



PHILIPPINE PEDIATRIC SOCIETY
PEDIATRIC INFECTIOUS DISEASE SOCIETY OF THE PHILIPPINES



FAQs on COVID-19 IgM/IgG RAPID DIAGNOSTIC TESTS
April 01, 2020

The Philippine Food and Drug Administration (PFDA) approved the use of antibody-based (IgM/IgG) rapid diagnostic test (RDT) kits for SARS-CoV2 testing on March 30, 2020. The Philippine Pediatric Society (PPS) and Pediatric Infectious Disease Society of the Philippines (PIDSP) are releasing this rapid advice for pediatricians on the utility of these kits for children.

To date, there are no published data available on their use in children. The preferred etiologic testing method remains to be PCR, and PCR is the only method included in the PPS/PIDSP Interim Guidelines for Screening, Assessment, and Clinical Management of Pediatric Patients with Suspected or Confirmed COVID -19 (released Mar 31, 2020). Nevertheless, if individual clinicians choose to use IgM/IgG RDTs, the following FAQs provide further information.

1. What are the tests currently available in the Philippines for diagnosing COVID-19 infection?

There are a number of tests which have been granted registration by the Philippine FDA. These are PCR-based tests and more recently, immunologic tests commonly referred to as “rapid test kits”. The most recent PFDA-approved immunologic tests detect antibodies (IgM and IgG) to SARS CoV-2.

2. What is a PCR-based test for COVID-19 infection?

The PCR-based method is the **gold standard test** for diagnosing COVID-19 infections. It detects the presence of the viral genetic material of SARS-CoV-2, using nucleic acid testing such as reverse transcriptase polymerase chain reaction (RT-PCR). Various PCR-based tests vary depending on what coronavirus gene each test targets.

The test may detect the virus and be positive even before symptoms begin. In a person with symptoms of COVID-19, nasopharyngeal or oropharyngeal swabs are collected and sent to the DOH designated national or subnational laboratories or validated private laboratories capable of doing PCR testing.

3. What are the limitations of PCR-based tests?

RT-PCR tests need an accredited laboratory to process specimens from oropharyngeal or nasopharyngeal swabs. Turn-around times range from 2-6 hours depending on the PCR kit and machine capability. Currently, there are 6 fully operational molecular diagnostic laboratories around the country; more laboratories are in the last phase of accreditation, which hopefully will shorten the time from receipt of specimen to release of results.



PHILIPPINE PEDIATRIC SOCIETY
PEDIATRIC INFECTIOUS DISEASE SOCIETY OF THE PHILIPPINES



4. Is a repeat PCR test after an initial positive COVID-19 test necessary?

The current local clinical management guideline states that admitted patients who initially test positive require 2 negative tests taken at least 24 hours apart prior to discharge. These repeat tests are done either 14 days after the first positive COVID-19 test or once patient is afebrile for 72 hours, whichever is longer. However, the guideline also states that in settings with limited test capacity, clinical improvement can be used as the basis for discharge.

5. What is the IgG and IgM rapid diagnostic test (RDT) for COVID-19 infection?

The currently registered rapid tests detect IgG and IgM antibodies that the body develops once a person is infected with SARS-CoV-2. These antibodies can be detected by a variety of methods, e.g. immunochromatography, ELISA, chemiluminescence immunoassay, etc. However, these tests are not useful for early detection of disease, because IgM is only detectable 5-10 days after symptom onset, while IgG is detectable approximately 21 days after symptom onset.

Thus, if the test is done early in the course of the disease, the result can be falsely negative, even if the patient is already infected with the virus.

6. What are the limitations of rapid IgM IgG tests?

The true accuracy of immunoassays for COVID-19 have not yet been established, but they have been licensed because of the urgency of the present situation. The likelihood of false negative results from immunoassays, in general, should be considered. Furthermore, analytical specificity and sensitivity have not yet been determined, and no systematic analysis of serologic testing in COVID-19 has been done. Current data are available only from small studies. Cross reactivity with other coronaviruses and flu viruses, as well as the detection limit, have not yet been determined. There is insufficient evidence to use the kits as stand-alone tests for definitive diagnosis of COVID-19.

7. Who can be tested using the COVID-19 rapid diagnostic test (RDT)?

The test can only be used in patients who have had symptoms for at least 5 days, as only then can the test possibly yield positive IgM results and negative IgG. If symptoms have started 21 days or more before the day of testing, IgM and IgG maybe positive. Different test kits have different interpretations of results; thus it is best to read and understand the specific kit's product information before recommending to patients.

8. What should be done if the COVID-19 rapid diagnostic test result is positive?

Any positive result obtained from an RDT should be confirmed with an RT-PCR test. IgM/IgG results alone do not definitively diagnose COVID-19 infection. In addition, the patient should be clinically assessed if there is any indication for admission, and if not, then advised on proper self-isolation.



PHILIPPINE PEDIATRIC SOCIETY
PEDIATRIC INFECTIOUS DISEASE SOCIETY OF THE PHILIPPINES



9. What should be done if the COVID-19 rapid diagnostic test result is negative?

A negative RDT test **does not** rule out COVID-19 infection. Physicians should follow the algorithms set by the PPS/PIDSP or PSMID, and if confirmatory testing is warranted, then the patient should undergo RT-PCR testing and be advised on proper self-isolation.

10. Who can request for COVID-19 RDT?

Only **medical doctors can request and interpret** the use of the antibody-based test kits. These kits will not be available over the counter, as proper collection of a blood sample should be in a laboratory by a health care worker equipped with PPE.

11. Can COVID-19 RDT replace PCR - based kits in the diagnosis and decision to discharge COVID -19 positive patients?

No. PCR-based tests are still the gold standard in diagnosing COVID-19. Further, at least one negative PCR test is preferred prior to discharge of patients. However, in situations where PCR kits are in limited supply, patients who meet discharge criteria can be sent home and advised to continue self-quarantine for 14 days.

12. Is there benefit to the use of COVID-19 RDT for mass testing?

A COVID-19 antibody test **CANNOT** be used for mass testing because of its limited utility for screening and diagnosis. There is higher likelihood of false negative results, which could undermine the preventive measures already in place to avert spread of COVID-19.

13. What is the role of COVID-19 RDT in diagnosing COVID-19 in children?

There is **NO** published data on the use of RDTs in the screening and diagnosis of COVID-19 in children. The gold standard remains to be the PCR-based test. Rapid test kits, however, may have a limited role to supplement PCR-based methods for COVID-19 diagnosis, e.g. to document recent infection and for sero-epidemiologic determination. Interpretation, however, must be made with caution until more data are available. Development and research on rapid diagnostic kits that can be used at the community level is imperative in the light of the COVID-19 pandemic. Molecular-based rapid test kits that can be employed for point-of-care diagnosis are being developed at a fast pace but are not yet available locally.