CARPHA’s Role in COVID-19 Testing

The CARPHA Medical Microbiology Laboratory (CCML), as the regional reference laboratory, currently conducts tests for suspected COVID-19 cases for 18 of its Member States. CARPHA is committed to providing science based, World Health Organization (WHO) recommended testing and timely results.

The CMML currently tests ALL suspect cases of COVID-19 as recommended by the WHO case definition provided by the WHO Global surveillance for COVID-19 caused by human infection with COVID-19 virus document last updated March 20, 2020 as follows:

Suspect case

A) A patient with acute respiratory illness (fever and at least one symptom of respiratory disease, e.g., cough, shortness of breath), AND a history of travel to or residence in a location reporting community transmission of COVID-19 disease during the 14 days prior to symptom onset;

OR

B) A patient with any acute respiratory illness AND having been in contact with a confirmed or probable COVID-19 case in the last 14 days prior to symptom onset;

OR

C) A patient with severe acute respiratory illness AND requiring hospitalization AND in the absence of an alternative diagnosis that fully explains the clinical presentation.

Samples can only be sent to CARPHA from the designated national public health laboratory in a country. Once samples are received, CARPHA will produce the results within 24-48 hours.

COVID-19 results are immediately sent to the Chief Medical Officers at the Ministries of Health, who are responsible for the dissemination.

CARPHA cannot and will not disseminate any country’s results directly to patients or individuals. It is an ethical breach and constitutes a violation of the Agency’s ethical standards to share confidential patient information with unauthorized persons.

What is the test method used at CARPHA?

The CMML uses the PCR test method as recommended by WHO and published in its website in January 2020. PCR and PCR-based methods are the only recommended for COVID-19 detection. PCR remains the gold-standard for COVID-19 testing.

The method is called Polymerase Chain Reaction or PCR. It is a molecular detection method. Its principle is the logarithmic amplification of a small portion of the viral genome (RNA, which encodes the genetic information of the virus) to a level that is possible to detect with the current technology.
**Why PCR:** the sensitivity (the capacity of a test to detect a pathogen present in a specimen) and specificity (the capacity of a test to discriminate a pathogen from others) are both 100% for PCR. The PCR is a 2-stage process, using two machines:

- **EXTRACTION** (extracting the genomic material from the virus)
- **AMPLIFICATION**
  - *This involves screening for coronavirus first followed by COVID-19 specific confirmation*
    
    The total process takes 6-8 hours.

**What is CARPHA’s Acceptance and Rejection Criteria**

**Acceptance**
- A) Samples taken from patients that meet the WHO case definition of suspected case (as above)
- B) Samples taken within the recommended period 0-10 days from the onset of symptoms
- C) Laboratory Investigation Forms correctly filled.
- D) Samples taken following the best clinical practices, with the right materials (flocked Dacron or synthetic - not cotton- swabs in transport medium), not contaminated, not leaking, correctly identified.
- E) Samples shipped following the international standards of biosafety

**Rejection criteria:**
- A) Samples taken from patients that do not meet case definition or from asymptomatic patients.
- B) Samples taken beyond the recommended period for sampling
- C) Samples without laboratory investigation form or with incomplete information (e.g. no date of onset, no reference to symptoms, no demographics information, etc.)
- D) Leaked, unidentified or defective samples. Inappropriate samples (e.g. stools for COVID-19 testing)
- E) Samples sent without triple package containers (for samples sent from abroad). *Visit CARPHA website for information available in CMML User Manual.*

**Currently, we do not test any asymptomatic cases.**

The WHO case definitions do not at this time include asymptomatic individuals to be considered for testing.

**We also currently do NOT Test samples taken after >10 days:** Because the likelihood of obtaining an amplified viral RNA declines over the progression of the disease. For samples taken with more than 10 days from the onset of symptoms, the sensitivity of the assay may be affected, producing false negative results. This is especially certain in those patients with a mild disease or with no other complications, i.e. Pneumonia.

**Rapid Tests:**
At this time, the WHO does NOT recommend rapid tests based on serology since it is a risk to Public Health; serological tests are based on detection of antibodies (serology) are experimental and have showed lower sensitivity and specificity, compared to PCR thus, there is the likelihood of false negatives results (due to low sensitivity) and false positives (due to low specificity).

Recently, the U.S. Food and Drug Administration (FDA) has approved molecular test kits for emergency use with GeneXpert® Systems. CARPHA concurs that this kit could be used by countries which may only require 2-4 test/hour. However, verification studies should accompany these tests to determine their quality indicators in comparison to PCR.
CARPHA’s testing capacity:

CARPHA has enough manpower to conduct tests. We are currently working on a shift system to deliver timely results and this has been aptly demonstrated by our turnaround time of less than 24 hours. We are also hiring 3 more technologists.

The CMML has been impacted by the global shortage of reagents just like ALL laboratories in the world but we can assure you that we are working hard to alleviate this and have placed orders since January which are expected to arrive soon.

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