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**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND
THE COUNCIL**

**pursuant to Article 16(1) of Regulation (EU) 2021/953 of the European Parliament and
of the Council 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**

1. INTRODUCTION

On 14 June 2021, the European Parliament and the Council adopted Regulation (EU) 2021/953 establishing the EU Digital COVID Certificate (the “EU Digital COVID Certificate Regulation”)¹. The Regulation sets out a common framework for the issuance, verification and acceptance of interoperable certificates for COVID-19 vaccination, test or recovery certificates to facilitate free movement of EU citizens and their family members during the COVID-19 pandemic. The Regulation is accompanied by Regulation (EU) 2021/954², which extends the EU Digital COVID Certificate framework to third-country nationals who are legally staying or residing in a Member State’s territory and who are entitled to travel to other Member States in accordance with EU law.

The EU Digital COVID Certificate is a simple and secure way to demonstrate a person’s COVID-19 status. It is free of charge and can be used both in a digital and paper-based format³. The EU Digital COVID Certificate has been a crucial element in Europe’s response to the COVID-19 pandemic. Its rapid adoption and rollout enabled European citizens to move freely and safely and the European travel sector to open in time for summer 2021. Today, more than 591 million EU Digital COVID Certificates have been issued.

The EU Digital COVID Certificate is increasingly seen as an international benchmark and global standard, with many third countries developing solutions that are interoperable with the EU system. The system does not require the exchange of any personal data and there is no EU database storing the data contained in the certificates. There are currently 43 countries and territories connected.

The EU Digital COVID Certificate Regulation requires the Commission to submit a report to the European Parliament and to the Council by 31 October 2021⁴. This report provides an overview of the EU Digital COVID Certificate Regulation in practice since its adoption on 14 June 2021. In the reporting period, the Commission gathered data on the technical implementation of the Regulation, including the connection of third countries to the system; developments in the issuance of certificates of recovery and vaccination; the use of certificates by the air transport sector; and the use of certificates by Member States for non-travel related purposes.

¹ 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).

² Regulation (EU) 2021/954 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) with regard to third-country nationals legally staying or residing in the territories of Member States during the COVID-19 pandemic (OJ L 211, 15.6.2021, p. 24).

³ A template for the paper format is available at:
https://ec.europa.eu/health/sites/default/files/ehealth/docs/covid-certificate_paper_guidelines_en.pdf

⁴ Article 16(1) of the EU Digital COVID Certificate Regulation.

Apart from the topics required by the Regulation, this report also contains information on other developments regarding the EU Digital COVID Certificate. This includes the connection of third countries to the EU Digital COVID Certificate environment, guidance received on the validity period of certificates of recovery, developments regarding the issuance of vaccination certificates, and Member States' use of the EU Digital COVID Certificate for domestic purposes.

2. DEVELOPMENTS SINCE THE ADOPTION OF THE EU DIGITAL COVID CERTIFICATE

2.1. Technical implementation

2.1.1. Number of EU Digital COVID Certificates issued

As of 13 October 2021, Member States have issued more than 591 million EU Digital COVID Certificates, made up of 437 million vaccination certificates⁵, 144 million test certificates, and 10 million certificates of recovery. A detailed breakdown per Member State is included in Annex I.

2.1.2. EU Gateway and work at technical level

The technical specifications, standards and guidelines for the common issuance, verification and acceptance of the EU Digital COVID Certificate were jointly developed by the Commission and the Member States within the framework of the eHealth Network⁶. All of the specifications developed by the eHealth Network are based on open standards and are published as open source on the eHealth Network website⁷. This has facilitated interoperability with systems developed by third countries (see Section 2.2 below).

Overall, the system is versatile, robust and designed to accommodate the heterogeneity of Member States' systems. The trust framework of the EU Digital COVID Certificate system is based on a public key infrastructure that ensures the authenticity and integrity of issued certificates by means of digitally signed Quick Response (QR) codes. Authorised certificate issuers (for example hospitals or laboratories) convert the data required by the EU Digital COVID Certificate Regulation into a QR code. The issuers then digitally sign the QR code using an asymmetric cryptographic algorithm and their own private key. Issuers' corresponding public keys, used for verifying the authenticity, integrity and validity of the digitally signed QR codes, are exchanged via the EU Digital COVID Certificate Gateway

⁵ Where a Member State was only able to provide a total figure for all three types of certificates, these are included in the number of vaccination certificates issued given that these constitute the vast majority of certificates issued.

⁶ The eHealth Network is a voluntary network connecting national authorities responsible for eHealth designated by the Member States set up on the basis of Article 14 of Directive 2011/24/EU.

⁷ https://ec.europa.eu/health/ehealth/covid-19_en

(‘the EU Gateway’),⁸ operated and maintained by the Commission⁹. Public key information (which does not contain personal data) is then transferred between Member States’ national digital infrastructures (‘back-ends’) via the Gateway and distributed from the national back-ends to the verification software in mobile devices.

While Member States are responsible for developing their national back-ends and deploying their respective national solutions, the Commission has developed reference implementations for certificate issuance, verification and storage apps, which are publicly available as open source solutions¹⁰. As a result, for many Member States and EEA countries, the reference implementations formed the basis for the development of their national solutions. The reference implementations have also been useful for third countries developing national solutions, as well as for their connection to the EU Gateway.

Work to further improve the EU Digital COVID Certificate system is ongoing in the eHealth Network. For example, it is now possible for Member States to exchange, via the EU Gateway, their national rules on the acceptance of certificates. This allows for the automatic checking of these rules via the verification applications, in addition to the verification of the authenticity of the certificates’ QR codes. Moreover, this allows for faster and more reliable checking of certificates against national rules, since a manual check for compliance with national rules is no longer necessary. To date, 13 countries connected to the Gateway have uploaded their rules and 20 countries have downloaded these rules to their national verifiers. The Commission invites all Member States to share their rules considering that this would improve travel experience and reduce uncertainty for passengers.

In a similar vein, Member States and the Commission are also coordinating efforts on the revocation of certificates. According to the EU Digital COVID Certificate Regulation, for medical and public health reasons and in the event of fraudulently issued or obtained certificates, Member States should be able to establish and exchange with other Member States certificate revocation lists. This can be done in limited cases, in particular to revoke certificates that have been issued erroneously, as a result of fraud or following the suspension of a COVID-19 vaccine batch found to be defective¹¹. The bilateral exchange of certificate revocation lists containing the unique certificate identifiers of revoked certificates may be supported by the EU Digital COVID Certificate trust framework¹². Experts in the eHealth Network are exploring how this could be achieved technically while preserving the current nature of data processing by the EU Gateway. It is important that Member States support this work to develop a solution quickly.

⁸ For more information, see Annex IV of Commission Implementing Decision (EU) 2021/1073 of 28 June 2021 laying down technical specifications and rules for the implementation of the trust framework for the EU Digital COVID Certificate established by Regulation (EU) 2021/953 of the European Parliament and of the Council (OJ L 230, 30.6.2021, p. 32).

⁹ Recital 51 of the EU Digital COVID Certificate Regulation.

¹⁰ <https://github.com/eu-digital-green-certificates>

¹¹ Recital 19 of the EU Digital COVID Certificate Regulation.

¹² Article 4(2) of the EU Digital COVID Certificate Regulation.

2.2. Equivalence decisions and international interoperability

2.2.1. Framework for EU Digital COVID Certificate equivalence decisions

Given its relevance to the Agreement on the **European Economic Area**, the EU Digital COVID Certificate Regulation has been incorporated in that agreement and as such it also applies to Iceland, Liechtenstein and Norway¹³. For other countries, where certain interoperability requirements are met, the EU Digital COVID Certificate Regulation stipulates that the Commission can issue a decision establishing that the certificates of a third country are to be considered as equivalent to EU Digital COVID Certificates (“**equivalence decisions**”). This results in the third country concerned being connected to the EU Gateway.

A third country that is interested in joining the EU system is first asked to assess its compliance with the technical specifications of the EU Digital COVID Certificate system. If, after this self-assessment, the third country considers that it is technically ready, it can send an official request to the Commission. The Commission then assesses the application, in order to ensure that all technical requirements are met. During this process, all third countries undergo the same technical screening and testing procedures as were applied to Member States when they connected to the system.

To support third countries interested in seeking an equivalence decision for their COVID-19 certificate system, general and technical information about the EU Digital COVID Certificate system is shared via the European External Action Service and EU Delegations. In addition, all technical requirements are publicly available on the eHealth Network website.

As the purpose of the EU Digital COVID Certificate Regulation is to facilitate free movement of EU citizens within the EU, the effect of equivalence decisions is to permit EU citizens and their family members, if they hold a certificate issued by a third country, to use it when exercising their right of free movement. For the same reason, the Regulation as such does not explicitly require that third countries seeking an equivalence decision reciprocally accept the EU Digital COVID Certificate for travelling to their respective countries. However, before adopting an equivalence decision, the Commission has asked all third countries concerned to accept the EU Digital COVID Certificate and, so far, all have confirmed that they do accept it.

Although the EU Digital COVID Certificate is intended to facilitate free movement within the EU, the interest from third countries to be connected to the EU Digital COVID Certificate system also indirectly facilitates the entry of third-country nationals into the EU. Due to the COVID-19 pandemic, a restriction on non-essential travel into the EU has been in place since mid-March 2020, which has been coordinated through a Council Recommendation¹⁴. This

¹³ Decision of the EEA Joint Committee No 187/2021 of 30 June 2021 amending Annex V (Free movement of workers) and Annex VIII (Right of establishment) to the EEA Agreement (OJ L 124, 8.5.2008, p. 20).

¹⁴ Council Recommendation (EU) 2020/912 of 30 June 2020 on the temporary restriction on non-essential travel into the EU and the possible lifting of such restriction (OJ L 208I, 1.7.2020, p. 1).

Recommendation was amended on 20 May 2021 to allow fully vaccinated third-country nationals' entry into the EU¹⁵. While the Recommendation states that Member States could accept third-country vaccination certificates in accordance with national law, taking into account the need to be able to verify the authenticity, validity and integrity of the certificate, this process is facilitated once an equivalence decision for a third country has been adopted.

By 13 October 2021, there had been preliminary contacts with 60 interested third countries or territories, 40 of which had formally submitted the results of the self-assessment of their readiness to join the EU system. With the EU Digital COVID Certificate, the EU has set a global trend and exercised global technological leadership in the midst of the global pandemic while guaranteeing data protection and security, maintaining the core value of human-centricity during the digital transition, and remaining open to the world.

The Regulation contains two separate legal bases for this purpose: Article 3(10) and Article 8(2), depending on the EU's relationship with the third country concerned in the field of free movement.

2.2.2. Equivalence decision pursuant to Article 3(10)

Article 3(10) of the Regulation empowers the Commission to adopt implementing acts establishing that COVID-19 certificates issued by a third country which has concluded a free movement agreement with the EU and the Member States that does not contain a mechanism of incorporation of EU legal acts are equivalent to EU Digital COVID Certificates.

This provision currently only covers **Switzerland**, with which the Agreement between the European Union and its Member States and Switzerland on the free movement of persons is in force¹⁶. On 8 July 2021, the Commission adopted an Implementing Decision connecting Switzerland to the EU system¹⁷. As a result, COVID-19 certificates issued by Switzerland are accepted under the conditions referred to in Article 5(5), Article 6(5) and Article 7(8) of the EU Digital COVID Certificate Regulation.

2.2.3. Equivalence decisions pursuant to Article 8(2)

Based on Article 8(2) of the Regulation, the Commission may adopt implementing acts establishing that interoperable COVID-19 certificates issued by a third country are to be

¹⁵ Council Recommendation (EU) 2021/816 20 May 2021 amending Recommendation (EU) 2020/912 on the temporary restriction on non-essential travel into the EU and the possible lifting of such restriction (OJ L 182, 21.5.2021, p. 1).

¹⁶ Agreement between the European Community and its Member States, of the one part, and the Swiss Confederation, of the other, on the free movement of persons - Final Act - Joint Declarations - Information relating to the entry into force of the seven Agreements with the Swiss Confederation in the sectors free movement of persons, air and land transport, public procurement, scientific and technological cooperation, mutual recognition in relation to conformity assessment, and trade in agricultural products (OJ L 114, 30.4.2002, p. 6).

¹⁷ Commission Implementing Decision (EU) 2021/1126 establishing the equivalence of COVID-19 certificates issued by Switzerland to the certificates issued in accordance with Regulation (EU) 2021/953 of the European Parliament and of the Council (OJ L 243, 9.7.2021, p. 49).

considered as equivalent to EU Digital COVID Certificates, for the purpose of facilitating the holders' exercise of their right to free movement within the Union. By 13 October 2021, the Commission has adopted such equivalence decisions regarding COVID-19 certificates issued by Albania¹⁸, Andorra¹⁹, Faroe Islands²⁰, Israel²¹, Monaco²², Morocco²³, North Macedonia²⁴, Panama²⁵, San Marino²⁶, Turkey²⁷, Ukraine²⁸ and Vatican City²⁹. Additional equivalence decisions are in preparation.

¹⁸ Commission Implementing Decision (EU) 2021/1477 of 14 September 2021 establishing the equivalence, for the purpose of facilitating the right of free movement within the Union, of COVID-19 certificates issued by the Republic of Albania to the certificates issued in accordance with Regulation (EU) 2021/953 of the European Parliament and of the Council (OJ L 325, 15.9.2021, p. 36).

¹⁹ Commission Implementing Decision (EU) 2021/1476 of 14 September 2021 establishing the equivalence, for the purpose of facilitating the right of free movement within the Union, of COVID-19 certificates issued by Andorra to the certificates issued in accordance with Regulation (EU) 2021/953 of the European Parliament and of the Council (OJ L 325, 15.9.2021, p. 33).

²⁰ Commission Implementing Decision (EU) 2021/1478 of 14 September 2021 establishing the equivalence, for the purpose of facilitating the right of free movement within the Union, of COVID-19 certificates issued by the Faroe Islands to the certificates issued in accordance with Regulation (EU) 2021/953 of the European Parliament and of the Council (OJ L 325, 15.9.2021, p. 39).

²¹ Commission Implementing Decision (EU) 2021/1482 of 14 September 2021 establishing the equivalence, for the purpose of facilitating the right of free movement within the Union, of COVID-19 certificates issued by the State of Israel to the certificates issued in accordance with Regulation (EU) 2021/953 of the European Parliament and of the Council (OJ L 325, 15.9.2021, p. 51).

²² Commission Implementing Decision (EU) 2021/1479 of 14 September 2021 establishing the equivalence, for the purpose of facilitating the right of free movement within the Union, of COVID-19 certificates issued by Monaco to the certificates issued in accordance with Regulation (EU) 2021/953 of the European Parliament and of the Council (OJ L 325, 15.9.2021, p. 42).

²³ Commission Implementing Decision (EU) 2021/1481 of 14 September 2021 establishing the equivalence, for the purpose of facilitating the right of free movement within the Union, of COVID-19 certificates issued by the Kingdom of Morocco to the certificates issued in accordance with Regulation (EU) 2021/953 of the European Parliament and of the Council (OJ L 325, 15.9.2021, p. 48).

²⁴ Commission Implementing Decision (EU) 2021/1381 of 19 August 2021 establishing the equivalence, for the purpose of facilitating the right of free movement within the Union, of COVID-19 certificates issued by the Republic of North Macedonia to the certificates issued in accordance with Regulation (EU) 2021/953 of the European Parliament and of the Council (OJ L 297, 20.8.2021, p. 38).

²⁵ Commission Implementing Decision (EU) 2021/1480 of 14 September 2021 establishing the equivalence, for the purpose of facilitating the right of free movement within the Union, of COVID-19 certificates issued by the Republic of Panama to the certificates issued in accordance with Regulation (EU) 2021/953 of the European Parliament and of the Council (OJ L 325, 15.9.2021, p. 45).

²⁶ Commission Implementing Decision (EU) 2021/1273 of 30 July 2021 establishing the equivalence, for the purpose of facilitating the right of free movement within the Union, of COVID-19 certificates issued by San Marino to the certificates issued in accordance with Regulation (EU) 2021/953 of the European Parliament and of the Council (OJ L 277, 2.8.2021, p. 151).

²⁷ Commission Implementing Decision (EU) 2021/1382 of 19 August 2021 establishing the equivalence, for the purpose of facilitating the right of free movement within the Union, of COVID-19 certificates issued by the Republic of Turkey to the certificates issued in accordance with Regulation (EU) 2021/953 of the European Parliament and of the Council (OJ L 297, 20.8.2021, p. 41).

²⁸ Commission Implementing Decision (EU) 2021/1380 of 19 August 2021 establishing the equivalence, for the purpose of facilitating the right of free movement within the Union, of COVID-19 certificates issued by Ukraine to the certificates issued in accordance with Regulation (EU) 2021/953 of the European Parliament and of the Council (OJ L 297, 20.8.2021, p. 35).

²⁹ Commission Implementing Decision (EU) 2021/1272 of 30 July 2021 establishing the equivalence, for the purpose of facilitating the right of free movement within the Union, of COVID-19 certificates issued by the Vatican City State to the certificates issued in accordance with Regulation (EU) 2021/953 of the European Parliament and of the Council (OJ L 277, 2.8.2021, p. 148).

2.2.4. Interoperability with systems developed at international level

In accordance with Article 4(3) of the Regulation, the EU Digital COVID Certificate trust framework should ensure interoperability with technological systems established at international level.

The International Civil Aviation Organization (ICAO) has recently developed the Visible Digital Seal for Non-Constrained Environments (VDS-NC)³⁰ standard. The Commission is currently in discussions with the ICAO to identify ways to bridge the gap in specifications between its standard and the EU Digital COVID Certificate. There are a number of challenges in this regard, linked to differences between the two standards, such as in terms of the datasets, vaccine encoding, or the size of the ICAO VDS-NC QR code which could make verification difficult unless specific readers are used. At the same time, according to the information available to the Commission, no third country has yet implemented and deployed a COVID-19 certificate systems based on the ICAO VDS-NC standard³¹. While technical discussions will continue, workable solutions may require time and financial investment by Member States. In addition, based on the EU Digital COVID Certificate Regulation, the adoption of equivalence decisions is limited to COVID-19 certificate systems developed by third countries, posing difficulties in relation to international organisations.

On 27 July 2021, the WHO published technical specifications and implementation guidance on digital documentation for COVID-19 certificates: vaccination status³² underlining that the EU Digital COVID Certificate complies with their guidance and is not a parallel or conflicting standard. On 26 August 2021, the International Air Transport Association (IATA) urged countries to adopt the EU Digital COVID Certificate as the global standard³³. In the high-level principles for a safe and sustainable resumption of international travel adopted on 30 September 2021, the members of the Group of Seven (G7) acknowledge the “*positive development of the EU Digital COVID Certificate, which is operational internationally*”³⁴.

³⁰ <https://www.icao.int/Security/FAL/TRIP/PublishingImages/Pages/Publications/Guidelines%20-%20VDS%20for%20Travel-Related%20Public%20Health%20Proofs.pdf>

³¹ On 1 October 2021, Australia announced that it would start issuing certificates meeting the ICAO VDS-NC standard by the end of October (<https://www.pm.gov.au/media/national-cabinet-statement-56>).

³² WHO reference number: WHO/2019-nCoV/Digital_certificates/vaccination/2021.1.

³³ <https://www.iata.org/en/pressroom/2021-releases/2021-08-26-01/>

³⁴ <https://www.gov.uk/government/publications/g7-high-level-principles-for-a-safe-and-sustainable-resumption-of-international-travel/g7-high-level-principles-for-a-safe-and-sustainable-resumption-of-international-travel>

2.3. Developments regarding the issuance of certificates of recovery

2.3.1. Possible issuance of certificates of recovery based on rapid antigen test results

2.3.1.1. *Guidance received from the European Centre for Disease Prevention and Control*

The issuance of a certificate of recovery based on a positive **rapid antigen test**³⁵ is not covered by the EU Digital COVID Certificate even though it was in the original Commission proposal, since at the time of adoption, ECDC considered that the performance of rapid antigen tests was sufficient for the issuance of test certificates but not for the issuance of certificates of recovery. This is because rapid antigen tests were initially designed and approved for testing symptomatic people with an ongoing SARS-CoV-2 infection and high viral loads. A higher performance would be needed in order to limit the number of false positives resulting from rapid antigen test.

Since then, the clinical performance of rapid antigen tests has improved. In May 2021, the Technical Working Group on COVID-19 diagnostic tests established by the Health Security Committee³⁶, responsible for maintaining the EU common list of rapid antigen tests³⁷, put in place a more structured, coherent and swift procedure for updating the list. Moreover, on 29 June 2021, the experts of the Technical Working Group agreed on further definitions and criteria that should be considered for independent validation studies assessing the clinical performance of rapid antigen tests for COVID-19 diagnosis, in addition to those set out in the Council Recommendation of 21 January 2021³⁸.

One of the criteria agreed was an increased specificity rate of 98%. Nowadays, the EU common list includes rapid antigen tests that have been assessed through independent evaluation studies, showing a sensitivity of $\geq 90\%$ (some even of $\geq 95\%$) and a specificity of $\geq 98\%$. As a consequence of these improved estimates of the test characteristics, the proportion likely to have a false positive test is now known to be lower. Furthermore, in July 2021, the Technical Working Group agreed to exclude from the list rapid antigen tests based on saliva and other alternative sample types, as well as rapid antigen self-tests, further increasing the likely consistency of the performance of the tests included in the list.

In view of these developments, ECDC now supports the issuance of certificates of recovery to persons who have received a positive result for SARS-CoV-2 infection following a rapid antigen test listed in the common and updated list of COVID-19 rapid antigen tests (for more information, see Annex II).

³⁵ ‘Rapid antigen test’, that is, a test that relies on detection of viral proteins (antigens) using a lateral flow immunoassay that gives results in less than 30 minutes.

³⁶ https://ec.europa.eu/health/security/crisis-management/twg_covid-19_diagnostic_tests_en

³⁷ https://ec.europa.eu/health/sites/default/files/preparedness_response/docs/covid-19_rat_common-list_en.pdf

³⁸ Council Recommendation of 21 January 2021 on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU (OJ C 24, 22.1.2021, p. 1).

2.3.1.2. Assessment by the Commission

Based on the guidance from the ECDC, the Commission consulted Member States' experts in different fora, such as the Health Security Committee, the eHealth Network and the Technical Working Group on COVID-19 diagnostic tests, to obtain further scientific and technical input regarding the possible issuance of certificates of recovery based on positive rapid antigen test results.

Following these consultations, the Commission concludes that for the time being there is insufficient support among Member States' experts for the issuance of certificates of recovery based on the result of a rapid antigen test only, that is, without further confirmation by a reverse transcription polymerase chain reaction (RT-PCR) test. Several Member State experts consider that rapid antigen tests are still not sufficiently reliable in terms of their specificity levels, with several reports mentioning quality issues in particular, high level of false positive results. According to experts, current testing policies in a majority of Member States require a confirmatory RT-PCR test in case of a positive rapid antigen test result. Where positive, the result of the confirmatory RT-PCR test can then form the basis for the issuance of a certificate of recovery.

In view of the above, for the time being the Commission will continue to monitor this issue and may consider the option of adopting a delegated act to amend the EU Digital COVID Certificate Regulation to allow for the issuance of certificates of recovery on the basis of rapid antigen test results at a later date³⁹.

2.3.2. Possible issuance of certificates of recovery based on antibody test results

2.3.2.1. Guidance received from the European Centre for Disease Prevention and Control

In May 2021, the ECDC and the Joint Research Centre published a technical report on the use of **antibody tests** for SARS-CoV-2 in the context of EU Digital COVID Certificates⁴⁰, which lists the main points for consideration in their recommendation not to provide for the issuance of certificates of recovery based on antibody test results. These considerations included, among others:

- A positive antibody test result cannot provide any indication of the time of infection, and cannot exclude a current ongoing infection.
- Even if antibody tests provide some evidence of an immune response, it is not known if the antibody levels offer sufficient protection or how long such protection would last.
- It is still unknown whether the antibodies detected by commercial tests currently in use would prevent infection with newly emerging SARS-CoV-2 variants.

³⁹ Based on Article 7(4) of the EU Digital COVID Certificate Regulation.

⁴⁰ <https://www.ecdc.europa.eu/sites/default/files/documents/Use-of-antibody-tests-for-SARS-COV-2-in-the-context-of-Digital-Green-Certificates.pdf>

- Due to the variety of antibody tests, a comparison of their results is extremely difficult due to the lack of standardisation.
- Tests that target the spike protein will be unable to distinguish between people who have been previously infected and those who have received at least one dose of a vaccine.

The ECDC has reviewed these conclusions (for more information, see Annex II) and considers that the abovementioned points remain valid and that there has not been any substantial change in the scientific evidence. As a result, the ECDC considers that currently available antibody tests are not suitable for the assessment of the time of infection and immunity status of an individual. Therefore, positive antibody test results are not considered sufficient for the issuance of certificates of recovery.

2.3.2.2. Assessment by the Commission

Based on the guidance from the ECDC, the Commission is currently not considering the adoption of a delegated act to amend the EU Digital COVID Certificate Regulation to allow for the issuance of certificates of recovery on the basis of antibody tests. The Commission may reconsider its position on the basis of new guidance from the ECDC.

2.3.3. Validity period of certificates of recovery

2.3.3.1. Guidance received from the European Centre for Disease Prevention and Control

In accordance with Point 3(h) of the Annex of the EU Digital COVID Certificate Regulation, **the validity of certificates of recovery** is currently limited to 180 days after the date of first positive nucleic acid amplification test (NAAT)⁴¹ result. This is due to the currently limited knowledge regarding the duration of immunity of persons infected with SARS-CoV-2. To date, the correlation between measured immunity and clinical protection from SARS-CoV-2 infection still needs to be established.

The validity of certificates of recovery depends on the emerging scientific evidence on the duration of protective immunity after natural infection and effectiveness of the previous infection in the presence of current and potential future SARS-CoV-2 variants, which is a dynamic process changing on a regular basis.

Having examined all the available information, the ECDC considers that there is currently insufficient evidence to support an increase of the validity period of certificates of recovery beyond 180 days (for more information, see Annex II).

⁴¹ Such as reverse transcription polymerase chain reaction (RT-PCR), loop-mediated isothermal amplification (LAMP) and transcription-mediated amplification (TMA) techniques, used to detect the presence of the SARS-CoV-2 ribonucleic acid (RNA).

2.3.3.2. Assessment by the Commission

Based on the guidance from the ECDC, the Commission is currently not considering the adoption of a delegated act to amend the EU Digital COVID Certificate Regulation to extend the validity period of certificates of recovery beyond 180 days after the date of first positive NAAT result.

2.4. Developments regarding the issuance of vaccination certificates

2.4.1. Validity period of vaccination certificates

2.4.1.1. Guidance received from the European Centre for Disease Prevention and Control

According to the EU Digital COVID Certificate Regulation, it is up to Member States to decide how long to accept the validity of vaccination certificates and only the acceptance of EU-approved vaccines is obligatory. Acceptance of COVID-19 vaccines that have completed the WHO emergency use listing procedure⁴² is optional. The European Medicines Agency (EMA) has recently evaluated the use of a booster dose of the COVID-19 vaccine Comirnaty (by BioNTech/Pfizer) for people from 18 to 55 years old with normal immune systems⁴³. On the basis of data showing a rise in antibody levels when a booster dose is given approximately six months after the second dose to these individuals, EMA concluded that booster doses may be considered at least six months after the second dose for people aged 18 years and older.

According to ECDC⁴⁴, the currently available evidence regarding vaccine effectiveness and the duration of protection shows that all EU-authorized vaccines are currently highly protective against COVID-19-related hospitalisation, severe disease and death. While there could be a need to administer additional doses to medically vulnerable groups (immunosuppressed persons, elderly persons, etc.), and several EU Member States are currently already doing so, the ECDC concludes that there is no urgent need for the administration of booster doses of vaccines to fully vaccinated individuals in the general population.

2.4.1.2. Assessment by the Commission

Taking into account the absence of conclusive scientific evidence on waning immunity after a certain period of time, the Commission is not currently considering an amendment to the EU Digital COVID Certificate Regulation in order to specify the validity of vaccination certificates. The Commission will continue to monitor this issue very closely as the scientific evidence develops.

⁴² <https://extranet.who.int/pqweb/key-resources/documents/status-covid-19-vaccines-within-who-eulpq-evaluation-process>

⁴³ <https://www.ema.europa.eu/en/news/comirnaty-spikevax-ema-recommendations-extra-doses-boosters>

⁴⁴ <https://www.ecdc.europa.eu/en/publications-data/covid-19-public-health-considerations-additional-vaccine-doses>

It is also important to underline that, where booster doses are administered, this does not affect the validity of the certificates issued as part of the primary vaccination cycle. Following technical discussions in the eHealth Network, the Commission is currently preparing an implementing act amending the technical specifications of the EU Digital COVID Certificate⁴⁵ to ensure that there are uniform rules for the coding of additional COVID-19 vaccine doses in vaccination certificates issued afterwards.

2.5. Information received from Member States

2.5.1. Information received pursuant to Article 11 of the EU Digital COVID Certificate Regulation

The Commission monitors Member States' implementation of the EU Digital COVID Certificate Regulation. This is linked to the monitoring of Council Recommendation 2020/1475⁴⁶, which established a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic based on a traffic-light map published weekly by the ECDC⁴⁷. To make best use of the EU Digital COVID Certificate system, the Council, following a proposal from the Commission, amended the Recommendation in June 2021⁴⁸. The Recommendation sets out, among other things, a coordinated understanding of 'full vaccination' and validity periods for tests in the context of travel. Information from Member States on the EU Digital COVID Certificate is collected by means of overview tables submitted by the Member States to the Commission and the Council, and is also made available on the Re-open EU platform⁴⁹.

The EU Digital COVID Certificate Regulation provides that, without prejudice to Member States' competence to impose restrictions on grounds of public health, where Member States accept vaccination certificates, test certificates indicating a negative result or certificates of recovery, they are to refrain from imposing additional restrictions to free movement, unless they are necessary and proportionate for the purpose of safeguarding public health in response to the COVID-19 pandemic⁵⁰.

Where a Member State requires holders of EU Digital COVID Certificates to undergo, after entry into its territory, quarantine or self-isolation or to be tested for SARS-CoV-2 infection, or if the Member State imposes other restrictions on the holders of such certificates, because

⁴⁵ Commission Implementing Decision (EU) 2021/1073 of 28 June 2021 laying down technical specifications and rules for the implementation of the trust framework for the EU Digital COVID Certificate established by Regulation (EU) 2021/953 of the European Parliament and of the Council (OJ L 230, 30.6.2021, p. 32).

⁴⁶ Council Recommendation (EU) 2020/1475 of 13 October 2020 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic (OJ L 337, 14.10.2020, p. 3).

⁴⁷ <https://www.ecdc.europa.eu/en/covid-19/situation-updates/weekly-maps-coordinated-restriction-free-movement>

⁴⁸ Council Recommendation (EU) 2021/961 of 14 June 2021 amending Recommendation (EU) 2020/1475 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic (OJ L 213I, 16.6.2021, p. 1).

⁴⁹ <https://reopen.europa.eu/en>

⁵⁰ Article 11(1) of the EU Digital COVID Certificate Regulation.

the epidemiological situation in a Member State worsens quickly, for example as a result of a SARS-CoV-2 variant of concern or interest, the Member State should inform the Commission and the other Member States accordingly⁵¹. Member States provide such information in the form of formal notices to the Commission and the Council. By 13 October 2021, Denmark, Ireland, Malta and Slovakia had submitted information pursuant to this provision. The additional requirements notified by these Member States amount to additional tests after arrival for holders of test certificates arriving from higher-risk areas, quarantine for holders of test certificates arriving from areas with variants of concern or interest, or quarantine requirements for unvaccinated travellers. The reasons invoked by these Member States were high case notification rates or the detection of variants of concern or interest, notably the so-called Delta variant (at a stage where that variant was not yet the dominant strain of SARS-CoV-2 across the EU)⁵². The duration of the measures varied, being in force until mid-July, the end of September 2021, October 2021, or for an indeterminate period. The Member States concerned indicated that the restrictions were being continually assessed. The Commission will continue to monitor compliance of Member States' public health measures affecting citizens' right to free movement with EU law, in particular the principles of non-discrimination and proportionality.

2.5.2. Other information on the implementation of the EU Digital COVID Certificate Regulation

The EU Digital COVID Certificate Regulation provides that **vaccination certificates are to be issued by the Member State where the vaccine has been administered**. If citizens are vaccinated in two different Member States, the first Member State should issue an EU Digital COVID Certificate indicating the first dose and the second Member State should issue, upon presentation of proof that the first dose was administered in another Member State, an EU Digital COVID Certificate indicating the second dose (the certificate will indicate "2/2"). However, in certain cases citizens have reported difficulties receiving an EU Digital COVID Certificate correctly indicating the administration of a second dose, despite providing proof of the first dose.

Some Member States have also not yet found a satisfying solution to issue **EU Digital COVID Certificates for certain categories of people**. This is mainly the case for vaccination certificates. Issues were most reported for persons not permanently residing in the Member State concerned, persons without health insurance in the Member State, or persons without a national register or social security number in the Member State⁵³. Some Member States also encountered difficulties in setting up a system that would allow for the (timely) issuance of test certificates to travellers residing in other Member States.

⁵¹ Article 11(2) of the EU Digital COVID Certificate Regulation.

⁵² See also: <https://www.ecdc.europa.eu/en/covid-19/variants-concern>

⁵³ While health insurance affiliation and national register numbers (where they exist) are not included in the EU Digital COVID Certificates themselves, these data items are sometimes processed in the process for (re)issuing certificates, in line with national rules.

When it comes to the **format** of EU Digital COVID Certificates, some difficulties were reported in relation to paper versions of test certificates, and the need to be able to receive a paper format of these certificates. Some Member States do not issue test certificates in a paper format, arguing that sending test certificates via post would result in them arriving past their validity period. It was also reported that the issuance of EU Digital COVID Certificates in paper format by healthcare providers was not always free of charge.

The Commission maintains regular contacts with the Member States at technical level with regard to their implementation of the EU Digital COVID Certificate. Some of the issues outlined above have already been resolved. For example, Belgium has confirmed that no electronic ID is needed to receive a test certificate; Croatia confirmed that it issues vaccination certificates to mobile EU citizens; Germany confirmed that the results of rapid antigen tests are also issued in a paper format; Ireland confirmed that COVID-19 test providers are issuing test certificates in a format that complies with the Regulation; and Spain confirmed that non-resident EU citizens vaccinated or tested in Spain can receive an EU Digital COVID Certificate.

Issues have also arisen in some Member States where citizens have reported disparities between the name mentioned in their travel documents and the name indicated in the EU Digital COVID Certificate. On 26 July 2021, a Corrigendum⁵⁴ related to the French version of the EU Digital COVID Certificate Regulation was published to further clarify that certificates should include “*nom(s) et prénom(s)*” instead of “*nom(s) de famille et prénom(s)*”, which can be misunderstood as the person’s birth name. The Commission has clarified towards the Member States that the name included on the certificate should match the name stated on the holder’s travel documents. Where mistakes occur, citizens are encouraged to get in touch with the national authorities that have issued the certificate to have them corrected.

As far as the implementation of Regulation (EU) 2021/954 is concerned, no specific issues were reported when it comes to the issuance of EU Digital COVID Certificates to third-country nationals who are legally staying or residing in their territory and who are entitled to travel to other Member States in accordance with EU law. However, this is most likely due to the fact that Member States established one single system to issue EU Digital COVID Certificates to both EU citizens and legally residing third-country nationals. Furthermore, as far as short-term visitors are concerned, this can be explained by the absence of an obligation on Member States to issue persons who have proof of vaccination in a third country with an EU Digital COVID Certificate. Pursuant to Article 8(1) of the EU Digital COVID Certificate Regulation, such issuance is optional, although several Member States are offering this possibility.

⁵⁴ Rectificatif au règlement (UE) 2021/953 du Parlement européen et du Conseil du 14 juin 2021 relatif à un cadre pour la délivrance, la vérification et l’acceptation de certificats COVID-19 interopérables de vaccination, de test et de rétablissement (certificat COVID numérique de l’UE) afin de faciliter la libre circulation pendant la pandémie de COVID-19 (OJ L 265, 26.7.2021, p. 49).

To provide citizens with additional information, the Commission has published frequently asked questions on the EU Digital COVID Certificate, vaccinations and travel restrictions⁵⁵.

2.5.3. Information received pursuant to Article 15 of the EU Digital COVID Certificate Regulation (phasing-in period)

The EU Digital COVID Certificate Regulation applies since 1 July 2021. Where a Member State was not able to issue EU Digital COVID Certificates as of that date, it was to inform the Commission and the other Member States accordingly⁵⁶. Where they contained the data set out in the Annex, the COVID-19 certificates issued by such a Member State in a format that did not comply with the Regulation had to be accepted by the other Member States until 12 August 2021. The Commission received such information, which in some cases only concerned a delay of a couple of days, from eight Member States⁵⁷.

To ensure a smooth rollout of the system, the Commission encouraged Member States to start issuing EU Digital COVID Certificates already before its entry into application⁵⁸. The Commission supported this process by launching the EU Gateway on 1 June 2021⁵⁹. Given that no personal data is exchanged via the EU Gateway, Member States were able to make use of its functionality already in advance of the entry into application of the Regulation. On the same day, the first Member States started to issue certificates⁶⁰ and, 21 Member States in total anticipated the deadline of 1 July 2021⁶¹. This was the result of a clear commitment by Member States to the EU Digital COVID Certificate and its aim to open up Europe for its citizens in time for the summer months.

2.6. Air transport sector

The air transport sector was one of the first sectors to make use of the EU Digital COVID Certificate, on a large scale and is a good test case to understand how the certificate works in practice. The European Union Aviation Safety Agency and ECDC updated their recommendations in the COVID-19 Aviation Health Safety Protocol to align it with the EU Digital COVID Certificate immediately after the adoption of the Regulation⁶².

The EU Digital COVID Certificate Regulation leaves the decision on how to verify certificates to Member States. A Commission survey among Member States on the

⁵⁵ Available at: https://ec.europa.eu/info/policies/justice-and-fundamental-rights/eu-citizenship/movement-and-residence/eu-digital-covid-certificate-vaccinations-and-travel-restrictions_en

⁵⁶ Article 15(2) of the EU Digital COVID Certificate Regulation.

⁵⁷ Denmark, Finland, France, Ireland, Malta, Slovakia, Spain and Sweden.

⁵⁸ Recital 12 of the Proposal for a Council Recommendation amending Council Recommendation (EU) 2020/1475 of 13 October 2020 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic (COM(2021) 294 final).

⁵⁹ https://ec.europa.eu/commission/presscorner/detail/en/IP_21_2721

⁶⁰ Bulgaria, Czechia, Denmark, Germany, Greece, Croatia and Poland.

⁶¹ https://ec.europa.eu/commission/presscorner/detail/en/ip_21_3343

verification of the EU Digital COVID Certificate for air travel showed at least 15 different ways of organising the verification process, bearing the risk of significant duplication, and resulting in a lack of clarity and delays for passengers.

To address this issue, the Commission published a Communication with recommendations to Member States to streamline the verification⁶³. To avoid unnecessary checks of the EU Digital COVID Certificate by more than one actor (airline operators, airport operators, public authorities, etc.), the Commission recommended a ‘one-stop’ verification process prior to departure. The verification should also be carried out as early as possible and preferably before the passenger arrives at the departure airport, and Member States are encouraged to ensure complete, comprehensible and timely provision of information to operators and travellers about the verification requirements and processes.

While air passenger numbers continue to be significantly below pre-pandemic levels, the airport association Airports Council International (ACI) Europe reported that preliminary data for July 2021 revealed total passenger volumes more than doubling compared to July 2020, with significant improvements compared to the second quarter of 2021. ACI Europe attributes this change to the rollout of the EU Digital COVID Certificate along with the easing of travel restrictions⁶⁴.

In this context, further functionalities of the EU Digital COVID Certificate system are currently being considered, including improved digital wallet features as well as a ticketing solution showcasing how airlines and other transport service operators could seamlessly integrate proofs of certificate verification into online check-in procedures without sharing personal data.

2.7. Use of the EU Digital COVID Certificate for domestic purposes

The EU Digital COVID Certificate Regulation covers the use of certificates for travel within the EU during the COVID-19 pandemic. It neither prescribes nor prohibits other uses for the certificate and the use of COVID-19 certificates for domestic purposes, such as for access to events or venues, goes beyond the scope of the Regulation.

Where Member States decide to use the EU Digital COVID Certificate for other purposes, this must be provided for in national law, which must comply in particular with data protection requirements⁶⁵. At the same time, where a Member State establishes a system of COVID-19 certificates for domestic purposes, it should ensure that the EU Digital COVID

⁶³ Communication from the Commission, “Reaping the full benefits of EU Digital COVID Certificates: Supporting free movement of citizens and the recovery of the air transport sector through guidelines and recommendations for EU Member States”, C(2021) 5594 final, 22 July 2021.

⁶⁴ https://mcusercontent.com/66a62c6d1a4692e5a3b79a788/files/6ddf5241-a7e7-b614-e826-04720e836172/21_09_17_Holiday_season_improvements_in_passenger_traffic_cannot_be_called_a_recovery_says_airport_body_as_gradual_gains_already_plateau_across_Europe.03.pdf

⁶⁵ Recital 48 of the EU Digital COVID Certificate Regulation.

Certificates can also be used and are fully accepted⁶⁶. The objective is to make sure that travellers going to another Member State do not have to obtain an additional national certificate. In this way it is ensured that the interoperable system of the EU Digital COVID Certificate is used to its full potential.

In a survey conducted in September 2021, twenty Member States⁶⁷ indicated that they use the EU Digital COVID Certificate for such purposes. Five Member States⁶⁸ noted that the domestic use of the certificates was being considered. Member States use the certificate for the access to large events (by far the most common use-case), restaurants, cinemas and museums, nightclubs, fitness centres and other sports facilities, close-contact occupations such as hairdressers, beauty and massage parlours, hotels, hospitals and care homes, or universities and schools.

3. CONCLUSION AND NEXT STEPS

When originally proposed by the Commission in March 2021⁶⁹, many voiced doubts regarding the Commission's plans to have the system up and running in time for the summer. But the fact that it took the European Parliament and the Council only three months to find agreement – and Member States and the Commission only two more weeks to have the system up and running – demonstrates that when EU institutions and Member States act together, they are able to act fast.

The EU Digital COVID Certificate has proven to be a major success in Europe's efforts to address and mitigate the impact of the COVID-19 pandemic on societies and economies. The certificate facilitates travel and has been crucial to support Europe's hard-hit tourism industry. The EU Digital COVID Certificate is also a success worldwide. Today it is the global standard and currently the only system in operation internationally. It is used by countries across four continents. It is also the first example of an interoperable electronic record deployed at scale across such a large number of countries in a very short period of time.

This success is also appreciated by citizens. According to a Eurobarometer survey published in September 2021, about two thirds (65%) of respondents agreed that the EU Digital COVID Certificate is the safest means for free travel in Europe during the COVID-19 pandemic⁷⁰.

Although the Regulation has a time-limited application, the EU Digital COVID Certificate has demonstrated that it is possible to develop a safe and secure, privacy-preserving and data-

⁶⁶ Recital 49 of the EU Digital COVID Certificate Regulation.

⁶⁷ Belgium, Czechia, Denmark, Germany, Estonia, Ireland, Greece, France, Croatia, Italy, Cyprus, Latvia, Lithuania, Luxembourg, Hungary, Malta, Austria, Poland, Portugal and Slovenia. In view of the progress of its vaccination campaign, Denmark has lifted the requirement to present the certificate for domestic purposes in the meantime.

⁶⁸ Bulgaria, Spain, the Netherlands, Romania and Finland.

⁶⁹ COM(2021) 130 final.

⁷⁰ Available at: <https://www.europarl.europa.eu/at-your-service/files/be-heard/eurobarometer/2021/soteu-flash-survey/soteu-2021-report-en.pdf>

protecting system in an accessible manner. The certificates are available free of charge, in a digital and paper-based format, and are both human and machine-readable. It is therefore an important test case for the development of an EU Digital Identity ‘toolbox’⁷¹.

The EU Digital COVID Certificate Regulation currently applies until 30 June 2022⁷². By 31 March 2022, the Commission will submit another report to the European Parliament and to the Council on the application of the Regulation, which may be accompanied by a legislative proposal to extend the period of application of the Regulation, taking into account the evolution of the epidemiological situation with regard to the COVID-19 pandemic⁷³.

However, the Commission does not exclude that it will put forward such a proposal already at an earlier stage, in order to ensure that, for reasons of legal certainty, the necessary legislative procedure can be concluded sufficiently in time before June 2022. This extension may be necessary, for example, if it is likely that the pandemic has not yet abated in time for the summer of 2022 and not extending the EU Digital COVID Certificate would likely result in additional restrictions to free movement as EU citizens would be deprived of an effective, secure and privacy-preserving way of proving their COVID-19 status. Any proposal by the Commission to extend the Regulation would be time-limited as the Commission’s goal is to return to unrestricted free movement as soon as the epidemiological situation allows it.

⁷¹ Commission Recommendation (EU) 2021/946 of 3 June 2021 on a common Union Toolbox for a coordinated approach towards a European Digital Identity Framework: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021H0946&qid=1478030835186>

⁷² Article 17 of the EU Digital COVID Certificate Regulation.

⁷³ Article 16(2) of the EU Digital COVID Certificate Regulation.



Brussels, 18.10.2021
COM(2021) 649 final

ANNEXES 1 to 2

ANNEXES

to the

Report from the Commission to the European Parliament and the Council pursuant to Article 16(1) of Regulation (EU) 2021/953 of the European Parliament and of the Council 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.

ANNEX I

Detailed breakdown of number of EU Digital COVID Certificates issued (by 13 October 2021)

	Vaccination certificates issued	Test cert. issued (NAAT ¹)	Test cert. issued (RAT ²)	Recovery certificates issued	Total issued
Austria	11.125.292	10.872.756	20.482.546	577.981	43.058.575
Belgium*	17.440.792	5.822.096		608.250	23.871.138
Bulgaria	1.372.297	307.779	705.533	37.251	2.422.860
Czechia	7.199.918	1.935.056	3.413.355	377.589	12.925.918
Denmark**					
Germany***	119.750.418	1.629.445	1.267.528	607.075	123.254.466
Estonia*	662.125	3.073		63.597	728.795
Ireland	3.978.823	186.203	37.461	69.317	4.271.804
Greece	3.419.809	17.064	200.551	471.751	4.109.175
Spain*	25.371.410	809.495		515.562	26.696.467
France	72.186.091	24.593.086	38.226.112	1.896.065	136.901.354
Croatia	1.600.824	17.241	597.661	126.353	2.342.079
Italy	72.726.630	7.078.397	15.092.611	2.160.524	97.058.162
Cyprus	739.837	14.118	314.614	76.179	1.144.748
Latvia	1.387.323	270.523	21.397	77.337	1.756.580
Lithuania	1.770.546	3.501.075	358.855	333.994	5.964.470
Luxembourg	1.363.875	621.868	138.140	46.493	2.170.376
Hungary	4.746.433	183.653	79.521	356.155	5.365.762
Malta*	282.886	619		145	283.650
Netherlands****	42.179.079				42.179.079
Poland*	14.098.319	307.336		495.632	14.901.287
Portugal	7.147.103	81.387	178.954	227.940	7.635.384
Romania	4.726.990	61.642	98.909	111.190	4.998.731
Slovenia	4.170.614	473.674	1.582.643	561.128	6.788.059
Slovakia	4.623.889	933.324	1.046.082	214.011	6.817.306
Finland	1.820.819	202.113	5.386	28.533	2.056.851
Sweden*	4.857.039	143.834		1.573	5.002.446
Iceland	538.095	73.760	148.121	3.431	763.407
Lichtenstein	47.288	21.975	13.830	1.322	84.415
Norway****	6.175.000				6.175.000
Total EU/EEA	437.509.564	60.162.592	84.009.810	10.046.378	591.728.344

* Combined total for NAAT and RAT test certificates

** Figures not available

*** Reporting for RAT tests issued only as of 27 September 2021

**** Total number issued for all three types of certificates

¹ 'Nucleic acid amplification test', such as reverse transcription polymerase chain reaction (RT-PCR), loop-mediated isothermal amplification (LAMP) and transcription-mediated amplification (TMA) techniques, used to detect the presence of the SARS-CoV-2 ribonucleic acid (RNA).

² 'Rapid antigen test', that is, a test that relies on detection of viral proteins (antigens) using a lateral flow immunoassay that gives results in less than 30 minutes.

ANNEX II

Guidance provided by the European Centre for Disease Prevention and Control

Possible issuance of certificates of recovery based on rapid antigen test results

Appropriately validated rapid antigen detection tests (RADTs) can be used for issuing the recovery certificates for the purposes of the EU DCC. According to the Council Recommendation on a common framework for the use and validation of rapid antigen tests, the mutual recognition of COVID-19 test results in the EU (2021/C 24/01) and the 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. Self-test RADTs should NOT be used for the purpose of issuing a formal certificate such as testing, or recovery certificates. Proper sampling is one of the most crucial steps for SARS-CoV-2 diagnosis and, if performed incorrectly, a reliable test result cannot be assured³.

The RADTs have generally lower sensitivity but high specificity. The use of RADTs is primarily intended to detect individuals with an ongoing SARS-CoV-2 infection, i.e. while they are most infectious. The use of RADTs is appropriate in settings with high COVID-19 prevalence when a positive result is likely to indicate true infection, as well as in low prevalence settings for rapid identification of highly infectious individuals. However, in low prevalence settings, the use of RADTs could result in false positive test results. The lower the prevalence in the population to be tested, the higher the likelihood of false positive test results. This means that there could be a proportion of people certified to have recovered, whereas they are still susceptible (i.e. people with a false positive RADT result for COVID-19). This is true for all test types.

All COVID-19 tests, including NAATs, have the risk of producing false positive test results, but this proportion may be higher for RADTs than for RT-PCR if the clinical performance (i.e. specificity level) of the used test is lower. If RADTs of lower specificity are used, this should be taken into consideration, especially in low prevalence settings when these tests are used for screening of asymptomatic individuals and where the positive predictive value of the RADTs would thus be low. The validity period of the recovery certificate would be the same for positive RADTs and positive NAAT.

The list of mutually recognised RADTs is regularly updated by the Technical working group on COVID-19 diagnostic tests and agreed by the Health Security Committee.

³ ECDC (2021). Considerations on the use of rapid antigen detection (including self-) tests for SARS-CoV-2 in occupational settings. Available at: <https://www.ecdc.europa.eu/sites/default/files/documents/Considerations-on-use-of-rapid-antigen-detection-tests-for-SARS-CoV-2-in-occupational-settings.pdf>

Possible issuance of certificates of recovery based on antibody test results

Regarding antibody tests, the European Centre for Disease Prevention and Control (ECDC) and the Joint Research Centre (JRC) have produced technical notes⁴ where the main points for consideration are listed, namely:

- Antibody tests are currently mostly used in research studies (sero-epidemiological studies) of population rather than for individual diagnosis of COVID-19 cases.
- The detection and quantification of antibodies cannot be used as a direct indication of protective immunity.
 - A positive antibody test result can be a proof of a past infection but is not an absolute proof that a person is not infectious and/or protected against a new infection and cannot transmit the virus further.
 - So far, it is not known which antibody levels would protect against re-infection.
 - Conversely, individuals that have recovered may not test positive to serological tests (over an extended period).
 - Moreover, not all antibodies induced by a SARS-CoV-2 infection neutralise the virus effectively.
 - Most antibody tests available cannot assess if the antibodies detected offer effective protection.
- Antibody tests cannot define the time of infection.
 - Antibody tests cannot give any indication about the time of the infection, so without any additional evidence, e.g. NAAT and/or RAT test performed at the time of infection, it is impossible to determine the validity period of the recovery certificate.
 - It may well be that soon after a positive antibody test, the antibodies become undetectable.
- There is a risk that the antibodies detected by currently used commercial tests do not prevent infection with newly emerging SARS-CoV-2 variants.
 - Current testing systems are not validated against new variants.
- When a serological test results positive, this does not necessarily mean the individual has recovered from SARS-CoV-2.
 - For example, patients that have received one dose of a vaccine may develop antibodies similar to the ones present in recovered patients and this category would represent 'false positive results'.
 - There is evidence of high risk of false positive results in areas of low SARS-CoV-2 prevalence.
 - Regional differences in the prevalence of SARS-CoV-2 infections may have an impact on the (positive/negative) predictive value of serological tests.
 - Antibodies presented in autoimmune diseases (e.g. rheumatoid factors) might give a positive result without ever having the infection.

⁴ <https://www.ecdc.europa.eu/sites/default/files/documents/Use-of-antibody-tests-for-SARS-COV-2-in-the-context-of-Digital-Green-Certificates.pdf>

- There is a variety of antibody tests and a comparison of their results is extremely difficult due to this variety and the lack of standardisation.
 - Antibody tests currently used in Member States are not harmonised/standardised and results are not comparable.
 - Laboratory methods may target different antibodies (IgM / IgG), which may also recognise different parts of the virus.
 - Most commercially available tests only provide qualitative results (presence or absence of antibodies).
 - These qualitative antibody tests are useful from a population, rather than individual perspective.
 - Quantitative detection kits are primarily used for research purposes but the comparability between laboratories is hindered by the lack of available reference material
 - Therefore, it may not be possible to propose a single list of recommended serological tests to be applied across the EU.
- Use of certificates issued on the basis of positive antibody tests (IgM and IgG) in the context of public health measures.
 - It is possible that individuals with certificates issued on the basis of a positive antibody test may be falsely reassured that they can relax attitudes towards behaviours that are essential to limiting risk of infection and onwards transmission, such as physical distancing, mask use and hand washing. As mentioned above, whilst a positive antibody test result may be suggestive of prior infection, it may not guarantee protection from reinfection, or to newly emerging variants with possible immune-escape potential.
 - Any implementation of certificates based on a positive antibody test should be carefully considered and be accompanied by strong public messages and relevant communication about the importance of both vaccination and public health measures to reduce SARS-CoV-2 transmission.

After reviewing the technical notes and the evidence published later, we conclude that currently available antibody tests are not suitable for the assessment of the time of infection and immunity status of an individual. Therefore, the positive antibody test results are not considered sufficient for issuing of a recovery certificate that would exempt the holder from certain public health measures.

ECDC and JRC will continue their monitoring of antibody tests and their usage, including via the "COVID-19 Diagnostic Testing database" of the JRC and the sero-epidemiological study network in the WHO European Region that is coordinated jointly by ECDC and the WHO Regional Office for Europe.

Validity period of certificates of recovery

Evidence on duration of immunity for recovered individuals is ideally drawn from longitudinal cohorts comparing infection risk amongst naïve and recovered individuals at 3- or 6-monthly intervals. Unfortunately, such studies are sparse. A systematic review of 11 key studies conducted by Health Information and Quality Authority in Ireland suggests that reinfection risk amongst recovered individuals is low (absolute rate 0%–1.1%), with protection maintained for up to 10 months post initial infection [1]. More recently, Vitale *et al.* observed protection from reinfection for recovered individuals for a period of at least 12 months [2]. However, a critical limitation of these studies, is that their observation periods predate the emergence and subsequent dominance of the B.1.617.2 (Delta) SARS-CoV-2 variant of concern (VOC) across the EU/EEA.

Preliminary analysis of national surveillance data from the UK indicates that recovered individuals have an increased risk of reinfection with Delta compared to the previously dominant B.1.1.7 (Alpha) strain, with the overall odds around 46% higher [3]. The Public Health England analysis included 83,197 individuals ≥15 years, who became SARS-CoV-2 PCR positive during an 11-week observation period (12 April and 27 June 2021), of whom 980 (1.2%) were possible reinfections. The adjusted odds ratio of reinfection with the Delta variant was 1.46 (95% CI 1.03 to 2.05) compared to the previously dominant Alpha variant. The **risk of reinfection** was not elevated for Delta if the primary infection was <180 days (adjusted odds ratio = 0.79, 95% CI 0.49 to 1.28) but was **higher for those with a prior infection ≥180 days earlier** (adjusted odds ratio = 2.37, 95%CI 1.43 to 3.93). This finding has not yet been replicated in other settings, and additional age-stratified data on reinfection risk over time, specifically in the context of Delta, is needed.

Table 7: Multivariable logistic regression model of the risk of reinfection with alpha and delta variants during a period of emergent delta infection in England

		Totals	Risk of reinfection-week 2021-15 to 2021-25		
			Crude OR	aOR (95% CI)*	aP-Value
Definition of reinfection applied	All possible reinfections	980 (1.2%)			
	All first infections	82,217 (98.8%)			
All possible reinfections arising at least 90 days after prior infection	Alpha variant	83/14,509 (0.6%)	1	1	
	Delta variant	897/68,688 (1.3%)	2.30 (1.84 to 2.88)	1.46 (1.03 to 2.05)	0.031
Possible reinfections arising between 90-179 days after prior infection	Alpha variant	54/14,480 (0.4%)	1	1	
	Delta variant	243/68,034 (0.4%)	0.96 (0.71 to 1.29)	0.79 (0.49 to 1.28)	0.342
Possible reinfections arising at least 180 days after prior infection	Alpha variant	29/14,455 (0.2%)	1	1	
	Delta variant	654/68,445 (1.0%)	4.80 (3.31 to 6.96)	2.37 (1.43 to 3.93)	0.001

*adjusted for age group (<30 years, 30+years), sex, Region, vaccination status (any vaccine at least 14 days earlier vs no vaccine), ethnicity and week

Source: Public Health England [3].

In the absence of a universal immune correlate which can be measured in recovered individuals to infer protection, the virus-neutralising capability of serum antibodies provide the best current indication of protection from reinfection. Whilst the majority of SARS-CoV-2

infected individuals will develop serum antibodies, recovered individuals demonstrate highly variable antibody dynamics over time [4], with waning of neutralising antibodies widely documented [5]. In a key study by Planas *et al.*, sera collected from 56 convalescent individuals 6 months post symptom onset were shown to be four-fold less potent against the Delta variant relative to the Alpha variant. The authors also observed a similar four-fold reduction in a separate cohort of 26 convalescent individuals evaluated 12 months post symptom onset, stressing that neutralisation activity was globally low by month 12 [6]. Waning of serum antibodies may be entirely mitigated by the presence of SARS-CoV-2-specific memory B cells, which can rapidly expand when supported by SARS-CoV-2-specific memory T cells. Memory T cells may also contribute to protection and recovery from infection by directly lysing SARS-CoV-2 infected cells. However, specific T cell correlates remain elusive.

Conclusions

- Duration of immunity is a complex issue and to date the correlation between measured immunity and clinical protection from SARS-CoV-2 infection still needs to be established.
- The validity of the recovery certificates depends on the emerging scientific evidence on the duration of protective immunity after natural infection and effectiveness of the previous infection in the presence of current and potential future variants, which is a dynamic process changing on a regular basis.
- Taken together, in absolute terms, the risk of reinfection with Delta variant remains low at 180 days post infection, albeit with evidence of an increased risk relative to the previously circulating Alpha variant. Given these factors, there is currently insufficient evidence to support an increase of the recovery certificate validity period beyond 180 days.
- ECDC will continue to regularly monitor the relevant new scientific evidence in this area in order to provide updates on the duration of immunity following natural infection.

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