# ANNEX I: Common list of rapid antigen tests[1]

As agreed by Member States on […]

***Disclaimer**: This list was agreed by the HSC based on a proposal by the Technical Working Group on COVID-19 Diagnostic Tests. Experts participating in the Technical Working Group strongly recommend that use of rapid antigen tests is primarily intended for preliminary testing for SARS-CoV-2 infection in symptomatic patients, and note that rapid antigen tests should in particular be used in the specific contexts and circumstances referred to by the Commission Recommendation (EU) 2020/1743 of 18 November 2020 and the technical guidance by ECDC on 19 November 2020. The content of the common list is based on the clinical performance data and information that is available at this moment in time. Updates to the common list are based on the criteria as described in Council Recommendation 2021/C 24/01 as well as the additional criteria and definitions agreed by the Technical Working Group on 14 September 2021 (tbc). The Medical Device Coordination Group Guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical devices[2], envisaged to form the basis for common specifications to be adopted according to Article 9 of Regulation (EU) 2017/746, has been taken into consideration in this regard.*

**Questions to TWG:**

- Please review the entries below. In particular, for those tests where the study design is listed as 'unknown', please assess these cases, collect more information and evaluate if and how these evaluation studies and their results should be listed.
- In case any new data or results are known from evaluation studies (matching the criteria and definition) not yet listed, please provide these details.
- Which tests included in the list are 'twin tests'?

[1] This is the list of rapid antigen tests as referred to in Article 3 of the Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic, OJ L 211, 15.6.2021, p. 1–22.

[2] https://ec.europa.eu/health/sites/default/files/md_sector/docs/mdcg_2021-21_en.pdf

| Manufacturer | RAT commercial name | Device ID # [3] | Clinical performance as reported by independent validation studies | Clinical performance *Data by manufacturer* | EU Member States using in practice | Other countries using in practice | Completed validation studies | MS currently validating | Included in EU common list since: |
|---|---|---|---|---|---|---|---|---|---|
| AAZ-LMB | COVID-VIRO® Rapid antigen test COVID-19 | 1833 | *Study design unknown*<br>**BE**: 96.6% sensitivity, 100% specificity, NP swab<br>**FR:** >95%% sensitivity, 100% specificity<br>**SI**: 96.6% sensitivity, 100% specificity, NP swab | 96.6% sensitivity<br>100% specificity | BE, FR, SI | CH | FR<br>CH | | 10 May 2021 |
| Abbott Rapid Diagnostics | Panbio™ COVID-19 Ag Rapid Test | 1232 | *Prospective clinical field study*<br>**FIND evaluation studies**<br>DE (10 Dec 2020)<br>1108 samples, NP swab<br>Clinical sensitivities:<br>- Days ≤ 7: 90.8%;<br>- Ct ≤ 33: 88.3%;<br>- Ct ≤ 25: 95.8%;<br>Clinical specificity: 99.9%<br><br>CH (10 Dec 2020)<br>535 samples, NP swab<br>Clinical sensitivities:<br>- Days ≤ 7: 85.6%;<br>- Ct ≤ 33: 89.7%;<br>- Ct ≤ 25: 96.8%;<br>Clinical specificity: 100%<br><br>India (25 June 2021)<br>526 samples, NP swab<br>Clinical sensitivities:<br>- Days ≤ 7: 61.3%-100%;<br>- Ct ≤ 33: 74.2%-86.7%;<br>- Ct ≤ 25: 91.9%-100%;<br>Clinical specificity: 100%<br>*Retrospective in vitro studies*<br>**FI:**<br>Validated in several laboratories (studies not published), meeting criteria.<br>*Study design unknown*<br>**DE**:<br>91.4% sensitivity 99.8% specificity, NP swab; 98.1% sensitivity, | 91.4% sensitivity<br>99.8% specificity<br>NP swab (Ct ≤ 33)<br><br>98.1% sensitivity<br>99.8% specificity<br>Nasal swab (Ct ≤ 33) | AT, BE, BG, CY, CZ, DE[2], DK, EE, EL, ES, FR[1], HR, IT, LT, LV, MT, NL[5], PL, PT, RO, SE, SK | CH, ME, MK, NO, UK, UA | DE[2], ES, FI, NL[5], PT CH, NO | CY, ES, HR, HU, IE, LU, SE | 17 February 2021 |

[3] As registered in and used by the JRC database, see: https://covid-19-diagnostics.jrc.ec.europa.eu/.

| Manufacturer | RAT commercial name | Device ID # [3] | Clinical performance as reported by independent validation studies | Clinical performance *Data by manufacturer* | EU Member States using in practice | Other countries using in practice | Completed validation studies | MS currently validating | Included in EU common list since: |
|---|---|---|---|---|---|---|---|---|---|
| | | | 99,8 specificity, Nasal swab<br><br>**BE**[6]:<br>Small-scale head-to-head comparison of 5 RATs in Belgian hospital lab. Panbio overall sensitivity (Ct range 14,6 – 35,5): 45/57 samples (79%). Sensitivity for Ct≤25: 17/18 samples. Overall specificity 100%. | | | | | | |
| Acon Biotech (Hangzhou) Co., Ltd | SARS-CoV-2 Antigen Rapid Test | 1457 | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 99.54% | 96.9% sensitivity<br>Nasal swab | DE[2], FR, PT | | DE[2] | | 14 July 2021 |
| ACON Laboratories, Inc. | Flowflex SARS-CoV-2 Antigen Rapid Test | 1468 | *Prospective clinical field study*<br>**FIND evaluation**<br>CH (9 June 2021)<br>279 samples, nasal swab<br>Clinical sensitivities:<br>- Days ≤ 7: 92.2%;<br>- Ct ≤ 33: 98.3%;<br>- Ct ≤ 25: 100%;<br>Clinical specificity: 99.5%<br>*Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 98,7%<br>*Study design unknown*<br>**BE:** 96.9% sensitivity, 99.5% specificity, NP swab | 96.9% sensitivity<br>Nasal swab | AT, BE, DE[2], LT, LV, SI | | DE[2] | | 10 May 2021 |
| AESKU.DIAGNOSTICS GmbH & Co, KG | AESKU.RAPID SARS-CoV-2 | 2108 | *Study design unknown*<br>**DE**: 96% sensitivity, 98% specificity<br>**SI**: 96% sensitivity, 98% specificity, Nasal swab | 96% sensitivity<br>98% specificity<br>NP swab | AT, DE[2], SI | | DE[2] | | 10 May 2021 |
| Affimedix Inc. | TestNOW® - COVID-19 Antigen Test | 2130 | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 99,4% | 96.1% sensitivity<br>99.4% specificity<br>NP swab | DE[2] | | DE[2] | | 10 May 2021 |
| AMEDA | AMP Rapid Test SARS- | 1304 | *Retrospective in vitro studies* | 97.3% sensitivity | AT, BG, | CH, UA | DE[2] | HR | 17 February |

| Manufacturer | RAT commercial name | Device ID # [3] | Clinical performance as reported by independent validation studies | Clinical performance *Data by manufacturer* | EU Member States using in practice | Other countries using in practice | Completed validation studies | MS currently validating | Included in EU common list since: |
|---|---|---|---|---|---|---|---|---|---|
| Labordiagnostik GmbH | CoV-2 Ag | | **DE**: Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 100%<br>*Study design unknown*<br>**BE**: 97.3% sensitivity, 100% specificity, NP swab<br>**SI**: 97.3% sensitivity, 100% specificity, NP swab | NP swab<br>97.3% sensitivity<br>Nasal swab<br>100% specificity | DE[2] HR, SI | | CH | | 2021 |
| Anbio (Xiamen) Biotechnology Co., Ltd | Rapid COVID-19 Antigen-Test (colloidal Gold) | 1822 | *Study design unknown*<br>**DE**: 99.27% sensitivity, 100% specificity | | AT, DE[2] | | DE[2] | | 10 May 2021 |
| Anhui Deep Blue Medical Technology Co., Ltd | COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) | 1736 | *Retrospective in vitro studies*<br>**DE**: Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: >99%<br>*Study design unknown*<br>**BE**: 95% sensitivity, 99% specificity, NP/OP swab | Nasal swab: 96,4% sensitivity, 99,8% specificity<br>NP swab: 95,7% sensitivity, 99,3% specificity<br>OP swab: 96,4% sensitivity, 99,8% specificity | BE, DE[2] | UK | DE[2] | | 10 May 2021 |
| Anhui Deep Blue Medical Technology Co., Ltd | COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) – Nasal swab | 1815 | *Study design unknown*<br>**DE:** 96,4 % sensitivity, 99,8 % specificity | 96.4 % sensitivity<br>99.8 % specificity<br>Nasal swab | DE[2] | | DE[2] | | 10 May 2021 |
| ArcDia International Ltd | mariPOC SARS-CoV-2 | 768 | *Study design unknown*<br>**FI:** Meets the minimum performance requirements – see the report for details. | 92% sensitivity<br>100% specificity | FI | | FI | | 10 May 2021 |
| ArcDia International Oy Ltd | mariPOC Respi+ | 2078 | *Retrospective in vitro studies*<br>**FI:** Validated in several laboratories (studies not published), meeting criteria. | 100 % sensitivity<br>100 % specificity<br>NP swab | FI, PT | | FI | | 14 July 2021 |
| ArcDia International Oy Ltd | mariPOC Quick Flu+ | 2079 | *Retrospective in vitro studies*<br>**FI:** Validated in several laboratories (studies not published), meeting criteria. | 100 % sensitivity<br>100 % specificity<br>NP swab | FI, PT | | FI | | 14 July 2021 |
| Artron Laboratories Inc. | Artron COVID-19 Antigen Test | 1618 | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 100% | 96.67% (Nasal)sensitivity<br>91.67% (NP) sensitivity<br>100 % specificity<br>Nasal/NP swab | DE[2] | | DE[2] | | 14 July 2021 |
| Asan Pharmaceutical | Asan Easy Test COVID-19 | 1654 | *Study design unknown* | | DE[2] | | DE[2] | | 10 May 2021 |

| Manufacturer | RAT commercial name | Device ID # [3] | Clinical performance as reported by independent validation studies | Clinical performance *Data by manufacturer* | EU Member States using in practice | Other countries using in practice | Completed validation studies | MS currently validating | Included in EU common list since: |
|---|---|---|---|---|---|---|---|---|---|
| Co., Ltd | Ag | | **DE**:<br>94.67% sensitivity, 97.71% specificity | | | | | | |
| Assure Tech. (Hangzhou) Co., Ltd. | ECOTEST COVID-19 Antigen Rapid Test Device | 770 | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 95% at <Ct25) + Manufacturer specificity: 99.2% | 92.5 % sensitivity<br>99.2 % specificity<br>Nasal/NP/ OP swab | DE[2] | | DE[2] | | 14 July 2021 |
| Assure Tech. (Hangzhou) Co., Ltd. | ECOTEST COVID-19 Antigen Rapid Test Device | 2350 | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 95% at <Ct25) + Manufacturer specificity: 99.1% | Sensitivity: 97.7%,<br>Specificity: 99.1%<br>NP and OP swab | CZ, DE[2] | | DE[2] | | 23 July 2021 |
| Atlas Link Technology Co. Ltd. | NOVA Test ® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) | 2010 | *Study design unknown*<br>**DE**:<br>97.6% sensitivity, 99.2% specificity | 98.5 % sensitivity<br>99.4 % specificity<br>Nasal/OP swab | AT, DE[2], SI | CH | DE[2]<br>CH | | 10 May 2021 |
| Avalun | Ksmart® SARS-COV2 Antigen Rapid Test | 1800 | *Retrospective in vitro studies*<br>**DE:**<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 99,32% | Clinical Sensitivity: 93.18 %<br>Clinical Specificity: 99.32 %<br>NP swab | DE[2] | | DE[2] | | 7 July 2021 |
| AXIOM Gesellschaft für Diagnostica und Biochemica mbH | COVID-19 Antigen Rapid Test | 2101 | *Study design unknown*<br>**DE**:<br>98.1% sensitivity, 100% specificity | 98% sensitivity<br>100% specificity<br>NP/Nasal swab | DE[2] | | DE[2] | | 10 May 2021 |
| Azure Biotech, Inc. | COVID-19 Antigen Rapid Test Device | 1906 | *Study design unknown*<br>**DE**:<br>94.3% sensitivity, 99.1% specificity | 95% sensitivity<br>99.2% specificity<br>NP swab | DE[2] | | DE[2] | | 10 May 2021 |
| Becton Dickinson | BD Veritor™ System for Rapid Detection of SARS CoV 2 | 1065 | *Prospective clinical field study*<br>**NL:**<br>Independent field study in symptomatic individuals - sampling was Nasal mid-turbinate and OP swab. Sensitivity overall: 79.5% - Sensitivity Ct<30: 93.2% - Specificity overall: 99.8% | Clinical Sensitivity: 91.1 %<br>Clinical Specificity: 99.6 %<br>Nasal swab | NL | | NL | | 7 July 2021 |
| Beijing Hotgen | Novel Coronavirus 2019- | 1870 | *Retrospective in vitro studies* | 97.1% sensitivity | AT, BE, | | DE[2] | | 10 May 2021 |

| Manufacturer | RAT commercial name | Device ID # [3] | Clinical performance as reported by independent validation studies | Clinical performance *Data by manufacturer* | EU Member States using in practice | Other countries using in practice | Completed validation studies | MS currently validating | Included in EU common list since: |
|---|---|---|---|---|---|---|---|---|---|
| Biotech Co., Ltd | nCoV Antigen Test (Colloidal Gold) | | **DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 99.76%<br>*Study design unknown*<br>**BE**:<br>98.6% sensitivity, 100% specificity, NP Swab<br>97.3% sensitivity, 99.2% specificity. OP swab<br>**SI**:<br>96.6% sensitivity, 99.8% specificity, NP swab | 99.76% specificity | DE[2], RO, SI | | | | |
| Beijing Jinwofu Bioengineering Technology Co.,Ltd. | Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Kit | 2072 | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 100% | 96.88 % sensitivity<br>100 % specificity<br>Nasal/ NP/ OP swab | DE[2] | | DE[2] | | 14 July 2021 |
| Beijing Lepu Medical Technology Co., Ltd | SARS-CoV-2 Antigen Rapid Test Kit | 1331 | *Study design unknown*<br>**BE**: 92% sensitivity, 99.3% specificity, Nasal<br>**DE**: 92.0% sensitivity, 99.26% specificity<br>**SI**: 92% sensitivity, 99.2% specificity, NP | 92% sensitivity<br>Nasal swab | AT, BE, DE[2], SI, RO | UA | DE[2] | | 17 February 2021 |
| Beijing Wantai Biological Pharmacy Enterprise Co., Ltd | Wantai SARS-CoV-2 Ag Rapid Test (FIA) | 1484 | *Study design unknown*<br>**DE**:<br>96.6% sensitivity, 96.9% specificity | 96.6% sensitivity,<br>Nasal swab | DE[2] | | DE[2] | | 17 February 2021 |
| Beijing Wantai Biological Pharmacy Enterprise Co., Ltd | Wantai SARS-CoV-2 Ag Rapid Test (colloidal gold) | 1485 | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 99% | 96.1 % sensitivity<br>99% specificity<br>Nasal swab | DE[2] | | DE[2] | | 14 July 2021 |
| BioGnost Ltd | CoviGnost AG Test Device 1x20 | 2247 | *Retrospective in vitro studies*<br>**HR:**<br>300 NP samples (retrospective), symptomatic (<7 dps): 200 PCR+ samples (range Ct 16-30), Ct<30: sensitivity 96.5%<br>100 PCR- samples: specificity 100% | Sensitivity: 96%,<br>Specificity: 99%<br>NP swab | HR | | HR | | 23 July 2021 |
| BIOHIT HealthCcare (Hefei) Co., Ltd. | SARS-CoV-2 Antigen Rapid Test Kit (Fluorescence Immunochromato-graphy) | Yes (1286) | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 98.9% | Sensitivity: 96.77%<br>Specificity: 98.9%<br>NP/OP swab | DE[2] | | DE[2] | | 23 July 2021 |
| BioMaxima SA | SARS-CoV-2 Ag Rapid Test | Yes | *Study design unknown* | Sensitivity: 95% | PL | | PL | | 23 July 2021 |

| Manufacturer | RAT commercial name | Device ID # [3] | Clinical performance as reported by independent validation studies | Clinical performance *Data by manufacturer* | EU Member States using in practice | Other countries using in practice | Completed validation studies | MS currently validating | Included in EU common list since: |
|---|---|---|---|---|---|---|---|---|---|
| | | (2035) | **PL:**<br>Diagnostic sensitivity: 93.43% (95% CI: 91.61%~97.19%); diagnostic specificity: 97.75%, manufacturer specificity: 99.1% | Specificity: 99%<br>NP Swab | | | | | |
| Biomerica Inc. | Biomerica COVID-19 Antigen Rapid Test (nasopharyngeal swab) | 1599 | *Retrospective in vitro studies*<br>**DE:**<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 99,7% | Clinical Sensitivity: 94.7 %<br>Nasal/NP swab | DE[2] | | DE[2] | | 7 July 2021 |
| BIONOTE | NowCheck COVID-19 Ag Test | 1242 | *Prospective clinical field study*<br>**FIND evaluation**<br>**Brazil** (20 April 2021)<br>400 samples, NP swab<br>Clinical sensitivities:<br>- Days ≤ 7: 92.2%;<br>- Ct ≤ 33: 91.4%;<br>- Ct ≤ 25: 94.8%;<br>Clinical specificity: 97.3%<br><br>**Brazil** (30 March 2021)<br>218 samples, Nasal/NP swab. Clinical sensitivities:<br>- Days ≤ 7: 92.5% (N/NP);<br>- Ct ≤ 33: 97.2% (N/NP);<br>- Ct ≤ 25: 100% (N/NP);<br>Clinical specificity: 98.6%<br>*Retrospective in vitro studies*<br>**DE:**<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 98,6% | Clinical Sensitivity: 90.91 %<br>Clinical Specificity: 99.43 % | DE[2] | | DE[2] | | 7 July 2021 |
| BIO-RAD | CORONAVIRUS AG RAPID TEST CASSETTE | 2031 | *Study design unknown*<br>**ES:**<br>NP swab: sensitivity 98,3%; specificity 99,6% (119 positive samples, 746 negative samples)<br>Nasal swab: sensitivity 97,2%; specificity 100% (109 positive samples, 128 negative samples) | Clinical Sensitivity: 98 % (NP: 98,32% / Nasal: 97,25%)<br>Clinical Specificity: 99 % (NP: 99,6% / Nasal: 100%) | ES | | ES | | 7 July 2021 |
| BIOSYNEX S.A. | BIOSYNEX COVID-19 Ag BSS | 1223 | *Prospective clinical field study*<br>**NL**:<br>Independent field study, mainly symptomatic individuals, sensitivity Ct≤30: 96.0%; specificity overall: 100%<br>*Retrospective in vitro studies* | 96% sensitivity, 100% specificity, NP swab | AT, BE, DE[2], DK,FR, NL[5], PT | CH | DE[2], NL[5], CH | DK | 17 February 2021 |

| Manufacturer | RAT commercial name | Device ID # [3] | Clinical performance as reported by independent validation studies | Clinical performance *Data by manufacturer* | EU Member States using in practice | Other countries using in practice | Completed validation studies | MS currently validating | Included in EU common list since: |
|---|---|---|---|---|---|---|---|---|---|
| | | | **DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 100%<br>*Study design unknown*<br>**BE**[6]:<br>Small-scale head-to-head comparison of 5 RATs in Belgian hospital lab. Biosynex overall sensitivity (Ct range 14,6 – 35,5): 52/58 samples (89,7%). Sensitivity for Ct≤25: 18/18 samples. Overall specificity only 46,2%, but this is probably linked to the use of transport medium instead of the swab included in the kit. | | | | | | |
| BIOSYNEX SA | BIOSYNEX COVID-19 Ag+ BSS | 1494 | *Prospective clinical field study*<br>**FR**:<br>Validation study data: 125 positive and 118 negative samples; sensitivity 96%, specificity: 99% | Clinical Sensitivity: 97.5 % | FR | | FR | | 7 July 2021 |
| BIOTEKE CORPORATION (WUXI) CO., LTD | SARS-CoV-2 Antigen Test Kit (colloidal gold method) | 2067 | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 95% at <Ct25) + Manufacturer specificity: 99.28% | 96.49 % sensitivity<br>99.28 % specificity<br>OP/NP swab | DE[2] | | DE[2] | | 14 July 2021 |
| Biotical Health S.L.U.BIOTICAL HEALTH S.L.U | biotical SARS-CoV-2 Ag Card | Yes (2013) | *Retrospective in vitro studies*<br>**BE**:<br>Validation study 1: sensitivity 91.7% for Ct<25; Validation study 2: 94% for Ct<25. Manufacturer specificity: 99% | Sensitivity: 96%,<br>Specificity: 99%<br>NP swab | BE | | BE | | 23 July 2021 |
| Boditech Med Inc | AFIAS COVID-19 Ag | Yes (1989) | *Prospective clinical field study*<br>**NL**:<br>Independent field study in mild symptomatic (n= 427); overall sensitivity: 81.1% (106 PCR+), Ct <30: 96.4% (85 PCR+), PCR on NP+OP, Target antigen = nucleoprotein | Sensitivity: 91.7%,<br>Specificity: 98.7%<br>NP swab | FR, NL | | NL | | 23 July 2021 |
| BTNX Inc | Rapid Response COVID-19 Antigen Rapid Test | 1236 | *Study design unknown*<br>**DE**:<br>94.55% sensitivity, 100% specificity | 90.2% sensitivity<br>100% specificity<br>NP swab, NP swab, OP swab | AT, DE[2], ES, SI | | DE[2] | | 10 May 2021 |
| CerTest Biotec | CerTest SARS-CoV-2 Card test | 1173 | *Prospective clinical field study*<br>**ES**:<br>Ct ≤ 25, sensitivity: 94,0%; sensitivity for samples within the first 5 days after symptom onset: 84,8% | 92.9% sensitivity<br>99.6% specificity<br>NP swab | ES, PT, SI | | DE[2], ES | | 17 February 2021 |
| Core Technology | Coretests COVID-19 Ag | 1919 | *Study design unknown* | 98.1% sensitivity | AT, DE[2], | | DE[2] | | 10 May 2021 |

| Manufacturer | RAT commercial name | Device ID # [3] | Clinical performance as reported by independent validation studies | Clinical performance *Data by manufacturer* | EU Member States using in practice | Other countries using in practice | Completed validation studies | MS currently validating | Included in EU common list since: |
|---|---|---|---|---|---|---|---|---|---|
| Co., Ltd | Test | | **DE**:<br>98.1% sensitivity, 99.6% specificity | 99.6% specificity<br>NP swab | RO | | | | |
| CTK Biotech, Inc | OnSite COVID-19 Ag Rapid Test | 1581 | *Prospective clinical field study*<br>**DK:**<br>107 samples; Nasal swab - clinical sensitivity 86%; (from asymptomatic and mild symptomatic individuals), Clinical specificity: 100%<br>*Study design unknown*<br>**ES:**<br>219 samples; Nasal swab - Clinical sensitivity 86% (90%: Ct <30)<br>Specificity: 100% (Method B) | Clinical Sensitivity: 92.3 %<br>Clinical Specificity: 100 %<br>Nasal, NP swab | DK | | DK, ES | | 7 July 2021 |
| DDS DIAGNOSTIC | Test Rapid Covid-19 Antigen (tampon nazofaringian) | 1225 | *Study design unknown*<br>**RO:**<br>Meets the minimum performance requirements. | 98.77% sensitivity<br>99.03% specificity<br>Nasal swab | RO | | RO<br>China | RO | 10 May 2021 |
| DIALAB GmbH | DIAQUICK COVID -19 Ag Cassette | 1375 | *Study design unknown*<br>**BE**:<br>Z20401CE: 93.2% sensitivity, 100% specificity, NP swab<br>Z20601CE: 96.4% sensitivity, 99.2% specificity, NP swab<br>**DE**: 97.3% sensitivity, 100% specificity | | AT, BE, DE[2] | | DE[2] | | 10 May 2021 |
| DNA Diagnostic | COVID-19 Antigen Detection Kit | Yes (2242) | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 99.56% | Sensitivity: 93.8%,<br>Specificity: 99.6%<br>Nasal swab | DE[2] | | DE[2] | | 23 July 2021 |
| Edinburgh Genetics Limited | Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit | 1243 | *Prospective clinical field study*<br>**FIND evaluation**<br>Peru (26 April 2021)<br>120 samples, NP swab<br>Clinical sensitivities:<br>- Days ≤ 7: 62%;<br>- Ct ≤ 33: 75%;<br>- Ct ≤ 25: 100%;<br>Clinical specificity: 100%<br>*Retrospective in vitro studies* | | DE[2] | | DE[2] | | 14 July 2021 |

| Manufacturer | RAT commercial name | Device ID # [3] | Clinical performance as reported by independent validation studies | Clinical performance *Data by manufacturer* | EU Member States using in practice | Other countries using in practice | Completed validation studies | MS currently validating | Included in EU common list since: |
|---|---|---|---|---|---|---|---|---|---|
| | | | **DE:**<br>Positive evaluation by Paul-Ehrlich-Institut<br>(Sensitivity of 100% at <Ct25) + Manufacturer Specificity: 99,24% | | | | | | |
| Eurobio Scientific | EBS SARS-CoV-2 Ag Rapid Test | 1739 | *Prospective clinical field study*<br>**FR**:<br>Validation study data: 119 positive and 125 negative samples; sensitivity 93%, specificity: 99%<br>*Retrospective in vitro studies*<br>**DE:**<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 99,1% | Clinical Sensitivity: 95.7 %<br>Nasal swab | DE[2], FR | | DE[2], FR | | 7 July 2021 |
| Fujirebio | ESPLINE SARS-CoV-2 | 2147 | *Prospective clinical field study*<br>**FIND evaluation**<br>DE (29 March 2021)<br>723 samples, NP swab<br>Clinical sensitivities:<br>- Days ≤ 7: 88.5%;<br>- Ct ≤ 33: 87.8%;<br>- Ct ≤ 25: 92.4%;<br>Clinical specificity: 100%<br>*Retrospective in vitro studies*<br>**DE:**<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 99,13% | Clinical Sensitivity: 87.8 % ( (n=98, Ct<33))<br>Clinical Specificity: 100 %<br>NP swab | DE[2] | | DE[2] | | 7 July 2021 |
| GA Generic Assays GmbH | GA CoV-2 Antigen Rapid Test | Yes (1855) | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 99.2% | Sensitivity: 97.059%,<br>Specificity: 99.2%<br>NP swab | DE[2] | | DE[2] | | 23 July 2021 |
| GenBody Inc | Genbody COVID-19 Ag Test | 1244 | *Study design unknown*<br>**DE**: 90% sensitivity 98% specificity | 90% sensitivity<br>98% specificity<br>NP/OP swab | DE[2] | UA | DE[2] | | 17 February 2021 |
| Genrui Biotech Inc | SARS-CoV-2 Antigen Test Kit (Colloidal Gold) | 2012 | *Retrospective in vitro studies*<br>**DE:**<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 99,02% | Sensitivity: 91.15%<br>Specificity: 99.02%<br>Nasal/NP/OP swab | DE[2] | | DE[2] | | 7 July 2021 |
| GenSure Biotech Inc | GenSure COVID-19 | 1253 | *Retrospective in vitro studies* | 96.86% sensitivity, | DE[2] | | DE[2] | | 10 May 2021 |

| Manufacturer | RAT commercial name | Device ID # [3] | Clinical performance as reported by independent validation studies | Clinical performance *Data by manufacturer* | EU Member States using in practice | Other countries using in practice | Completed validation studies | MS currently validating | Included in EU common list since: |
|---|---|---|---|---|---|---|---|---|---|
| | Antigen Rapid Test Kit | | **DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 100% | 100% specificity<br>Nasal swab | | | | | |
| Getein Biotech, Inc | SARS-CoV-2 Antigen (Colloidal Gold) | 1820 | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 98.71% | 97.06% sensitivity<br>98.71% specificity<br>Nasal swab | AT, DE[2] | | DE[2] | | 14 July 2021 |
| Getein Biotech, Inc. | One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) | 2183 | *Retrospective in vitro studies*<br>**DE:**<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 90% at <Ct30 and 100% at <Ct25) | 97.06% sensitivity<br>98.71% specificity<br>Nasal swab | DE[2] | | DE[2] | | 16 June 2021 |
| Goldsite Diagnostic Inc. | SARS-CoV-2 Antigen Kit (Colloidal Gold) | 1197 | *Retrospective in vitro studies*<br>**DE:**<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity 100% at <Ct25) | | BE, BG, CY, FR, RO, SI, ES | UK | FR, DE[2], ES | | 14 July 2021 |
| Green Cross Medical Science Corp. | GENEDIA W COVID-19 Ag | 1144 | *Study design unknown*<br>**BE**: 90.2% sensitivity, 100% specificity, NP swab<br>**DE**: 90.1% sensitivity, 100% specificity | 100% sensitivity<br>90.1% sensitivity<br>NP swab, Anterior nasal swab | AT, BE, DE[2] | | DE[2] | | 10 May 2021 |
| Guangdong Hecin Scientific, Inc. | 2019-nCoV Antigen Test Kit (colloidal gold method) | 1747 | *Study design unknown*<br>**DE**: 96.6% sensitivity, 99.07% specificity | 96.23% sensitivity<br>Nasal swab | AT, DE[2] | | DE[2] | | 10 May 2021 |
| Guangdong Longsee Biomedical Co., Ltd. | COVID-2019-nCoV Ag Rapid TestDetection Kit(Immuno-Chromatography) | 1216 | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 99.5% | 99.72% specificity<br>NP/OP swab | DE[2] | | DE[2] | | 14 July 2021 |
| Guangdong Wesail Biotech Co. Ltd | COVID-19 Ag Test Kit | 1360 | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 98%<br>*Study design unknown*<br>**SI**: 90% sensitivity, 98% specificity, NP/Nasal swab | 90% sensitivity<br>98% specificity<br>Nasal swab | DE[2], SI | | DE[2] | | 17 February 2021 |
| Guangzhou Decheng Biotechnology CO., Ltd | V-CHEK, 2019-nCoV Ag Rapid Test Kit (Immunochromatography) | 1324 | *Retrospective in vitro studies*<br>**DE:**<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 99,5% | Clinical Sensitivity: 96.67 %<br>Nasal swab | DE[2] | | DE[2] | | 7 July 2021 |
| Guangzhou Wondfo | Wondfo 2019-nCoV | 1437 | *Prospective clinical field study* | | AT, BE, BG, | CH | DE[2] | | 10 May 2021 |

| Manufacturer | RAT commercial name | Device ID # [3] | Clinical performance as reported by independent validation studies | Clinical performance *Data by manufacturer* | EU Member States using in practice | Other countries using in practice | Completed validation studies | MS currently validating | Included in EU common list since: |
|---|---|---|---|---|---|---|---|---|---|
| Biotech Co., Ltd | Antigen Test (Lateral Flow Method) | | **FIND evaluation**<br>CH (25 Feb 2020)<br>328 samples, NP swab<br>Clinical sensitivities:<br>- Days ≤ 7: 85.7%;<br>- Ct ≤ 33: 92.2%;<br>- Ct ≤ 25: 100%;<br>Clinical specificity: 100%<br>*Study design unknown*<br>**BE**: 96.2% sensitivity, 99.7% specificity, NP/OP swab<br>**DE**: 96.18 % sensitivity, 99.72% specificity | | DE[2], FR | | | | |
| Hangzhou Lysun Biotechnology Co. Ltd | COVID-19 Antigen Rapid Test Device (Colloidal Gold) | 2139 | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 100% | 96.46% sensitivity<br>100% specificity<br>Nasal swab | DE[2] | CH | DE[2] | | 10 May 2021 |
| Hangzhou AllTest Biotech Co., Ltd | COVID-19 Antigen Rapid Test | 1257 | *Study design unknown*<br>**DE:** 93,40% sensitivity, 99,90% specificity | NP swab | AT, BE, BG, FR, SI, RO | CH | DE[2] | AT | 10 May 2021 |
| Hangzhou Clongene Biotech Co., Ltd | COVID-19 Antigen Rapid Test Casette | 1610 | *Retrospective in vitro studies*<br>**DE:**<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,4% at <Ct25) + Manufacturer specificity: 100% | Clinical Sensitivity: 91.4 %<br>Clinical Specificity: 100 %<br>NP swab | DE[2] | | DE[2] | | 7 July 2021 |
| Hangzhou Clongene Biotech Co., Ltd. | Covid-19 Antigen Rapid Test Kit | 1363 | *Study design unknown*<br>**BE**: 91.4% sensitivity, 100% specificity, NP/OP swab<br>**DE**: 91.4% sensitivity, 99.4% specificity<br>**SI**: 91.4% sensitivity, 100% specificity, NP/OP swab | 98.5% (Ct<33) sensitivity<br>Nasal swab | AT,BE, DE[2], FR, SI | CH | DE[2]<br>CH | HR | 17 February 2021 |
| Hangzhou Clongene Biotech Co., Ltd. | COVID-19/Influenza A+B Antigen Combo Rapid Test | 1365 | *Study design unknown*<br>**DE**: 97.7% sensitivity, 99.8% specificity | 91% sensitivity<br>100% specificity<br>NP swab | DE[2] | | DE[2] | | 10 May 2021 |
| Hangzhou Immuno Biotech Co., Ltd | Immunobio SARS-CoV-2 Antigen ANTERIOR NASAL Rapid Test Kit (minimal invasive) | 1844 | *Study design unknown*<br>**DE**: 94.39% sensitivity 97.67% specificity | 94% sensitivity<br>100% specificity<br>Nasal swab, NP | DE[2] | | DE[2] | | 10 May 2021 |
| Hangzhou Immuno | SARS-CoV2 Antigen Rapid | 2317 | *Study design unknown* | Clinical Sensitivity | AT, DE[2] | | DE[2] | | 10 May 2021 |

| Manufacturer | RAT commercial name | Device ID # [3] | Clinical performance as reported by independent validation studies | Clinical performance *Data by manufacturer* | EU Member States using in practice | Other countries using in practice | Completed validation studies | MS currently validating | Included in EU common list since: |
|---|---|---|---|---|---|---|---|---|---|
| Biotech Co., Ltd | Test | | **DE**: 95.6% sensitivity, 100% specificity | 98 %<br>Clinical Specificity 100 % | | | | | |
| Hangzhou Laihe Biotech Co. | LYHER Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) | 1215 | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 99,7% | Clinical Sensitivity: 95.07% %<br>Clinical Specificity: 99.74%<br>Nasal swab | AT, DE[2] | CH | DE[2] | | 10 May 2021 |
| Hangzhou Testsea Biotechnology Co., Ltd. | Covid-19 Antigen Test Cassette | 1392 | *Study design unknown*<br>**DE**: 97.6% sensitivity 98.4% specificity | 92.1% sensitivity<br>98.1% specificity<br>Nasal swab | DE[2] | | DE[2] | | 10 May 2021 |
| Healgen Scientific | Coronavirus Ag Rapid Test Cassette | 1767 | *Study design unknown*<br>**DE**: 97.25% sensitivity, 100% specificity<br>**SI**:96.7% sensitivity, 99.2% specificity, NP/Nasal swab | 80.6 % sensitivity<br>99.7% specificity<br>NP swab | AT, DE[2], NL[5], SE, SI | CH | DE[2], NL[5] | SE[3] | 17 February 2021 |
| Hubei Jinjian Biology Co., Ltd | SARS-CoV-2 Antigen Test Kit | Yes (1759) | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 99.3 % | Sensitivity: 98.02%<br>Nasal Swab | DE[2] | | DE[2] | | 23 July 2021 |
| Humasis | Humasis COVID-19 Ag Test | 1263 | *Study design unknown*<br>**BE**: 95.5% sensitivity, 100% specificity, NP swab<br>**DE**: 95.5% sensitivity, 100% specificity<br>**SI**: 95.5% sensitivity, 100% specificity, NP swab | 95.3% sensitivity<br>Nasal swab | AT, BE, BG, DE[2], FR, HR, SE, SI | | DE[2] | HR, SE | 10 May 2021 |
| Jiangsu Bioperfectus Technologies Co., Ltd. | Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit | 2107 | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 99.15% | 97.06 % sensitivity<br>99.15 % specificity<br>Nasal/NP/ OP swab | DE[2] | | DE[2] | | 14 July 2021 |
| Jiangsu Diagnostics Biotechnology Co., Ltd | COVID-19 Antigen Rapid Test Cassette (Colloidal Gold) | 1920 | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 100% | 97.58 % sensitivity<br>100 % specificity<br>Nasal/NP/ OP swab | DE[2] | | DE[2] | | 14 July 2021 |
| Jiangsu Medomics medical technology Co.,Ltd. | SARS-CoV-2 antigen Test Kit (LFIA) | 2006 | *Retrospective in vitro studies*<br>**DE:**<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 99,51% | Clinical Sensitivity: 97.73 %<br>Clinical Specificity: 99.51 %<br>Anterior nasal swab, NP swab | DE[2] | | DE[2] | | 7 July 2021 |
| Joinstar Biomedical | COVID-19 Rapid Antigen | 1333 | *Study design unknown* | 96.1% sensitivity | AT, DE[2], | | DE[2] | | 17 February |

| Manufacturer | RAT commercial name | Device ID # [3] | Clinical performance as reported by independent validation studies | Clinical performance *Data by manufacturer* | EU Member States using in practice | Other countries using in practice | Completed validation studies | MS currently validating | Included in EU common list since: |
|---|---|---|---|---|---|---|---|---|---|
| Technology Co. Ltd | Test (Colloidal Gold) | | **DE**: 96.1% sensitivity, 98.1% specificity<br>**SI**:96.1% sensitivity, 98.1% specificity, NP swab | 98.1% specificity<br>Nasal swab | PT, SI | | | | 2021 |
| JOYSBIO (Tianjin) Biotechnology Co., Ltd. | SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold immunochromatography) | 1764 | *Prospective clinical field study*<br>**FIND Evaluation**<br>CH (11 Feb 2021)<br>265 samples, Nasal swab<br>Clinical sensitivities:<br>- Days ≤ 7: 74.2%;<br>- Ct ≤ 33: 78.9%;<br>- Ct ≤ 25: 91.3%;<br>Clinical specificity: 99.1%<br>*Study design unknown*<br>**CZ:**<br>Meets the minimum performance requirements – see report for details. | 98.13% sensitivity<br>Nasal swab | AT, CZ, SI | | CZ, DE[2]<br>CH | | 10 May 2021 |
| Labnovation Technologies Inc. | SARS-CoV-2 Antigen Rapid Test Kit | 1266 | *Study design unknown*<br>**DE**: 96.3% sensitivity, 97.3% specificity<br>**SI**: 96.3% sensitivity, 97.3% specificity, NP/OP swab | NP/OP swab | DE[2], IT, SI | | DE[2] | | 10 May 2021 |
| Lumigenex (Suzhou) Co., Ltd | PocRoc® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) | 2128 | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 99,16% | 93.33% sensitivity<br>99.16% specificity<br>Nasal/NP/OP swab | DE[2] | | DE[2] | | 10 May 2021 |
| LumiQuick Diagnostics Inc. | QuickProfile™ COVID-19 Antigen Test | 1267 | *Study design unknown*<br>**BE**: 94% sensitivity, 99% specificity, NP swab<br>**DE**: 93.7% sensitivity, 98.8% specificity<br>**SI**: 93.7% sensitivity, 98.8% specificity, NP swab | | BE, DE[2] ,FR, SI, | | DE[2] | | 10 May 2021 |
| LumiraDX | LumiraDx SARS-CoV-2 Ag Test | 1268 | *Study design unknown*<br>**DE**:93.8% sensitivity, 98.8% specificity<br>**SI**: 97.6% sensitivity, 97.7% specificity, NP/Nasal swab<br>**SKUP/2021/124**: 90% sensitivity, 97,8% specificity, NP swab (Scandinavian evaluation of laboratory equipment for point of care testing)) | 97.6% sensitivity<br>96.6% specificity<br>Nasal swab | DE[2], ES, SI | CH | DE[2], ES, SKUP<br>CH | | 17 February 2021 |
| MEDsan GmbH | MEDsan SARS-CoV-2 | 1180 | *Study design unknown* | 92.5% sensitivity | AT, BE, DE[2] | CH | DE[2] | | 17 February |

| Manufacturer | RAT commercial name | Device ID # [3] | Clinical performance as reported by independent validation studies | Clinical performance *Data by manufacturer* | EU Member States using in practice | Other countries using in practice | Completed validation studies | MS currently validating | Included in EU common list since: |
|---|---|---|---|---|---|---|---|---|---|
| | Antigen Rapid Test | | **BE**: 92.5% sensitivity, 99.8% specificity, Nasal/OP swab<br>**DE**: 92.5% sensitivity, 99.8% specificity | 99.8% specificity NP/OP swab | | | CH | | 2021 |
| Merlin Biomedical (Xiamen) Co., Ltd. | SARS-CoV-2 Antigen Rapid Test Cassette | 2029 | *Retrospective in vitro studies*<br>**DE:**<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 90% at <Ct30 and 100% at <Ct25) | 95.05% sensitivity<br>98.99% specificity<br>Nasal/NP swab | DE[2] | | DE[2] | | 16 June 2021 |
| MEXACARE GmbH | MEXACARE COVID-19 Antigen Rapid Test | 1775 | *Retrospective in vitro studies*<br>**DE:**<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 99,1% | Clinical Sensitivity: 96.17 %<br>Nasal swab | DE[2] | | DE[2] | | 7 July 2021 |
| möLab | mö-screen Corona Antigen Test | 1190 | *Study design unknown*<br>**DE**:<br>97.25% sensitivity , 99.99% specificity | NP swab | DE[2], IE | | DE[2], IE | | 10 May 2021 |
| MP Biomedicals | Rapid SARS-CoV-2 Antigen Test Card | 1481 | *Study design unknown*<br>**BE**: 96.4% sensitivity, 99% specificity, NP/OP swab<br>**DE:** 96.39 % sensitivity, 99.03% specificity | 96.17% sensitivity<br>99.16% specificity<br>Nasal swab, Anterior nasal swab | AT, BE, DE[2] | CH | DE[2]<br>CH | | 17 February 2021 |
| Nal von minden GmbH | NADAL COVID -19 Ag +Influenza A/B Test | 2104 | *Study design unknown*<br>**DE**:<br>97.6% sensitivity, 99.9% specificity | 97% sensitivity<br>98% specificity<br>NP swab | DE[2] | | DE[2] | | 10 May 2021 |
| Nal von minden GmbH | NADAL COVID -19 Ag Test | 1162 | *Prospective clinical field study*<br>**FIND evaluation**<br>CH (26 April 2021)<br>462 samples, NP swab<br>Clinical sensitivities:<br>- Days ≤ 7: 88.5%;<br>- Ct ≤ 33: 92.4%;<br>- Ct ≤ 25: 97.8%;<br>Clinical specificity: 99.2%<br>*Study design unknown*<br>**BE**: 97.6% sensitivity, 99.9% specificity, NP/OP swab<br>**DE**:97.6% sensitivity, 99.9% specificity<br>**SI**: 97.6% sensitivity, 99.9% specificity, NP/OP swab | 97.6% sensitivity<br>99.9% specificity<br>Nasal swab | AT, BE, CY DE[2], FR, PT, SI | | DE[2], FR<br>China | HR, SKUP | 17 February 2021 |
| NanoEntek | FREND COVID-19 Ag | 1420 | *Study design unknown* | 94.12% sensitivity | DE[2] | | DE[2] | | 10 May 2021 |

| Manufacturer | RAT commercial name | Device ID # [3] | Clinical performance as reported by independent validation studies | Clinical performance *Data by manufacturer* | EU Member States using in practice | Other countries using in practice | Completed validation studies | MS currently validating | Included in EU common list since: |
|---|---|---|---|---|---|---|---|---|---|
| | | | **DE**:<br>94.12% sensitivity , 100% specificity | 100% specificity<br>NP swab | | | | | |
| NanoRepro AG | NanoRepro SARS-CoV-2 Antigen Rapid Test | 2200 | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 98.4% | 97.2 % sensitivity<br>98.4% specificity<br>Nasal/NP/OP swab | DE[2] | | DE[2] | | 14 July 2021 |
| NESAPOR EUROPA SL | MARESKIT COVID-19 ANTIGEN RAPID TEST KIT | Yes (2241) | *Study design unknown*<br>**ES:**<br>Independent validation study; Nasal test compared to nasal PCR. Sensitivity 95.24%, Specificity 100%. | Sensitivity: 95.24%,<br>Specificity: 100%<br>Nasal swab | ES | | ES | | 23 July 2021 |
| New Gene (Hangzhou) Bioengineering Co., Ltd. | COVID-19 Antigen Detection Kit | 1501 | *Retrospective in vitro studies*<br>**DE:**<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 92,5% at <Ct30 and 100% at <Ct25) | 98% sensitivity<br>Nasal swab | DE[2] | | DE[2] | | 16 June 2021 |
| Novatech | SARS-CoV-2 Antigen Rapid Test | 1762 | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 100% | 95 % sensitivity<br>100% specificity<br>Nasal/ NP swab | DE[2] | | DE[2] | | 14 July 2021 |
| Oncosem Onkolojik Sistemler San. ve Tic. A.S. | CAT | 1199 | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 98,04% | 93.75% sensitivity<br>98.04% specificity<br>Nasal swab | DE[2] | | DE[2] | | 10 May 2021 |
| PCL Inc. | PCL COVID19 Ag Rapid FIA | 308 | *Study design unknown*<br>**DE**: 94,92 % sensitivity, 99,99 % specificity<br>**SI**: 95.5% sensitivity, 98.6% specificity, NP/OP swab | | FR, DE[2], RO, SI | | DE[2] | | 10 May 2021 |
| PCL Inc. | PCL COVID19 Ag Gold | 2243 | *Prospective clinical field study*<br>**FR**:<br>Validation study data: 120 positive and 200 negative samples; sensitivity 92%, specificity: 100% | | FR, PT | | FR | | 7 July 2021 |
| PerGrande Bio Tech Development Co., Ltd. | SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromato-graphic Assay) | 2116 | *Study design unknown*<br>**DE**:<br>94.28% sensitivity, 99.11% specificity | 94.28% sensitivity<br>99.11% specificity<br>NP/Nasal/OP swab | AT, DE[2] | | DE[2] | | 10 May 2021 |
| Precision Biosensor | Exdia COVI-19 Ag | 1271 | *Study design unknown* | 93.9% sensitivity | SI, DE[2] | CH | DE[2] | | 17 February |

| Manufacturer | RAT commercial name | Device ID # [3] | Clinical performance as reported by independent validation studies | Clinical performance *Data by manufacturer* | EU Member States using in practice | Other countries using in practice | Completed validation studies | MS currently validating | Included in EU common list since: |
|---|---|---|---|---|---|---|---|---|---|
| Inc. | | | **DE**: 93.88% sensitivity , 98% specificity<br>**SI**:93.9% sensitivity, 98% specificity, NP swab | 98% specificity<br>NP swab | | | CH | | 2021 |
| Prognosis Biotech | Rapid Test Ag 2019-nCov | 1495 | *Retrospective in vitro studies*<br>**DE:**<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 99,58% | Clinical Sensitivity: 95.56 %<br>Nasal swab | CY, DE[2] | | DE[2] | | 7 July 2021 |
| Qingdao Hightop Biotech Co. Ltd | SARS-CoV-2 Antigen Rapid Test (Immunochromatography) | 1341 | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct30 and 100% at <Ct25) | 95% sensitivity<br>Nasal swab | AT, DE[2] | | DE[2] | | 17 February 2021 |
| Quidel Corporation | Sofia SARS Antigen FIA | 1097 | *Study design unknown*<br>**BE**: 96.7% sensitivity, 100% specificity, NP/nasal swab<br>**DE**: 96.7% sensitivity , 100% specificity<br>**SI**: 96.7% sensitivity, 100% specificity, NP/Nasal swab | 96.7% sensitivity<br>100% specificity<br>NP/Nasal swab | AT, BE, DE[2], FI, NL[5], PT, SI | CH | DE[2], NL[5]<br>CH | SI | 17 February 2021 |
| Rapid Pathogen Screening, Inc | LIAISON® Quick Detect Covid Ag Assay | Yes (2290) | *Study design unknown*<br>**IT:** Independent validation study, 100 pos. and 100 neg. samples; sensitivity: 92.7% with Ct<25; specificity: 100%. | Sensitivity: 96.1%, Specificity: 97%<br>NP and Nasal swab | IT | | IT | | 23 July 2021 |
| Roche (SD BIOSENSOR) | SARS-CoV-2 Rapid Antigen Test | 1604 | *Retrospective in vitro studies*<br>**FI:** Validated in several laboratories (studies not published), meeting criteria.<br>*Study design unknown*<br>**DE**: 96.52% sensitivity, 99.68% specificity | 96.52% sensitivity<br>99.2% specificity<br>NP swab | AT, DE[2], MT, NL, RO | CH, NO | DE[2], FI | | 10 May 2021 |
| Roche (SD BIOSENSOR) | SARS-CoV-2 Rapid Antigen Test Nasal | 2228 | *Prospective clinical field study*<br>**FIND evaluation**<br>DE (12 April 2021)<br>179 samples, nasal swab<br>Clinical sensitivities:<br>- Days ≤ 7: 81.2%;<br>- Ct ≤ 33: 87.5%;<br>- Ct ≤ 25: 100%;<br>Clinical specificity: 99.3%<br>Brazil (12 April 2021)<br>214 samples, nasal swab<br>Clinical sensitivities:<br>- Days ≤ 7: 81.2%; | Clinical Sensitivity: 89.6 % ( (Ct ≤ 30) 93.1 % (Ct ≤ 27)<br>Clinical Specificity: 99.1 %<br>Nasal swab | DK, SK | CH, UK | DE[2] | | 7 July 2021 |

| Manufacturer | RAT commercial name | Device ID # [3] | Clinical performance as reported by independent validation studies | Clinical performance *Data by manufacturer* | EU Member States using in practice | Other countries using in practice | Completed validation studies | MS currently validating | Included in EU common list since: |
|---|---|---|---|---|---|---|---|---|---|
| | | | - Ct ≤ 33: 91.7%;<br>- Ct ≤ 25: 100%;<br>Clinical specificity: 99.3%<br>*Retrospective in vitro studies*<br>**DE:**<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 89.6% at <Ct30) | | | | | | |
| Safecare Biotech (Hangzhou) Co. Ltd | COVID-19 Antigen Rapid Test Kit (Swab) | 1489 | *Study design unknown*<br>**DE**:<br>97.27 % sensitivity , 99.42% specificity | 97.04% sensitivity<br>Nasal swab | AT, DE[2], FR | CH | DE[2] | | 17 February 2021 |
| Safecare Biotech (Hangzhou) Co. Ltd | Multi-Respiratory Virus Antigen Test Kit (Swab) (Influenza A+B/COVID-19) | 1490 | *Study design unknown*<br>**DE**:<br>97.04% sensitivity , 99.44% specificity | 97.04% sensitivity<br>Nasal swab | DE[2] | | DE[2] | | 10 May 2021 |
| ScheBo Biotech AG | ScheBo SARS CoV-2 Quick Antigen | 1201 | *Retrospective in vitro studies*<br>**DE:**<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 95% at <Ct30 and 100% at <Ct25) | 96.6% sensitivity<br>(Ct ≤ 30)<br>NP/ OP swab | DE[2] | | DE[2] | | 16 June 2021 |
| SD Biosensor Inc | STANDARD Q COVID-19 Ag Test Nasal | 2052 | *Prospective clinical field study*<br>**FIND evaluation**<br>DE (12 April 2021)<br>179 samples, nasal swab<br>Clinical sensitivities:<br>- Days ≤ 7: 81.2%;<br>- Ct ≤ 33: 87.5%;<br>- Ct ≤ 25: 100%;<br>Clinical specificity: 99.3%<br><br>Brazil (12 April 2021)<br>214 samples, nasal swab<br>Clinical sensitivities:<br>- Days ≤ 7: 81.2%;<br>- Ct ≤ 33: 91.7%;<br>- Ct ≤ 25: 100%;<br>Clinical specificity: 99.3%<br>*Retrospective in vitro studies* | Clinical Sensitivity: 97.12 %<br>Clinical Specificity: 100 %<br>Nasal swab | FI, PT, SK | | DE[2], FI, FR | | 7 July 2021 |

| Manufacturer | RAT commercial name | Device ID # [3] | Clinical performance as reported by independent validation studies | Clinical performance *Data by manufacturer* | EU Member States using in practice | Other countries using in practice | Completed validation studies | MS currently validating | Included in EU common list since: |
|---|---|---|---|---|---|---|---|---|---|
| | | | **FI:** Validated in several laboratories (studies not published), meeting criteria.<br>*Study design unknown*<br>**DE**: Published study: https://www.medrxiv.org/content/10.1101/2021.01.06.20249009v1 | | | | | | |
| SD BIOSENSOR Inc. | STANDARD F COVID-19 Ag FIA | 344 | *Prospective clinical field study*<br>**FIND evaluation**<br>DE (10 Dec 2020)<br>676 samples, NP swab<br>Clinical sensitivities:<br>- Days ≤ 7: 81.2%;<br>- Ct ≤ 33: 75%;<br>- Ct ≤ 25: 100%;<br>Clinical specificity: 96.9%<br><br>Brazil (10 Dec 2020)<br>453 samples, NP swab<br>Clinical sensitivities:<br>- Days ≤ 7: 80.2%;<br>- Ct ≤ 33: 80.9%;<br>- Ct ≤ 25: 87.9%;<br>Clinical specificity: 97.9%<br><br>India (25 June 2020)<br>417 samples, NP swab<br>Clinical sensitivities:<br>- Days ≤ 7: 61.8%;<br>- Ct ≤ 33: 53.6%;<br>- Ct ≤ 25: 68.5%;<br>Clinical specificity: 99.5%<br>*Study design unknown*<br>**BE**: 96.5% sensitivity, 99.7% specificity, NP swab<br>**DE**: 94% sensitivity 97% specificity | 94,09% sensitivity<br>98.52% specificity<br>NP swab | AT, BE, BG, DE[2], IT , LU, LV, NL[5], PT, RO, SK | CH | DE[2], IT, NL[5], DK CH, UK, BR | LU, PT | 17 February 2021 |
| SD BIOSENSOR Inc. | STANDARD Q COVID-19 | 345 | *Prospective clinical field study* | 96.52% sensitivity | AT, BE, BG, | ME, NO, CH | DE[2], ES, | HR, IE, LU, | 17 February |

| Manufacturer | RAT commercial name | Device ID # [3] | Clinical performance as reported by independent validation studies | Clinical performance *Data by manufacturer* | EU Member States using in practice | Other countries using in practice | Completed validation studies | MS currently validating | Included in EU common list since: |
|---|---|---|---|---|---|---|---|---|---|
| | Ag Test | | **FIND evaluation**<br>DE (10 Dec 2020)<br>1263 samples, NP swab<br>Clinical sensitivities:<br>- Days ≤ 7: 80%;<br>- Ct ≤ 33: 87.8%;<br>- Ct ≤ 25: 100%;<br>Clinical specificity: 99.3%<br><br>Brazil (10 Dec 2020)<br>400 samples, NP swab<br>Clinical sensitivities:<br>- Days ≤ 7: 90.7%;<br>- Ct ≤ 33: 91.9%;<br>- Ct ≤ 25: 95.9%;<br>Clinical specificity: 97.6%<br><br>CH (10 Dec 2020)<br>529 samples, NP swab<br>Clinical sensitivities:<br>- Days ≤ 7: 89.8%;<br>- Ct ≤ 33: 91.8%;<br>- Ct ≤ 25: 97.2%;<br>Clinical specificity: 99.7%<br><br>India (22 April 2021)<br>334 samples, NP swab<br>Clinical sensitivities:<br>- Days ≤ 7: 58.3%;<br>- Ct ≤ 33: 65.5%;<br>- Ct ≤ 25: 89.4%;<br>Clinical specificity: 97.3%<br><br>Peru (22 April 2021)<br>335 samples, NP swab<br>Clinical sensitivities:<br>- Days ≤ 7: 81.4%;<br>- Ct ≤ 33: 83.3%;<br>- Ct ≤ 25: 96.2%;<br>Clinical specificity: 99.6%<br>*Retrospective in vitro studies* | 99.68% specificity<br>NP swab | CY, DE[2], DK, EE, ES, FI, FR, HR, IT, LU, LV, MT, NL[5], PT, RO, SE, SK, SI | | IT, NL[5], DK, PT<br>CH, UA,<br>UK, BR, NO | SI, SE | 2021 |

| Manufacturer | RAT commercial name | Device ID # [3] | Clinical performance as reported by independent validation studies | Clinical performance *Data by manufacturer* | EU Member States using in practice | Other countries using in practice | Completed validation studies | MS currently validating | Included in EU common list since: |
|---|---|---|---|---|---|---|---|---|---|
| | | | **FI:**<br>Validated in several laboratories (studies not published), meeting criteria.<br>*Study design unknown*<br>**BE**: 96.5% sensitivity, 99.7% specificity, NP swab<br>**DE**: 96.52% sensitivity, 99.68% specificity<br>**SI**: 96.5% sensitivity, 99.7% specificity, NP swab | | | | | | |
| SGA Medikal | V-Chek SARS-CoV-2 Ag Rapid Test Kit (Colloidal Gold) | 1319 | *Study design unknown*<br>**DE**:<br>96.6% sensitivity, 99% specificity | 96.6% sensitivity, Nasal swab | DE[2] | | DE[2] | | 10 May 2021 |
| SGA Medikal | V-Chek SARS-CoV-2 Rapid Ag Test (colloidal gold) | 1357 | *Retrospective in vitro studies*<br>**DE:**<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 99,5% | Clinical Sensitivity: 96.60%<br>Nasal swab | DE[2] | | DE[2] | | 7 July 2021 |
| Shenzen Ultra-Diagnostics Biotec Co., Ltd | SARS-CoV-2 Antigen Test Kit | 2017 | *Study design unknown*<br>**BE**:<br>92% sensitivity, 100% specificity, NP swab<br>100% sensitivity, 100% specificity, OP swab<br>**SI**: 95.9% sensitivity, 99.9% specificity, NP/OP/Nasal swab | Clinical Sensitivity: 95.33 % (Nasal), 95.48(NP)<br>Clinical Specificity: 99.16 % (Nasal), 99.61 % (NP) | AT, BE, ES, SI | | BE, SI | | 10 May 2021 |
| Shenzhen Lvshiyuan Biotechnology Co., Ltd. | Green Spring SARS-CoV-2 Antigen-Rapid test-Set | 2109 | *Study design unknown*<br>**DE**: 98% sensitivity , 100% specificity | 98% sensitivity<br>100% specificity<br>NP/OP/Nasal swab | DE[2] | | DE[2] | | 10 May 2021 |
| Shenzhen Microprofit Biotech Co., Ltd | SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay) | 1967 | *Retrospective in vitro studies*<br>**DE:**<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 100% | Clinical Sensitivity: 92.93 %<br>Clinical Specificity: 100 %<br>Nasal/NP/OP swab | DE[2], ES | | DE[2] | | 7 July 2021 |
| Shenzhen Microprofit Biotech Co., Ltd. | SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay) | 1178 | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 100% | Sensitivity: 86.3%, Specificity: 100%<br>Nasal Swab | DE[2] | | DE[2] | | 23 July 2021 |
| Shenzhen Watmind Medical Co., Ltd | SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold) | 1769 | *Study design unknown*<br>**DE**: 95.15% sensitivity , 99.12% specificity | 95.15% Sensitivity<br>Nasal swab | AT, DE[2], FR | | DE[2] | | 10 May 2021 |
| Shenzhen Watmind | SARS-CoV-2 Ag Diagnostic | 1768 | *Retrospective in vitro studies* | Clinical Sensitivity: | DE[2] | | DE[2] | | 7 July 2021 |

| Manufacturer | RAT commercial name | Device ID # [3] | Clinical performance as reported by independent validation studies | Clinical performance *Data by manufacturer* | EU Member States using in practice | Other countries using in practice | Completed validation studies | MS currently validating | Included in EU common list since: |
|---|---|---|---|---|---|---|---|---|---|
| Medical Co., Ltd | Test Kit (Immuno-fluorescence) | | **DE:**<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 99,13% | 97.83 % (CT ≤ 33)<br>Clinical Sensitivity: 90.08 % (Ct ≤ 36)<br>Nasal swab | | | | | |
| Shenzhen Zhenrui Biotech Co., Ltd | Zhenrui ®COVID-19 Antigen Test Cassette | 1574 | *Study design unknown*<br>**DE**: 96% sensitivity 97% specificity | 96% sensitivity<br>Nasal swab | DE[2] | | DE[2] | | 10 May 2021 |
| Siemens Healthineers | CLINITEST Rapid COVID-19 Antigen Test | 1218 | *Study design unknown*<br>**BE**:<br>98.32% sensitivity, 99.6% specificity, NP swab<br>97.25% sensitivity, 100% specificity, Nasal swab<br>**SI**: 96.7% sensitivity, 99.2% specificity, NP/Nasal swab | 98.32% sensitivity (NP swab)<br>97.25% sensitivity<br>100% specificity (Nasal swab) | AT, BE, DE[2], FR, HR, NL[5], PT, SE, SI | CH | DE[2], ES, NL[5] | HR, PT, SE[3] | 17 February 2021 |
| Sugentech, Inc. | SGTi-flex COVID-19 Ag | 1114 | *Retrospective in vitro studies*<br>**DE**: Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct30 and 100% at <Ct25) | 100% sensitivity<br>100% specificity<br>OP/NP swab | AT, DE[2] | | DE[2] | | 10 May 2021 |
| TODA PHARMA | TODA CORONADIAG Ag | 1466 | *Study design unknown*<br>**BE**: 96.6% sensitivity, 100% specificity, NP/OP swab<br>**DE**: 96.6% sensitivity, 100 specificity<br>**SI**: 96.6% sensitivity, 100% specificity, NP/OP swab | 98.6% sensitivity<br>Nasal swab | BE, DE[2], SI | | DE[2] | | 10 May 2021 |
| Triplex International Biosciences Co., Ltd | SARS-CoV-2 Antigen Rapid Test Kit | 2074 | *Retrospective in vitro studies*<br>**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 92,5% at <Ct30 and 100% at <Ct25) | 98.33% sensitivity<br>100% specificity<br>Nasal/OP/NP swab | DE[2] | | DE[2] | | 16 June 2021 |
| Triplex International Biosciences Co., Ltd, China | SARS-CoV-2 Antigen Rapid Test Kit | 1465 | *Retrospective in vitro studies*<br>**DE**: Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 100% | 98.51 % sensitivity<br>Nasal swab | DE[2], FR, PT | | DE[2] | | 14 July 2021 |
| Vitrosens Biotechnology Co., Ltd | RapidFor SARS-CoV-2 Rapid Ag Test | 1443 | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct30 and 100% at <Ct25)<br>*Study design unknown*<br>**SI**:<br>97.3% sensitivity, 99% specificity, NP/OP/Nasal swab | 97.3% sensitivity<br>Nasal swab | DE[2], SI | | DE[2] | | 10 May 2021 |

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|---|---|---|---|---|---|---|---|---|---|
| VivaChek Biotech (Hangzhou) Co., Ltd. | VivaDiag Pro SARS-CoV-2 Ag Rapid Test | 2103 | *Study design unknown*<br>**AT**:<br>97,06% sensitivity, 100% specificity, all specimen types, i.e. N&OP&NP swab | 97.04% sensitivity<br>99.9% specificity<br>Nasal/OP/NP swab | AT, SI | | AT, DE[2], SI | AT | 10 May 2021 |
| Wuhan EasyDiagnosis Biomedicine Co., Ltd. | COVID-19 (SARS-CoV-2) Antigen-Test Kit | 2098 | *Study design unknown*<br>**DE**: 96.15% sensitivity , 99.26% specificity | 96.1% sensitivity<br>100% specificity<br>Nasal/OP/NP swab | DE[2] | | DE[2] | | 10 May 2021 |
| Wuhan Life Origin Biotech Joint Stock Co., Ltd. | SARS-CoV-2 Antigen Assay Kit (Immunochromatography) | 1773 | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: xx% | 92.67% sensitivity<br>Nasal swab | DE[2] | | DE[2] | | 14 July 2021 |
| Wuhan UNscience Biotechnology Co., Ltd. | SARS-CoV-2 Antigen Rapid Test Kit | 2090 | *Retrospective in vitro studies*<br>**DE:**<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 99,57% | Sensitivity: 96.33%<br>Specificity: 99.57%<br>Nasal/NP/OP swab | DE[2] | | DE[2], FR | | 7 July 2021 |
| Xiamen AmonMed Biotechnology Co., Ltd | COVID-19 Antigen Rapid Test Kit (Colloidal Gold) | 1763 | *Retrospective in vitro studies*<br>**DE**:<br>Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 99.55% | 93.2% sensitivity<br>99.55% specificity<br>Nasal swab | DE[2] | | DE[2] | | 10 May 2021 |
| Xiamen Boson Biotech Co. Ltd | Rapid SARS-CoV-2 Antigen Test Card | 1278 | *Study design unknown*<br>**BE**: 93.8% sensitivity, 100% specificity, NP swab<br>**DE**: 96.49% sensitivity, 99.03% specificity | Not specified<br>NP swab | AT, BE, BG, CY, DE[2], FR, RO | CH | DE[2]<br>CH | | 17 February 2021 |
| Xiamen Wiz Biotech Co., Ltd | SARS-CoV-2 Antigen Rapid Test | 1456 | *Study design unknown*<br>**DE**: 96.3% sensitivity, 100% specificity | 96.3% sensitivity,<br>Nasal swab | AT, DE[2] | | DE[2] | | 10 May 2021 |
| Xiamen Wiz Biotech Co., Ltd | SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) | 1884 | *Study design unknown*<br>**DE**: 95.91% sensitivity , 100% specificity | 95.91% sensitivity<br>100% specificity<br>Nasal swab | AT, DE[2] | | DE[2] | | 10 May 2021 |
| Zhejiang Anji Saianfu Biotech Co.., Ltd | AndLucky COVID-19 Antigen Rapid Test | 1296 | *Study design unknown*<br>**DE**: 97.5% sensitivity, 99.1% specificity | 95.8% sensitivity,<br>Nasal swab | AT, DE[2] | | DE[2] | | 10 May 2021 |
| Zhejiang Anji Saianfu Biotech Co.., Ltd | reOpenTest COVID-19 Antigen Rapid Test | 1295 | *Retrospective in vitro studies*<br>**DE**: Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 99% | 95.8% sensitivity,<br>Nasal swab | DE[2] | | DE[2] | | 10 May 2021 |

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|---|---|---|---|---|---|---|---|---|---|
| Zhejiang Orient Gene Biotech Co., Ltd | Coronavirus Ag Rapid Test Cassette (Swab) | 1343 | *Study design unknown*<br>**BE**: 98.32% sensitivity, 99.6% specificity, NP swab; 97.25% sensitivity, 100% specificity, Nasal swab<br>**DE**: 96.72% sensitivity, 99.22% specificity | 98.32 % sensitivity 99.6 % specificity Nasal/NP swab | AT, BE, BG, DE[2], PT | CH, UK | DE[2] | SE[3] | 17 February 2021 |
| Zhuhai Lituo Biotechnology Co., Ltd. | COVID-19 Antigen Detection Kit (Colloidal Gold) | 1957 | *Retrospective in vitro studies*<br>**DE**: Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 100% | 96.12% sensitivity Nasal swab (CT≤33); 99.59% sensitivity NP swab; 100% specificity Nasal swab (CT≤33) | CZ, DE[2], SI | | DE[2] | | 14 July 2021 |