1 Basics

1.1 Definition
- 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: non-specific, primarily characterized by fever, cough, possibly dyspnea; less frequent symptoms including fatigue, myalgias, sputum production, nausea, diarrhea.
- 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, but this is not thought to be the main way the virus spreads.

Can someone spread the virus without being sick?
- People are thought to be most contagious when they are most symptomatic (the sickest).
- Some spread might be possible before people show symptoms; there have been reports of this occurring with this new coronavirus, but this is not thought to be the main way the virus spreads.

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 1 meter), 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 they have a fever, cough, and difficulty breathing, and share their previous travel and contact history with their healthcare provider.

1.5 Screening

- Early case detection is an excellent way to prevent further spread.
- 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 their exposure.
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 persons 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 works for the sick. When care is not available, patients will not come forward for testing.
- 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.

- **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 to ministries:** Support ministries of health and national partners (including national public health labs) to ensure access to RT-PCR testing and strong referral services for patients tested at periphery by RDTs.
- **Provide global coordination and leverage partnerships:** Provide global coordination with WHO, 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

<table>
<thead>
<tr>
<th>Sample</th>
<th>Reverse transcriptase polymerase chain reaction (RT-PCR)</th>
<th>Antibody (IgM/IgG) rapid diagnostic test (RDT)</th>
<th>Antigen (Ag) rapid diagnostic test (RDT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Window period</td>
<td>Short</td>
<td>3-5 days</td>
<td>5-10 days</td>
</tr>
<tr>
<td>False-positives</td>
<td>Almost none</td>
<td>Low</td>
<td>Almost none</td>
</tr>
<tr>
<td>Turn around time</td>
<td>Days</td>
<td>15 min</td>
<td>15 min</td>
</tr>
<tr>
<td>Follow-up</td>
<td>Re-test in several days if high clinical suspicion.</td>
<td>Re-test if sample was obtained during the window period.</td>
<td>Re-test if sample was obtained during the window period.</td>
</tr>
</tbody>
</table>

Reverse transcriptase polymerase chain reaction (RT-PCR)
- This test is done on a deep sputum or nasopharyngeal swab.
- Note, deep sputum is not saliva but the thick mucus—sometimes called phlegm—which is coughed up from the lungs.
- A nasopharyngeal swab is taken from deep in the nose or oropharynx.
- RT-PCR is highly specific when means the chance of a false positive is low.
- RT-PCR may have a sensitivity of around 75%.
- A single negative RT-PCR doesn’t exclude COVID-19 (especially if obtained from a nasopharyngeal source or if taken relatively early in the disease course).
- If the RT-PCR is negative but suspicion for COVID-19 remains, then ongoing isolation and re-sampling several days later should be considered.

Antibody (IgM/IgG) RDT
- This test is done on blood (finger stick or blood draw).
- Sensitivity and specificity are around 90%.
- In general IgM can be detected 3-5 days after the onset of symptoms and IgG becomes positive a few days after the rise of IgM.
- The lag time of antibodies creates a window period where the patient may have a negative Ab RDT but still have COVID-19.

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

- Contacts of patients with documented COVID-19 have the highest priority.
- Major hospitals.
  - Asymptomatic nurses in high patient flow areas.
  - Inpatients and outpatients with respiratory symptoms and no alternative diagnosis or symptoms highly consistent with COVID-19 disease.
- Congregate settings—active outreach.
  - Prisons.
  - Nursing homes.
  - Psychiatric hospitals.
- Symptomatic persons coming from COVID-19 affected areas.

3.3 Asymptomatic health workers in high patient flow areas

- Test a sample of health workers in the unit.
- Test with IgM/IgG RDT only (Ag RDT or RT-PCR not necessary unless symptomatic).

<table>
<thead>
<tr>
<th>If</th>
<th>Then</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>• Report to the MOH as a presumptive case of COVID-19.</td>
</tr>
<tr>
<td></td>
<td>• The health worker may be infectious, even if asymptomatic and should be instructed to self-quarantine.</td>
</tr>
<tr>
<td></td>
<td>• Take a detailed work history and intensify screening of workers and patients in those units.</td>
</tr>
<tr>
<td>Negative</td>
<td>• If all health workers in the unit are negative, retest another group of workers in 2 weeks.</td>
</tr>
</tbody>
</table>
3.4 Inpatients and outpatients with respiratory symptoms

- Test all those who fit the MOH clinical case definition.
- Test a sample of patients in the ICU, as well as patients with pneumonia of unclear etiology.
- Where available, administer Ab RDT, Ag RDT, and RT-PCR testing simultaneously.
- Any positive result of any test is considered positive for COVID-19.

<table>
<thead>
<tr>
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<th>Then</th>
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<tbody>
<tr>
<td>Positive</td>
<td>• Report to the MOH as a presumptive case of COVID-19.</td>
</tr>
<tr>
<td></td>
<td>• If patient will be managed as outpatient, instruct them on home quarantine.</td>
</tr>
<tr>
<td></td>
<td>• Take a detailed contact history in preparation for tracing all contacts.</td>
</tr>
<tr>
<td>Negative</td>
<td>• If still in window period and high clinical suspicion, test again 3 days.</td>
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<tr>
<td></td>
<td>• If out of window period, no need for isolation.</td>
</tr>
</tbody>
</table>

3.5 Travelers

- People travelling from areas with a high risk of infection may be screened using questionnaires about their travel, contact with ill persons, symptoms of infection, and/or measurement of their temperature. This can apply for persons coming from international destinations or from hotspots within the country.
- Screening with questionnaires and temperature of persons coming from an affected area has been relatively ineffective and may miss many of the COVID-19 cases, particularly those with no symptoms during an incubation period, which may be up to 14 days.
- Enforced quarantine has been used in some countries to isolate easily identifiable cohorts of people at potential risk of recent exposure (e.g., groups evacuated by airplane from affected areas, or groups on cruise ships with infected people on board). The psychosocial effects of enforced quarantine may have long-lasting repercussions.

3.6 Congregate settings

These include places where people live or socialize in large numbers:

- Churches, madrasses.
- Psychiatric institutions.
- Long-term facilities (e.g. nursing homes).
- Prisons.
4 Contact tracing

Contact Tracing Algorithm for Contacts of People With Documented COVID-19

4.1 Definition of a contact

Applies to the preceding 14 days:
- Providing direct care to COVID-19 patients without proper PPE.
- Staying in the same close environment of a COVID-19 patient (workplace, classroom, household, gatherings).
- Traveling together in close proximity (<1m) with a COVID-19 patient in any kind of vehicle.

4.2 Personnel and the contact tracing team

- Teams can include trained personnel including community health nurses, CHWs, other clinical staff, trained community leaders.
- Personnel should be equipped with PPE. Improper PPE is particularly dangerous as infected workers could be asymptomatic and infectious, thereby potentially serving to spread the virus to community members they visit.

4.3 Testing of contacts

- Any symptomatic contacts should be tested.
- Asymptomatic contacts should be told to self-isolate for 14 days and call if symptoms develop. Self-isolation may mean living in a separate house, or distant room in a shared house.
- Use IgM/IgG rapid test and Ag rapid test at the same time, and where available, RT-PCR testing.
<table>
<thead>
<tr>
<th>If</th>
<th>Then</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>• Report to the MOH as a presumptive case of COVID-19.</td>
</tr>
<tr>
<td></td>
<td>• If patient will be managed as outpatient, instruct them on home quarantine.</td>
</tr>
<tr>
<td></td>
<td>• Take a detailed contact history in preparation for tracing all contacts.</td>
</tr>
<tr>
<td>Negative</td>
<td>• If no symptoms, home quarantine for 14 days and call if symptoms develop.</td>
</tr>
<tr>
<td></td>
<td>• If symptoms:</td>
</tr>
<tr>
<td></td>
<td>o And inside the window period, home quarantine for 14 days. Test again in 5 days.</td>
</tr>
<tr>
<td></td>
<td>o If outside the window period, no need for home quarantine.</td>
</tr>
</tbody>
</table>

### 4.4 Contact follow-up and discharge

- Daily or frequent communication with a healthcare provider via phone or visit is ideal to monitor for symptoms.

- Instructions for the contact:
  - Where to seek care if they develop a cough, fever, shortness of breath, or other symptoms.
  - The facility should be notified in advance.
  - IPC instructions for reporting to a facility: whenever possible with a means where a >1m distance is possible. Use an ambulance if available, or on foot, or a private vehicle if possible.
  - Clean surfaces that come into contact during transport with 0.5% diluted bleach (this is one part bleach to 9 parts water).
5 Laboratory

5.1 Personal protective equipment (PPE)

<table>
<thead>
<tr>
<th></th>
<th>Sample</th>
<th>PPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibody (IgM/IgG) RDT</td>
<td>Whole blood, serum, plasma</td>
<td>Masks, gloves, gowns</td>
</tr>
<tr>
<td>Antigen (Ag) RDT</td>
<td>Nasopharyngeal swab or deep sputum</td>
<td>N95, gloves, gowns, face shield</td>
</tr>
<tr>
<td>RT-PCR</td>
<td>Nasopharyngeal swab or deep sputum</td>
<td>N95, gloves, gowns, face shield</td>
</tr>
</tbody>
</table>

5.2 Laboratory Procedure for COVID-19 IgM/IgG RDT

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

**Product description:**
The COVID-19 IgM/IgG Rapid Test kit is a rapid, qualitative lateral flow immunoassay kit for the detection of human IgM and IgG against SARS-CoV-2 virus infection using fingerstick (no anticoagulant) and K2EDTA-anticoagulated venous whole blood. The test results can aid in diagnosis of SARS-CoV-2 virus infection. The diagnosis of COVID-19 must be made based on history, signs, symptoms, exposure likelihood, and other laboratory evidence in addition to the identification the COVID-19 IgM/IgG Rapid Test.

**Warnings and Precautions:**
- Wear personal protective equipment (PPE) such as gown, gloves, and a surgical mask when performing the test. Refer to procedure for the proper use of PPEs.
- Clean work surface with 70% alcohol before starting work.
- Place absorbent bench liner soaked with disinfectant on work surface to capture splatters and splashes.
- Store test kits in the dark at room temperature (18° to 26°C).
- Test kits have a shelf-life of 12 months. They should be protected from light after being opened. Do not freeze test cassette or buffer solution.
- Do not open the pouch containing the cassette until ready to use.

It is widely accepted that IgM provides the first line of defense during viral infections, followed by the generation of adaptive, high affinity IgG responses for long term immunity and immunological memory. Therefore, testing of COVID-19 IgM and IgG antibodies is an effective method for the rapid diagnosis of COVID-19 infection. Furthermore, detection of COVID-19 IgM antibodies tends to indicate a recent exposure to COVID-19, whereas detection of COVID-19 IgG antibodies indicates a later stage of infection. Thus, this combined antibody test could also provide information on the stage of infection.
After opening the sealed cassette pouch the test should be used within one hour. Do not use the test cassette, buffer solution beyond the indicated expiration date.

Do not use samples with hemolysis, high lipid concentration or turbidity, which can affect results.

Use universal precautions when handling blood samples.

**Sample Collection and Requirements:**

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

**Blood by fingerstick:**

- Use the middle or ring finger, ideally of the nondominant hand.
- The puncture should be made slightly off center from the fleshy portion of the finger, near the side of the fingertip.
- Disinfect thoroughly using an alcohol pad and let air-dry the puncture site.
- Stick side of the finger with lancet. Apply only light pressure on the fingertip until a blood drop appears. Don’t press or milk the finger.
- Discard lancet into a sharp container.
- Wipe away the first two to three drops of blood with the alcohol pad and make sure there is a free blood flow.
- Collect blood into capillary tube or sampler (~20-50 uL).

**Venous blood:**

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

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

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

**Interpretation of results**

![Detection Lines Diagram](image)

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

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

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

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

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

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

**Test Method Limitations**

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

Test results can be affected by temperature and humidity.

**Internal Quality Control Procedure**

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

**How accurate is the COVID-19 Rapid Test?**

In order to test the detection sensitivity and specificity of the COVID-19 IgG-IgM combined antibody test, blood samples were collected from COVID-19 patients from multiple hospitals and Chinese CDC laboratories. The tests were done separately at each site. A total of 525 cases were tested: 397 (positive) clinically confirmed (including PCR test) SARS-CoV-2-infected patients and 128 non-SARS-CoV-2-infected patients (128 negative). The testing results of vein blood without viral inactivation were summarized in the Table 1. Of the 397 blood sample from SARS-CoV-2-infected patients, 352 tested positive, resulting in a sensitivity of 88.66%. Twelve of the blood samples from the 128 non-SARS-CoV-2 infection patients tested positive, generating a specificity of 90.63% (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).
### 5.3 Job aid for COVID-19 IgM/IgG RDT

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

<table>
<thead>
<tr>
<th>EMR number / Hospital ID</th>
<th>Date of test</th>
<th>Name</th>
<th>Address</th>
<th>Phone number</th>
<th>Age</th>
<th>Gender</th>
<th>Date of symptom onset</th>
<th>Previously tested?</th>
<th>Ab test number</th>
<th>IgM result (+/-/I)</th>
<th>IgG result (+/-/I)</th>
<th>Ag test number</th>
<th>Result (+/-/I)</th>
<th>PCR swab (Y/N)</th>
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References

