Hage-Moussa, Vanessa

From: Theis, Rick
Sent: Thursday, September 24, 2020 8:58 AM
To: MacKendrick, Andrew; Hage-Moussa, Vanessa
Subject: Fwd: Authorization of bCUBE PoC test device September 23
Attachments: Hyris bCUBE Brief Sept 23.docx; ATT00001.htm

Literally the first I have heard of.

Begin forwarded message:

> **From:** "Saini, Sabina (HC/SC)" <sabina.saini@canada.ca>
> **Date:** September 24, 2020 at 8:49:47 AM EDT
> **To:** Rick Theis <rick.theis@pmo-cpm.gc.ca>
> **Subject: Fwd: Authorization of bCUBE PoC test device September 23**
>
> Sabina Saini
> Chief of Staff to the Minister of Health / Chef du cabinet pour la ministre de la sante
>
> Begin forwarded message:
>
> > **From:** "Lucas, Stephen (HC/SC)" <stephen.lucas@canada.ca>
> > **Date:** September 23, 2020 at 4:33:54 PM EDT
> > **To:** Minister Patty Hajdu [redacted] "Saini, Sabina (HC/SC)" <sabina.saini@canada.ca>
> > **Subject: Fwd: Authorization of bCUBE PoC test device September 23**
> >
> > This test was approved today. Info on it here.
> >
> > NML is evaluating its utility for roll-out and working with Les and PSPC on procurement options.
> >
> > Steve

Health Canada
Health Products and Food Branch
Medical Devices Directorate

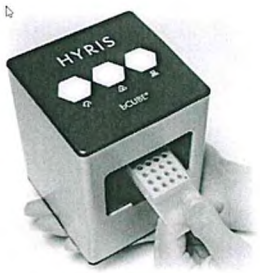
September 23, 2020

Hyris Global Diagnostics bKIT and bCUBE

Hyris – the company

- Hyris Global Diagnostics (Hyris) has no medical device licences in Canada.
- The company is based in the UK and Italy, and their test is manufactured in Italy.
- On September 18, the manufacturer indicated that it has 200 instruments in stock and with authorization, plans to ramp up to produce 1000 by January 2021. They also confirmed that they have capacity to produce 20,000 bKIT tests per month. They are in discussions with a contract manufacturer to significantly increase their output of test kits per month.

Hyris bKIT and bCUBE



- The bKIT is a point-of-care real-time PCR diagnostic test that runs on a device called the bCUBE. The kit tests for two targets in the SARS-CoV-2 genome.
- The bCUBE is a small portable device that weighs 2.3 lbs, controlled by a software called the bAPP.
- The bKIT consists of cartridges that are inserted into the bCUBE.
- Standard nasopharyngeal or nasal swabs (non-proprietary) are compatible with the test.
- One run of the bCUBE takes 1 hour 45 minutes, and can assess 6 samples. A second cartridge is in development that would be able to analyse 16 samples within that same period of time. Preparation of each sample is estimated to require approximately 4 minutes.
- The device has to be connected to the internet at least once a week in order to upload data and clear the local memory. This may mean it is not a good solution in certain remote locations with no internet access.

Intended use

- The test is carried out at point-of-care by a trained healthcare professional.
    - The company has provided evidence that the test can be used appropriately by trained operators, by providing a user study on untrained individuals. On this basis, Health Canada considers this test to be a point-of-care device.
- The kit involves steps that include micropipetting, and mixing of the sample using a vortex.
    - These additional tools will need to be deployed for use with the kit if it is to be used at point-of-care.
- The test must be stored at low temperatures before use.
- The clinical data provided by the manufacturer indicate 100% sensitivity and specificity.

Interim Order application

- This test device does not have US FDA Emergency Use Authorization, but the company has confirmed that they have made a submission and are working with the FDA toward authorization. They are also seeking a CE mark for the EU market.

Next steps

- Health Canada has authorized the device on September 23, 2020.
- The list of authorized devices will be updated on September 24, 2020 to include this authorization.
- Media lines and QP notes will be updated.