RAPID COVID-19 IgG/IgM TESTING GUIDANCE

Consistent with FDA guidance, docket FDA-2020-D-0987, the State of Delaware has identified point-of-care lateral flow immunoassays ("rapid antibody tests") as useful diagnostic adjuncts for COVID-19 and subsequently developed guidance for use of these tests. Use of rapid antibody tests is contingent upon implementation in appropriate clinical scenarios. Guidance is described and diagrammed herein.

Only rapid antibody tests that have received an Emergency Use Authorization (EUA) from the FDA **OR** that have been independently verified by a CLIA certified laboratory may be used.

All testing must be performed in compliance with OSHA guidance on bloodborne pathogens (https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030), or if conducted in a clinical laboratory setting, in accordance with standards set forth by the Commission on Office Laboratory Accreditation (COLA).

Testing may only be performed under the direction and order of an independently licensed medical practitioner (MD/DO, DMD/DDS, PA, or APRN). For the purposes of this guidance, pharmacists are also considered independently licensed medical practitioners and may direct and order testing for COVID-19.

Testing implementation and interpretation should follow DPH testing algorithms (See Appendix A).

Use of COVID-19 testing is contingent upon reporting of results using the provided datasheet to the Delaware Division of Public Health (DPH) via the resource email inbox (ReportDisease@delaware.gov) or the DPH fax (302-223-1540). COVID-19 remains a reportable disease and failure to report may result in adverse action (See Appendix B).

All patients undergoing testing must be provided with detailed instructions on test interpretation and subsequent care and isolation instructions (See Appendix C).

The ultimate implementation of, the clinical decision making from, and the reporting of COVID-19 testing, are the responsibilities of the licensed practitioner (MD/DO, DMD/DDS, PA, APRN, or pharmacist) to whom the tests are distributed and who is listed as the ordering practitioner for the testing procedure.

FOR PATIENTS –
FREQUENTLY ASKED QUESTIONS (FAQS) FOR
RAPID COVID-19 IgG/IgM TESTING

1. What does the COVID-19 Rapid IgG/IgM Rapid Test look for?

The rapid antibody test evaluates for the presence of antibodies in your blood. These results can help guide your health care provider about your infection status.

2. Is the test FDA-approved?

The FDA has permitted distribution of tests that have received or that have applied for an Emergency Use Authorization (EUA); however, the State of Delaware requires all tests that have not received an EUA undergo validation by an authorized laboratory.

3. Why does the test use blood instead of a nasal or oral swab?

The rapid antibody test looks for the presence of antibodies, a component of the body's natural immune response to infection. Nasal and oral swab tests use a different testing method to look for genetic material of the virus that causes COVID-19.

4. My health care provider said the test was negative, what does that mean?

This does NOT mean that you are not infected with COVID-19. Your health care provider may recommend additional testing. You must continue to practice safe social distancing, hand washing, and other infection prevention recommendations as suggested by your health care provider and/or the Division of Public Health.

5. I have symptoms, and my health care provider said the test was positive. What does that mean?

You are at high risk to be infected with COVID-19. Follow your health care provider's directions. You **must** isolate from others until at least **24 hours** after your fever goes away and your breathing returns to normal **and** at least **10 days** since you first noticed you were sick. Discuss with your employer or health department regarding when you may return to work.

6. Does the presence of antibodies mean I am immune to COVID-19?

At this time, little is known about the duration and strength of immune response to COVID-19. You should continue to follow all infection prevention instructions to avoid giving COVID-19 to others, including social distancing and wearing appropriate protective equipment including face coverings if in close contact with others.

Standard Operating Procedure

I. Purpose

Standard Operating Procedure (SOP) will establish procedure for Rapid, Point of Care Testing for the following populations (Appendix A):

- Health care and residential facilities and other high-risk settings with an outbreak
- Vulnerable populations reached through community-based organizations, mental and behavioral health providers, and social service organizations
- Patients evaluated at primary care offices and other ambulatory settings

II. Concept of Operations

DPH will train and provide resources to organizations, offices, and agencies who are strategically positioned to reach the target populations who are at risk of COVID-19 infection.

III. Scope

This SOP will apply to trained personnel working to identify COVID-19 infection within the target populations.

IV. Procedure

1. Organization information

a) Trained personnel would screen individual to determine if the person needs a COVID-19 test (nasal/oral polymerase chain reaction (PCR), point-of-care, etc.)

2. Screening for Symptoms

a) When trained staff determines if person is asymptomatic or symptomatic
    1. Symptomatic persons may include those with fever > 100.4°F, shaking chills, severe sore throat, loss of taste or smell, shortness of breath, cough, or muscle aches
    2. Alternate symptoms including headache, nausea, vomiting, and diarrhea, and others have been identified as potential COVID-19 symptoms and may prompt further screening, action, or investigation.

b) Trained personnel should refer to Appendix B - SOP for Rapid COVID-19 Testing

c) If eligible for testing, staff person lets individual know they are eligible for testing based on DPH criteria for Rapid COVID-19 Test (Appendix B).

3. Approved for testing and testing protocol

a) Trained personnel perform a Rapid Point of Care test (blood test) and provides patient with results.
b) Trained personnel perform subsequent PCR testing if indicated.
c) Prior to ending visit with person, trained personnel reiterate protective measures and follows SOP for Rapid COVID-19 testing regarding repeat testing if necessary (Appendix B).

4. Follow-up/closure

a) Support staff ensures that the DPH COVID-19 Report form (Appendix C) is completed for each person receiving a rapid, point of care test and that the form is submitted to the Division of Public Health within 24 hours.

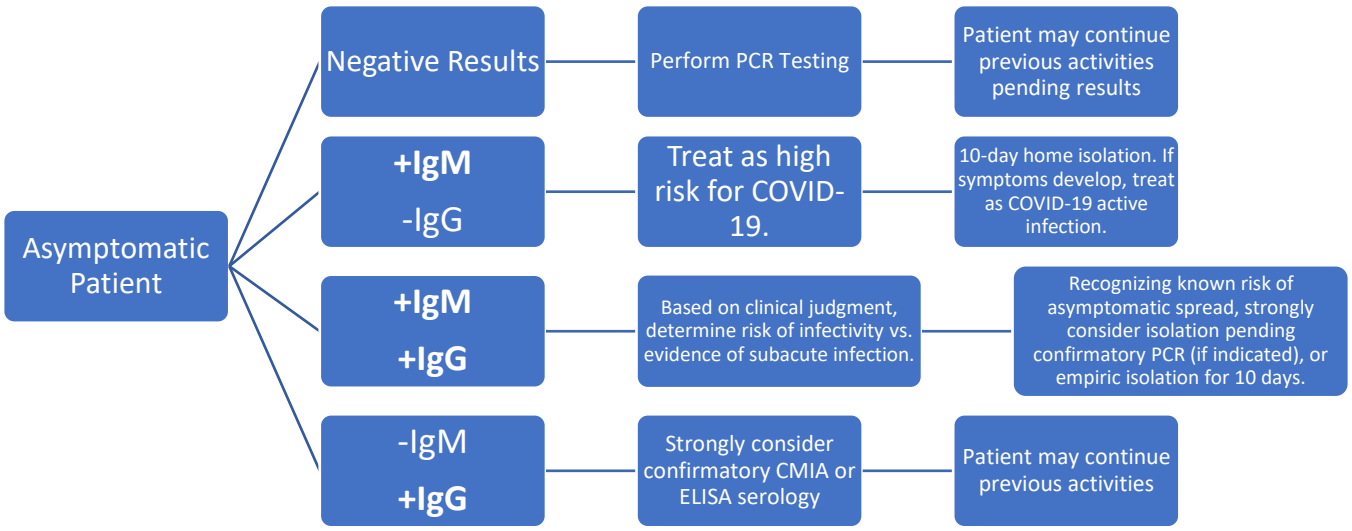
V. References & Definitions

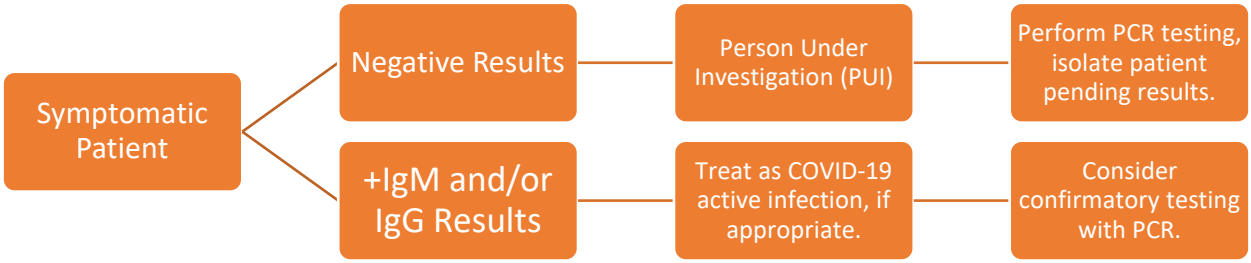
Requirements - Community place-based testing

- All organizations, offices and agencies providing rapid, point of care testing would have a standing medical order for which to operate
    - Order would be written and signed by a Delaware licensed provider (MD/DO, DMD/DDS, PA, APRN, or pharmacist) to whom the tests are distributed and who is listed as the ordering practitioner for the testing procedure. The licensed provider is ultimately responsible for reporting test results to patients and DPH
- Organizations, offices and agencies would receive training, testing criteria, and testing supplies from DPH
- Organizations, offices and agencies would utilize their own staff to support implementation of this effort
- Organizations, offices and agencies need to follow proper personal protective equipment guidance (https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html)

– APPENDIX A –

SOP for Rapid COVID-19 Testing





Asymptomatic Persons

Use of the rapid antibody test for asymptomatic persons may help identify those with asymptomatic, sub-clinical, or post-acute infection.

At this time, due to decreased analytical sensitivity of the test in early and pre-symptomatic infection, a negative result should be followed by confirmatory PCR. Pre-symptomatic individuals may not mount an IgM response for up to two (2) weeks following exposure. **A negative result does not rule out active COVID-19 infection.**

The presence of IgM without IgG in an asymptomatic person should be considered high risk for transmission of COVID-19 and should trigger ten (10) days of home isolation. Home isolation may be discontinued under existing DPH guidance as long as the person remains without symptoms consistent with COVID-19.

The presence of both IgM and IgG may indicate evidence of acute OR subacute infection with COVID-19. Practitioners should use their clinical judgment to investigate the possibility of subacute infection and the resultant risk of continued viral shedding. Consistent with emerging data regarding the risk of asymptomatic spread of SARS-CoV-2, practitioners should determine the need for follow-on testing with PCR, as well as the need for empiric isolation. Practitioners may ultimately decide to release patient, to perform follow-on testing with PCR, and/or to empirically isolate patient for 10 days or pending PCR results.

The presence of IgG without IgM in an asymptomatic person may be considered as evidence of previous sub-clinical infection and presumed durable immune response to COVID-19. **Despite high specificity of rapid tests for SARS-CoV-2, cross-reactivity with previously circulating coronaviruses has been documented and should be considered.** Practitioners should strongly consider confirmatory CMIA or ELISA serology (available through commercial laboratories or DPHL).

Practitioners are reminded: at this time—limited data exist on the rate or significance of re-infection.

Symptomatic Persons

Use of the rapid antibody test for symptomatic persons should only be employed in specific clinical scenarios where the strength (specificity) of rapid testing may be most beneficial. Example scenarios are listed below, however implementation is deferred to the ordering clinician. **A negative test does not rule out COVID-19 infection and should be followed by empiric isolation and treatment, as well as molecular testing via PCR, as determined by the ordering clinician.**

Descriptive Clinical Scenarios

Scenario 1: An asymptomatic patient. A negative result provides no actionable information and should be followed by PCR testing. The presence of IgM WITHOUT IgG should be interpreted as evidence concerning for **acute COVID-19 infection** and the patient placed under home isolation for a period of ten (10) days. The practitioner should heavily consider confirmatory PCR testing. The presence of IgM WITH IgG may indicate evidence of acute OR subacute infection with COVID-19, and further action taken as appropriate per practitioner's clinical judgment. The presence of IgG without IgM may be interpreted as evidence of previous COVID-19 infection with presumed recovery, and the individual permitted to return to previous activities. Practitioner should strongly consider confirmatory CMIA or ELISA serology.

Scenario 2: A symptomatic patient. A negative result must be followed immediately by PCR, and the patient treated as a PUI and isolated pending results. Confirmation of IgM or IgG from any tested symptomatic individuals should be treated as active COVID-19 infection. Confirmatory PCR testing should be considered.

Scenario 3: Facility outbreak investigation. When multiple persons within a facility (e.g. long-term care facility) manifest symptoms suspected to be COVID-19, wide application of rapid antibody testing can be used to identify the presence of COVID-19 in symptomatic individuals. Confirmation of IgM or IgG from any tested symptomatic individuals should be treated as active COVID-19 infection and all similarly symptomatic persons that the tested individual has been in contact with should be presumed to be infected with COVID-19.

Use of COVID-19 testing is contingent upon reporting of results using the provided datasheet to DPH via the resource email inbox (ReportDisease@delaware.gov) or the DPH fax (302-223-1540). COVID-19 remains a reportable disease and failure to report may result in adverse action.

The ultimate implementation of, the clinical decision making from, and the reporting of COVID-19 testing, are the responsibilities of the licensed practitioner (MD/DO, DMD/DDS, PA, APRN, or pharmacist) to whom the tests are distributed as the ordering practitioner for the testing procedure.

– APPENDIX B –

DELAWARE DIVISION OF PUBLIC HEALTH COVID-19 Report Form
(Must be completed for every rapid, point-of-care test to detect COVID-19 Disease)

Patient Name _____ Date_____ Phone _____

Birthdate _____ Sex: _____

Address _____Zip code _____

School or Type of Employment _____

Disease or Condition _____COVID-19_____

Date of Onset _____

Results: (Choose all that apply)

- ☐ Negative
- ☐ IgM Positive
- ☐ IgG Positive
- ☐ Indeterminate

Ethnicity:

- ☐ Hispanic or Spanish Origin
- ☐ Not Hispanic or Latino or Spanish Origin

Race:

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ White
- ☐ Multiracial

Healthcare Setting (Hospital, Office, Long-Term Care, etc.)

_____

Symptoms : (Choose all that apply)

- ☐ Cough ☐ Myalgias ☐ Headache ☐ Sore Throat ☐ Asymptomatic
- ☐ Fever ☐ Anosmia ☐ Nausea/Vomiting/Diarrhea

Remarks _____

Practitioner's Name _____ Practitioner's NPI _____

Phone _____

X _____ X _____

Name (please print) Signature

Complete this form and Fax to 302-223-1540 or Email reportdisease@delaware.gov

24 hour Office of Infectious Disease Epidemiology Phone 1-888-295-5156

– APPENDIX C –

Patient Instructions

Today you had a blood test performed by your doctor. This "rapid test" will *not* show your doctor whether you currently have the COVID-19 virus. Instead it looks to see if your body is fighting an infection to the COVID-19 virus.

Patients who had symptoms (fever, cough, shortness of breath) at time of testing

☐ Your test was **NEGATIVE – this does not mean that you are not infected with COVID-19**. Follow-on testing is usually performed. You **must** continue to isolate yourself at home, away from others, and should **consider yourself to be infected** until follow-up has resulted and your health care provider gives you further instructions.

☐ Your test was **POSITIVE** – **you are at high risk to be infected with COVID-19**. Follow your health care provider's directions. You **must** isolate from others for at least **3 days** after your fever goes away and your breathing returns to normal **and** at least **10 days** since you first noticed you were sick. DPH recommends exclusion from work until **7 days** after your fever goes away and your breathing improves, however please discuss this with your employer.

For patients without symptoms at time of testing

☐ Your test was **NEGATIVE – this does not mean that you are not infected with COVID-19**. Your healthcare provider should have performed additional testing. You may not notice symptoms for up to 2 weeks following exposure to the virus that causes COVID-19. You **must** continue to practice social distancing and any other appropriate instructions. Your employer may consider allowing you to return to work. Please notify your supervisor if you begin to develop symptoms and self-isolate at home.

☐ Your test was **POSITIVE for IgM** and **NEGATIVE for IgG – this suggests you have an active infection. You must consider yourself actively infected with COVID-19**. You **must** self-isolate for 10 days following the test. Please notify your supervisor if you develop symptoms, as isolation requirements may change in this setting. Home isolation may be discontinued under existing DPH guidance, using the rapid test result as the date of first positive test as long as you do not develop COVID-19 symptoms.

☐ Your test was **POSITIVE for IgM** and **POSITIVE for IgG – this suggests you may have been infected with COVID-19 at some point in the recent past.** Follow all of your health care provider's instructions. If additional testing was performed, discuss with your health care provider what you should do while you wait for the results of that test.

☐ Your test was **POSITIVE for IgG – an antibody that indicates you may have previously had the COVID-19 virus**. You should continue to follow all infection prevention instructions to avoid giving COVID-19 to others, including social distancing and wearing appropriate protective equipment.