Chief Medical Officers
Laboratory Directors
National Epidemiologists

Dear CMOs, Laboratory Directors and National Epidemiologists,

LABORATORY UPDATE 16: COVID-19 (SARS-CoV-2)

This is a new COVID-19 Laboratory Update circulated today, July 20, 2020.

We are pleased to inform you that the kit “LabGun® COVID-19 RT-PCR Kit” produced by LabGenomics Co. Ltd. (Republic of Korea) has received the approval for Emergency Use/Import in CARICOM countries by the Caribbean Regulatory System (CRS).

The intended use of the product is the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal, or oropharyngeal, anterior nasal and mid-turbinate nasal swabs, as well as nasopharyngeal wash/aspirate or nasal aspirate specimens and sputum, from individuals who are suspected of COVID-19 by their healthcare provider. Emergency use of this test is limited to authorized laboratories.

According to the technical specifications provided by the company, the kit has a sensitivity and specificity > 95%. The product has also received approval for Emergency Use in Europe and North America. The kit meets the standard ISO 13485:2016.

The LabGun® COVID-19 RT-PCR Kit is compatible with the following PCR platforms:

- Applied Biosystems™ 7500 Real-time PCR Instrument system with software version 2.3 (Thermo Fisher).
- CFX96™ Real-time PCR detection system with Bio-Rad CFX Manager 3.1 (Bio-Rad).

For more specifications and information please click the link:

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,

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Joy St. John

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)