Diagnostic testing for SARS-CoV-2

Interim guidance

11 September 2020

World Health Organization

Introduction

This document provides interim guidance to laboratories and other stakeholders involved in diagnostics for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). It covers the main considerations for specimen collection, nucleic acid amplification testing (NAAT), antigen (Ag), antibody (Ab) detection and quality assurance. This document will be updated as new information becomes available. Feedback can be sent to WHElab@who.int.

Changes from the previous version

The title of this interim guidance has changed from "Laboratory testing for COVID-19 in suspected human cases" to "Diagnostic testing for SARS-CoV-2". Additional relevant background information and a clinical diagnostic algorithm has been added to the document. Furthermore, the guidance has been updated with new findings from the literature and best practices.

Relevant WHO documents

WHO has developed interim guidance and technical briefs to assist policy-makers and laboratories on testing for SARS-CoV-2. These documents cover laboratory testing strategy [1], laboratory assessment tool [2], laboratory biosafety [3], advice on the use of point-of-care immunodiagnostic tests [4], antigen detection in diagnosis of SARS-CoV-2 infection using rapid immunoassays [5], guidance for the investigations of clusters [6], public health surveillance [7] and operational considerations for surveillance using GISRS [8]. In addition, early investigation protocols [9] can be used by countries to implement epidemiological studies and enhance understanding of transmission patterns, disease severity and prevalence, clinical features and risk factors of SARS-CoV-2 infection.

Individuals infected with SARS-CoV-2 may never develop symptoms (asymptomatic cases), they may have very mild disease (pauci-symptomatic), or they may develop moderate to severe COVID-19 disease [18-26]. The most robust evidence for viral infection comes from the detection of fragments of the virus, such as proteins or nucleic acids, through virological testing. Infected individuals may test positive for viral nucleic acids or viral proteins without symptoms (asymptomatic), or before symptom onset (pre-symptomatic), and throughout a disease episode (symptomatic). For those who develop COVID-19 illness, symptoms can be wide-ranging at initial presentation of disease. Individuals may present with very mild symptoms, with apparent pneumonia, febrile illnesses/sepsis, and less commonly with gastro-enteritis or neurological symptoms [99]. If required for case management, patients should also be tested for other pathogens, as recommended in local clinical management guidelines, but this should never delay testing for SARS-CoV-2 [99, 100]. Co-infections of SARS-CoV-2 with other pathogens have been reported, thus a positive test for another pathogen does not rule out COVID-19 and vice versa [27, 101-109]. Cases of false positive dengue antibody test results using a dengue rapid diagnostic test (RDT) in COVID-19 patients have been reported [110, 111]. There is also a risk of false positive or false negative SARS-CoV-2 results, if testing is not performed with adequate assays or not done under adequate conditions.

20(5): p. 536.
111. Lustig, Y., et al., *Potential antigenic cross-reactivity between SARS-CoV-2 and Dengue viruses.* Clin Infect Dis, 2020.
112. Hammitt, L.L., et al., *Added value of an oropharyngeal swab in detection of viruses in children hospitalized*