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PRE-SCREENING COVID-19 IgG/IgM Test Cassette Analytical testing & tracing

SCIENCE TO MEDICINE

2020 INFORMATION

Canada | United States | China | Europe

1 COVID RAPID TEST KITS / TRACING

2 CLINICAL SUMMARY

3 CERTIFICATIONS

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COVID-19 RAPID TEST KITS & TRACING

01

COVID-19 ANTI-BODY RAPID TESTING

Canada | United States | China | Europe

The COVID-19 IgG/IgM Test Cassette is an in vitro immunoassay for the direct and qualitative detection of anti-SARS-CoV-2 IgM and anti-SARS-CoV-2 IgG in human whole blood, serum, or plasma as an aid in the diagnosis of COVID-19. The test is for professional in vitro diagnostic and point of care use only.

Certification

European CE certified

FDA APPROVED
POINT OF CARE & VITRO DIAGNOSTIC

THE 1st FDA APPROVED
POINT OF CARE EU ANTIBODY TEST ISSUED

World Health Organization

*WHO urges world to '**test, test, test**' for COVID-19*

COVID-19 RAPID TEST KITS

Canada | United States | China | Europe

Benefits
of pre-screening

1. Exponentially **faster**
2. **No** Queues, **No** Wait time for results
3. Exponentially more **cost effective**
4. Early **Detection & Elimination**
5. Effort less, and **accessible** to everyone nationwide, instantly
6. Viable **precautionary step**
7. **Cost Effective**

Very Cost Effective Solution

15 MINUTES
DETECTION TIME

>No lab visits, no doctors

>**Just one finger prick of blood**

COVID TESTING METHOD

Canada | United States | China | Europe

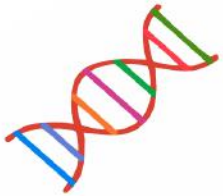
Current method

Citizen with symptoms

>

Consulates their **GP for advise**

>



Lab test conducted

>

Results Positive or Negative

Pre-screening

Concerned **Citizens**

>

No symptoms, **no need to worry**

Negative

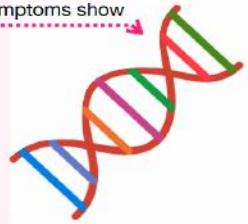
if symptoms show

Postive

Early Stage Detection

Self-conducted **Pre-screen test**

>



Lab test conducted

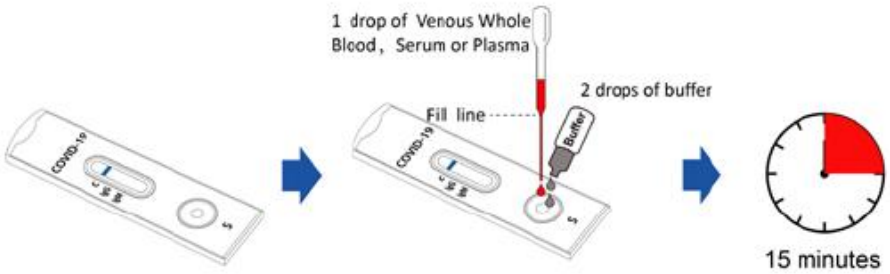
>

Final Results Positive or Negative

CE European CE certified

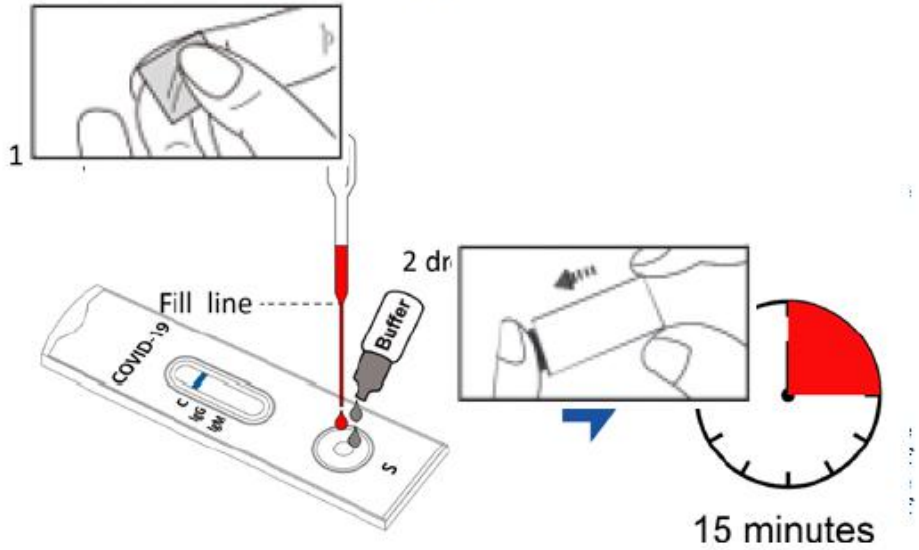
TEST KIT INSTRUCTIONS OF USE

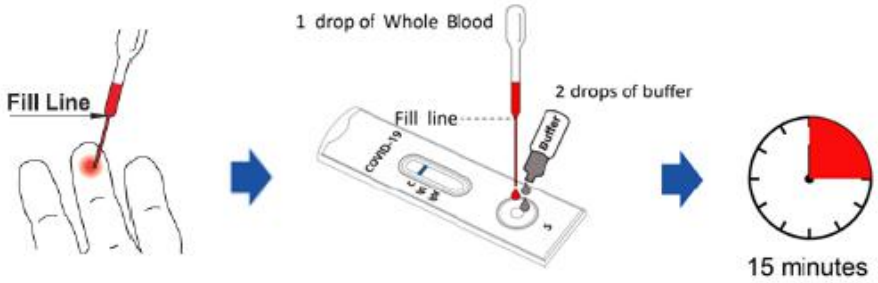
Canada | United States | China | Europe



For Fingerstick Whole Blood

a) Clean the puncture site with the alcohol prep pad provided





Detection Period

15 MINUTES

> **Easy operation** without requirement of any Doctor or Professional Nurse

> No special equipment storage and transportation conditions required

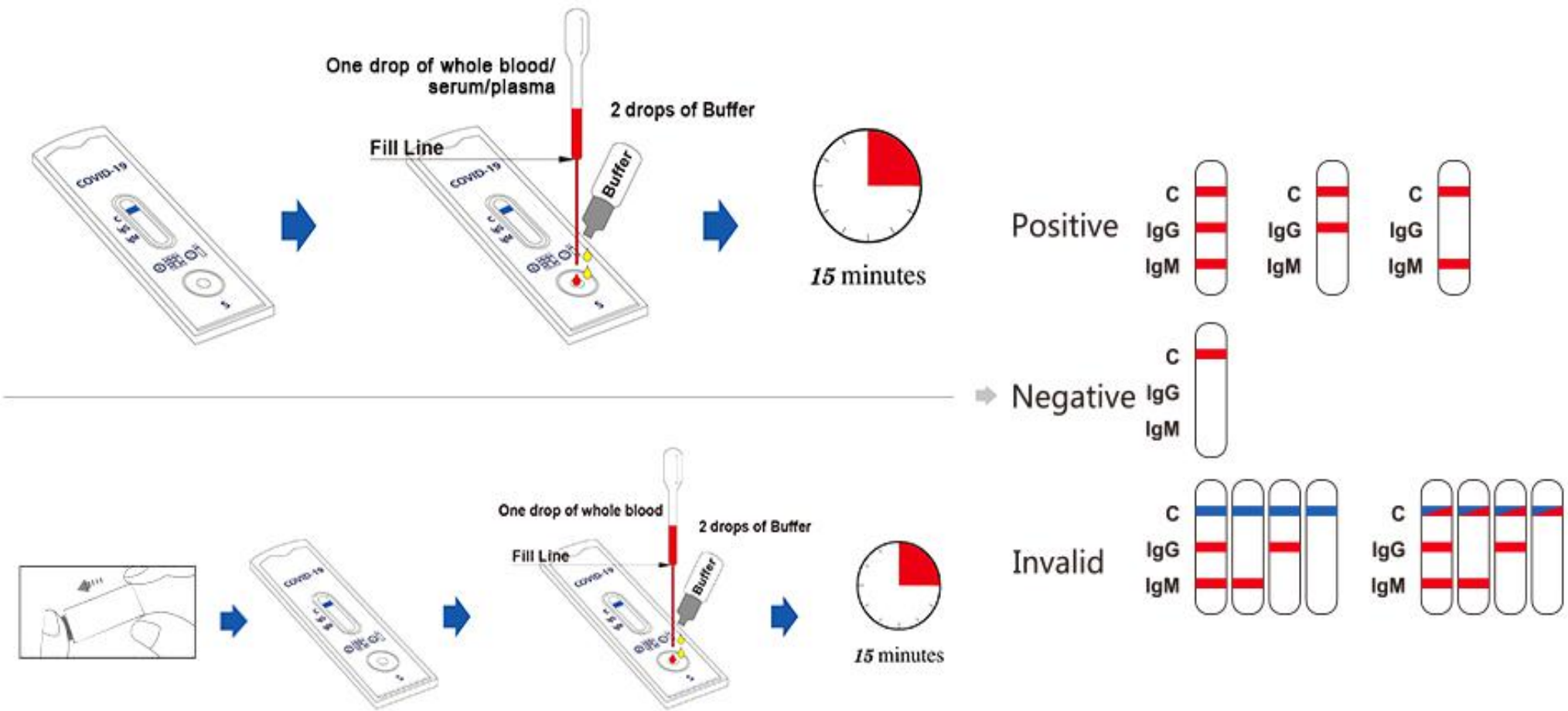
> Works with whole blood, serum, and plasma

> **Tests for 2 antibodies** IgM and IgG simultaneously

> **Instant Field screening**

100% Accurate
in detecting Corona Virus antibodies.
99.31% Accurate in ruling them out.

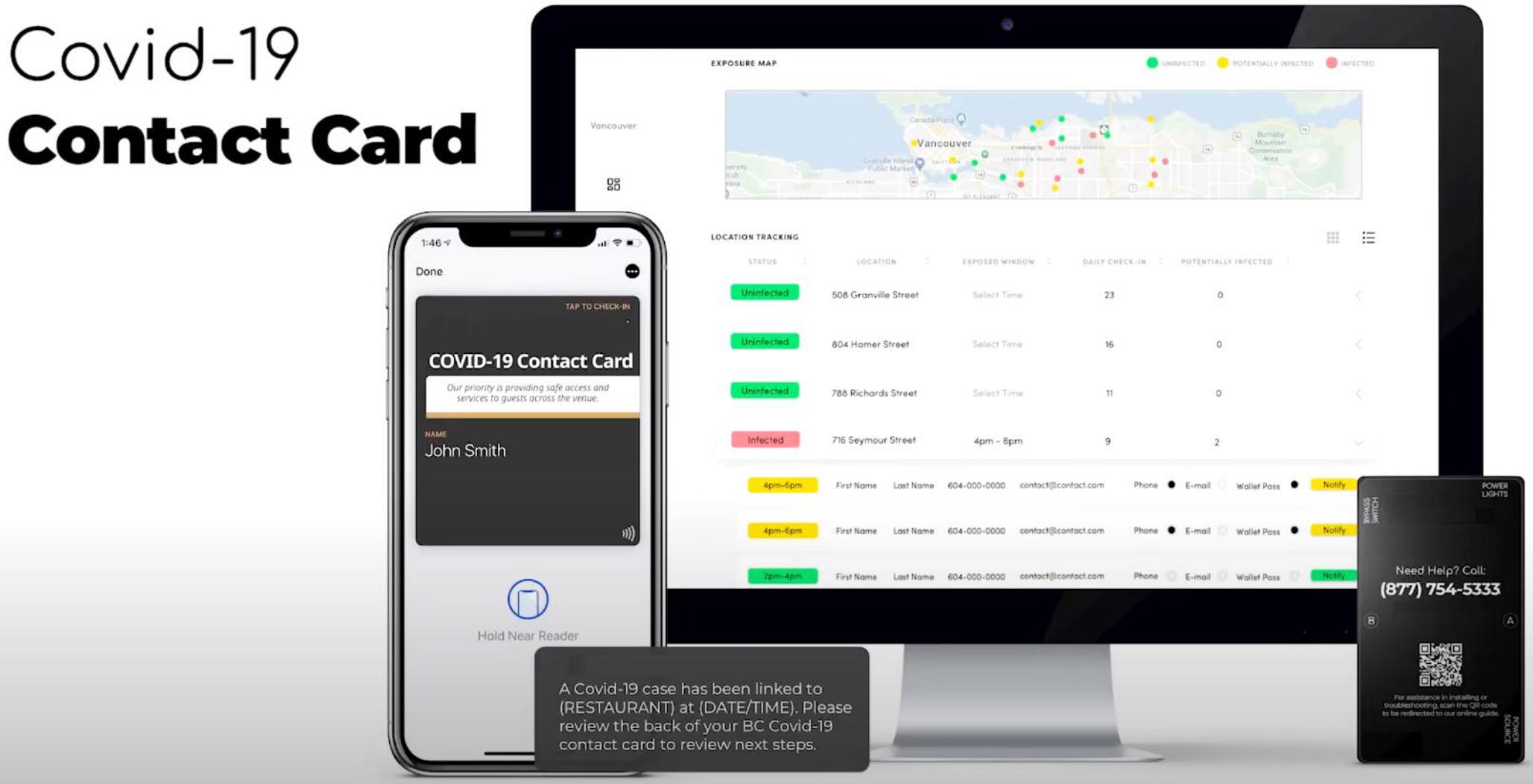
Reading the Results



Cutting edge technology embedded

Canada | United States | China | Europe

At CCS we have partnered up with our technological partner to work hand in hand to implement COVID Rapid Testing with COVID Tracing capabilities to be the cutting edge leader in testing kits.

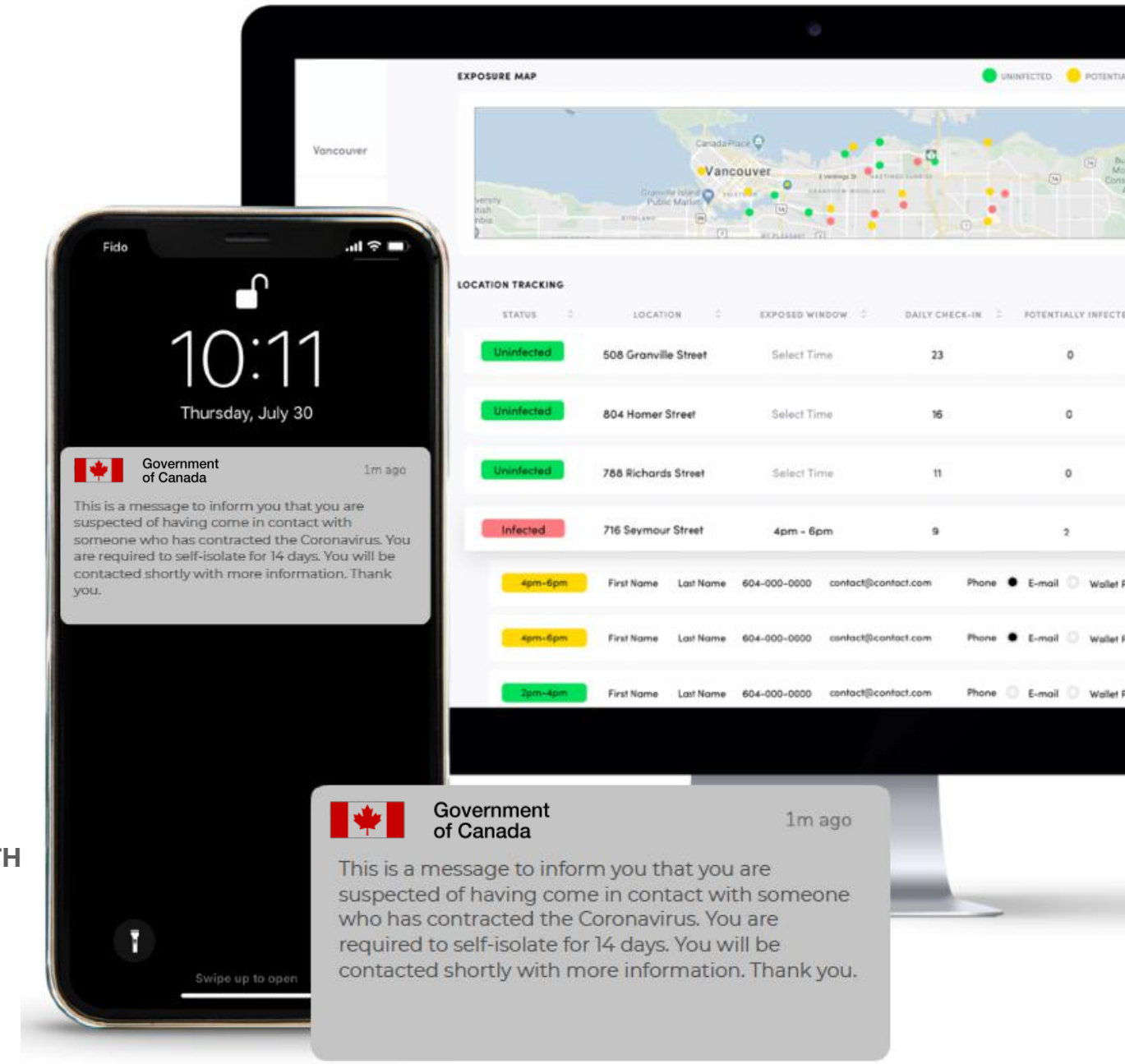


COVID TRACING WALLET PASS

Canada | United States | China | Europe

- REAL TIME DATA INPUT
- SMART ALERT SYSTEM.
- SCAN, TAP AND GO.
- SECURE WALLET PASS.
- AFFORDABLE.
- BUILDING SAFE ECONOMIES.
- UNIQUE ID PASS CODES.

EACH COVID ANTIGEN KIT WILL COME WITH THE TECHNOLOGY TO BUILD A SAFE ECOSYSTEM FREE FROM COVID-19.



COVID TRACING WALLET PASS

Canada | United States | China | Europe

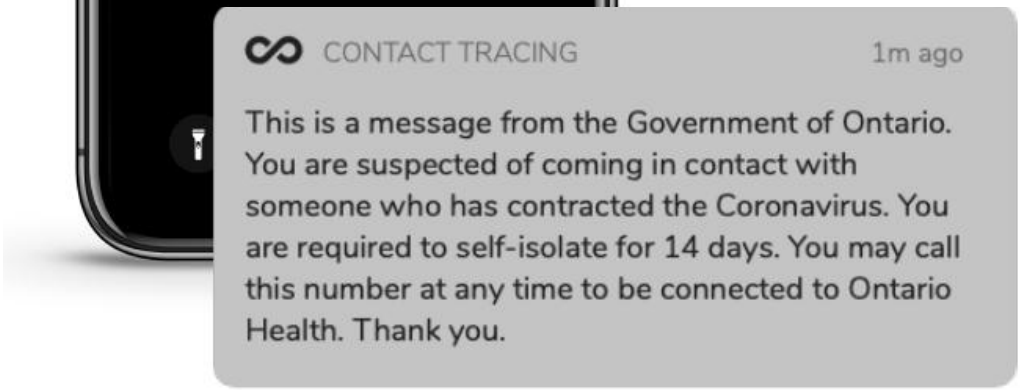
SmarTap device: place these devices at entry points for employees to check in and out.

Contact tracing card or wearables for workers: employees simply tap card or wearable on the SmarTap device to check in securely and quickly.

Fobi: Loop's artificial intelligence IoT device reads and connects all data and securely pushes to the cloud in real time.

Dashboard: platform comes with real-time reporting of potential exposure risks, based on time of check in and location. The data is de-identified and encrypted.

Automated notifications and messaging: Once risks or exposures are reported, all impacted families are notified directly to their mobile phone (can be delivered through text, email, and/or automated voice message).

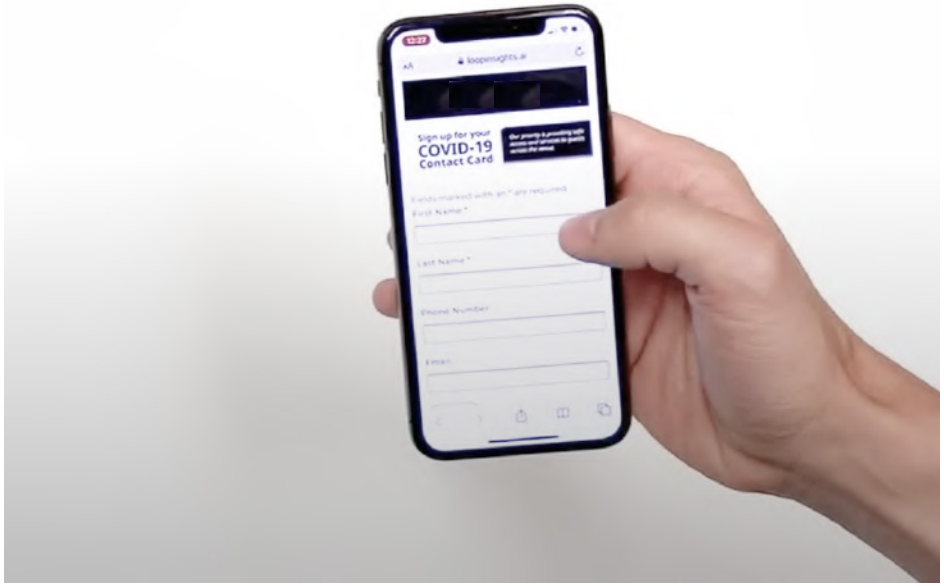


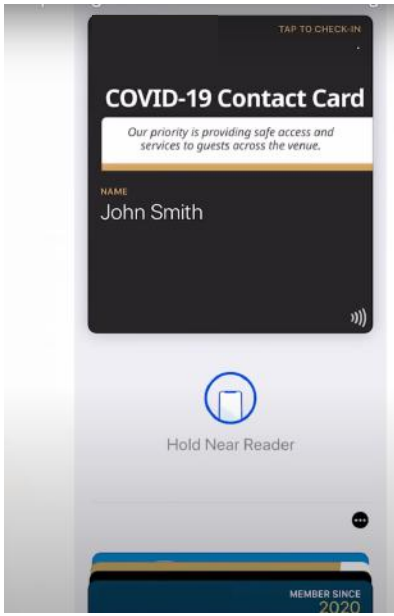
COVID TRACING 3 EASY STEPS

Canada | United States | China | Europe

2) USER FILLS OUT THE COVID TRACING FORM WILL OPEN AND EMBEDD AS A WALLET PASS ON THE USERS PHONE.

1) SCAN THE QR CODE

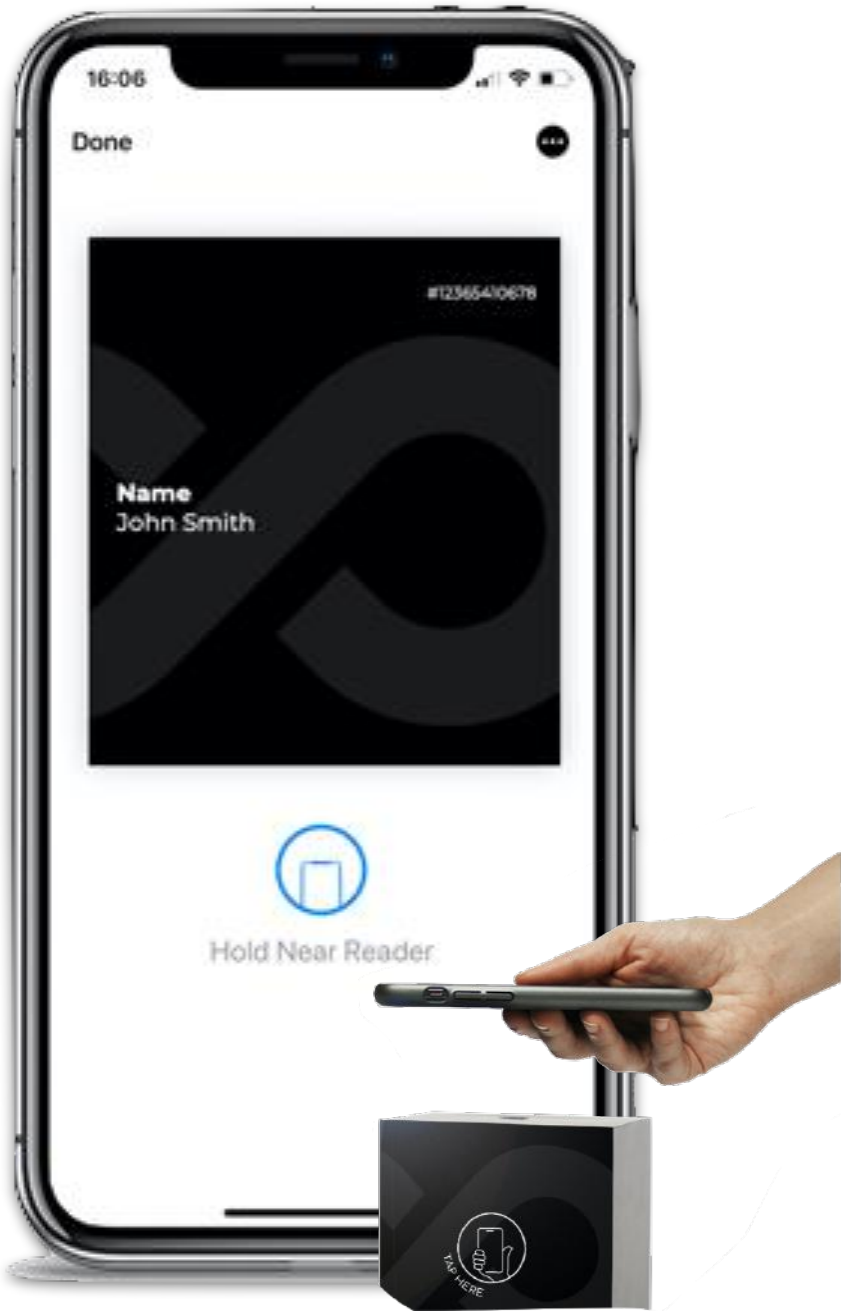




3) WHEN NEAR A STATION, WALLET PASS WILL OPEN AND DOUBLE TAP TO CHECK IN

COVID-19 TRACING & ANTIBODY KIT

Canada | United States | China | Europe



Each IgG/IgM Rapid Test provided will be be equipped with a unique QR code and will include our advanced COVID-19 Contact Tracing technology.

The Implementation of wallet pass technology with COVID-19 Rapid Testing will rapidly reduce the exposures of COVID-19 and maintain a healthy and COVID free environment.

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CLINICAL SUMMARY

02

FDA Clinical summary

Canada | United States | China | Europe

EUA Authorized Serology Test

fda.gov

COVID-19 IgG/IgM Rapid Test Device

Test: COVID-19 IgG/IgM Rapid Test Device
Technology: Lateral Flow
Target: Spike and Nucleocapsid

Performance Data

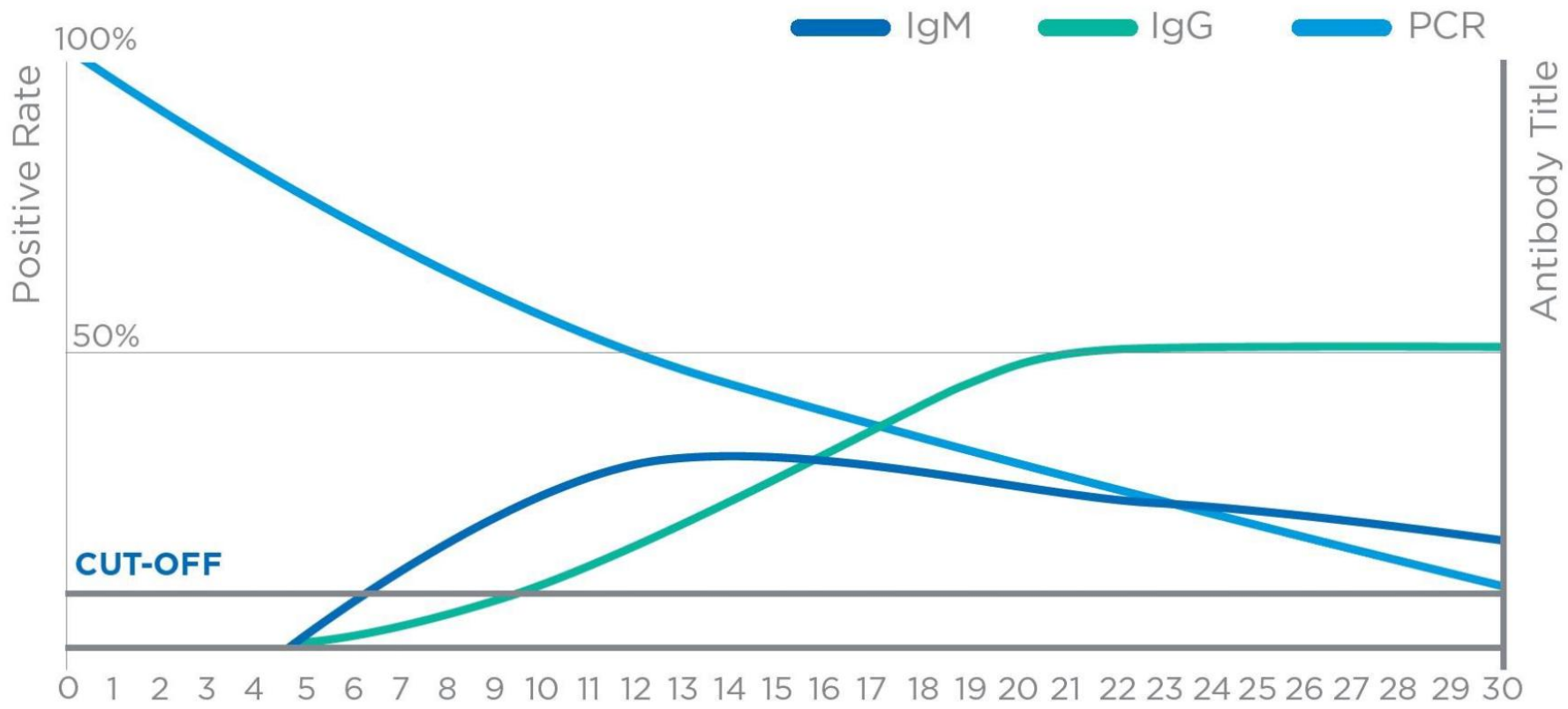
Antibody	Performance Measure	Estimate of Performance	95% Confidence Interval
IgM	Sensitivity	93.7% (74/79)	(86.0%; 97.3%)
IgM	Specificity	99.1% (225/227)	(98.6%; 99.8%)
IgG	Sensitivity	98.8% (82/83)	(93.5%; 98.8%)
IgG	Specificity	98.7% (224/227)	(96.2%; 99.5%)

FULL CLINICAL TESTING AND STABILITY STUDY AVAILABLE UPON REQUEST

ANTIBODY TIMEFRAME PRODUCTION

Canada | United States | China | Europe

The time kinetics of antibodies isotypes produced against SARS-CoV-2 compared with PCR

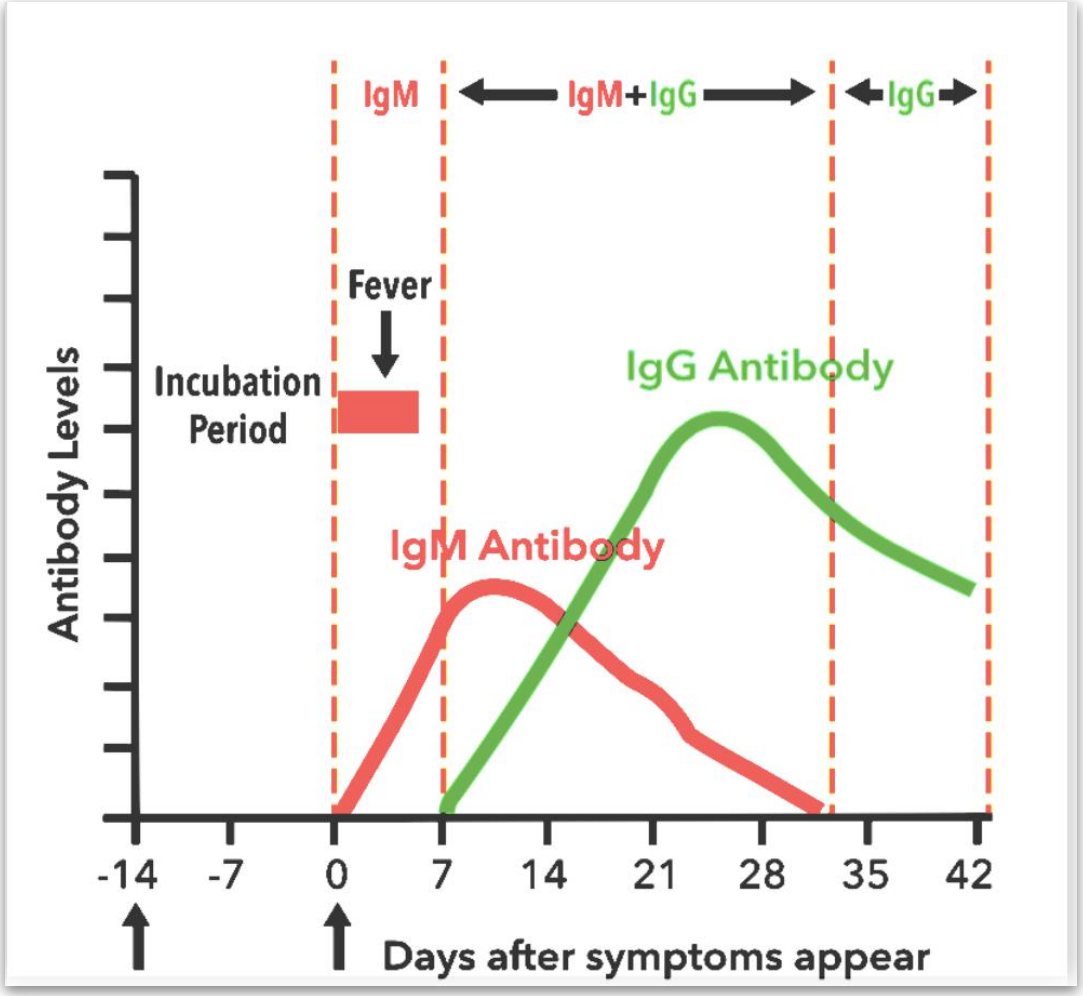


Adapted from different publications on the trend of SARS-CoV-2 positives in relation to the antibody titer IgG, and IgM with PCR of molecular tests.[1,7]

FULL CLINICAL TESTING AND STABILITY STUDY AVAILABLE UPON REQUEST

Diagnostic Process

It is widely accepted that IgM provides the first line of defence during viral infections, followed by the generation of adaptive, high affinity IgG responses for long term immunity and immunological memory. Therefore testing of COVID-19 IgM and IgG antibodies is an effective method for the rapid diagnosis of COVID-19 infection. Furthermore, detection of COVID-19 IgM antibodies tends to indicate a recent exposure to COVID-19, whereas detection of COVID-19 IgG antibodies indicates a later stage of infection. Thus, this combined antibody test could also provide information on the stage of infection.



FULL CLINICAL TESTING AND STABILITY STUDY AVAILABLE UPON REQUEST

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CERTIFICATIONS

03

DISTRIBUTION AUTHORIZATION

Canada | United States | China | Europe

Assure Tech. (Hangzhou) Co., Ltd.
Add.: Building 4, No. 1418-50, Moganshan Road, Gongshu District, Hangzhou, Zhejiang 310011, China
Tel: 0086-571-81022698 Fax: 0086-571-88865920 Website: www.diarcagent.com Email: contact@diarcagent.com

Date: 2020-11-26

Letter of Authorization

We, Assure Tech. (Hangzhou) Co., Ltd., (at Building 4, No.1418-50, Moganshan Road, Gongshu District, Hangzhou, China ,310011) herewith certify that Canadian Choice is authorized as the distributor for our products: Ecotest brand COVID-19 Antigen Rapid Test Device(Nasopharyngeal/Oropharyngeal Swab), in the interior of Peru.

1) VALIDITY:

This Letter of Authorization will be effective Nov. 26th,2020 until May. 26th,2021.

Assure Tech. (Hangzhou) Co., Ltd.

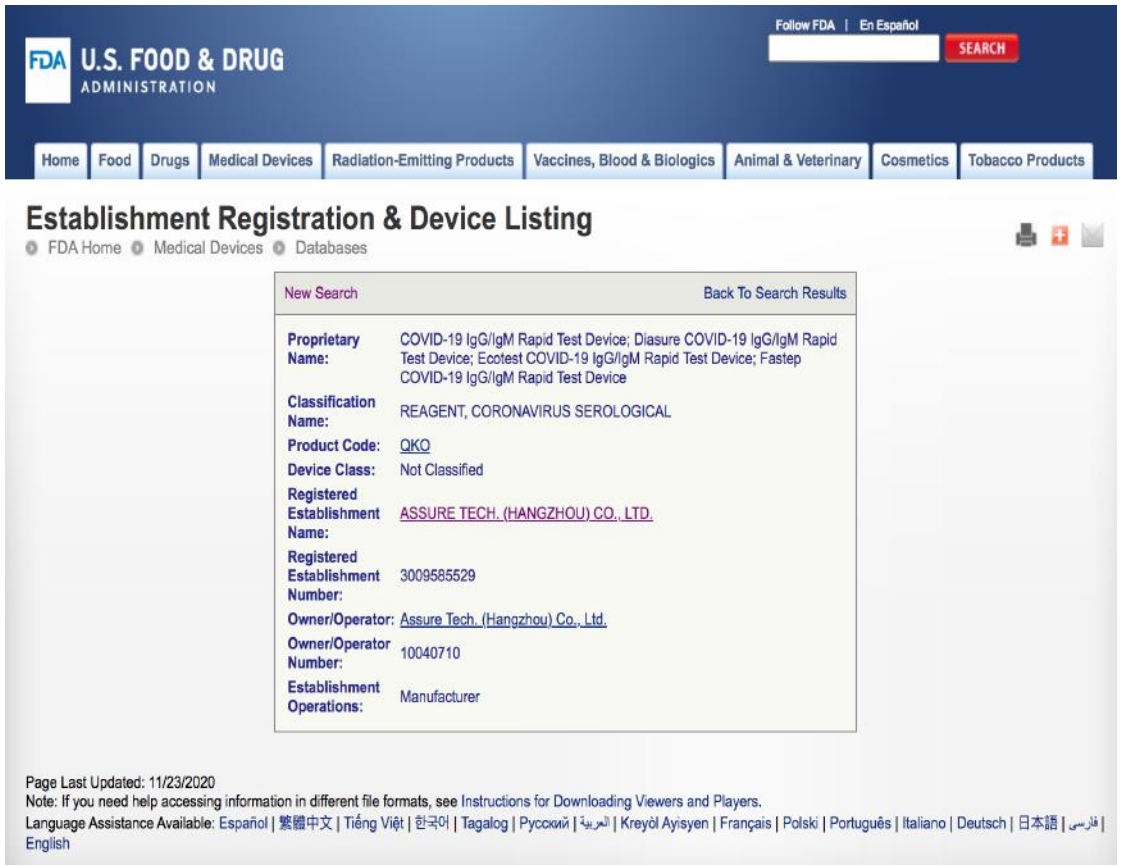
Signature:

杭州安旭科技有限公司
ASSURE TECH. (HANGZHOU) CO.,LTD.

EUROPEAN CE APPROVED

CERTIFICATIONS

Canada | United States | China | Europe



U.S. FOOD & DRUG ADMINISTRATION

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Establishment Registration & Device Listing

FDA Home > Medical Devices > Databases

New Search | Back To Search Results

Proprietary Name:	COVID-19 IgG/IgM Rapid Test Device; Diasure COVID-19 IgG/IgM Rapid Test Device; Ecotest COVID-19 IgG/IgM Rapid Test Device; Fastep COVID-19 IgG/IgM Rapid Test Device
Classification Name:	REAGENT, CORONAVIRUS SEROLOGICAL
Product Code:	QKO
Device Class:	Not Classified
Registered Establishment Name:	ASSURE TECH. (HANGZHOU) CO., LTD.
Registered Establishment Number:	3009585529
Owner/Operator:	Assure Tech. (Hangzhou) Co., Ltd.
Owner/Operator Number:	10040710
Establishment Operations:	Manufacturer

Page Last Updated: 11/23/2020

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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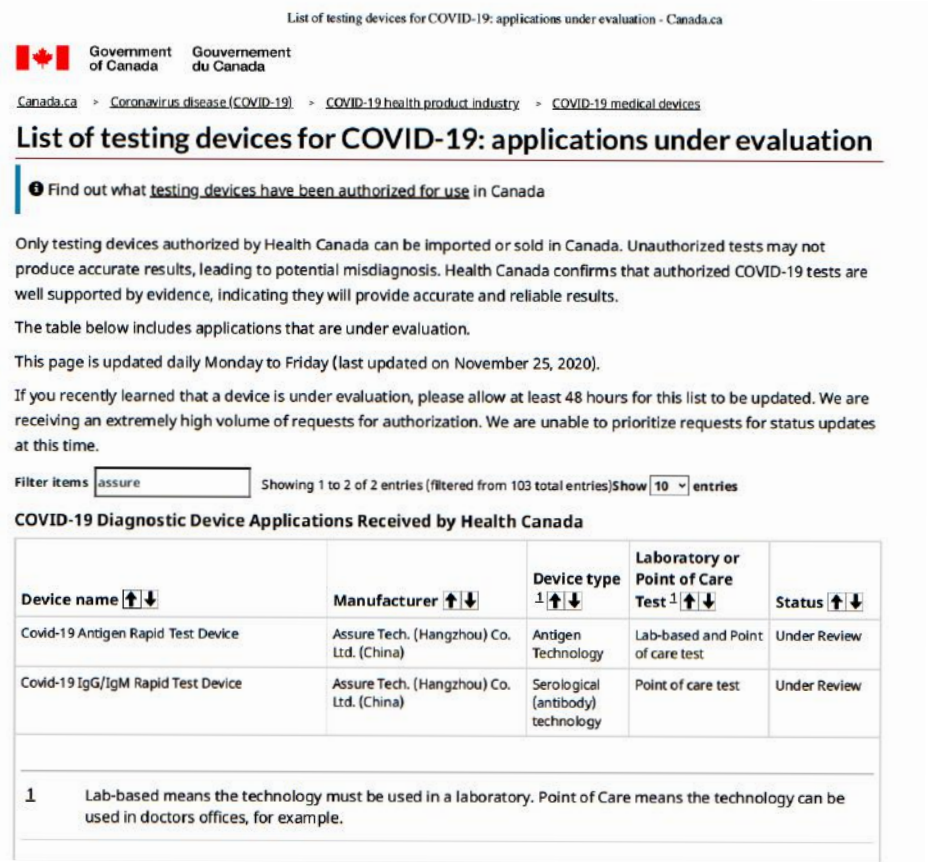

List of testing devices for COVID-19: applications under evaluation - Canada.ca

Government of Canada | Gouvernement du Canada

Canada.ca > Coronavirus disease (COVID-19) > COVID-19 health product industry > COVID-19 medical devices

List of testing devices for COVID-19: applications under evaluation

Find out what testing devices have been authorized for use in Canada

Only testing devices authorized by Health Canada can be imported or sold in Canada. Unauthorized tests may not produce accurate results, leading to potential misdiagnosis. Health Canada confirms that authorized COVID-19 tests are well supported by evidence, indicating they will provide accurate and reliable results.

The table below includes applications that are under evaluation.

This page is updated daily Monday to Friday (last updated on November 25, 2020).

If you recently learned that a device is under evaluation, please allow at least 48 hours for this list to be updated. We are receiving an extremely high volume of requests for authorization. We are unable to prioritize requests for status updates at this time.

Filter items: assure | Showing 1 to 2 of 2 entries (filtered from 103 total entries) Show 10 entries

COVID-19 Diagnostic Device Applications Received by Health Canada

Device name	Manufacturer	Device type [1]	Laboratory or Point of Care Test [1]	Status
Covid-19 Antigen Rapid Test Device	Assure Tech. (Hangzhou) Co. Ltd. (China)	Antigen Technology	Lab-based and Point of care test	Under Review
Covid-19 IgG/IgM Rapid Test Device	Assure Tech. (Hangzhou) Co. Ltd. (China)	Serological (antibody) technology	Point of care test	Under Review

1 Lab-based means the technology must be used in a laboratory. Point of Care means the technology can be used in doctors offices, for example.

HEALTH CANADA PENDING
POINT OF CARE AND LAB BASED

U.S. FOOD & DRUG ADMINISTRATION

September 23, 2020

Frank Lou
Director
Azure Biotech Inc.
Representing: Assure Tech. (Hangzhou) Co., Ltd.
5250 Gulfton St. #2C
Houston, TX 77081

Device:	Assure COVID-19 IgG/IgM Rapid Test Device
Company:	Assure Tech. (Hangzhou) Co., Ltd.
Indication:	Qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human venous whole blood (sodium EDTA), serum, plasma (sodium EDTA) and fingerstick whole blood. Intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Use of this test with all authorized specimen types is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform moderate or high complexity tests. This test is also authorized for use with fingerstick whole blood specimens only at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Dear Mr. Lou:

On July 6, based on your[1] request, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of your product,[2] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).[3]

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Assure Tech. (Hangzhou) Co., Ltd.
[2] For ease of reference, this letter will use the term "your product" to refer to the Assure COVID-19 IgG/IgM Rapid Test Device for the indication identified above.
[3] The July 6, 2020, authorization was for use of your product for qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human venous whole blood (sodium EDTA), serum, or plasma (sodium EDTA). Your product was intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. Testing was limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform moderate or high complexity tests.

On August 16, 2020, you requested to revise the Scope of Authorization to add a new indication for use. Based on that request, and having concluded that revising the July 6, 2020, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the July 6, 2020, letter in its entirety with the revisions incorporated.[4] Accordingly, your product is hereby authorized pursuant to section 564 of the Act when used pursuant to the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter.

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[5]

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is contained in the Instructions for Use (identified below).

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing recent or prior infection with SARS-CoV-2 by identifying individuals with an adaptive immune response to the virus that causes COVID-19, and that the known and potential benefits of your product when used for such use, outweigh the known and potential risks of your product; and

[4] The revisions to the July 6, 2020, letter include: 1) addition of fingerstick specimen type, 2) addition of POC laboratories as authorized laboratories, and 3) conforming updates to the authorized labeling.
[5] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 7, 2020).

Thank you

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