PIH Guide | COVID-19

Part I: Testing, Contact Tracing and Community Management of COVID-19

Updated 4 April 2020

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Abbreviations

Ag	Antigen
CDC USA	Centers for Disease Control USA
CDC Africa	Centers for Disease Control Africa
CMW	Community health workers
COVID-19	Coronavirus disease 2019
HCW	Health Care Worker
PAHO	Pan-American Health Organization
RDT	Rapid diagnostic test
RT-PCR	Reverse transcription polymerase chain reaction
SARS-CoV-2	Severe acute respiratory syndrome coronavirus
SOP	Standard Operating Procedure
WHO	World Health Organization

1 Basics

1.1 Definition

- Corona Virus Disease 2019 (COVID-19) is an infectious disease caused by the novel SARS-CoV-2 coronavirus that can cause an acute and severe respiratory illness.

1.2 Epidemiology

- Median incubation period: approximately 5 days.
- Most infected persons will have symptoms within approximately 12 to 14 days of infection.
- Clinical syndrome is non-specific, characterized by:
  - Fever at any time 88-99%
  - Cough 59-79%
  - Dypsnea 19-55%
  - Fatigue 23-70%
  - Myalgias 15%-44%
  - Sputum production 23-34%
  - Nausea or vomiting 4%-10%
  - Diarrhea 3%-10%
  - Headache 6%-14%
  - Sore throat 14%
- Approximately 80% of laboratory-confirmed patients have had mild to moderate disease, 15% have had severe disease (requiring oxygen), and 5% have been critically ill (requiring intensive care with mechanical ventilation).

1.3 Mechanism of transmission

The virus is thought to spread mainly from person-to-person.

- Between people who are in close contact with one another (within about 2 meters).
- Through respiratory droplets produced when an infected person coughs or sneezes.
- These droplets can land in the mouths or noses of people who are nearby or possibly be inhaled into the lungs.

Spread from contact with contaminated surfaces or objects

- It may be possible that a person can get COVID-19 by touching a surface or object that has the virus on it and then touching their own mouth, nose, or possibly their eyes.

Can someone spread the virus without being sick?

- People are thought to be most contagious near the onset of illness.
- Some spread might be possible before people show symptoms and there have been reports of this occurring with this new coronavirus.

How easily the virus spreads

- How easily a virus spreads from person-to-person can vary. Some viruses are highly contagious (spread easily), like measles, while other viruses do not spread as easily. Another factor is whether the spread is sustained, spreading continually without stopping.

- The virus that causes COVID-19 seems to be spreading easily and sustainably in the community ("community spread").
- "Community spread" means people have been infected with the virus in an area, including some who are not sure how or where they became infected.

1.4 General primary prevention

The only way to prevent infection is to avoid exposure to the virus:

- Wash hands often with soap and water or an alcohol-based hand sanitizer and avoid touching the eyes, nose, and mouth with unwashed hands.
- Avoid close contact with people (i.e., maintain a distance of at least 2 meters), particularly those who have a fever or are coughing or sneezing.
- Practice respiratory hygiene (i.e., cover mouth and nose when coughing or sneezing, discard tissue immediately in a closed bin, and wash hands).
- Seek medical care early if symptoms such as fever, cough, and difficulty breathing develop.
- Follow your Ministry of Health indications regarding Social Distancing.

1.5 Screening and secondary prevention

- Isolation (quarantine), early case detection, and use of a medical mask when a patient has symptoms are all examples of secondary prevention.
- Early case detection through screening or contact tracing is an excellent way to prevent further spread (see Chapter 3 for more on contact tracing)
- People who may have been exposed to individuals with suspected COVID-19 (including healthcare workers) should be advised to monitor their health for 14 days from the last day of possible contact, and seek immediate medical attention if they develop any symptoms, particularly fever, respiratory symptoms such as coughing or shortness of breath, or diarrhea.
- Local health authorities may request people enter into voluntary quarantine depending on their risk of exposure.
- Symptomatic or confirmed COVID-19 patients should wear a medical mask while waiting in triage or waiting areas or during transportation out of isolation.

2 PIH strategy and response

We know that the best way to both care for the sick and minimize the spread of disease is a strong health system—one that has the necessary staff, stuff, space, systems and social support in place to be able to prevent, detect, diagnose, and treat disease.

We know that we can beat COVID-19 with a strong and nimble health system.

We also know that community health workers (CHWs) are strategically placed to educate the population about a new disease, perform active case finding, accompany those who are ill to health facilities and support those who are not ill but need to remain isolated at home through targeted social support.

To fight COVID-19, we must:

- Massively scale-up access to rapid diagnostics and provide care for those who test positive.
- Safely and humanely separate infected patients from those not infected.
- Educate the population on the ways COVID-19 spreads and how they can stop the spread and protect themselves (for example washing hands frequently, cough etiquette, and avoiding contact with people when they have respiratory symptoms).
- Prepare the health system to act swiftly and be ready for a possible large outbreak.
- Leverage PIH's network of skilled Community Health Workers (CHWs) to conduct contact tracing in PIH catchment areas.
- Implement a health system that people trust and which works for the sick. When care is not available, patients will not come forward for testing.
- Have clear guidelines on the best practices for prevention, testing and treatment of COVID-19.
- Collaborate with and support the leadership of the Ministry of Health (MoH).

Objective 1 of PIH's four-pronged approach is to protect our patients, communities and staff against COVID-19 through initiating safe testing, triage and isolation. Laboratory services and diagnostics play a critical role across all diseases and geographies. PIH will work to create and provide access to safe, accurate and timely testing. This is a rapidly changing field and we will do our best to stay up to date with technology to ensure that any country we work in will have access to rapid testing as quickly and safely as possible.

- Provision of testing and accompanying personal protective equipment (PPE): Procure and provide rapid diagnostic (RDT) testing and appropriate PPE for all frontline health care workers at every level of the health system (nurses, physicians and community health workers).
- Accompaniment of ministries: Support ministries of health and other national partners (including national public health labs) to ensure access to reverse transcription - polymerase chain reaction (RT-PCR) testing and strong referral services for patients tested by rapid diagnostic tests (RDTs).
- Provide global coordination and leverage partnerships: Provide global coordination with the World Health Organization (WHO), Pan American Health Organization (PAHO), Centers for Disease Control (CDC) Africa and others to ensure collaboration and coordination amongst all

stakeholders. Collaborate with private sector partners (i.e. for molecular technology) to ensure swift development and subsequent access to tests and reagents.

3 Testing

3.1 Types of Tests

	Reverse transcriptase polymerase chain reaction (RT-PCR)	Antibody (IgM/IgG) rapid diagnostic test (RDT)	Antigen (Ag) rapid diagnostic test (RDT)
Sample	Nasopharyngeal swab or deep sputum	Blood (finger stick or blood draw)	Nasopharyngeal swab or deep sputum
Window period	Short	3-5 days	Short
False negatives	Occasionally[1]	Low[2]	Low[3]
False positives	Almost none	Low	Almost none
Turn-around time	Days	15 min	15 min
Follow-up	Re-test in several days if high clinical suspicion	Re-test if sample was obtained during the window period	Re-test if sample was obtained during the window period

Reverse transcriptase polymerase chain reaction (RT-PCR)

- This test is done on bronchoalveolar lavage fluid, fibrobronchoscope brush biopsy, deep sputum or nasopharyngeal swab.
- Note: deep sputum is not saliva but the thick mucus—sometimes called phlegm—which is coughed up from the lungs.
- A nasopharyngeal swab is taken from deep in the nose or oropharynx.
- The patient can take their own nasal swab (observed and instructed by the HCW at a safe distance); this results in less risk to the HCW.
- RT-PCR is highly specific, which means the chance of a false positive is low.
- RT-PCR may have a sensitivity of around 75%.
- A single negative RT-PCR doesn't exclude COVID-19 (especially if obtained from a nasopharyngeal source or if taken relatively early in the disease course).
- If the RT-PCR is negative but suspicion for COVID-19 remains, then ongoing isolation and re-sampling several days later should be considered.

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[1] Xie, C., et al., Comparison of different samples for 2019 novel coronavirus detection by nucleic acid amplification tests. Int J Infect Dis, 2020.
Google Scholar
Ai, T., et al., Correlation of Chest CT and RT-PCR Testing in Coronavirus Disease 2019 (COVID-19) in China: A Report of 1014 Cases. Radiology, 2020: p. 200642.
Xie, X., et al., Chest CT for Typical 2019-nCoV Pneumonia: Relationship to Negative RT-PCR Testing. Radiology, 2020: p. 200343
Li, Y.Y., et al., [Comparison of the clinical characteristics between RNA positive and negative patients clinically diagnosed with 2019 novel coronavirus pneumonia]. Zhonghua Jie He He Hu Xi Za Zhi, 2020. **43**(0): p. E023.

[2] Zhengtu Li et al., "*Development and Clinical Application of A Rapid IgM-IgG Combined Antibody Test for SARS-CoV-2 Infection Diagnosis" J. of Med. Virology, published on 2/20/2020*

[3] Bioeasy. "2019-Novel Coronavirus (2019-nCoV) Ag GICA Rapid Test (Colloidal Gold) clinical report" 4th March, 2020

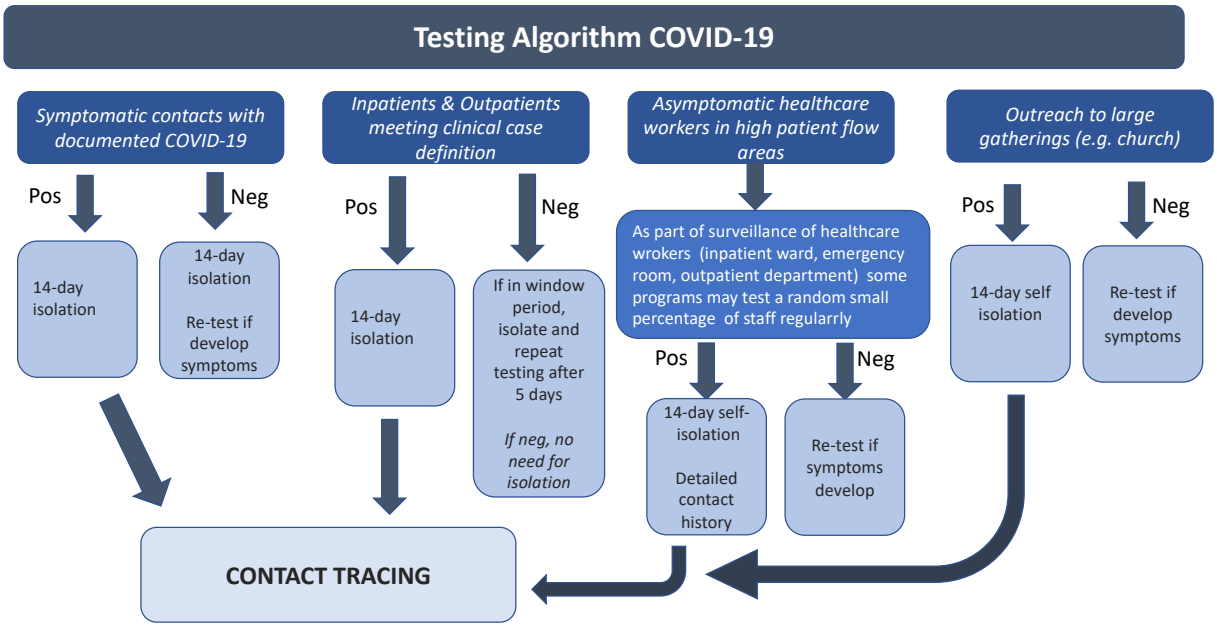
Antibody (IgM/IgG) RDT

- This test is done on blood (finger stick or blood draw).
- Sensitivity and specificity are around 90%.
- In general IgM can be detected 3-5 days after the onset of symptoms and IgG becomes positive a few days after the rise of IgM.
- The lag time of antibodies creates a window period where the patient may have a negative IgM/IgG RDT, but still have COVID-19.
- If the IgM/IgG RDT is negative, but suspicion for COVID-19 remains, then ongoing isolation and re-sampling several days later should be considered.

Antigen (Ag) RDT

- This test is done on a deep sputum or nasopharyngeal swab.
- A single negative Ag RDT doesn't exclude COVID-19 (especially if taken relatively early in the disease course).
- If the Ag RDT is negative, but suspicion for COVID-19 remains, then ongoing isolation and re-sampling several days later should be considered.

3.2 Who should be tested?



3.3 Contacts

- Persons that have had contact in the last 14 days with a documented COVID-19 patient have the highest priority.
- The testing algorithm for symptomatic and asymptomatic contacts is discussed further in Chapter 4.

- Where available, administer Ab RDT, Ag RDT, and RT-PCR testing simultaneously.
- Any positive result of any test is considered positive for COVID-19.

3.4 Inpatients and outpatients with respiratory symptoms

- Test all those who fit the MOH clinical case definition.
- Where available, administer Ab RDT, Ag RDT, and RT-PCR testing simultaneously.
- Inpatients and outpatients with respiratory symptoms and no alternative diagnosis or symptoms highly consistent with COVID-19 disease fall into this category.
- Also consider a sample of patients in the ICU, as well as patients with pneumonia of unclear etiology.
- Symptomatic healthcare workers also fall into this category.
- Any positive result of any test is considered positive for COVID-19.

If	Then
Positive	• Report to the MOH as a presumptive case of COVID-19. • If patient will be managed as outpatient, instruct them on home quarantine. • Take a detailed contact history in preparation for tracing all contacts.
Negative	• If still in window period and high clinical suspicion, test again in 5 days. • If out of window period, no need for isolation.

3.5 Asymptomatic health workers in high patient flow areas

- As part of surveillance, test a sample of health workers in the unit. For example, 10% of the nurses working on an inpatient ward could be tested periodically.
- Test with IgM/IgG RDT only (Ag RDT or RT-PCR not necessary unless symptomatic).

If	Then
Positive	• Report to the MOH as a presumptive case of COVID-19. • The health worker may be infectious, even if asymptomatic and should be instructed to self-quarantine. • Take a detailed work history and intensify screening of workers and patients in those units.
Negative	• If all health workers in the unit are negative, retest another group of workers in 2 weeks.

3.6 Congregate settings

- Congregate settings include places where people live or socialize in large numbers; COVID-19 can easily propagate in such setting.
  - Churches, madrassas.
  - Psychiatric institutions.
  - Long-term care facilities (e.g. nursing homes).
  - Prisons.
  - Refugee camps.
  - Detention centers.
- If working up an individual from the group for active disease, administer all three testing modalities Ab RDT, Ag RDT, and RT-PCR testing simultaneously (if all three are available).
- If trying to determine infection prevalence in the setting use the IgM/IgG RDT only (and add Ag RDT, and RT-PCR for those patients testing positive with the IgM/IgG RDT or who are negative and symptomatic).

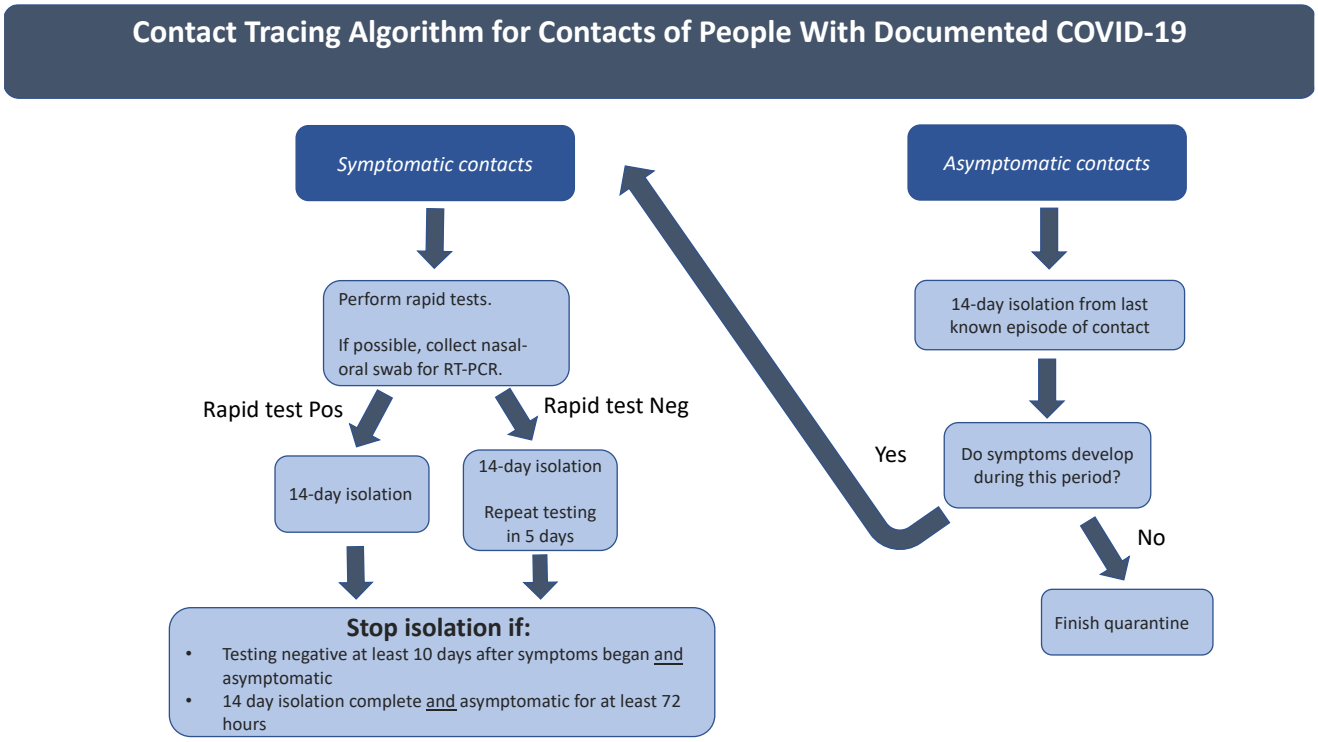
3.7 Travelers

- People travelling from areas with a high risk of infection may be screened using questionnaires about their travel, contact with ill persons, symptoms of infection, and/or measurement of their

temperature. This can apply for persons coming from international destinations or from hotspots within the country.

- Screening with questionnaires and temperature of persons coming from an affected area has been relatively ineffective and may miss many of the COVID-19 cases, particularly those with no symptoms during an incubation period, which may be up to 14 days.
- Enforced quarantine has been used in some countries to isolate easily identifiable cohorts of people at potential risk of recent exposure (e.g., groups evacuated by airplane from affected areas, or groups on cruise ships with infected people on board). The psychosocial effects of enforced quarantine may have long-lasting repercussions.

4 Contact tracing



4.1 Definition of a contact

Applies to the preceding 14 days:

- Providing direct care to COVID-19 patients without proper PPE.
- Staying in the same close environment with a COVID-19 patient (workplace, classroom, household, other gatherings).
- Traveling together in close proximity (<2 m) with a COVID-19 patient in any kind of vehicle.

4.2 Personnel and the contact tracing team

- Teams can include trained personnel including community health nurses, CHWs, other clinical staff, and trained community leaders.

- Personnel should be equipped with PPE. Improper PPE is particularly dangerous as infected workers could be asymptomatic and infectious, thereby potentially serving to spread the virus to community members they visit.

4.3 Testing of contacts

- Any symptomatic contacts should be tested.
- Asymptomatic contacts should be told to self-isolate for 14 days and call if symptoms develop. Self-isolation may mean living in a separate house, or distant room in a shared house.
- Use IgM/IgG rapid test and Ag rapid test at the same time, and where available, RT-PCR testing.

If	Then
Positive	• Report to the MOH as a presumptive case of COVID-19. • If patient will be managed as outpatient, instruct them on home quarantine. • Take a detailed contact history in preparation for tracing all contacts.

Negative	• If no symptoms, home quarantine for 14 days and call if symptoms develop.
	• If symptoms:
	  ○ And inside the window period, home quarantine for 14 days. Test again in 5 days.
	  ○ If outside the window period, no need for home quarantine.

4.4 Contact follow-up and discharge

- Daily or frequent communication with a healthcare provider via phone or visit is ideal to monitor for symptoms.
- Instructions for the contact:
  - Where to seek care if they develop a cough, fever, shortness of breath, or other symptoms.
  - The facility should be notified in advance.
  - Whenever possible, patients should remain at least 2 meters apart from anyone accompanying them to a healthcare facility. Use an ambulance if available, or on foot, or a private vehicle if possible.
  - Clean surfaces that come into contact during patient transport with 0.5% diluted bleach (this is 1 part bleach to 9 parts water).

5 Laboratory

5.1 Suggested personal protective equipment (PPE) for testing

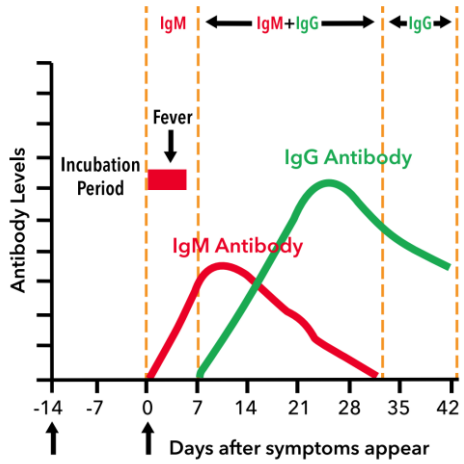
	Sample	PPE
Antibody (IgM/IgG) RDT	Whole blood, serum, plasma	Masks, gloves, gowns
Antigen (Ag) RDT	Nasopharyngeal swab or deep sputum	N95, gloves, gowns, face shield
RT-PCR	Nasopharyngeal swab or deep sputum	N95, gloves, gowns, face shield

5.2 Laboratory Procedure for COVID-19 IgM/IgG RDT

Standard operating procedure (SOP) for testing performed at laboratories and medical facilities by health care personnel.

Product description:

The COVID-19 IgM/IgG RDT is a rapid, qualitative lateral flow immunoassay kit for the detection of human IgM and IgG against SARS-CoV-2 virus infection using fingerstick (no anticoagulant) and K_2EDTA-anticoagulated venous whole blood. The test results can aid in diagnosis of SARS-CoV-2 virus infection. The diagnosis of COVID-19 must be made based on history, signs, symptoms, exposure likelihood, and other laboratory evidence in addition to the COVID-19 IgM/IgG RDT.



It is widely accepted that IgM provides the first line of defense during viral infections, followed by the generation of adaptive, high affinity IgG responses for long term immunity and immunological memory. Therefore, testing of COVID-19 IgM and IgG antibodies is an effective method for the rapid diagnosis of COVID-19 infection. Furthermore, detection of COVID-19 IgM antibodies tends to indicate a recent exposure to COVID-19, whereas detection of COVID-19 IgG antibodies indicates a later stage of infection. Thus, this combined antibody test could also provide information on the stage of infection.

Test Principle

The rapid IgM-IgG combined antibody test for COVID-19 is immunochromatography based. The test card contains (1) colloidal gold-labeled recombinant novel coronavirus antigen and quality control antibody colloidal gold marker, two detection lines (G and M lines) and one quality control line (C) fixed on a nitrocellulose membrane. M is fixed with monoclonal anti-human IgM antibody for detecting the novel coronavirus IgM antibody. G is fixed with monoclonal antihuman IgG antibody for detecting the novel coronavirus IgG antibody. The quality control antibody is fixed on the C line. When an appropriate amount of test sample is added to the sample well of the test cassette, the sample will move forward along the test card via capillary action. If the sample contains IgM

antibody, the antibody will bind to the colloidal gold-labeled novel coronavirus antigen. The antibody/antigen complex will be captured by the anti-human IgM antibody immobilized on the membrane, forming a red M line and indicating a positive result for the IgM antibody. If the sample contains IgG antibodies, the antibody will bind to the colloidal gold-labeled novel coronavirus antigen and the antibody/antigen complex will be captured by the antibody immobilized on the membrane, forming a red G line and indicating a positive result for the IgG antibody. If neither antibody is present, a negative result is displayed.

Warnings and Precautions:

- Wear personal protective equipment (PPE) such as a gown, gloves, and a surgical mask when performing the test. Refer to procedure for the proper use of PPE.
- Clean work surface with 70% alcohol before starting work.
- Place absorbent bench liner soaked with disinfectant on work surface to capture splatters and splashes.
- Store test kits in the dark at room temperature (18-26°C).
- Test kits have a shelf-life of 12 months. They should be protected from light after being opened. Do not freeze test cassette or buffer solution.
- Do not open the pouch containing the cassette until ready to use.
- The test should be used within one hour of opening the sealed cassette pouch. Do not use the test cassette or buffer solution beyond the indicated expiration date.
- Do not use samples with hemolysis, high lipid concentration or turbidity, which can affect results.
- Use universal precautions when handling blood samples.

Sample Collection and Requirements:

- Specimens for testing are human sera, plasma, or whole blood samples, including samples prepared by commonly used anticoagulants (EDTA, heparin, sodium citrate) as well as fingerstick. Fresh samples should be collected and tested immediately.
- Serum and plasma samples can be stored at 2-8°C for 5 days. If long-term storage of serum or plasma samples is required, store at -20°C and avoid repeated freeze/thaw cycles.
- Anticoagulated whole blood samples can be stored at 2-8°C for 7 days.
- Before testing, samples stored in refrigerated or frozen storage should be slowly returned to room temperature (15-30° C) and stirred. When particulates are clearly visible in the sample the precipitate should be removed by centrifugation before testing.

Blood by fingerstick:

- Use the middle or ring finger, ideally of the nondominant hand.
- The puncture should be made slightly off center from the fleshy portion of the finger, near the side of the fingertip.
- Disinfect thoroughly using an alcohol pad and let the puncture site air-dry.
- Stick side of the finger with lancet. Apply only light pressure on the fingertip until a blood drop appears. Don’t press or milk the finger.
- Discard lancet into a sharps container.
- Wipe away the first two to three drops of blood with the alcohol pad and make sure there is a free blood flow.

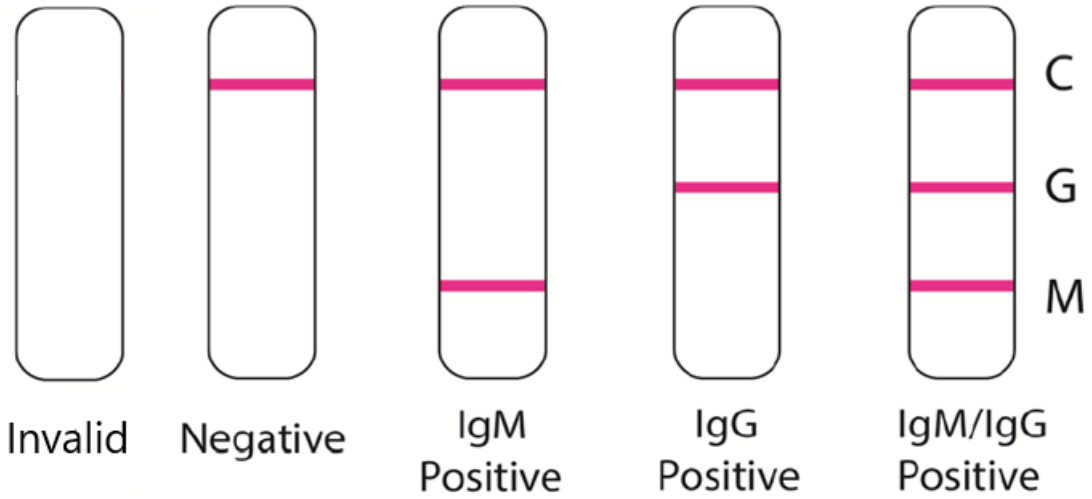
- Collect blood into capillary tube or sampler (~20-50 uL).

Venous blood:
Collect blood using one tube with EDTA as per instructions for phlebotomy. Materials required but not provided:

- Lancet.
- Alcohol wipes.
- Gloves.
- Timer.
- Other venipuncture materials (EDTA-containing tube, needle and or syringe).

1. Identify the specimen number on the cassette.
2. Mix the blood by inverting the tube gently, and using capillary sampler obtain 20µL of whole blood or fingerstick or 10 uL of serum or plasma.
3. Dispense the specimen into the sample well of the cassette.
4. Discard capillary sampler in a sharps container.
5. After the specimen has completely entered the sample well, add 2 to 3 drops (70 to 100µl) of buffer solution. Make sure to test on a level surface at room temperature.
6. Set timer to 15 minutes.
7. Wash hands (keep one pair of gloves on) with 70% alcohol.
8. After 15 minutes, test results should be read by viewing the detection window.
9. Write all results on the laboratory worksheet and report form.
10. Dispose the cassettes and pipettes as biohazard materials.
11. Clean work surfaces and plastic materials (pipettors, pens, and timer) with alcohol at the end of this process.

Interpretation of results



A total of three detection lines are possible, with the control (C) line appearing when sample has flowed through the cassette.

1. **Invalid Result:** If the control line does not appear, the test is invalid.

2. **Negative Result:** If only the quality control line (C) appears and the detection lines G and M are not visible, then no novel coronavirus antibody has been detected and the result is negative.

3. **Positive Result, M only**: If both the quality control line (C) and the detection line M appears, then the novel coronavirus IgM antibody has been detected and the result is positive for the IgM antibody.

4. **Positive Result, G only**: If both the quality control line (C) and the detection line G appears, then the novel coronavirus IgG antibody has been detected and the result is positive for the IgG antibody.

5. **Positive Result, G and M**: If the quality control line (C) and both detection lines G and M appear, then the novel coronavirus IgG and IgM antibodies have been detected and the result is positive for both the IgG and IgM antibodies.

Test Method Limitations

- This product can only be used to detect the IgG and IgM antibodies of the novel coronavirus in human blood, serum, or plasma. It cannot be used with other body fluids or secretions.
- This product is only for qualitative testing and the specific content of each antibody must be measured using other quantitative methodologies.
- Negative results may be caused by low concentrations of the novel coronavirus IgG/IgM antibody in the sample and therefore cannot completely rule out the possibility of infection.
- Test results can be affected by temperature and humidity.

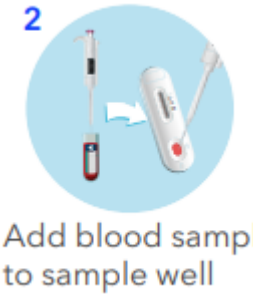
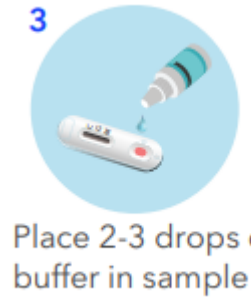
Internal Quality Control Procedure

Each test cassette device has a built-in control. A red colored line in the detection window at the Control line can be considered an internal positive procedural control. The Control line will appear if the test procedure has been correctly performed. If the Control line does not appear, the test is invalid and a new test must be performed.

How accurate is the COVID-19 Rapid Test?

In order to test the detection sensitivity and specificity of the COVID-19 IgG-IgM combined antibody test, blood samples were collected from COVID-19 patients from multiple hospitals and Chinese CDC laboratories. The tests were done separately at each site. A total of 525 cases were tested: 397 (positive) clinically confirmed (including PCR test) SARS-CoV-2-infected patients and 128 non- SARS-CoV-2-infected patients (128 negative). Of the 397 blood samples from SARS-CoV-2-infected patients, 352 tested positive, resulting in a sensitivity of 88.66%. Twelve of the blood samples from the 128 non-SARS-CoV-2 infection patients tested positive, generating a specificity of 90.63%.

5.3 Job aid for COVID-19 IgM/IgG RDT

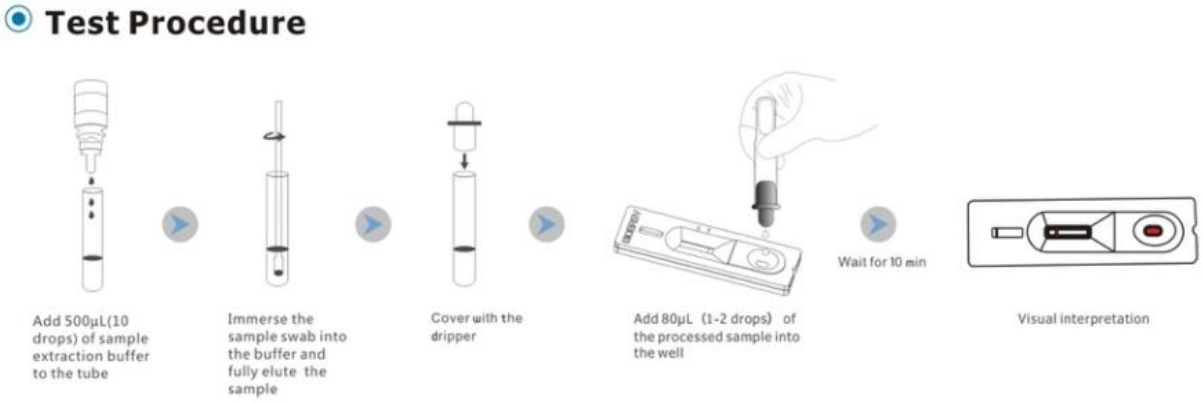
STEP	DESCRIPTION	
1		Do not open pouch until ready to use. Materials Provided: A: COVID-19 IgM/IgG Rapid Test cartridge B: Assay Dilution Buffer Bottle Collect blood samples by following standard medical procedure.
2		Add specimen (20µL whole blood, 10µl serum /plasma) into the sample port of the cassette.
3		After the sample completely enters the sample port, add 23 drops (70 to 100µl) of assay buffer *Take care when opening the Module. It contains a premeasured volume of assay dilution buffer.
4		After 15 minutes the COVID-19 IgM/IgG Rapid Test can be read by viewing the detection window. *Test results that have run over 15 minutes are considered invalid.

5.4 Laboratory Procedure for COVID-19 Antigen RDT Point of Care (POC) Tests

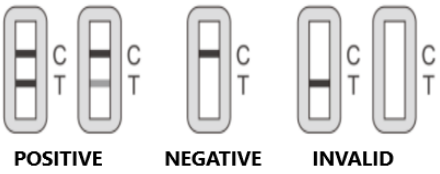
SOP for testing performed at laboratories and medical facilities by health care personnel

The POC market landscape is changing day by day with multiple new products coming to market—clinical experience and scientific evidence regarding their use is quickly being generated. We continue to research the market for POC tests of high reliability and accuracy.

The Laboratory Procedure for COVID-19 Antigen POC section of this guide will be updated as more and new evidence becomes available about the accuracy of specific products.



INTERPRETATION OF TEST RESULTS



1. **Positive result:** Both purplish test band and purplish control band appear on the membrane. Within the specified observation time, a very weak purplish band should be judged as a positive result.

2. **Negative result:** Only the purplish control band appears on the membrane. The absence of the test band indicates a negative result.

3. **Invalid result:** There should always be a purplish control band in the control region regardless of test result. If control band is not seen, the test is considered invalid. Reasons for invalid results:
   - Incorrect operation process.
   - Test kit has deteriorated or damaged.
   - The antibody content in the specimen is too high. In this case, read the instructions carefully again and dilute the sample to be tested with a new test device.
   - If the problem persists, stop using this lot number immediately and contact your local supplier.

Test Method Limitations

- The result of the product should not be taken as a confirmed diagnosis. Judgement should be made along with clinical symptoms, epidemic condition and further clinical data.
- In the early stage of infection, the test result may be negative because the 2019-nCoV antigen or low antigen level has not yet appeared in the sample.
- Due to the limitation of the detection method, the negative test result of this reagent cannot exclude the possibility of infection.
- This reagent can only qualitatively detect antigens in human nasopharyngeal swabs and oropharyngeal swab samples. It cannot determine the amount of antigen in the samples.

Internal Quality Control Procedure

Each test card has a built-in control. A purple colored band in the detection window at the Control line can be considered an internal positive procedural control. The Control line will appear if the test procedure has been correctly performed. If the Control line does not appear, the test is invalid and a new test must be performed.

How accurate is the Ag RDT?

Based on its clinical report, a total of 295 nasal swab samples were tested in this clinical trial, 145 were positive for nucleic acid detection and 131 were detected by this rapid test, for a positive coincidence rate of 90.34%. Among them, 150 cases were negative by nucleic acid test, 149 cases were also negative by this rapid test for negative coincidence rate of 99.33%. Kappa test results show that the consistency of this rapid test and nucleic acid test results is good (Kappa = 0.898).

6 Data Collection

6.1 Data flow

Data collection forms have been designed in a modular fashion, to allow for flexible adoption across disparate care delivery contexts. While most forms have been designed for settings where paper and Excel-based data entry are the primary solution, this content is also in the process of being integrated into various digital health platforms, including CommCare, OpenMRS, and REDCap.

The goal for all of the data collection solutions profiled below is to facilitate data-driven service provision while also minimizing data entry burdens on busy staff.

Please see annex for further detail and data collection forms.

6.2 Forms

Based on WHO standard forms and input from PIH's clinical leads, individual-level forms have been developed to cover the following topics:

- Symptom screening for COVID-19 cases and contacts
- Lab testing registers & lab request & result forms
- Patient intake and exposure history for COVID-19 cases and contacts
- Facility admission, daily progress, and discharge forms
- Final outcomes for COVID-19 cases and contacts

Additionally, several registers have been developed to facilitate efficient tracking of large numbers of cases and contacts who may need to be followed over time in community and facility settings:

- Contact tracing and isolation monitoring register for COVID-19 contacts
- Suspected case testing follow-up register
- Case monitoring in community register
- COVID-19 Patient treatment register

The following forms are currently under development and will be available soon:

- Management of home-based care patients (daily symptom diaries, etc.)
- Mental health and social support forms

6.3 Practical concerns

In times like these where PPE is in short supply and we are fighting a disease with high transmissibility, data collection practices must adapt—for example, paper forms should not exit isolation areas and data collection staff should not enter these areas unless they are equipped with appropriate PPE. In order to continue collecting data under these circumstances, some creative tactics may be employed.

For example, clinicians with appropriate PPE use paper forms to record vital information. For information that needs to leave the isolation unit for programmatic or research purposes, a cell phone or tablet can be used to photograph the data forms. Data clerks outside the isolation unit can

then enter the data from the photographs into Excel. If the isolation unit is internet connected, the photos can be securely transmitted electronically, using Microsoft 365 shared folders or other encrypted file sharing solution (email Dave Mayo dmayo@pih.org for advice on specific secure data transfer options). If the isolation units are not internet connected, the cell phone or tablet can be sterilized and brought out of the isolation unit to share the photos with data clerks through wired upload from phone to laptop.

For community health workers or other outreach staff collecting data at households or other community settings, IDinsight has created a helpful guide with resources for maximizing staff safety even as they engage in this important work (https://www.idinsight.org/data-collection-practices-and-recommendations-for-covid-19)

6.4 Digital data collection tools

For sites with sufficient human resources and other required infrastructure, digital data solutions may allow health workers to avoid lengthy paper forms and benefit from real-time decision support and other features available through phone or tablet-based applications. Currently, there are a variety of COVID-19 modules built in software platforms that are commonly used at PIH sites, specifically:

- **CommCare**: Standard application available based on WHO FFX protocol; a simplified, PIH-specific app under development by Zanmi Lasante, which could be adapted to other care delivery site contexts. A simple SMS-based app also under development to assist with home-based monitoring for mild cases in self-isolation.
- **OpenMRS**: COVID-19 related laboratory functionality in use at 2 PIH facilities: University Hospital in Mirebalais, Haiti, and Wellbody Health Center in Sierra Leone. Additional functionality currently under development by the OpenMRS global community.
- **REDCap**: App under development by Harvard Research Core to support operational research around healthcare provider screening; Research Core team is available to help create a broader suite of REDCap forms to support patient care, if requested.

For sites interested in potentially using/adapting an application in CommCare, REDCap, or OpenMRS, please contact Annie Michaelis (amichaelis@pih.org).

6.5 Aggregation, synthesis & dissemination of data

Whether entered in Excel or a digital health solution, data can be imported into PIH's data warehouse and then aggregated into helpful dashboards using JET Reports or PowerBI. Draft dashboards are under development. To provide inputs on what data would be most useful to see visualized in PIH dashboards please email BostonSIS@pih.or

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