EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health, country knowledge, crisis management
Health Security and Vaccination

EU health preparedness:

A common list of COVID-19 rapid antigen tests, including those whose 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

on 17 February 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, new tests are rapidly entering the market, allowing faster and cheaper ways to detect ongoing infection. 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. 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:

(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.

This list should be shared with ECDC and the Commission to prevent duplication of work and to feed into ongoing initiatives, particularly in the context of the redevelopment of the "COVID-19 In Vitro Diagnostic Devices and Test Methods" database[6], hosted by the Joint Research Centre (JRC). As referred to in the Commission Communication of 19 January[7], the JRC will play a role in establishing a common list of rapid antigen tests and their uses, as agreed by Member States and with support from the Health Security Committee.

Annex I to this document sets out a common list of rapid antigen tests that, as of 17 February 2021 meet the criteria as specified above. This list will serve as a basis for the JRC to redevelop and update its COVID-19 testing database, with the aim of incorporating the

[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
[7] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021DC0035&from=EN

information in this platform and ensuring that the common list as agreed by Member States will be publicly available online.

The common list of rapid antigen tests will be regularly reviewed by Member States in the context of Health Security Committee meetings, and, if necessary, be updated in line with new results from independent validation studies becoming available and new tests entering the markets. Future updates to the list should also take 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.

Future updates to the common list of rapid antigen tests will be published as an update to the JRC database on COVID-19 In Vitro Diagnostic Devices and Test Methods.

III. Rapid antigen tests of which the test results are mutually recognised

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, Member States agree that the results of the following rapid antigen tests will be mutually recognised for public health measures:

- Abbott Rapid Diagnostics, Panbio™ COVID-19 Ag Rapid Test
- AMEDA Labordiagnostik GmbH, AMP Rapid Test SARS-CoV-2 Ag
- Becton Dickinson, BD Veritor System for Rapid Deteciton os SARS-CoV-2
- Beijing Lepu Medical Technology, SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold immunochromatography)
- BIOSYNEX SWISS SA, BIOSYNEX COVID-19 Ag BSS
- CerTest Biotect S.L., CerTest SARS-CoV-2 CARD TEST
- Hangzhou Clongene Biotech, Clungene COVID-19 Antigen Rapid Test Kit
- Healgen Scientific Limited, Coronavirus Ag Rapid Test Cassette (Swab)
- LumiraDX UK LTd, LumiraDx SARS-CoV-2 Ag Test
- nal von minden GmbH, NADAL COVID -19 Ag Test
- Quidel Corporation, Sofia 2 SARS Antigen FIA
- SD BIOSENSOR, Inc., STANDARD F COVID-19 Ag FIA
- SD BIOSENSOR, Inc., STANDARD Q COVID-19 Ag Test
- Siemens Healthineers, CLINITEST Rapid COVID-19 Antigen Test
- Xiamen Boson Biotech Co, Rapid SARS-CoV-2 Antigen Test card
- Zhejiang Orient Gene Biotech Co.,Ltd, Coronavirus Ag Rapid Test Cassette (Swab)

The JRC will specify in its updated database the specific rapid antigen tests of which Member States mutually recognise their test results.

Whenever Member States will review the common list of rapid antigen tests and consider whether any tests should be added or deleted, they will also take into account – also based on new results from independent national validation studies - whether any rapid antigen tests should be removed from or added to the selection of rapid antigen tests of which their results are being mutually recognised. This information will be provided to the JRC, who will update its database accordingly.

Future updates to the agreed list of rapid antigen tests of which the results are mutually recognised, will be published as an update to the JRC database on COVID-19 In Vitro Diagnostic Devices and Test Methods.

IV. 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.

The dataset was agreed by taking into consideration the guidelines that were published by the eHealth Network on proof of vaccination for medical purposes, setting out basic interoperability elements[8]. While these guidelines aim to support interoperability between vaccination certificates rather than COVID-19 test results, they provided helpful input regarding minimum data that would enable basic information to be captured and represented in a structured manner that facilitates sharing and interpretation. Moreover, should Member States wish to standardise COVID-19 test results and COVID-19 vaccination, streamlining of datasets facilitates such processes.

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.

[8] https://ec.europa.eu/health/sites/health/files/ehealth/docs/vaccination-proof_interoperability-guidelines_en.pdf

V. Continuous discussions and further work on the common rapid antigen tests list and common dataset for COVID-19 test result certificates

As described in the sections above, the content of this document, as agreed by the Health Security Committee on 17 February 2021, will continue to be discussed by Member States and updated whenever deemed relevant.

Whenever updates are required, these will either be published as an update to this current document or as an update to the JRC database on COVID-19 In Vitro Diagnostic Devices and Test Method, depending on scope of the required update and when the redeveloped database by JRC will be available.

In the context of the ongoing discussions and, if relevant, future updates to the current document, Member States have raised the following points that require particular attention:

Common RAT list

- **Harmonised methodology for national validation studies on the clinical performance of rapid antigen tests**

This will be addressed by future guidelines to be developed by the JRC and the ECDC, also taking into consideration the implementation guide published by WHO on 21 December 2020 on SARS-CoV-2 antigen-detecting rapid diagnostic tests[9].

Moreover, Member States will continue sharing details via the HSC on the implementation of national validation studies, particularly concerning the validation methodologies and protocols applied.

- **Quality of data produced through independent validation studies**

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. In this context, the JRC is planning to verify the science behind the validation data that has been made available from the Member States through the Health Security Committee, and to verify the findings (eventually in laboratory settings). For the validation of rapid antigen tests, the JRC plans to use the "gold standard" method of NAAT, in particular RT-PCR, by benchmarking the antigen test samples against qPCR and digital PCR.

Moreover, Member States will continue sharing details via the HSC on the results produced by national validation studies, particularly concerning 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.

[9] https://www.who.int/publications/i/item/9789240017740

- **Occurrence of SARS-CoV-2 variants of concern**

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, allowing for the removal of tests no longer deemed effective. The effect of mutations of the SARSCoV-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).

Mutual recognition of COVID-19 test results

- **Criteria to be used for the mutual recognition of rapid antigen test results**

At the moment, the extent to which rapid antigen tests are being used in practice by Member States differs greatly. In this context, Member States have agreed that, for now, the criterion that at least 3 Member States should be using a specific type of rapid antigen test in practice for it to be mutually recognised, applies. Member States will further discuss and explore whether other criteria should be used in the future. It is key that such discussions are held in the context of quality assurance measures.

- **Context in which mutual recognition should be applied**

Member States should further discuss the situation in which there is a need for mutual recognition of rapid antigen test results (as well as other COVID-19 test results). In addition to the context of travel, it is relevant to further discuss between countries when the list of rapid antigen tests of which their results will be mutually recognised should be applied.

COVID-19 test result certificates

- **Possible creation of a digital platform**

As also called for by the Council Recommendation of 21 January, Member States will explore the need and possibility, including time and cost considerations, for the creation of a digital platform, that can be used to validate the authenticity of standardised COVID-19 test certificates. Member States that are developing or that have already such digital systems in place will share their experiences in this regards. In the context of these discussions, the eHealth Network and in particular their semantic experts in Member States, will be closely involved.

ANNEX I: Common list of rapid antigen tests, as agreed by Member States on 17 February 2021

Manufacturer	RAT commercial name	CE marking	Clinical performance (JRC database)	Clinical performance (FIND database)	Clinical performance (Data used in BE)	Clinical performance (Data used in DE)	Clinical performance (Data used in SI)	MS using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS that are currently validating this RAT	In JRC database	In FIND database
Abbott Rapid Diagnostics	Panbio™ COVID-19 Ag Rapid Test	Yes	91.4% sensitivity, 99.8% specificity NP swab	FIND Evaluation - Studies in DE and CH, NP swab, 10 Dec 2020	93.3% sensitivity 99.4% specificity NP Swab 98.1% sensitivity 99.8% specificity Nasal swab	91.4% sensitivity 99.8% specificity		AT, BE, BG, CY, CZ, DE[2], EL, ES, FR[1], HR, IT, MT, NL[5], PL, PT, RO, SE, SK	CH, ME, MK, NO, UK, UA	DE, ES, NL[5], CH, NO	CY, ES, HR, HU, IE, LU, PT, SE	Yes	Yes
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		97.3% sensitivity 100% specificity NP swab		97.3% sensitivity 100% specificity NP swab	BE, BG, DE[2] HR, SI,	CH, UA	DE	HR	Yes	Yes
Becton Dickinson	BD Veritor System for Rapid Deteciton os SARS-CoV-2	Yes	93.5% sensitivity 99.3% specificity Nasal swab					DE[2], ES, NL[5], SE	CH, UA	DE, ES, NL[5]	SE[3]	Yes	Yes
Beijing Lepu Medical Technology	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold immunochromatography)	Yes	92% sensitivity unknown specificity Nasal swab		92% sensitivity 99.3% specificity Nasal swab		92% sensitivity 99.2% specificity NP swab	BE, DE[2], SI	UA	DE		Yes	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[2]		DE		Yes	Yes
BIONOTE	NowCheck® COVID-19 Ag Test	Yes	89.2% sensitivity 97.6% specificity NP/Nasal swab	FIND Evaluation - Study in Brazil, NP swab, 10 Dec 2020				DE[2]	CH	DE		Yes	Yes

Manufacturer	RAT commercial name	CE marking	Clinical performance (JRC database)	Clinical performance (FIND database)	Clinical performance (Data used in BE)	Clinical performance (Data used in DE)	Clinical performance (Data used in SI)	MS using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS that are currently validating this RAT	In JRC database	In FIND database
BIOSYNEX SWISS SA	BIOSYNEX COVID-19 Ag BSS	Yes	Not specified		96% sensitivity 100% specificity NP swab			BE, DE[2], FR, NL[5]	CH	DE, NL[5]		Yes	Yes
CerTest Biotect S.L.	CerTest SARS-CoV-2 CARD TEST	Yes	92.9% sensitivity 99.6% specificity NP swab		92.9% sensitivity 99.6% specificity NP swab		92.9% sensitivity 98.4% specificity NP/OP swab	DE[2], ES, SI		ES		Yes	No
GenBody Inc	GenBody COVID-19 Ag Test	Yes	90% sensitivity 98% specificity NP/OP swab	Withdrawn				DE[2]	UA	DE		Yes	Yes
Guangdong Wesail Biotech Co. Ltd	COVID-19 AG Test Kit	Yes	90% sensitivity 98% specificity NP/Nasal swab				90% sensitivity 98% specificity NP/Nasal swab	DE[2], SI		DE		Yes	No
Hangzhou Clongene Biotech	Clungene COVID-19 Antigen Rapid Test Kit	Yes	98.5% sensitivity unknown specificity Nasal swab		91.4% sensitivity 100% specificity NP/OP swab		91.4% sensitivity 100% specificity NP/OP swab	BE, DE[2], FR, SI	CH	DE	HR	Yes	No
Healgen Scientific Limited	Coronavirus Ag Rapid Test Cassette (Swab)	Yes					96.7% sensitivity 99.2% specificity NP/Nasal swab	DE[2], NL[5], SE, SI		NL[5]	SE[3]	No	No
Joinstar Biomedical Technology	COVID-19 Antigen Rapid Test (Colloidal Gold)	Yes	96.1% sensitivity 98.1% specificity Nasal swab				96.1% sensitivity 98.1% specificity NP swab	DE[2], SI		DE		Yes	Yes
LumiraDX UK LTd	LumiraDx SARS-CoV-2 Ag Test	Yes	97.6% sensitivity 96.7% specificity Nasal swab				97.6% sensitivity 97.7% specificity NP/Nasal swab	DE[2], ES, SI	CH	DE, ES		Yes	No
MEDsan GmbH	MEDsan® SARS-CoV-2 Antigen Rapid Test	Yes	92.5% sensitivity 99.8% specificity NP/OP swab		92.5% sensitivity 99.8% specificity Nasal/OP swab			BE, DE[2]	CH	DE		Yes	No

Manufacturer	RAT commercial name	CE marking	Clinical performance (JRC database)	Clinical performance (FIND database)	Clinical performance (Data used in BE)	Clinical performance (Data used in DE)	Clinical performance (Data used in SI)	MS using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS that are currently validating this RAT	In JRC database	In FIND database
MP Biomedicals Germany	Rapid SARS-CoV-2 Antigen Test Card	Yes	96.39% sensitivity 99.03% specificity Nasal swab		96.4% sensitivity 99% specificity NP/OP swab			BE, DE[2]	CH	DE		Yes	No
nal von minden GmbH	NADAL COVID -19 Ag Test	Yes	97.6% sensitivity 99.9% specificity Nasal swab		97.6% sensitivity 99.9% specificity NP/OP swab		97.6% sensitivity 99.9% specificity NP/OP swab	AT, BE, DE[2], SI		DE	HR	Yes	No
Precision Biosensor Inc (Axon Lab SG)	Exdia COVI-19 Ag Test	Yes	93.9% sensitivity 98% specificity NP swab				93.9% sensitivity 98% specificity NP swab	SI	CH	DE		Yes	Yes
Qingdao Hightop Biotech Co Ltd	SARS-CoV-2 Antigen Rapid Test	Yes	95% sensitivity unknown specificity Nasal swab					DE[2]		DE		Yes	No
Quidel Corporation	Sofia 2 SARS Antigen FIA	Yes	96.7% sensitivity 100% specificity NP/Nasal swab		96.7% sensitivity 100% specificity NP/nasal swab		96.7% sensitivity 100% specificity NP/Nasal swab	AT, BE, DE[2], FI, NL[5], SI	CH	DE, NL[5]	SI	Yes	Yes
Safecare Biotech Hangzhou Co	COVID-19 Ag Rapid Test Kit (Swab)	Yes	97.04% sensitivity unknown specificity Nasal swab					DE[2], FR	CH	DE		Yes	No
SD BIOSENSOR, Inc.	STANDARD F COVID-19 Ag FIA	Yes		FIND Evaluation - Studies in DE and Brazil, 10 Dec 2020	96.5% sensitivity 99.7% specificity NP swab			BE, BG, DE[2], IT , LU, LV, NL[5], PT, RO, SK		DE, IT, NL[5]	LU, PT	No	Yes
SD BIOSENSOR, Inc.	STANDARD Q COVID-19 Ag Test	Yes	96.52% sensitivity 99.68% specificity NP swab	FIND Evaluation - Studies in DE, CH and Brazil, 10 Dec 2020	96.5% sensitivity 99.7% specificity NP swab		96.5% sensitivity 99.7% specificity NP swab	AT, BE, BG, CY, DE[2], ES, FI, FR, HR, IT, LU, LV, MT, NL[5], RO, SE, SK, SI	ME, NO, CH	DE, ES, IT, NL[5], CH, UA	HR, IE, LU, SI, SE	Yes	Yes

Manufacturer	RAT commercial name	CE marking	Clinical performance (JRC database)	Clinical performance (FIND database)	Clinical performance (Data used in BE)	Clinical performance (Data used in DE)	Clinical performance (Data used in SI)	MS using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS that are currently validating this RAT	In JRC database	In FIND database
Siemens Healthineers	CLINITEST Rapid COVID-19 Antigen Test	Yes	96.72% sensitivity 96.72% specificity Nasal swab		98.32% sensitivity 99.6% specificity NP swab 97.25% sensitivity 100% specificity Nasal swab		96.7% sensitivity 99.2% specificity NP/Nasal swab	AT, BE, DE[2], FR, HR, NL[5], SE, SI		DE, NL[5]	ES, HR, PT, SE[3]	Yes	Yes
Xiamen Boson Biotech Co	Rapid SARS-CoV-2 Antigen Test card	Yes	Not specified		93.8% sensitivity 100% specificity NP swab			BE, BG, DE[2], FR	CH	DE		Yes	Yes
Zhejiang Orient Gene Biotech Co.,Ltd	Coronavirus Ag Rapid Test Cassette (Swab)	Yes	96.72% sensitivity unknown specificity Nasal swab		98.32% sensitivity 99.6% specificity NP swab 97.25% sensitivity 100% specificity Nasal swab			AT, BE, BG, DE[2]	UK	DE	SE[3]	Yes	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 fulfils the defined minimum criteria for reimbursement in Germany. See: https://antigentest.bfarm.de/ords/antigen/r/antigentests-auf-sars-cov-2/liste-der-antigentests?session=13130597074531

[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

Section	Data element	Description	Preferred Code System
Person identification	Person name	The legal name of the tested person	
	Person identifier (optional)	An identifier of the tested person, according to the policies applicable in each country. It should be captured what type of identifier is used. Examples: citizen ID card or identifier within the health system/IIS/e-registry.	
	Person date of birth	Tested person's date of birth. Mandatory if no Person identifier is provided.	Complete date, without time, following the ISO 8601.
Test information	Type of test	Description of the type of test that was conducted, e.g. RT-PCR or rapid antigen test. In the case of a rapid antigen tests, the form should provide details on the manufacturer and commercial name of the test used.	
	Disease or agent targeted	Specification that it concerns the detection of SARS-CoV-2 infection	
	Sample origin (optional)	The type of sample that was taken (e.g. nasopharyngeal swab, oropharyngeal swab, nasal swab, saliva)	
	Date and time	Date and time when the test was taken. In case of NAAT, e.g. RT-PCR, the certificate should also specify when the test result was produced.	Complete date, without time, following ISO 8601
	Result of the test	Negative or positive	
	Testing centre or facility	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	
	Country where the test was taken	The country in which the individual was tested	ISO 3166 Country Codes
Test certificate metadata	Test result issuer	Entity that issued the COVID-19 test result certificate (allowing to check the certificate)	
	Certificate identifier (optional)	Reference of the COVID-19 test result certificate (unique identifier)	