

Belliveau, Sébastien

From: Lemkay, Kevin
Sent: September 24, 2020 11:46 AM
To: PMO.F Senior Staff / personnel supérieur F.CPM; Hage-Moussa, Vanessa; Gagnon, Chantal
Cc: PMO.O.IM All Staff / Tout le personnel GE.O.CPM; MacKendrick, Andrew; Vaillancourt, Ann-Clara; Wellstead, Alex
Subject: Flag - Health Canada approved new PCR test

Good morning,

Yesterday afternoon Health Canada authorized a point-of-care PCR test, the Hyris Global Diagnostics bKIT and bCUBE. The company is based in the UK and the test is manufactured in Italy. To note, this is not a rapid (eg. antigen or saliva) test.

What it is

The bKIT is a point-of-care PCR test that runs on the bCUBE, a small portable device that's controlled by a software called the bAPP. The bKIT consists of cartridges that are inserted into the bCUBE for testing and uses standard nasopharyngeal swabs. The device needs to be connected to the internet at least once a week to upload data and clear its local memory. One run of the test takes 1 hour 45 minutes and can assess 6 samples. Hyris is developing a second cartridge that could analyze 16 samples in the same time. It is designed for use by a trained healthcare professional at the point-of-care.

Next steps

Health plans to update the list of authorized devices on its website this late this afternoon, after Question Period, exact timing to be confirmed.

Health Canada will work with PSPC to determine procurement options, Health Canada has flagged the data uploaded from the bCUBE is stored on servers located in Ireland. While this wasn't a consideration for Health Canada, who evaluates the device for safety, effectiveness and quality, it could be a consideration for procurement as health data would leave Canada. Health Canada officials are working on this with PSPC officials on this.

Please let me know if you have questions.

Thanks,

Kevin Lemkay

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