

02.03.2021

Comparative evaluation of the sensitivities of SARS-CoV-2 antigen rapid tests

Aim

Comparison of different antigen rapid tests with using identical sample material

Material

Pools from nasopharyngeal and oropharyngeal swabs.

Dry swabs were included in PBS; moist swabs were already included in the transport media of various compositions. Pools are random mixtures obtained from up to 10 samples of comparable CT values diluted 1:10 in negative samples in PBS. The CT values of a pool were determined by means of different PCR assays, and the putative number of RNA copies calculated with the aid of the INSTAND standards. In the case of the PCRs used, a CT value of 25 corresponds to around 10^6 RNA copies/mL. 18 samples each were analysed with $CT < 25$, 23 samples with CT between 25 and 30, and 9 samples with $CT > 30$. The replication of the virus in cell culture was determined as a possible correlate for infectiousness as another characteristic of the samples.

Method

The pools were aliquoted, frozen, shipped, and thawed for evaluation of the tests. For each test, 50 µL of the pool were analysed using the components of the test provided, e.g. swabs. Laboratories participating in the comparative evaluation included the Robert Koch-Institut, the Paul-Ehrlich-Institut, the reference laboratory for coronaviruses (Charité), and the Institute for Microbiology of the German Army (Bundeswehr).

Summary

This comparative evaluation of a large number of SARS-CoV-2 rapid antigen tests (point of care tests; POCT) of different designs and manufacturers with the same sample set allows an overview of the current state of art regarding sensitivity. The results do not allow any conclusions regarding specificity of the tests.

Those POCTs which have up to now been included in the evaluation and have been assessed as reflecting the current state of the art are listed in the table below. Other tests, which were assessed as not reflecting the state of the art were deleted from the list of the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM). This comparative evaluation is constantly continued, and the table is amended accordingly.

You should be aware that this comparative evaluation can only cover a random sample of the SARS-CoV-2 rapid antigen tests listed by the BfArM, thus eligible for refunding, and that few other products could not (yet) be taken into account, despite the interests on the part of the manufacturers/distributors.

Contact

Email: sarscov2ivd@pei

Last updated: 02.03.2021

Overview of SARS-CoV-2 Antigen Rapid Tests Assessed as Reflecting the Current State of the Art

| Name of Test | Manufacturer (Distributor) |
|--|--|
| 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. |

| Name of Test | Manufacturer (Distributor) |
|---|---|
| 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 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 COVI-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 |