

PIH Guide | COVID-19

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

Updated 26 June 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

Definitions

General definitions are provided below, countries should make definitions align with MoH definitions. Definitions matter because they inform where the patient should be hospitalized and managed.

COVID-19 Suspected case: Includes any person that is being tested for COVID-19.

- Avoid negative terminology such as “COVID Suspect” instead use the terminology of “a person, or patient, with suspected COVID-19”.
- If hospitalization is needed, these cases are hospitalized on the suspected-case ward.
- If possible, the suspected case ward can be divided into high-risk COVID and low-risk COVID

COVID-19 Presumptive case: Includes persons that are likely to have COVID-19 because they have either (1) a positive antigen or antibody test or (2) because they have a close contact of a person with COVID-19 and are exhibiting signs and symptoms of COVID-19.

- In general, if they need hospitalization, they can be placed on the COVID-19 confirmed-ward or in the high-risk suspect ward (depending on hospital protocol); they should not be placed on the low-risk suspected-case ward.
- Treat and manage the patient as if they have confirmed COVID-19.

COVID-19 Confirmed case: a case that has been confirmed with RT-PCR testing or Xpert testing.

- This is what most countries use as a confirmed case definition.
- Some countries include positive rapid tests with a contact or strong clinical history for COVID-19 as a confirmed case.

COVID-19 Recovered case: Persons with COVID-19 (presumptive or confirmed) who meet the following conditions (if all three conditions are met, isolation can be stopped):

- At least 3 days (72 hours) have passed since recovery defined as resolution of fever without the use of fever-reducing medications; and,
- Improvement in respiratory symptoms (e.g., cough, shortness of breath); and,
- At least 7 days have passed since symptoms first appeared.
- (If a person is going to a skilled nursing facility or returning to work in patient care consider documenting with RT-PCR the patient is negative before defining the patient as recovered).

Isolation: Isolation separates sick people with a contagious disease from people who are not sick. This guide recommends isolation for suspected, presumptive and confirmed cases.

Quarantine: Quarantine separates and restricts the movement of people who were exposed to a contagious disease to see if they become sick. This guide recommends to quarantine persons that have been exposed to COVID-19 cases. Sometimes quarantine is referred to self-isolation or a person under observation.



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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%
 - Dyspnea 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 4 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

- As the global pandemic grows, suspect cases should be immediately isolated regardless of test status. All tests have both false positives and false negatives. A high index of suspicion should be used to protect staff and other patients.
- There are three types of tests for COVID-19, as described in Table 1.
 - Reverse transcriptase polymerase chain reaction (RT-PCR)** – The PCR test detects the genetic material of the virus. This type of test is also called a “molecular test.” This is considered the gold standard.
 - Antibody (IgM/IgG) rapid diagnostic test (RDT)** – Detects antibodies in the blood to SARS-CoV-2. Because this test measures the body’s response to the virus there is a window period between infection and having a positive antibody response. While a positive antibody test is helpful, a negative antibody test should NEVER be equated with the absence of infection. All suspects should be isolated even if the antibody test is negative.
 - Antigen rapid RDT** – Rapid antigen testing is new and Partners In Health is working on procuring and validating.
- The gold standard is considered the RT-PCR. Partners In Health has worked to expand availability of testing through trying to procure rapid antibody tests and rapid antigen tests.
- The Xpert® Xpress SARS-CoV-2 cartridge also uses PCR technology and uses the same Xpert machines as used for diagnosis of tuberculosis (TB), cartridges will be available in July 2020.
- Window period:**
 - at the onset of symptoms the patient may test negative for PCR but have the disease if the viral load is low
 - Antibodies have not yet been produced in the body to the level at which they are detectable by the test (antibody RDT).
 - This is why all suspect cases should be isolated.

Table 3.1. Types of tests

Characteristic	RT-PCR	Antibody (IgM/IgG) RDT	Antigen (Ag) (RDT)
Sample	Nasopharyngeal swab or deep sputum ^{ii,iii}	Blood (finger stick or blood draw)	Nasopharyngeal swab or deep sputum
Window period	Short	7-10 days after symptoms	Short
False positives	Almost none	Low to moderate. It is possible to have cross-reactivity to other cross-reactivity with other coronavirus different from SARS-CoV-2	Very Low
False negatives	Occasionally (especially in the window period)	Variable. High at the onset of the symptoms	Moderate (not as sensitive as RT-PCR)
Turn-around time/ Laboratory requirements	Hours - requires a laboratory with high technical capacity.	15 min – No Laboratory required.	30 min – No Laboratory required.

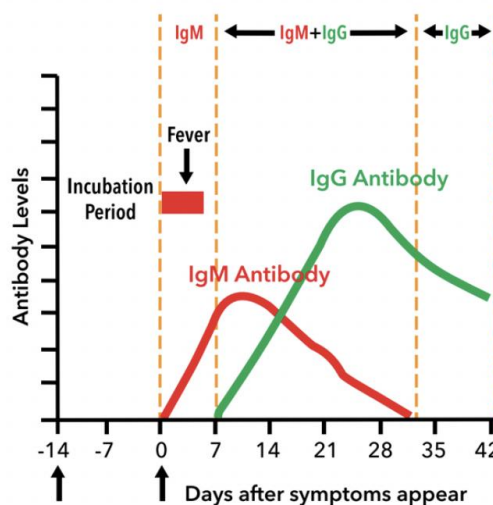
Reverse transcriptase polymerase chain reaction (RT-PCR)

- This test is done most commonly on a nasopharyngeal swab. The test can also be done on a bronchoalveolar lavage fluid or deep sputum.
- Note: Deep sputum is not saliva but the thick mucus—sometimes called phlegm—which is coughed up from the lungs and should be collected in a similar way to how a TB sputum is collected. If the patient has a dry cough, or has no sputum production, sputum collection may not be possible.
- Avoid sputum induction as the virus will be aerosolized which creates a potentially high transmission condition.
- A nasopharyngeal swab is taken from deep in the nose or oropharynx (see Chapter 5).
- 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% especially early in person's infection.
- 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.

Antibody (IgM/IgG) RDT

- This test is done on blood (finger stick or blood draw).
- Sensitivity and specificity can vary depending on the brand of antibody test but are generally around 90% compared to RT-PCR.
- False positives can happen when there is cross-reactivity to other coronavirus different from SARS-CoV-2 (for example, there are coronaviruses that cause the common cold and the antibodies to them could produce a false positive).
- In general IgM is indicative of acute infection and can be detected in most patients 8 days after the onset of symptoms, and IgG becomes positive a few days after the rise of IgM (see Figure 3.1) and can remain elevated after the infection has resolved.

Figure 3.1. The lag time between onset of symptoms and production of detectable antibodies



- The lag time of antibodies creates a window period during which the patient may have a negative IgM/IgG RDT, but still have COVID-19.
- Interpretations of the IgM/IgG antibody is provided in the Table 3.2 below.

Table 3.2 Interpretation of the IgM/IgG antibody test

IgM	IgG	Interpretation	Instructions
Negative	Negative	<ul style="list-style-type: none"> No serological evidence of infection with COVID-19. Possibly in the “window period of infection” Possibly a weak, late or absent antibody response. This has been reported in patients of older age, poor nutritional status, with severe COVID-19 disease. Also, medications or infections like HIV that suppress the immune system can blunt the antibody response. 	<ul style="list-style-type: none"> If symptomatic, quarantine in hospital or at home. Consider repeat testing in 5 days.
Positive	Negative	<ul style="list-style-type: none"> Probably in the early stage of infection, no IgG has been produced yet or IgG level does not reach the lowest level of detection. Possibly a false-positive IgM (cross-reaction to other coronaviruses). 	<ul style="list-style-type: none"> Likely a case. Quarantine in hospital or at home. Refer sample for RT-PCR testing if possible.
Negative	Positive	<ul style="list-style-type: none"> Probably in the advanced stages of infection or has had a past infection that has resolved (the time frame of when IgM disappears in old infection has not been determined, IgG remains in the blood for a long time). Possibly a false-positive IgG (cross-reaction to other coronaviruses). This pattern with IgG positive, but IgM negative suggest a possible cross-reaction to a other coronavirus. 	<ul style="list-style-type: none"> Possibly a case but resolving or resolved. May no longer be infectious if symptoms have resolved. Refer sample for RT-PCR testing if possible. May quarantine to be on the safe side.
Positive	Positive	<ul style="list-style-type: none"> Probably in the active phase of infection or is in the recovery phase of the disease and the IgM is still above the level of detection. Possibly a false-positive resulting from immunity to other coronaviruses. 	<ul style="list-style-type: none"> Likely a case Quarantine in hospital or at home. Refer sample for RT-PCR testing if possible

- To decrease the number of false negatives, use the antibody test at least 8 days after the onset of symptoms such as fever.
- It is widely accepted that IgM provides the first line of defense during viral infections, followed by the generation of IgG responses for long term immunity and immunological memory.

Antigen (Ag) RDT

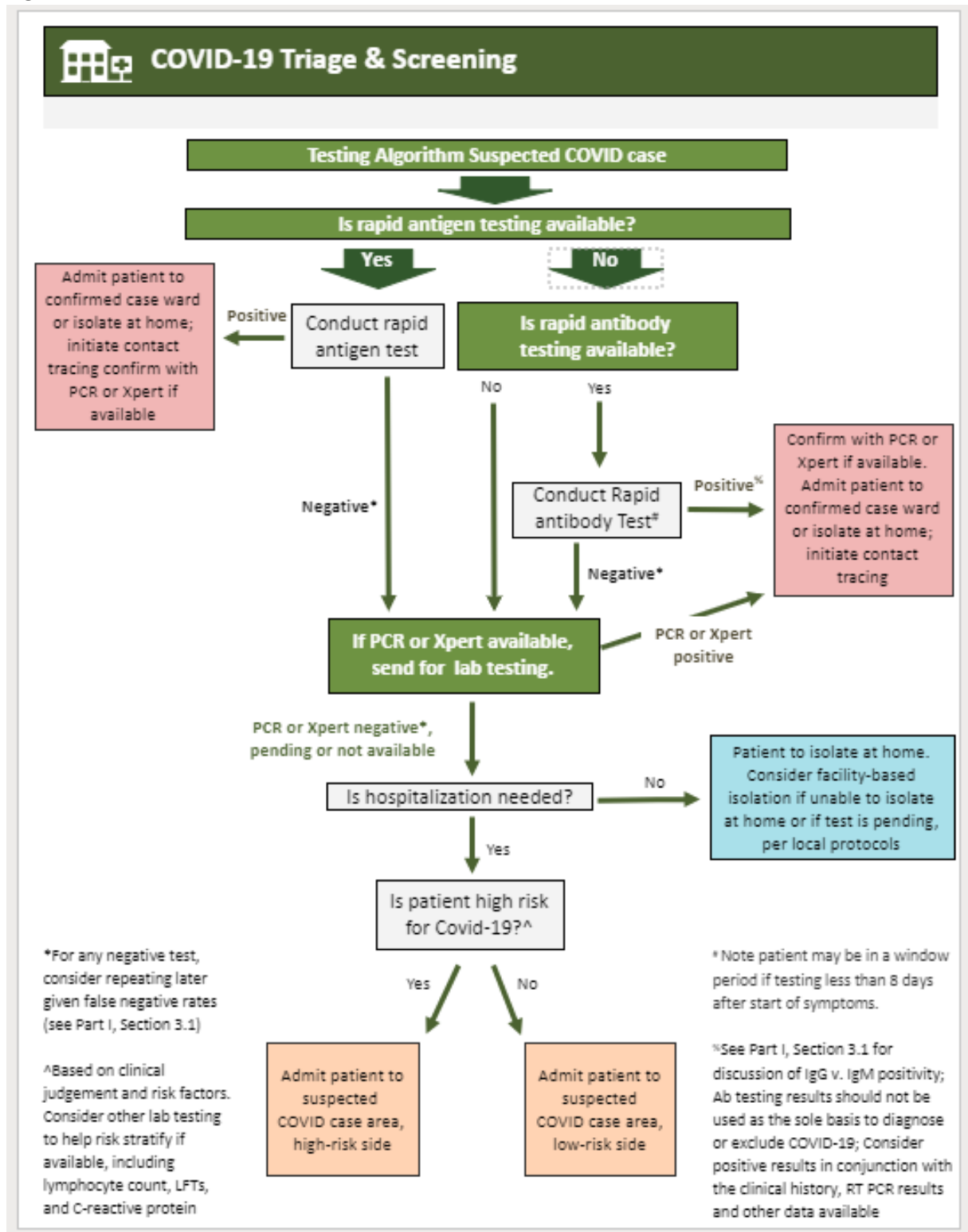
- Consult the manufacture’s insert to see what the specimen collection requirements are, many are designed for nasopharyngeal swab only.
- A single negative Ag RDT doesn't exclude COVID-19 (especially if taken relatively early in the disease course). If the Ag RDT is negative, but suspicion for COVID-19 remains, then ongoing isolation and re-testing several days later should be considered.
- False positives are quite rare for the antigen tests.

3.2 Who should be tested?

- In areas of limited availability of tests, persons that have symptoms consistent with COVID-19 infection should be prioritized for testing. Testing of certain high-risk of certain high-risk asymptomatic individuals (CHWs, high-risk contacts, etc.) should be considered if testing resources permit.

- A symptomatic person with COVID-19 often has a fever, respiratory symptoms or shortness of breath. However, presentation can vary and they can have any of the symptoms listed in section 1.2 and may present with a single symptom.
- Nasal congestion with no fever or lower respiratory symptoms is more consistent with the common cold or allergic rhinitis; in general these patients are not tested unless they have had recent exposure to a person with COVID-19.
- A loss of smell (and sometimes changes in taste) has been seen with COVID-19. Although it is not all that common, a respiratory illness together with the loss of smell should alert the HCW to test the patient for COVID-19.
- In an areas where there is suspicion of an outbreak in a cluster, even persons with mild or moderate symptoms should be tested to better identify clusters and perform contract tracing.
- Eventually, when tests become more available, programs may want to test asymptomatic persons with known exposure to COVID-19 (asymptomatic contacts) to better identify, isolate and monitor cases that have the potential to spread the disease or become symptomatic themselves.
- A person is no longer considered to be contact if the last contact with a COVID-19 patient was greater than 14 days; however, there are some outliers where the incubation is longer than 14 days (rare). See Chapter 4 below for more information on contacts.
- Patients with bilateral pneumonia on chest X-ray are also good candidates to test for COVID-19 as this is a sign highly consistent with COVID-19.
- Report all confirmed cases of COVID-19 to the MOH as per their guidelines.
- The below figure is a flow diagram for testing based on the availability of which rapid test is available.

Figure 3.2



3.3 Screening high-risk groups

- As part of surveillance or contact tracing, high-risk groups can be screened for COVID-19.
- Although screening can be done with simple questionnaires to alert who to test, this section concentrates on testing a group of persons with one of the testing modalities discussed in section 3.1.
- Screening is commonly done in asymptomatic persons who have a high-risk of COVID-19.
- If a person being screened has symptoms of COVID-19, use Testing Algorithms 1 through 4, depending on which tests are available.
- When tests are limited, general screening should be restricted to groups at very high-risk of having COVID-19 – in an outbreak in a cluster of persons.
- Common high-risk groups to be considered for screening:
 - Health care workers (HCWs) caring for patients with COVID-19.
 - Congregate settings where an outbreak is suspected or has occurred.
 - Travelers coming from high prevalence areas.

HCWs in high patient flow areas

- As part of surveillance or infection prevalence studies, consider screening a sample of health workers on the wards or in a clinic. For example, 10% of the nurses working on an inpatient ward could be tested periodically if sufficient tests are available. Consider staff limitations that may occur if these HCWs test positive.
- The antibody test is used if only looking to document infection prevalence studies and understand who may be immune.
- Of note, a positive antibody test in someone that has recovered from COVID-19 likely conveys immunity, although this has not been fully proven and the length of that immunity is not yet established.
- For symptomatic HCWs use Algorithm 1 through 4.
- How to perform surveillance or infection prevalence studies is not covered in this guide.
- Study/surveillance protocols will be available from www.PIH.org for guidance performing surveillance of HCWs in the near future.

Congregate settings

- Congregate settings include places where people live or socialize in large numbers; COVID-19 can easily propagate in such settings.
 - Churches or mosques.
 - Psychiatric institutions.
 - Long-term care facilities (e.g. nursing homes).
 - Prisons.
 - Refugee camps.
 - Detention centers.
- Such settings are very vulnerable to COVID-19 outbreaks and screening early can pick up cases and prevent larger scale outbreaks.
- 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

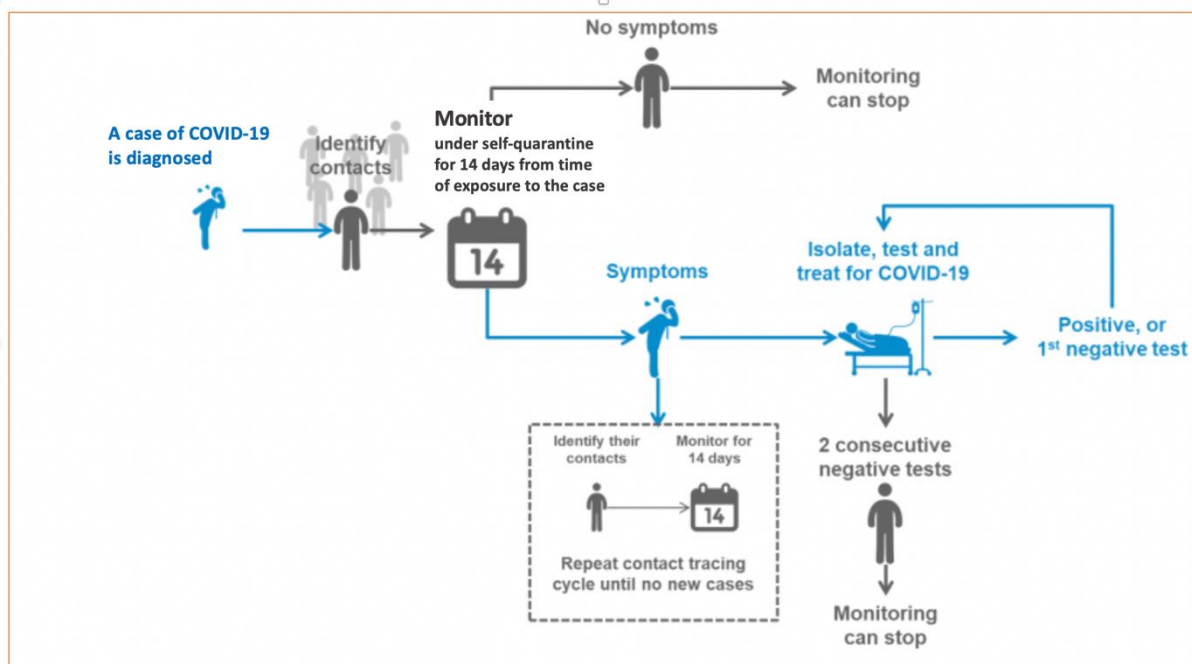
temperature. This can apply for persons coming from international destinations or from hotspots within the country.

- 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 or voluntary 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). Consider the psychosocial effects of enforced quarantine.

4 Contact tracing

- A key strategy to stopping the spread of COVID-19 is contact tracing.
- Figure 4.1 below, illustrates the flow for contact tracing.

Figure 4.1. Contact tracing in COVID-19



4.1 Definition of a contact

- Anyone who has been in contact with a person documented to have COVID-19 during the time the person with COVID-19 was symptomatic or two days before symptoms began
 - Providing direct care or other ancillary medical services to COVID-19 patients without proper PPE;
 - Spending significant time in the same close environment with a person with COVID-19 (in the workplace, classroom, or household, at church, or at other close gatherings); or
 - Traveling together in close proximity (<2 m) with a COVID-19 patient in any kind of vehicle for an extended period of time.
- A person is no longer considered to be at risk for COVID-19 if the last contact with a COVID-19 patient was greater than 14 days; however, there are some outliers where the incubation is longer than 14 days. If the person is returning to a situation where they may endanger others,

- In some cases, two negative PCRs, 24 hours apart will be used to document that a person is no longer infectious
- Definition of close contact for the purpose of the case definition, by European CDC (<https://www.ecdc.europa.eu/en/case-definition-and-european-surveillance-human-infection-novel-coronavirus-2019-ncov>)
 - A person living in the same household as a COVID-19 case;
 - A person having had direct physical contact with a COVID-19 case (e.g. shaking hands);
 - A person having unprotected direct contact with infectious secretions of a COVID-19 case (e.g. being coughed on, touching used paper tissues with a bare hand);
 - A person having had face-to-face contact with a COVID-19 case within 2 metres and > 15 minutes;
 - A person who was in a closed environment (e.g. classroom, meeting room, hospital waiting room, etc.) with a COVID-19 case for 15 minutes or more and at a distance of less than 2 metres;
 - A healthcare worker (HCW) or other person providing direct care for a COVID-19 case, or laboratory workers handling specimens from a COVID-19 case without recommended personal protective equipment (PPE) or with a possible breach of PPE;
 - A contact in an aircraft sitting within two seats (in any direction) of the COVID-19 case, travel companions or persons providing care, and crew members serving in the section of the aircraft where the index case was seated (if severity of symptoms or movement of the case indicate more extensive exposure, passengers seated in the entire section or all passengers on the aircraft may be considered close contacts).

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. Proper PPE is important to protect the contact tracing team and the person being interviewed (infected healthcare workers could be asymptomatic and infectious, thereby potentially serving to spread the virus to community members they visit them during contact tracing).
- The CHW's role in case finding for COVID-19 is determined country by country (see Section 4.3 below on possible roles of CHWs).

4.3 Contact tracing procedures, follow-up and discharge

- The contact tracing procedure is illustrated in Figure 4.1 above.
- Contact tracing involves finding out who a patient with COVID-19 has been in close contact with, finding those individuals, and screening them for COVID-19.
- Any symptomatic contacts should be tested (if testing availability permits, asymptomatic contacts can also be tested) .
- Asymptomatic contacts should be told to self-isolate for 14 days from last day of exposure.
- The patient can be instructed to self-quarantine, which may mean living in a separate house, or distant room in a shared house.

- If this is not possible, the contact should self-isolate and all household members should self-isolate together in the same house.
- If all members of the family are not able to self-isolate together, they could self-isolate as soon as they develop symptoms; this is not ideal as people can spread the disease a few days before symptoms develop. Family members that are asymptomatic should practice social distancing if they leave the house and use covering over their mouth and nose.
- Daily or frequent communication with a member of the contact tracing team via phone or in person is ideal to monitor for symptoms.
- CHWs can also be used to check on the patient and monitor him or her for symptoms, preferably without entering the house and staying 2 meters away (or with appropriate PPE if available).
- Provide all contacts identified with information on when and how to seek care if they develop a cough, fever, shortness of breath, or other symptoms.
- If a contact develops mild symptoms of COVID-19, he or she should alert their CHW, and self-quarantine at home. The person can be discharged from self-isolation and monitoring 14 days after the last contact with a COVID-19 case if the person has not developed symptoms.
- If a contact develops symptoms of COVID-19 that require hospital care, the following steps should be taken:
 - If possible, that individual or a CHW should notify the health center or hospital that the patient is on their way there.
 - Whenever possible, patients should remain at least 2 meters apart from anyone accompanying them to a healthcare facility.
 - Avoid public transportation, use an ambulance if available, go by foot, or use a private vehicle if possible.
 - Clean vehicle surfaces that come into contact during patient transport with a liquid disinfectant as per Chapter 2, section 5, Part II.
- If the contact has not developed any symptoms of COVID-19 during the 14 days of self-isolation and monitoring, he or she can stop self-isolation measures.

5 Public use of face coverings for prevention of COVID-19

- This guide strongly recommends the use of face coverings (non-medical masks) for the public during a COVID-19 outbreak in urban, semi-urban and in rural areas where people gather.
- All MoHs should have a media campaign to promote and educate the public on the use of face coverings, including how to safely use them.
- In urban hotspots of COVID-19, it is reasonable to make face coverings mandatory in spaces where social distancing is not possible. However, we discourage fining people without a mask but rather for MoHs to have a strong campaign on how wearing a face cover protects others.
- Face coverings are NOT a substitute for other preventive measures like regular handwashing, cleaning surfaces, social distancing and contact tracing – all must be done together
- It is easy to tell at a glance in a public space how well a population is following this very important preventive measure. When it is not being followed, measure to increase awareness and compliance should be implemented immediately.
- Countries are encouraged to mass produce cloth face coverings and give them out for free to all.
- While waiting for mass production, people can make their own masks (see Section 5.5)

- This chapter is in large part adapted from the South African recommendations.¹

5.1 Justification

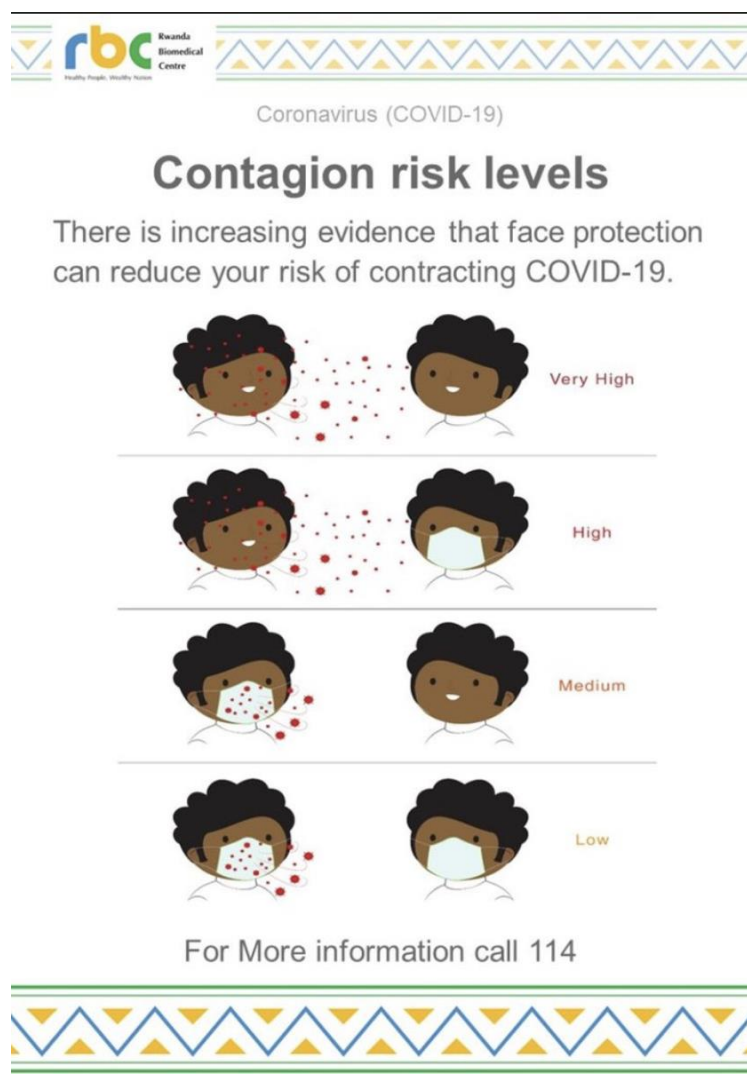
- Research shows N95 masks, medical masks, even homemade masks could block a very high percentage of the virus in aerosols that come from a wearer's nose and mouth.²
- Maximal viral shedding of SARS-CoV-2 (the cause of COVID-19) occurs early in the course of the illness. Patients can be contagious before they develop symptoms or even know that they are infected. Face coverings can be effective at decreasing spread from presymptomatic or asymptomatic individuals.
- Face covers are simple, cheap, and there is some evidence that shows them to be effective.³ While no randomized control studies exist on the use of public face covering, general scientific consensus is they could have a substantial impact on transmission with a relatively small impact on social and economic life.
- Face coverings should be worn outside the home in situations where meeting others is likely (for example, shopping, public transport).
- Face coverings can also be used at home by a person showing symptoms to help protect other family members when quarantining outside of the house is not possible.
- The public is likely to comply more closely with face cover advice than wider stay at home orders in some settings. People have to leave their houses for essential items. Face coverings allow them to do this with less risk to others.
- Modelling studies suggest that even a small reduction in community transmission could make a major difference in the epidemic and save many lives.
- Figure 5.1 demonstrates the theory of how transmission is decreased the most when EVERYONE in public wears a face covering: "My Face Cover Protects You, Your Face Cover Protects Me".
- In summary, a cloth face covering, if appropriately used and cleaned, can offer the following protection:
 - Reduce the transmission of droplets from the source (any person coughing or sneezing)
 - Reduce inhaling a large number of droplets from others
 - Reduce exposure in overcrowded areas such as taxis, shops, or government buildings

¹ <https://www.westerncape.gov.za/departments-of-health/news/covid-19-cloth-masks-public-use>

² Ma QX, Shan H, Zhang HL, Li GM, Yang RM, Chen JM. Potential utilities of mask wearing and instant hand hygiene for fighting SARS-CoV-2 [published online ahead of print, 2020 Mar 31]. J Med Virol. 2020;10.1002/jmv.25805

³ <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover.html>

Figure 5.1 Example on public face covering from Rwanda



Rwanda Biomedical Medical Center. Kigali Rwanda

5.2 Medical masks and N95 respirators should NOT be used by the public

- The cloth face coverings recommended for the public are NOT surgical masks or N-95 respirators.
- At top priority of the MoH is to ensure front-line healthcare workers caring for COVID-19 patients have the required N95 respirators and/or medical masks so that they are protected while caring for patients.
- In addition, there is a global shortage of medical masks, so we are urging non-healthcare workers not to wear medical masks. This is to ensure an adequate supply of medical masks are available to frontline healthcare workers.
- It should also be noted that **cloth masks** are not considered appropriate for health care workers.
- Patients with suspected or confirmed COVID-19 can wear a medical mask because they are very good at capturing droplets coming from the persons' nose and mouth. However, if medical masks are not available for COVID-19 cases, a face covering described in this chapter will likely do just as well.

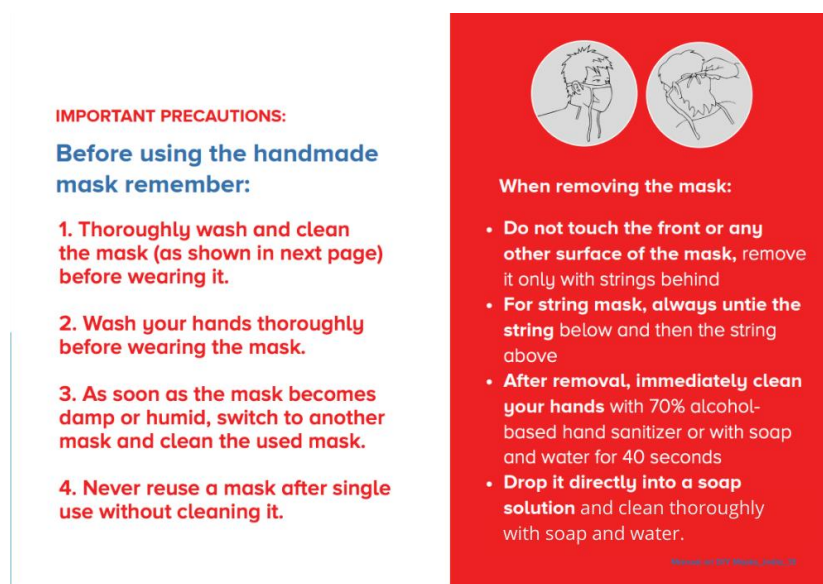
5.3 When to use cloth face covering

- When less than one meter from people who may have COVID-19 infection, for example:
 - Travel to and from work in public transport
 - When stepping outside the house to go shopping or seeking healthcare
 - In quarantine/self-quarantine/isolation when contact with others is necessary.
 - In offices when physical distance is not feasible.
 - When conducting interviews during house to house visits, quarantine homes (e.g., community health workers, etc.)
 - When cleaning the streets/ disposing of domestic rubbish
- A face covering is not needed outside if the road or area is scarcely populated, and the person can keep 2 meters away from all other persons at all times.

5.4 How to properly use a cloth face covering:

- Wash your hands before putting on and removing of a cloth face covering, never touch the cloth part, never touch the inside whilst wearing, avoid touching your face.
- Wash cloth face coverings with warm soapy water and iron when dry.
- Only use a cloth face covering that has been cleaned and disinfected/ ironed
- Place the face covering carefully, ensuring it covers the mouth and nose, and tie it securely to minimize any gaps between the face and the cover.
- Tie the strings behind your head, or if you are using elastic bands, make sure these are tight
- Make sure it fits well. Move it around to get the best fit. Never touch the cloth part.
- Once you have put on the cloth face covering, DO NOT TOUCH YOUR FACE or the front of the face cover again until you take it off.
- When you take it off, undo the ties, and carefully fold the cloth face covering inside out, hold it by the strings/elastic and place it in a plastic/container preserved for washing the cloth face covering only
- After removal or whenever a used face cover is inadvertently touched, clean hands using an alcohol-based hand rub or soap and water if hands are visibly dirty.
- Replace face covers as soon as they become damp with a new clean, dry one.
- If a person can manage to have several face covers it is better. That way it can be changed as soon as it becomes moist or damp.
- Keep small plastic bag for placing dirty cloth face cover. Do not re-use a face cover that has been stored in a plastic bag before washing it.
- Figure 5.2 illustrates the key components of using a face covering.

Figure 5.2 Important instructions on using a cloth face covering.



5.5 Making cloth face coverings (homemade)

- A cloth face covering can be made in any non- industrial or domestic setup and is relatively simple to make. There are many YouTube videos that suggest how to make a homemade face cover.
- The following features related to nonmedical masks should be taken into consideration:
 - Numbers of layers of fabric/tissue
 - Breathability of material used
 - Water repellence/hydrophobic qualities
 - Shape of cover
 - Fit of cover
- A cloth cover typically comprises of square pieces of cloth with three pleats that can cover the face from ABOVE the nose to BELOW the chin and almost up to the ears.
- A typical T-shirt is often very loosely woven and if used three layers of cloth should be used to comprise the face cover.
- A favorite design of ours is to use the combination of a cotton T-shirt with a paper towel placed in between (see Figure 5.3).

Figure 5.3 – how to make a face cover out of a T-shirt and paper towel



- Cloth face coverings can be also hand-made with sewing machines. They can be designed with a pocket to insert a paper towel or tissue paper.
- Basic design tips of a handmade sewn face covering include:
 - Two layers, an inner and outer surface of the face cover:
 1. Outer layers:
 - Made from thick weave cotton like denim, calico or upholstery cotton fabric that can be easily washed.
 - Comprising two different patterns on the cloth - if possible - to distinguish between inside and outside of the cloth face cover
 2. Inner layers:
 - Two layers of ordinary cotton typically used for linen;
 - If possible – between the two inner cotton layers - a breathable layer of non-woven fabric which is washable at high temperatures – or if you don't have that, something like a jacket lining inner.
 - Alternative to having an inner later of non-woven cloth, is to have a pocket where filter paper (like a paper coffee filter), tissue paper or paper towel can be inserted.
 3. Strings or strap:
 - Strings or straps can be sewn, tied through a small whole in the cloth's edge.

5.6 Harms are unlikely

- The general scientific consensus is that the use of face coverings for the population will be largely beneficial and harms are unlikely.
- One potential harm is face coverings can give a person a false sense of protection and they do not do other preventive measures like handwashing and social distancing.
- A second potential harm is if the cloth face cover is not handled correctly or washed correctly the person could self-infect themselves with a contaminated cover.
- If education on the use of cloth face coverings is done correctly, it is unlikely and of the potential harms will materialize.

5.7 Evaluation of implementation of face coverings

- It is very easy to evaluate how well face coverings are being used by a population.
- Simple take a look at a public street, park or market and estimate the percentage of persons wearing a mask.

6 Laboratory

6.1 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

6.2 Laboratory Procedure for IgM/IgG RDT (SD Biosensor, STANDARD Q COVID-19 IgM/IgG ComboTest)

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

Product description and principle

The STANDARD Q COVID-19 IgM/IgG Combo Test Kit is a rapid immunochromatography test designed for the qualitative presumptive detection of specific IgM and IgG to SARS-CoV-2 in humoral fluid (capillary whole blood, venous whole blood, serum, or plasma). Either 10µl (serum, plasma) or 20µl (whole blood) of specimen is required and the results are available within 15 minutes. No extra equipment is needed to perform the test, making this suitable for point-of-care (POC) testing.

Clinical evaluation studies have indicated that this test gives 94.51% % sensitivity (from the 7th day after symptom onset) and 95.74 % specificity.

Note:

1. **Positive results** detect the presence of viral antigens, but clinical observation with patient history and other diagnostic information should be considered in order to determine infection status.
2. **Negative results** do not rule out SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions: recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19 should all be considered in the context of the patient, and confirmed with a molecular assay, if possible.

Warnings and Precautions

- Wear PPE such as gown, gloves, surgical mask and face shield when collecting or performing the test. Refer to procedure for the proper use of PPEs.
- Clean work surface with available disinfectant before starting work.
- Place absorbent bench liner on work surface to capture potential splatters and splashes.
- Store test kits at 2 - 30°C / 36 - 86°F.
- Test kits have a shelf-life of 24 months.
- Use universal precautions when handling blood samples.
- Discard all materials used for sample collection and test procedures in a biohazard container and/or sharps bin.
- Good laboratory practice recommends the use of the control materials. Users should follow the appropriate guidelines concerning the frequency and use of external control materials. Refer to Section "Laboratory Procedure for External Quality Controls for Antibody and Antigen Rapid Tests" in the PIH Guide to Community and Clinical Management of COVID-19.

Requirements and Sample Collection

<i>Materials required but not provided:</i>	<ul style="list-style-type: none"> ▪ Proper PPE (for sample collection and test procedure) ▪ Permanent marker <p>For capillary whole blood samples:</p> <ul style="list-style-type: none"> ▪ Lancet ▪ Alcohol wipes <p>For serum/plasma/venous whole blood:</p> <ul style="list-style-type: none"> ▪ Venipuncture materials (tube with EDTA, heparin or sodium citrate, needle and/or syringe) ▪ Micropipette ▪ Sterile filtered tips for micropipette ▪ Centrifuge (for separating serum and plasma)
<i>Materials provided:</i>	<ul style="list-style-type: none"> • Capillary tube

Sample collection:

1. **Blood by Fingerstick:**
 - Use the middle or ring finger, ideally of the non-dominant hand.
 - Note: the puncture should be made slightly off center from the fleshy portion of the finger, near the side of the fingertip.



- Thoroughly disinfect the puncture site using an alcohol pad and let air-dry.
 - Stick the side of the finger with the lancet. Apply only light pressure to the fingertip, until a blood drop appears. Do not press or milk the finger.
 - Discard the lancet into a sharps bin.
 - Wipe away the first 2-3 drops of blood with the alcohol pad. Ensure there is a free blood flow.
 - Collect 10 µl blood with the capillary tube (refer to Test Procedure, below).
2. Venous blood:
- Collect blood using a tube with anticoagulant (EDTA, heparin, sodium citrate), as per instructions for phlebotomy.

Test Procedure

<i>Materials required but not provided:</i>	<ul style="list-style-type: none">• Timer• Permanent marker• Proper PPE• Micropipette• Sterile filtered tips for micropipette
<i>Materials provided:</i>	<ul style="list-style-type: none">• Capillary tube• IgM/IgG test device

1. Identify the sample ID number on the test devices.
2. Obtain 20µl of sample using the provided capillary tube (up to the black line of the capillary tube) if the specimen is capillary whole blood. For venous whole blood, micropipette 20µl of specimen. For serum, or plasma, micropipette 10 µl of specimen.
3. Dispense specimen into the specimen well of the test device.
4. Discard the capillary tube in a sharps bin.
5. Add 3 drops (90 µl) of buffer vertically into the buffer well of the test device.
6. Read test result at 10 to 15 minutes, but not after 15 minutes. It may give false results.
7. Record all results on the laboratory worksheet and report form.
8. Dispose of the test devices as biohazard materials.
9. Clean work surface with disinfectant at the end of the work.

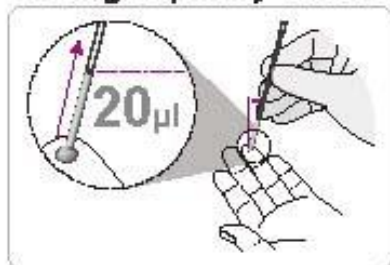
Interpretation of test result

There are three lines in the result window: one control line in the top (C), one test line at the middle for IgG (G), and one test line at the bottom for IgM (M). Look for the presence or absence of colored bands on the corresponding lines:

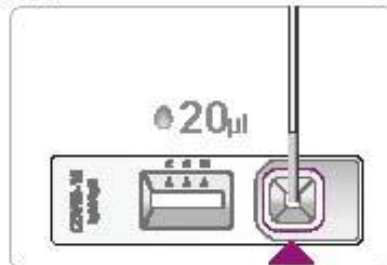
- **Negative Result for IgM:** The band of the control line (C) is colored (dark or faint) and the band of the test line IgM (M) is not colored.
- **Negative Result for IgG:** The band of the control line (C) is colored (dark or faint) and the band of the test line IgG (G) is not colored.
- **Positive Result for IgM:** The band of the control line (C) is colored (dark or faint) and the band of the test line IgM (M) is colored (uniform or not uniform).
- **Positive Result for IgG:** The band of the control line (C) is colored (dark or faint) and the band of the test line IgG (G) is colored (uniform or not uniform).
- **Invalid Result:** No colored band on line C. The band of the test line could be or not colored. Invalid result needs to be repeated with a new test device.

➤ Test Procedure

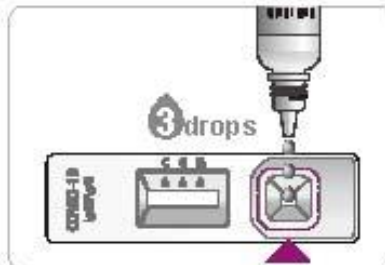
➤ Using Capillary whole blood



- 1 Collecting of Specimen**
Using a capillary tube, collect the 20 µl of capillary whole blood to the black line of the capillary tube.



- 2 Adding of Specimen**
Add the collected capillary whole blood to the specimen well of the test device.

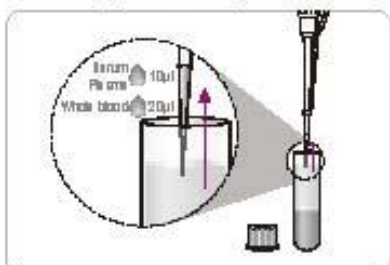


- 3 Dropping of buffer**
Add 3 drops (90µl) of buffer vertically into the buffer well of the test device.

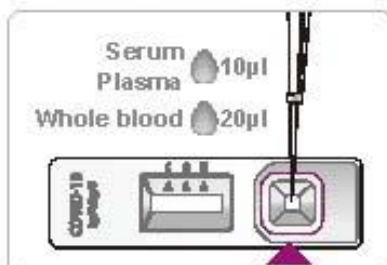


- 4 Reading Time**
Read the test result at 10~15 minutes.
Do not read test results after 15 minutes.
It may give false results.

➤ Using serum/plasma/venous whole blood



- 1 Collecting of Specimen**
Using a micropipette, collect the 10µl of serum, plasma or 20µl of venous whole blood with micropipette.



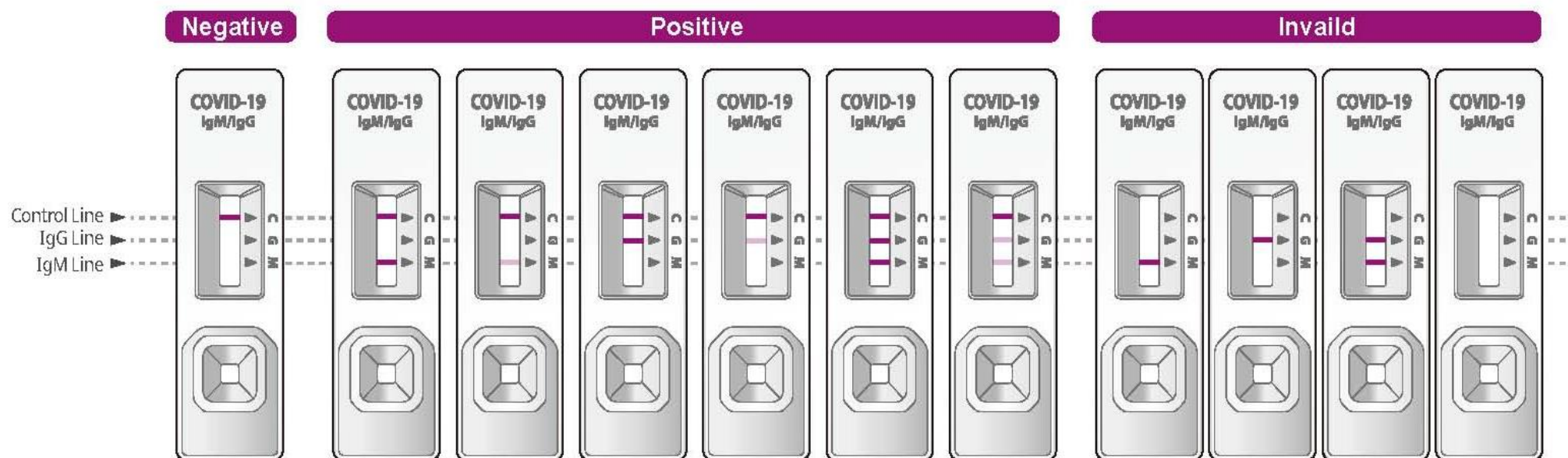
- 2 Adding of Specimen**
Add the collected serum, plasma or venous whole blood to the specimen well of the test device.



- 3 Dropping of buffer**
Add 3 drops (90µl) of buffer vertically into the buffer well of the test device.



- 4 Reading Time**
Read the test result at 10~15 minutes.
Do not read test results after 15 minutes.
It may give false results.



Re-test with a new test device.

1. A colored band will appear in the top section of the result window to show that the test is working properly. This band is control line (C).
 2. A colored bands will appear in the lower section of the result window. These bands are each test line of IgM/IgG (M, G).
 3. Even if the control line is faint, or the test line isn't uniform, the test should be considered to be performed properly and the test result should be interpreted as a positive result.
- * **STANDARD Q COVID-19 IgM/IgG Combo Test may cross-react with antibody against SARS-CoV-1.**
 - * **Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.**
 - * **Positive results should be considered in conjunction with the clinical history, RT-PCR results and other data available.**



Internal Quality Control

The test device has a built-in control line (C). Appearance of a colored band (dark or faint) at the control line can be considered as an internal positive procedural control. A band at the control line will appear (dark or faint) if the test procedure has been correctly performed. If a band at the control line does not appear, the test is invalid and a new test must be performed.

If the problem persists, please contact your local vendor or SD BIOSENSOR.

Limitation of Test

1. The test procedure, precautions, and interpretation of results must be followed strictly.
2. STANDARD Q COVID-19 IgM/IgG Combo test may cross-react with antibodies against SARS-CoV-1.
3. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
4. Positive test results should be considered in conjunction with clinical history, RT-PCR results, and other data available.
5. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
6. Neither the quantitative value nor the rate anti- SARS-CoV-2 IgM/IgG concentration can be determined by this qualitative test.
7. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.

References:

1. Instructions for using STANDARD Q COVID-19 IgM/IgG Combo Test, <http://sdbiosensor.com/xe/product/12509>
2. PIH Guide to Community and Clinical Management of COVID-19, <https://partnersinhealth.sharepoint.com/:f:/r/sites/COVID19/PIH%20Clinical%20Guides%20Protocols%20%20Job%20Aids%20for%20COVID1/Guides%20for%20Clinical%20and%20Community%20Management%20of%20COVID-19?csf=1&web=1&e=I3oPIb>.

6.3 Laboratory Procedure for Lateral Flow Immunoassay Ag RDT for Detection of SARS-CoV-2 Antigen (SD Biosensor STANDARD™ Q COVID-19 Ag)

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

Product Description

The STANDARD Q COVID-19 Ag Test is a lateral flow immunoassay used for the qualitative detection of nucleocapsid antigen protein from SARS-CoV-2 in nasopharyngeal swabs from persons suspected of COVID-19 infection.

Test Principle

The STANDARD Q COVID-19 Ag test is a rapid lateral flow immunochromatography test designed for the qualitative presumptive detection of SARS-CoV-2 nucleocapsid antigen from nasopharyngeal swabs collected during the acute phase of infection.



The test device (cartridge or cassette) contains a nitrocellulose membrane with two colorless, pre-coated lines: “C” control line and “T” test line. The control line region is coated with mouse monoclonal anti-chicken IgY antibodies. The test line region is coated with mouse monoclonal anti-SARS-CoV-2 antibodies. These mouse monoclonal anti-SARS-CoV-2 antibodies are conjugated with color particles and serve as indicators for the presence of SARS-CoV-2 antigen. This occurs when SARS-CoV-2 antigen (if present in the specimen) interacts with monoclonal anti-SARS-CoV-2 antibody conjugated with color particles, forming an antigen-antibody color particle complex. Via capillary action, this complex then migrates on the nitrocellulose membrane up to the test line, where (if present), it is captured by the mouse monoclonal anti-SARS-CoV-2 antibody.

A colored test line becomes visible in the result window if SARS-CoV-2 antigens are present in the specimen. The intensity of the colored test line will vary, dependent upon the amount of SARS-CoV-2 antigen present. A test line with no color indicates that SARS-CoV-2 antigens are not present in the specimen. The control line serves as a procedural control and should always appear (with color) if the test procedure was performed properly and the test reagents are working.

Note:

1. Positive results detect the presence of viral antigens, but clinical observation with patient history and other diagnostic information should be considered in order to determine infection status.
2. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions: recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19 should all be considered in the context of the patient, and confirmed with a molecular assay, if possible.

Warnings and Precautions

1. The package insert must be read completely before performing the test. Failure to do so may yield inaccurate test results.
2. Wear PPE such as gown, gloves, surgical mask, and face shield when collecting sample and/or performing the test. Refer to procedure for the proper use of PPEs. Wash hands thoroughly after the test is done.
3. Observe biosafety measures and good laboratory practices when handling specimen or performing the test, such as:
 - Clean work surface with disinfectant available before starting work.
 - Place absorbent bench liner on work surface to capture potential splatters and splashes.
 - Clean up spills thoroughly using an appropriate disinfectant.
 - Handle all specimens as if they contain infectious agents.
 - Dispose of all specimens and test materials as bio-hazard waste.
 - Laboratory chemical and biohazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
 - Clean the work bench and all non-disposable materials with disinfectant at the end of the work.
- Store the kit at room temperature or between 2-30°C / 36-86°F and out of direct sunlight.
- Kit materials are stable until the expiration date printed on the outer box.



- Do not freeze the kit.
- Do not re-use the test kit.
- Do not use the buffer of another lot.
- Do not use expired test devices.
- Do not use the test kit if the pouch is damaged or the seal is broken.
- Prior to starting the procedure, all reagents of the test kit must be brought to room temperature (15-25°C / 59-77°F).
- Test results should be read between 15 and 30 minutes after a specimen is applied to the sample well. Results read after 15 minutes may give erroneous results.
- Do not smoke, eat, or drink while handling specimen and performing test.
- Handle all specimens as if they contain infectious agents.
- Observe established precautions against microbiological hazards throughout the entire testing procedure.
- Desiccant is present in the foil pouch to absorb moisture and prevent humidity from affecting products. If moisture is present, the desiccant beads change from yellow to green, indicating that the test device in the pouch should be discarded.
- Good laboratory practice recommends the use of the control materials. Users should follow the appropriate guidelines concerning the frequency and use of external control materials. Refer to Section “Laboratory Procedure for External Quality Controls for Antibody and Antigen Rapid Tests” in the PIH Guide to Community and Clinical Management of COVID-19.

Sample Collection

Please note that inadequate sample collection and transport may impact the sensitivity of the PCR or GeneXpert test. A deep nasopharyngeal swab is necessary and often evokes coughing, that is why personnel collecting the sample must be in PPE.

<i>Materials required but not provided:</i>	<ul style="list-style-type: none">• Proper PPE• Permanent marker• Viral Transport Medium (VTM) – optional, may not be required
<i>Materials provided:</i>	<ul style="list-style-type: none">• Sterile swab

Sample Collection

Nasopharyngeal swab

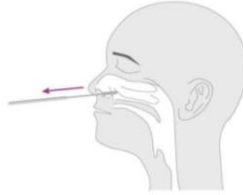
1. Seat the patient comfortably.
2. Using gentle rotation, insert the sterile swab (parallel to the floor of nose without pointing upwards) into the nostril of the patient, reaching the surface of the nasopharyngeal wall (posterior nasopharynx).



3. Rotate the sterile swab a few times against the nasopharyngeal wall.



4. Remove the sterile swab from the nasal cavity, carefully.

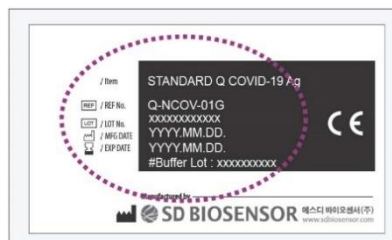


5. Specimen should be labeled with sample number and collection date.
6. Specimen ("fresh specimen") should be tested as soon as possible after collection.
 - Specimen in **extraction buffer** is stable for:
 - Up to 1 hour at room temperature ($20 \pm 5^{\circ}\text{C}$)
 - Up to 4 hours when stored refrigerated at $5 \pm 3^{\circ}\text{C}$
 - Only for one (1) freeze/thaw cycle when stored frozen at -20°C
 - Specimen in a **clean, dry, closed container (tube)** may be stored:
 - Up to 24 hours at room temperature ($20 \pm 5^{\circ}\text{C}$)
 - Up to 48 hours at $5 \pm 3^{\circ}\text{C}$ / $36-46^{\circ}\text{F}$
7. If transport of specimen in Viral Transport Medium (VTM) is required, minimal dilution of the sample is recommended – dilution may result in decreased test sensitivity. (**NOTE: for this reason, PIH Laboratory Services highly recommends not using VTM for this test.**)
 - Specimens in VTM ("stored specimen") are stable for:
 - Up to 8 hours at room temperature ($20 \pm 5^{\circ}\text{C}$)
 - Up to 12 hours when stored refrigerated at $5 \pm 3^{\circ}\text{C}$
 - Only for one (1) freeze/thaw cycle when stored frozen at -20°C

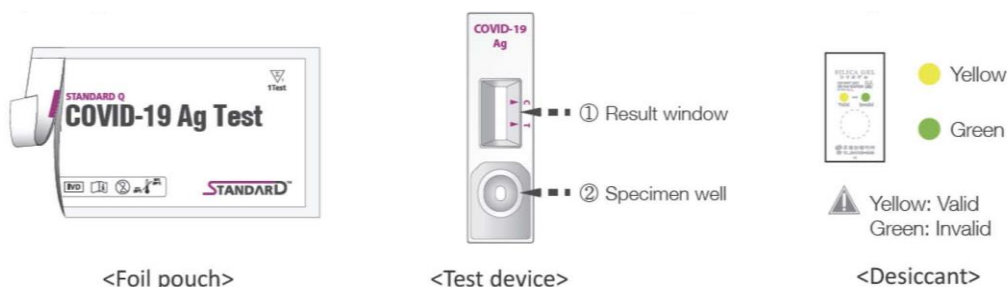


Test Preparation

1. Carefully read the instructions (package insert) for using the STANDARD Q COVID-19 Ag Test.
2. Check the expiration date on the back of the foil pouch that the test device is in. Do not use if the expiration date has passed.



3. Open the foil pouch and check both the test device and the desiccant pack in the foil pouch.



Test Procedure

<i>Materials required but not provided:</i>	<ul style="list-style-type: none"> • Timer • Permanent marker • Proper PPE
<i>Materials provided:</i>	<ul style="list-style-type: none"> • Test device (individually packed in a foil pouch with desiccant) • Extraction buffer tube with nozzle cap • Filter cap for extraction tube

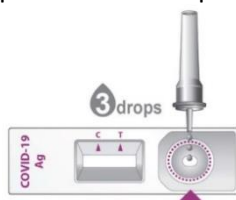
- Allow specimen (if test is not performed immediately after collection) and test device to be brought up to room temperature (15-25°C / 59-77°F).
- Label the extraction buffer tube with sample number.

For fresh specimen (swab, no VTM)

1. Insert the swab into an extraction buffer tube. While squeezing the buffer tube, stir the swab more than 5 times.
2. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab
3. Press the nozzle cap tightly onto the tube.



4. Apply 3 drops of the extracted specimen to the specimen well of the test device.



5. Read the test result at 15-30 minutes (CAUTION: do not read test results after 30 minutes, as it may give false results).



For stored specimen (swab in VTM)

- Using a micropipette, collect 300µL of specimen from the collection tube with VTM.
- Apply the collected specimen into an extraction buffer tube.
- Press the nozzle cap tightly onto the tube (same as for fresh specimen, shown above, step 5).
- Apply 3 drops of extracted specimen to the specimen well of the test device (same as for fresh specimen, shown above, step 6).
- Read the test result at 15-30 minutes (same as for fresh specimen, shown above, step 7).
Caution: do not read test results after 30 minutes, as it may give false results.

External Quality Control

Positive and negative controls are not included with the STANDARD Q COVID-19 Ag Test, however, external controls for this test can be separately purchased from SD Biosensor (Cat No. C-NCOV-01G). These controls serve as a means for additional quality control to demonstrate a positive or negative reaction. External quality controls should be treated and tested the same as patient specimens.

It is recommended that positive and negative controls be run:

- a. Once for each new lot
- b. Once for each untrained operator



- c. Once for each new shipment of test kits
- d. As required by test procedures in these instructions and in accordance with local, state, and federal regulations or accreditation requirements

Important: ensure that test results from positive and negative controls are recorded and securely saved for quality purposes.

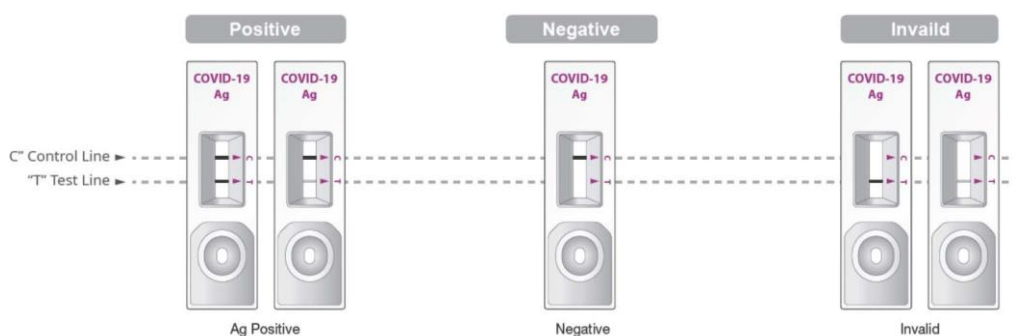
Interpretation of Test

A colored band will appear in the top section of the result window to indicate that the test is working properly. This band is the control line, “C”.

A colored band will appear in the lower section of the result window to indicate that SARS-CoV-2 antigen is detected. This is the test line, “T”.

Even if the control line is faint or the test line is not uniform, the test should be considered to have performed properly and the test result should be interpreted as a positive result.

Caution: the presence of any line, *no matter how faint the result*, is considered positive. Positive results should be considered in concert with the clinical history and other data available (see “Note” under Test Principle, above).



Limitation of Test

- **Please note that inadequate sample collection and transport may impact the sensitivity of the PCR or GeneXpert test. A deep nasopharyngeal swab is necessary and often evokes coughing, that is why personnel collecting the sample must be in PPE.**
- The test procedure, precautions, and interpretation of results for this test must be followed strictly when testing.
- Failure to follow the Test Procedure as described above and in the package insert, may adversely affect test performance and/or invalidate the test result.
- The test should be used for the detection of SARS-CoV-2 antigen from human nasopharyngeal swab specimens.
- This test detects viable (live) and non-viable SARS-CoV **and** SARS-CoV-2 in the sample specimen. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- A negative test result may occur if the level of antigen in a specimen is below the limit of detection of the test, or if the sample was collected and/or transported improperly.
- Test results must be considered with other clinical data available to the clinician.



- Neither the quantitative value nor the rate of SARS-CoV-2 antigen concentration can be determined by this qualitative test.
- Negative results should be treated as presumptive and confirmed with a US FDA authorized molecular assay, if necessary, for clinical management, including infection control.
- If the differentiation of specific SARS viruses and strains is need, additional testing is required.
- Positive test results do not rule out co-infection with other pathogens.
- Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
- Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children.

References:

- Instructions for using STANDARD Q COVID-19 Ag Test
<http://sdbiosensor.com/xs/product/7672>
- PIH Guide to Community and Clinical Management of COVID-19,
<https://partnersinhealth.sharepoint.com/:f:/r/sites/COVID19/PIH%20Clinical%20Guides%20Protocols%20%20Job%20Aids%20for%20COVID1/Guides%20for%20Clinical%20and%20Community%20Management%20of%20COVID-19?csf=1&web=1&e=INXcsp>
- STANDARD Q COVID-19 Ag Test, Package Insert. SD Biosensor.

6.4 Laboratory Procedure for External Quality Controls for Antibody and Antigen Rapid Tests

Standard operating procedure (SOP) for utilization of external quality controls for rapid antibody testing (Part A) and antigen testing (Part B) for COVID-19 testing performed at laboratories and medical facilities by health care personnel.

Control Test Procedure

Both the “STANDARD COVID-19 IgM/IgG Control” and the “STANDARD COVID-19 Ag Control” should be performed in the same manner as unknown specimens according to instructions of the STANDARD Q COVID-19 IgM/IgG Combo Test and the STANDARD Q COVID-19 Ag Test, respectively. It is recommended that these external positive and negative controls be run:

- Once for each new lot number
- Once for each untrained operator
- Once for each new shipment of test kits
- As required by test procedures in this instructions and in accordance with local, state and federal regulations of accreditation requirements.

Warnings and Precautions

- If there is evidence of microbial contamination in the reconstituted control, discard the control.
- Wear PPE such as gown, gloves, surgical mask and face shield when collecting or performing the test. Refer to procedure for the proper use of PPEs.
- Clean work surface with available disinfectant before starting work.
- Place absorbent bench liner on work surface to capture potential splatters and splashes.
- Store test kits at 2 - 30°C / 36 - 86°F.



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- Kit materials are stable until the expiration date printed on the outer box.
- Do not use kit materials if the expiry date has passed.
- Handle all materials as though they contain infectious agents and dispose of all materials used for sample collection and test procedures in a biohazard container and/or sharps bin.

Limitation of Test

8. This product is provided for quality assurance purposes and must not be used for calibration or as primary reference preparations in any test procedure.
9. Adverse storage conditions or use of outdated reagents may produce erroneous results.
10. This product should not be used past the expiration date.
11. Alterations in physical appearance may indicate instability or deterioration of this product. If there is evidence of microbial contamination in this product, discard of it properly.



6.5 Part A: SD Biosensor STANDARD COVID-19 IgM/IgG Control

Intended Use and Test Principle

The STANDARD COVID-19 IgM/IgG Control (“antibody control”) is intended for use as an external positive and negative quality control to monitor the performance of the STANDARD Q COVID-19 IgM/IgG Combo Test (and other IgM/IgG rapid diagnostic testing from SD Biosensor).

The antibody controls should be performed in the same manner as unknown specimens according to instructions of the STANDARD Q COVID-19 IgM/IgG Combo Test.

Requirements

<i>Materials required but not provided:</i>	<ul style="list-style-type: none">• Proper PPE• Permanent marker• Distilled water• Micropipette and tips• STANDARD Q COVID-19 IgM/IgG Combo Test devices (3)
<i>Materials provided:</i>	<ul style="list-style-type: none">• IgM positive control (tablet from violet colored tube)• IgG positive control (tablet from red colored tube)• Negative control (tablet from transparent tube)

IgM positive control
(violet)



IgG positive control
(red)



Negative control
(transparent)



Test Procedure

NOTE: this product should be treated the same as patient specimens and run in accordance with instructions accompanying the STANDARD Q COVID-19 IgM/IgG Combo Test (section in the guide).

10. Allow 3 test devices from the STANDARD Q COVID-19 IgM/IgG Combo Test kit and the control tubes from the STANDARD Q COVID-19 IgM/IgG Control (one positive IgM, one positive IgG, and one negative) to rest at room temperature (15 - 30°C / 59 - 86°F) for at least 30 minutes prior to performing the test.
11. Carefully read the instructions included in the STANDARD COVID-19 IgM/IgG Control test package insert.
12. Label the three STANDARD Q COVID-19 IgM/IgG Combo test devices with “IgM positive control”, “IgG positive control” and “negative control”, respectively.



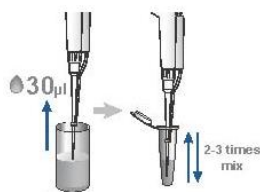
13. Check the expiration date of the control on the bottle and of the test device on the pouch. Do not use expired controls and test devices.



14. Open the bottle of the STANDARD COVID-19 IgM/IgG Control and take out one control tube from each. You should have three tubes (violet, red, and transparent).



15. Add 30 μ l of distilled water using the pipette and mix the distilled water and the control tablet in the control tube at least 2-3 times. **This serves as your “sample” to be loaded in the well of the STANDARD Q COVID-19 IgM/IgG Combo test device.** Repeat for the remaining two control tubes.



16. Continue to test in accordance with the instructions for use with the STANDARD Q COVID-19 IgM/IgG Combo Test.
17. Apply the prepared control mixture (10 μ l) into the well of the STANDARD Q COVID-19 IgM/IgG Combo test device (the same well you apply sample).
18. Apply 3 drops of buffer into the same well of the STANDARD Q COVID-19 IgM/IgG Combo test device.

Interpretation of test result

1. Interpret the test results in accordance with the instructions for use with the accompanying the STANDARD Q COVID-19 IgM/IgG Combo Test
2. Utilize the following tables as guidance for next steps for the STANDARD COVID-19 IgM/IgG Control:

IgM Positive		
Result	Interpretation	Follow up
Pass	Positive result for IgM	None
Fail	Negative result for IgM	Re-test*
Invalid	No Control (C) line	Re-test*



IgG Positive		
Result	Interpretation	Follow up
Pass	Positive result for IgG	None
Fail	Negative result for IgG	Re-test*
Invalid	No Control (C) line	Re-test*

Negative		
Result	Interpretation	Follow up
Pass	Negative result for IgM and/or IgG	None
Fail	Positive result for IgM and/or IgG	Re-test*
Invalid	No Control (C) line	Re-test*

*Use new test devices and new control for re-test.

- Record all test results, as per Quality Management Program practices.
- Dispose of the test devices as biohazard materials.
- Clean work surface with disinfectant at the end of the work.

References:

- Instructions for using STANDARD Q COVID-19 IgM/IgG Combo Test, <http:sdbiosensor.com/xen/product/12509>
- PIH Guide to Community and Clinical Management of COVID-19, <https://partnersinhealth.sharepoint.com/:f:/r/sites/COVID19/PIH%20Clinical%20Guides%20Protocols%20%20Job%20Aids%20for%20COVID1/Guides%20for%20Clinical%20and%20Community%20Management%20of%20COVID-19?csf=1&web=1&e=I3oPIb>.
- STANDARD COVID-19 IgM/IgG Control. Package Insert. SD Biosensor.

6.6 Part B: SD Biosensor STANDARD COVID-19 Ag Control

Intended Use and Test Principle

The STANDARD COVID-19 Ag Control ("Ag control") is intended for use as an external positive and negative quality control to monitor the performance of the STANDARD Q COVID-19 Ag Test (and other Ag-based diagnostic testing from SD Biosensor).

The antigen controls should be performed in the same manner as unknown specimens according to instructions of the STANDARD Q COVID-19 Ag Test.



Requirements

<i>Materials required but not provided:</i>	<ul style="list-style-type: none">• Proper PPE• Permanent marker• Distilled water• STANDARD Q COVID-19 Ag Test devices (2)• STANDARD Q COVID-19 Ag buffer extraction tubes (2)
<i>Materials provided:</i>	<ul style="list-style-type: none">• Positive control (tablet from red colored tube)• Negative control (tablet from transparent tube)

Positive control
(red)



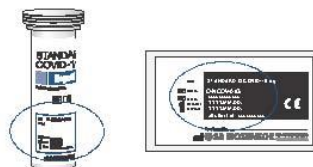
Negative control
(transparent)



Test Procedure

NOTE: this product should be treated the same as patient specimens and run in accordance with instructions accompanying the STANDARD Q COVID-19 Ag Test (section 6.3 in the guide).

1. Allow 2 test devices from the STANDARD Q COVID-19 Ag Test and 2 tubes from STANDARD COVID-19 Ag Control (one positive and one negative) to rest at room temperature (15 - 30°C / 59 - 86°F) for at least 30 minutes prior to performing the test.
2. Carefully read the instructions included in the STANDARD COVID-19 Ag Control test package insert.
3. Label both STANDARD Q COVID-19 Ag test devices and extraction buffer tubes with “positive control” and “negative control”, respectively. Check the expiration date of the control on the bottle and of the test device on the pouch. Do not use expired controls and test devices.



4. Open the bottle of the STANDARD COVID-19 Ag Control and take out one control tube, each. You should have two tubes, one positive and one negative (red and transparent).





5. Insert the positive or negative control tablet into the correspondingly labeled extraction buffer tube (provided in the STANDARD Q COVID-19 Ag test).



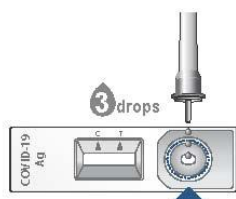
6. Gently press the nozzle cap tightly onto the tube.



7. Mix the control tablet and the extraction buffer using a vortex or by hand swirling. **This mixture now serves as your “sample” to be loaded in the well of the STANDARD Q COVID-19 Ag test device (labeled “positive” or “negative” control).**



8. Continue to test in accordance with the instructions for use with the STANDARD Q COVID-19 Ag Test.
9. Apply 3 drops of the prepared control mixture into the specimen well of the correspondingly labeled STANDARD Q COVID-19 Ag test device.



Interpretation of test result

1. Interpret the test results in accordance with the instructions for use with the accompanying the STANDARD Q COVID-19 Ag Test.
2. Utilize the following tables as guidance for next steps, for the STANDARD COVID-19 Ag Control:

Positive		
Result	Interpretation	Follow up
Pass	Positive result for Ag	None
Fail	Negative result for Ag	Re-test*
Invalid	No Control (C) line	Re-test*



Negative		
Result	Interpretation	Follow up
Pass	Negative result for Ag	None
Fail	Positive result for Ag	Re-test*
Invalid	No Control (C) line	Re-test*

*Use new test devices and new control for re-test.

3. Record all test results, as per Quality Management Program practices.
4. Dispose of the test devices as biohazard materials.
5. Clean work surface with disinfectant at the end of the work.

References:

1. Instructions for using STANDARD Q COVID-19 Ag Test,
<http:sdbiosensor.com/xs/product/7672>
2. PIH Guide to Community and Clinical Management of COVID-19,
<https://partnersinhealth.sharepoint.com/:f:/r/sites/COVID19/PIH%20Clinical%20Guides%20Protocols%20%20Job%20Aids%20for%20COVID19/Guides%20for%20Clinical%20and%20Community%20Management%20of%20COVID-19?csf=1&web=1&e=I3oPIb>.
3. STANDARD COVID-19 Ag Control. Package Insert. SD Biosensor.

7 Data Collection

7.1 Data flow

Data collection tools 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 has also been integrated into various digital health platforms, including CommCare (for screening, testing, and contact tracing) and OpenMRS (for laboratory services and inpatient care).

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

7.2 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 data collection annex provides PDF copies of each form along with more detailed information on how and where they may be useful. Editable versions of all forms and French translations can be accessed [here](#). If you have questions about these forms or difficulty accessing the editable versions, please contact Annie Michaelis (amichaelis@pih.org).

7.3 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. Alternatively, some sites with reliable local area networks and/or wifi connection are using OpenMRS and/or CommCare on tablets and laptops to facilitate point of care electronic data entry and easy access to the same patient information both within and outside isolation units.

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>)

7.4 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:** A variety of CommCare applications have been developed to support COVID-19 contact tracing, screening, and testing. Information on applications developed for US contexts can be found [here](#). Live demonstrations of the app developed by PIH and Zanmi Lasante for use in Haiti and other global contexts are available upon request (please email Natalie Price, nprice@pih.org for more info) or see [here](#) for recorded demos and user manuals.
- **OpenMRS:** COVID-19 related laboratory functionality and inpatient care forms are now available on the OpenMRS platform, available in English and French. Please see [here](#) for overview materials or contact David Desimone (d-desimone@pih.org) for more information.

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- 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.
- ¹ 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
- ¹ Bioeasy. “2019-Novel Coronavirus (2019-nCoV) Ag GICA Rapid Test (Colloidal Gold) clinical report” 4th March, 2020

- Instructions for using STANDARD F COVID-19 Ag FIA Test
<http:sdbiosensor.com/xen/product/7662>
- PIH Guide to Community and Clinical Management of COVID-19,
<https://partnersinhealth.sharepoint.com/:f:/r/sites/COVID19/PIH%20Clinical%20Guides%20Protocols%20%20Job%20Aids%20for%20COVID1/Guides%20for%20Clinical%20and%20Community%20Management%20of%20COVID-19?csf=1&web=1&e=INXcsp>
- Instructions for using STANDARD Q COVID-19 IgM/IgG Duo Test,
<http:sdbiosensor.com/xen/product/7662>