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|  | EUROPEAN COMMISSIONDIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETYPublic health, country knowledge, crisis management**Health Security** |

EU health preparedness:

A common list of COVID-19 rapid antigen tests and a common standardised set of data to be included in COVID-19 test result certificates

Agreed by the Health Security Committee

*This document was agreed by the HSC on 17 February 2021*

**Annex I**

**Common list of COVID-19 rapid antigen tests**

*A first update was agreed by the HSC on 10 May 2021; A second update was agreed by the HSC on 16 June 2021; A third update was agreed by the HSC on 7 July 2021; A fourth update was agreed by the HSC on 14 July 2021; A fifth update was agreed by the HSC on 23 July 2021.*

**IMPORTANT: A (interim) grace period of 8 weeks applies whenever updates are made to Annex I, the common list of COVID-19 rapid antigen tests**

**Annex II**

**Common standardised data set to be included in COVID-19 test result certificates**

*An update to Annex II was agreed by the HSC on 19 March 2021*

## ANNEX I: Common list of rapid antigen tests10

As agreed by Member States on 23 July 2021

***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. The common list of rapid antigen tests does not include rapid antigen self-tests nor rapid antigen tests that are based on samples other than those collected from nasal, oropharyngeal or nasopharyngeal specimens. 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 29 June 2021. Discussions on criteria and definitions will continue during summer 2021, also taking into consideration the work carried out by the In Vitro Diagnostics Working Group of the Medical Device Coordination Group9 on guidance on the performance of COVID-19 tests in the context of CE-marking and common specifications under Article 9 of Regulation (EU) 2017/746.*

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| **Manufacturer** | **RAT commercial name** | **CE****marking** | **Clinical performance *Data by manufacturer*** | **Clinical performance*****Data used in MS*** | **FIND evaluation studies** | **EU Member States using in practice** | **Other countries using in practice** | **Completed validation studies** | **MS currently validating** | **Device ID # *in JRC database11*** | **Included in Common list of RATs as of:** |
| AAZ-LMB | COVID-VIRO® Rapid antigen test COVID-19 | Yes | 96.6% sensitivity100% specificity | **BE**: 96.6% sensitivity, 100% specificity, NP swab**FR:** >95%% sensitivity, 100% specificity**SI**: 96.6% sensitivity, 100% specificity, NP swab |  | BE, FR, SI | CH | FR CH |  | 1833 | 10 May 2021 |
| Abbott Rapid Diagnostics | Panbio™ COVID-19 Ag Rapid Test | Yes | 91.4% sensitivity99.8% specificity NP swab (Ct ≤ 33)98.1% sensitivity99.8% specificity Nasal swab (Ct ≤ 33) | **BE[6]**: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%.**DE**:91.4% sensitivity 99.8% specificity, NPswab; 98.1% sensitivity, 99,8 specificity,Nasal swab | [**DE**](https://www.finddx.org/wp-content/uploads/2021/06/Panbio_Ag-Public-Report_v2.1.pdf) (10 Dec 2020)1108 samples, NP swab Clinical sensitivities:- Days < 7: 90.8%;- Ct < 33: 88.3%;- Ct < 25: 95.8%;Clinical specificity: 99.9%[**CH**](https://www.finddx.org/wp-content/uploads/2021/06/Panbio_Ag-Public-Report_v2.1.pdf) (10 Dec 2020)535 samples, NP swab | 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 | 1232 | 17 February2021 |

10 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.

11 See: [https://covid-19-diagnostics.jrc.ec.europa.eu/.](https://covid-19-diagnostics.jrc.ec.europa.eu/)

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| **Manufacturer** | **RAT commercial name** | **CE****marking** | **Clinical performance *Data by manufacturer*** | **Clinical performance*****Data used in MS*** | **FIND evaluation studies** | **EU Member States using in practice** | **Other countries using in practice** | **Completed validation studies** | **MS currently validating** | **Device ID # *in JRC database11*** | **Included in Common list of RATs as of:** |
|  |  |  |  | **FI:**Validated in several laboratories (studies not published), meeting criteria. | Clinical sensitivities:- Days < 7: 85.6%;- Ct < 33: 89.7%;- Ct < 25: 96.8%;Clinical specificity: 100%[**India**](https://www.finddx.org/wp-content/uploads/2021/06/Panbio_Ag-India-Public-Report_v1.pdf) (25 June 2021) 526 samples, NP swab Clinical sensitivities:- Days < 7: 61.3%-100%;- Ct < 33: 74.2%-86.7%;- Ct < 25: 91.9%-100%;Clinical specificity: 100% |  |  |  |  |  |  |
| Acon Biotech (Hangzhou) Co., Ltd | SARS-CoV-2 Antigen Rapid Test | Yes | 96.9% sensitivity Nasal swab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) +Manufacturer specificity: 99.54%xx% |  | DE[2], FR, PT |  | DE[2] |  | 1457 | 14 July 2021 |
| ACONLaboratories, Inc. | Flowflex SARS-CoV-2 Antigen Rapid Test | Yes | 96.9% sensitivity Nasal swab | **BE:**96.9% sensitivity, 99.5% specificity, NP swab**DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) +Manufacturer specificity: 98,7% | [**CH**](https://www.finddx.org/wp-content/uploads/2021/06/Acon_Flowflex_Ag-Public-Report_v1_20200609.pdf) (9 June 2021)279 samples, nasal swab Clinical sensitivities:- Days < 7: 92.2%;- Ct < 33: 98.3%;- Ct < 25: 100%;Clinical specificity: 99.5% | AT, BE, DE[2], LT, LV, SI |  | DE[2] |  | 1468 | 10 May 2021 |
| AESKU.DIAGNOSTICS GmbH & Co, KG | AESKU.RAPID SARS-CoV- 2 | Yes | 96% sensitivity98% specificity NP swab | **DE**:96% sensitivity, 98% specificity**SI**:96% sensitivity, 98% specificity, Nasalswab |  | AT, DE[2], SI |  | DE[2] |  | 2108 | 10 May 2021 |
| Affimedix Inc. | TestNOW® - COVID-19Antigen Test | Yes | 96.1% sensitivity99.4% specificity NP swab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) +Manufacturer specificity: 99,4% |  | DE[2] |  | DE[2] |  | 2130 | 10 May 2021 |
| AMEDALabordiagnostik GmbH | AMP Rapid Test SARS- CoV-2 Ag | Yes | 97.3% sensitivity NP swab97.3% sensitivity Nasal swab 100% specificity | **BE**: 97.3% sensitivity, 100% specificity, NP swab**DE**: Positive evaluation by Paul-Ehrlich- Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 100% |  | AT, BG, DE[2] HR, SI | CH, UA | DE[2] CH | HR | 1304 | 17 February2021 |

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| **Manufacturer** | **RAT commercial name** | **CE****marking** | **Clinical performance *Data by manufacturer*** | **Clinical performance*****Data used in MS*** | **FIND evaluation studies** | **EU Member States using in practice** | **Other countries using in practice** | **Completed validation studies** | **MS currently validating** | **Device ID # *in JRC database11*** | **Included in Common list of RATs as of:** |
|  |  |  |  | **SI**:97.3% sensitivity, 100% specificity, NPswab |  |  |  |  |  |  |  |
| Anbio (Xiamen) BiotechnologyCo., Ltd | Rapid COVID-19 Antigen-Test (colloidalGold) | Yes |  | **DE**:99.27% sensitivity, 100% specificity |  | AT, DE[2] |  | DE[2] |  | 1822 | 10 May 2021 |
| Anhui Deep Blue Medical Technology Co., Ltd | COVID-19 (SARS-CoV-2)Antigen Test Kit (Colloidal Gold) | Yes | Nasal swab: 96,4%sensitivity, 99,8% specificityNP swab: 95,7%sensitivity, 99,3% specificityOP swab: 96,4%sensitivity, 99,8%specificity | **BE**: 95% sensitivity, 99% specificity, NP/OP swab**DE**: Positive evaluation by Paul-Ehrlich- Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: >99% |  | BE, DE[2] | UK | DE[2] |  | 1736 | 10 May 2021 |
| Anhui Deep Blue Medical Technology Co.,Ltd | COVID-19 (SARS-CoV-2)Antigen Test Kit (Colloidal Gold) – Nasalswab | Yes | 96.4 % sensitivity99.8 % specificity Nasal swab | **DE:** 96,4 % sensitivity, 99,8 % specificity |  | DE[2] |  | DE[2] |  | 1815 | 10 May 2021 |
| ArcDia International Ltd | mariPOC SARS-CoV-2 | Yes | 92% sensitivity100% specificity | **FI:** Meets the minimum performance requirements – see the report for details. |  | FI |  | [FI](https://www.medrxiv.org/content/10.1101/2021.02.08.21250086v2) |  | 768 | 10 May 2021 |
| ArcDia International OyLtd | mariPOC Respi+ | Yes | 100 % sensitivity100 % specificityNP swab | **FI:**Validated in several laboratories (studiesnot published), meeting criteria. |  | FI, PT |  | FI |  | 2078 | 14 July 2021 |
| ArcDia International OyLtd | mariPOC Quick Flu+ | Yes | 100 % sensitivity100 % specificityNP swab | **FI:**Validated in several laboratories (studiesnot published), meeting criteria. |  | FI, PT |  | FI |  | 2079 | 14 July 2021 |
| Artron Laboratories Inc. | Artron COVID-19 Antigen Test | Yes | 96.67%(Nasal)sensitivity 91.67% (NP)sensitivity100 % specificityNasal/NP swab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 100% |  | DE[2] |  | DE[2] |  | 1618 | 14 July 2021 |
| Asan PharmaceuticalCo., Ltd | Asan Easy Test COVID- 19 Ag | Yes |  | **DE**:94.67% sensitivity, 97.71% specificity |  | DE[2] |  | DE[2] |  | 1654 | 10 May 2021 |
| Assure Tech. (Hangzhou) Co., Ltd. | ECOTEST COVID-19Antigen Rapid Test Device | Yes | 92.5 % sensitivity99.2 % specificity Nasal/NP/ OPswab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 95% at <Ct25) +Manufacturer specificity: 99.2% |  | DE[2] |  | DE[2] |  | 770 | 14 July 2021 |

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| **Manufacturer** | **RAT commercial name** | **CE****marking** | **Clinical performance *Data by manufacturer*** | **Clinical performance*****Data used in MS*** | **FIND evaluation studies** | **EU Member States using in practice** | **Other countries using in practice** | **Completed validation studies** | **MS currently validating** | **Device ID # *in JRC database11*** | **Included in Common list of RATs as of:** |
| Assure Tech. (Hangzhou) Co., Ltd. | ECOTEST COVID-19Antigen Rapid Test Device | Yes | Sensitivity: 97.7%,Specificity: 99.1% NP and OP swab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 95% at <Ct25) + Manufacturer specificity: 99.1% |  | CZ, DE[2] |  | DE[2] |  | 2350 | 23 July 2021 |
| Atlas Link Technology Co. Ltd. | NOVA Test ® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) | Yes | 98.5 % sensitivity99.4 % specificity Nasal/OP swab | **DE**:97.6% sensitivity, 99.2% specificity |  | AT, DE[2], SI | CH | DE[2] CH |  | 2010 | 10 May 2021 |
| Avalun | Ksmart® SARS-COV2 Antigen Rapid Test | Yes | Clinical Sensitivity:93.18 %Clinical Specificity:99.32 %NP swab | **DE:**Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 99,32% |  | DE[2] |  | DE[2] |  | 1800 | 7 July 2021 |
| AXIOMGesellschaft für Diagnostica undBiochemica mbH | COVID-19 Antigen Rapid Test | Yes | 98% sensitivity100% specificity NP/Nasal swab | **DE**:98.1% sensitivity, 100% specificity |  | DE[2] |  | DE[2] |  | 2101 | 10 May 2021 |
| Azure Biotech, Inc. | COVID-19 Antigen Rapid Test Device | Yes | 95% sensitivity99.2% specificityNP swab | **DE**:94.3% sensitivity, 99.1% specificity |  | DE[2] |  | DE[2] |  | 1906 | 10 May 2021 |
| Becton Dickinson | BD Veritor™ System for Rapid Detection of SARS CoV 2 | Yes | Clinical Sensitivity:91.1 %Clinical Specificity:99.6 % Nasal swab | **NL:**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% |  | NL |  | NL |  | 1065 | 7 July 2021 |
| Beijing Hotgen Biotech Co., Ltd | Novel Coronavirus2019-nCoV Antigen Test (Colloidal Gold) | Yes | 97.1% sensitivity99.76% specificity | **BE**:98.6% sensitivity, 100% specificity, NP Swab97.3% sensitivity, 99.2% specificity. OP swab**DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 99.76%**SI**:96.6% sensitivity, 99.8% specificity, NPswab | *Ongoing* | AT, BE, DE[2], RO, SI |  | DE[2] |  | 1870 | 10 May 2021 |

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| **Manufacturer** | **RAT commercial name** | **CE****marking** | **Clinical performance *Data by manufacturer*** | **Clinical performance*****Data used in MS*** | **FIND evaluation studies** | **EU Member States using in practice** | **Other countries using in practice** | **Completed validation studies** | **MS currently validating** | **Device ID # *in JRC database11*** | **Included in Common list of RATs as of:** |
| Beijing Jinwofu Bioengineering TechnologyCo.,Ltd. | Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Kit | Yes | 96.88 % sensitivity 100 % specificity Nasal/ NP/ OPswab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) +Manufacturer specificity: 100% |  | DE[2] |  | DE[2] |  | 2072 | 14 July 2021 |
| Beijing Lepu Medical Technology Co., Ltd | SARS-CoV-2 Antigen Rapid Test Kit | Yes | 92% sensitivity Nasal swab | **BE**:92% sensitivity, 99.3% specificity, Nasal**DE**: 92.0% sensitivity, 99.26% specificity**SI**: 92% sensitivity, 99.2% specificity, NP |  | AT, BE, DE[2], SI, RO | UA | DE[2] |  | 1331 | 17 February2021 |
| Beijing Wantai Biological Pharmacy Enterprise Co.,Ltd | Wantai SARS-CoV-2 Ag Rapid Test (FIA) | Yes | 96.6% sensitivity, Nasal swab | **DE**:96.6% sensitivity, 96.9% specificity |  | DE[2] |  | DE[2] |  | 1484 | 17 February2021 |
| Beijing Wantai Biological Pharmacy Enterprise Co.,Ltd | Wantai SARS-CoV-2 Ag Rapid Test (colloidal gold) | Yes | 96.1 % sensitivity 99% specificity Nasal swab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 99% |  | DE[2] |  | DE[2] |  | 1485 | 14 July 2021 |
| BioGnost Ltd | CoviGnost AG Test Device 1x20 | Yes | Sensitivity: 96%,Specificity: 99% NP swab | **HR:**300 NP samples (retrospective), symptomatic (<7 dps): 200 PCR+ samples(range Ct 16-30), Ct<30: sensitivity 96.5%100 PCR- samples: specificity 100% |  | HR |  | HR |  | 2247 | 23 July 2021 |
| BIOHITHealthCcare (Hefei) Co., Ltd. | SARS-CoV-2 Antigen Rapid Test Kit (Fluorescence Immunochromato-graphy) | Yes | Sensitivity: 96.77%Specificity: 98.9% NP/OP swab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 98.9% |  | DE[2] |  | DE[2] |  | Yes (1286) | 23 July 2021 |
| BioMaxima SA | SARS-CoV-2 Ag Rapid Test | Yes | Sensitivity: 95%Specificity: 99% NP Swab | [**PL:**](https://evereth.pl/zastosowanie-szybkiego-testu-antygenowego-do-diagnostyki-covid-19-w-porownaniu-z-molekularnym-testem-rt-pcr/)Diagnostic sensitivity: 93.43% (95% CI: 91.61%~97.19%); diagnostic specificity:97.75%, manufacturer specificity: 99.1% |  | PL |  | PL |  | Yes (2035) | 23 July 2021 |
| Biomerica Inc. | Biomerica COVID-19 Antigen Rapid Test (nasopharyngeal swab) | Yes | Clinical Sensitivity:94.7 % Nasal/NP swab | **DE:**Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) +Manufacturer specificity: 99,7% |  | DE[2] |  | DE[2] |  | 1599 | 7 July 2021 |
| BIONOTE | NowCheck COVID-19 Ag Test | Yes | Clinical Sensitivity:90.91 %Clinical Specificity:99.43 % | **DE:**Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 98,6% | [**Brazil**](https://www.finddx.org/wp-content/uploads/2021/06/Bionote_Ag-Public-Report_20210420-v1-5.pdf) (20 April 2021) 400 samples, NP swab Clinical sensitivities:- Days < 7: 92.2%;- Ct < 33: 91.4%; | DE[2] |  | DE[2] |  | 1242 | 7 July 2021 |

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| **Manufacturer** | **RAT commercial name** | **CE****marking** | **Clinical performance *Data by manufacturer*** | **Clinical performance*****Data used in MS*** | **FIND evaluation studies** | **EU Member States using in practice** | **Other countries using in practice** | **Completed validation studies** | **MS currently validating** | **Device ID # *in JRC database11*** | **Included in Common list of RATs as of:** |
|  |  |  |  |  | - Ct < 25: 94.8%;Clinical specificity: 97.3%[**Brazil**](https://www.finddx.org/wp-content/uploads/2021/06/Bionote_Nasal_Ag-Public-Report_20210330-v1.pdf) (30 March 2021)218 samples, Nasal/NP swab. Clinical sensitivities:- Days < 7: 92.5% (N/NP);- Ct < 33: 97.2% (N/NP);- Ct < 25: 100% (N/NP);Clinical specificity: 98.6% |  |  |  |  |  |  |
| BIO-RAD | CORONAVIRUS AG RAPID TEST CASSETTE | Yes | Clinical Sensitivity: 98 % (NP Swab:98,32% / NasalSwab: 97,25%)Clinical Specificity: 99 % (NP Swab:99,6% / NasalSwab: 100%) | **ES:**NP swab: sensitivity 98,3%; specificity 99,6% (119 positive samples, 746 negative samples)Nasal swab: sensitivity 97,2%; specificity 100% (109 positive samples, 128 negative samples) |  | ES |  | ES |  | 2031 | 7 July 2021 |
| BIOSYNEX S.A. | BIOSYNEX COVID-19 Ag BSS | Yes | 96% sensitivity,100% specificity, NP swab | **BE[6]**: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.**DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 100%**NL**:Independent field study, mainly symptomatic individuals, sensitivity Ct<30: 96.0%; specificity overall: 100% |  | AT, BE, DE[2],DK,FR, NL[5], PT | CH | DE[2], NL[5], CH | DK | 1223 | 17 February2021 |
| BIOSYNEX SA | BIOSYNEX COVID-19 Ag+ BSS | Yes | Clinical Sensitivity:97.5 % | **FR**:Validation study data: 125 positive and 118 negative samples; sensitivity 96%,specificity: 99% |  | FR |  | FR |  | 1494 | 7 July 2021 |

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| **Manufacturer** | **RAT commercial name** | **CE****marking** | **Clinical performance *Data by manufacturer*** | **Clinical performance*****Data used in MS*** | **FIND evaluation studies** | **EU Member States using in practice** | **Other countries using in practice** | **Completed validation studies** | **MS currently validating** | **Device ID # *in JRC database11*** | **Included in Common list of RATs as of:** |
| BIOTEKE CORPORATION (WUXI) CO., LTD | SARS-CoV-2 Antigen Test Kit (colloidal gold method) | Yes | 96.49 % sensitivity99.28 % specificity OP/NP swab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 95% at <Ct25) +Manufacturer specificity: 99.28% |  | DE[2] |  | DE[2] |  | 2067 | 14 July 2021 |
| Biotical Health S.L.U.BIOTICAL HEALTH S.L.U | biotical SARS-CoV-2 Ag Card | Yes | Sensitivity: 96%,Specificity: 99% NP swab | **BE**:Validation study 1: sensitivity 91.7% forCt<25; Validation study 2: 94% for Ct<25. Manufacturer specificity: 99% |  | BE |  | BE |  | Yes (2013) | 23 July 2021 |
| Boditech Med Inc | AFIAS COVID-19 Ag | Yes | Sensitivity: 91.7%,Specificity: 98.7% NP swab | **NL**:Independent field study in mild symptomatic (n= 427); overall sensitivity: 81.1% (106 PCR+), Ct <30: 96.4% (85PCR+), PCR on NP+OP, Target antigen =nucleoprotein |  | FR, NL |  | NL |  | Yes (1989) | 23 July 2021 |
| BTNX Inc | Rapid Response COVID- 19 Antigen Rapid Test | Yes | 90.2% sensitivity100% specificity NP swab, NP swab,OP swab | **DE**:94.55% sensitivity, 100% specificity |  | AT, DE[2], ES, SI |  | DE[2] |  | 1236 | 10 May 2021 |
| CerTest Biotec | CerTest SARS-CoV-2 Card test | Yes | 92.9% sensitivity99.6% specificity NP swab | [**ES**:](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7897407/)Ct < 25, sensitivity: 94,0%; sensitivity for samples within the first 5 days aftersymptom onset: 84,8% |  | ES, PT, SI |  | DE[2], ES |  | 1173 | 17 February2021 |
| Core Technology Co., Ltd | Coretests COVID-19 Ag Test | Yes | 98.1% sensitivity99.6% specificityNP swab | **DE**:98.1% sensitivity, 99.6% specificity |  | AT, DE[2], RO |  | DE[2] |  | 1919 | 10 May 2021 |
| CTK Biotech, Inc | OnSite COVID-19 Ag Rapid Test | Yes | Clinical Sensitivity:92.3 %Clinical Specificity: 100 %Nasal, NP swab | **ES:**219 samples; Nasal swab - Clinical sensitivity 86% (90%: Ct <30) Specificity:100% (Method B)**DK:**107 samples; Nasal swab - clinical sensitivity 86%; (from asymptomatic and mild symptomatic individuals), Clinicalspecificity: 100% | *To start* | DK |  | DK, ES |  | 1581 | 7 July 2021 |
| DDS DIAGNOSTIC | Test Rapid Covid-19 Antigen (tamponnazofaringian) | Yes | 98.77% sensitivity99.03% specificityNasal swab | **RO:**Meets the minimum performancerequirements. |  | RO |  | ROChina | RO | 1225 | 10 May 2021 |
| DIALAB GmbH | DIAQUICK COVID -19 AgCassette | Yes |  | **BE**:Z20401CE: 93.2% sensitivity, 100%specificity, NP swab |  | AT, BE, DE[2] |  | DE[2] |  | 1375 | 10 May 2021 |

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| **Manufacturer** | **RAT commercial name** | **CE****marking** | **Clinical performance *Data by manufacturer*** | **Clinical performance*****Data used in MS*** | **FIND evaluation studies** | **EU Member States using in practice** | **Other countries using in practice** | **Completed validation studies** | **MS currently validating** | **Device ID # *in JRC database11*** | **Included in Common list of RATs as of:** |
|  |  |  |  | Z20601CE: 96.4% sensitivity, 99.2% specificity, NP swab**DE**: 97.3% sensitivity, 100% specificity |  |  |  |  |  |  |  |
| DNA Diagnostic | COVID-19 Antigen Detection Kit | Yes | Sensitivity: 93.8%,Specificity: 99.6% Nasal swab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) +Manufacturer specificity: 99.56% |  | DE[2] |  | DE[2] |  | Yes (2242) | 23 July 2021 |
| Edinburgh Genetics Limited | Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit | Yes |  | **DE:**Positive evaluation by Paul-Ehrlich-Institut (Sensitivity of 100% at <Ct25) + Manufacturer Specificity: 99,24% | [**Peru**](https://www.finddx.org/wp-content/uploads/2021/06/Edinburgh-Ag-Public-Report_v1-20210426.pdf) **(**26 April 2021) 120 samples, NP swab Clinical sensitivities:- Days < 7: 62%;- Ct < 33: 75%;- Ct < 25: 100%;Clinical specificity: 100% | DE[2] |  | DE[2] |  | 1243 | 14 July 2021 |
| Eurobio Scientific | EBS SARS-CoV-2 AgRapid Test | Yes | Clinical Sensitivity:95.7 % Nasal swab | **DE:**Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 99,1%**FR**:Validation study data: 119 positive and 125 negative samples; sensitivity 93%,specificity: 99% |  | DE[2], FR |  | DE[2], FR |  | 1739 | 7 July 2021 |
| Fujirebio | ESPLINE SARS-CoV-2 | Yes | Clinical Sensitivity: 87.8 % ( (n=98, Ct<33))Clinical Specificity: 100 %NP swab | **DE:**Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 99,13% | [**DE**](https://www.finddx.org/wp-content/uploads/2021/06/Fujirebio_Ag-Public-Report_v1_20210329.pdf) (29 March 2021)723 samples, NP swab Clinical sensitivities:- Days < 7: 88.5%;- Ct < 33: 87.8%;- Ct < 25: 92.4%;Clinical specificity: 100% | DE[2] |  | DE[2] |  | 2147 | 7 July 2021 |
| GA Generic Assays GmbH | GA CoV-2 Antigen Rapid Test | Yes | Sensitivity: 97.059%,Specificity: 99.2%NP swab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) +Manufacturer specificity: 99.2% |  | DE[2] |  | DE[2] |  | Yes (1855) | 23 July 2021 |
| GenBody Inc | Genbody COVID-19 Ag Test | Yes | 90% sensitivity98% specificityNP/OP swab | **DE**: 90% sensitivity 98% specificity | *Withdrawn* | DE[2] | UA | DE[2] |  | 1244 | 17 February2021 |
| Genrui Biotech Inc | SARS-CoV-2 Antigen Test Kit (Colloidal Gold) | Yes | Sensitivity: 91.15%Specificity: 99.02% Nasal/NP/OP swab | **DE:**Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) +Manufacturer specificity: 99,02% |  | DE[2] |  | DE[2] |  | 2012 | 7 July 2021 |

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| **Manufacturer** | **RAT commercial name** | **CE****marking** | **Clinical performance *Data by manufacturer*** | **Clinical performance*****Data used in MS*** | **FIND evaluation studies** | **EU Member States using in practice** | **Other countries using in practice** | **Completed validation studies** | **MS currently validating** | **Device ID # *in JRC database11*** | **Included in Common list of RATs as of:** |
| GenSure Biotech Inc | GenSure COVID-19 Antigen Rapid Test Kit | Yes | 96.86% sensitivity,100% specificity Nasal swab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) +Manufacturer specificity: 100% |  | DE[2] |  | DE[2] |  | 1253 | 10 May 2021 |
| Getein Biotech, Inc | SARS-CoV-2 Antigen (Colloidal Gold) | Yes | 97.06% sensitivity98.71% specificity Nasal swab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) +Manufacturer specificity: 98.71% |  | AT, DE[2] |  | DE[2] |  | 1820 | 14 July 2021 |
| Getein Biotech, Inc. | One Step Test for SARS- CoV-2 Antigen (Colloidal Gold) | Yes | 97.06% sensitivity98.71% specificity Nasal swab | **DE:**Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 90% at <Ct30 and 100% at<Ct25) |  | DE[2] |  | DE[2] |  | 2183 | 16 June 2021 |
| Goldsite Diagnostic Inc. | SARS-CoV-2 Antigen Kit (Colloidal Gold) | Yes |  | **DE:**Positive evaluation by Paul-Ehrlich-Institut(sensitivity 100% at <Ct25) |  | BE, BG, CY, FR, RO, SI, ES | UK | FR, DE[2], ES |  | 1197 | 14 July 2021 |
| Green Cross Medical Science Corp. | GENEDIA W COVID-19Ag | Yes | 100% sensitivity90.1% sensitivity NP swab, Anterior nasal swab | **BE**:90.2% sensitivity, 100% specificity, NP swab**DE**: 90.1% sensitivity, 100% specificity |  | AT, BE, DE[2] |  | DE[2] |  | 1144 | 10 May 2021 |
| Guangdong Hecin Scientific,Inc. | 2019-nCoV Antigen Test Kit (colloidal goldmethod) | Yes | 96.23% sensitivity Nasal swab | **DE**: 96.6% sensitivity, 99.07% specificity |  | AT, DE[2] |  | DE[2] |  | 1747 | 10 May 2021 |
| Guangdong Longsee Biomedical Co.,Ltd. | COVID-2019-nCoV AgRapid TestDetection Kit(Immuno-Chromatography) | Yes | 99.72% specificity NP/OP swab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) +Manufacturer specificity: 99.5% |  | DE[2] |  | DE[2] |  | 1216 | 14 July 2021 |
| Guangdong Wesail Biotech Co. Ltd | COVID-19 Ag Test Kit | Yes | 90% sensitivity98% specificity Nasal swab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 98%**SI**: 90% sensitivity, 98% specificity, NP/Nasal swab |  | DE[2], SI |  | DE[2] |  | 1360 | 17 February2021 |
| Guangzhou Decheng BiotechnologyCO., Ltd | V-CHEK, 2019-nCoV AgRapid Test Kit (Immunochromatography) | Yes | Clinical Sensitivity:96.67 % Nasal swab | **DE:**Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) +Manufacturer specificity: 99,5% |  | DE[2] |  | DE[2] |  | 1324 | 7 July 2021 |
| Guangzhou Wondfo Biotech Co., Ltd | Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) | Yes |  | **BE**:96.2% sensitivity, 99.7% specificity, NP/OP swab**DE**: 96.18 % sensitivity, 99.72% specificity | [**CH**](https://www.finddx.org/wp-content/uploads/2021/06/Wondfo_Ag-Public-Report_20210225_v1.0.pdf) (25 Feb 2020)328 samples, NP swab Clinical sensitivities:- Days < 7: 85.7%; | AT, BE, BG,DE[2], FR | CH | DE[2] |  | 1437 | 10 May 2021 |

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| **Manufacturer** | **RAT commercial name** | **CE****marking** | **Clinical performance *Data by manufacturer*** | **Clinical performance*****Data used in MS*** | **FIND evaluation studies** | **EU Member States using in practice** | **Other countries using in practice** | **Completed validation studies** | **MS currently validating** | **Device ID # *in JRC database11*** | **Included in Common list of RATs as of:** |
|  |  |  |  |  | - Ct < 33: 92.2%;- Ct < 25: 100%;Clinical specificity: 100% |  |  |  |  |  |  |
| Hangzhou Lysun Biotechnology Co. Ltd | COVID-19 Antigen Rapid Test Device (Colloidal Gold) | Yes | 96.46% sensitivity100% specificity Nasal swab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 100% |  | DE[2] | CH | DE[2] |  | 2139 | 10 May 2021 |
| Hangzhou AllTest Biotech Co., Ltd | COVID-19 Antigen Rapid Test | Yes | NP swab | **DE:** 93,40% sensitivity, 99,90% specificity |  | AT, BE, BG, FR, SI, RO | CH | DE[2] | AT | 1257 | 10 May 2021 |
| Hangzhou Clongene Biotech Co., Ltd | COVID-19 Antigen Rapid Test Casette | Yes | Clinical Sensitivity:91.4 %Clinical Specificity: 100 %NP swab | **DE:**Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,4% at <Ct25) + Manufacturer specificity: 100% |  | DE[2] |  | DE[2] |  | 1610 | 7 July 2021 |
| Hangzhou Clongene Biotech Co., Ltd. | Covid-19 Antigen Rapid Test Kit | Yes | 98.5% (Ct<33)sensitivity Nasal swab | **BE**: 91.4% sensitivity, 100% specificity, NP/OP swab**DE**: 91.4% sensitivity, 99.4% specificity**SI**: 91.4% sensitivity, 100% specificity, NP/OP swab |  | AT,BE, DE[2], FR, SI | CH | DE[2] CH | HR | 1363 | 17 February2021 |
| Hangzhou ClongeneBiotech Co., Ltd. | COVID-19/Influenza A+B Antigen Combo RapidTest | Yes | 91% sensitivity100% specificityNP swab | **DE**: 97.7% sensitivity, 99.8% specificity |  | DE[2] |  | DE[2] |  | 1365 | 10 May 2021 |
| Hangzhou Immuno Biotech Co., Ltd | Immunobio SARS-CoV-2 Antigen ANTERIOR NASAL Rapid Test Kit(minimal invasive) | Yes | 94% sensitivity100% specificity Nasal swab, NP | **DE**: 94.39% sensitivity 97.67% specificity |  | DE[2] |  | DE[2] |  | 1844 | 10 May 2021 |
| Hangzhou Immuno Biotech Co., Ltd | SARS-CoV2 Antigen Rapid Test | Yes | Clinical Sensitivity 98 %Clinical Specificity100 % | **DE**: 95.6% sensitivity, 100% specificity |  | AT, DE[2] |  | DE[2] |  | 2317 | 10 May 2021 |
| Hangzhou Laihe Biotech Co. | LYHER Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) | Yes | Clinical Sensitivity: 95.07% %Clinical Specificity: 99.74%Nasal swab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 99,7% |  | AT, DE[2] | CH | DE[2] |  | 1215 | 10 May 2021 |
| Hangzhou Testsea BiotechnologyCo., Ltd. | Covid-19 Antigen Test Cassette | Yes | 92.1% sensitivity98.1% specificity Nasal swab | **DE**: 97.6% sensitivity 98.4% specificity |  | DE[2] |  | DE[2] |  | 1392 | 10 May 2021 |

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| **Manufacturer** | **RAT commercial name** | **CE****marking** | **Clinical performance *Data by manufacturer*** | **Clinical performance*****Data used in MS*** | **FIND evaluation studies** | **EU Member States using in practice** | **Other countries using in practice** | **Completed validation studies** | **MS currently validating** | **Device ID # *in JRC database11*** | **Included in Common list of RATs as of:** |
| Healgen Scientific | Coronavirus Ag Rapid Test Cassette | Yes | 80.6 % sensitivity 99.7% specificity NP swab | **DE**: 97.25% sensitivity, 100% specificity**SI**:96.7% sensitivity, 99.2% specificity,NP/Nasal swab |  | AT, DE[2], NL[5], SE, SI | CH | DE[2], NL[5] | SE[3] | 1767 | 17 February2021 |
| Hubei Jinjian Biology Co., Ltd | SARS-CoV-2 Antigen Test Kit | Yes | Sensitivity: 98.02% Nasal Swab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) +Manufacturer specificity: 99.3 % |  | DE[2] |  | DE[2] |  | Yes (1759) | 23 July 2021 |
| Humasis | Humasis COVID-19 Ag Test | Yes | 95.3% sensitivity Nasal swab | **BE**:95.5% sensitivity, 100% specificity, NP swab**DE**: 95.5% sensitivity, 100% specificity**SI**: 95.5% sensitivity, 100% specificity, NP swab |  | AT, BE, BG, DE[2], FR, HR, SE, SI |  | DE[2] | HR, SE | 1263 | 10 May 2021 |
| Jiangsu Bioperfectus TechnologiesCo., Ltd. | Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit | Yes | 97.06 % sensitivity99.15 % specificity Nasal/NP/ OPswab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) +Manufacturer specificity: 99.15% |  | DE[2] |  | DE[2] |  | 2107 | 14 July 2021 |
| Jiangsu Diagnostics BiotechnologyCo., Ltd | COVID-19 Antigen Rapid Test Cassette (Colloidal Gold) | Yes | 97.58 % sensitivity 100 % specificity Nasal/NP/ OPswab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) +Manufacturer specificity: 100% |  | DE[2] |  | DE[2] |  | 1920 | 14 July 2021 |
| Jiangsu Medomics medical technology Co.,Ltd. | SARS-CoV-2 antigen Test Kit (LFIA) | Yes | Clinical Sensitivity:97.73 %Clinical Specificity:99.51 % Anterior nasalswab, NP swab | **DE:**Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 99,51% |  | DE[2] |  | DE[2] |  | 2006 | 7 July 2021 |
| Joinstar Biomedical Technology Co. Ltd | COVID-19 Rapid Antigen Test (Colloidal Gold) | Yes | 96.1% sensitivity98.1% specificity Nasal swab | **DE**: 96.1% sensitivity, 98.1% specificity**SI**:96.1% sensitivity, 98.1% specificity, NPswab |  | AT, DE[2], PT, SI |  | DE[2] |  | 1333 | 17 February2021 |
| JOYSBIO (Tianjin) Biotechnology Co., Ltd. | SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold immunochromatograph y) | Yes | 98.13% sensitivity Nasal swab | **CZ:**Meets the minimum performance requirements – see [report](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8071529/) for details. | [**CH**](https://www.finddx.org/wp-content/uploads/2021/06/Joysbio_Ag-Public-Report_v1_20210211.pdf) (11 Feb 2021)265 samples, Nasal swab Clinical sensitivities:- Days < 7: 74.2%;- Ct < 33: 78.9%;- Ct < 25: 91.3%;Clinical specificity: 99.1% | AT, CZ, SI |  | CZ, DE[2] CH |  | 1764 | 10 May 2021 |

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| **Manufacturer** | **RAT commercial name** | **CE****marking** | **Clinical performance *Data by manufacturer*** | **Clinical performance*****Data used in MS*** | **FIND evaluation studies** | **EU Member States using in practice** | **Other countries using in practice** | **Completed validation studies** | **MS currently validating** | **Device ID # *in JRC database11*** | **Included in Common list of RATs as of:** |
| Labnovation Technologies Inc. | SARS-CoV-2 Antigen Rapid Test Kit | Yes | NP/OP swab | **DE**: 96.3% sensitivity, 97.3% specificity**SI**:96.3% sensitivity, 97.3% specificity, NP/OPswab |  | DE[2], IT, SI |  | DE[2] |  | 1266 | 10 May 2021 |
| Lumigenex (Suzhou) Co., Ltd | PocRoc® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) | Yes | 93.33% sensitivity99.16% specificity Nasal/NP/OP swab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) +Manufacturer specificity: 99,16% |  | DE[2] |  | DE[2] |  | 2128 | 10 May 2021 |
| LumiQuick Diagnostics Inc. | QuickProfile™ COVID-19 Antigen Test | Yes |  | **BE**:94% sensitivity, 99% specificity, NP swab**DE**: 93.7% sensitivity, 98.8% specificity**SI**:93.7% sensitivity, 98.8% specificity, NPswab |  | BE, DE[2] ,FR, SI, |  | DE[2] |  | 1267 | 10 May 2021 |
| LumiraDX | LumiraDx SARS-CoV-2 Ag Test | Yes | 97.6% sensitivity96.6% specificity Nasal swab | **DE**:93.8% sensitivity, 98.8% specificity**SI**:97.6% sensitivity, 97.7% specificity, NP/Nasal swab**SKUP/2021/124**:90% sensitivity, 97,8% specificity, NP swab | *To start* | DE[2], ES, SI | CH | DE[2], ES, SKUP –(Scandinavia n evaluation of laboratory equipment for point of care testing)CH |  | 1268 | 17 February2021 |
| MEDsan GmbH | MEDsan SARS-CoV-2Antigen Rapid Test | Yes | 92.5% sensitivity99.8% specificity NP/OP swab | **BE**:92.5% sensitivity, 99.8% specificity, Nasal/OP swab**DE**: 92.5% sensitivity, 99.8% specificity |  | AT, BE, DE[2] | CH | DE[2] CH |  | 1180 | 17 February2021 |
| Merlin Biomedical (Xiamen) Co.,Ltd. | SARS-CoV-2 Antigen Rapid Test Cassette | Yes | 95.05% sensitivity98.99% specificity Nasal/NP swab | **DE:**Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 90% at <Ct30 and 100% at<Ct25) |  | DE[2] |  | DE[2] |  | 2029 | 16 June 2021 |
| MEXACAREGmbH | MEXACARE COVID-19Antigen Rapid Test | Yes | Clinical Sensitivity:96.17 % Nasal swab | **DE:**Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) +Manufacturer specificity: 99,1% |  | DE[2] |  | DE[2] |  | 1775 | 7 July 2021 |
| möLab | mö-screen Corona Antigen Test | Yes | NP swab | **DE**:97.25% sensitivity , 99.99% specificity |  | DE[2], IE |  | DE[2], IE |  | 1190 | 10 May 2021 |

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| **Manufacturer** | **RAT commercial name** | **CE****marking** | **Clinical performance *Data by manufacturer*** | **Clinical performance*****Data used in MS*** | **FIND evaluation studies** | **EU Member States using in practice** | **Other countries using in practice** | **Completed validation studies** | **MS currently validating** | **Device ID # *in JRC database11*** | **Included in Common list of RATs as of:** |
| MP Biomedicals | Rapid SARS-CoV-2 Antigen Test Card | Yes | 96.17% sensitivity99.16% specificity Nasal swab, Anterior nasal swab | **BE**:96.4% sensitivity, 99% specificity, NP/OP swab**DE:**96.39 % sensitivity, 99.03% specificity |  | AT, BE, DE[2] | CH | DE[2] CH |  | 1481 | 17 February2021 |
| Nal von minden GmbH | NADAL COVID -19 Ag+Influenza A/B Test | Yes | 97% sensitivity98% specificityNP swab | **DE**:97.6% sensitivity, 99.9% specificity |  | DE[2] |  | DE[2] |  | 2104 | 10 May 2021 |
| Nal von minden GmbH | NADAL COVID -19 AgTest | Yes | 97.6% sensitivity99.9% specificity Nasal swab | **BE**: 97.6% sensitivity, 99.9% specificity, NP/OP swab**DE**:97.6% sensitivity, 99.9% specificity**SI**: 97.6% sensitivity, 99.9% specificity, NP/OP swab | [**CH**](https://www.finddx.org/wp-content/uploads/2021/06/Nadal_Ag-Public-Report_v1-20210427.pdf) (26 April 2021)462 samples, NP swab Clinical sensitivities:- Days < 7: 88.5%;- Ct < 33: 92.4%;- Ct < 25: 97.8%;Clinical specificity: 99.2% | AT, BE, CY DE[2], FR, PT, SI |  | DE[2], FRChina | HR, SKUP | 1162 | 17 February2021 |
| NanoEntek | FREND COVID-19 Ag | Yes | 94.12% sensitivity100% specificityNP swab | **DE**:94.12% sensitivity , 100% specificity |  | DE[2] |  | DE[2] |  | 1420 | 10 May 2021 |
| NanoRepro AG | NanoRepro SARS-CoV-2 Antigen Rapid Test | Yes | 97.2 % sensitivity 98.4% specificity Nasal/NP/OP swab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) +Manufacturer specificity: 98.4% |  | DE[2] |  | DE[2] |  | 2200 | 14 July 2021 |
| NESAPOR EUROPA SL | MARESKIT COVID-19 ANTIGEN RAPID TEST KIT | Yes | Sensitivity: 95.24%,Specificity: 100%Nasal swab | **ES:**Independent validation study; Nasal test compared to nasal PCR. Sensitivity 95.24%,Specificity 100%. |  | ES |  | ES |  | Yes (2241) | 23 July 2021 |
| New Gene (Hangzhou) BioengineeringCo., Ltd. | COVID-19 Antigen Detection Kit | Yes | 98% sensitivity Nasal swab | **DE:**Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 92,5% at <Ct30 and 100% at<Ct25) |  | DE[2] |  | DE[2] |  | 1501 | 16 June 2021 |
| Novatech | SARS-CoV-2 Antigen Rapid Test | Yes | 95 % sensitivity100% specificity Nasal/ NP swab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) +Manufacturer specificity: 100% |  | DE[2] |  | DE[2] |  | 1762 | 14 July 2021 |
| Oncosem Onkolojik Sistemler San. ve Tic. A.S. | CAT | Yes | 93.75% sensitivity98.04% specificity Nasal swab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) + Manufacturer specificity: 98,04% |  | DE[2] |  | DE[2] |  | 1199 | 10 May 2021 |

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| **Manufacturer** | **RAT commercial name** | **CE****marking** | **Clinical performance *Data by manufacturer*** | **Clinical performance*****Data used in MS*** | **FIND evaluation studies** | **EU Member States using in practice** | **Other countries using in practice** | **Completed validation studies** | **MS currently validating** | **Device ID # *in JRC database11*** | **Included in Common list of RATs as of:** |
| PCL Inc. | PCL COVID19 Ag Rapid FIA | Yes |  | **DE**:94,92 % sensitivity, 99,99 % specificity**SI**:95.5% sensitivity, 98.6% specificity, NP/OPswab, sputum |  | FR, DE[2], RO, SI |  | DE[2] |  | 308 | 10 May 2021 |
| PCL Inc. | PCL COVID19 Ag Gold | Yes |  | **FR**:Validation study data: 120 positive and 200 negative samples; sensitivity 92%,specificity: 100% |  | FR, PT |  | FR |  | 2243 | 7 July 2021 |
| PerGrande Bio Tech DevelopmentCo., Ltd. | SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromato-graphic Assay) | Yes | 94.28% sensitivity99.11% specificity NP/Nasal/OP swab | **DE**:94.28% sensitivity, 99.11% specificity |  | AT, DE[2] |  | DE[2] |  | 2116 | 10 May 2021 |
| Precision Biosensor Inc. | Exdia COVI-19 Ag | Yes | 93.9% sensitivity98% specificity NP swab | **DE**:93.88% sensitivity , 98% specificity**SI**:93.9% sensitivity, 98% specificity, NP swab |  | SI, DE[2] | CH | DE[2] CH |  | 1271 | 17 February2021 |
| Prognosis Biotech | Rapid Test Ag 2019- nCov | Yes | Clinical Sensitivity:95.56 % Nasal swab | **DE:**Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) +Manufacturer specificity: 99,58% |  | CY, DE[2] |  | DE[2] |  | 1495 | 7 July 2021 |
| Qingdao Hightop Biotech Co. Ltd | SARS-CoV-2 Antigen Rapid Test (Immunochromatograp hy) | Yes | 95% sensitivity Nasal swab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct30 and 100% at<Ct25) |  | AT, DE[2] |  | DE[2] |  | 1341 | 17 February2021 |
| Quidel Corporation | Sofia SARS Antigen FIA | Yes | 96.7% sensitivity100% specificity NP/Nasal swab | **BE**:96.7% sensitivity, 100% specificity, NP/nasal swab**DE**:96.7% sensitivity , 100% specificity**SI**:96.7% sensitivity, 100% specificity,NP/Nasal swab |  | AT, BE, DE[2],FI, NL[5], PT, SI | CH | DE[2], NL[5] CH | SI | 1097 | 17 February2021 |
| Rapid Pathogen Screening, Inc | LIAISON® Quick Detect Covid Ag Assay | Yes | Sensitivity: 96.1%,Specificity: 97% NP and Nasal swab | **IT:**Independent validation study, 100 pos. and 100 neg. samples; sensitivity: 92.7%with Ct<25; specificity: 100%. |  | IT |  | IT |  | Yes (2290) | 23 July 2021 |

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| **Manufacturer** | **RAT commercial name** | **CE****marking** | **Clinical performance *Data by manufacturer*** | **Clinical performance*****Data used in MS*** | **FIND evaluation studies** | **EU Member States using in practice** | **Other countries using in practice** | **Completed validation studies** | **MS currently validating** | **Device ID # *in JRC database11*** | **Included in Common list of RATs as of:** |
| Roche (SD BIOSENSOR) | SARS-CoV-2 Rapid Antigen Test | Yes | 96.52% sensitivity99.2% specificity NP swab | **DE**:96.52% sensitivity, 99.68% specificity**FI:**Validated in several laboratories (studiesnot published), meeting criteria. |  | AT, DE[2], MT, NL, RO | CH, NO | DE[2], FI |  | 1604 | 10 May 2021 |
| Roche (SD BIOSENSOR) | SARS-CoV-2 Rapid Antigen Test Nasal | Yes | Clinical Sensitivity: 89.6 % ( (Ct ≤ 30)93.1 % (Ct ≤ 27) Clinical Specificity:99.1 % Nasal swab | **DE:**Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 89.6% at <Ct30) | [**DE**](https://www.finddx.org/wp-content/uploads/2021/06/SDQ_Nasal_Ag-Public-Report_20210412_v2.pdf) (12 April 2021)179 samples, nasal swab Clinical sensitivities:- Days < 7: 81.2%;- Ct < 33: 87.5%;- Ct < 25: 100%;Clinical specificity: 99.3%[**Brazil**](https://www.finddx.org/wp-content/uploads/2021/06/SDQ_Nasal_Ag-Public-Report_20210412_v2.pdf) (12 April 2021) 214 samples, nasal swab Clinical sensitivities:- Days < 7: 81.2%;- Ct < 33: 91.7%;- Ct < 25: 100%;Clinical specificity: 99.3% | DK, SK | CH, UK | DE[2] |  | 2228 | 7 July 2021 |
| Safecare Biotech (Hangzhou) Co. Ltd | COVID-19 Antigen Rapid Test Kit (Swab) | Yes | 97.04% sensitivity Nasal swab | **DE**:97.27 % sensitivity , 99.42% specificity |  | AT, DE[2], FR | CH | DE[2] |  | 1489 | 17 February2021 |
| Safecare Biotech (Hangzhou) Co. Ltd | Multi-Respiratory Virus Antigen Test Kit (Swab) (Influenza A+B/COVID-19) | Yes | 97.04% sensitivity Nasal swab | **DE**:97.04% sensitivity , 99.44% specificity |  | DE[2] |  | DE[2] |  | 1490 | 10 May 2021 |
| ScheBo Biotech AG | ScheBo SARS CoV-2 Quick Antigen | Yes | 96.6% sensitivity(Ct ≤ 30)NP/ OP swab | **DE:**Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 95% at <Ct30 and 100% at<Ct25) |  | DE[2] |  | DE[2] |  | 1201 | 16 June 2021 |
| SD Biosensor Inc | STANDARD Q COVID-19Ag Test Nasal | Yes | Clinical Sensitivity:97.12 %Clinical Specificity: 100 %Nasal swab | **FI:**Validated in several laboratories (studies not published), meeting criteria.**DE**:Published study: https://[www.medrxiv.org/content/10.110](http://www.medrxiv.org/content/10.110) 1/2021.01.06.20249009v1 | [**DE**](https://www.finddx.org/wp-content/uploads/2021/06/SDQ_Nasal_Ag-Public-Report_20210412_v2.pdf) (12 April 2021)179 samples, nasal swab Clinical sensitivities:- Days < 7: 81.2%;- Ct < 33: 87.5%;- Ct < 25: 100%;Clinical specificity: 99.3%[**Brazil**](https://www.finddx.org/wp-content/uploads/2021/06/SDQ_Nasal_Ag-Public-Report_20210412_v2.pdf) (12 April 2021) | FI, PT, SK |  | DE[2], FI, FR |  | 2052 | 7 July 2021 |

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| **Manufacturer** | **RAT commercial name** | **CE****marking** | **Clinical performance *Data by manufacturer*** | **Clinical performance*****Data used in MS*** | **FIND evaluation studies** | **EU Member States using in practice** | **Other countries using in practice** | **Completed validation studies** | **MS currently validating** | **Device ID # *in JRC database11*** | **Included in Common list of RATs as of:** |
|  |  |  |  |  | 214 samples, nasal swab Clinical sensitivities:- Days < 7: 81.2%;- Ct < 33: 91.7%;- Ct < 25: 100%;Clinical specificity: 99.3% |  |  |  |  |  |  |
| SD BIOSENSORInc. | STANDARD F COVID-19 Ag FIA | Yes | 94,09% sensitivity98.52% specificity NP swab | **BE**:96.5% sensitivity, 99.7% specificity, NP swab**DE**:94% sensitivity 97% specificity | [**DE**](https://www.finddx.org/wp-content/uploads/2021/06/STANDARD_F_Ag-Public-Report_20201210-v2-1.pdf) (10 Dec 2020)676 samples, NP swab Clinical sensitivities:- Days < 7: 81.2%;- Ct < 33: 75%;- Ct < 25: 100%;Clinical specificity: 96.9%[**Brazil**](https://www.finddx.org/wp-content/uploads/2021/06/STANDARD_F_Ag-Public-Report_20201210-v2-1.pdf) (10 Dec 2020) 453 samples, NP swab Clinical sensitivities:- Days < 7: 80.2%;- Ct < 33: 80.9%;- Ct < 25: 87.9%;Clinical specificity: 97.9%[**India**](https://www.finddx.org/wp-content/uploads/2021/06/STANDARD_F_Ag_India_Public-Report_20210407_v1.0.pdf) (25 June 2020) 417 samples, NP swab Clinical sensitivities:- Days < 7: 61.8%;- Ct < 33: 53.6%;- Ct < 25: 68.5%;Clinical specificity: 99.5% | 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 | 344 | 17 February2021 |
| SD BIOSENSORInc. | STANDARD Q COVID-19Ag Test | Yes | 96.52% sensitivity99.68% specificity NP swab | **BE**:96.5% sensitivity, 99.7% specificity, NP swab**DE**:96.52% sensitivity, 99.68% specificity**SI**:96.5% sensitivity, 99.7% specificity, NP swab**FI:**Validated in several laboratories (studiesnot published), meeting criteria. | [**DE**](https://www.finddx.org/wp-content/uploads/2021/06/SDQ-Ag-Public-Report_20201210-v2-1.pdf) (10 Dec 2020)1263 samples, NP swab Clinical sensitivities:- Days < 7: 80%;- Ct < 33: 87.8%;- Ct < 25: 100%;Clinical specificity: 99.3%[**Brazil**](https://www.finddx.org/wp-content/uploads/2021/06/SDQ-Ag-Public-Report_20201210-v2-1.pdf) (10 Dec 2020) 400 samples, NP swab Clinical sensitivities:- Days < 7: 90.7%;- Ct < 33: 91.9%; | AT, BE, BG, CY,DE[2], DK, EE,ES, FI, FR, HR,IT, LU, LV, MT,NL[5], PT, RO, SE, SK, SI | ME, NO, CH | DE[2], ES, IT,NL[5], DK, PTCH, UA, UK, BR, NO | HR, IE, LU, SI, SE | 345 | 17 February2021 |

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| **Manufacturer** | **RAT commercial name** | **CE****marking** | **Clinical performance *Data by manufacturer*** | **Clinical performance*****Data used in MS*** | **FIND evaluation studies** | **EU Member States using in practice** | **Other countries using in practice** | **Completed validation studies** | **MS currently validating** | **Device ID # *in JRC database11*** | **Included in Common list of RATs as of:** |
|  |  |  |  |  | - Ct < 25: 95.9%;Clinical specificity: 97.6%[**CH**](https://www.finddx.org/wp-content/uploads/2021/06/SDQ-Ag-Public-Report_20201210-v2-1.pdf) (10 Dec 2020)529 samples, NP swab Clinical sensitivities:- Days < 7: 89.8%;- Ct < 33: 91.8%;- Ct < 25: 97.2%;Clinical specificity: 99.7%[**India**](https://www.finddx.org/wp-content/uploads/2021/06/SDQ_Ag-Public-Report_Continue_v1.pdf) (22 April 2021) 334 samples, NP swab Clinical sensitivities:- Days < 7: 58.3%;- Ct < 33: 65.5%;- Ct < 25: 89.4%;Clinical specificity: 97.3%[**Peru**](https://www.finddx.org/wp-content/uploads/2021/06/SDQ_Ag-Public-Report_Continue_v1.pdf) (22 April 2021) 335 samples, NP swab Clinical sensitivities:- Days < 7: 81.4%;- Ct < 33: 83.3%;- Ct < 25: 96.2%;Clinical specificity: 99.6% |  |  |  |  |  |  |
| SGA Medikal | V-Chek SARS-CoV-2 AgRapid Test Kit (ColloidalGold) | Yes | 96.6% sensitivity, Nasal swab | **DE**:96.6% sensitivity, 99% specificity |  | DE[2] |  | DE[2] |  | 1319 | 10 May 2021 |
| SGA Medikal | V-Chek SARS-CoV-2Rapid Ag Test (colloidal gold) | Yes | Clinical Sensitivity: 96.60%Nasal swab | **DE:**Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 94,1% at <Ct25) +Manufacturer specificity: 99,5% |  | DE[2] |  | DE[2] |  | 1357 | 7 July 2021 |
| Shenzen Ultra- Diagnostics Biotec Co., Ltd | SARS-CoV-2 Antigen Test Kit | Yes | Clinical Sensitivity:95.33 % (Nasal), 95.48(NP)Clinical Specificity:99.16 % (Nasal),99.61 % (NP) | **BE**:92% sensitivity, 100% specificity, NP swab100% sensitivity, 100% specificity, OP swab**SI**:95.9% sensitivity, 99.9% specificity,NP/OP/Nasal swab |  | AT, BE, ES, SI |  | BE, SI |  | 2017 | 10 May 2021 |

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| **Manufacturer** | **RAT commercial name** | **CE****marking** | **Clinical performance *Data by manufacturer*** | **Clinical performance*****Data used in MS*** | **FIND evaluation studies** | **EU Member States using in practice** | **Other countries using in practice** | **Completed validation studies** | **MS currently validating** | **Device ID # *in JRC database11*** | **Included in Common list of RATs as of:** |
| Shenzhen Lvshiyuan BiotechnologyCo., Ltd. | Green Spring SARS-CoV- 2 Antigen-Rapid test-Set | Yes | 98% sensitivity100% specificity NP/OP/Nasal swab | **DE**: 98% sensitivity , 100% specificity |  | DE[2] |  | DE[2] |  | 2109 | 10 May 2021 |
| Shenzhen Microprofit Biotech Co., Ltd | SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay) | Yes | Clinical Sensitivity:92.93 %Clinical Specificity: 100 %Nasal/NP/OP swab | **DE:**Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 100% |  | DE[2], ES |  | DE[2] |  | 1967 | 7 July 2021 |
| Shenzhen Microprofit Biotech Co., Ltd. | SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold ChromatographicImmunoassay) | Yes | Sensitivity: 86.3%,Specificity: 100% Nasal Swab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 100% |  | DE[2] |  | DE[2] |  | 1178 | 23 July 2021 |
| Shenzhen WatmindMedical Co., Ltd | SARS-CoV-2 AgDiagnostic Test Kit(Colloidal Gold) | Yes | 95.15% Sensitivity Nasal swab | **DE**: 95.15% sensitivity , 99.12% specificity |  | AT, DE[2], FR |  | DE[2] |  | 1769 | 10 May 2021 |
| Shenzhen Watmind Medical Co., Ltd | SARS-CoV-2 AgDiagnostic Test Kit (Immuno-fluorescence) | Yes | Clinical Sensitivity:97.83 % (CT ≤ 33) Clinical Sensitivity:90.08 % (Ct ≤ 36)Nasal swab | **DE:**Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 99,13% |  | DE[2] |  | DE[2] |  | 1768 | 7 July 2021 |
| Shenzhen Zhenrui BiotechCo., Ltd | Zhenrui ®COVID-19 Antigen Test Cassette | Yes | 96% sensitivity Nasal swab | **DE**: 96% sensitivity 97% specificity |  | DE[2] |  | DE[2] |  | 1574 | 10 May 2021 |
| Siemens Healthineers | CLINITEST Rapid COVID-19 Antigen Test | Yes | 98.32% sensitivity (NP swab) 97.25% sensitivity100% specificity (Nasal swab) | **BE**:98.32% sensitivity, 99.6% specificity, NP swab97.25% sensitivity, 100% specificity, Nasal swab**SI**:96.7% sensitivity, 99.2% specificity,NP/Nasal swab |  | AT, BE, DE[2],FR, HR, NL[5], PT, SE, SI | CH | DE[2], ES, NL[5] | HR, PT, SE[3] | 1218 | 17 February2021 |
| Sugentech, Inc. | SGTi-flex COVID-19 Ag | Yes | 100% sensitivity100% specificityOP/NP swab | **DE**: Positive evaluation by Paul-Ehrlich- Institut (sensitivity of 100% at <Ct30 and100% at <Ct25) |  | AT, DE[2] |  | DE[2] |  | 1114 | 10 May 2021 |
| TODA PHARMA | TODA CORONADIAG Ag | Yes | 98.6% sensitivity Nasal swab | **BE**:96.6% sensitivity, 100% specificity, NP/OP swab**DE**: 96.6% sensitivity, 100 specificity |  | BE, DE[2], SI |  | DE[2] |  | 1466 | 10 May 2021 |

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| **Manufacturer** | **RAT commercial name** | **CE****marking** | **Clinical performance *Data by manufacturer*** | **Clinical performance*****Data used in MS*** | **FIND evaluation studies** | **EU Member States using in practice** | **Other countries using in practice** | **Completed validation studies** | **MS currently validating** | **Device ID # *in JRC database11*** | **Included in Common list of RATs as of:** |
|  |  |  |  | **SI**: 96.6% sensitivity, 100% specificity, NP/OP swab |  |  |  |  |  |  |  |
| Triplex International Biosciences Co.,Ltd | SARS-CoV-2 Antigen Rapid Test Kit | Yes | 98.33% sensitivity100% specificity Nasal/OP/NP swab | **DE:** Positive evaluation by Paul-Ehrlich- Institut (sensitivity of 92,5% at <Ct30 and 100% at <Ct25) |  | DE[2] |  | DE[2] |  | 2074 | 16 June 2021 |
| Triplex International Biosciences Co.,Ltd, China | SARS-CoV-2 Antigen Rapid Test Kit | Yes | 98.51 % sensitivity Nasal swab | **DE**: Positive evaluation by Paul-Ehrlich- Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 100% |  | DE[2], FR, PT |  | DE[2] |  | 1465 | 14 July 2021 |
| Vitrosens Biotechnology Co., Ltd | RapidFor SARS-CoV-2 Rapid Ag Test | Yes | 97.3% sensitivity Nasal swab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct30 and 100% at<Ct25)**SI**:97.3% sensitivity, 99% specificity,NP/OP/Nasal swab |  | DE[2], SI |  | DE[2] |  | 1443 | 10 May 2021 |
| VivaChek Biotech (Hangzhou) Co.,Ltd. | VivaDiag Pro SARS-CoV- 2 Ag Rapid Test | Yes | 97.04% sensitivity99.9% specificityNasal/OP/NP swab | **AT**:97,06% sensitivity, 100% specificity, allspecimen types, i.e. N&OP&NP swab |  | AT, SI |  | AT, DE[2], SI | AT | 2103 | 10 May 2021 |
| Wuhan EasyDiagnosis Biomedicine Co.,Ltd. | COVID-19 (SARS-CoV-2)Antigen-Test Kit | Yes | 96.1% sensitivity100% specificity Nasal/OP/NP swab | **DE**: 96.15% sensitivity , 99.26% specificity |  | DE[2] |  | DE[2] |  | 2098 | 10 May 2021 |
| Wuhan Life Origin Biotech Joint Stock Co.,Ltd. | SARS-CoV-2 Antigen Assay Kit (Immunochromatography) | Yes | 92.67% sensitivity Nasal swab | **DE**:Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 100% at <Ct25) +Manufacturer specificity: xx% |  | DE[2] |  | DE[2] |  | 1773 | 14 July 2021 |
| Wuhan UNscience Biotechnology Co., Ltd. | SARS-CoV-2 Antigen Rapid Test Kit | Yes | Clinical Sensitivity:96.33 %Clinical Specificity:99.57 %Nasal/NP/OP swab | **DE:** Positive evaluation by Paul-Ehrlich- Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 99,57% |  | DE[2] |  | DE[2], FR |  | 2090 | 7 July 2021 |
| Xiamen AmonMed BiotechnologyCo., Ltd | COVID-19 Antigen Rapid Test Kit (Colloidal Gold) | Yes | 93.2% sensitivity99.55% specificity Nasal swab | **DE**: Positive evaluation by Paul-Ehrlich- Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 99.55% |  | DE[2] |  | DE[2] |  | 1763 | 10 May 2021 |
| Xiamen Boson Biotech Co. Ltd | Rapid SARS-CoV-2 Antigen Test Card | Yes | Not specified NP swab | **BE**: 93.8% sensitivity, 100% specificity, NP swab**DE**: 96.49% sensitivity, 99.03% specificity |  | AT, BE, BG, CY,DE[2], FR, RO | CH | DE[2] CH |  | 1278 | 17 February2021 |

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| **Manufacturer** | **RAT commercial name** | **CE****marking** | **Clinical performance *Data by manufacturer*** | **Clinical performance*****Data used in MS*** | **FIND evaluation studies** | **EU Member States using in practice** | **Other countries using in practice** | **Completed validation studies** | **MS currently validating** | **Device ID # *in JRC database11*** | **Included in Common list of RATs as of:** |
| Xiamen Wiz Biotech Co., Ltd | SARS-CoV-2 Antigen Rapid Test | Yes | 96.3% sensitivity, Nasal swab | **DE**: 96.3% sensitivity, 100% specificity |  | AT, DE[2] |  | DE[2] |  | 1456 | 10 May 2021 |
| Xiamen Wiz Biotech Co., Ltd | SARS-CoV-2 Antigen Rapid Test (ColloidalGold) | Yes | 95.91% sensitivity100% specificityNasal swab | **DE**: 95.91% sensitivity , 100% specificity |  | AT, DE[2] |  | DE[2] |  | 1884 | 10 May 2021 |
| Zhejiang Anji Saianfu BiotechCo.., Ltd | AndLucky COVID-19 Antigen Rapid Test | Yes | 95.8% sensitivity, Nasal swab | **DE**: 97.5% sensitivity, 99.1% specificity |  | AT, DE[2] |  | DE[2] |  | 1296 | 10 May 2021 |
| Zhejiang Anji Saianfu BiotechCo.., Ltd | reOpenTest COVID-19 Antigen Rapid Test | Yes | 95.8% sensitivity, Nasal swab | **DE**: Positive evaluation by Paul-Ehrlich- Institut (sensitivity of 94,1% at <Ct25) +Manufacturer specificity: 99% |  | DE[2] |  | DE[2] |  | 1295 | 10 May 2021 |
| Zhejiang Orient Gene Biotech Co., Ltd | Coronavirus Ag Rapid Test Cassette (Swab) | Yes | 98.32 % sensitivity99.6 % specificity Nasal/NP swab | **BE**: 98.32% sensitivity, 99.6% specificity,NP swab; 97.25% sensitivity, 100% specificity, Nasal swab**DE**: 96.72% sensitivity, 99.22% specificity |  | AT, BE, BG,DE[2], PT | CH, UK | DE[2] | SE[3] | 1343 | 17 February2021 |
| Zhuhai Lituo Biotechnology Co., Ltd. | COVID-19 Antigen Detection Kit (Colloidal Gold) | Yes | 96.12% sensitivity Nasal swab (CT<33)99.59% sensitivity NP swab100% specificity Nasal swab(CT<33) | **DE**: Positive evaluation by Paul-Ehrlich- Institut (sensitivity of 100% at <Ct25) + Manufacturer specificity: 100% |  | CZ, DE[2], SI |  | DE[2] |  | 1957 | 14 July 2021 |

*Notes:*

1. FR: Reference to validation study (not specifying which specific RAT is being recommended or was tested in practice): [https://www.has-sante.fr/upload/docs/application/pdf/2020-](https://www.has-sante.fr/upload/docs/application/pdf/2020-10/synthese_tests_antigeniques_vd.pdf) [10/synthese\_tests\_antigeniques\_vd.pdf](https://www.has-sante.fr/upload/docs/application/pdf/2020-10/synthese_tests_antigeniques_vd.pdf)
2. DE: Rapid antigen tests that have completed practical validation studies in Germany: See: [https://www.pei.de/SharedDocs/Downloads/DE/newsroom/dossiers/evaluierung-sensitivitaet-sars-](https://www.pei.de/SharedDocs/Downloads/DE/newsroom/dossiers/evaluierung-sensitivitaet-sars-cov-2-antigentests-04-12-2020.pdf?__blob=publicationFile&v=43) [cov-2-antigentests-04-12-2020.pdf? blob=publicationFile&v=43](https://www.pei.de/SharedDocs/Downloads/DE/newsroom/dossiers/evaluierung-sensitivitaet-sars-cov-2-antigentests-04-12-2020.pdf?__blob=publicationFile&v=43)
3. SE: Smaller evaluations ongoing in some of the regions.
4. BE: In the clinical performance study performed in three different clinical laboratories during the ascendant phase of the epidemiological curve, we found an overall sensitivity and specificity of 57.6 and 99.5%, respectively with an accuracy of 82.6%.
5. NL: Collected validation data from accredited laboratories in the Netherlands. The report includes evaluations of various RAT that labs performed at their own initiative. <https://lci.rivm.nl/antigeensneltesten>
6. BE: Van Honacker E. et al., Comparison of five SARS-CoV-2 rapid antigen detection tests in a hospital setting and performance of one antigen assay in routine practice: a useful tool to guide isolation precautions? J Hosp Infect. In press.

**ANNEX II:** Common standardised set of data to be included in COVID-19 test result certificates, as agreed by Member States on 17 February 2021 and updated on 19 March 2021

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| **Section** | **Data element** | **Description** | **Preferred Code****System** |
| **Person identification** | Person name | The legal name of the tested person. Surname(s) and forename(s), in that order. |  |
| Person identifier*(optional)* | An identifier of the tested person, according to the policies applicable in each country.Examples: citizen ID and/or document number (ID-card/passport). |  |
| Person date of birth*(optional)* | Tested person’s date of birth.Mandatory if no Person identifier is provided. | Complete date, without time, following the ISO 8601. |
| **Test information** | Disease or agent targeted | Specification that it concerns the detection of SARS-CoV-2 infection. | ICD-10, SNOMED CT |
| Type of test | Description of the type of test that was conducted, e.g. NAAT or rapid antigen test. | LOINC, NPU |
| Test name*(optional for NAAT)* | Commercial or brand name of the test. |  |
| Test Manufacturer*(optional for NAAT)* | Legal manufacturer of the test. |  |
| Sample origin*(optional)* | The type of sample that was taken (e.g. nasopharyngeal swab, oropharyngeal swab, nasal swab). | SNOMED CT |
| Date and time of the test sample collection | Date and time when the sample was collected. | Complete date, with time and time zone, following ISO 8601 |
| Date and time of the test result production*(optional)* | Date and time when the test result was produced. | Complete date, with time and time zone, following ISO 8601 |
| Result of the test | For example, negative, positive, inconclusive or void. | SNOMED CT |
| Testing centre or facility*(mandatory for NAAT)* | Name/code of testing centre, facility or a health authority responsible for the testing event.*Optional*: address of the testing facility. |  |
| Health Professional identification*(optional)* | Name or health professional code responsible for conducting (and validating) the test.Surname(s) and forename(s), in that order. |  |
| Country where the test was taken | The country in which the individual was tested. | ISO 3166 Country Codes |
| **Test certificate metadata** | Test result certificate issuer | Entity that issued the COVID-19 test result certificate (allowing to check the certificate). |  |
| Certificate identifier | Reference of the COVID-19 test result certificate (unique identifier). |  |

**NOTĂ**: În acest moment, Health Security Committee (HSC) a agreat ca în lista comună a testelor rapide antigenice mutual recunoscute la nivelul Uniunii sa includă doar testele antigenice rapide efectuate din probe recoltate din nas, orofaringe sau nasofaringe. Testul antigenic rapid produs de Tody Laboratories Int., sub denumirea ”Coronavirus (SARS-CoV 2) Antigen - Oral Fluid”, este recunoscut doar dacă este efectuat din probe recoltate din nas, orofaringe sau nasofaringe.