Health Canada
Health Products and Food Branch
Medical Devices Directorate

November 12, 2020

Roche COBAS SARS-COV-2 & INFLUENZA A/B for use in lab or at PoC on the cobas Liat System

Roche and the regulatory approval of the Roche COBAS SARS-COV-2 & INFLUENZA A/B for use on the cobas Liat System

- Roche operates under 5 different entities who hold 433 medical device licences in Canada
    - Roche Diagnostics GmbH (Germany), **379** licences for Class II, Class III and Class IV *In Vitro* Diagnostic Devices
    - Roche Molecular Systems, Inc. (New Jersey, USA), **33** licences for Class II, Class III and Class IV *In Vitro* Diagnostic Devices
    - Roche Diabetes Care GmbH (Germany), **18** licences for Class II and Class III Blood glucose monitoring devices and their accessories
    - Roche MTM Laboratories AG (Germany), **2** licences for Class II *In Vitro* Devices
    - Roche Sequencing Solutions, Inc. (California, USA), **1** licence for a Class III *In Vitro* Diagnostic Device
- Roche's first licence was issued on 1999-01-07

- In the context of the pandemic, Health Canada already issued authorizations under the Interim Order for the following tests:
    - cobas SARS-CoV-2 test (nucleic acid-based test) (March 18)
    - Elecsys Anti-SARS-CoV-2 (serology test) (June 5)
    - Cobas Sars-Cov-2 & Influenza A/B (nucleic acid-based test –lab based) (November 6)
- **On November 12, Health Canada issued an authorization under the Interim Order for the Roche COBAS SARS-COV-2 & INFLUENZA A/B for use on the cobas Liat System.**
- The **IO authorization includes conditions** the manufacturer must fulfil to maintain authorization. Applying conditions can help Health Canada expedite authorization without compromising patient safety. The conditions include:
    - When available:
        - Provide crossreactivity testing for all organisms recommended in the EUA Template in support of a respiratory specimen claim and not yet submitted (i.e. all organisms other than SARS-CoV-1).
        - Provide the results of the real-time stability study.
- The test received an Emergency Use Authorization (EUA) in the US.

Roche COBAS SARS-COV-2 & INFLUENZA A/B for use on the cobas Liat System

- This is an automated multiplex PCR test for simultaneous detection and differentiation of SARS-CoV-2, influenza A, and influenza B virus RNA. It uses nasopharyngeal and nasal swabs.
- The analyzer tests one sample at a time, the whole testing process takes about 20 minutes.
- The cobas Liat system is intended for use by health professionals or trained operators who are proficient in using the cobas® Liat® System at the point of care (POC) or in a clinical laboratory setting.

- The clinical performance of the assay is as follows:
    - With respect to SARS-CoV-2: 100% sensitivity and specificity
    - With respect to Influenza A: 98.3% sensitivity and 96% specificity in prospective samples and 98.7% sensitivty and 99.1% specificity in retrospective samples
    - With respect to Influenza B: 95.2% sensitivity and 99.4% specificity in prospective samples and 99% sensitivity and 99.5% specificity in retrospective samples
        - The Influenza A and B studies were conducting during the 2013 -2015 flu seasons.

Intended use

- The cobas® SARS-CoV-2 & Influenza A/B Nucleic acid test for use on the cobas® Liat® System (cobas® SARS-CoV-2 & Influenza A/B) is an automated multiplex real-time RT-PCR assay.
- It is intended for the simultaneous rapid in vitro qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B virus RNA in healthcare provider-collected nasopharyngeal and nasal swabs and self-collected nasal swabs (collected in a healthcare setting with instruction by a healthcare provider) from individuals suspected of a viral respiratory infection.
- It is intended for use by health professionals or trained operators who are proficient in using the cobas® Liat® System at the point of care (POC) or in a clinical laboratory setting.

Next steps

- The list of authorized testing devices will be updated on October 13, 2020 to include this authorization.
- Media lines and QP notes will be updated as necessary.
- Federal partners will be informed.

Approved by
David Boudreau
Director General
Medical Devices Directorate