Health Canada
Health Products and Food Branch
Medical Devices Directorate

November 4, 2020

Precision Biomonitoring TRIPLELOCK SARS-COV-2 TEST STRIPS

Precision Biomonitoring and the regulatory approval of the Triplelock SARS-CoV-2 Test Strips

- Precision Biomonitoring holds no medical devices licences in Canada.
- **On November 2, Health Canada issued an authorization under the Interim Order for the Precision Biomonitoring Triplelock SARS-CoV-2 Strips**
- 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:
    - Within one month:
        - Provide the complete in silico inclusivity study using all eligible SARS-CoV-2 sequences available at NCBI (https://www.ncbi.nlm.nih.gov/sars-cov-2/).
    - Within two months:
        - Provide accelerated stability study data including RNaseP target evaluation and applying a minimum of three elevated temperatures, as recommended by CLSI EP25 A:2009.
    - Within three months:
        - Provide the results of a "wet" cross-reactivity study with SARS-coronavirus, MERS-coronavirus, Bordetella pertussis and Pneumocystis jirovecii (PJP).
    - When available:
        - Provide the results of the ongoing real time stability testing of reagents.
        - Submit the ISO 13485 certificate and its report as soon as available.
- This test is a made-in-Canada solution supported by NGEN and NRC IRAP.

The Triplelock SARS-CoV-2 Test Strips

- This is a qualitative lab-based PCR test that uses nasopharyngeal swabs stored in viral transport media.
- It is for use on the Biomeme platform (IO 312839), which can analyse one sample at a time.
- Evidence of clinical performance showed 100% match with the results of an authorized test.

Intended use

- The Precision Biomonitoring TripleLockTM SARS-CoV-2 test is a qualitative RT-qPCR test for detection of novel human coronavirus from clinical-collected nasopharyngeal swabs stored in viral transport media from patients who meet COVID-19 clinical and/or epidemiological criteria for testing.
- This device is not intended for use at the point of care (near patient). For laboratory use only.

Communications

- The list of authorized testing devices was updated on November 3, 2020 to include this authorization.
- Media lines and QP notes have been updated as required only to update the total number of authorized tests.

Approved by
David Boudreau
Director General
Medical Devices Directorate