Health Canada
Health Products and Food Branch
Medical Devices Directorate

October 26, 2020

Diagnostics Biochem Anti-SARS-CoV-2 IgG ELISA Kit

Diagnostics Biochem Canada and the regulatory approval of the Anti-SARS-CoV-2 IgG ELISA Kit

- Diagnostics Biochem Canada (DBC) holds 56 medical device licences in Canada.
- In the context of the pandemic, this is the first authorization issued to DBC under the Interim Order.
- DBC is one of the 'made-in-Canada' testing devices being supported by the NRC IRAP.
- **On October 26 Health Canada issued an authorization under the Interim Order for the DBC Anti-SARS-CoV-2 IgG ELISA Kit.**
- 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 2 months of authorization, provide the results of cross-reactivity studies.
    - When available, provide real-time stability study results. Health Canada expects that stability studies will be initiated upon authorization at the latest.
- The test has not received an Emergency Use Authorization (EUA) in the US.

The Anti-SARS-CoV-2 IgG ELISA Kit

- The Anti-SARS-CoV-2 IgG kit is a lab-based serology test intended for the detection of IgG antibodies to SARS-CoV-2.
- IgG antibodies may not be detected in the first few days of infection; the sensitivity of the test early after infection is unknown.
- Clinical evidence from the manufacturer indicates **99.1% sensitivity** for PCR confirmed samples and **98.3% specificity**.
- NML assessment indicates that products meets minimum standards for sensitivity and specificity.

Intended use

- The Anti-SARS-CoV-2 IgG kit is a qualitative ELISA test intended for the detection of IgG antibodies to SARS-CoV-2 in human serum or K2/K3 EDTA plasma from the adult population.
- The assay is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.
- The assay **is not intended to be used for screening patients or as an aid for diagnosis of patients with suspected COVID-19 infection.**
- False negative results can occur in elderly and immunocompromised patients.
- The kit is intended for use by trained laboratory personnel and is for laboratory use only.

Next steps

- The list of authorized testing devices will be updated on October 27, 2020 to include this authorization.
- Media lines and QP notes will be updated as needed to reflect the increased number of authorized devices.
- Federal partners will be informed.

Approved by
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