



FOR IMMEDIATE RELEASE

Update on Molecular Diagnostic Laboratory (MDL) Registration and Accreditation

- The Bermuda Health Council continues to work with MDL in its pathway towards ISO accreditation by 31 March 2022.
- There are currently four laboratories conducting SARS-CoV-2 PCR testing to identify viral infection within the country.

(Hamilton, Bermuda 28 June 2021) – In its regulatory role, the Health Council is responsible for ensuring the accreditation of all clinical laboratories on island according to Bermuda’s Public Health (Clinical Laboratories) Regulations 2002. A clinical laboratory is defined as a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings. As such, the Council is aware of questions related to the accreditation status of the Molecular Diagnostic Laboratory (MDL).

This laboratory was originally established as a facility of a temporary nature intended to assist with the diagnosis of SARS-CoV-2 infection during the initial phases of Bermuda’s COVID-19 pandemic response. It was established through a collaboration between The Caribbean Public Health Agency’s (CARPHA) regional reference laboratory, Pan American Health Organization (PAHO), and local laboratory professionals. Given the ongoing duration of the COVID-19 pandemic response, and to ensure efficient use public health system funding, MDL has now taken on a more permanent nature, with considerations towards the expansion of its clinical laboratory and research science services. With a long term view of its operations, the Health Council has designated a pathway for MDL’s provisional registration, with criteria that the accreditation of the clinical laboratory, by an approved accreditation body, is sought and completed no later than 31 March 2022.

These accreditation standards include compliance with ISO 9001 and ISO/IEC 17025:2017, and require an independent assessment of each medical laboratory’s: personnel qualifications and competence, equipment, reagents and supplies, quality assurance, and analytical, pre-analytical, and post-analytical factors. While moving towards accreditation, MDL has gone through proficiency testing, and is regularly being monitored through local and international verification of results.

Accreditation status may be granted by the College of American Pathologists, Caribbean Laboratory Accreditation Scheme, Commission on Office Laboratory Accreditation, or Joint Commission International. In addition, other qualified accreditation bodies may be considered pending review by the Minister of Health. There are currently 11 accredited laboratories operating on island, and four laboratories conducting SARS-CoV-2 PCR testing.

Ricky C. Brathwaite, PhD, MSHS, MSBE -- CEO, Bermuda Health Council notes: “While provisional registration does provide compliance with local legislation, we recognize the need for robust technical



approval to ensure the public's sustained confidence in our laboratories, their scientific methodologies, and their testing results. The Bermuda Health Council is working with MDL's Laboratory Director, Carika Weldon -- PhD, MRSB, FIBMS to continue the laboratory's valued work in providing SARS-CoV-2 PCR results while in parallel ensuring that MDL is progressing towards achieving accreditation status. Despite the notion that we have, collectively, leveraged more than 250,000 SARS-CoV-2 PCR results from MDL -- in support of a comprehensive, effective, and progressive public health response to this pandemic -- it is still critically important that all of our laboratories and their standards can stand the rigor of international scrutiny and peer review."

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About Bermuda Health Council

Established by the Bermuda Health Council Act 2004, the Bermuda Health Council ("Health Council") is tasked with regulating, coordinating and enhancing the delivery of health services in Bermuda. Led by a Board representing a broad range of sectors in Bermuda's community, and staffed by a team of committed professionals, the Health Council works with health system stakeholders towards achieving a quality, equitable and sustainable health system.