

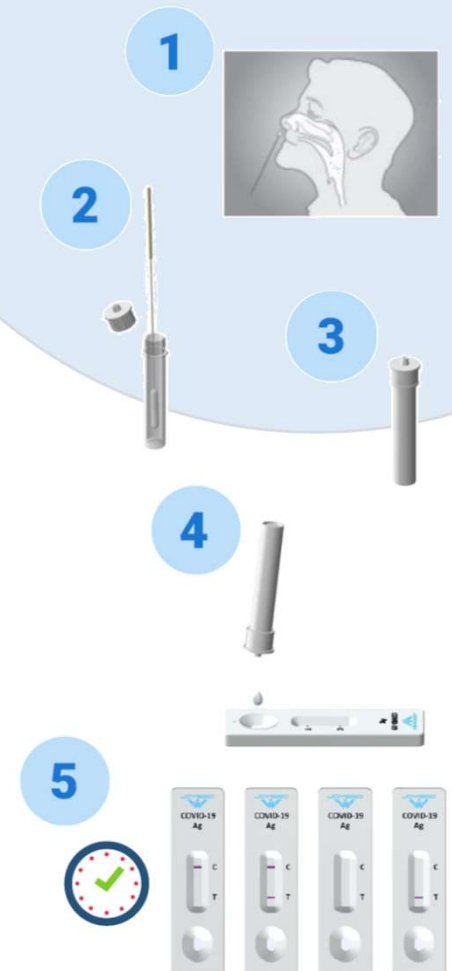
## Test zur Eigenanwendung an Laien

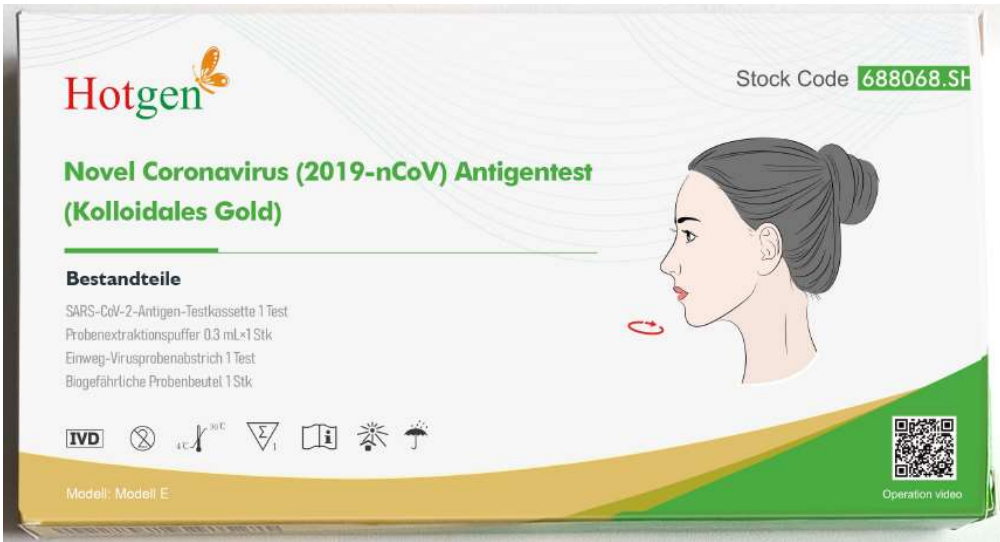
### HOTGEN<sup>®</sup> Novel Coronavirus19 Antigen Schnelltest Kolloidale Goldmethode

- BfArM-Listung
- BfArM Sonderzulassung
- Paul-Ehrlich-Institut Listung
- Sehr gute Sensitivität 97,33%
- Sehr gute Spezifität 99,18%
- Erkennung nach spätestens 15 Minuten
- Vorderer Nasenbereich (2-3cm/Kinder 1-2cm)
- Lieferzeit 14-16 Tage nach Auftragserteilung
- Einzelverpackungen – sicher und gut verteilbar
- 3,90.-€ zzgl. MwSt./ Testkit



## ANWENDUNG





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 SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromatographic Assay)	Xiamen WIZ Biotech Co., Ltd. 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	Guanazhou Wondfo Biotech Co. Ltd

BfArM-AT-  
Nummer\*

Hersteller

Antragsteller

Testname

Aktenzeichen der  
Sonderzulassung  
des BfArM

5640-S-057/21

Beijing Hotgen  
Biotech Co., Ltd

Beijing Hotgen  
Biotech Co., Ltd

Coronavirus (2019-  
nCoV)-Antigentest

AT282/21

# Declaration of Conformity

**Manufacturer:**

Name: Beijing Hotgen Biotech Co.,Ltd  
Address: 9th building, No.9 Tianfu Street, Biomedical Base,Daxing District, Beijing,  
102600, P.R.China

**European Representative:**

MedNet GmbH Borkstrasse 10,48163 Muenster,Germany

**Product Name:**

Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)  
Novel Coronavirus 2019-nCoV Antigen Test (Up-converting Phosphor Immunochromatographic  
Technology)

Classification : **Others of ANNEX II of IVDD**

Conformity Assessment Route: **Annex III**

*We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.*

**General applicable directives:**

In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

**Harmonized standards:**

EN ISO 13485:2016, EN ISO 15223-1:2016, EN ISO 14971:2012,EN 13975:2003,  
EN ISO 18113-1:2011, EN ISO 18113-2:2011,EN 13612:2002,EN ISO 17511:2003,  
EN ISO 23640:2015, EN 13641:2002,EN 13975:2003, EN 62366:2008



Signature: *Lin Changqing*

Name: Lin Changqing  
Title: General manager

Place: Beijing, China.  
Date of Issue: Aug 27, 2020