

Coronavirus Disease 2019 (COVID-19) Dual IgG/IgM Rapid Test

Intended Use

The Coronavirus Disease 2019 (COVID-19) IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) is a lateral flow immunoassay for the qualitative detection and differentiation of IgG and IgM of COVID-19 in human whole blood, serum or plasma. This test is intended to be used as an aid in the diagnosis of infection with coronavirus disease.

Negative results do not rule out SARS- CoV-2 infection (the virus that causes COVID-19), particularly in those who have been in contact with the virus.

Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status. Tests should only be performed in conjunction with history and physical exam performed by an independently licensed health care professional. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains.

Testing procedures must follow Division of Public Health (DPH) guidance. Guidance is available at

<https://coronavirus.delaware.gov/resources-medical-providers/>

Warnings and Precautions

1. Before using the kit, read the instructions carefully and control the reaction time strictly. Inadequate blood supply may deliver inaccurate results. Be sure to deliver adequate blood supply to the sample well. Operational experience has shown that venipuncture may provide a more reliable volume of blood for sampling. The sample well should be saturated to the point of blood pooling. If using the accompanying pipette, ensuring 10-30 µL is delivered to the sample well of the cassette; **2.** Do not allow the product to get wet; **3.** Do not dilute the specimen for testing; **4.** Dispose of kit in accordance with infectious disease protocol; **5.** Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Testing procedures must follow DPH guidance.

Rapid COVID-19 Test: Targeted Population / Rationale

POPULATION	RATIONALE
Asymptomatic HCWs and first responders with high/medium risk exposures to a confirmed COVID-19 case*	<i>Support of health care staff and first responder infrastructure</i>
Rapid testing during an outbreak in health care and residential facilities and other high-risk settings	<i>Timely identification and infection control within these settings</i>
Community-based organizations serving vulnerable populations	<i>Increased capacity for testing of vulnerable populations</i>
Patients evaluated at primary care offices	<i>Increased capacity for testing in ambulatory setting</i>

*** Asymptomatic persons should only be tested to assist in risk stratification for the purpose of returning quarantined critical infrastructure personnel to irreplaceable roles in the setting of exhausted, and/or crisis, staffing concordant with current CDC guidance**

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html>



DELAWARE HEALTH AND SOCIAL SERVICES
Division of Public Health

Performing the Testing Procedure

1. Follow testing procedures as outlined in the package insert.
2. Obtain blood sample from patient. If performing fingerstick, fill the pipette dropper with the blood specimen to at least the indicated line on the pipette. Holding the dropper vertically, dispense about 10-30 µL of into the sample well, making sure that there are no air bubbles. The sample well should be saturated with blood and cause pooling.
- 3. If able, venipuncture may provide more reliable blood sampling.** Dispense about 10-30 µL of blood into the sample well, making sure that there are no air bubbles. The sample well should be saturated with blood and cause pooling.
4. Then add two drops (about 70-100 µL) of Sample Diluent immediately.
5. Set up timer for 15 minutes. Read and record results at the 14-to-15-minute mark. **It is important not to read results after 15 minutes.**

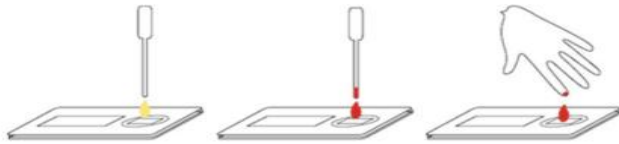
Limitations of the Test

1. The assay procedure and DPH guidance for implementation and result interpretation must be followed strictly when testing. Failure to follow procedure may give inaccurate results.
2. All positive results should be deemed presumptive positives and appropriate follow-up testing should be immediately sought.
3. Negative results do not rule out SARS- CoV-2 infection, particularly in those who have been in contact with the virus. Testing procedures must follow DPH guidance.

Asymptomatic Testing

1. Asymptomatic persons should only be tested to assist in risk stratification for the purpose of returning quarantined critical infrastructure personnel to irreplaceable roles in the setting of exhausted, and/or crisis, staffing concordant with current CDC guidance (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html>)
2. For quarantined personnel with MEDIUM risk exposures (see DPH and CDC guidance on exposure risk), testing should not be performed until at least **seven days** following exposure.
3. For quarantined personnel with HIGH risk exposures (see DPH and CDC guidance on exposure risk), testing should not be performed until at least **10 days** following exposure.

Sample Collection



10-30 μ l of blood should saturate the sample well.

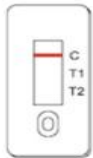


2 drops buffer



read result in 15 minutes

Results Interpretation



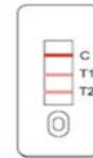
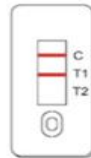
both IgG IgM Negative



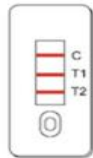
IgM positive, IgG Negative



IgM Negative, IgG positive



both IgG IgM positive



both IgG IgM invalid

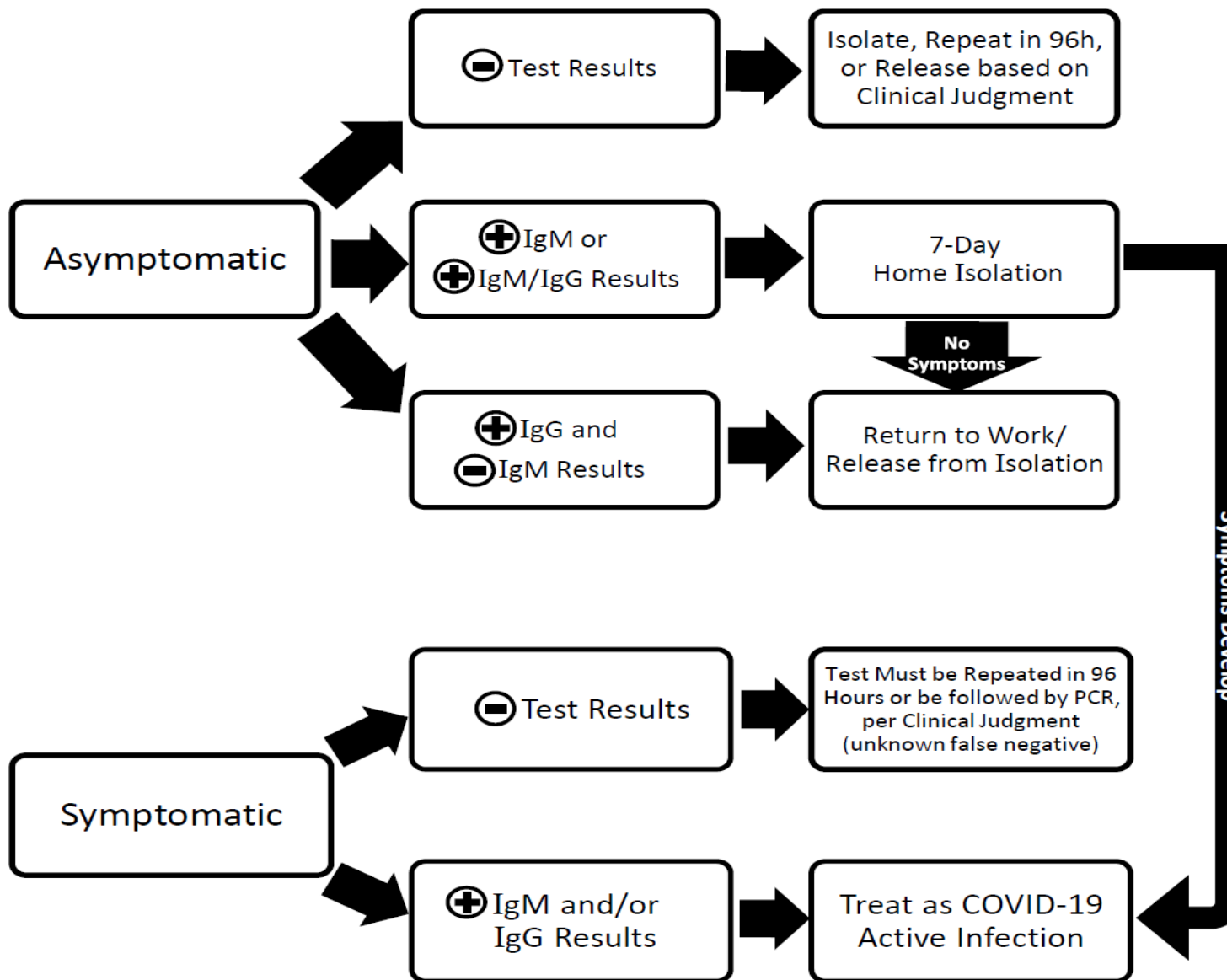
If using the pipette bulb, ensure the pipette is filled halfway up the conduit with no bubbles or visible air.

Operational experience has shown that venipuncture may provide a more reliable volume of blood for sampling. The sample well should be saturated to the point of blood pooling.



Failure to deliver adequate blood supply to the sample well may lead to inaccurate results.

Operational experience has shown that venipuncture may provide a more reliable volume of blood for sampling. The sample well should be saturated to the point of blood pooling.



Asymptomatic Testing

1. Asymptomatic persons should only be tested to assist for the purpose of risk stratification in returning quarantined critical infrastructure personnel to irreplaceable roles in the setting of exhausted and/or crisis staffing concordant with current CDC guidance (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html>)
2. For quarantined personnel with MEDIUM risk exposures (see DPH and CDC guidance on exposure risk), testing should not be performed until at least **seven days** following exposure.
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Testing procedures must follow Division of Public Health (DPH) guidance. Guidance is available at <http://de.gov/coronavirus/testing>