CARPHA/SDPC/LSN/007/20
Chief Medical Officers
Laboratory Directors
National Epidemiologists

5th February 2020

Dear CMOs, Laboratory Directors and National Epidemiologists,

LABORATORY UPDATE 1: 2019 novel Coronavirus (2019-nCoV)

Since our first correspondence regarding the discovery of the new coronavirus in Wuhan, China (Ref. CARPHA/SDPC/LSN/005/20, attached), the World Health Organization (WHO) has declared this emerging situation to be a Public Health Emergency of International Concern (PHEIC).

Currently the risk level of importation into the Caribbean remains LOW as deliberated by the Regional Coordinating Mechanism on Health Security (RCM-HS) on 29th January 2020.

CARPHA Medical Microbiology Laboratory (CMLM) has been actively involved as part of the regional response during this preparedness phase. We will be accepting specimens for diagnostic testing by molecular method (Polymerase Chain Reaction, PCR) and referral to the WHO Collaborative Center at Centers for Disease Control and Prevention (CDC), United States, for confirmation of initial positive cases per Member State.

The turnaround time (TAT) is 24 – 48 hours from receipt of the specimen/s at CMLM.

In order to ensure timely detection of this new and emerging pathogen, we wish to share the following guidelines for your use:

1. **CASE DEFINITION**

   **Suspect case**
   A. Patients with Severe Acute Respiratory Infection (fever, cough, and requiring admission to hospital), AND with no other etiology that fully explains the clinical presentation AND at least one of the following:
      • a history of travel to or residence in the city of Wuhan, Hubei Province, China in the 14 days prior to symptom onset, or
      • patient is a healthcare worker who has been working in an environment where severe acute respiratory infections of unknown etiology are being cared for.
   
   B. Patients with any acute respiratory illness AND at least one of the following:
      • close contact with a confirmed or probable case of 2019-nCoV in the 14 days prior to illness onset, or
      • visiting or working in a live animal market in Wuhan, Hubei Province, China in the 14 days prior to symptom onset, or
      • worked or attended a health care facility in the 14 days prior to onset of symptoms where patients with hospital-associated 2019-nCov infections have been reported.
Probable case
A suspect case for whom testing for 2019-nCoV is inconclusive or for whom testing was positive or a pan-coronavirus assay.

Confirmed case
A person with laboratory confirmation of 2019-nCoV infection, irrespective of clinical signs and symptoms.

Testing for the 2019-nCoV should only be considered for patients who fit the case definition, once Influenza and avian influenza have been ruled out.

2. SPECIMEN COLLECTION AND REQUIREMENTS:

Specimens: Nasopharyngeal swabs (Dacron or polyester flocked) in Viral Transport Media, 1 ml. of urine, and a serum collected ≤ 5 days from Date of Onset (DOO) of symptoms.

Biosafety considerations: A trained healthcare worker wearing appropriate personal protective equipment (PPE) (N95 mask, gloves, fluid resistant gown) should take the primary samples from the suspect case/patient.

Storage (until testing): ≤ 5 days: 4 °C, >5 days: -70 °C or -20 °C if -70 °C is not available. Avoid repeated freezing/thawing cycles.

3. SPECIMEN REFERRAL:

Classification and Packaging: The samples are classified as Category B, Biological Substances. Follow instructions for preparing and packaging the samples in accordance with IATA regulations for Infectious substances, Packaging Instruction P650, Category B, Biological Substances.

Documentation: Complete CARPHA Laboratory Investigation Form (patient demographics, DOO, travel history, symptoms), courier Air Way Bill, CARICOM Invoice.

4. LABORATORY BIOSAFETY AND BIOSECURITY:

Containment/Biosafety Level: Diagnostic protocols which do not involve the propagation (e.g. cell culture) of the virus can be performed under Biosafety Level (BSL) 2 conditions.

Safety Equipment: Manipulations of the specimen with the potential to generate fine particle aerosols (e.g. sample preparation with open tubes, vortexing) should be performed under a certified Biological Safety Cabinet (BSC) in accordance with Good Laboratory Practices.

Any procedure which generates aerosols and is performed outside a BSC (or the cleaning up highly suspicious samples spilling, for example) must be performed using a N95 mask.

Personal Protective Equipment: disposable gloves, surgical mask, anti-fluid gown, and eye protection when handling potentially infectious specimens.
5. **COMMUNICATION:**

**Notification:** Before submitting a sample for testing to CMML there must be confirmation to proceed from the Member State’s Chief Medical Officer, National Laboratory Director, the National IHR Focal Point and CMML Head, Laboratory Services and Networks.

Please contact us at escobaga@carpha.org or +1 868 3246809.

**Shipment:** Once confirmation is received, please send an email containing all shipment documentation and the accompanying laboratory Investigation form/s to customerservice@carpha.org.

**Reports:** All laboratory results will be issued via the online system, Senaite. All first positive cases will be reported verbally directly to the Chief Medical Officer and the National Laboratory Director.

6. **KEY REFERENCES:**

1. Novel Coronavirus (2019-nCoV) technical guidance: Laboratory testing for 2019-nCoV in humans

2. CARPHA Algorithm for the Management of Suspected 2019-novel coronavirus Cases in CARPHA Member States
   http://carpha.org/Portals/0/Documents/nCoV_Algorithm-Management.pdf

3. WHO Interim Guidance for Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases

4. PAHO/WHO Laboratory Guidelines for Detection and Diagnosis of the Novel Coronavirus (2019-nCoV) Infection

5. PAHO/WHO Interim laboratory biosafety guidelines for the handling and transport of samples associated with the novel coronavirus 2019 (2019-nCoV) (attached)

Yours Sincerely,

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