

BTNX update - 14 October

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Hello, Bonjour, Pierre, Manon,

BTNX antigen test (not US FDA authorized, manufactured in China/Canada)

Regulatory update

- Health Canada has been engaging with BTNX on an ongoing basis.
- On September 30th, a call took place with the company who informed us of their intention to file an application for antigen test. Regulatory guidance was shared and details about the priority given to antigen tests was discussed.
- A submission was received on October 6.
- The screening of the application was completed on October 8, and as a result of the file having passed the screening stage, an automated email was generated advising the company that they could expect to hear from Health Canada within our service standard of 40 days.
- This service standard for COVID applications is published on [Health Canada's website](#) and is automatically communicated to applicants of any file that passes the screening stage, regardless of the priority status of the file.
- Given that this file is for an antigen test, efforts are being made to review the file in priority, as soon as possible. We will communicate with the company within a short period of time, most likely to share questions arising from the first review of the application.
- This application is currently under review.

Assessment by the National Microbiology Laboratory (NML)

- The company committed to sending 200 samples for testing to the NML.
- NML received the samples and has completed their evaluation. A report is to be sent to Health Canada the week of Oct 13. The NML data will be considered in the context of Health Canada's scientific review.

David