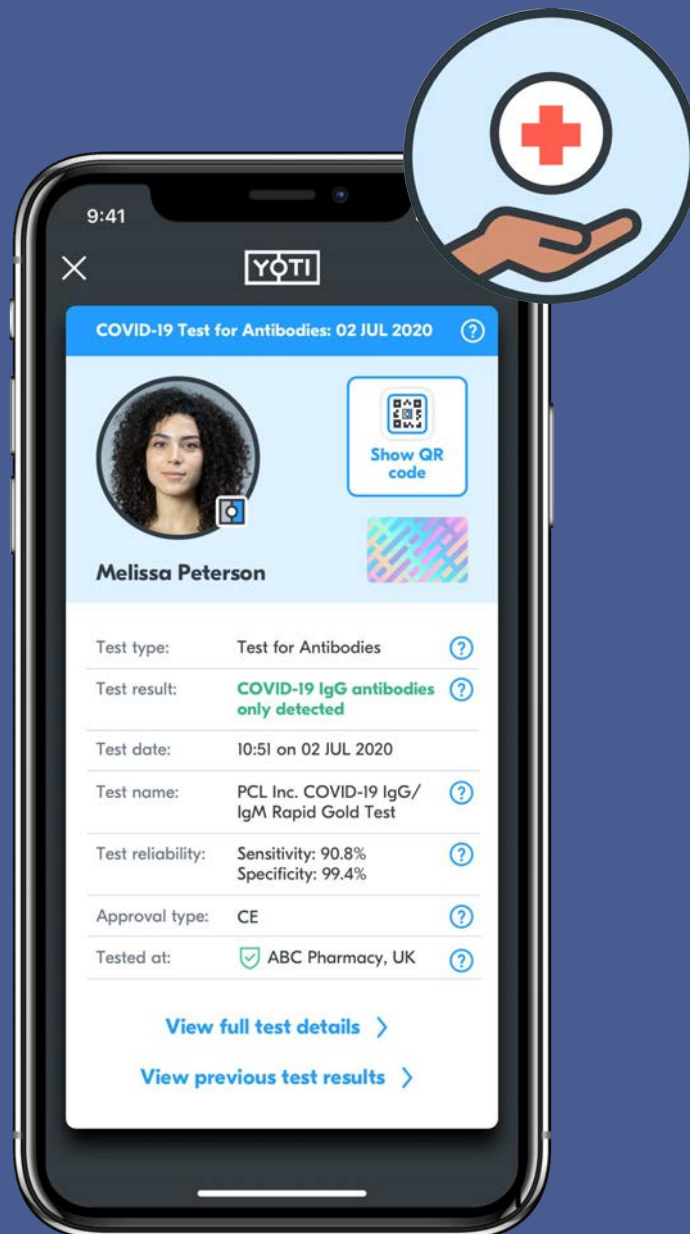


WHITE PAPER

It's my health: A global Code of Practice for sharing personal health credentials

5 May 2020



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Background

The COVID-19 pandemic has given rise to the need to restrict the movement of individuals to limit further spread of the virus. This has had a damaging effect on society and the economy and, in particular, has caused disruption to the ability of workers to return to their jobs.

To help ease the restrictive measures placed on individuals, including key workers, trusted health organisations should be able to issue COVID-19 antibody or viral RNA antigen test results to individuals. Individuals may then choose to share their test results with relying parties so that the individual may return to work.

This could provide a mechanism to enable those who present reasonable evidence that they pose a low risk of transmitting the COVID-19 virus (either that they have recovered from the infection and are, presumably, immune, or have had a very recent test indicating that they are not currently infected) to return to work, board a flight or return to some specific, limited access venues and activities.

An individual's medical data is regarded as highly sensitive and therefore it is of utmost importance that the data is only shared in accordance with applicable law. Individuals who decide to submit or share their medical data must feel assured that their data will be handled securely and for the intended and declared purposes. Organisations that receive such data must be assured that the data is valid and is a trustworthy, accurate representation of an individual's health status.

The terms "Immunity Certificate" or "Immunity Passport" are vague and potentially confusing, as well as lacking granularity and adaptability. Yoti can support the granularity of the specific test result, whether the detection viral RNA, antigens or antibodies using a swab or blood test, the credential issuer, and the duration of the test result stored securely in the individual's secure wallet.

We believe that abiding by a Code of Practice is the right approach to achieving the required public health objectives and organisational requirements, without compromising privacy and security. Many bodies are looking at the crucial issues of ethics and accessibility of testing. This document does not cover those angles, focusing primarily instead on the identity issues.

We have proactively drafted a Code of Practice to govern the sharing of medical data for a range of purposes including creating a Health Test Credential. The key organisations covered by this Code / these standards are those that:

- test and issue test results or certificates;
- provide the Health Test Credential; and
- require information on an individual's health status.

We welcome feedback from these organisations and civil society bodies on the Code. Given the potential for reinfection, and that the duration of any acquired immunity remains an open question, the proposed Code will need to be updated as the scientific evidence and public policy develops.

The first section of this paper sets out the proposed Code. The second part sets out how Yoti could comply with such a Code.

Please provide any feedback to: julie.dawson@yoti.com

Code of Practice

Definitions

“Coronavirus” and “COVID-19” have the same meanings as given in section 1(1) of the UK Coronavirus Act 2020.

“COVID-19” stands for Coronavirus Disease 2019, which is the disease caused by the virus SARS-CoV-2.

“COVID-19 Status” means positive or negative status for either being currently infected with, or having been infected with, COVID-19.

“Digital Credential Provider” is the organisation that receives the Health Test Credential from the Issuing Authority and provides it to the individual in a digital format.

“Issuing Authority” is the organisation providing the Health Test Certificate or Credential.

“Medical Data” includes information on or about the individual in relation to their Health Test Certificate or Credential and associated COVID-19 antigen and antibody testing.

“Health Test Credential” is a certificate, paper or electronic, provided by an Issuing Authority, that a person has been tested and a COVID-19 status result has been issued for that test.

“Relying Party” is the organisation requesting a Health Test Certificate or Credential from an individual.

“SARS-CoV-2” stands for Severe Acute Respiratory Syndrome Coronavirus 2.

Requirement 1: Trusted identity verification of individuals

It is important that Issuing Authorities are able to issue Medical Data to the right people. Therefore, the identity of individuals must be verified in a robust, secure and effective way.

To achieve this, identity verification and authentication should be undertaken in alignment with recognised standards. Examples of acceptable recognized identity verification and authentication standards are NIST SP 800-63A and 63B in the USA, GPG 44 and 45 in the UK and eIDAS in the EU.

Requirement 2: Trusted and transparent health testing of individuals by medical authorities

The science is still evolving in terms of the health testing of individuals for SARS-CoV-2 infection, which causes COVID-19.

SARS-CoV-2 RNA, antigen and antibody testing must meet recognised standards and test results should provide transparent metadata to identify the provenance of tests.

Issuing authorities must be able to update or revoke Health Test Certificate Credentials.

Elements to consider when reviewing metrics:-

COVID-19 antigen and antibody testing should be independently tested in multiple institutions and be shown to reach suitable sensitivity and specificity criteria.

When examining metrics for sensitivity and specificity, metrics for IgG results, IgM results, and IgG combined with IgM results, may be different and should not be blended.

There is no universal consensus amongst the world's health regulators or scientists as to the minimum required sensitivity and specificity values for these antibody tests. It is agreed that both metrics should be as high as possible, especially specificity, which helps to reduce the likelihood of false positive results.

There is likely to be a need for both higher-cost, lower-volume (often laboratory-based) tests with exacting sensitivity/specificity scores, as well as less exacting and less expensive tests that are widely accessible in the community (or even at home) at scale.

This combination of testing will allow the highest number of individuals to gain at least temporary peace of mind of their IgG positive status. High volume testing also helps health authorities monitor disease spread and guides decision making around lockdown restrictions, social and economic policies.

Requirement 3: Trusted storage of credentials or Medical Data

Organisations storing Health Test Credentials, including associated Medical Data, must have an effective information security management system that meets recognised standards, so it can control information security risks.

They must demonstrate that they have proportionate organisational and technical controls to manage the risks posed to the security of the service provided, protecting the confidentiality, integrity and availability of the information processed.

Data should be encrypted when in storage.

Organisations that undertake verification or authentication should be certified against recognised security standards, such as ISO/IEC 27001:2013, ISAE SOC2 or the HIPAA Security Rules. They must be audited against the chosen recognised standard on a regular basis.

Requirement 4: Trusted presentation and transfer of Health Test Credentials

Interoperability / data format

In terms of data format, attributes containing medical certificates should be interoperable across digital devices and systems, and device-agnostic as much as possible, e.g. in the form of a W3C Verifiable Credential and /or compatible with OpenID Connect, OpenID Connect CIBA, SAML.

Validity / anti-spoofing

Relying parties must have trust that the Health Test Credentials presented by individuals are valid.

To achieve this, Digital Credential Providers must put in place measures to prevent the presentation of false Health Test Credentials. They must also be able to identify when someone is spoofing the system using a sophisticated artefact that has taken considerable time, money, effort or criminal activity to create. If a facial biometric modality is being checked, this could mean making sure the person is not using a mask or showing a 3D animated avatar on a hijacked computer or device.

Expiry, revocation, security

Digital Credential Providers should ensure that Health Test Certificates can be revoked and indicate visually how long they are valid for.

Data should be encrypted when in transit.

Data minimisation

Data minimisation should be Practiced in terms of the presentation of credentials. As far as possible, Digital Credential Providers should adhere to the principles of privacy by design.

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Accessibility

Wherever feasible organisations should offer options, in terms of accessibility, to enable all individuals to choose to present their Health Test Credentials.

Digital Credential Providers should assess any ethical and trust issues that might be caused by offering their services. Where identified and within their control, Digital Credential Providers should mitigate any negative unintended consequences.

Secure data transmission

An individual may choose or be required to share Health Test Credentials with a Relying Party. Proportionate safeguards should be put in place to prevent the interception of that data. They should be able to prevent a determined individual using sophisticated methods of compromising the security of data transmission.

Transparency

Prior to requesting data, relying parties should clarify the purpose of the request being made to the individual.

Individuals should be able to track the relying parties with which they have shared their Health Test Credentials.

Requirement 5: Privacy requirements

All organisations collecting, using, storing or disclosing Medical Data will need to comply with all applicable privacy or data protection laws they are subject to.

The following principles should be followed by all organisations processing Medical Data:

- Full transparency to the individual of how their data will be collected, used, stored and disclosed.
- The Medical Data must be used for specific, necessary and proportionate purposes, and any additional uses may require the individual's consent.
- Issuing authorities must provide, and relying parties must request, only the information that is necessary for the purpose(s).
- Any onward sharing with other third parties must be necessary and proportionate and, depending on the relevant legal obligations in place, may need the individual's consent.
- Individuals should be able to access and export their Medical Data.
- Individuals should be able to update and delete their Medical Data.
- Organisations may not use the Medical Data for any marketing purposes.
- Organisations must have appropriate technical and organisational security measures in place to protect the Medical Data.

Additionally, when a credential is shared with a Relying Party, the Relying Party should comply with an individual's request to delete that data where it is no longer necessary or proportionate to store it, or where there is a regulatory requirement to delete the data.

How Yoti complies with the draft Code of Practice

Requirement 1: Trusted verification and authentication of individuals

Yoti allows consumers to create a reusable digital identity that they can then use in real world scenarios and anywhere across mobile and web services that have integrated Yoti. Yoti enables businesses to verify consumers' identities using biometrics and government-issued IDs.

The Yoti business model is very transparent. It is free for consumers and for eligible not-for-profit organisations. Other organisations pay for checks and attributes requested.

If an individual elects to set up a Yoti they can subsequently apply for and get issued a credential such as an employment status or the results of health tests. Those Verifiable Credentials can then be shared in person and online. Yoti uniquely combines the strong cryptographic proof of a W3C Verifiable Credential with the assurance that only a certain individual is its rightful owner.

Yoti has been engineered with privacy by design in mind. We distinguish ourselves with our approach to privacy and security; our design and architecture makes it impossible for us to identify or decrypt users' personal data (see our [FAQs](#) for technical detail).

Yoti is certified to the ISO 27001 standard. It also holds a clean SOC 2 Type 2 audit. It is audited against these standards on a regular basis. Yoti is also aligned with the national identity proofing and authentication standards in GPG 44 and 45, as well as NIST SP 800-63A and 63B.

For Yoti's ethical framework and principles see Appendix 1. For more on Yoti's approach to privacy and security read [here](#)

Yoti can also offer a biometric e-signature option to testing labs, if any regulators require "strong" evidence of a consumer's decision to be tested, fill in a health form or share their tamper-proof electronic test result.

Requirement 2: Trusted and transparent health testing of individuals by medical authorities

Relying parties and Digital Credential Providers should review the metrics available e.g. provenance, independent testing, and status of a test in terms of specificity, sensitivity and proposed deployment, as well as to ensure that the credential depicts the key data about the rightful owner.

By way of example, Yoti is in discussions with QuestCap Inc, a company which has exclusive rights in the Americas to use a COVID-19 serological antibody test developed by PCL Inc, a South Korean medical diagnostics firm. This is currently designed to be deployed in controlled settings.

One example of deployment is as part of the Standard for Safe Sport™, created by Glenco Medical Corp., led by Dr. Copeland, a physician and consultant for the Ottawa Redblacks, Toronto Blue Jays and Atlanta Braves (Canadian Professional Football, Canadian Professional Baseball and American Professional Baseball teams respectively)

Several phases of supervised screening, interpretation and reporting have been defined. It incorporates medical screening, interpretation and reporting protocols - and involves self-assessment and health testing within a given league executed by trained, certified individuals. It includes self-reporting, aggregating test results and collaborating with governing bodies; and self-regulation. It also enforces medical recommendations and measures for recovery with a commitment to players, staff and support. This test is expected to provide the confidence to return the players back to the field in a controlled environment.

The role that Yoti can play is to supply ID verification, authentication and credential management to facilitate the trusted and secure administration of the Standard for Safe Sport™ testing.

How does the Standard for Safe Sport™ work in practice and how does Yoti help?

- Preparation: consent obtained and a baseline assessment completed via temperature assessment, a medical questionnaire and antibody testing.
- Testing: scheduled volumes, administrators and location with antibody tests.
- Preventing transmission: via rapid data analysis to quarantine infected individuals and provide necessary care.
- High quality, verified information and securing it properly is key - requiring infrastructure to collect input from many sources while limiting access and permissions. IDs with COVID-19 results are verified and distributed by organisations using the Yoti app to provide a mobile phone-based digital identity that preserves privacy and boosts security.
 - Players and supporting staff within clubs will create a Yoti digital ID and share identity details including the new COVID-19 antibody test credentials, in person or online, in seconds with a tap of a button or scan of a QR code.
 - Clubs can issue, update and revoke trusted credentials through the Yoti APIs and Yoti app, including employer, job title, work location, test expiry date, verified work email address and also COVID-19 antibody test results.

1. <https://nationalpost.com/news/world/scott-stinson-on-covid-19-meet-the-canadian-doctor-behind-efforts-to-restart-colombian-pro-socce>

The PCL finger prick (point-of-care lateral flow immunoassay) antibody test was evaluated at three different university hospitals in South Korea: Chosun University Hospital, Gwangju; Daegu Catholic University Hospital, Daegu; and Dongguk University Hospital, Ilsan. South Korea has a good track-record of dealing with viral epidemics, and Daegu (the site of one of these three university hospitals that evaluated the test) was the location of the first large COVID-19 outbreak that occurred outside of China.

They found the following results for the reliability of the PCL finger prick antibody test (when compared to cases confirmed for COVID-19 by RT-PCR², 10 days post diagnosis):

- If both IgG and IgM are positive:
Sensitivity 90.8% and Specificity 99.4%
- If only IgG is positive:
Sensitivity 87.4% and Specificity 99.4%

For both conditions where IgG antibodies are detected, the specificity scores are >99%, which helps to minimise the rate of false positive errors (see Appendix 3 for further explanation). This type of false positive error may be of particular concern in COVID-19, as an antibody test with a false positive might reassure someone that they have antibodies and have some immunity to infection, when in reality they do not have those antibodies.

We do not use the term Immunity Certificate, as it is not yet known whether having antibodies for COVID-19 offers immunity and prevents future infection, or if so, for how long that immunity may last. However, there are some indicators that having developed IgG antibodies, a person may be immune for some period of time, and the World Health Organization (WHO) recently released a statement saying “We expect that most people who are infected with #COVID19 will develop an antibody response that will provide some level of protection.”

2. RT-PCR is a laboratory-based test which detects the presence of viral genetic material (i.e. viral RNA).

Requirement 3: Trusted storage of health test credentials

Yoti has a well-established information security management system, and is subject to the EU GDPR and UK Data Protection Act 2018. Yoti is certified to ISO 27001:2013 and has a SOC2 Type II report written by a global top four auditing firm. Yoti is undergoing HIPAA assessment by an accredited auditor.

Issuing authorities can revoke previously issued credentials, as well as update details.

The issuing body will have the ability to revoke or update Verifiable Credentials. The credential can contain an expiry date and a list of test results. There is no real restriction on what the credential can contain.

Yoti, as well as supporting the W3C Verifiable Credential standard, could interface with the HL7 FHIR API and comply with their standard as well, bridging the two ecosystems by translating one standard to the other when needed.

See Appendix 1 for the W3C Verifiable credentials ecosystem and how Yoti operates within that, as well as steps for Yoti Credential Issuance and Usage.

Requirement 4: Trusted presentation and transfer of Health Test Credentials

Issuers are free to define the structure of their credentials and associated metadata.

Yoti enables the data minimised presentation of data. In other words, just the minimum amount of data required, and uses two primary methods to guard against spoofing of visually-presented 'cards':

- 1) A digital hologram, which shimmers in response to the device's accelerometer and shows a pattern which can be changed at random.
- 2) A 'verification QR Code': a simple way for any 'viewer' to verify the authenticity of the information shown on another person's Yoti app (the 'presenter'), by scanning a QR Code. This initiates a secure transaction between the two parties (the 'presenter' and the 'viewer') so that information can be exchanged via the Yoti platform, and which cannot be imitated. Each verification QR Code is for one-time-use, and time-limited.

Yoti provides an individual with a dashboard and receipts for all data they opt to share. Yoti explicitly includes contract clauses with relying parties covering the need for transparency and data minimisation.

Yoti is today interoperable across digital devices and systems and is device-agnostic (including portability from one OS to another). Yoti can present an attribute containing a medical certificate in the form of a W3C Verifiable Credential. Yoti is also compatible with OpenID Connect and SAML.

As well as enabling individuals to share with organisations online and in person, Yoti also enables peer-to-peer sharing. Yoti is a free app, and enables individuals with a smartphone, if they so choose, to send trusted credentials to anyone with a mobile number / email address.

Yoti is available for iPhone and Android users.

Yoti is founded upon core business principles. It also has both external and internal ethics and trust boards. See Appendix 2 for more detail.

Requirement 5: Privacy requirements

As a UK company, Yoti is subject to the EU GDPR and the UK Data Protection Act 2018 and has a comprehensive privacy governance framework in place to apply these standards to its business globally.

Individuals have access to their data in the app, and they can access and export it at any time. They will not be able to amend a test certificate, which is crucial to its integrity. They can delete their account at any time, which deletes all their data.

Yoti privacy information and app privacy notice: <https://www.yoti.com/privacypolicy/>

Appendix 1 - W3C verifiable credentials ecosystem

Yoti's platform can absorb much of the complexity of dealing with verifiable credentials (Figure 1). We can even help define the structure of credentials for third parties. Following these standards Yoti ensures that credentials are interoperable and portable.

Yoti uniquely combines the strong cryptographic proof of a verifiable credential with the assurance that only a certain individual is its rightful owner, making use of document verification, as well as biometric and anti spoofing technologies to remotely authenticate the holder and identity attributes before they are issued to the holder. Yoti's platform preserves the privacy of users at all times.

Users are free at any time to export their credentials out of Yoti, or delete their account and all associated data.

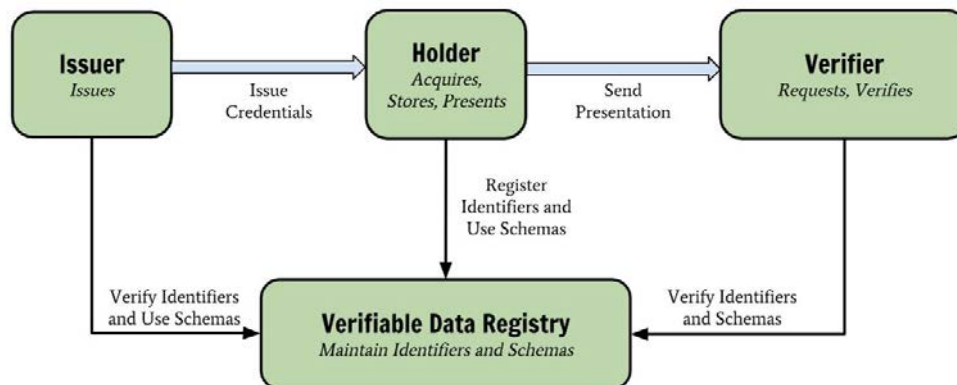


Figure 1. Roles in the Verifiable Credential ecosystem:

- Yoti acts as the Verifiable Data Registry.
- The Holder is the user using the Yoti App.
- Yoti can facilitate the interaction between Holder and Verifier at the time of presentation (online and in person). The verifier does not need to contact the issuer.
- Yoti can facilitate the interaction between Issuer and Holder at the time of issuance (online and in person).

Credentials issuance and usage

Credential issuance:

- Individuals create their Yoti digital ID on their smartphone, securely binding their account to their biometrics and to a private key that is stored in the secure enclave on their device.
- User chooses to enroll in a testing programme, facilitated by an authorised practitioner. Using Yoti, they can uniquely identify themselves to the testing practitioner in advance, or on the day of their first test. This unique identification can be completely anonymous or include verified personal details, as required by the testing authority.
- The test is carried out by the authorised practitioner. The test is linked to the user that, on the day of the test, or before or after the test, used their Yoti to 'check in'.
- The testing authority issues an individual's results as a Verifiable Credential (Figure 2), digitally signed and sent directly to the same Yoti app which uniquely identified itself in the previous step.

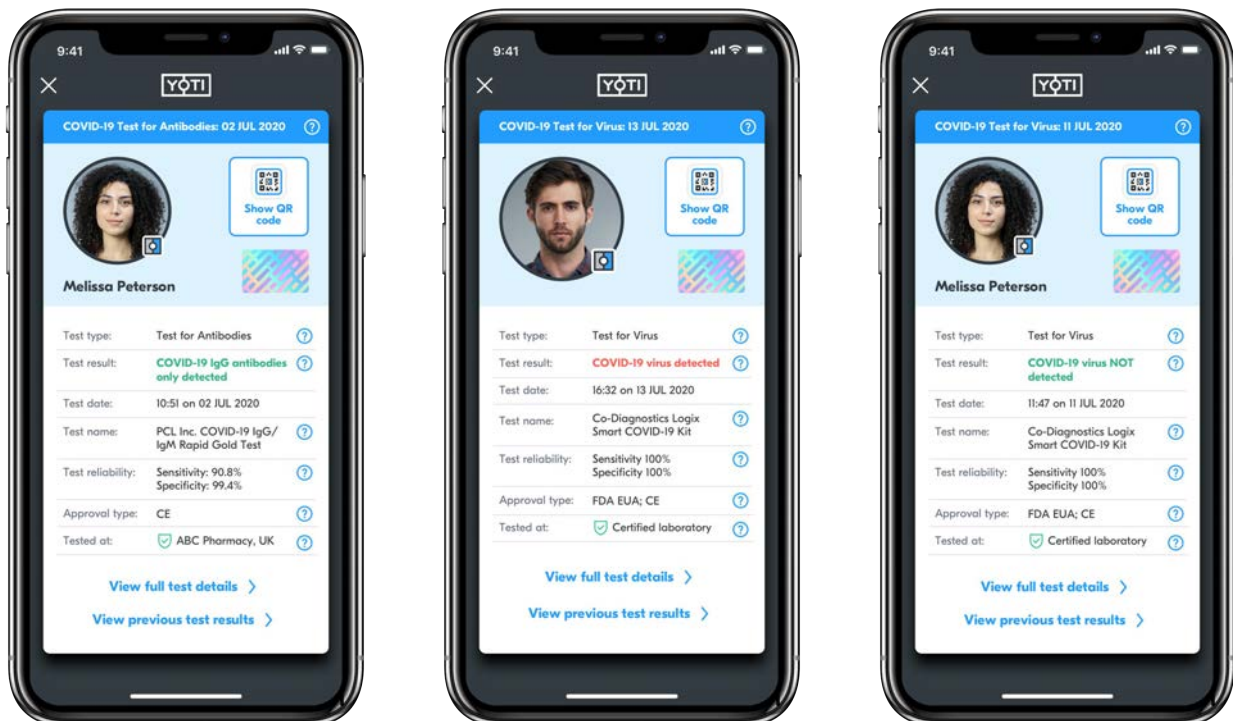


Figure 2. Example screens of test result credentials.

Credential use:

- Relying parties (verifiers) can request that the user proves their test status before granting access to, say, a place of work. This can happen online / remotely, or in person. Verifiers can check the digital signature on the credential to ensure that it is cryptographically valid, without contacting the issuer.
- Online, individuals can prove their test status remotely by sharing their Verifiable Credential with a relying party. Businesses can request that the user authenticates with their biometrics in Yoti - to prove that the rightful owner of that Yoti is using the account - without the user's photo being shared. The business requesting the credential (the verifier) does not need to contact the issuer, so preserving privacy.
- In person, Yoti can show a visual representation of the user's test status credential, incorporating a QR code which allows the authenticity of that visual representation to be instantly verified, without any personal details being shared (Figure 3).
-

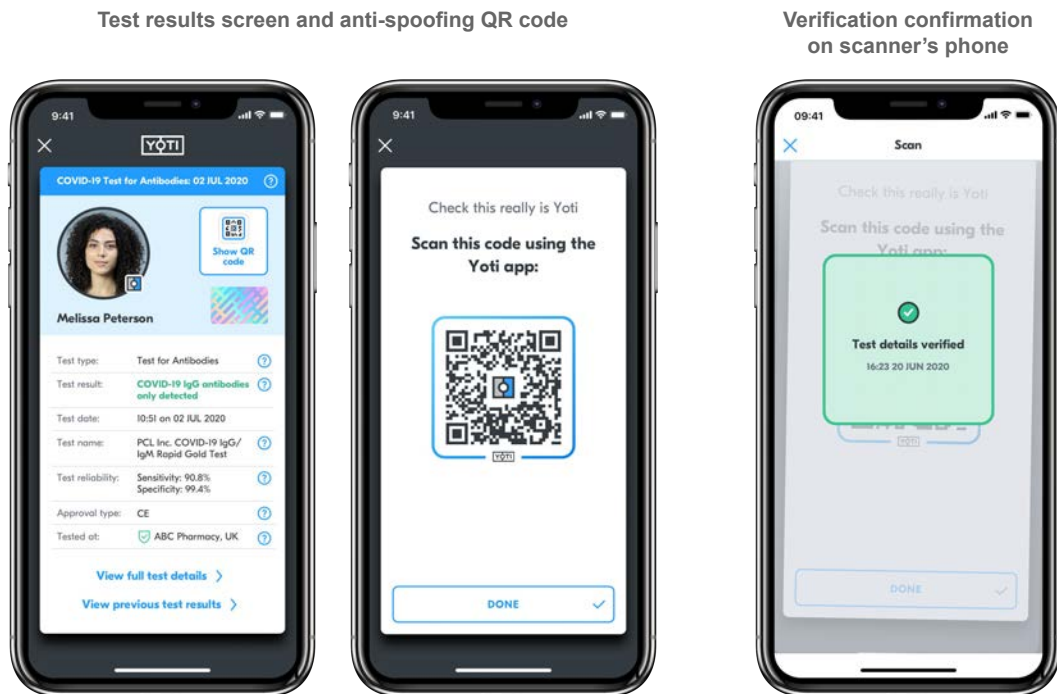


Figure 3. Example screens for anti-spoofing user flow.

Appendix 2 - Yoti's Ethical Framework and Guardian Council

Yoti has developed an Ethical Framework and put in place the Yoti Guardian Council, an external oversight board to ensure the company maintains its ethical integrity. More can be read about it [here](#).

Yoti's Founding Core Principles

1. Always act in the interest of our **users**
2. Enable **privacy** and anonymity
3. Keep sensitive data **secure**
4. Be **transparent** and **accountable**
5. Encourage personal data **ownership**
6. Keep our community **safe**
7. Make Yoti available to **anyone**

Accessibility

Social inclusion is an important issue for Yoti. Yoti is free for individuals to use.

Languages

The Yoti app is currently available in English and French. Spanish will be introduced by the end of May. If demand for Yoti grows strongly during May to July 2020, we will invest in making Yoti available in further languages.

We will also publish the textual copy for the Yoti app on the web so that volunteers in some countries can prepare first drafts of the Yoti app in languages they believe individuals will find it useful to use Yoti. Yoti will then pay for a second person to review the copy.

If there is significant demand, we are prepared to work with not-for-profits to enable organisations to offer a 'Key' solution for those without smartphones to store and present their Covid-19 health test results.

Yoti Keys

Yoti Keys are NFC-enabled tags which can securely hold information, such as someone's digital identity. As a result of extensive research across Africa and SE Asia, we have been developing a simple, Android-based app which allows Keys to be written, read and erased from a mobile phone or tablet. There is no need for expensive equipment, and no need for connectivity. Participants do not need a device of their own to enrol in a Keys-based project - written Keys are PIN protected and handed over to project participants to present each time they need to verify who they are, or any other attributes related to their identity.

The tablet app is forms-based, which allows organisations to customise the information they write to the Keys. It is also open source, allowing organisations to make changes to the code base so that custom functionality can be added. As part of our COVID-19 Pledge, access to the Keys app and code is free to any organisation working on a response, and we are able to donate a number of Keys to projects wishing to test, evaluate or deploy the technology.

You can read more about our offline Keys research [here](#).

Appendix 3 - Disclosure of Covid-19 Test Results

Next to each test attribute there is a 'help icon' which the user can click for further information on any test attribute (Figure 4).

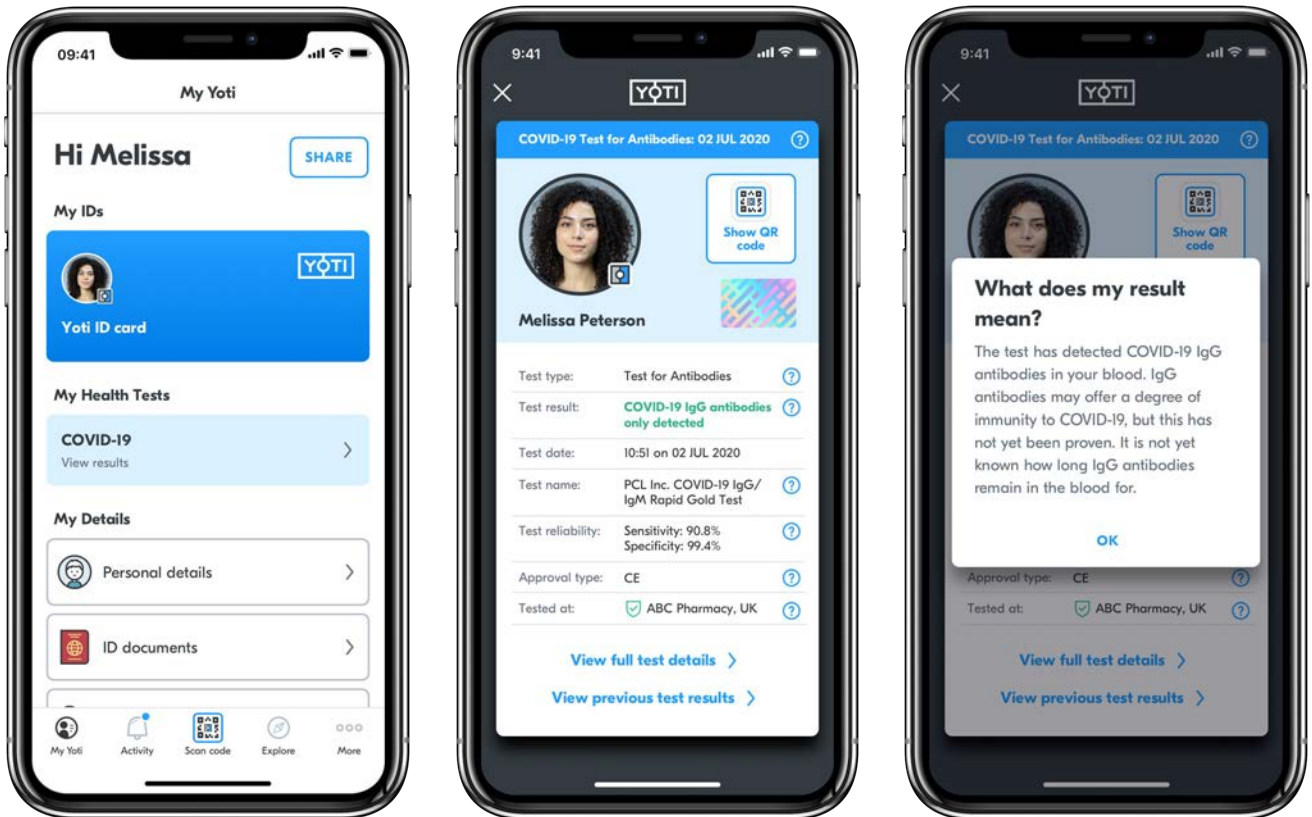


Figure 4. Example screens demonstrating help icon functionality.

We split test results into two types:

- 1) Detection for viral genetic material (RNA) or viral antigen are 'Test for Virus'
- 2) Detection of IgM or IgG antibodies are 'Test for Antibodies'

Table 1 below demonstrates some of the linked help icon text in the various test displays:

Test type	Result	Result summary	Result detail
Antibody Test	IgG only positive	"COVID-19 IgG antibodies only detected"	The test has detected COVID-19 IgG antibodies in your blood. IgG antibodies may offer a degree of immunity to COVID-19, but this has not yet been proven. It is not yet known how long IgG antibodies remain in the blood for.
	IgG and IgM positive	"COVID-19 IgG and IgM antibodies detected"	The test has detected both COVID-19 IgG and IgM antibodies in your blood. IgG antibodies may offer a degree of immunity to COVID-19, but this has not yet been proven. It is not yet known how long IgG antibodies remain in the blood for. IgM antibodies are usually produced in the early phase of infection and then decline once IgG antibodies are produced. Having IgM antibodies may suggest that the infection was recent, and that you may still be able to infect others. It is not yet known how long IgM antibodies remain in the blood for. You should self-isolate and contact your local health authority for advice on what to do next.
	IgM only positive	"COVID-19 IgM antibodies only detected"	The test has detected COVID-19 IgM antibodies in your blood. IgM antibodies are usually produced in the early phase of infection and then decline once IgG antibodies are produced. Having IgM antibodies may suggest that the infection was recent, and that you may still be able to infect others, especially if IgG antibodies have not yet been produced/detected. It is not yet known how long IgM antibodies remain in the blood for. You should self-isolate and contact your local health authority for advice on what to do next.
	No positive results	"No COVID-19 antibodies detected"	The test has NOT detected any COVID-19 IgG or IgM antibodies in your blood. This may suggest that you have not previously been infected with COVID-19 and so have not produced any antibodies to the virus. However, it is not yet known how long any antibodies that are produced by the body in response to infection by the virus will remain in the blood.
Viral Antigen Test	Positive	"COVID-19 antigen detected"	The test has detected the presence of the COVID-19 virus in your sample. This suggests that you have the COVID-19 virus and may be at risk of infecting others. You should self-isolate and contact your local health authority for advice on what to do next.
	Negative	"COVID-19 antigen NOT detected"	The test has NOT detected the presence of the COVID-19 virus in your sample. This suggests that you do not currently have the COVID-19 virus.
RT-PCR Test (Test for viral genetic material)	Positive	"COVID-19 RNA detected"	The test has detected the presence of the COVID-19 viral genetic material (RNA) in your sample. This suggests that you have the COVID-19 virus and may be at risk of infecting others. You should self-isolate and contact your local health authority for advice on what to do next.
	Negative	"COVID-19 RNA NOT detected"	The test has NOT detected the presence of the COVID-19 viral genetic material (RNA) in your sample. This suggests that you do not currently have the COVID-19 virus.

Here below is an example of the linked text for the help icon using 'Test Reliability'.

"No health test is 100% reliable all of the time. Two measures of the reliability of a health test are called Sensitivity and Specificity.

Sensitivity represents the proportion of people with the antibodies in whom the test is positive. In other words, the true positive rate. If a test is not very sensitive, it may miss out on detecting that someone has antibodies and indicate that they do not, when in reality they do (i.e. a false negative result).

Specificity represents the proportion of people without the antibodies in whom the test is negative. In other words, the true negative rate. If a test is not very specific, it may falsely tell someone that they have antibodies to COVID-19 when in reality they do not (i.e. a false positive result). This type of error may be of particular concern in COVID-19, as it might reassure someone that they have antibodies and have some immunity to infection, when in reality they do not have those antibodies. It is not yet known whether having antibodies for COVID-19 offers immunity and prevents future infection, and if so, for how long that immunity may last.

Negative results do not preclude SARS-CoV-2 infection (COVID-19 is the disease caused by the SARS-CoV-2 virus) and should not be used as the sole basis for patient management decisions. False positive results for IgM and IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes. At this time, it is unknown for how long IgM or IgG antibodies may remain following infection."

Where Yoti has further details relating to a test product's reliability, this is shared transparently, as below using the PCL finger prick antibody test as an example:

Details of PCL test reliability:-

When compared to people who have had COVID-19 (as confirmed by a test for the viral genetic material (RT-PCR) 10 days prior), this PCL test has a Sensitivity of 90.8% and a Specificity of 99.4% (if both IgG and IgM are detected); a Sensitivity of 87.4% and a Specificity of 99.4% (if only IgG is detected); and a Sensitivity of 70.6% and a Specificity of 99.9% (if only IgM is detected).

When compared to an ELISA antibody test (ELISA is a gold-standard laboratory-based antibody test), this PCL test has a Sensitivity of 93.4% and a Specificity of 99.2% (if both IgG and IgM are detected); a Sensitivity of 83.6% and a Specificity of 99.2% (if only IgG is detected); and a Sensitivity of 75.7% and a Specificity of 99.8% (if only IgM is detected).

Appendix 4 - Supplementary material on “COVID-19 testing”

1. **ADA Lovelace** [‘Rapid Evidence Review Exit through the App Store?’ A rapid evidence review on the technical considerations and societal implications of using technology to transition from the COVID-19 crisis](#)
2. **Harvard University Edmond J. Safra Center for Ethics & ID2020 COVID-19 Rapid Response Impact Initiative White Paper 10** [Immunity Certificates, if we must have them, they must be right](#)
3. FPF [Privacy and Pandemics: A Thoughtful Discussion](#)
FPF [A Practical Path Toward Genetic Privacy in the United States](#)
4. IAPP collated [DPA guidance on COVID-19](#)
5. [Imperial College COVID-19 Response Team](#)
6. [Our World in Data \(website resource, not a report, but comprehensive\)](#)
7. [The path to mass testing in the UK, Tony Blair Institute](#)
8. [‘Developing antibody tests for SARS-CoV-2’ from The Lancet](#)
9. [Future Agenda Proof of Immunity](#)

We recognise that there will be additional sources to add here as the scientific knowledge of COVID-19 continues to evolve.



To find out more visit
yoti.com