised for public health measures:

- Abbott Rapid Diagnostics, Panbio™ COVID-19 Ag Rapid Test
- AMEDA Labordiagnostik GmbH, AMP Rapid Test SARS-CoV-2 Ag
- Becton Dickinson, BD Veritor System for Rapid Deteciton os SARS-CoV-2
- **Beijing Lepu Medical Technology, SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold immunochromatography)**
- BIOSYNEX SWISS SA, BIOSYNEX COVID-19 Ag BSS
- CerTest Biotect S.L., CerTest SARS-CoV-2 CARD TEST
- Hangzhou Clongene Biotech, Clungene COVID-19 Antigen Rapid Test Kit
- Healgen Scientific Limited, Coronavirus Ag Rapid Test Cassette (Swab)
- LumiraDX UK LTd, LumiraDx SARS-CoV-2 Ag Test
- nal von minden GmbH, NADAL COVID -19 Ag Test
- Quidel Corporation, Sofia 2 SARS Antigen FIA
- SD BIOSENSOR, Inc., STANDARD F COVID-19 Ag FIA
- SD BIOSENSOR, Inc., STANDARD Q COVID-19 Ag Test
- Siemens Healthineers, CLINITEST Rapid COVID-19 Antigen Test
- Xiamen Boson Biotech Co, Rapid SARS-CoV-2 Antigen Test card
- Zhejiang Orient Gene Biotech Co.,Ltd, Coronavirus Ag Rapid Test Cassette (Swab)

LEPU MEDICAL

Document No.: CE-DOC-CG27
Rev.: 1/0

Declaration of Conformity

Manufacture Address:	Beijing Lepu Medical Technology Co., Ltd. Building 7-1 No.37 Chaoqian Road, Changping District, Beijing, 102200, P.R. China
European Representative:	Lepu Medical (Europe) Cooperatief U.A. Abe Lenstra Boulevard 36, 8448 JB, Heerenveen, The Netherlands
Product information:	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) Model: 1 test/kit; 5 tests/kit; 10 tests/kit; 25 tests/kit; 50 tests/kit
Classification:	Others (not in List A and List B)
Conformity Assessment Route:	Section 2 to 5 in annex III of IVDD 98/79/EC We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premise of the manufacturer.
General Applicable Directive:	DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on *in vitro* diagnostic medical devices
Standards Applied:	All applicable harmonized standards (published in the official journal of the European Communities on 25th March 2020). The applicable standards are listed in Annex 1.
Place, date of issue	Beijing, P.R. China, 3th, Sept., 2020
Signature of Management Representative	Zhao Changjue

Beijing Lepu Medical Technology Co., Ltd.
Building 7-1 No.37 Chaoqian Road, Changping District, Beijing, 102200, P.R. China

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Annex 1

EN ISO 13485:2016 Medical devices – quality management systems - requirements for regulatory purposes

EN ISO 14971:2019 Medical devices – application of risk management to medical devices

EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

EN 1041:2008+A1:2013 Information supplied by the manufacturer of medical devices

EN ISO 18113-1:2011 In vitro diagnostic medical devices – information supplied by the manufacturer (labelling) – Part 1: terms, definitions and general requirements

EN ISO 18113-2:2011 In vitro diagnostic medical devices – information supplied by the manufacturer (labelling) – Part 2: in vitro diagnostic reagents for professional use

EN ISO 23640:2015 In vitro diagnostic medical devices – evaluation of stability of in vitro diagnostic regents

EN 13612:2002/AC: 2002 Performance evaluation of in vitro diagnostic medical devices

IEC 62366-1:2015 Application of usability engineering to medical devices

Revision history:

Version	Revision history	Author	Date
1/0	First procedure	Wenna Li	3th, Sept., 2020