MEDIA RELEASE

CARPHA Caribbean Regulatory System (CRS) to Review In Vitro Diagnostics (Test Kits) for Emergency Use

Port of Spain, Trinidad and Tobago. 15 June 2020. Diagnostic testing for COVID-19 is critical to tracking the spread of the virus, understanding epidemiology, informing case management and reducing transmission.

CARPHA is leading the regional health response to COVID-19, in keeping with its Intergovernmental Agreement (IGA) mandate from CARICOM. As part of its efforts to combat the COVID-19 pandemic in Member States, CARPHA will now review In Vitro Diagnostic (IVD) test kits through its Caribbean Regulatory System Program (CRS) towards a recommendation for market authorization and/or importation for CARICOM.

IVDs can detect diseases or other conditions and can be used to monitor the overall health of a person to help cure, treat, or prevent illness.

The CRS requires that all products it reviews be approved in a reference authority, and in turn, conducts a procedure to verify the product is the same. In this case, eligible products must have an Emergency Use Authorization (EUA) given by a CARPHA/CRS-recognized reference authority.

“We are receiving many questions about the quality of test kits for COVID-19, and our review of these products is an important way that CARPHA can help Member States” said CARPHA Executive Director, Dr. Joy St. John.

Interested manufacturers or governments wishing to have the CRS review test kits for COVID-19 are invited to submit queries to CRSregistration@carpha.org. Per its processes, CARPHA will review all documentation electronically, and if favorable, will send a confidential assessment report to Member States via a network of focal points and list the product on its website.

The successful applicant will receive a Certificate of Recommendation for Emergency Use Authorization. The procedure conforms to criteria recently set out by PAHO/WHO using reliance for emergency use authorization of In Vitro Diagnostics and other medical products.

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