Hyris Global Diagnostics bKIT and bCUBE

Hyris and the regulatory approval of the bKIT and bCUBE

- 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 23, Health Canada issued an authorization under the Interim Order for the bKIT and bCUBE.**
- 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.

Hyris bKIT and bCUBE

- The bKIT is a point-of-care real-time PCR diagnostic test that runs on a platform 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. Preparation of each sample is estimated to require approximately 4 minutes.
- The bCUBE can process simultaneously up to 6 samples. The company indicated developing a new version that will process up to 16 samples, with no hardware change.
- 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.
- Clinical evidence from the manufacturer indicates **100% sensitivity and specificity**.
- More details on the test can be found at: http://hyris.net/index.php/covid-19

Intended use

- The test is carried out at point-of-care by a trained healthcare professional or a trained operator.
- The test is intended for use in patients who are suspected of COVID-19 infection.
- 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.