

## RE: urgent request - international approvals of antigen tests

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From:

"Jarvis, Mark" <"/o=pco-pmo-bnet/ou=first administrative group/cn=recipients/cn=m\_jarvis">

To:

"Blanchard, Dominique" <dominique.blanchard@pco-bcp.gc.ca>, "Wong-Fortin, Bonny" <bonny.wong-fortin@pco-bcp.gc.ca>, "Babad, Luke" <luke.babad@pco-bcp.gc.ca>

Date:

Wed, 23 Sep 2020 16:44:59 -0400

Attachments:

International Approvals of Antigen Tests.docx (16.8 kB)

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Hi

We didn't. HC has been overwhelmed with preparation of committee materials and have not reviewed the information we provided.

Nonetheless I have rolled up what they provided with what we found in the attached document.

I would just reiterate my caveat from this morning that the Australian reporting is clearest and most solid at this point. Everything else is the best we could scrape, but shld be treated somewhat cautiously.

mark

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**From:** Blanchard, Dominique <Dominique.Blanchard@pco-bcp.gc.ca>

**Sent:** Wednesday, September 23, 2020 4:24 PM

**To:** Jarvis, Mark <Mark.Jarvis@pco-bcp.gc.ca>; Wong-Fortin, Bonny <Bonny.Wong-Fortin@pco-bcp.gc.ca>; Babad, Luke <Luke.Babad@pco-bcp.gc.ca>

**Subject:** RE: urgent request - international approvals of antigen tests

Hi – did we get to a conclusion with HC on this? Thao has asked that our collective “final” be rolled into a Word document that can be shared with DPMO

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**From:** Jarvis, Mark <[Mark.Jarvis@pco-bcp.gc.ca](mailto:Mark.Jarvis@pco-bcp.gc.ca)>

**Sent:** Wednesday, September 23, 2020 10:23 AM

**To:** Blanchard, Dominique <[Dominique.Blanchard@pco-bcp.gc.ca](mailto:Dominique.Blanchard@pco-bcp.gc.ca)>; Wong-Fortin, Bonny <[Bonny.Wong-Fortin@pco-bcp.gc.ca](mailto:Bonny.Wong-Fortin@pco-bcp.gc.ca)>; Babad, Luke <[Luke.Babad@pco-bcp.gc.ca](mailto:Luke.Babad@pco-bcp.gc.ca)>

**Subject:** RE: urgent request - international approvals of antigen tests

Yep. Just saw your email. Connecting with Alison now. I don't think we are going to come with more on our end but will chat with Alison.

mark

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**From:** Blanchard, Dominique <[Dominique.Blanchard@pco-bcp.gc.ca](mailto:Dominique.Blanchard@pco-bcp.gc.ca)>

**Sent:** Wednesday, September 23, 2020 10:17 AM

**To:** Jarvis, Mark <[Mark.Jarvis@pco-bcp.gc.ca](mailto:Mark.Jarvis@pco-bcp.gc.ca)>; Wong-Fortin, Bonny <[Bonny.Wong-Fortin@pco-bcp.gc.ca](mailto:Bonny.Wong-Fortin@pco-bcp.gc.ca)>; Babad, Luke <[Luke.Babad@pco-bcp.gc.ca](mailto:Luke.Babad@pco-bcp.gc.ca)>

**Subject:** RE: urgent request - international approvals of antigen tests

Thanks Mark. Can you connect with Alison Mudge at the testing secretariat, so that we can cross-reference the information we have collected with what they are working on? You'll see that I sent an interim response to Thao based on what they provided this morning. We can send her another more final version when we've both concluded we have as much as we're likely to get.

Dominique

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**From:** Jarvis, Mark <[Mark.Jarvis@pco-bcp.gc.ca](mailto:Mark.Jarvis@pco-bcp.gc.ca)>

**Sent:** September 23, 2020 10:15 AM

**To:** Blanchard, Dominique <[Dominique.Blanchard@pco-bcp.gc.ca](mailto:Dominique.Blanchard@pco-bcp.gc.ca)>; Wong-Fortin, Bonny <[Bonny.Wong-Fortin@pco-bcp.gc.ca](mailto:Bonny.Wong-Fortin@pco-bcp.gc.ca)>; Babad, Luke <[Luke.Babad@pco-bcp.gc.ca](mailto:Luke.Babad@pco-bcp.gc.ca)>

**Subject:** RE: urgent request - international approvals of antigen tests

Hi Dom,

Here is what we have been able to find. Australian reporting is clearest and most solid at this point. Everything else is the best we could scrape, but shld be treated somewhat cautiously. We added India because we came some across some info in trying to uncover what has happening in SK.

mark

#### Germany

- We were not able to identify any approved tests in Germany.
- This is not to say that none are approved.
- The most recent updates (08/11/20) to the webpages of the German health ministry and the German public health agency (Robert Koch Institut) note that "Due to the early development phase and currently inadequately assessable performance in larger patient groups and situations, the WHO currently advises against the use of these tests outside of research projects".

#### Korea

- PCL Inc COV05 COVID19 Rapid Antigen Detection Kit

#### France

- According to news reports Minister of Health, Olivier Veran, announced "we expect to start using antigen tests in the Paris". The first targets are hospitals and airports. The goal was to roll out rapid antigen testing on a wider scale beginning Sept. 20. It is not clear if this has happened.
- Theradiag (France)
  - Approved for supply September 15, 2020
- Panbio COVID-19 Rapid Test
  - launched distribution September 18

#### Australia

- Access Bio Inc (USA) – CareStart COVID-19 Antigen
  - Sponsored by Australian firm Pantonic Health Pty Ltd
  - Approved for supply Sept 15 2020
- Becton Dickinson and Company (USA) – BD SARS-CoV-2 Reagents for BD MAX System
  - Sponsored by Australian firm Becton Dickinson Pty Ltd
  - Approved for supply Sept 22 2020
- BioNote Inc (Korea) – NowCheck COVID-19 Antigen Test

- Sponsored by Austrian firm Life Bioscience Pty Ltd
- Approved for supply Sept 11 2020
- Quidel Corporation (USA) – Sofia SARS Antigen FIA
  - Sponsored by Australian firm Point of Care Diagnostics Australia Pty Ltd
  - Approved for supply August 26 2020

## India

Antigen tests in India are being used as of June; 3 tests approved as of August 4

- The Indian Council for Medical Research recommended in June that those who test negative and are symptomatic, live in hot spots or work in healthcare should also have PCR tests done
- However, there is growing concern as India is reportedly using Rapid Antigen Tests for 25 – 30% of its lab work, with models that have a sensitivity between 55 and 85%;
- Mylab Discovery Solutions – Pathocatch COVID-19 Antigen Rapid testing kit
  - Approved July 23
- The other two Antigen tests are produced by companies in South Korea and Belgium. We are unable to confirm which companies.

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**From:** Blanchard, Dominique <[Dominique.Blanchard@pco-bcp.gc.ca](mailto:Dominique.Blanchard@pco-bcp.gc.ca)>

**Sent:** Wednesday, September 23, 2020 8:46 AM

**To:** Wong-Fortin, Bonny <[Bonny.Wong-Fortin@pco-bcp.gc.ca](mailto:Bonny.Wong-Fortin@pco-bcp.gc.ca)>; Jarvis, Mark <[Mark.Jarvis@pco-bcp.gc.ca](mailto:Mark.Jarvis@pco-bcp.gc.ca)>; Babad, Luke <[Luke.Babad@pco-bcp.gc.ca](mailto:Luke.Babad@pco-bcp.gc.ca)>

**Subject:** urgent request - international approvals of antigen tests

Good morning – we've received an urgent request regarding which antigen tests have been approved by:

- Germany
- Korea
- France
- Australia

I have asked Health Canada, but given how urgent it is and how many things they are scrambling on, we have been asked to do some digging as well.

Can someone see what information is available?

Thanks  
Dominique