Fwd: Serological tests

From:	"Lucas, Stephen (HC/SC)" <"/o=canadacentdepl/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=4c97a68326de408eb28e2c1fa4543df0-stephen.l">
To:	"Barker, Tyler (HC/SC)" <tyler.barker@canada.ca>
Date:	Mon, 13 Apr 2020 22:30:24 +0000

Stephen Lucas, PhD
Deputy Minister
Health Canada

Begin forwarded message:

From: "Sabourin, Pierre (HC/SC)" <pierre.sabourin@canada.ca>
Date: April 13, 2020 at 6:23:19 PM EDT
To: "Lucas, Stephen (HC/SC)" <stephen.lucas@canada.ca>
Cc: "Aung-Thin, Pamela (HC/SC)" <pamela.aung-thin@canada.ca>
Subject: Serological tests

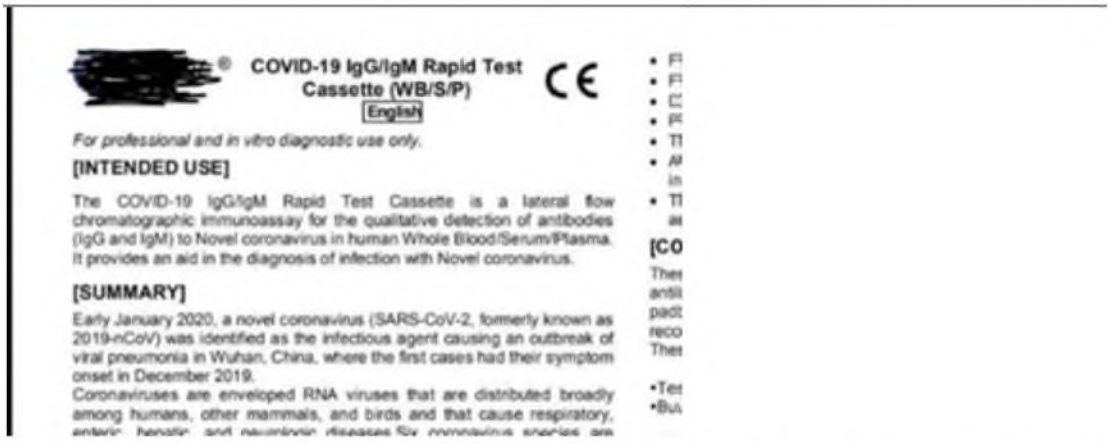
Nucleic acid-based COVID-19 diagnostic tests

- Nucleic acid amplification testing (based on Reverse Transcriptase - Polymerase Chain Reaction RT-PCR) is the gold standard technology used by the National Microbiology Laboratory (NML) and other public health laboratories across Canada and by trusted regulators around the world (like US, Australia, Japan, UK, France, Brazil) for determination of COVID-19 infection by detecting the presence of the virus itself.
- There are 12 COVID diagnostic tests authorized in Canada and they are posted on HC's website:
  https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19.html
- Out of the 12 tests
  - Most are lab-based, including Roche and ThermoFisher as examples of commercial tests well established in labs across the country.
  - two tests are portable and can be used at point of care, including the Cepheid and Spartan tests.

- Health Canada prioritized the review of diagnostic tests using nucleic acid technology first to increase the number of tests available in Canada to diagnose active and early stage infections of COVID-19.

Serological-based COVID-19 antibody detection tests

- Serological tests do not detect the virus itself. Instead, they detect the antibodies produced in response to an infection. It can take time (days to weeks) after an initial infection for antibodies to be produced. Antibodies also remain present for variable amounts of time after a viral infection is over.
- The Department has received about 100 submissions for serological tests, all at screening or under review. Health Canada is the only regulator to publish a list of received submissions for COVID tests: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-applications.html
- Most are incomplete submissions and lack validation results to support the test will perform as intended. We received submissions where the importer only provided the department with a photograph of the test label. Here is an example by Hangzhou clongene biotech :



[redacted]®

COVID-19 IgG/IgM Rapid Test Cassette (WB/S/P) CE

English

For professional and in vitro diagnostic use only.

[INTENDED USE]

The COVID-19 IgG/IgM Rapid Test Cassette is a lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG and IgM) to Novel coronavirus in human Whole Blood/Serum/Plasma. It provides an aid in the diagnosis of infection with Novel coronavirus.

[SUMMARY]

Early January 2020, a novel coronavirus (SARS-CoV-2, formerly known as 2019-nCoV) was identified as the infectious agent causing an outbreak of viral pneumonia in Wuhan, China, where the first cases had their symptom onset in December 2019.

Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds and that cause respiratory,

- Some manufacturers/importers claim falsely that there product has been authorized by the US FDA. For example, BTNX tests, discussed in the media, has not received an Emergency Use Authorization from the US FDA, but is being sold in the US under the administrative notification process. As such, the US FDA has not conducted a pre-market review the test performance.

- In addition, the submission received for this test is of poor quality. A significant request for additional information will go out to the two distributors today (April 13th), seeking information on clinical studies.

Concerns with serological testing

- The World Health Organization does not currently recommend serological assays for clinical diagnosis.
- Important questions remain unanswered about serological information. For example, how soon antibodies are produced after infection remains uncertain, though more data is being gathered every day. Also, there are outstanding questions about whether antibodies protect a person from catching the virus a second time or reduce the severity of a second infection.
- Serological tests have also been found to be unreliable by other jurisdictions. For example,
    - Correspondence with regulatory authorities in Spain indicated that quality studies performed on Tenacious tests resulted in a sensitivity of 13% - 30%. As a result, the quality studies were paused, pending request of follow up information from the manufacturer; and
    - the UK found that none of the millions of serological tests they had ordered performed as expected when assessed by Oxford University.

The way forward

- It is unlikely that those tests will be used for diagnosing COVID-19.
- As nucleic acid testing capacity reaches its peak, serological tests will play an important role in assessing which portion of the population has been infected and whether an individual has developed antibodies (usually associated with immunity) to the virus. They can also detect late-stage infection when the levels of virus in the patient have decreased.
- Serological tests will become more important as Canada moves into the phase of eliminating the virus from the population.
- Research into serological testing is ongoing within Canada and worldwide. Health Canada is working with the National Microbiology Laboratory (NML) to validate some serological technologies. We are also working with international partners to establish minimum

requirements for approval of serological tests. These steps will be crucial to enabling the approval of reliable technologies.

- Health Canada will leverage validation results obtained by the NML, when conducting its scientific review of serological-based tests.

Communications

- There is confusion around the different COVID detection/diagnosing technologies (acid nucleic-bases tests versus serological tests), how they function and for what purposes they can be used.
- The Department developed media lines and is making changes to HC's website to provide more information about our approach to serological tests to the public.