Chief Medical Officers
Laboratory Directors
National Epidemiologists

Dear CMOs, Laboratory Directors and National Epidemiologists,

LABORATORY UPDATE 15: COVID-19 (SARS-CoV-2)

This is a new COVID-19 Laboratory Update circulated today, July 2, 2020.

We are pleased to inform you about the first Enzyme-Linked Immuno-sorbent Assay (ELISA) that specifically detects IgM antibodies to SARS-CoV-2 which has received the Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) on July 1, 2020.

The company InBios International Inc., a leading developer of diagnostic tests for emerging infectious diseases, has developed an in vitro diagnostic ELISA test for the qualitative detection of IgM antibodies to SARS-CoV-2, the virus that causes COVID-19, in human serum.

According to the technical specifications provided by the company, the kit has a sensitivity of 92.5% and specificity of 99%. In many local and national public health laboratories in the Caribbean the ELISA platform is widely available, making this new development a sustainable diagnostic alternative for use by laboratories.

A few considerations for the use of this diagnostic kit include –
Intended use: For use in diagnosing acute SARS-CoV-2 infection; an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, which may indicate recent or prior infection.

Sample requirements: serum collected 7-64 days post symptom onset to avoid false negative results

Kit components: includes a 96 well plate with all necessary reagents and controls; up to 90 unknown specimens

Turnaround Time (TAT): approximately 2.5 hours

For more specifications and information please click the link:
https://inbios.com/scov-2-detect-igm-elisa-kit/

We advise Member States to utilize the CARPHA Guidance for the Evaluation and Selection of Diagnostic Tests for the COVID-19 Response to see whether this kit meets your national requirements. Click here for the document:
Should you require further assistance please contact Dr. Gabriel Gonzalez-Escobar, Head, Laboratory Services and Networks, via email: escobaga@carpha.org or telephone: +1 868 324-0869.

Please visit our dedicated web page for the most recent updates at http://carpha.org/What-We-Do/PublicHealth/Novel-Coronavirus

We also encourage you to view our test menu at https://carpha.org/What-We-Do/Laboratory/Laboratory-Testing-Services

Yours sincerely,

[/f/Dr. Joy St. John
Executive Director

cc: Dr. Gabriel González-Escobar, Head, Laboratory Services and Networks (LSN)
Dr. Lisa Indar, Assistant Director, Surveillance, Disease Prevention & Control Division (SDPC)