CERTIFICATE

EC Certificate No. 1434-IVDD-450/2021

EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

Qingdao Hightop Biotech Co., Ltd.
No.369 Hedong Road, Hi-tech Industrial Development Zone,Qingdao, Shandong, 266112, China

in vitro diagnostic medical devices
for self-testing

SARS-CoV-2 Antigen Rapid Test

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC
Validity of the Certificate: from 13.08.2021 to 27.05.2024

The date of issue of the Certificate: 13.08.2021

The date of the first issue of the Certificate: 27.05.2021

CE 1434

Issued under the Contract No. **MD-55/2021**
Application No: **105/2021**
Certificate bears the qualified signature.
Warsaw, 13/08/2021
Module A1

Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2021.08.13
09:51:23 +02'00'

Vice-President
Mgr Anna Wyroba

DECLARATION OF CONFORMITY

MANUFACTURER	Qingdao Hightop Biotech Co., Ltd. No.369 Hedong Road, Hi-tech Industrial Development Zone, Qingdao, Shandong, 266112, China
EUROPEAN REPRESENTATIVE	MedNet EC-REP GmbH Borkstrasse 10 · 48163 Muenster · Germany
PRODUCT	SARS-CoV-2 Antigen Rapid Test --- Analyte: SARS-CoV-2 Antigen
CLASSIFICATION	Self-testing
CONFORMITY ASSESSMENT ROUTE	IVDD 98/79/EC Annex Ⅲ section 6

WE, THE MANUFACTURER, IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY. WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC. ALL SUPPORTING DOCUMENTATIONS ARE RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED 98/79/EC, EN ISO 18113-1: 2011, EN ISO 18113-2:2011, EN ISO 18113-4: 2011, EN 13612: 2002, EN ISO 23640: 2015, EN 13641: 2002, EN ISO 15223-1: 2016, EN 13975: 2003, EN ISO 14971: 2019, EN ISO 13485: 2016, EN ISO 17511: 2003, EN 62366-1: 2015, EN 13532: 2002.

PLACE, DATE OF ISSUE Qingdao, 2021-06-01

SIGNATURE

Mr. Frank Yang

General Manager

CE 1434

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, including those of which their test results are mutually recognised, and a common standardised set of data to be included in COVID-19 test result certificates

Agreed by the Health Security Committee

This document was agreed by the HSC on 17 February 2021

Annex I

Common list of rapid antigen tests

A first update was agreed by the HSC on 10 May 2021
A second update was agreed by the HSC on 16 June 2021

Annex II

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

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

I. Introduction

Robust testing strategies are an essential aspect of preparedness and response to the COVID-19 pandemic, allowing for early detection of potentially infectious individuals and providing visibility on infection rates and transmission within communities. Moreover, they are a prerequisite to adequate contact tracing to limit the spread through prompt isolation. Also in the context of the circulation of SARS-CoV-2 variants of concern, surge testing in addition to existing testing deployment has proven to be key for controlling and suppressing further spread of the virus.

While the reverse transcription real-time polymerase chain reaction (RT-PCR) assay, which is a nucleic acid amplification test (NAAT) remains the 'gold standard' for COVID-19 diagnosis, rapid antigen tests, which detect the presence of viral proteins (antigens), are increasingly being used by Member States as a way of further strengthening countries' overall testing capacity, particularly in case of limited NAAT capacities or where prolonged testing turnaround times results in no clinical utility.

The Health Security Committee agreed on 17 September 2020 on Recommendations for a common EU testing approach for COVID-19[1], setting out various actions for consideration by countries when updating or adapting their testing strategies. The Recommendations included Member States' first experiences with rapid antigen tests and their deliberations concerning the settings and situations in which these tests should be used. Since then, the Committee has been discussing the use and application of rapid antigen tests in great depth, and has brought together a wealth of (technical) information on the types of tests used in European countries and the conditions applied.

On 21 January 2021, Member States unanimously agreed on a Council Recommendation setting a common framework for the use of rapid antigen tests and the mutual recognition of COVID-19 test results across the EU[2]. The Council Recommendation called on Member States to agree on three concrete deliverables:

1. **A common list of COVID-19 rapid antigen tests** that are considered appropriate for use in the context of the situations described in the Council Recommendation, that are in line with countries' testing strategies and that:
    a. carry CE marking;
    b. meet the minimum performance requirements of ≥ 90% sensitivity and ≥ 97% specificity; and
    c. have been validated by at least one Member State as being appropriate for their use in the context of COVID-19, providing details on the methodology and results of such studies, such as the sample type used for validation, the setting in which the use of the test was assessed, and whether any difficulties occurred as regards the required sensitivity criteria or other performance elements.

[1] https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/common_testingapproach_covid-19_en.pdf
[2] https://data.consilium.europa.eu/doc/document/ST-5451-2021-INIT/en/pdf

2. A selection of rapid antigen tests of which Member States will **mutually recognise the test results for public health measures**.
3. **A common standardised set of data to be included in COVID-19 test result certificates**, further facilitating the mutual recognition of COVID-19 test results.

Based on the information collected by the Health Security Committee, and taking into consideration the current epidemiological situation and the testing strategies and approaches that have been put in place across the EU, this document sets out the three deliverables as agreed by Member States. Its content is prepared based on the criteria set out in the Council Recommendation and considers the relevant recommendations published by the Commission[3] and technical guidance issued the European Centre for Disease Prevention and Control (ECDC)[4] and the World Health Organization (WHO)[5].

II. Annex I: Common list of rapid antigen tests

Point 11 of the Council Recommendation of 21 January 2021, calls on Member States to, without prejudice to Directive 98/79/EC, agree on and maintain a common and updated list of COVID-19 rapid antigen tests that are considered appropriate for use in the context of the situations described under point 6 and are in line with countries' testing strategies. Moreover, the antigen tests included in the list should meet the three performance criteria as outlined in section I of this document.

This list should be shared with ECDC and the Commission to prevent duplication of work and to feed into ongoing initiatives, particularly the "COVID-19 In Vitro Diagnostic Devices and Test Methods Database[6], hosted by the Joint Research Centre (JRC). **Annex I to this document sets out a common list of rapid antigen tests that meet the criteria as specified by the Council.** This list has been incorporated by the JRC in its COVID-19 In Vitro Diagnostic Devices and Test Methods Database.

A first update to Annex I was agreed by the Health Security Committee on 10 May 2021 and a second update on 16 June 2021.

The common list of rapid antigen tests is regularly being reviewed by Member States, and, if necessary, be updated in line with new results from independent validation studies becoming available and new tests entering the markets. These updates are also taking into account how mutations of the SARS-CoV-2 virus may affect the efficacy of any particular rapid antigen tests, allowing for the removal of tests no longer deemed effective. The effect of mutations of the SARS-CoV-2 virus on the efficacy of NAAT, in particular RT-PCR assays, will also be kept under review.

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020H1595 and https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020H1743&from=EN
[4] https://www.ecdc.europa.eu/en/publications-data/options-use-rapid-antigen-tests-covid-19-eueea-and-uk
[5] https://www.who.int/publications/i/item/9789240017740
[6] https://covid-19-diagnostics.jrc.ec.europa.eu/devices

III. Annex I: Mutual recognition of rapid antigen tests

As stipulated in point 15 of the Council Recommendation of 21 January 2021, Member States will agree on a selection of rapid antigen tests of which they will mutually recognise the test results for public health measures, based on the information included in the common list (see Annex I).

The Health Security Committee agrees that, for rapid antigen test results to be mutually recognised, at least three Member States should be using a rapid antigen tests in practice. Based on this criterion, those rapid antigen tests for which Member States agree that their results will be mutually recognised for public health measures, are **highlighted in yellow in Annex I**[7].

A first update to Annex I, including the selection of tests of which their results are mutually recognised, was agreed by the Health Security Committee on 10 May 2021 and a second update on 16 June 2021 – TBC.

IV. HSC Technical Working Group on COVID-19 Diagnostic Tests

Based on the increasing political and commercial interest in the HSC agreed common list of rapid antigen tests, particularly in the context of the EU Digital COVID Certificate[8], there is a need to put in place a more structured, coherent and swift procedure for updating the common list of rapid antigen tests. As a first step, since 10 May 2021, it is now possible for manufacturers to submit data and information concerning rapid antigen tests that they believe should be considered for inclusion in the HSC agreed common list. This information will thus be reviewed and considered alongside the proposals put forward by EU Member States.

Secondly, a HSC Technical Working Group on COVID-19 Diagnostic Tests was set up. This Working Group, consisting of technical experts from EU and EEA Member States, will be responsible for reviewing the information submitted by countries and manufacturers, taking into account the latest result of independent validation studies and country practices and experiences. Based on this, the technical working group will present proposals to the HSC for further updates to the common list of rapid antigen tests. The HSC will thus remain the platform where agreement between Member States is reached for updates to the list.

During the discussions held at the first meetings of the Technical Working Group on COVID-19 Diagnostic Tests, it became apparent that there is a strong need for a careful review of the selection criteria in place for inclusion of rapid antigen tests in the common list as well as the overall objectives of the common list. More specifically, the following points were agreed by the technical experts, which will be further discussed and reviewed in the course of summer

[7] This list has been incorporated by the JRC in its COVID-19 In Vitro Diagnostic Devices and Test Methods Database.

[8] On 17 March 2021, the Commission published a legislative proposal (COM(2021) 130 final), proposing that the test certificates of the EU Digital COVID Certificate should be linked to the test result produced by either a NAAT test or a rapid antigen test listed in the HSC agreed common list of rapid antigen tests.

2021, taking into account also ongoing work by the In Vitro Diagnostics Working Group of the Medical Device Coordination Group (MDCG IVD WG) regarding guidance on the performance of COVID-19 tests in the context of CE-marking and common specifications under Article 9 of Regulation (EU) 2017/746[9]:

Selection criteria

- There is a strong need to further define and agree on criteria in addition to the ones that were agreed in Council Recommendation 2021/24/01 of 21 January 2021 for rapid antigen tests to be included on the common list. In particular, in order to accurately assess the clinical performance of rapid antigen tests, other factors besides their sensitivity and specificity levels should be addressed (e.g. cycle threshold (Ct) value of comparative NAAT).
- The thresholds linked to such criteria strongly depend on the type of panel used (e.g. samples from symptomatic or asymptomatic individuals). Therefore, there may be a need to agree on different thresholds based on sample type/panel used (which can be linked to the overall testing objective – e.g. COVID-19 diagnosis among symptomatic people versus screening among the general population).

Validation studies

- There is a need to define what an "independent validation study" entails;
- A wide range of different methodologies and protocols are being applied in countries for carrying out validation studies aiming to assess the clinical performance of rapid antigen tests. There is an urgent need to agree on and develop a harmonised approach for validation studies assessing the clinical performance of rapid antigen tests.
- It is key that the sensitivity levels of the rapid antigen tests, as reported by independent national validation studies, reflect clinical performance as measures in practice, rather than the sensitivity reported by the manufacturer. For the validation of rapid antigen tests, samples should be benchmarked against qPCR and digital PCR.

Other elements

- The current HSC agreed common list of rapid antigen tests includes tests for which their clinical performance was measured based on samples collected from nasal, oropharyngeal or nasopharyngeal specimens. Other rapid antigen tests exist that have been validated in EU Member States based on alternative samples, such as saliva, sputum and/or faeces. Further discussions are required to reach consensus on whether these tests should also be included in the HSC agreed common RAT list.
- A further discussion is required on the situations in which there is a need for mutual recognition of rapid antigen test results between Member States, and to agree on the

[9] The Medical Device Coordination Group is set up according to Art. 103 of Regulation (EU) 2017/745 and Art. 98 of Regulation (EU) 2017/746. This group is also responsible for overseeing the implementation of Directive 98/79/EC. See also Register of Commission Expert Groups and Other Similar Entities, code number X03565, and its subgroups.

objective of those tests highlighted in Annex I. In this context, the criteria defined for a rapid antigen test to be mutually recognised (at least 3 Member States should be using the test in practice) should also be reviewed.

- Future updates to the common rapid antigen tests list should also take into account how mutations of the SARS-CoV-2 virus may affect the efficacy of any particular rapid antigen tests. The effect of mutations of the SARS-CoV-2 virus on the efficacy of RT-PCR tests should also be kept under review. In particular, in the current context of circulation of variants of concern, the use of rapid antigen tests does not allow samples to be used for subsequent detection of new variants (by NAAT and/or sequencing).

V. Annex II: Common standardised set of data for COVID-19 test certificates

In order to facilitate in practice the mutual recognition of results of rapid antigen tests as well as NAAT, including RT-PCR assays, point 18 of Council Recommendation 2020/1475 defines that Member States should agree on a common standardised set of data to be included in the form for test result certificates.

Based on information that was submitted by members of the Health Security Committee in response to a survey on mutual recognition on COVID-19 test results and further discussions that took place in the context of the Health Security Committee, Member States agree on **the common standardised set of data for COVID-19 test result certificates as presented in Annex II**. Member States agree that COVID-19 test results should be made available in the national language(s) of the country where the test was taken, as well as English.

An update to this Annex was agreed by the Health Security Committee on 19 March 2021, addressing input received from the eHealth Network and in particular the Semantic Subgroup and based on discussions that took place in the context of the EU Digital COVID Certificate.

The Health Security Committee will discuss, whenever relevant, possible updates to the agreed common standardised set of data for COVID-19 test certificates, and publish, if necessary, an updated agreed document.

ANNEX I: Common list of rapid antigen tests[10,11]

As agreed by Member States on 16 June 2201

***Disclaimer**: This list was agreed by the HSC based on a proposal by the Technical Working Group on COVID-19 Diagnostic Tests. Experts participating in the Technical Working Group strongly recommend that use of rapid antigen tests is primarily intended for preliminary testing for SARS-CoV-2 infection in symptomatic patients, and note that rapid antigen tests should in particular be used in the specific contexts and circumstances referred to by the Commission Recommendation (EU) 2020/1743 of 18 November 2020 and the technical guidance by ECDC on 19 November 2020. The content of the common list is based on the clinical performance data and information that is available at this moment in time. However, there is a strong need for defining further selection criteria that allow for the identification and selection of rapid antigen tests that meet different testing objectives, as well as a defining a common approach for carrying out independent clinical validation studies. These aspects will be addressed by the Technical Working Group during summer 2021, taking into consideration the work carried out by the In Vitro Diagnostics Working Group of the Medical Device Coordination Group[9] on guidance on the performance of COVID-19 tests in the context of CE-marking and common specifications under Article 9 of Regulation (EU) 2017/746. Until then, updates to the common list will continue to be proposed, based on the criteria as described in Council Recommendation 2021/C 24/01.*

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[12]	In FIND database
AAZ-LMB	COVID-VIRO® Rapid antigen test COVID-19	Yes	96.1% sensitivity 100% specificity	**BE**: 96.6% sensitivity, 100% specificity, NP swab **FR:** >95%% sensitivity, 100% specificity **SI**: 96.6% sensitivity, 100% specificity, NP swab		BE, FR, SI	CH	FR CH		Yes (1833)	Yes
Abbott Rapid Diagnostics	Panbio™ COVID-19 Ag Rapid Test	Yes	91.4% sensitivity 99.8% specificity Nasal/NP swab	**BE**: 93.3% sensitivity, 99.4% specificity, NP Swab 98.1% sensitivity, 99.8% specificity, Nasal swab **DE**: 91.4% sensitivity 99.8% specificity, NP swab 98.1% sensitivity, 99,8 specificity, Nasal swab	FIND Evaluation - Studies in DE and CH, NP swab, 10 Dec 2020	AT, BE, BG, CY, CZ, DE[2], DK, EE, EL, ES, FR[1], HR, IT, LT, LV, MT, NL[5], PL, PT, RO, SE, SK	CH, ME, MK, NO, UK, UA	DE[2], ES, NL[5] CH, NO	CY, ES, HR, HU, IE, LU, PT, SE	Yes (1232)	Yes

[10] This is the list of RATs as referred to by the Proposal for a Regulation of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic (Digital Green Certificate), COM/2021/130 final, of 17 March 2021, which is currently being negotiated in the European Parliament and the Council. Member States shall issue and accept Digital Green Certificates based on this list (and subsequent updates).

[11] The entries highlighted in yellow are the RATs of which Member States have agreed to mutually recognise their test results for public health measures.

[12] In case rapid antigen tests are not included in the JRC Database, manufacturers are invited to submit this information here: https://covid-19-diagnostics.jrc.ec.europa.eu/contact/feedback_ant.

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[12]	In FIND database
ACON Laboratories, Inc	Flowflex SARS-CoV-2 Antigen Rapid Test	Yes	97.1% sensitivity 99.6% specificity Nasal swab	**BE:** 96.9% sensitivity, 99.5% specificity, NP swab **DE**: 97.1% sensitivity, 99.5% specificity, NP/Nasal swab	Ongoing	AT, BE, LT, LV, SI		DE[2]		Yes (1468)	Yes
AESKU.DIAGNOSTICS GmbH & Co, KG	AESKU.RAPID SARS-CoV-2	Yes		**DE**: 96% sensitivity, 98% specificity **SI**: 96% sensitivity, 98% specificity, Nasal swab		AT, DE[2], SI		DE[2]		Yes (2108)	No
Affimedix Inc.	TestNOW® - COVID-19 Antigen Test	Yes		**DE**: 93.7% sensitivity, 99.2% specificity		DE[2]		DE[2]		Yes (2130)	No
AMEDA Labordiagnostik GmbH	AMP Rapid Test SARS-CoV-2 Ag	Yes	97.3% sensitivity 100% specificity NP swab 97.3% sensitivity 98.8% specificity Nasal swab	**BE**: 97.3% sensitivity, 100% specificity, NP swab **DE**: 97.3% sensitivity, 100% specificity **SI**: 97.3% sensitivity, 100% specificity, NP swab		AT, BG, DE[2] HR, SI	CH, UA	DE[2] CH	HR	Yes (1304)	Yes
Anbio (Xiamen) Biotechnology Co., Ltd.	Rapid COVID-19 Antigen-Test (colloidal Gold)	Yes	99.2% sensitivity 100% specificity	**DE**: 99.27% sensitivity, 100% specificity		AT, DE[2]		DE[2]		Yes (1822)	No
Anhui Deep Blue Medical Technology Co. Ltd	COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)	Yes		**BE**: 95% sensitivity, 99% specificity, NP/OP swab **DE**: 97.1% sensitivity, 99.8% specificity		BE, DE[2]	UK	DE[2]		Yes (1736)	Yes
Anhui DeepBlue Medical Technology Co. Ltd	COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) – Nasal swab	Yes	96.4 % sensitivity 99.8 % specificity Nasal swab	**DE:** 96,4 % sensitivity, 99,8 % specificity		DE[2]		DE[2]		Yes (1815)	No
ArcDia International Ltd	mariPOC SARS-CoV-2	Yes	92.3% sensitivity 100% specificity	**FI:** Meets the minimum performance requirements – see the report for details.		FI		FI		Yes (768)	Yes
Asan Pharmaceutical CO., LTD	Asan Easy Test COVID-19 Ag	Yes	94.7% sensitivity 97.7% specificity	**DE**: 94.67% sensitivity, 97.71% specificity		DE[2]		DE[2]		Yes (1654)	Yes
Atlas Link Technology Co. Ltd	NOVA Test ® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)	Yes		**DE**: 97.6% sensitivity, 99.2% specificity		AT, DE[2], SI	CH	DE[2] CH		Yes (2010)	Yes
Azure Biotech, Inc.	Dia Sure COVID-19 Antigen Rapid Test Device	Yes		**DE**: 94.3% sensitivity, 99.1% specificity		DE[2]		DE[2]		Yes (1906)	No

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[12]	In FIND database
AXIOM Gesellschaft für Diagnostica und Biochemica mbH	COVID-19 Antigen Rapid Test	Yes		**DE**: 98.1% sensitivity, 100% specificity		DE[2]		DE[2]		Yes (2101)	No
Beijing Hotgen Biotech Co., Ltd.	Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)	Yes	97.1% sensitivity 99.76% specificity	**BE**: 98.6% sensitivity, 100% specificity, NP Swab 97.3% sensitivity, 99.2% specificity. OP swab **DE**: 95.37% sensitivity, 99.13% specificity **SI**: 96.6% sensitivity, 99.8% specificity, NP swab	Validation study to start	AT, BE, DE[2], RO, SI		DE[2]		Yes (1870)	No
Beijing Lepu Medical Technology	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold immunochromatography)	Yes	92% sensitivity unknown specificity Nasal swab	**BE**: 92% sensitivity, 99.3% specificity, Nasal **DE**: 92.0% sensitivity, 99.26% specificity **SI**: 92% sensitivity, 99.2% specificity, NP swab		AT, BE, DE[2], SI, RO	UA	DE[2]		Yes (1331)	Yes
Beijing Wantai Biological Pharmacy Enterprise Co Ltd	WANTAI SARS-CoV-2 Ag Rapid Test (FIA)	Yes	96.6% sensitivity, unknown specificity Nasal swab	**DE**: 96.6% sensitivity, 96.9% specificity		DE[2]		DE[2]		Yes (1484)	Yes
BIOSYNEX SA	BIOSYNEX COVID-19 Ag BSS	Yes		**BE**: 96% sensitivity, 100% specificity, NP swab **DE**: 96% sensitivity, 100% specificity		AT, BE, DE[2], DK,FR, NL[5], PT	CH	DE, NL[5], CH	DK	Yes (1223)	Yes
BTNX Inc.	Rapid Response COVID-19 Antigen Rapid Test Device	Yes	94.55% sensitivity 100% specificity	**DE**: 94.55% sensitivity, 100% specificity		AT, DE[2], SI		DE[2]		Yes (1236)	No
CerTest Biotec	CerTest SARS-CoV-2 CARD TEST	Yes	92.9% sensitivity 99.6% specificity NP swab	**BE**: 92.9% sensitivity, 99.6% specificity, NP swab **SI**: 92.9% sensitivity, 98.4% specificity, NP/OP swab		ES, PT, SI		ES		Yes (1173)	Yes
Core Technology Co., ltd	Canea Covid-19 Antigen Rapid Test	Yes		**DE**: 97.5% sensitivity, 100% specificity		DE[2]		DE[2]		No	No
Core Technology Co., ltd	Coretests COVID-19 Ag Test	Yes	98.1% sensitivity	**DE**: 98.1% sensitivity, 99.6% specificity		AT, DE[2], RO		DE[2]		Yes (1919)	No

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[12]	In FIND database
DDS DIAGNOSTIC	Test Rapid Covid-19 Antigen (tampon nazofaringian)	Yes	98.77% sensitivity 99.03% specificity	**RO:** Meets the minimum performance requirements.		RO		RO China	RO	Yes (1225)	No
DIALAB GmbH	DIAQUICK COVID -19 Ag Cassette	Yes		**BE**: Z20401CE: 93.2% sensitivity, 100% specificity, NP swab Z20601CE: 96.4% sensitivity, 99.2% specificity, NP swab **DE**: 97.3% sensitivity, 100% specificity		AT, BE, DE[2]		DE[2]		Yes (1375)	Yes
GenBody Inc	GenBody COVID-19 Ag Test	Yes	90% sensitivity 98% specificity NP/OP swab	**DE**: 90% sensitivity 98% specificity	Withdrawn	DE[2]	UA	DE[2]		Yes (1244)	Yes
GenSure Biotech Inc	Gensure COVID-19 Antigen Rapid Test Kit (REF: P2004) (DIA-COVID -19 Ag Rapid Test)	Yes		**DE**: 96.86% sensitivity, 100% specificity		DE[2]		DE[2]		Yes (1253)	Yes
Getein Biotech, Inc.	One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)	Yes	97.06% sensitivity 98.71% specificity Nasal swab	**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 90% at <Ct30 and 100% at <Ct25)		DE[2]		DE[2]		Yes (2183)	No
Green Cross Medical Science Corp.	GENEDIA W COVID-19 Ag	Yes		**BE**: 90.2% sensitivity, 100% specificity, NP swab **DE**: 90.1% sensitivity, 100% specificity		AT, BE, DE[2]		DE[2]		Yes (1144)	Yes
Guangdong Hecin Scientific, Inc.	2019-nCoV Antigen Test Kit (colloidal gold method)	Yes	96.23% sensitivity 98.51% specificity Nasal swab	**DE**: 96.6% sensitivity, 99.07% specificity		AT, DE[2]		DE[2]		Yes (1747)	No
Guangdong Wesail Biotech Co. Ltd	COVID-19 AG Test Kit	Yes	90% sensitivity 98% specificity NP/Nasal swab	**DE**: 90% sensitivity, 99.2% specificity **SI**: 90% sensitivity, 98% specificity, NP/Nasal swab		DE[2], SI		DE[2]		Yes (1360)	No
Guangzhou Wondfo Biotech Co., Ltd	Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)	Yes		**BE**: 96.2% sensitivity, 99.7% specificity, NP/OP swab **DE**: 96.18 % sensitivity, 99.72% specificity		AT, BE, BG, DE[2], FR	CH	DE[2]		Yes (1437)	Yes

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[12]	In FIND database
Hangzhou AllTest Biotech Co., Ltd	COVID-19 Antigen Rapid Test	Yes		**DE:** 93,40% sensitivity, 99,90% specificity		AT, BE, BG, FR, SI, RO	CH	DE	AT	Yes (1257)	Yes
Hangzhou Clongene Biotech Co., Ltd.	COVID-19 Antigen Rapid Test Kit	Yes	98.5% sensitivity unknown specificity Nasal swab	**BE**: 91.4% sensitivity, 100% specificity, NP/OP swab **DE**: 91.4% sensitivity, 99.4% specificity **SI**: 91.4% sensitivity, 100% specificity, NP/OP swab		AT,BE, DE[2], FR, SI	CH	DE[2] CH	HR	Yes (1363)	No
Hangzhou Clongene Biotech Co., Ltd.	COVID-19/Influenza A+B Antigen Combo Rapid Test	Yes	91% sensitivity 100% specificity NP swab	**DE**: 97.7% sensitivity, 99.8% specificity		DE[2]		DE[2]		Yes (1365)	Yes
Hangzhou Immuno BiotechCo., Ltd	Immunobio SARS-CoV-2 Antigen ANTERIOR NASAL Rapid Test Kit (minimal invasive)	Yes	94% sensitivity 100% specificity Nasal swab, NP	**DE**: 94.39% sensitivity 97.67% specificity		DE[2]		DE[2]		Yes (1844)	
Hangzhou Immuno BiotechCo., Ltd	SARS-CoV2 Antigen Rapid Test	Yes		**DE**: 95.6% sensitivity, 100% specificity		AT, DE[2]		DE[2]		No	No
Hangzhou Laihe Biotech Co.	LYHER Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)	Yes		**DE**: 96.29% sensitivity, 100% specificity		AT	CH	DE[2]		Yes (1215)	No
Hangzhou Lysun Biotechnology Co., Ltd.	COVID-19 antigen Rapid Test Device (Colloidal Gold)	Yes		**DE**: 96.29% sensitivity, 100% specificity		DE[2]	CH	DE[2]		Yes (2139)	No
Hangzhou Testsea Biotechnology Co., Ltd.	Testsealabs Covid-19 Antigen Rapid Test Cassette	Yes	92.1% sensitivity 98.1% specificity Nasal swab	**DE**: 97.6% sensitivity 98.4% specificity		DE[2]		DE[2]		Yes (1392)	No
Healgen Scientific Limited	Coronavirus Ag Rapid Test Cassette (Swab)	Yes		**DE**: 97.25% sensitivity, 100% specificity **SI**: 96.7% sensitivity, 99.2% specificity, NP/Nasal swab		AT, DE[2], NL[5], SE, SI	CH	DE[2], NL[5]	SE[3]	Yes (1767)	No

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[12]	In FIND database
Humasis Co. Ltd	HUMASIS COVID-19 Ag test	Yes		**BE**: 95.5% sensitivity, 100% specificity, NP swab **DE**: 95.5% sensitivity, 100% specificity **SI**: 95.5% sensitivity, 100% specificity, NP swab		AT, BE, BG, DE[2], FR, HR, SE, SI		DE[2]	HR, SE	Yes (1263)	Yes
Joinstar Biomedical Technology Co. Ltd	COVID-19 Antigen Rapid Test (Colloidal Gold)	Yes	96.1% sensitivity 98.1% specificity Nasal swab	**DE**: 96.1% sensitivity, 98.1% specificity **SI**: 96.1% sensitivity, 98.1% specificity, NP swab		AT, DE[2], PT, SI		DE[2]		Yes (1333)	Yes
JOYSBIO (Tianjin) Biotechnology Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold immunochromatography)	Yes	98.13% sensitivity 99.2% specificity	**CZ:** Meets the minimum performance requirements – see the report for details.	FIND evaluation studies in CH 11 Feb 2021	CZ, SI		CZ CH		Yes (1764)	Yes
Labnovation Technologies Inc.	SARS-CoV-2 Antigen Rapid Test Kit	Yes		**DE**: 96.3% sensitivity, 97.3% specificity **SI**: 96.3% sensitivity, 97.3% specificity, NP/OP swab		DE[2], SI		DE[2]		Yes (1266)	Yes
Lumigenex (Suzhou) Co., Ltd	PocRoc® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	Yes		**DE**: 93.33% sensitivity , 99.16% specificity		DE[2]		DE[2]		Yes (2128)	No
LumiQuick Diagnostics Inc.	QuickProfile™ COVID-19 ANTIGEN Test	Yes		**BE**: 94% sensitivity, 99% specificity, NP swab **DE**: 93.7% sensitivity, 98.8% specificity **SI**: 93.7% sensitivity, 98.8% specificity, NP swab		BE, DE[2] ,FR, SI,		DE[2]		Yes (1267)	Yes
LumiraDX	LumiraDx SARS-CoV-2 Ag Test	Yes	97.6% sensitivity 96.7% specificity Nasal swab	**DE**: 93.8% sensitivity, 98.8% specificity **SI**: 97.6% sensitivity, 97.7% specificity, NP/Nasal swab **SKUP/2021/124**: 90% sensitivity, 97,8% specificity, NP swab		DE[2], ES, SI	CH	DE[2], ES, SKUP – (Scandinavian evaluation of laboratory equipment for point of care testing) CH		Yes (1268)	No

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[12]	In FIND database
MEDsan GmbH	MEDsan® SARS-CoV-2 Antigen Rapid Test	Yes	92.5% sensitivity 99.8% specificity NP/OP swab	**BE**: 92.5% sensitivity, 99.8% specificity, Nasal/OP swab **DE**: 92.5% sensitivity, 99.8% specificity		AT, BE, DE[2]	CH	DE[2] CH		Yes (1180)	No
Merlin Biomedical (Xiamen) Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Cassette	Yes		**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 90% at <Ct30 and 100% at <Ct25)		DE[2]		DE[2]		Yes (2029)	No
möLab	COVID-19 Rapid Antigen Test	Yes		**DE**: 97.25% sensitivity , 99.99% specificity		DE[2], IE		DE[2], IE		Yes (1190)	No
MP Biomedicals	Rapid SARS-CoV-2 Antigen Test Card	Yes	96.39% sensitivity 99.03% specificity Nasal swab	**BE**: 96.4% sensitivity, 99% specificity, NP/OP swab **DE:** 96.39 % sensitivity, 99.03% specificity		AT, BE, DE[2]	CH	DE[2] CH		Yes (1481)	Yes
nal von minden GmbH	NADAL COVID -19 Ag +Influenza A/B Test	Yes		**DE**: 97.6% sensitivity, 99.9% specificity		DE[2]		DE[2]		Yes (2104)	No
nal von minden GmbH	NADAL COVID -19 Ag Test	Yes	97.6% sensitivity 99.9% specificity Nasal swab	**BE**: 97.6% sensitivity, 99.9% specificity, NP/OP swab **DE**:97.6% sensitivity, 99.9% specificity **SI**: 97.6% sensitivity, 99.9% specificity, NP/OP swab	FIND Evaluation studies 26 April 21	AT, BE, DE[2], PT, SI		DE[2], FR China	HR	Yes (1162)	No
NanoEntek	FREND Covid-19 Ag	Yes	94.12% sensitivity 100% specificity NP swab	**DE**: 94.12% sensitivity , 100% specificity		DE[2]		DE[2]		Yes (1420)	Yes
New Gene (Hangzhou) Bioengineering Co., Ltd.	COVID-19 Antigen Detection Kit	Yes	98% sensitivity Nasal swab	**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 92,5% at <Ct30 and 100% at <Ct25)		DE[2]		DE[2]		Yes (1501)	No
Oncosem Onkolojik Sistemler San. ve Tic. A.S.	CAT	Yes	93.75% sensitivity 98.04% specificity Nasal swab	**DE**: 96.36% sensitivity, 98.04% specificity		DE[2]		DE[2]		Yes (1199)	No
PCL Inc	PCL COVID19 Ag Rapid FIA	Yes		**DE**: 94,92 % sensitivity, 99,99 % specificity **SI**: 95.5% sensitivity, 98.6% specificity, NP/OP swab, sputum		FR, DE, RO, SI		DE[2]		Yes (308)	No

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[12]	In FIND database
PerGrande Biotech Development Co., Ltd.	SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromato-graphic assay)	Yes		**DE**: 94.28% sensitivity, 99.11% specificity		AT, DE[2]		DE[2]		Yes (2116)	No
Precision Biosensor Inc.	Exdia COVI-19 Ag Test	Yes	93.9% sensitivity 98% specificity NP swab	**DE**: 93.88% sensitivity , 98% specificity **SI**:93.9% sensitivity, 98% specificity, NP swab		SI, DE[2]	CH	DE[2] CH		Yes (1271)	Yes
Qingdao Hightop Biotech Co. Ltd	SARS-CoV-2 Antigen Rapid Test	Yes	95% sensitivity unknown specificity Nasal swab	**DE**: 95% sensitivity 99.75% specificity		AT, DE[2]		DE[2]		Yes (1341)	No
Quidel Corporation	Sofia 2 SARS Antigen FIA	Yes	96.7% sensitivity 100% specificity NP/Nasal swab	**BE**: 96.7% sensitivity, 100% specificity, NP/nasal swab **DE**: 96.7% sensitivity , 100% specificity **SI**: 96.7% sensitivity, 100% specificity, NP/Nasal swab		AT, BE, DE[2], FI, NL[5], PT, SI	CH	DE[2], NL[5] CH	SI	Yes (1097)	Yes
Rapigen Inc.	BIOCREDIT COVID-19 Ag - SARS-CoV 2 Antigen test	Yes	90.2% sensitivity 100% specificity NP swab	**SI**: 90.2% sensitivity, 100% specificity, NP swab		AT, RO, SK, FR, SI		HU	PT	Yes (1606)	Yes
Roche (SD BIOSENSOR)	SARS-CoV-2 Antigen Rapid Test	Yes	96.52% sensitivity 99.2% specificity NP	**DE**: 96.52% sensitivity, 99.68% specificity		AT, DE[2], MT, NL, RO	CH, NO	DE[2]		Yes (1604)	Yes
Safecare Biotech Hangzhou Co	COVID-19 Antigen Rapid Test Kit (Swab)	Yes	97.04% sensitivity unknown specificity Nasal swab	**DE**: 97.27 % sensitivity , 99.42% specificity		AT, DE[2], FR	CH	DE[2]		Yes (1489)	No
Safecare Biotech Hangzhou Co	Multi-Respiratory Virus Antigen Test Kit (Swab) (Influenza A+B/COVID-19)	Yes	97.04% sensitivity	**DE**: 97.04% sensitivity , 99.44% specificity		DE[2]		DE[2]		Yes (1490)	No
ScheBo Biotech AG	ScheBo SARS CoV-2 Quick Antigen	Yes	96.6% sensitivity (Ct 30)	**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 95% at <Ct30 and 100% at <Ct25)		DE[2]		DE[2]		Yes (1201)	No

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[12]	In FIND database
SD BIOSENSOR Inc.	STANDARD F COVID-19 Ag FIA	Yes	94,09% sensitivity 98.52% specificity	**BE**: 96.5% sensitivity, 99.7% specificity, NP swab **DE**: 94% sensitivity 97% specificity	FIND Evaluation - Studies in DE and Brazil, 10 Dec 2020	AT, BE, BG, DE[2], IT , LU, LV, NL[5], PT, RO, SK	CH	DE[2], IT, NL[5], DK CH, UK, BR	LU, PT	Yes (344)	Yes
SD BIOSENSOR Inc.	STANDARD Q COVID-19 Ag Test	Yes	96.52% sensitivity 99.68% specificity NP swab	**BE**: 96.5% sensitivity, 99.7% specificity, NP swab **DE**: 96.52% sensitivity, 99.68% specificity **SI**: 96.5% sensitivity, 99.7% specificity, NP swab	FIND Evaluation - Studies in DE, CH and Brazil, 10 Dec 2020	AT, BE, BG, CY, DE[2], DK, EE, ES, FI, FR, HR, IT, LU, LV, MT, NL[5], RO, SE, SK, SI	ME, NO, CH	DE[2], ES, IT, NL[5], DK CH, UA, UK, BR, NO	HR, IE, LU, SI, SE	Yes (345)	Yes
SGA Medikal	V-Chek SARS-CoV2- Rapid Ag Tets (Coloidal Gold)	Yes	96.6% sensitivity, Nasal swab	**DE**: 96.6% sensitivity, 99% specificity		DE[2]		DE[2]		Yes (1319)	No
Shenzen Ultra-Diagnostics Biotec Co.	SARS-CoV-2 Antigen test Kit (colloidal gold)	Yes		**BE**: 92% sensitivity, 100% specificity, NP swab 100% sensitivity, 100% specificity, OP swab 96% sensitivity, 100% specificity, Saliva **SI**: 95.9% sensitivity, 99.9% specificity, NP/OP/Nasal swab, saliva		AT, BE, ES, SI		BE, SI		No	No
Shenzhen Lvshiyuan Biotechnology Co., Ltd.	Green Spring SARS-CoV-2 Antigen-Rapid test-Set	Yes		**DE**: 98% sensitivity , 100% specificity		DE[2]		DE[2]		Yes (2109)	Yes
Shenzhen Watmind Medical Co., Ltd	SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold)	Yes	95.15% Sensitivity Nasal swab, Salvia	**DE**: 95.15% sensitivity , 99.12% specificity		AT, DE[2], FR		DE[2]		Yes (1769)	No
Shenzhen Zhenrui Biotech Co., Ltd	Zhenrui ®COVID-19 Antigen Test Cassette	Yes	96% sensitivity Nasal swab, Salvia	**DE**: 96% sensitivity 97% specificity		DE[2]		DE[2]		Yes (1574)	No
Siemens Healthineers	CLINITEST Rapid COVID-19 Antigen Test	Yes	96.72% sensitivity 96.72% specificity Nasal swab	**BE**: 98.32% sensitivity, 99.6% specificity, NP swab 97.25% sensitivity, 100% specificity, Nasal swab **SI**: 96.7% sensitivity, 99.2% specificity, NP/Nasal swab		AT, BE, DE[2], FR, HR, NL[5], PT, SE, SI	CH	DE[2], ES, NL[5]	HR, PT, SE[3]	Yes (1218)	Yes

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[12]	In FIND database
Sugentech, Inc.	SGTi-flex COVID-19 Ag	Yes		**DE**: 95.1% sensitivity, 99% specificity		AT, DE[2]		DE[2]		Yes (1114)	No
TODA PHARMA	TODA CORONADIAG Ag®	Yes	98.6% sensitivity unknown specificity Nasal swab	**BE**: 96.6% sensitivity, 100% specificity, NP/OP swab **DE**: 96.6% sensitivity, 100 specificity **SI**: 96.6% sensitivity, 100% specificity, NP/OP swab		BE, DE[2], SI		DE[2]		Yes (1466)	No
Tody Laboratories Int.	Coronavirus (SARS-CoV 2) Antigen - Oral Fluid	Yes	90.1% sensitivity 99.3% specificity	**RO**: Meets the minimum performance requirements.		RO		ES UA, China	RO	Yes (1934)	Yes
Triplex International Biosciences Co., Ltd	SARS-CoV-2 Antigen Rapid Test Kit	Yes	98.33% sensitivity 100% specificity Nasal/OP/NP swab	**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 92,5% at <Ct30 and 100% at <Ct25)		DE[2]		DE[2]		Yes (2074)	No
Vitrosens Biotechnology Co. Ltd	RapidFor SARS-CoV-2 Ag Test Kit	Yes	97.3% sensitivity unknown specificity Nasal swab, saliva	**DE**: 97.3% sensitivity, 99% specificity **SI**: 97.3% sensitivity, 99% specificity, NP/OP/Nasal swab		DE[2], SI		DE[2]		Yes (1443)	Yes
VivaChek Biotech (Hangzhou) Co., Ltd.	Vivadiag Pro SARS-CoV-2 Ag Rapid Test	Yes		**AT**: 97,06% sensitivity, 100% specificity, all specimen types, i.e. N&OP&NP swab		AT		AT	AT	Yes (2103)	Yes
Wuhan EasyDiagnosis Biomedicine Co., Ltd.	COVID-19 (SARS-CoV-2) Antigen-Test kit	Yes		**DE**: 96.15% sensitivity , 99.26% specificity		DE[2]		DE[2]		Yes (2098)	Yes
Xiamen AmonMed Biotechnology Co., Ltd.	COVID-19 Antigen Rapid Test Kit (Colloidal Gold)	Yes	95.05% sensitivity Nasal swab	**DE**: 98.02% sensitivity , 99.6% specificity		DE[2]		DE[2]		Yes (1763)	Yes
Xiamen Boson Biotech Co	Rapid SARS-CoV-2 Antigen Test card	Yes	Not specified	**BE**: 93.8% sensitivity, 100% specificity, NP swab **DE**: 96.49% sensitivity, 99.03% specificity		AT, BE, BG, CY, DE[2], FR, RO	CH	DE[2] CH		Yes (1278)	Yes
Xiamen Wiz Biotech Co., Ltd.	SARS-CoV-2 Antigen Rapid Test	Yes		**DE**: 96.3% sensitivity, 100% specificity		AT, DE[2]		DE[2]		Yes (1456)	Yes

Manufacturer	RAT commercial name	CE marking	Clinical performance *Data by manufacturer*	Clinical performance *Data used in MS*	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)[12]	In FIND database
Xiamen Wiz Biotech Co., Ltd.	SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)	Yes		**DE**: 95.91% sensitivity , 100% specificity		AT, DE[2]		DE[2]		Yes (1884)	No
Zhejiang Anji Saianfu Biotech Co.., Ltd.	AndLucky COVID-19 Antigen Rapid Test	Yes	95.8% sensitivity, Nasal swab, Saliva	**DE**: 97.5% sensitivity, 99.1% specificity		AT, DE[2]		DE[2]		Yes (1296)	No
Zhejiang Anji Saianfu Biotech Co.., Ltd.	reOpenTest COVID-19 Antigen Rapid Test	Yes	95.8% sensitivity, Nasal swab, Saliva, Plasma	**DE**: 95.8% sensitivity, 99% specificity		DE[2]		DE[2]		Yes (1295)	No
Zhejiang Orient Gene Biotech Co., Ltd	Coronavirus Ag Rapid Test Cassette (Swab)	Yes	96.72% sensitivity unknown specificity Nasal swab	**BE**: 98.32% sensitivity, 99.6% specificity, NP swab 97.25% sensitivity, 100% specificity, Nasal swab **DE**: 96.72% sensitivity, 99.22% specificity		AT, BE, BG, DE[2], PT	CH, UK	DE[2]	SE[3]	Yes (1343)	No

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

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, saliva).	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).	