EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health, country knowledge, crisis management
Health Security

EU health preparedness:

A common list of COVID-19 rapid antigen tests; A common standardised set of data to be included in COVID-19 test result certificates; and A common list of COVID-19 laboratory based antigenic assays

Agreed by the Health Security Committee

Commented [A1]: **General note:** A proposal for a restructured EU common list document will be forwarded separately to the HSC for review. The restructured document is planned to be published in June, as part of the next update (the 15th) of the EU common list of RATs.

Common list of COVID-19 rapid antigen tests (Annex I)

Agreed by the Health Security Committee on 17 February 2021.

First update: 10 May 2021; Second update: 16 June 2021; Third update: 7 July 2021; Fourth update: 14 July 2021; Fifth update: 23 July 2021; Sixth update: 20 October 2021; Seventh update: 10 November 2021; Eight update: 8 December 2021; Ninth update: 21 December 2021; Tenth update: 21 January 2022; Eleventh update: 10 February 2022; Twelfth update: 4 March 2022; Thirteenth update: 8 April 2022; Fourteenth update: 6 May 2022.

Common standardised data set to be included in COVID-19 test result certificates (Annex II)

Agreed by the Health Security Committee on 17 February 2021.

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

List of mutually recognised COVID-19 laboratory based antigenic assays (Annex III)

Agreed by the Health Security Committee on 20 October 2021

First update: 10 February 2022; Second update: 8 April 2022.

ANNEX I: Common list of COVID-19 rapid antigen tests[1]

As agreed by EU Member States on 6 May 2022

***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 updated technical report by ECDC on 26 October 2021. 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 further criteria and definitions agreed by the Technical Working Group on 21 September 2021. 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.*

Rapid antigen tests presented in boxes are so-called 'twin tests'. These are rapid antigen tests that are identical in design and construction but, for example, branded or distributed under a different name. The results of independent validation studies may be transferred between twin tests.

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
			Prospective clinical field study					
AAZ-LMB	COVID-VIRO®	1833	**FR:** Prospective study carried out in the "Centre Hospitalier d'Orléans" on NP swabs simultaneously tested by RT PCR: sensitivity <7 days after onset of symptoms: 94,7% (72/76), specificity: 100%.	96.6% sensitivity 100% specificity Nasal swab, NP swab	FR CH	Nucleo-protein	Nasal swab, Nasopharyngeal swab	10 May 2021

[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

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

[4] As reported in the JRC database, see: https://covid-19-diagnostics.jrc.ec.europa.eu/.

[5] Only test results based on nasal, oropharyngeal and/or nasopharyngeal specimens should be valid for the issuance of test certificates for the EU Digital COVID Certificate. The information included in this column is based on the information provided by manufacturers to the JRC database.

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
Abbott Rapid Diagnostics	Panbio™ COVID-19 Ag Rapid Test	1232	*Prospective clinical field studies* **BE**: 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 Cts25: 17/18 samples. Overall specificity 100%. **NL**: 1367 and 208 subjects were enrolled in Utrecht and Aruba, respectively. Specificity of the Panbio™ COVID-19 Ag Rapid Test was 100% (95%CI: 99.7–100%) in both settings. Test sensitivity was 72.6% (95%CI: 64.5–79.9%) in the Netherlands and 81.0% (95% CI: 69.0–89.8%) in Aruba. Restricting RT-qPCR test positivity to Ct-values <32 yielded test sensitivities of 95.2% (95%CI: 89.3–98.5%) in Utrecht and 98.0% (95%CI: 89.2–99.95%) in Aruba. **PT:** 83 samples from symptomatic individuals (27 PCR positive and 56 negative by PCR) were tested. Sensitivity 63% (95%IC 42-81); specificity 100% (95%IC 94-100). LoD TCID50/ml 1,38 x 102 and CT<24. **SE:** Karolinska hospital evaluation of Lot 41ADF061A. Patient samples: 95 PCR positive, 150 negative. No detailed sample description available. Sensitivity 59%, specificity 100%. Sensitivity Ct<25 = 90.2%. **FIND evaluation studies** **DE** (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** (10 Dec 2020): 535 samples, NP swab. Clinical sensitivities: Days ≤ 7: 85.6%; Ct ≤ 33: 89.7%; Ct ≤ 25: 96.8%. Clinical specificity: 100% **India** (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%. Specificity: 100%	91.4% sensitivity 99.8% specificity NP swab (Ct ≤ 33) 98.1% sensitivity 99.8% specificity Nasal swab (Ct ≤ 33)	BE, DE[2], ES, FI, NL[5], PT, SE CH, India, NO, UK	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab	17 February 2021

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
			Retrospective in vitro studies **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity of 99.8%					
ABIOTEQ	Cora Gentest-19	2374	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.8%	Sensitivity 98,7%, Specificity 99,8%	DE[2]	Nucleo-capsid protein	Anterior nasal swab, Nasal swab, Nasopharyngeal swab, Oropharyngeal swab, Throat swab	20 October 2021
AccuBioTech Co.,Ltd	Accu-Tell SARS-CoV-2 Ag Cassette	2579	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.2%	Sensitivity: 95.7% Specificity: 99.2%	DE[2]	Nucleo-capsid protein	Nasopharyngeal swab	20 October 2021
Acon Biotech (Hangzhou) Co., Ltd	Flowflex SARS-CoV-2 Antigen Rapid Test	1457	*Prospective clinical field study* **FIND evaluation** CH (9 June 2021) 279 samples, nasal swab. Sensitivities: Days ≤ 7: 92.2%; Ct ≤ 33: 98.3%; Ct ≤ 25: 100%. Specificity: 99.5% *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99.54%	Nasal swab Clinical Sensitivity: 97.1 % Clinical Specificity: 99.5 % NP swab Clinical Sensitivity: 97.6 % Clinical Specificity: 99.4 %	DE[2] CH, UK	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab	14 July 2021
ACON Biotech(Hangzhou) Co., Ltd.	Flowflex SARS-CoV-2 Antigen Rapid Test (Nasal/Saliva)	1865	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99.5%	Clinical Sensitivity 97.1 % (Nasal Swab) Clinical Specificity 99.5 % (Nasal Swab)	DE[2]	Nucleo-capsid protein	Nasal swab ! Saliva	10 February 2022
ACON Laboratories, Inc.	Flowflex SARS-CoV-2 Antigen Rapid Test	1468	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 98,7%	96.9% sensitivity 98.7% specificity Nasal swab	DE[2]	Nucleo-protein	Nasal swab	10 May 2021

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
AESKU.DIAGNOSTICS GmbH & Co, KG	AESKU.RAPID SARS-CoV-2	2108	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 84% at Ct ≤ 25; Manufacturer specificity: 98%	Sensitivity: 100% (Ct<30), Specificity: 99% Nasal swab	DE[2]	Nucleo-capsid protein	Nasal swab	10 May 2021
Affimedix Inc.	TestNOW® - COVID-19 Antigen Test	2130	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99,2%	NP swab: 95% sensitivity 99.2% specificity Nasal swab: 98.1% sensitivity 100% specificity	DE[2]	Nucleo-protein	Nasal swab, Nasopharyngeal swab	10 May 2021
AMEDA Labordiagnostik GmbH	AMP Rapid Test SARS-CoV-2 Ag	1304	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	97.3% sensitivity NP swab 97.3% sensitivity Nasal swab 100% specificity	DE[2] CH, UK	Nucleo-protein	Nasal swab, Nasopharyngeal swab	17 February 2021
Anbio (Xiamen) Biotechnology Co., Ltd	Rapid COVID-19 Antigen-Test (colloidal Gold)	1822	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	97.33% sensitivity, 100% specificity, Nasal swab 98.33% sensitivity, 100% specificity, NP swab 97.67% sensitivity, 100% specificity, ~~OP~~ Throat swab	DE[2]	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab, ~~Oropharyngeal~~ Throat swab	10 May 2021
Anhui Deep Blue Medical Technology Co., Ltd	COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)	1736	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: ~~>~~99.8%	N~~Pasal~~/OP swab: 96.~~,~~4% sensitivity, 99.~~,~~8% specificity ~~NP swab: 95,7% sensitivity, 99,3% specificity~~	DE[2] UK	Nucleo-capsid protein~~Nucleo-protein~~	Nasopharyngeal swab, Oropharyngeal swab~~Nasal swab,~~ ~~I. Other~~	10 May 2021
	COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) – Nasal swab	1815	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: >99%	96.4 % sensitivity 99.8 % specificity Nasal swab	DE[2] UK	Nucleo-protein	Anterior nasal swab, Nasal swab	10 May 2021

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
Anhui Formaster Biosci Co., Ltd.	New Coronavirus (COVID-19) Antigen Rapid Test	2089	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.5%	sensitivity: 95.15%, specificity: 98.5%	DE[2]	Nucleo-protein	Nasopharyngeal swab, Oropharyngeal swab	20 October 2021
ArcDia International Ltd	mariPOC SARS-CoV-2	768	*Prospective clinical field study* **FI:** Clinical performance of the test was evaluated against qRT-PCR with nasopharyngeal swab specimens collected from patients suspected of acute SARS-CoV-2 infection. Sensitivity of the mariPOC test was 100.0% (13/13) directly from swab specimens and 84.4% (38/45) from swab specimens in undefined transport mediums. Specificity was 100.0% (201/201). **FI**: Clinical performance of the test was evaluated against RT-PCR with specimens from 962 symptomatic and asymptomatic individuals. Among the symptomatic subjects, overall sensitivity was 82.5% (33/40), which increased to 97.1% (33/34) in samples with a Ct value <30. The specificity was 100% (916/916).	100% sensitivity 100% specificity Nasopharyngeal swab	FI	Nucleo-protein	Nasopharyngeal swab	10 May 2021
ArcDia International Oy Ltd	mariPOC Respi+	2078	*Prospective clinical field study* **FI:** Clinical performance of the test was evaluated against qRT-PCR with nasopharyngeal swab specimens collected from patients suspected of acute SARS-CoV-2 infection. Sensitivity of the mariPOC test was 100.0% (13/13) directly from swab specimens and 84.4% (38/45) from swab specimens in undefined transport mediums. Specificity was 100.0% (201/201). **FI**: Clinical performance of the test was evaluated against RT-PCR with specimens from 962 symptomatic and asymptomatic individuals. Among the symptomatic subjects, overall sensitivity was 82.5% (33/40), which increased to 97.1% (33/34) in samples with a Ct value <30. The specificity was 100% (916/916).	100 % sensitivity 100 % specificity NP swab	FI	Nucleo-protein	Nasopharyngeal swab	14 July 2021

Commented [A2]: Note: this RAT will remain in the EU common list after 1 June 2022 if this change is indeed agreed by the HSC

Commented [A3]: Note: this RAT will remain in the EU common list after 1 June 2022 if this change is indeed agreed by the HSC

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
ArcDia International Oy Ltd	mariPOC Quick Flu+	2079	*Prospective clinical field study* **FI:** Clinical performance of the test was evaluated against qRT-PCR with nasopharyngeal swab specimens collected from patients suspected of acute SARS-CoV-2 infection. Sensitivity of the mariPOC test was 100.0% (13/13) directly from swab specimens and 84.4% (38/45) from swab specimens in undefined transport mediums. Specificity was 100.0%. **FI**: Clinical performance of the test was evaluated against RT-PCR with specimens from 962 symptomatic and asymptomatic individuals. Among the symptomatic subjects, overall sensitivity was 82.5% (33/40), which increased to 97.1% (33/34) in samples with a Ct value <30. The specificity was 100% (916/916).	100 % sensitivity 100 % specificity NP swab	FI	Nucleo-protein	Nasopharyngeal swab	14 July 2021
ARISTA Biotech Pte.LTD.	ARISTA™ COVID-19 Antigen Rapid Test	1926	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	Clinical Sensitivity 99.4 % Clinical Specificity 100 %	DE[2]	Nucleo-capsid protein	Nasopharyngeal swab	8 April 2022
Artron Laboratories Inc.	Artron COVID-19 Antigen Test	1618	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	91.59% sensitivity, Nasal 91.67% sensitivity, NP 100 % specificity Nasal/NP swab	DE[2]	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab	14 July 2021
Asan Pharmaceutical Co., Ltd	Asan Easy Test COVID-19 Ag	1654	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 97.71%	94.67% sensitivity, 97.71% specificity Nasal swab	DE[2]	*Unknown*	Nasal swab	10 May 2021
Assure Tech. (Hangzhou) Co., Ltd.	ECOTEST COVID-19 Antigen Rapid Test Device	770	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 95% at Ct ≤ 25; Manufacturer specificity: 99.2%	92.5 % sensitivity 99.2 % specificity Nasal/NP/OP swab	DE[2] UK	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab, Oropharyngeal swab	14 July 2021

Commented [A4]: Note: this RAT will remain in the EU common list after 1 June 2022 if this change is indeed agreed by the HSC

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
	ECOTEST COVID-19 Antigen Rapid Test Device	2350	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 95% at Ct ≤ 25; Manufacturer specificity: 99.1%	Sensitivity: 97.7%, Specificity: 99.1% NP and OP swab	DE[2] UK	Nucleo-protein	Nasopharyngeal swab, Oropharyngeal swab	23 July 2021
Avalun	Ksmart® SARS-COV2 Antigen Rapid Test	1800	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99,32%	Sensitivity: 93.18% Specificity: 99.32% NP swab	DE[2]	*Unknown*	Nasopharyngeal swab	7 July 2021
AXIOM Gesellschaft für Diagnostica und Biochemica mbH	COVID-19 Antigen Rapid Test	2101	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	98% sensitivity 100% specificity NP/Nasal swab	DE[2]	Nucleo-protein	Nasal swab, Nasopharyngeal swab, Throat swab	10 May 2021
Becton Dickinson	BD Veritor™ System for Rapid Detection of SARS CoV 2	1065	*Prospective clinical field studies* **ES:** Prospective study in four Spanish hospitals (n = 476); 108 positive samples, 368 negative samples. Sensitivity: 92%, specificity: 98.6%. **NL:** Independent field study in symptomatic individuals (n=979, PCR positive n=161) - sampling was Nasal mid-turbinate + OP swab. Sensitivity overall: 79.5% - Sensitivity Ct<30: 93.2% - Specificity overall: 99.8% **SE**: Karolinska hospital evaluation of Lot 0255648. Patient samples: 95 PCR positive, 150 negative. No detailed sample description available. Sensitivity 45%, specificity 97%. Sensitivity Ct<25 = 87.8%. *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 83% at Ct ≤ 25; Manufacturer specificity: 99.6%	Clinical Sensitivity: 91.1 % Clinical Specificity: 99.6 % Nasal swab	DE[2], ES, NL, SE	Nucleo-protein	Nasal swab	7 July 2021

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
Becton Dickinson	BD Kit for Rapid Detection of SARS-CoV-2	2282	*Prospective clinical field studies* **ES:** Prospective study in four Spanish hospitals (n = 476); 108 positive samples, 368 negative samples. Sensitivity: 92%, specificity: 98.6%. **NL:** Independent field study in symptomatic individuals (n=979, PCR positive n=161) - sampling was Nasal mid-turbinate + OP swab. Sensitivity overall: 79.5% - Sensitivity Ct<30: 93.2% - Specificity overall: 99.8%	Clinical Sensitivity: 91.1 % Clinical Specificity: 99.6 % Nasal swab	ES, NL	Nucleo-protein	Nasal swab	10 November 2021
Beijing Hotgen Biotech Co., Ltd	Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)	1870	*Prospective clinical field study* **FIND evaluation** Brazil (15 September 2021) 453 samples, nasal swab. Clinical sensitivities: Days ≤ 7: 90.1%; Ct ≤ 33: 89.5%; Ct ≤ 25: 95.5%. Clinical specificity: 100% UK (15 September 2021) 248 samples, NP swab. Clinical sensitivities: Days ≤ 7: 84.4%; Ct ≤ 33: 80.6%; Ct ≤ 25: 82.8%. Clinical specificity: 99.4% *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.76%	97.1% sensitivity 99.76% specificity	DE[2]	Nucleo-protein	Nasal swabs, Throat swabs, ! Saliva	10 May 2021
Beijing Hotgen Biotech Co., Ltd	Coronavirus (2019-nCoV)-Antigentest	2807	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.88%	Clinical sensitivity: 96.95% Clinical specificity: 98.88%	DE[2]	Nucleo-capsid protein	Nasal swab	21 January 2022
Beijing Jinwofu Bioengineering Technology Co.,Ltd.	Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Kit	2072	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25 + Manufacturer specificity: 100%	96.88 % sensitivity 100 % specificity Nasal/ NP/ OP swab	DE[2]	Nucleo-protein	Anterior nasal swab, Nasal swab, Nasopharyngeal swab, Oropharyngeal swab ! Saliva	14 July 2021
Beijing Kewei Clinical Diagnostic	COVID19 Antigen Rapid Test	1778	*Retrospective in vitro study*	Clinical Sensitivity: 96.18	DE[2]	*Unknown*	Nasal swab	21 December

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
Reagent Inc	Kit		**DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25 + Manufacturer specificity: 100%	% Specificity: 100%				2021
Beijing Lepu Medical Technology Co., Ltd	SARS-CoV-2 Antigen Rapid Test Kit	1331	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.26%	92.00% sensitivity, 99.26% specificity Nasal swab	DE[2]	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab	17 February 2021
Beijing O&D Biotech Co., Ltd.	COVID-19 Antigen Rapid Test	2494	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.67%	Nasal swab: sensitivity: 92.17% (95% CI: 85.26%-96.13%) specificity: 98.67 % (95% CI: 96.39%-99.57%) OP swab: sensitivity: 93.04% (95% CI: 86.33%-96.73%); specificity: 99% (95% CI: 96.86%-99.74%) NP swab: sensitivity: 93.91% (95% CI: 87.86%-97.52%) specificity: 99.33% (95% CI: 97.61%-99.92%)	DE[2]	Nucleo-capsid protein	Nasal swab, Oropharyngeal swab, Nasopharyngeal swab	20 October 2021
Beijing Wantai Biological Pharmacy Enterprise Co., Ltd	Wantai SARS-CoV-2 Ag Rapid Test (colloidal gold)	1485	*Prospective clinical field study* **CZ:** Independent prospective study by Public Health Institute Ostrava (CZ), including NP swabs from unselected symptomatic and asymptomatic participants. Sensitivity 80.6%, specificity 98.5% on 155 pos. and 325 neg. samples (as resulting by RT-PCR). Ct not reported. N total = 480 *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.2%	93.2% sensitivity 98.2% specificity Nasal swab	CZ, DE[2]	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab	14 July 2021
BioGnost Ltd	CoviGnost AG Test Device	2247	*Retrospective in vitro study*	Sensitivity: 96%,	HR	*Unknown*	Nasopharyngeal	23 July 2021

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
	1x20		**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%	Specificity: 99% NP swab			swab	
Biohit Healthcare (Hefei) Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit (Fluorescence Immunochromato-graphy)	1286	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.9%	Sensitivity: 96.77% Specificity: 98.9% NP/OP swab	DE[2]	Nucleo-capsid protein	Anterior nasal swab	23 July 2021
Biohit Healthcare (Hefei) Co., Ltd.	SARS-CoV-2 Antigen Rapid Test (Colloidal Gold Method)	2230	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.49%	Sensitivity: 96.12%, Specificity: 99.49 %	DE[2]	Nucleo-capsid protein	Nasal swab	8 December 2021
BIOLAN HEALTH, S.L.	COVID-19 Antigen Rapid Test (Colloidal Gold Method)	2519	*Prospective clinical field study* **ES:** Prospective study performed in Hospital Universitario de Cruces (independent public institution). Nasal specimen, 314 negative samples and 116 positive samples. CT distribution described. Sensitivity 98,1% at Ct<25; overall sensitivity 81%; specificity 98,1%.	Clinical sensitivity 96.5 % (within 5 days of symptom onset). Clinical sensitivity 91.6 % (7 days) Clinical Specificity 98.3 %	ES	Nucleo-capsid protein	Nasal swab	4 March 2022

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
BioMaxima SA	SARS-CoV-2 Ag Rapid Test	2035	*Prospective clinical field studies* **FR**: NP swabs, Diagnostic sensitivity: 96,4% (80/83) (95% CI: 89,8-99,2%); diagnostic specificity: 99,2%, (120/121) **PL:** Evaluation of the test was performed on 480 samples of NP swabs taken from patients with symptoms of COVID-19 and from people in contact with an infected person but without symptoms of infection. Positive results were obtained in 205 patients and in the molecular test 213 people. Negative results were obtained in 275 people and in the molecular test 267 people. The above results permitted calculation of diagnostic sensitivity, which was 93.43% (95% CI: 91.61%~97.19%) and diagnostic specificity, which was 97.75% (95% CI: 93.74%~98.92%) *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99%	Sensitivity: 95% Specificity: 99% NP Swab	DE[2], FR, PL	Nucleo-protein	Nasopharyngeal swab	23 July 2021
Biomerica Inc.	Biomerica COVID-19 Antigen Rapid Test (nasopharyngeal swab)	1599	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99,7%	Clinical Sensitivity: 94.7%; Clinical specificity: 99.7% Nasal/NP swab	DE[2]	Nucleo-protein	Nasal swab, Nasopharyngeal swab	7 July 2021
BIONOTE	NowCheck COVID-19 Ag Test	1242	*Prospective clinical field study* **FIND evaluation** **Brazil** (20 April 2021) 400 samples, NP swab. Clinical sensitivities: Days ≤ 7: 92.2%; Ct ≤ 33: 91.4%; Ct ≤ 25: 94.8%. Clinical specificity: 97.3% **Brazil** (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% *Retrospective in vitro study*	Clinical Sensitivity: 90.91 % Clinical Specificity: 99.43 % Nasal swab, NP swab	DE[2] Brazil	*Unknown*	Nasal swab, Nasopharyngeal swab	7 July 2021

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
			DE: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98,6%					
BIO-RAD	CORONAVIRUS AG RAPID TEST CASSETTE	2031	*Prospective clinical field studies* **ES[7]:** • Prospective study; 96 positive samples and 269 negative samples. Sensitivity 94%. Specificity 99.2%. No Ct distribution specified. • 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)	Clinical Sensitivity: 98% (NP: 98,32% / Nasal: 97,25%) Clinical Specificity: 99% (NP: 99,6% / Nasal: 100%)	ES	Nucleo-protein	Nasal swab, Nasopharyngeal swab	7 July 2021
BioSpeedia International	COVID19Speed-Antigen Test BSD_0503	2380	*Prospective clinical field studies* **FR:** Independent prospective study by the University Hospital of Saint-Etienne: samples from unselected symptomatic and asymptomatic individuals (255 pos., 365 neg.), overall sensitivity: 95.29% (sensitivity Ct<25: 97.72%), specificity: 99.73%.	Clinical sensitivity: 97.5% Clinical specificity: 99.3%	FR	Nucleo-capsid protein	Nasopharyngeal swab	21 January 2022

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
BIOSYNEX SWISS S.A.	BIOSYNEX COVID-19 Ag BSS	1223	*Prospective clinical field studies* **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%, probably linked to the use of transport medium instead of the swab included in the kit. **FR**: NP swabs, prospective study (71/71) : sensitivity 100% (45/45, specificity 100% **NL**: Independent field study, mainly symptomatic individuals (n=568, PCR positive n=39), NP swab; sensitivity Ct≤30: 96.0%, sensitivity ≤25: 100%; specificity overall: 100% **NL**: Independent field study, symptomatic individuals (n=270, PCR positive n=17), NP+OP swab; sensitivity Ct≤30: 94.1%, sensitivity Cts≤25: 100%; specificity overall: 100% **SE**: Karolinska hospital evaluation of Lot 20100103. Patient samples; 95 PCR positive, 150 negative. No detailed sample description available. Sensitivity 76%, specificity 96%. Sensitivity Ct<25 = 100%. *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	96% sensitivity, 100% specificity, NP/Nasal swab	BE, DE[2], FR, NL[3], SE CH	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab	17 February 2021
BIOSYNEX SA	BIOSYNEX COVID-19 Ag+ BSS	1494	*Prospective clinical field study* **FR**: Validation study data: 125 positive and 118 negative samples; sensitivity 96%, specificity: 99% FR: Prospective clinical study carried out in a public health hospital (centre cardiologique du Nord):	Clinical Sensitivity: 97.5 % Specificity: 99% Nasal swab, NP swab	FR UK	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab	7 July 2021

Commented [A5]: Note: this RAT will remain in the EU common list after 1 June 2022 if this change is indeed agreed by the HSC

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
			sensitivity 100% (188/188), specificity 100% (3013/313).					
BIOTEKE CORPORATION (WUXI) CO., LTD	SARS-CoV-2 Antigen Test Kit (colloidal gold method)	2067	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 95% at Ct ≤ 25; Manufacturer specificity: 99.28%	96.49 % sensitivity 99.28 % specificity OP/NP swab	DE[2]	Nucleo-protein	Nasopharyngeal swab, Oropharyngeal swab	14 July 2021
Biotical Health S.L.U.BIOTICAL HEALTH S.L.U	biotical SARS-CoV-2 Ag Card	2013	*Retrospective in vitro study* **BE**: Validation study 1: sensitivity 91.7% for Ct<25; Validation study 2: 94% for Ct<25. Manufacturer specificity: 99%	Sensitivity: 96%, Specificity: 99% NP swab	BE	Nucleo-protein	Nasopharyngeal swab	23 July 2021
Boditech Med Inc	AFIAS COVID-19 Ag	1989	*Prospective clinical field study* **NL**: Independent field study in mild symptomatic (n= 427, PCR positive: 106); unknown swab, overall sensitivity: 81.1%, sensitivity Ct <30: 96.4%; specificity: 100%,	Sensitivity: 91.9% (95%CI: 86.0% ~ 95.4%), Specificity: 98.8% (95%CI: 95.6% - 99.7%) NP swab	NL	Nucleo-capsid protein	Nasopharyngeal swab	23 July 2021
BTNX Inc	Rapid Response COVID-19 Antigen Rapid Test	1236	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (NP swab): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	90.2% sensitivity 100% specificity NP swab, NP swab, OP swab	DE[2]	Nucleo-protein	Nasal swab, Nasopharyngeal swab, Oropharyngeal swab	10 May 2021
CerTest Biotec	CerTest SARS-CoV-2 Card test	1173	*Prospective clinical field study* **ES**: Ct ≤ 25, sensitivity: 94,0%; sensitivity for samples within the first 5 days after symptom onset: 84,8%; 150 positive samples, 170 negative samples	Clinical Sensitivity: Nasal swab: 82.7% NP swab: 93% Clinical Specificity: Nasal swab: 99.2% NP swab: 99.8%	DE[2], ES	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab	17 February 2021
Cesna Biyoteknoloji Araştırma Geliştirme Laboratuvar Sist.İnş.Müh.Dan.San.Tic.Ltd. Şti.	CHECK UP SARS-COV-2 NASAL ANTIGEN RAPID TEST	2696	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.8%	Clinical Sensitivity: 99.3 % Clinical Specificity: 98.8 %	DE[2]	Nucleo-capsid protein	Nasal swab	21 December 2021
Cesna Biyoteknoloji Araştırma Geliştirme Laboratuvar Sist.İnş.Müh.Dan.San.Tic.Ltd. Şti.	CHECK UP SARS-COV-2 NASOPHARYNGEAL RAPID ANTIGEN TEST	2746	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer	Clinical Sensitivity: 99.3 % Clinical Specificity: 99.7 %	DE[2]	Nucleo-capsid protein	Nasopharyngeal swab	21 December 2021

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
			specificity: 99.7%					
Chil Tıbbi Malzeme Sanayi ve Ticaret Limited Şirketi	CHIL COVID-19 Antigen Rapid Test (Nasopharyngeal / Oropharyngeal Swab-Casette)	1691	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.57%	Sensitivity 99.01% Specificity: 99.57%	DE[2]	Nucleo-protein	Nasopharyngeal swab, Oropharyngeal swab	20 October 2021
Chongqing M&D Biotechnology Co. Ltd	2019-nCoV Antigen Test Kit	2150	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 95% at Ct ≤ 25; Manufacturer specificity: 100%	sensitivity: 91.53%, specificity:100%	DE[2]	Nucleo-protein	Nasopharyngeal swab	20 October 2021
Core Technology Co., Ltd	Coretests COVID-19 Ag Test	1919	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity: 99.6%	98.1% sensitivity 99.6% specificity NP swab	DE[2]	Nucleo-protein	Nasopharyngeal swab	10 May 2021
CTK Biotech, Inc	OnSite COVID-19 Ag Rapid Test	1581	*Prospective clinical field study* **DK:** 107 samples; Nasal swab - clinical sensitivity 86%; (from asymptomatic and mild symptomatic individuals), Clinical specificity: 100% *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	Clinical Sensitivity: 92.3 % Clinical Specificity: 100 % Nasal, NP swab	DK, ES	Nucleo-protein	Nasal swab, Nasopharyngeal swab	7 July 2021
DDS DIAGNOSTIC	Test Rapid Covid-19 Antigen (tampon nazofaringian)	1225	*Prospective clinical field study* **RO:** Clinical study based on 228 COVID-19 positive samples and 597 COVID-19 negative samples. All the samples were confirmed using PCR (Applied Biosystems™ 7500 and SLAN®- 96P) and clinical symptoms. The relative sensitivity of Rapid Test COVID-19 Antigen (Nasopharyngeal Swab) was 99.56%, the relative specificity was 99.66%, and the accuracy was 99.64% compared to the qRT-PCR result.	99.6% sensitivity 99.67% specificity NP swab	RO China	Nucleo-capsid protein	Nasopharyngeal swab	10 May 2021

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
DNA Diagnostic	COVID-19 Antigen Detection Kit	2242	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct < 25; Manufacturer specificity: 99.56%	Sensitivity: 93.8%, Specificity: 99.6% Nasal swab	DE[2] UK	Nucleo-protein	Nasal swab	23 July 2021
DNA Diagnostic	SARS-CoV-2 Antigen Rapid Test	2756	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct < 25; Manufacturer specificity: 99.3%	Clinical sensitivity: 93.4% Clinical specificity: 99.3%	DE[2]	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab	21 January 2022
Dräger Safety AG & Co. KGaA	Dräger Antigen Test SARS-CoV-2	2273	*Prospective clinical field studies* **DE:** Independent prospective study, mainly symptomatic <7 dps (n=378, PCR positive = 70), self-collected nasal swab; sensitivity overall: 88.6%, sensitivity Ct<26: 96.8%; specificity overall: 99.7% **CH:** Independent prospective study, mainly symptomatic ≤7 dps (n=464, PCR positive = 57), self-collected nasal swab; sensitivity Ct<30: 85.1%, sensitivity Ct<26: 90.0%; specificity overall: 100% *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 95% at Ct < 25; Manufacturer specificity: 99.6%	Sensitivity: 96.1% (Ct values ≤25) Specificity: 99.6%	DE[2] CH	Nucleo-capsid protein	Nasal swab	20 October 2021
Dynamiker Biotechnolgy(Tianjin) Co., Ltd.	Dynamiker SARS-CoV-2 Ag Rapid Test	2533	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer Specificity: 99.1%	sensitivity: 95.7%, specificity: 99.1%	DE[2]	Nucleo-capsid protein	Nasopharyngeal swab, Oropharyngeal swab	20 October 2021
Edinburgh Genetics Limited	Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit	1243	*Prospective clinical field study* **FIND evaluation** **Peru (**26 April 2021) 120 samples, NP swab. Clinical sensitivities: Days ≤ 7: 62%; Ct ≤ 33: 75%; Ct ≤ 25: 100%. Clinical specificity: 100%	Clinical Sensitivity 97.27% NP swab Clinical Specificity 99.62% NP swab	DE[2] Peru	Nucleo-protein	Nasal swab, Nasopharyngeal swab, Oropharyngeal swab	14 July 2021

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
			Retrospective in vitro study **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer Specificity: 99,24%	Clinical Sensitivity 95.63% OP swab Clinical Specificity 99.24% OP swab				
Fosun Diagnostics (Shanghai) Co.,Ltd., China	Fosun Covid-19 Ag Card	2724	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer Specificity: 99,7%	Clinical Sensitivity 97.7 % Clinical Specificity 98.7 %	DE[2]	Nucleo-capsid protein	Nasopharyngeal swab	4 March 2022
Eurobio Scientific	EBS SARS-CoV-2 Ag Rapid Test	1739	*Prospective clinical field study* **FR**: Validation study data: 119 positive and 125 negative samples; sensitivity 93%, specificity: 99% *Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99,1%	Clinical Sensitivity: 95.7 % Nasal swab	DE[2], FR	Nucleo-protein	Nasal swab	7 July 2021
Fujirebio	ESPLINE SARS-CoV-2	2147	*Prospective clinical field study* **FIND evaluation** DE (29 March 2021) 723 samples, NP swab. Sensitivities: Days ≤ 7: 88.5%; Ct ≤ 33: 87.8%; Ct ≤ 25: 92.4%. Clinical specificity: 100% South Africa (6 Oct 2021) 494 samples, NP swab. Sensitivities: Days ≤ 7: 75%; Ct ≤ 33: 78.9%; Ct ≤ 25: 90.1%. Clinical specificity: 99.7% *Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99,13%	Clinical Sensitivity: 87.8 % ((n=98, Ct<33)) Clinical Specificity: 100 % NP swab	DE[2]	Nucleo-protein	Nasopharyngeal swab	7 July 2021
GA Generic Assays GmbH	GA CoV-2 Antigen Rapid Test	1855	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.2%	Sensitivity: 97.059%, Specificity: 99.2% NP swab	DE[2]	Nucleo-protein	Nasopharyngeal swab	23 July 2021

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
GenBody Inc	GenBody COVID-19 Ag Test	1244	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94% at Ct ≤ 25; Manufacturer specificity: 99.19%	Clinical Sensitivity 89.05 % (if Ct≤30, 97.58%) Clinical Specificity 99.19 %	DE[2]	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab, Oropharyngeal swab	8 April 2022
Genobio Pharmaceutical Co., Ltd.	Virusee® SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)	2642	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.2%	OP: sensitivity: 97.14%, specificity: 99.28% NP: sensitivity: 97.22%, specificity: 99.23%	DE[2]	Nucleo-capsid protein	Oropharyngeal swab; Nasopharyngeal swab	8 December 2021
Genrui Biotech Inc	SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	2012	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99,02%	Sensitivity: 91.15% Specificity: 99.02% Nasal/NP/OP swab	DE[2]	Nucleo-protein	Nasal swab, Nasopharyngeal swab, Oropharyngeal swab	7 July 2021
GenSure Biotech Inc	GenSure COVID-19 Antigen Rapid Test Kit	1253	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 100%	96.86% sensitivity 100% specificity Nasal swab	DE[2] UK	*Unknown*	Nasal swab	10 May 2021
GenSure Biotech Inc.	GenSure COVID-19 Antigen Rapid Test Kit	2853	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 100%	Clinical Sensitivity 96.73 % Clinical Specificity 100 %	DE[2]	Nucleo-capsid protein	Nasal swab ! Saliva	10 February 2022
Getein Biotech, Inc	SARS-CoV-2 Antigen (Colloidal Gold)	1820	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.71%	97.06% sensitivity 98.71% specificity Nasal swab	DE[2]	Nucleo-protein	Nasal swab ! Saliva	14 July 2021
Getein Biotech, Inc.	One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)	2183	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 90% at Ct ≤ 30 and 100% at Ct ≤ 25; Manufacturer specificity: 98.71%	97.06% sensitivity 98.71% specificity Nasal swab	DE[2] UK	Nucleo-protein	Nasal swab ! Saliva	16 June 2021
Glallergen CO., LTD.	Novel Coronavirus (2019-nCoV) Antigen Test Kit (Colloidal gold immunochromatography)	2695	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.02%	Clinical Sensitivity: 94.44 % Clinical Specificity: 99.02 %	DE[2]	Nucleo-capsid protein	Nasal swab	21 December 2021

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
Goldsite Diagnostic Inc.	SARS-CoV-2 Antigen Kit (Colloidal Gold)	1197	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	Nasal: Clinical sensitivity: 93.04% (95% CI: 86.75 – 96.95%); Clinical specificity: 100.00% (95% CI: 98.56 – 100.0%) Nasopharyngeal: Clinical sensitivity: 97.14% (95% CI: 91.88 – 99.41%); Clinical specificity: 99.60% (95% CI: 98.58 – 99.95%)	FR, DE[2], ES UK	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab ! Other	14 July 2021
Green Cross Medical Science Corp.	GENEDIA W COVID-19 Ag	1144	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 83% at Ct ≤ 25; Manufacturer specificity: 100%	100% sensitivity 90.1% sensitivity 100% specificity NP swab, Anterior nasal swab	DE[2]	Nucleo-protein	Anterior nasal swab, Nasopharyngeal swab	10 May 2021
Guangdong Hecin Scientific, Inc.	2019-nCoV Antigen Test Kit (colloidal gold method)	1747	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 82% at Ct ≤ 25; Manufacturer specificity: 99.07%	97.09% sensitivity 99.78% specificity Nasal swab	DE[2]	Nucleo-capsid protein	Nasopharyngeal swab	10 May 2021
Guangdong Longsee Biomedical Co., Ltd.	2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)	1216	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.5%	OP swab: sensitivity 95.22%, specificity 99.72% Nasal swab: sensitivity 94.15%, specificity 99.68% NP swab: sensitivity 95.51%, specificity 99.72%	DE[2]	Nucleo-capsid protein	Nasopharyngeal swab, Oropharyngeal swab, Nasal swab	14 July 2021
Guangdong Wesail Biotech Co. Ltd	COVID-19 Ag Test Kit	1360	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98%	90% sensitivity 98% specificity Nasal swab	DE[2]	Nucleo-protein	Nasal swab, Nasopharyngeal swab	17 February 2021
Guangzhou Decheng Biotechnology CO., Ltd	V-CHEK, 2019-nCoV Ag Rapid Test Kit (Immuno-chromatography)	1324	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct < 25; Manufacturer specificity: 99,5%	Clinical Sensitivity: 95.83% Specificity 99.57% Nasal swab	DE[2]	Nucleo-protein	Nasal swab	7 July 2021

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
Guangzhou Wondfo Biotech Co., Ltd	Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)	1437	*Prospective clinical field study* **FIND evaluation** **CH** (25 Feb 2020) 328 samples, NP swab. Clinical sensitivities: Days ≤ 7: 85.7%; Ct ≤ 33: 92.2%; Ct ≤ 25: 100%. Clinical specificity: 100% **Brazil** (10 Oct 2021) 237 samples, NP swab. Clinical sensitivities: Days ≤ 7: 90.4%; Ct ≤ 33: 89.3%; Ct ≤ 25: 96.7%. Clinical specificity: 98.8% *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity: 99.74%	Sensitivity: 98.11% Specificity: 99.72%	DE[2] CH, UK	Nucleo-capsid protein	Nasopharyngeal swab Oropharyngeal swab	10 May 2021
Hangzhou AllTest Biotech Co., Ltd	SARS-CoV-2 Antigen Rapid Test (COVID-19 Antigen Rapid Test) (Swab)	1257	*Prospective clinical field study* **FR**: Prospective study, sensitivity 96,4% (80/83), specificity 99,2% (120/121)	93,40% sensitivity, 99,90% specificity NP swab	FR	Nucleo-capsid protein	Nasopharyngeal swab	10 May 2021
Hangzhou AllTest Biotech Co., Ltd	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)	2257	*Prospective clinical field study* **PL**: Prospective study performed in Polish university, nasal specimen, 300 negative samples and 200 positive samples. CT distribution described. Overall sensitivity: 97,3%, overall specificity: 98,70% *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 90% at Ct ≤ 25; Manufacturer specificity: 99.9%	Clinical Sensitivity 97.4 % Clinical Specificity 99.9 %	DE[2], PL	Nucleo-capsid protein	Nasal swab	4 March 2022
Hangzhou AllTest Biotech Co., Ltd	COVID-19 Antigen Test Cassette (Nasopharyngeal Swab)(FIA)	2302	*Prospective clinical field study* **SI**: Prospective clinical field study in a public hospital, unselected patients, normal Ct distribution, NP samples, sample size: 102 positive samples and 312 negative samples; sensitivity: 95.1% and specificity: 100%.	Clinical Sensitivity 95.6 % Clinical Specificity 98.4 %	SI	Nucleo-protein	Nasopharyngeal swab	8 April 2022
Hangzhou Biotest Biotech Co.,	COVID-19 Antigen Rapid Test	1876	*Retrospective in vitro study*	Sensitivity: 93.2%,	DE[2]	Nucleo-	Nasal swab	8 December

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
Ltd	Cassette (Nasal Swab)		**DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.2%	Specificity: 99.2% Nasal swab		capsid protein		2021
Hangzhou Clongene Biotech Co., Ltd.	COVID-19 Antigen Rapid Test Casette	1610	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,4% at Ct ≤ 25; Manufacturer specificity: 100%	Clinical Sensitivity: 91.4 % Clinical Specificity: 100 % NP swab	DE[2] UK	Nucleo-protein	Nasopharyngeal swab	7 July 2021
	Covid-19 Antigen Rapid Test Kit	1363	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,4% at Ct ≤ 25; Manufacturer specificity: 100%	Clinical Sensitivity: Nasal swab: 95.5 % NP swab: 96 % Clinical Specificity: 100% Nasal swab, NP swab	DE[2] CH	Nucleo-protein	Nasal swab, Nasopharyngeal swab	17 February 2021
	COVID-19/Influenza A+B Antigen Combo Rapid Test	1365	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,4% at Ct ≤ 25; Manufacturer specificity: 100%	91% sensitivity 100% specificity NP swab	DE[2]	Nucleo-protein	Nasopharyngeal swab	10 May 2021
Hangzhou Immuno Biotech Co., Ltd	Immunobio SARS-CoV-2 Antigen ANTERIOR NASAL Rapid Test Kit (minimal invasive)	1844	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity: 100%	94% sensitivity 100% specificity Nasal swab, NP swab	DE[2]	Nucleo-protein	Nasal swab, Nasopharyngeal swab	10 May 2021
	SARS-CoV2 Antigen Rapid Test	2317	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity: 100%	Clinical Sensitivity: 98 % Clinical Specificity: 100 % Anterior nasal swab, NP swab, OP swab,	DE[2]	Nucleo-protein	Anterior nasal swab, Nasopharyngeal swab, Oropharyngeal swab ! Sputum	10 May 2021
Sigmed Sp. z o.o.	Redtest Professional Sars-CoV-2 Antigen Rapid Test (Covid-19 Ag)	2256	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity: 100%	Sensitivity: Nasal swab: 93.64% NP swab: 98.29% OP swab: 94.66% Specificity: 100% (Nasal sawb, NP swab, OP swab)	DE[2]	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab, Oropharyngeal swab	8 December 2021

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
Hangzhou DIAN Biotechnology Co., Ltd.	COVID-19 Antigen Test Cassette	2629	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 90% at Ct ≤ 25; Manufacturer specificity: 98.4%	Clinical Sensitivity: 97.6 % Clinical Specificity: 98.4 %	DE[2]	*Unknown*	Nasal swab, Nasopharyngeal swab	21 December 2021
Hangzhou Funworld Biotech Co., Ltd	SARS-CoV-2 Antigen Rapid Test Device	2862	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98%	Clinical Sensitivity 93.5 % Clinical Specificity 98 %	DE[2]	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab I Saliva	8 April 2022
Hangzhou Jucheng Medical Products Co., Ltd	SARS-CoV-2 Ag Rapid Test Kit	2979	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	Clinical Sensitivity 95.9 % Clinical Specificity 100 %	DE[2]	Nucleo-capsid protein	Anterior nasal swab	8 April 2022
Hangzhou Laihe Biotech Co.	LYHER Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)	1215	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99,7%	OP: Sensitivity 95.49%, Specificity 99.32% NP: Sensitivity 97.47%, Specificity 100.00%	DE[2] UK	Nucleo-capsid protein	For professional use: Nasopharyngeal swab, Oropharyngeal swab	10 May 2021
Hangzhou Lysun Biotechnology Co. Ltd	COVID-19 Antigen Rapid Test Device (Colloidal Gold)	2139	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	96.46% sensitivity 100% specificity Nasal swab	DE[2]	Nucleo-protein	Nasal swab	10 May 2021
Hangzhou Sejoy Electronics & Instruments Co.Ltd	SARS-CoV-2 Antigen Rapid Test Cassette	1945	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	Sensitivity: 94.5%, Specificity:100% Nasal swab	DE[2]	Nucleo-capsid protein	Nasal swab	8 December 2021
Hangzhou Testsea Biotechnology Co., Ltd.	Covid-19 Antigen Test Cassette	1392	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (NP swab): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.4%	92.1% sensitivity 98.1% specificity Nasal swab	DE[2]	Nucleo-protein	Nasal swab, Nasopharyngeal swab	10 May 2021
Healgen Scientific	Coronavirus Ag Rapid Test Cassette	1767	*Prospective clinical field studies* **NL**: **1):** Clinical field study, symptomatic individuals (n=417, PCR positive n=70), NP swab; sensitivity	98.32 % sensitivity 99.6% specificity (NP swab) 97.25% sensitivity	DE[2], NL[5]	Nucleo-proteins, S1, S1-RBD, S2	Nasal swab, Nasopharyngeal swab	17 February 2021

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
			overall: 75.7%, sensitivity Ct≤30: 85.2%, sensitivity Ct≤25: 90.7%; specificity: 100% **2):** Clinical field study, symptomatic individuals (n=240, PCR positive n=21), NP+OP swab; sensitivity overall: 85.7%, sensitivity Ct≤30: 89.5%, sensitivity Ct≤25: 100%; specificity: 100% **3)**: Clinical field study, symptomatic individuals (n=94, PCR positive n=18), NP+OP swab in VTM; sensitivity overall: 90.0%, sensitivity Ct≤30: 100%, sensitivity Ct≤25: 100%; specificity: 97.3% *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (NP swab): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	100% specificity (Nasal swab)				
Siemens Healthineers	CLINITEST Rapid COVID-19 Antigen Test	1218	*Prospective clinical field studies* **NL**: **1):** Clinical field study, symptomatic individuals (n=417, PCR positive n=70), NP swab; sensitivity overall: 75.7%, sensitivity Ct≤30: 85.2%, sensitivity Ct≤25: 90.7%; specificity: 100% **2):** Clinical field study, symptomatic individuals (n=240, PCR positive n=21), NP+OP swab; sensitivity overall: 85.7%, sensitivity Ct≤30: 89.5%, sensitivity Ct≤25: 100%; specificity: 100% **3)**: Clinical field study, symptomatic individuals (n=94, PCR positive n=18), NP+OP swab in VTM; sensitivity overall: 90.0%, sensitivity Ct≤30: 100%, sensitivity Ct≤25: 100%; specificity: 97.3% **ES**: Independent prospective study; 192 positive and 258 negative samples (NP swab). Sensitivity: 93,3%, Specificity. 99.2%, compared against NP PCR. **IE** Independent prospective study: overall sensitivity 79,4% and among Ct ≤25 89,7% (34 samples). Overall specificity 98.8% (249 samples) and in only the symptomatic cohort 98% (153 samples).	98.32% sensitivity (NP swab) 97.25% sensitivity (Nasal swab) 100% specificity	DE[2], ES, IE, NL[5]	Nucleo-proteins, S1, S1-RBD, S2	Nasal swab, Nasopharyngeal swab	17 February 2021

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
			Retrospective in vitro study **DE**: Positive evaluation by Paul-Ehrlich-Institut (NP swab): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%					
Zhejiang Orient Gene Biotech Co., Ltd	Coronavirus Ag Rapid Test Cassette (Swab)	1343	*Prospective clinical field studies* **NL**: **1):** Clinical field study, symptomatic individuals (n=417, PCR positive n=70), NP swab; sensitivity overall: 75.7%, sensitivity Ct≤30: 85.2%, sensitivity Cts25: 90.7%; specificity: 100% **2):** Clinical field study, symptomatic individuals (n=240, PCR positive n=21), NP+OP swab; sensitivity overall: 85.7%, sensitivity Ct≤30: 89.5%, sensitivity Cts25: 100%; specificity: 100% **3)**: Clinical field study, symptomatic individuals (n=94, PCR positive n=18), NP+OP swab in VTM; sensitivity overall: 90.0%, sensitivity Ct≤30: 100%, sensitivity Cts25: 100%; specificity: 97.3% *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.6%	98.32 % sensitivity 99.6 % specificity Nasal/NP swab	DE[2] UK	Nucleo-protein	Nasal swab, Nasopharyngeal swab	17 February 2021
Hangzhou Zheda Dixun Biological Gene Engineering Co., Ltd.	SARS-CoV-2 Nucleocapsid (N) Antigen Rapid Test Cassette (Swab)	2942	*Retrospective in vitro study* DE: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct < 25; Manufacturer specificity: 100%	Clinical Sensitivity 95.14 % Clinical Specificity 100 %	DE[2]	Nucleo-capsid protein	Nasopharyngeal swab, Oropharyngeal swab	6 May 2021
Hoyotek Biomedical Co.,Ltd.	Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold)	1929	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 90% at Ct ≤ 25; Manufacturer specificity: 99%	NP swab - Sensitivity: 96%, Specificity: 99% OP swab - Sensitivity: 93%, Specificity: 97.5%	DE[2]	*Unknown*	Nasopharyngeal swab, Oropharyngeal swab	20 October 2021
Hubei Jinjian Biology Co., Ltd	SARS-CoV-2 Antigen Test Kit	1759	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.3%	Sensitivity: 98.02% Nasal Swab	DE[2]	Nucleo-protein	Nasopharyngeal swab	23 July 2021

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
Humasis	Humasis COVID-19 Ag Test	1263	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (NP swab): Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity: 100%	95.3% sensitivity 100% specificity Nasal swab	DE[2] UK	*Unknown*	Nasal swab	10 May 2021
Immunospark s.r.l.	Rapid SARS-Cov2 Antigen Test	1791	*Prospective clinical field study* **IT**: Prospective independent study with unselected individuals (with delayed antigen testing), supervised by a public university. Sample size (NP samples): 120 positive, 320 negative. Sensitivity overall: 75.8% (91/120), sensitivity at Ct<25: 98.8% (86/87). Specificity: 100% (320).	Clinical Sensitivity 98.5 % Clinical Specificity 100 %	IT	*Unknown*	Nasopharyngeal swab	6 May 2022
Innova Medical Group.Inc	Innova SARS-CoV-2 Antigen Rapid Qualitative Test	1801	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99%	Sensitivity 94.0% : CI 95% (86.7%-98.0%) Specificity: 99.6% - CI:95%(99.4%-99.8%)	DE[2]	Nucleo-capsid protein	Anterior nasal swab, Nasal swab	20 October 2021
Innovation Biotech(Beijing) Co.Ltd	Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (Nasal swab)	2278	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99%	Sensitivity: 95.6% Specificity: 100%	DE[2]	Nucleo-protein	Nasal swab	20 October 2021
InTec PRODUCTS, INC.	Rapid SARS-CoV-2 Antigen Test (nasopharyngeal specimen)	2419	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	Sensitivity 90.2% (95% CI: 83.1% to 95.0%); Specificity 100.0% (95% CI: 96.5% - 100.00%)	DE[2]	Nucleo-capsid protein	Nasopharyngeal swab	20 October 2021
InTec PRODUCTS, INC	Rapid SARS-CoV-2 Antigen Test (nasopharyngeal/nasal specimen)	1783	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	Clinical Sensitivity 95.5 % (95%CI: 93.7%~97.3%) Clinical Specificity 99.6 % (95%CI: 99.3%~99.9%)	DE[2]	Nucleo-capsid protein	Nasa swab, Nasopharyngeal swab	8 April 2022
Inzek International Trading B.V.	Biozek covid-19 Antigen Rapidtest BCOV-502	1988	*Prospective clinical field studies* **NL**: Independent prospective study, local public health authority involved (n=950, PCR positive = 61), NP swab; sensitivity overall: 85.25%; specificity: 99.78%	Clinical Sensitivity: 93.63% Clinical Specificity: 99.73%	NL	Nucleo-capsid protein	Nasopharyngeal swab	4 March 2022

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
			NL: Independent prospective study, healthcare workers (n=294, PCR positive = 44), NP swab; sensitivity overall: 81.8%, sensitivity Ct<30: 91.9%; specificity: 99.7%					
Jiangsu Bioperfectus Technologies Co., Ltd.	Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit	2107	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.15%	Sensitivity: NP: 96.67% (95% CI: 88.64%−99.08%), Nasal: 97.06% (95% CI: 93.30%−98.74%) Specificity: NP: 97.87% (95% CI: 95.12%−99.09%), Nasal: 99.15% (95% CI: 98.25%− 99.59%)	DE[2] UK	Nucleo-protein	Nasal swab, Nasopharyngeal swab,	14 July 2021
Jiangsu Diagnostics Biotechnology Co., Ltd	COVID-19 Antigen Rapid Test Cassette (Colloidal Gold)	1920	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	98.31 % sensitivity 100 % specificity Nasal/NP/ OP swab	DE[2]	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab, Oropharyngeal swab, Throat swab	14 July 2021
Jiangsu Konsung Bio-Medical Science and Technology Co.	COVID-19 Antigen Rapid Test Kit (Colloidal Gold)	1899	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.34%	Clinical Sensitivity 97.14 % Clinical Specificity 99.34 %	DE[2]	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab, Oropharyngeal swab	10 February 2022
Jiangsu Medomics medical technology Co.,Ltd.	SARS-CoV-2 antigen Test Kit (LFIA)	2006	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99,51%	Sensitivity: 97.73% Specificity: 99.51% Anterior nasal swab, NP swab	DE[2]	Nucleo-protein	Anterior nasal swab, Nasopharyngeal swab, Throat swab	7 July 2021
Jiangsu Mole Bioscience CO., LTD.	SARS-CoV-2 Antigen Test Cassette	2586	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99,17%	sensitivity: 98.31 %, specificity: 99.17 %	DE[2]	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab	8 December 2021
Jiangsu Well Biotech Co., Ltd.	COVID-19 Ag Rapid Test Device	2144	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99%	sensitivity: 94.74%, specificity: 99%	DE[2]	Nucleo-protein	Nasal swab	20 October 2021
Jiangxi Province JinHuan	DREHA Novel Coronavirus	2963	*Retrospective in vitro study*	Clinical Sensitivity	DE[2]	Nucleo-	Nasal swab	8 April 2022

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
Medical Instrument Co., LTD.	(SARS-CoV-2) Antigen Rapid Detection Kit		**DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99%	96 % Clinical Specificity 99.7 %		capsid protein		
JINAN BABIO BIOTECHNOLOGY CO., LTD., China	SARS-CoV-2 Antigen Rapid Detection Kit (Colloidal Gold Method)	2151	*Prospective clinical field study* **PL:** Prospective study with nasal samples in a Polish hospital; 210 positive samples, overall sensitivity 96,7%; 450 negative samples, including 100 hospitalized patients and 50 potentially cross-reacting samples. Specificity 100%.	Clinical Sensitivity 96.67 % Clinical Specificity 100 %	PL	Nucleo-capsid protein	Nasal swab	10 February 2022
Joinstar Biomedical Technology Co. Ltd	COVID-19 Rapid Antigen Test (Colloidal Gold)	1333	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.1%	96.1% sensitivity 98.1% specificity Nasal swab	DE[2]	Nucleo-protein	Nasal swab, Nasopharyngeal swab, Oropharyngeal swab	17 February 2021
IEDAU INTERNATIONAL GMBH	Covid-19 Antigen Schnelltest (Colloidales Gold)	2555	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.2%	OP/Nasal: sensitivity: 96,1%, specificity: 99,2% NP: sensitivity: 97,1%, specificity: 99,2 %	DE[2]	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab, Oropharyngeal swab	8 December 2021
JOYSBIO (Tianjin) Biotechnology Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	1764	*Prospective clinical field studies* CZ N=225 (90 RT-PCR positive), 60.3% symptomatic patients. Test parameters for a subgroup of symptomatic patients (estimates and 95% confidence intervals): sensitivity 92% (80.8–97.8), specificity 97.6% (91.5–99.7). Test parameters for a subgroup of asymptomatic patients (estimates and 95% confidence intervals): sensitivity 100% 100 (54.1–100), specificity 100% (95.5–100). IT Prospective study (nasal swab) including asymptomatic or mild symptomatic participants, compared against RT-PCR from NP swab. Study was designed by researchers from a public university and carried out by a private laboratory. Sample size: 115 positive, 386	98.13% sensitivity Nasal swab	CZ, DE[2] CH	Nucleo-capsid protein	Nasal swab	10 May 2021

Commented [A6]: Note: this RAT will remain in the EU common list after 1 June 2022 if this change is indeed agreed by the HSC

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
			negative samples. Overall sensitivity: 98.3%, specificity 99.2%. **FIND Evaluation** **CH** (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%					
Labnovation Technologies Inc.	SARS-CoV-2 Antigen Rapid Test Kit	1266	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94% at Ct ≤ 25; Manufacturer specificity: 97.3%	97.45% sensitivity, 100% specificity Nasal/NP/OP swab	DE[2]	Nucleo-protein	Nasal swab, Nasopharyngeal swab, Oropharyngeal swab	10 May 2021
Lifecosm Biotech Limited	COVID-19 Antigen Test Cassette	2866	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct < 25; Manufacturer specificity: 99%	Clinical Sensitivity 96 % Clinical Specificity 99 %	DE[2]	Nucleo-capsid protein	Nasopharyngeal swab, Oropharyngeal swab	6 May 2022
LINKCARE (NANTONG DIAGNOS BIO)	COVID-19 Antigen Test Kit (Colloidal Gold)	1353	*Prospective clinical trial study* **ES:** Prospective validation study, N = 504 nasal samples (385 negative and 115 positive), performed by University Hospital Son Espases (PCR Ct ≤ 30). Sensitivity: 96.33% (CI95 0.91-0.99) and specificity: 100%. *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.04%	Clinical Sensitivity: 92.59 % Specificity: 99.04%	DE[2]	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab	21 December 2021
Lumigenex (Suzhou) Co., Ltd	PocRoc® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	2128	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99,16%	93.33% sensitivity 99.16% specificity Nasal/NP/OP swab	DE[2]	Nucleo-protein	Nasal swab, Nasopharyngeal swab, Oropharyngeal swab	10 May 2021
LumiQuick Diagnostics Inc.	QuickProfile™ COVID-19 Antigen Test	1267	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.8%	93.7% sensitivity, 98.8% specificity NP swab	DE[2]	*Unknown*	Nasopharyngeal swab	10 May 2021

Commented [A7]: Note: this device would move from the 'B-category' to the 'A-category' if this change is agreed by the HSC.

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
LumiraDX	LumiraDx SARS-CoV-2 Ag Test	1268	*Prospective clinical field study* **SKUP/2021/124**: 448 samples: 83 positive samples and 365 negative samples. Nasal specimen: diagnostic sensitivity of 87% (79-92) and diagnostic specificity of 99,5% (98,3-99,9). NP specimen: diagnostic sensitivity of 90% (83-95) and diagnostic specificity of 97,8% (96,0-98,8) (Scandinavian evaluation of laboratory equipment for point of care testing) **FIND Evaluation** **DE** (8 Oct 2021) 761 samples, NP swab. Clinical sensitivities: Days ≤ 7: 86.4%; Ct ≤ 33: 87.2%; Ct ≤ 25: 92.6%; Clinical specificity: 99.3% **Brazil** (8 Oct 2021) 251 samples, NP swab. Clinical sensitivities: Days ≤ 7: 85.7%; Ct ≤ 33: 87.7%; Ct ≤ 25: 94.1%; Clinical specificity: 99% *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.8%	97.6% sensitivity 96.6% specificity Nasal swab	DE[2], ES SKUP CH	Nucleo-protein	Nasal swab	17 February 2021
MEDsan GmbH	MEDsan SARS-CoV-2 Antigen Rapid Test	1180	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.8%	92.5% sensitivity 99.8% specificity NP/OP swab	DE[2] CH	*Unknown*	Nasopharyngeal swab, Oropharyngeal swab	17 February 2021
Merlin Biomedical (Xiamen) Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Cassette	2029	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 90% at Ct ≤ 30 and 100% at Ct ≤ 25; Manufacturer specificity: 98.99%	95.05% sensitivity 98.99% specificity Nasal/NP swab	DE[2]	Nucleo-protein	Nasal swab, Nasopharyngeal swab	16 June 2021
MEXACARE GmbH	MEXACARE COVID-19 Antigen Rapid Test	1775	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99,1%	Sensitivity: 96.17% Specificity: 99,1% Nasal swab	DE[2]	Nucleo-protein	Nasal swab	7 July 2021

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
möLab	mö-screen Corona Antigen Test	1190	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99,99%	Sensitivity: 97.25% Specificity: 99.99% NP swab	DE[2], IE	*Unknown*	Nasopharyngeal swab	10 May 2021
Mologic Ltd	COVIOS Ag COVID-19 Antigen Rapid Diagnostic Test	2640	*Prospective clinical field study* **FIND evaluation** **DE**: Symptomatic and asymptomatic (n=649, PCR positive = 191), nasal and nasal-mouth-throat swab; sensitivity overall: 90.6%, sensitivity Ct ≤ 25: 96.4%; specificity: 100%	Sensitivity: 90.6%, Specificity:100% Nasal swab	DE[2] UK	Nucleo-capsid protein	Nasal swab	8 December 2021
MP Biomedicals	Rapid SARS-CoV-2 Antigen Test Card	1481	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.03%	96.17% sensitivity 99.16% specificity Nasal swab, Anterior nasal swab	DE[2] CH, UK	Nucleo-protein	Anterior nasal swab, Nasal swab, Nasopharyngeal swab, Oropharyngeal swab	17 February 2021
Multi-G bvba	Covid19Check-NAS	2260	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.5%	Clinical Sensitivity 97 % ((99.35% for Ct values ≤25)) Clinical Specificity 99.5 %	DE[2]	Nucleo-capsid protein	Nasal swab	10 February 2022
Nal von minden GmbH	NADAL COVID -19 Ag +Influenza A/B Test	2104	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 83% at Ct ≤ 25; Manufacturer specificity: 99.9%	97% sensitivity 98% specificity NP swab	DE[2]	Nucleo-protein	Nasopharyngeal swab	10 May 2021
Nal von minden GmbH	NADAL COVID -19 Ag Test	1162	*Prospective clinical field study* **FIND evaluation** **CH** (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% *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 83% at Ct ≤ 25; Manufacturer specificity: 99.9%	Nasal: sensitivity (Ct<30): 94.1%, specificity: 99.9% OP: sensitivity (Ct 20-30): 97.6%, specificity: 99.9% NP: sensitivity (Ct 20-30): 97.6%, specificity: 99.9%	DE[2], FR China	Nucleo-protein	Nasal swab, Nasopharyngeal swab, Oropharyngeal swab	17 February 2021

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
Nanjing Liming Bio-Products Co., Ltd.	StrongStep® SARS-CoV-2 Antigen Rapid Test	2301	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.26%	Sensitivity: 96.19 %, Specificity: 99.26 % Nasal swab	DE[2]	Nucleo-capsid protein	Nasal swab	8 December 2021
Nanjing Norman Biological Technology Co., Ltd.	Novel Coronavirus (2019-nCoV) Antigen Testing Kit (Colloidal Gold)	2506	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94% at Ct ≤ 25; Manufacturer specificity: 99.9%	Clinical sensitivity: 91.13% (Saliva); 93.02% (Anterior Nasal); 93.21% (NP) Clinical specificity: 93.02% (Anterior Nasal); 99.23% (Anterior Nasal); 99.29% (NP)	DE[2]	Nucleo-capsid protein	Anterior nasal swab, Nasopharyngeal swab, Oropharyngeal swab I Saliva	10 November 2021
Nanjing Synthgene Medical Technology Co., Ltd.	SARS-COV-2 Nucleocapsid (N) Antigen Rapid Detection Kit (Colloidal gold method)	2164	*Retrospective in vitro study* Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.5%	Clinical sensitivity: 99.33% Clinical specificity: 99.5%	DE[2]	Nucleo-capsid protein	Nasopharyngeal swab	21 January 2022
NanoEntek	FREND COVID-19 Ag	1420	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity: 100%	94.12% sensitivity 100% specificity NP swab	DE[2]	Nucleo-protein	Nasopharyngeal swab	10 May 2021
NanoRepro AG	NanoRepro SARS-CoV-2 Antigen Rapid Test	2200	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 98.4%	97.2 % sensitivity 98.4% specificity Nasal/NP/OP swab	DE[2]	Nucleo-protein	Anterior nasal swab, Nasopharyngeal swab, Oropharyngeal swab	14 July 2021
Nantong Egens Biotechnology Co.,Ltd	COVID-19 Antigen Rapid Test Kit	1573	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.5%	sensitivity: 95.8 %, specificity: 99.5 %	DE[2]	Nucleo-protein	Nasal swab	10 February 2022
NESAPOR EUROPA SL	MARESKIT COVID-19 ANTIGEN RAPID TEST KIT	2241	*Prospective clinical field study* **ES:** Independent validation study; Nasal test compared to nasal PCR. Sensitivity 95.24% (Ct<30), Specificity 100%.	Sensitivity: 95.24% (95% CI: 83.84% to 99.42%), Specificity: 100% (95% CI: 97.22% to 100.00%) Nasal swab	ES	Nucleo-protein	Nasal swab	23 July 2021
Neo-nostics (Suzhou)	COVID 19 Antigen Test Kit	2608	*Retrospective in vitro study*	Clinical Sensitivity	DE[2]	Nucleo-	Nasal swab,	10 February

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
Bioengineering Co., Ltd.	(Colloidal Gold Method)		**DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.19%	95.93 % Clinical Specificity 99.19 %		capsid protein	Nasopharyngeal swab, Oropharyngeal swab	2022
New Gene (Hangzhou) Bioengineering Co., Ltd.	COVID-19 Antigen Detection Kit	1501	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 92,5% at Ct ≤ 30 and 100% at Ct ≤ 25; Manufacturer specificity: 99.2%	98% sensitivity 99.2% specificity Nasal swab	DE[2]	Nucleo-protein	Nasal swab, Nasopharyngeal swab, Oropharyngeal swab ! Saliva, Sputum	16 June 2021
NG Biotech	Ninonasal	1880	*Prospective clinical field study* **FR:** Prospective validation study for NP and nasal swabs: NP sensitivity 89% (75/84) , specificity 99% (92/93). Nasal sensitivity 98% (125/128), specificity 99% (388/390)	Clinical sensitivity: 98%, Clinical specificity: 99%	FR	Nucleo-protein	Nasal swab, Nasopharyngeal swab	10 November 2021
Novatech Tıbbi Cihaz Ürünleri Sanayi ve Ticaret A.Ş.	SARS-CoV-2 Antigen Rapid Test	1762	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 100%	95.91 % sensitivity 100% specificity Nasal swab 93.75 % sensitivity 100% specificity NP swab	DE[2]	Nucleo-protein	Nasal swab, Nasopharyngeal swab	14 July 2021
Oncosem Onkolojik Sistemler San. ve Tic. A.S.	CAT	1199	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 98,04%	93.75% sensitivity 98.04% specificity Nasal swab	DE[2]	Nucleo-capsid protein	Nasal swab	10 May 2021
OSANG Healthcare Co., Ltd.	GeneFinder COVID-19 Ag Plus Rapid Test	2741	*Prospective clinical field study* **IT**: Independent prospective evaluation study carried out in Hospital Pugliese Ciaccio, Italy. Sample type: NP swab; sample size: 100 pos., 400 neg.; Sensitivity: 94%; Specificity: 100% **IT**: Independent prospective field study, 151 positive samples, 452 negative samples. Sensitivity: 96.03%; Specificity: 99.78%.	Clinical Sensitivity: 96.03% (95% CI : 91.55% - 98.53% : 146/151)~~94% (95% CI: 87.52% ~ 97.22%)~~ Clinical Specificity: 99.78% (95% CI : 98.76% - 99.96% : 451/452)~~100% (95% CI: 99.05% ~ 100.00%)~~	IT	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab, Oropharyngeal swab ! Samples in transport media	21 December 2021

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
PCL Inc.	PCL COVID19 Ag Rapid FIA	308	*Prospective clinical field study* **FR**: Validation study data: NP swabs, sensitivity 94.29% (33/35) and specificity 100% (70/70)	94, 92% sensitivity, 99, 99% specificity	DE[2], FR	*Unknown*	Nasopharyngeal Swab	10 May 2021
PCL Inc.	PCL COVID19 Ag Gold	2243	*Prospective clinical field study* **FR**: Validation study data: 120 positive and 200 negative samples; sensitivity 92%, specificity: 100%	Clinical Sensitivity: 90.83 % Clinical Specificity: 99.5 %	FR	Nucleo-protein	Nasal swab, Nasopharyngeal swab ! Saliva	7 July 2021
PerGrande Bio Tech Development Co., Ltd.	SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromato-graphic Assay)	2116	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.11%	94.28% sensitivity 99.11% specificity NP/Nasal/OP swab	DE[2]	Nucleo-protein	Nasal swab, Nasopharyngeal swab, Oropharyngeal swab	10 May 2021
Pierenkemper GmbH	(SARS-CoV-2) Antigen Rapid Test COVIDENT (SWAB) COVID-19	2672	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	Clinical Sensitivity 99.27 % Clinical Specificity 100 %	DE[2]	Nucleo-capsid protein	Anterior nasal swab, Nasal swab, Nasopharyngeal swab, Oropharyngeal swab, Throat swab	4 March 2022
Precision Biosensor Inc.	Exdia COVI-19 Ag	1271	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.3%	93.9% sensitivity 98% specificity NP swab	DE[2] CH	*Unknown*	Nasopharyngeal swab	17 February 2021
PRIMA Lab SA	COVID-19 Antigen Rapid Test	2685	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.3%	Clinical Sensitivity 93.4 % Clinical Specificity 99.9 %	DE[2]	Nucleo-capsid protein	Nasopharyngeal swab	8 April 2022
Prognosis Biotech	Rapid Test Ag 2019-nCov	1495	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99,58%	98.59 % Clinical Sensitivity 99.74% Clinical Specificity Nasal swab 95.56 % Clinical Sensitivity 99.58 % Clinical Specificity NP swab	DE[2]	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab	7 July 2021

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
Qingdao Hightop Biotech Co., Ltd	SARS-CoV-2 Antigen Rapid Test	1341	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 30 and 100% at Ct ≤ 25; Manufacturer specificity: 99.75%	98.04% sensitivity 100% specificity Anterior nasal, Nasal, NP, OP swab	DE[2]	Nucleo-capsid protein	Anterior nasal swab, Nasal swab, Nasopharyngeal swab, Oropharyngeal swab	17 February 2021
Qingdao Hightop Biotech Co., Ltd.	SARS-CoV-2/Flu A+B/RSV Antigen Rapid Test	2754	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 30 and 100% at Ct ≤ 25; Manufacturer specificity: 99.75%	Clinical Sensitivity: 100 % (SARS-CoV-2 at Ct lower or equal to 25) Clinical Specificity: 99.75 % (SARS-CoV-2)	DE[2]	Nucleo-capsid protein	Nasopharyngeal swab	21 December 2021
Quidel Corporation	Sofia SARS Antigen FIA	1097	*Prospective clinical field studies* **FR**: Validation study data: NP swabs sensitivity 84,44% (76/90), specificity 99,19 (491/495) **NL:** Independent prospective clinical field study in symptomatic (n=733, PCR positive 144); NP swab; sensitivity overall: 84.0%, sensitivity Ct<30: 90.1%, sensitivity Ct<25: 92.5%; specificity overall: 99.8%. **PT:** 80 samples from symptomatic individuals (27 PCR positive and 53 negative by PCR) were tested. Sensitivity 70% (95%IC50-86); specificity 100% (95%IC 93-100). TCID50/ml 0,68x 102 and CT<25. *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 89% at Ct ≤ 25; Manufacturer specificity: 100%	96.7% sensitivity 100% specificity NP/Nasal swab	DE[2], NL[5], PT CH	Nucleo-protein	Nasal swab, Nasopharyngeal swab	17 February 2021
Rapid Pathogen Screening, Inc	LIAISON® Quick Detect Covid Ag Assay	2290	*Retrospective in vitro study* **IT:** Independent validation study, 100 pos. and 100 neg. samples; sensitivity: 92.7% with Ct<25; specificity: 100%.	Sensitivity: 96.1%, Specificity: 97% NP and Nasal swab	IT	Nucleo-protein	Nasal swab, Nasopharyngeal swab	23 July 2021

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
Roche (SD BIOSENSOR)	SARS-CoV-2 Rapid Antigen Test	1604	*Prospective clinical field study* **NL:** Independent prospective clinical field study in symptomatic (n=970, PCR positive 186); NP swab; sensitivity overall: 84.9%, sensitivity Cts30: 94.3%, sensitivity Cts25: 99.1%; specificity overall: 99.5% **SE**: Karolinska hospital evaluation of Lot QCO3020109. Patient samples: 95 PCR positive, 150 negative. No detailed sample description available. Sensitivity 43%, specificity 100%. Sensitivity Ct<25 = 80.5%. *Retrospective in vitro studies* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 89% at Ct ≤ 25; Manufacturer specificity: 99.68%	96.52% sensitivity 99.2% specificity NP swab	DE[2], FI, NL, PT, SE UK	Nucleo-protein	Nasopharyngeal swab	10 May 2021
Roche (SD BIOSENSOR)	SARS-CoV-2 Rapid Antigen Test Nasal	2228	*Prospective clinical field studies* **FIND evaluation** DE (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 (12 April 2021) 214 samples, nasal swab. Clinical sensitivities: Days ≤ 7: 81.2%; Ct ≤ 33: 91.7%; Ct ≤ 25: 100%; Clinical specificity: 99.3% *Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 89.6% at Ct ≤ 30; Manufacturer specificity: 99.1%	Clinical Sensitivity: 89.6 % ((Ct ≤ 30) 93.1 % (Ct ≤ 27) Clinical Specificity: 99.1 % Nasal swab	DE[2] Brazil, UK	Nucleo-protein	Nasal swab	7 July 2021
Safecare Biotech (Hangzhou) Co. Ltd	COVID-19 Antigen Rapid Test Kit (Swab)	1489	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.42%	97.27% sensitivity 99.42% specificity Nasal swab	DE[2]	Nucleo-protein	Nasal swab	17 February 2021

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
	Multi-Respiratory Virus Antigen Test Kit (Swab) (Influenza A+B/COVID-19)	1490	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.44%	97.04% sensitivity 99.44% specificity Nasal swab	DE[2]	Nucleo-protein	Nasal swab	10 May 2021
Sansure Biotech Inc	SARS-CoV-2 Rapid Antigen Test (Colloidal Gold Method)	2097	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.1%	Clinical Sensitivity: 98.4 % Clinical Specificity: 98.1 %	DE[2]	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab	21 December 2021
ScheBo Biotech	ScheBo SARS CoV-2 Quick Antigen	1201	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 95% at Ct ≤ 30 and 100% at Ct ≤ 25; Manufacturer specificity: 99%	96.6% sensitivity (Ct ≤ 30) 99.00% specificity NP/ OP swab	DE[2]	Nucleo-protein	Nasopharyngeal swab, Oropharyngeal swab ! Serum	16 June 2021
ScheBo Biotech	ScheBo SARS CoV-2 Quick ANTIGEN (Colloidal Gold Method)	2763	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.49%	Clinical sensitivity: 96.12% Clinical specificity: 99.49%	DE[2]	Nucleo-capsid protein	Nasal swab	21 January 2022

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
SD Biosensor Inc	STANDARD Q COVID-19 Ag Test Nasal	2052	*Prospective clinical field studies* **DE** 146 symptomatic adults, 40 (27.4%) were RT-PCR-positive for SARS-CoV-2. Sensitivity with 85.0% (34/40; 95% CI 70.9-92.9) with professional testing. At high viral load (>7.0 log10 SARS-CoV-2 RNA copies/ml), sensitivity was 96.6% (28/29; 95% CI 82.8-99.8) for professional testing. **FIND evaluation** **DE** (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** (12 April 2021) 214 samples, nasal swab. Clinical sensitivities: Days ≤ 7: 81.2%; Ct ≤ 33: 91.7%; Ct ≤ 25: 100%; Clinical specificity: 99.3%	Clinical Sensitivity: 97.12 % Clinical Specificity: 100 % Nasal swab	DE[2], FI, FR Brazil, UK	Nucleo-protein	Nasal swab	7 July 2021
SD BIOSENSOR Inc.	STANDARD F COVID-19 Ag FIA	344	*Prospective clinical field studies* **NL** Independent prospective clinical field study in symptomatic (n=628, PCR positive 118); NP swab; sensitivity overall: 78.0%, sensitivity Ct<30: 84.4%, sensitivity Ct<25: 90.3%; specificity overall: 99.6% **FIND evaluation** **DE** (10 Dec 2020) 676 samples, NP swab. Clinical sensitivities: Days ≤ 7: 81.2%; Ct ≤ 33: 75%; Ct ≤ 25: 100%; Clinical specificity: 96.9% **Brazil** (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** (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%	94,09% sensitivity 98.52% specificity NP swab	DE[2], IT, NL[5], DK Brazil, CH, India, UK	Nucleo-capsid protein	Nasopharyngeal swab	17 February 2021

Field Code Changed

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
			Retrospective in vitro study **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.52%					
SD BIOSENSOR Inc.	STANDARD Q COVID-19 Ag Test	345	*Prospective clinical field studies* **PT** 80 samples from symptomatic individuals (27 PCR positive and 53 negative by PCR) were tested. Sensitivity 70% (95%IC50-86); specificity 100% (95%IC 93-100). TCID50/ml 0,68x 102 and CT<25. **FIND evaluation** **DE** (10 Dec 2020) 1263 samples, NP swab. Clinical sensitivities: Days ≤ 7: 80%; Ct ≤ 33: 87.8%; Ct ≤ 25: 100%; Clinical specificity: 99.3% **Brazil** (10 Dec 2020) 400 samples, NP swab. Clinical sensitivities: Days ≤ 7: 90.7%; Ct ≤ 33: 91.9%; Ct ≤ 25: 95.9%; Clinical specificity: 97.6% **CH** (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** (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** (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% *Retrospective in vitro studies* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 89% at Ct ≤ 25; Manufacturer specificity: 99.68%	96.52% sensitivity 99.68% specificity NP swab	DE[2], ES, IT, NL[3], DK, PT Brazil, CH, India, NO, UA, UK	Nucleo-capsid protein	Nasopharyngeal swab	17 February 2021

Field Code Changed

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
SGA Medikal	V-Chek SARS-CoV-2 Ag Rapid Test Kit (Colloidal Gold)	1319	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99,5%	96.6% sensitivity, 99.5% specificity, Nasal swab	DE[2]	Nucleo-protein	Nasal swab	10 May 2021
	V-Chek SARS-CoV-2 Rapid Ag Test (colloidal gold)	1357	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99,5%	96.60% sensitivity: 99.5% specificity, Nasal swab	DE[2]	Nucleo-protein	Nasal swab	7 July 2021
Shenzhen Ultra-Diagnostics Biotec Co., Ltd.	SARS-CoV-2 Antigen Test Kit	2017	*Prospective clinical field study* **SI:** Sensitivity in unselected symptomatic population: 86.4% (172 RAT pos. / 199 RT-PCR pos.), sensitivity of 97.8% at Ct≤25. Specificity: 99.1% (1972 RAT neg. / 1990 RT-PCR neg.), NP swab	Clinical Sensitivity: 95.33 % (Nasal), 95.48(NP) Clinical Specificity: 99.16 % (Nasal), 99.61 % (NP)	BE, SI	Nucleo-protein	Nasal swab, Nasopharyngeal swab ! Saliva	10 May 2021
Shenzhen CAS-Envision Medical Technology Co., Ltd.	SARS-CoV-2-Antigen Rapid Detection Kit	2152	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct < 25; Manufacturer specificity: 99.5%	OP: Sensitivity: 98.1% 94.7%-99.4%), Specificity: 99.5% 97.0%-99.9%) NP: Sensitivity: 98.1% 94.7%-99.4%), Specificity: 99.5% 97.0%-99.9%)	DE[2]	Nucleo-capsid protein	Oropharyngeal swab; Nasopharyngeal swab	8 December 2021
Shenzhen Dymind Biotechnology Co., Ltd	SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	2415	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct < 25; Manufacturer specificity: 96.58%	Sensitivity: 96.58%, Specificity: 98.37%	DE[2]	Nucleo-protein	Nasal swab, Nasopharyngeal swab	20 October 2021
Shenzhen Huaree Technology Co.,Ltd	SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography)	2812	*Retrospective in vitro study* DE: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct < 25; Manufacturer specificity: 100%	Clinical Sensitivity 98 % (95% CI: 97.12%~99.98%) Clinical Specificity 100 % (95% CI: 98.12%~99.99%)	DE[2]	Nucleo-capsid protein	Nasal swab	6 May 2022
Shenzhen Huian Biosci Technology Co., Ltd.	SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	2414	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.1%	NP/OP swab: Sensitivity: 95.0%, Specificity: 99.1% Nasal swab: Sensitivity: 94.6%, Specificity: 99.1%	DE[2]	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab	20 October 2021

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
Shenzhen Kingfocus Biomedical Engineering Co., Ltd.	COVID-19 Antigen Detection Kit (Quantum Dots-Based Immunofluorescence Chromatography)	2941	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.28%	Clinical Sensitivity 90.83 % Clinical Specificity 99.28 %	DE[2]	Nucleo-capsid protein	Nasal swab	8 April 2022
Shenzhen Kisshealth Biotechnology Co., Ltd	SARS-CoV-2 Antigen Test Kit (GICA)	1813	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.2%	NP swabs: Sensitivity: 96.43%, Specificity: 100%. Nasal (Anterior) swabs: Sensitivity: 99.43%, Specificity: 99.23%.	DE[2]	Nucleo-capsid protein	Anterior nasal swab, Nasal swab, Nasopharyngeal swab, Oropharyngeal swab	20 October 2021
Shenzhen Lvshiyuan Biotechnology Co., Ltd.	Green Spring SARS-CoV-2 Antigen-Rapid test-Set	2109	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	96.43% sensitivity 100% specificity NP/OP/Nasal swab	DE[2]	Nucleo-protein	Anterior nasal swab, Nasal swab, Nasopharyngeal swab, Oropharyngeal swab ! Saliva	10 May 2021
Shenzhen Microprofit Biotech Co., Ltd	SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)	1967	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	Sensitivity: 92.93% Clinical Specificity: 100 % Nasal/NP/OP swab	DE[2]	Nucleo-protein	Nasal swab, Nasopharyngeal swab, Oropharyngeal swab	7 July 2021
Shenzhen Microprofit Biotech Co., Ltd.	SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay)	1178	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct < 25; Manufacturer specificity: 100%	Sensitivity: 86.3%, Specificity: 100% Nasal Swab	DE[2]	Spike protein	Nasal swab, Nasopharyngeal swab, Oropharyngeal swab	23 July 2021
Shenzhen Microprofit Biotech Co., Ltd	SARS-CoV-2 Spike Protein Test Kit (Fluorescence Immunoassay)	1228	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct < 25; Manufacturer specificity: 100%	Sensitivity: 93.46%, Specificity: 100%	DE[2]	Nucleo-protein, S protein (S1)	Nasopharyngeal swab	8 December 2021
Shenzhen Reagent Technology Co.,Ltd.	SARS-CoV-2 antigen IVD kit SWAB	2026	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct < 25; Manufacturer specificity: 98.1%	Sensitivity: 95.23 %, specificity: 98.71 %	DE[2]	Nucleo-capsid protein	Nasopharyngeal swab, Oropharyngeal swab	20 October 2021
Shenzhen Watmind Medical	SARS-CoV-2 Ag Diagnostic	1769	*Retrospective in vitro study*	NP/OP swab: Sensitivity	DE[2]	Nucleo-	Nasal swab,	10 May 2021

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
Co., Ltd	Test Kit (Colloidal Gold)		**DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct < 25; Manufacturer specificity: 99.12%	95.15%, specificity 99.12%. Nasal swab: Sensitivity: 91.51% for onset of symptoms < 7 days, specificity: 99.02%.		capsid protein	Nasopharyngeal swab, Oropharyngeal swab	
Shenzhen Watmind Medical Co., Ltd	SARS-CoV-2 Ag Diagnostic Test Kit (Immuno-fluorescence)	1768	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99,13%	Clinical Sensitivity: 97.83 % (CT ≤ 33); Clinical Sensitivity: 90.08 % (Ct ≤ 36); Specificity: 99,13% Nasal swab	DE[2]	Nucleo-protein	Nasal swab	7 July 2021
Shenzhen YHLO Biotech Co., Ltd.	GLINE-2019-nCoV Ag	1347	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 90% at Ct ≤ 25; Manufacturer specificity: 99.85%	Nasal: Sensitivity: 97.37% (95%CI: 92.50% - 99.45%); Specificity: 99.25% (95%CI: 97.82% - 99.85%) NP: Sensitivity: 96.49% (95%CI: 91.26% - 99.04%); Specificity: 99.25% (95%CI: 97.82% - 99.85%)	DE[2]	Nucleo-capsid protein	Nasal swab; Nasopharyngeal swab	8 December 2021
Shenzhen Zhenrui Biotech Co., Ltd	Zhenrui ®COVID-19 Antigen Test Cassette	1574	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 82% at Ct ≤ 25; Manufacturer specificity: 97%	96% sensitivity 97% specificity Nasal swab	DE[2]	Nucleo-protein	Nasal swab ! Saliva	10 May 2021
Sugentech, Inc.	SGTi-flex COVID-19 Ag	1114	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 30 and 100% at Ct ≤ 25; Manufacturer specificity: 99.0%	95,07% sensitivity 99,38% specificity NP swab 95,06% sensitivity 99,29% specificity Nasal swab	DE[2]	Nucleo-capsid protein	Nasopharyngeal swab, Nasal swab	10 May 2021
SureScreen Diagnostics	SARS-CoV-2 Rapid Antigen Test Cassette	2297	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99%	96.1% Clinical Sensitivity 99% Clinical Specificity	DE[2] UK	Nucleo-capsid protein	Nasal swab	20 October 2021
Surge Medical Inc.	COVID-19 Antigen Test Kit	1942	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 97.69%	Clinical sensitivity: 93.33% Clinical specificity: 97.69%	DE[2]	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab, Oropharyngeal swab	21 January 2022

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
Suzhou Soochow University Saier Immuno Biotech Co., Ltd.	InstantSure Covid-19 Ag CARD	3015	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct < 25; Manufacturer specificity: 99.52%	Clinical Sensitivity 96.69 % Clinical Specificity 99.52 %	DE[2]	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab	6 May 2022
TODA PHARMA	TODA CORONADIAG Ag	1466	*Prospective clinical field study* **FR:** Validation data: NP swabs, sensitivity : 96,1-100%, specificity 99,2-100% *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	98.6% sensitivity Nasal swab	DE[2], FR	Nucleo-protein	Nasal swab, Nasopharyngeal swab	10 May 2021
Triplex International Biosciences(China) CO.,LTD.	SARS-CoV-2 Antigen Rapid Test Kit	2074	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 92,5% at Ct ≤ 30 and 100% at Ct ≤ 25; Manufacturer specificity: 99.91%	98.51% sensitivity 99.91% specificity Nasal/OP/NP swab	DE[2]	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab, Oropharyngeal swab ! Saliva	16 June 2021
Triplex International Biosciences(China) CO.,LTD.	SARS-CoV-2 Antigen Rapid Test Kit	1465	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	98.51 % sensitivity 100% specificity Nasal swab	DE[2]	Nucleo-protein	Nasal swab	14 July 2021
TÜRKLAB TIBBİ MALZEMELER SAN. ve TİC. A.Ş.	INFO Covid-19 Ag Test	2584	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 90% at Ct ≤ 25; Manufacturer specificity: 99.54%	92.71% Clinical Sensitivity 99.54% Clinical Specificity Nasal swab	DE[2]	Nucleo-capsid protein	Nasal swab	21 December 2021
TÜRKLAB TIBBİ MALZEMELER SAN. ve TİC. A.Ş.	Covid-19 Ag Test	1689	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 90% at Ct ≤ 25; Manufacturer specificity: 99.54%	92.71% Clinical Sensitivity 99.54% Clinical Specificity Nasal swab	DE[2]	Nucleo-capsid protein	Nasal swab	21 January 2022
TÜRKLAB TIBBİ MALZEMELER SAN. ve TİC. A.Ş.	RAPIDAN TESTER Covid-19 Ag Test	1751	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 90% at Ct ≤ 25; Manufacturer	92.71% Clinical Sensitivity 99.54% Clinical Specificity Nasal swab	DE[2]	Nucleo-capsid protein	Nasal swab	21 January 2022

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
			specificity: 99.54%					
TÜRKLAB TIBBİ MALZEMELER SAN. ve TİC. A.Ş.	TOYO Covid-19 Ag Tes	1722	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 90% at Ct ≤ 25; Manufacturer specificity: 99.54%	92.71% Clinical Sensitivity 99.54% Clinical Specificity Nasal swab	DE[2]	Nucleo-capsid protein	Nasal swab	21 January 2022
Vitrosens Biotechnology Co., Ltd	RapidFor SARS-CoV-2 Rapid Ag Test	1443	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 30 and 100% at Ct ≤ 25; Manufacturer specificity: 99.05%	97.30% sensitivity 99.05% specificity	DE[2]	Nucleo-capsid protein	Anterior nasal swab, Nasal swab, Nasopharyngeal swab, Oropharyngeal swab, Throat swab	10 May 2021
VivaChek Biotech (Hangzhou) Co., Ltd, China	Verino Pro SARS CoV 2 Ag Rapid Test	2100	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.9%	Clinical Sensitivity: 97.42% Clinical Specificity: 99.9%	DE[2]	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab, Oropharyngeal swab	21 December 2021
Wuhan EasyDiagnosis Biomedicine Co., Ltd.	COVID-19 (SARS-CoV-2) Antigen-Test Kit	2098	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.26%	96.1% sensitivity 100% specificity Nasal/OP/NP swab	DE[2] UK	Nucleo-protein	Nasal swab, Nasopharyngeal swab, Oropharyngeal swab	10 May 2021
Wuhan HealthCare Biotechnology Co. Ltd.	SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	2742	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 90% at Ct ≤ 25; Manufacturer specificity: 100%	Clinical Sensitivity: 97.8 % (Nasal Swab) Clinical Sensitivity: 96.7 % (NP Swab) Clinical Specificity: 100 % (Nasal Swab) Clinical Specificity: 100 % (NP Swab)	DE[2]	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab	4 March 2022
Wuhan Life Origin Biotech Joint Stock Co., Ltd.	SARS-CoV-2 Antigen Assay Kit (Immuno-chromatography)	1773	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.13%	95.24% sensitivity 99.13% specificity	DE[2]	Nucleo-protein	Nasal swab, Nasopharyngeal swab, Oropharyngeal swab	14 July 2021
Wuhan UNscience Biotechnology Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit	2090	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99,57%	Sensitivity: 96.33% Specificity: 99.57% Nasal/NP/OP swab	DE[2], FR	Nucleo-protein	Mid-turbinates swab, Nasal swab, Nasopharyngeal swab, Oropharyngeal	7 July 2021

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
							swab	
Wuxi Biohermes Bio & Medical Technology Co., Ltd.	SARS-CoV-2 Antigen Test Kit (Lateral Flow Assay)	2143	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.02%	Sensitivity: 95.31 %, Specificity: 98.02 %	DE[2]	Nucleo-protein	Nasopharyngeal swab, Oropharyngeal swab	20 October 2021
Xiamen AmonMed Biotechnology Co., Ltd	COVID-19 Antigen Rapid Test Kit (Colloidal Gold)	1763	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.55%	93.2% sensitivity 99.55% specificity Nasal swab	DE[2]	Nucleo-protein	Nasal swab	10 May 2021
Xiamen Boson Biotech Co. Ltd	Rapid SARS-CoV-2 Antigen Test Card	1278	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.03%	NP swab 96.08% sensitivity 99.14% specificity Nasal swab 97.8% sensitivity 99.84% specificity OP swab 96.23% sensitivity 99.2% specificity	DE[2] CH, UK	Nucleo-capsid protein	Nasopharyngeal swab, Oropharyngeal swab, Nasal swab	17 February 2021
Xiamen Wiz Biotech Co., Ltd	SARS-CoV-2 Antigen Rapid Test	1456	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity: 100%	96.3% sensitivity, 100% specificity Nasal swab	DE[2]	Nucleo-protein	Nasal swab ! Other	10 May 2021
	SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)	1884	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 88% at Ct ≤ 25; Manufacturer specificity: 100%	95.91% sensitivity 100% specificity Nasal swab	DE[2]	Nucleo-capsid protein	Anterior nasal swab	10 May 2021
Zhejiang Anji Saianfu Biotech Co.., Ltd	AndLucky COVID-19 Antigen Rapid Test	1296	*Retrospective in vitro study* **DE:** Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99%	95.8% sensitivity, 99% specificity, Nasal swab	DE[2]	Nucleo-protein	Nasal swab, Nasopharyngeal swab, Oropharyngeal swab	10 May 2021

Manufacturer	RAT commercial name	Device ID # [3]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [4]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [5]	Included in EU common list since:
Zhejiang Anji Saianfu Biotech Co.., Ltd	reOpenTest COVID-19 Antigen Rapid Test	1295	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct ≤ 25; Manufacturer specificity: 99%	95.8% sensitivity, 99% specificity, Nasal swab	DE[2]	Nucleo-protein	Nasal swab, Nasopharyngeal swab	10 May 2021
Pantest SA	Pantest Coronavirus Ag (Nasopharyngeal Swab)	2271	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94% at Ct ≤ 25; Manufacturer specificity: 99.1%	sensitivity: 95,70%, specificity: 99,10%	DE[2]	Nucleo-capsid protein	Nasopharyngeal swab	8 December 2021
Zhejiang GENE SCIENCE Co., Ltd	Novel Coronavirus (COVID-19) Antigen Detection Kit (Swab)	2684	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98.73%	OP: Sensitivity: 95.65%, Specificity: 99.17% NP: Sensitivity: 94.58%, Specificity: 98.73%	DE[2]	Nucleo-capsid protein	Oropharyngeal swab; Nasopharyngeal swab	8 December 2021
Zhuhai Encode Medical Engineering Co.,Ltd	ENCODE SARS-COV-2 Antigen Rapid Test Device	1902	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 95% at Ct ≤ 25; Manufacturer specificity: 100%	Throat swab/Nasal Swab: Sensitivity 96.49%, Specificity 100% Anterior Swab: Sensitivity 94.74%, Specificity: 100%	DE[2] UK	Nucleo-capsid protein	Anterior nasal swab, Nasal swab, Throat swab	20 October 2021
Zhuhai Lituo Biotechnology Co., Ltd.	COVID-19 Antigen Detection Kit (Colloidal Gold)	1957	*Prospective clinical field study* **SI**: Independent prospective field study at a public hospital, Nasal specimens, normal Ct distribution, sensitivity 189/191 PCR positives: 98.95%, specificity 403/404: 100 % *Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 100%	Nasal: sensitivity: 100.00% (Ct value<30), specificity: 99.75%; sensitivity: 98.95%（Ct value<33), specificity: 99.75%. NP: sensitivity: 100.00%, specificity: 99.71% (PCR≤25)； sensitivity: 99.00%, specificity: 99.71% (PCR<33)	DE[2]	Nucleo-protein	Nasal swab, Nasopharyngeal swab	14 July 2021
Zybio Inc.	SARS-CoV-2 Antigen Assay Kit (Colloidal Gold Method)	2201	*Prospective clinical field study* **SI:** Independent prospective study by a public hospital, nasal samples, study population: unselected hospital patients, 107 positive and 417 negative samples (as defined by RT-PCR testing of matched NP swabs), Sensitivity: 88.8%; specificity: 99%.	Clinical Sensitivity 97.87 % Clinical Specificity 99.62 %	SI	Nucleo-capsid protein	Anterior nasal swab	4 March 2022

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/2020-10/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-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

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).	

ANNEX III: List of mutually recognised COVID-19 laboratory based antigenic assays

As agreed by Member States on 8 April 2022

Manufacturer	RAT commercial name	Device ID # [6]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	Completed validation studies	SARS-CoV-2 Target protein	Specimen [7]	Included in EU common list since:
DIASORIN	LIAISON SARS-CoV-2 Ag assay	1960	*Prospective clinical field studies* **BE**: Independent prospective study (random selection), symptomatic and asymptomatic (n=414, PCR positive = 204, PCR negative = 210), NP swab; sensitivity Ct<35: 73.4%, sensitivity Ct<25: 96.4%; specificity: 100% **FR**: Independent prospective study, symptomatic and asymptomatic (n=378, PCR positive = 46), NP swab; overall sensitivity: 84.8%, sensitivity Ct=<25 100%; specificity: 99.4% **IT**: Independent prospective study, asymptomatic (n=1075, PCR positive = 23), NP swab; sensitivity Ct=<30 90.5%; specificity: 99.8% **NL** : Independent field study, mainly symptomatic individuals (n=980, PCR positive n=98), NP+OP swab; sensitivity overall 82.7%, sensitivity Ct<30: 91.9%; specificity overall: 99.1%.	Nasal Swab: Sensitivity: 99/101 (98.0%, 95% CI: 93.1 – 99.5%). Specificity: 210/211 (99.5%, 95% CI: 97.4 – 99.9%). NP Swabs: Sensitivity: 108/109 (99.1%, 95% CI: 95.0 – 99.8%). Specificity: 295/299 (98.7%, 95% CI: 96.6 – 99.5%).	BE, FR, IT, NL	Nucleo-capside protein	Nasal swab, Nasopharyngeal swab	20 October 2021

[6] As registered in and used by the JRC database, see: https://covid-19-diagnostics.jrc.ec.europa.eu/.
[7] The information included in this column is based on the information provided by manufacturers to the JRC database.

Manufacturer	RAT commercial name	Device ID # [6]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer*	Completed validation studies	SARS-CoV-2 Target protein	Specimen [7]	Included in EU common list since:
Fujirebio	Lumipulse G SARS-CoV-2 Ag	2124	*Prospective clinical field studies* **BE:** Independent prospective study, NP samples: 102 positive samples, 400 negative samples (including 100 hospitalized patients), sensitivity 93%, specificity: 99%. **IT**: Independent prospective study, Sample size (NP): 194 positive and 400 negative. Sensitivity (overall): 79.9% (155/194); sensitivity (Ct<25): 100% (87/87); specificity: 99.3% (397/400).	Clinical Sensitivity 97.6 % (NPS: 95% CI: 93.3-99.2% (124/127) ; Ct-value <30) Clinical Sensitivity 100 % (NSP: 95%CI: 95.8-100.0% (87/87) ; Ct-value <25) Clinical Specificity 99.3 % (Nasopharyngeal swab: (95% CI: 97.8-99.7%) (397/400))	BE, IT	Nucleo-capside protein	Nasopharyngeal swab	8 April 2022
Ortho Clinical Diagnostics	VITROS Immunodiagnostic Products SARS-CoV-2 Antigen	1200	*Prospective clinical field studies* **BE:** Independent prospective study: 80 positive NP samples (sensitivity 100%), 108 negative samples (specificity 100%). **FR**: Independent prospective study: 107 positive NP samples with Ct≤35 (sensitivity 93,5% for Ct≤35), 1614 negative samples (specificity 100%). *Retrospective in vitro study* A retrospective study including 134 positive NP samples with Ct<35 (sensitivity 82,8% for Ct≤35).	Clinical Sensitivity 95 % (CI: 92.0% - 100%) Clinical Sensitivity 98 % (95% CI: 92.2–99.4%) Clinical Specificity 98.9 % (95% CI: 96.3-99.9%)	BE, FR	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab	10 February 2022
Roche Diagnostics GmbH	Elecsys® SARS-CoV-2 Antigen	2156	*Prospective clinical field study* **DE:** Total N: 3139 (2747 negative, 392 positive) Germany participated in the validation. Roche coordinated and performed partially the data analysis. Relative specificity overall 99.9%; relative sensitivity (n=390) overall 92.5% (CT<26).	Sensitivity: NP/OP: 94.5 % (95% CI: 90.4-97.2); Nasal swabs: 96.8% (95% CI: 88.8-99.6%) Specificity: 99.9% (95 % CI: 99.6-100%)	DE[2]	Nucleo-capsid protein	Nasal swab, Nasopharyngeal swab, Oropharyngeal swab	20 October 2021