Antigen Tests approved by other jurisdictio

From:

"Blanchard, Dominique" <"/o=pco-pmo-bnet/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=d_blanchardca4">

To:

"Pham, Thao" <thao.pham@pco-bcp.gc.ca>

Cc:

"Wong-Fortin, Bonny" <bonny.wong-fortin@pco-bcp.gc.ca>, "Jarvis, Mark" <mark.jarvis@pco-bcp.gc.ca>, "Babad, Luke" <luke.babad@pco-bcp.gc.ca>

Date:

Wed, 23 Sep 2020 10:12:07 -0400

Good morning Thao – in response to the question from DPMO regarding which antigen tests have been approved by other jurisdictions, Health Canada has provided the following. They are continuing to dig, as are Mark and Luke (copied here), but this is what they know so far:

Australia

• Australia approved 3 antigen tests for use at the point-of-care by specified health professionals.
    1. CareStart COVID-19 Antigen (Point of care test): Manufacturer: Access Bio Inc. (USA) – September 15, 2020
    2. NowCheck COVID-19 Antigen Test (Point of care test): Manufacturer: BioNote Inc (Korea) – September 11, 2020
    3. Sofia SARS antigen FIA (Point of care test): Manufacturer: Quidel (USA) – August 26, 2020
• So far, they have not set any minimum sensitivity requirements for these tests require that the performance claims and test limitations are made clear in the instructions for use provided with the tests.
• The approved tests claimed sensitivities varying from 88.37% to 96.7% for testing performed within 5-7 days of onset of symptoms.

UK

• UK continues to work on the development of target product profiles (TPPs) for various types of diagnostic test, but has not yet completed for antigen tests.

Germany/France

• As for Germany and France, in the EU – medical devices are not regulated by the member states individually. Manufacturers must obtain a CE mark by a third party notified body that has been designated in one of the member states to carry out conformity assessment of medical devices and then it can be sold in all EU member states. Currently there is not a database that would contain all these CE marked devices nor all there publically accessible databases in these countries to determine what is being sold or registered in these markets.

S.Korea

• The group responsible advises that they will have to seek the information from S Korea, as they have an old list that did not include antigen testing and the information is not publically available.