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A	Executive Director, Medical Device Evaluation Bureau
	MDD
FROM	Emily Hollink
DE	Medical Device Directorate

Application Information Information de soumission			
Application ***Soumission*** 320087	**Name of device** ***Nom de l'homologation*** ID NOW COVID-19	**Licence Number** ***No. de l'homologation*** N/A	**Risk Class** ***Classe de l'instrument*** 4
Application Type ***Type de soumission*** Application under IO	**Licence Type** ***Type d'homologation*** Test Kit	**Manufacturer** ***Fabricant*** ABBOTT DIAGNOSTICS SCARBOROUGH, INC.	**Company ID** ***No. d'entreprise*** 150768

Test Setting	Both Lab and POC

1 Background/*Antécédents*

The application for the ID NOW COVID-19 Assay was reviewed under the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19. This Interim Order allows the Department to issue expedited authorization for sale or import of medical devices to deal with the current significant risk of COVID-19 to the health and safety of Canadians.

The information submitted was evaluated based on the Interactive Review Template for Molecular-Based Tests for SARS-CoV-2 that causes COVID-19, issued by the US FDA on July 28, 2020.

The ID NOW COVID-19 Assay received a US FDA Emergency Use Authorization (EUA) on March 27, 2020. The US authorization includes point of care use outside of a laboratory setting.

2 Intended Use

ID NOW COVID-19 assay performed on the ID NOW Instrument is a rapid molecular *in vitro* diagnostic test utilizing an isothermal nucleic acid amplification technology intended for the

qualitative detection of nucleic acid from the SARS-CoV-2 viral RNA in direct nasal, nasopharyngeal or throat swabs from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory samples during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses.

Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with different authorized or cleared molecular tests. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

The ID NOW COVID-19 test is intended for use by medical professionals or trained operators who are proficient in performing tests using the ID NOW Instrument in laboratory and point of care settings.

3 Discussion/*Évaluation*

The information provided meets the minimum to authorize the ID NOW COVID-19 Assay under the Interim Order.

The Abbott ID NOW instrument has a Class III medical device licence in Canada (95748). This amendment includes a new software version to add the ID NOW COVID-19 Assay.

The manufacturer holds a valid MDSAP Certificate.

While most COVID-19 diagnostic tests target two genes, the design of the ID NOW COVID-19 Assay targets a single gene in the SARS-CoV-2 virus. This is same test design as licensed ID NOW tests for influenza A and B. Given that this presents a risk for viruses that mutate frequently, Abbott manages this risk by conducting analyses multiple times per week; a condition will require notification to Health Canada in the event that a mutation is found.

Results of an in silico analysis show high overlap with eight organisms. However, these organisms are unlikely to generate a false positive result because of the test design.

Software validation was provided to support addition of the test, and assay-specific studies included limit of detection and inclusivity. Wet testing for cross-reactivity is pending and will be the subject of a condition.

Real-time stability studies are ongoing.

Clinical performance was initially assessed using 30 contrived positive samples, with most of them near the limit of detection, and 30 negative samples; all results were as expected. Following use in the US, a study published in the Journal of Clinical Microbiology compared the ID NOW COVID-19 Assay to the Xpert Xpress (authorized in Canada). When strong positive samples were assessed, there was good positive percent agreement for nasopharyngeal

samples in viral transport media. However, weak positive samples had only a 33% agreement when diluted. Similar results were demonstrated for dry nasal swabs used with the ID NOW COVID-19 Assay, with a positive percent agreement of 54.8%. Assessment of the raw data confirmed that the disagreement occurred in weakly positive samples.

While the manufacturer disputes these results, the US FDA has required labelling updates that communicate the test is intended for use in symptomatic individuals, within seven days of the onset of symptoms. This reflects the scientific knowledge available, which suggests that the virus is produced in larger quantities during this time. The same labelling will be used in Canada.

An additional study to provide evidence of clinical performance was initiated for nasal swab specimens, and interim results were shared: Positive agreement was 92.9% (157/169), and negative agreement was 98.2% (671/683) out of a total number of 852 samples. The interim data has been included in the labelling, and a condition has been added to request the final clinical study report for review, once completed. A condition will be added to request clinical data using nasopharyngeal specimens be provided within 3 months.

Given that the instrument was previously authorized for point-of-care use in Canada and in the US, and that the COVID-19 test follows the exact same user steps as the authorized flu test, point-of-care studies were not requested to support this authorization.

Labelling meets the minimum requirements of the Regulations, with the exception of the outer box labeling, which needs to be updated to reflect the product's new reference number, as part of quality management. This will be requested as a condition to correct before import to Canada. The limitations section indicates the possibility of false-negative results, and states that negative results should be treated as presumptive and tested with an alternative authorized molecular assay. The Public Health Agency of Canada has purchased the entire supply available for Canada, thus there is opportunity to ensure that the federal distributor is aware of the intended use.

The assay is manufactured in the US.

Based on the scientific evidence available, it is reasonable that the test will be effective for the claimed intended use. In the current context related to COVID-19 pandemic, the risks related to the use of this assay are outweighed by the benefits that will be facilitated by the authorization for sale of this assay.

4 Recommendation

Authorization of the ID NOW COVID-19 Assay under the Interim Order with the following conditions:

Before import to Canada:

1) Provide an updated outer box labelling for the ID NOW COVID-19 kit with a revised reference number.

Within 2 months:

2) To supplement information included in your application, provide the results of the "wet" cross-reactivity study with the organisms recommended in the EUA Interactive Review Template for Molecular-Based Tests for SARS-CoV-2 that Causes COVID-19, published by the USA FDA.

Within 3 months:

3) Provide a study evaluating real clinical positive (30) and negative (30) nasopharyngeal swab specimens by December 31, 2020.

When available:

4) To complete the review of the interim results already provided for a significant number of samples, provide the final study report that outlines the clinical performance using nasal swabs.
5) Provide the results of the reagent real time stability study.

If required:

6) Notify Health Canada if the routine in silico analyses detect mutations in the target detection region used in the ID NOW test.

		I concur / Je suis d'accord	
Signed in Docubridge	2020-9-30	*Signed in Docubridge*	
Emily Hollink	Date	Rosslynn Miller-Lee Director/ Directrice Medical Devices Evaluation Bureau/ Bureau de l'évaluation des instruments médicaux	Date