Partners In Health Guide | COVID-19

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

Updated: 24 September 2020

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1. List of Standard 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
MoH	Ministry of Health
PAHO	Pan-American Health Organization
RDT	Rapid diagnostic test
RT-PCR	Reverse transcription polymerase chain reaction
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SOP	Standard Operating Procedure
WHO	World Health Organization

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

Quarantine: Separation and restriction of 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.

3. Basics

3.1. 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.

3.2. 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 (from PIH Guide Part II) :
    - 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).

3.3. 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.

3.4. 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.

3.5. 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 6 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.

4. 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.

5. Testing

5.1. 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.
    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 for diagnosing active disease.
    2. **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. There can also be false positives. The antibody test can also stay positive long after the infection has resolved. Given the characteristics of the test, it should not be used as the sole basis to diagnose COVID-19 rather as a complementary tool to viral testing (PCR-based testing or Antigen RDT) – also see Section 5.1.3 below. The antibody test is most commonly used in surveillance and research to determine the percentage of the population that has been exposed to the virus.
    3. **Antigen (Ag) RDT –** Detects an antigen of the SARS-CoV-2 virus, most often the nucleocapsid protein. Most manufactured tests require a nasopharyngeal swab. Sensitivity and specificity of the test is comparable to RT-PCR, see Section 5.1.3 below for more information.
- The Xpert® Xpress SARS-CoV-2 cartridge also uses PCR technology and uses the same Xpert® machines as used for diagnosis of tuberculosis (TB)

5.1.1. **Time period when the test is positive:**

- The RT-PCR and Antigen RDT perform well in patients with high viral loads which usually appear in the pre-symptomatic (1-3 days before symptom onset) and early symptomatic phases of the illness (within the first 5-7 days of illness).
- The Ab RDT only turns positive 7 to 10 days after the symptoms have begun (before this, antibodies have not yet been produced in the body to the level at which they are detectable by the Ab RDT).

5.1.2. Table 1. Types of tests

Characteristic	RT-PCR	Antibody (IgM/IgG) RDT	Antigen (Ag) (RDT)
Sample	Nasopharyngeal swab Less commonly a deep sputum specimen is used Saliva as an option is being studied with one platform FDA approved.[1]	Blood (finger stick or blood draw)	Nasopharyngeal swab
Time period for when the test has the best performance (likely to detect yield a positive result)	Pre-symptomatic (1-3 days before symptom onset) and early symptomatic phases (first 5-7 days of illness)	7-10 days after symptoms	Pre-symptomatic (1-3 days before symptom onset) and early symptomatic phases (first 5-7 days of illness)
False positives	Almost none	**Low to moderate** It is possible to have cross-reactivity to other coronavirus different from SARS-CoV-2	**Very Low**
False negatives	**Occasionally** Especially in patients that are a few days after transmission occurred or in patients who present more than 5-7 days after the onset of symptoms.	**Variable** High at the onset of the symptoms, especially less than 10 days after the onset of 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.

5.1.3. Reverse transcriptase polymerase chain reaction (RT-PCR)

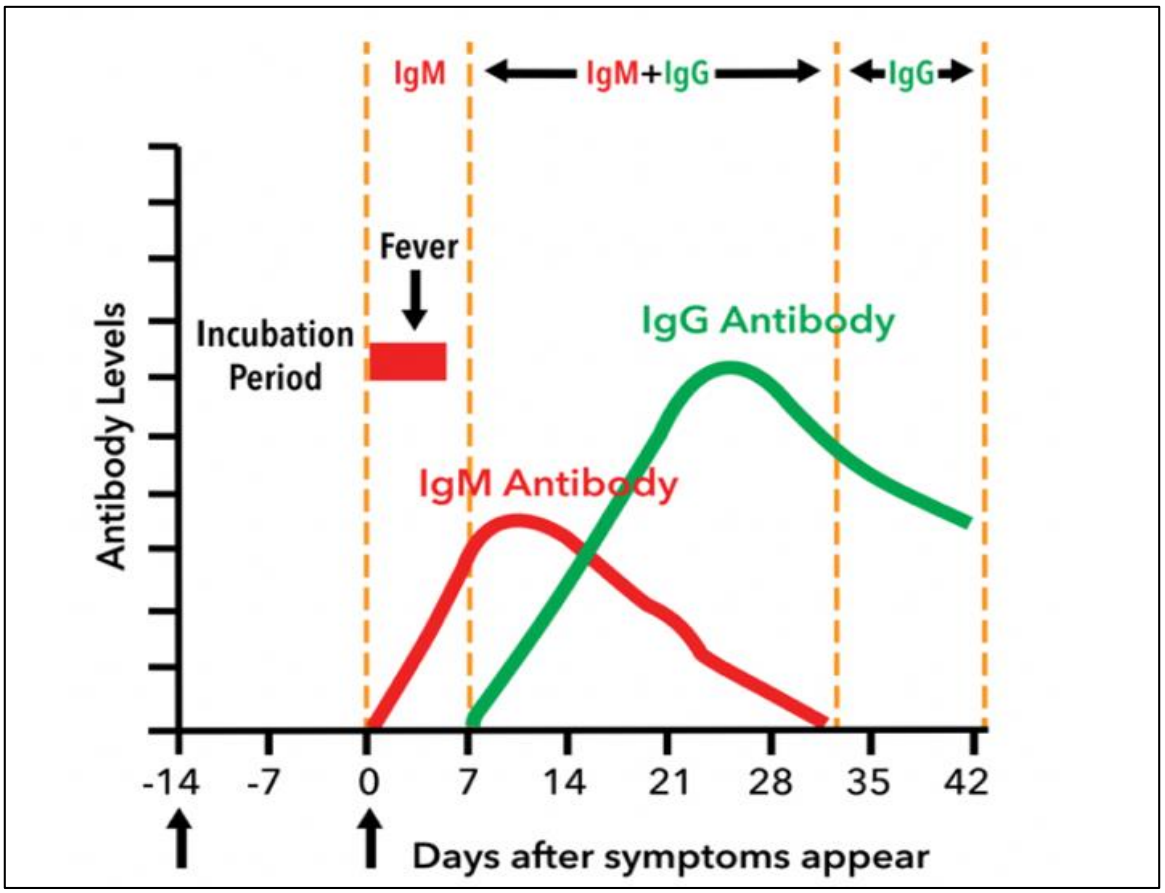
- This test is done most commonly on a nasopharyngeal swab. The test can also be done on a bronchoalveolar lavage fluid or deep sputum.
- Deep sputum is not saliva but the thick mucus—sometimes called phlegm—which is coughed up from the lungs and should be collected in a similar way to how a TB sputum is collected. Sputum needs special processing for RT-PCR and most programs do not use deep sputum because of the extra processing.
- Saliva is showing promising results as possible specimen for use with RT-PCR instruments. SalivaDirect is a platform approved by the US FDA under Emergency Use Authorization. It reduces the cost and complexity while also enabling non-invasive sample collection and reduces the need for trained healthcare professionals during collection. It is not yet approved or validated for all RT-PCR instruments but shows much promise to become an alternative to nasopharyngeal swabs.
- 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 PIH Guide Appendix: Laboratory Procedures)
- 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.

5.1.4. **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 7 to 10 days after the onset of symptoms, and IgG becomes positive a few days after the rise of IgM (see Figure 1) and can remain elevated after the infection has resolved.
- 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 2 below.

5.1.5. **Figure 1. Lag time between onset of symptoms and production of detectable antibodies**



5.1.6. **Table 2. Interpretation of the IgM/IgG antibody test**

WARNING: The Ab RDT is NOT recommended to clinically diagnose active COVID-19 infection – use RT-PCR or Ag test to rule in or rule out active COVID-19 disease.

IgM	IgG	Interpretation	instructions
Negative	Negative	• No serological evidence of infection with COVID-19. • Possibly in the "window period" where it is too early in the course 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.	• If symptomatic, quarantine and obtain an RT-PCR or Ag Test.
Positive	Negative	• 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).	• Likely a recent or active case. • Obtain RT-PCR or Ag Test. • Quarantine in hospital or at home.
Negative	Positive	• 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 another coronavirus.	• Possibly a case but resolving or resolved. • Obtain RT-PCR or Ag Test. • May no longer be infectious if symptoms have resolved. • May quarantine to be on the safe side.
Positive	Positive	• 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.	• Likely a case • Quarantine in hospital or at home. • Obtain RT-PCR or Ag Test

- 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.
- PIH recommendations on the use of Antibody rapid test include:
- Do not use serological (antibody) tests as the sole basis to diagnose COVID-19 but instead as a complementary tool to viral testing (RT-PCR, Xpert® Xpress SARS-CoV-2 or Ag RDT) for additional information about whether a person is previously exposed to COVID-19 or is in the active disease phase of COVID-19.
- In general, this guide recommends to mainly use the Ab RDT as an immunodiagnostic test for surveillance and in research, not in clinical decision-making. Use of serologic antibody assays in populations can help determine the burden of disease and the proportion of a population previously infected with SARS-CoV-2. Thus, demographic and geographic patterns of antibody prevalence provide data that can be used in forecasts of disease spread that can support resource allocation, decision-making and planning by local and state officials.

5.1.7. **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.

5.2. Who Should Be Tested?

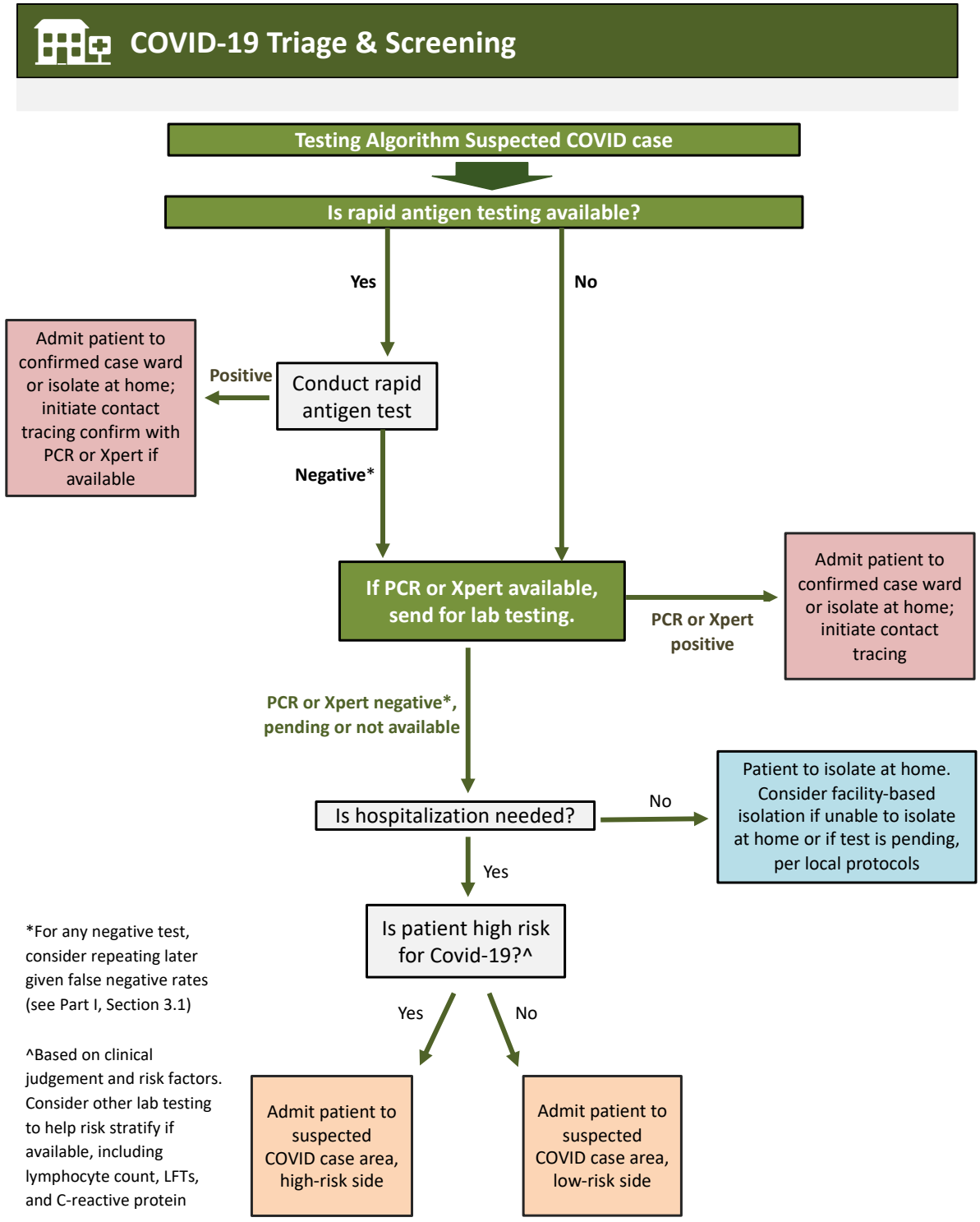
- In areas of limited availability of tests, persons that have symptoms consistent with COVID-19 infection should be prioritized for testing. Testing of certain high-risk asymptomatic individuals (CHWs, high-risk contacts, etc.) should be considered if testing resources permit.
- A symptomatic person 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 3.2 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.
- 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.
- Because the RT-PCR tests are expensive and often limited in how many can be done, the Ag RDTs can serve as an easier and less expensive test for widespread testing. For example, testing asymptomatic contacts or groups of persons where an outbreak is suspected. Table 3 lists different scenarios that the WHO[2] as deemed as appropriate for use of the Ag RDT.
- Of note, Ag RDTs used in the manner describe in Table 3 should meet the minimum performance requirements of >80% sensitivity and >97% specificity compared to a Nucleic Acid Amplification Test (NAAT) reference assay (e.g. RT-PCR or Xpert® Xpress SARS-CoV-2).

5.2.1. **Table 3. Scenarios for use of SARS-CoV-2 Ag-RDT**

Scenarios for use of SARS-CoV-2 Ag-RDT	***Population Recommended to be screened***
Outbreak response	To respond to suspected outbreaks of COVID-19 in remote settings, institutions and semi-closed communities where NAAT is not immediately available.
Outbreak investigation/Contact tracing	To support outbreak investigations (e.g. in closed or semi-closed groups including schools, care-homes, cruise ships, prisons, workplaces and dormitories, etc.) and to screen at-risk individuals.
Monitor trends in disease incidence	To monitor trends in disease incidence in communities, and particularly among essential workers and health workers during outbreaks or in regions of widespread community transmission
Community Transmission Screening ***(for prevention of outbreaks in vulnerable communities like nursing homes, TB/MDR-TB wards, prisons, and hospitals in general)***	Where there is widespread community transmission, RDTs may be used for early detection and isolation of positive cases in health facilities, COVID-19 testing centers/sites, care homes, prisons, schools, front-line and health-care workers and for contact tracing.
Testing of Asymptomatic contacts	Testing of asymptomatic contacts of cases may be considered even if the Ag-RDT is not specifically authorized for this use

- 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).
- The below figure is a flow diagram for testing based on the availability of which rapid test is available.

5.2.2. **Figure 2. Triage and screening algorithm**



5.3. 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 5.1.
- Screening is commonly done in asymptomatic persons who have a high-risk of COVID-19.
- 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.

5.3.1. **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.
- The RT-PCR or Ag RDTs should be used if screening for active disease and contagious persons is the goal. This is often done to prevent outbreaks by catching an early case and quarantining all contacts. The Ag RDT is often used for this purpose, see Section 5.1.7 above.
- How to perform surveillance or infection prevalence studies is not covered in this guide.
- Study/surveillance protocols are under development by PIH. Check www.PIH.org for further guidance on performing surveillance of HCWs, to be posted on the website in the near future.

5.3.2. **Congregate settings**

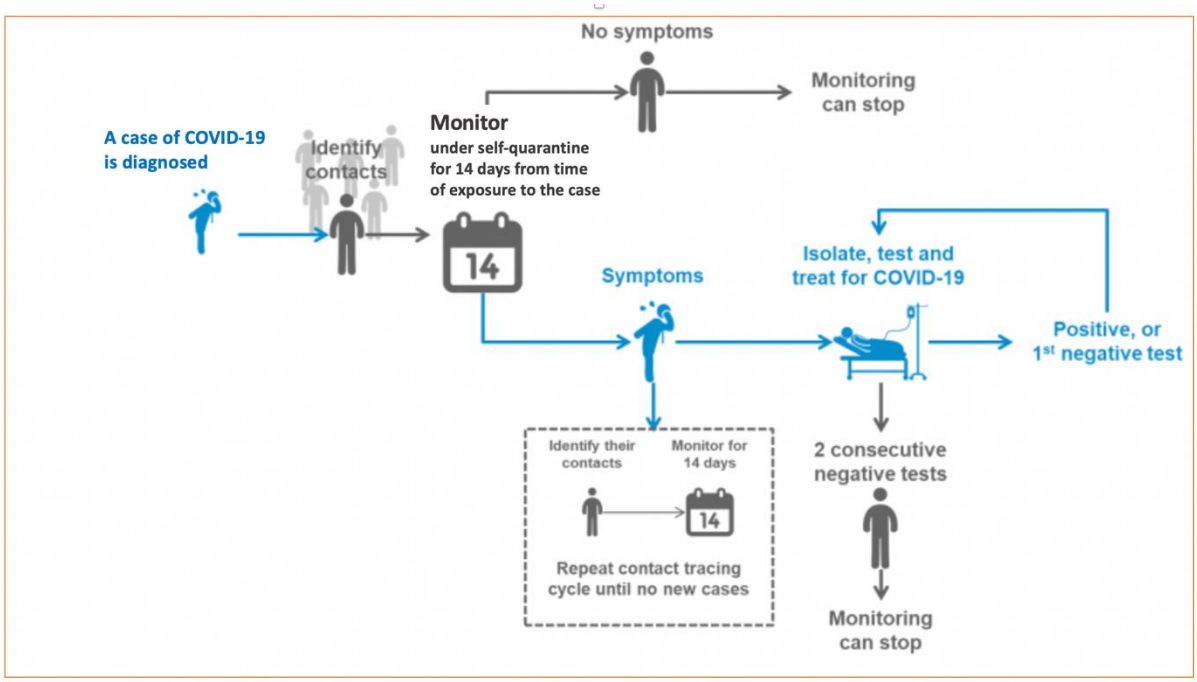
- Congregate settings include places where people live or socialize in large numbers; COVID-19 can easily propagate in such settings.
    - Churches or mosques.
    - Psychiatric institutions.
    - Long-term care facilities (e.g. nursing homes, TB/MDR-TB wards).
    - Prisons.
    - Refugee camps.
    - 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. RT-PCR or Ag RDT can be used to help identify patients that may be asymptomatic but infected with COVID-19 (see Table 2 above).

- 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: this guide advocates for voluntary quarantine and putting in place strong socio-economic support measures to assure all persons can adhere to quarantine.

6. Contact Tracing

A key strategy to stopping the spread of COVID-19 is contact tracing. Figure 3 (below), illustrates the flow for contact tracing.

6.1.1. **Figure 3. Contact tracing in COVID-19**



6.2. 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, 24hours 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 meters 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 meters;
- 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).

6.3. 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 6.4 below on possible roles of CHWs).

6.4. Contact Tracing Procedures, Follow-Up, and Discharge

- The contact tracing procedure is illustrated in Figure 3 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 in Part II of the PIH Guide.
- 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.

7. Public Use of Face Coverings for Prevention of COVID-19

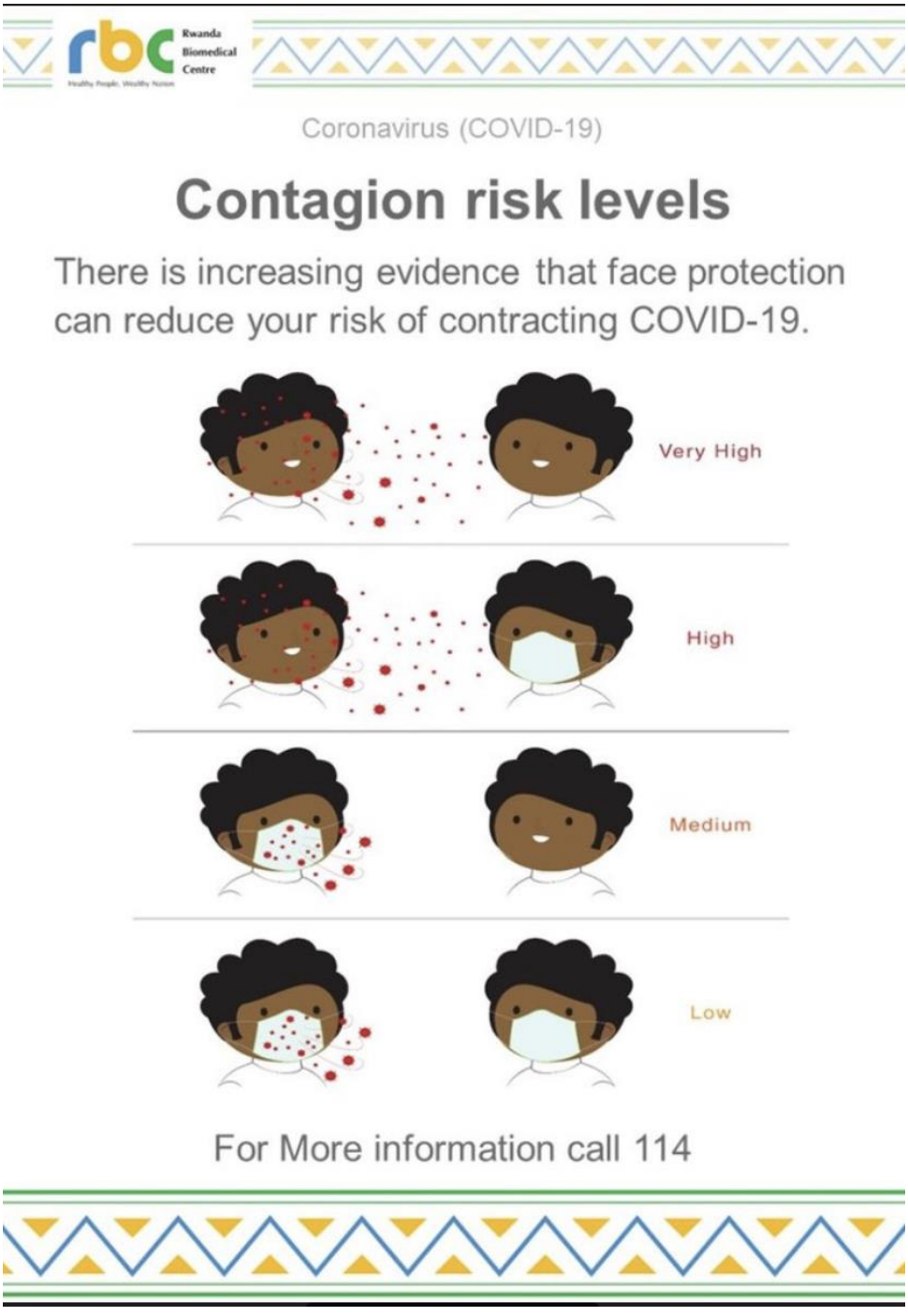
- This guide strongly recommends the use of face coverings (non-medical masks) for the public during a COVID-19 outbreak in urban, semi-urban and in rural areas where people gather.
- All MoHs should have a media campaign to promote and educate the public on the use of face coverings, including how to 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 7.5)
- This chapter is in large part adapted from the South African recommendations.[3]

7.1. 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.[4]
- 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 pre-symptomatic or asymptomatic individuals.
- Face covers are simple, cheap, and there is some evidence that shows them to be effective.[5] 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 4 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

7.1.1. **Figure 4. Examples of public face coverings from Rwanda**



Source: Rwanda Biomedical Medical Center. Kigali, Rwanda

7.2. 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.
- A top priority 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.

7.3. When to Use Cloth Face Covering

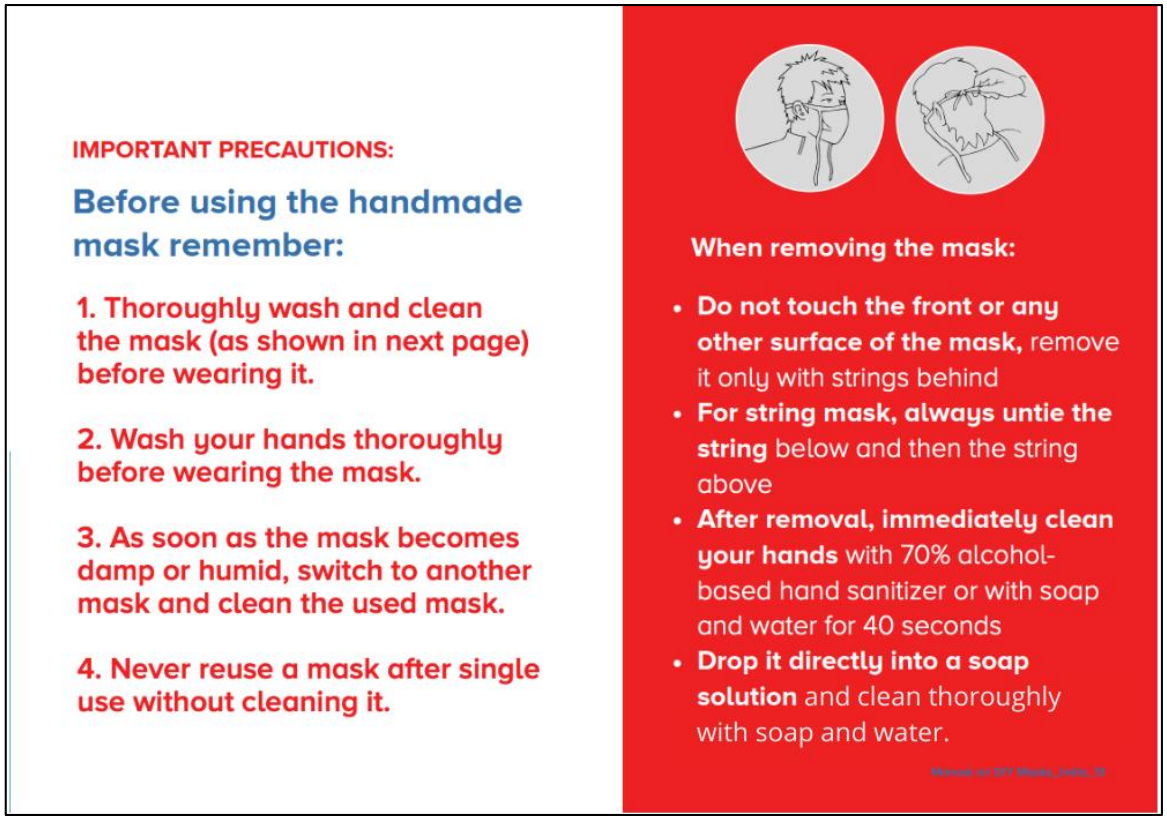
- When less than one meter from people who may have COVID-19 infection, for example**:**
    - Travel to and from work in public transport
    - When stepping outside the house to go shopping or seeking healthcare
    - In quarantine/self-quarantine/isolation when contact with others is necessary.
    - 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.

7.4. 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 own 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 illustrates the key components of using a face covering.

7.4.1. **Figure 5. Important instructions on using a cloth face covering.**



7.5. 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
- WHO has guidance on selecting what fabric type to use in a mask and what layers a mask should contain.[6]
- 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 6).

7.5.1. **Figure 6. 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.

7.5.2. **Basic design tips of a handmade sewn face covering**

The design includes two layers (an inner and outer surface of the face cover) and strings or straps.

- **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
- **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 layer 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.
- **Strings or strap:**
  - Strings or straps can be sewn, tied through a small whole in the cloth's edge.

7.6. 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.

7.7. 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.

8. Laboratory

As mentioned in Chapter 5, the most commonly used and reliable assays for diagnosis of COVID-19 has been those based on molecular testing, mainly RT-PCR (reverse transcriptase polymerase chain reaction), which detects viral genomic RNA. However, assays based upon this type of technology require highly skilled personnel, well-controlled laboratory environments, and more expensive equipment. In addition, the turn-around time can be 3 days or longer for routine testing. This long lead- time to result can create anxiety and a higher risk of disease transmission if individuals do not self-isolate. On the other hand, rapid tests (similar to an over-the-counter pregnancy test) for detection of either viral antigen or human antibodies, are faster, less costly, simpler and easier to use. Although their sensitivity and specificity are generally lower than those reported for RT-PCR assays, this difference in performance is offset by the rapid turn-around time and lower cost. Ultimately, this can allow for individuals to be tested more often, therefore decreasing the likelihood of transmission.

Two different point-of-care tests were successfully procured by PIH: the antibody and antigen rapid tests from SD Biosensor, STANDARD Q COVID-19 IgG/IgM Combo Test and STANDARD Q COVID-19 Ag Test. In this chapter, we describe the general aspects of the laboratory procedures for these tests but defer to the annex where the corresponding Standard Operating Procedures (SOP) with more specific information for use of these tests are located.

NOTE: Recently, WHO published an interim guidance "Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays"[2] on Sep 11, 2020, which offers advice on the potential role of antigen-detecting RDTs (Ag-RDT) in the diagnosis of COVID-19 and the need for careful test selection. Despite some limitations in performance, Ag-RDTs could play a significant role in guiding patient management, public health decision making and in surveillance of COVID-19.

The WHO Interim Guidance also provides guidance on selection of tests for procurement and implementation. Ten factors are listed for consideration when selecting rapid Antigen tests such as reported performance, cost, kit contents, quality of available validation data, etc. It is noteworthy to mention that the antigen test procured by PIH, STANDARD Q COVID-19 Ag test is included in the validation studies performed by FIND as well as in the Emergency Use Listings assessment pipeline from WHO. Based on several verification studies performed at different countries, the overall sensitivity of this Ag test is 92.66% and the specificity is 99.25% under the conditions tested.

The SOPs for both rapid tests and corresponding external controls are located in the annex and contain: Product Description, Test Principle, Warnings and Precautions, Sample Collection, Test Procedure, External Quality Control and Interpretation and Limitation of Test. For your reference, the following are brief summaries of each.

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

For detection of antibodies in the blood as a response to the presence of SARS-CoV-2 infection. Because this test examines the body's response to the virus, there is a window period between infection and a positive antibody response when the use of this test is ideal (>10 days after onset of symptoms).

8.1.2. Laboratory procedure for Lateral Flow Immunoassay Ag RDT for Detection of SARS-CoV-2 Antigen (SD Biosensor STANDARD™ Q COVID-19 Ag):

For detection of viral protein from the nasopharynx. Because this test detects viral particles and therefore active infection, there is a window period between initial infection and symptom onset when the use of this test is ideal (within the first ~7 days of symptoms).

8.1.3. Laboratory procedure for external quality controls for antibody and antigen rapid tests

Good laboratory practices recommend the use of control materials. Users should follow the appropriate guidelines concerning the frequency and use of external control materials. 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 these instructions and in accordance with local, state and federal regulations of accreditation requirements

8.1.4. Warnings and Precautions common to these commercial kits:

- The package insert must be read completely before performing the test. Failure to do so may yield inaccurate test results.
- 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.
- 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 biohazard waste.
- Laboratory chemical and biohazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
- Clean the workbench 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 the indicated time (15 or 30 minutes) after a specimen is applied to the sample well. Results read after the indicated time 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.

8.1.5. **Table 4. 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	N95, gloves, gowns, face shield
RT-PCR	Nasopharyngeal swab or deep sputum	N95, gloves, gowns, face shield

9. Data Collection

Please see Chapter 10 **Part II: Guide to Clinical Management of COVID-19. Available at https://www.pih.org/covid-response**

10. Citations

1. Vogels CB, Brackney DE, Wang J, et al. SalivaDirect: Simple and sensitive molecular diagnostic test for SARS-CoV-2 surveillance One sentence summary. *medRxiv*. 2020:2020.08.03.20167791. doi:10.1101/2020.08.03.20167791
2. World Health Organization. Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays. 2020;(September).
3. Western Cape Government. Covid-19: Cloth masks for public use.
4. 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. *J Med Virol*. 2020;92(9):1567-1571. doi:10.1002/jmv.25805
5. Centers for Disease Control and Prevention. Considerations for Wearing Masks.
6. World Health Organization. Advice on the use of masks in the context of COVID-19: interim guidance-2. 2020. doi:10.1093/jiaa077

11. Additional References

1. BMJ Best Practices COVID-19. 2 March 2020 version.
2. Guan et al. Clinical characteristics of coronavirus disease 2019 in China. *NEJM*. Feb 2020.
3. Huang et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. *Lancet*. Jan 2020.
4. Li Z, Yi Y, Luo X, Xiong N, Liu Y, et al. Development and clinical application of a rapid IgM-IgG combined antibody test for SARS-CoV-2 infection diagnosis. J Med Virol. 2020. doi: 10.1002/jmv.25727
5. Wang D, Hu B, Hu C, Zhu F, Liu X, Zhang J, Wang B, Xiang H, Cheng Z, Xiong Y, Zhao Y, Li Y, Wang X, Peng Z. Clinical Characteristics of 138 Hospitalized Patients With 2019 Novel Coronavirus-Infected Pneumonia in Wuhan, China. *JAMA*. 2020.
6. World Health Organization. Report of the WHO-China Joint Mission on Coronavirus Disease 2019 (COVID-19). February 2020.
7. Zhou et al. Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study. Lancet. March 2020.
8. Xie, C., et al., Comparison of different samples for 2019 novel coronavirus detection by nucleic acid amplification tests. *Int J Infect Dis,* 2020.
9. 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.
10. Xie, X., et al., Chest CT for Typical 2019-nCoV Pneumonia: Relationship to Negative RT-PCR Testing. Radiology, 2020: p. 200343
11. 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.
12. 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. 2020.
13. Instructions for using STANDARD Q COVID-19 IgM/IgG Combo Test, http:sdbiosensor.com/xe/product/12509

Part II: PIH Guide to Clinical Management of COVID-19 can be found at:
https://www.pih.org/covid-response