

Performance Update on World Health Organisation SARS-CoV2 Serology Standards

HALIFAX, NOVA SCOTIA, CANADA, June 14, 2021 /EINPresswire.com/ -- MedMira Inc. (MedMira) (TSXV: MIR) announces the World Health Organization (WHO) SARS-CoV-2 serology standards testing results. The REVEALCOVID-19TM PLUS Total Antibody [PLUS] and the REVEALCOVID-19TM Nab-Y Competitive Neutralizing Antibody Test [Nab-Y] have achieved a 100% agreement.

On March 29th, 2021, the WHO announced the first International Standards for SARS-CoV-2 serology tests. These WHO standards can serve as the foundation for the calibration of tests that quantify antibodies as per the CDC's latest update on "the Interim Guidelines for COVID-19 Antibody Testing in Clinical and Public Health Settings". These panels and standards included 20/136 First WHO International Standard Anti-SARS-CoV-2 Immunoglobulin (Human); 20/B770 Anti-SARS-CoV-2 Verification Panel For Serology Assay; 20/268 1st International Reference Panel for Anti-SARS-CoV-2 Immunoglobulin; 20/162 NIBSC Anti-SARS-CoV-2 Antibody Diagnostic Calibrant; and the quality control standard, QCRSARSCoV2QC1.

According to WHO, accurate tests are key to ensure generating accurate data for studying the COVID-19 disease and interventions. Currently, a variety of molecular and serological assays are globally in use to detect SARS-CoV-2 infections and to measure an antibody response to the SARS-CoV-2 infection and to COVID-19 vaccines. In support of the global response to COVID-19, WHO has highlighted the importance of the availability of International Standards and/or reference reagents for anti-SARS-CoV-2 antibody and for SARS-CoV-2 RNA. The availability of International Standards will facilitate development, validation and assessment of the assays and allow for comparability between results from different assays, thus eventually facilitate and harmonize evaluation of diagnostics, vaccines, therapeutics and other products. Vaccines and treatments for COVID-19 are rapidly being developed and reliable assays are needed for their evaluation.

"Regulators are working diligently on creating set standards to assess and evaluate COVID-19 related products. The establishment of the WHO first International Standards play a key role in this development and MedMira has already taken the initiative to comply with these standards and demonstrate our product performance." Hermes Chan, CEO of MedMira. "We are delighted that our products have performed in such an exceptional way. Specifically, panel 20/268 contained individual panel members evaluated in a WHO international collaborative study to contain specific International Unit (IU) for the Neutralizing Antibody rating from low to high. The presence of a sufficient amount of Neutralizing Antibodies may serve to protect individuals from

developing serious COVID-19 complications, it is important to know the presence of these antibodies. Nab-Y was found to successfully determine the presence of these Neutralizing Antibodies from moderate to high level. The excellent results have further validated our product claims and we believe this will be a well-received additional support to our various applications."

MedMira will provide further updates on regulatory progress when available.

About MedMira

MedMira is a leading developer and manufacturer of Rapid Vertical Flow® diagnostics. The Company's tests provide hospitals, labs, clinics, and individuals with instant disease diagnosis, such as HIV, Syphilis, Hepatitis, and SARS-CoV-2, in just three easy steps. The Company's tests are sold globally under the Reveal®, Multiplo® and Miriad® brands. Based on its patented Rapid Vertical Flow® Technology, MedMira's rapid HIV test is the only one in the world to achieve regulatory approvals in Canada, the United States, China, and the European Union. MedMira's corporate offices and manufacturing facilities are located in Halifax, Nova Scotia, Canada. For more information visit medmira.com. Follow us on Twitter and LinkedIn.

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Markus Meile MedMira Inc. +1 902-450-1588 ir@medmira.com Visit us on social media: Facebook Twitter

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