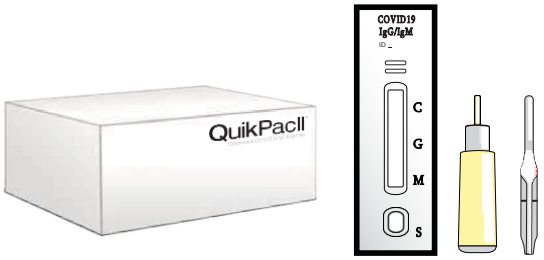
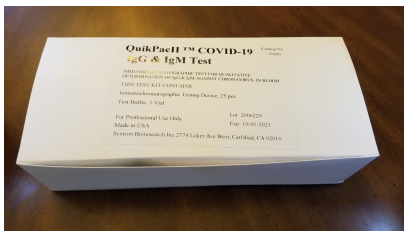
QuikPacII™

Coronavirus (COVID-19) IgG & IgM Test



Rapid lgM-lgG Combined Antibody Test for Coronavirus



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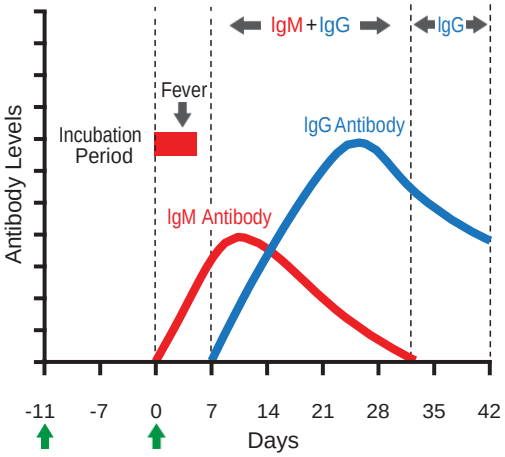
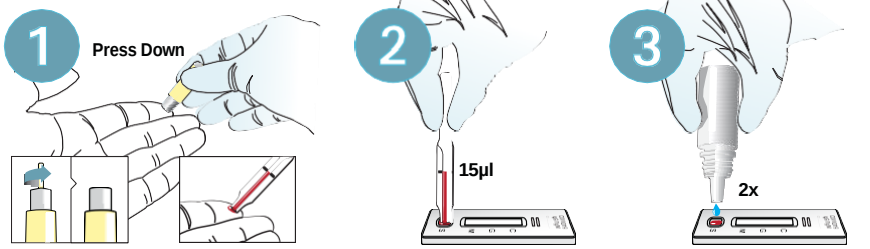
QuikPacII™ is the New Rapid Test That Provides Accurate COVID-19 Infection Diagnosis in 15 Minutes.

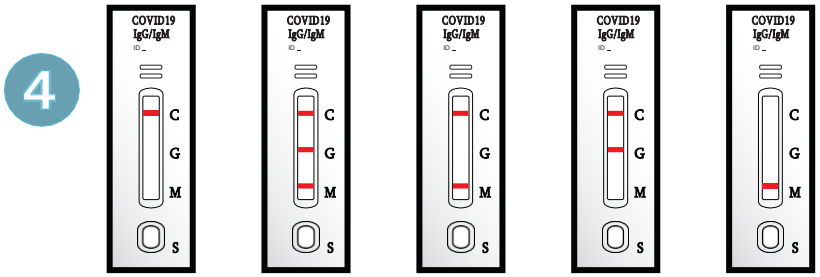
It is widely accepted that IgM provides the first line of defense during viral infections, followed by the generation of adaptive, high affinity IgG responses for long term immunity and immunological memory. Testing of COVID-19 IgM and IgG antibodies is an effective method for the rapid diagnosis of COVID-19 infection. Detection of COVID-19 IgM antibodies 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.



4 Simple Steps



1. Collect Blood Sample
2. Add Blood Sample
3. Add 2 Drops Buffer



4. Read Result After 15 Minutes

It can be used for rapid screening of carriers of the virus that are symptomatic or asymptomatic. Recent studies suggest that a high percentage of patients show no clinical symptoms of the virus, thus screening patients is vitally important. The test is ideally suited for hospitals, clinics and test laboratories. The test can also be effectively deployed in businesses, schools, airports, seaports and train stations, etc., giving it the potential to become a compelling force in the fight against this global threat.

Comparison With PCR Nucleic Acid Tests

Device Comparison With PCR Nucleic Acid Tests	PCR Nucleic Acid Tests	Syntron IgM/IgG Rapid Test
Intended Use	Detection Coronavirus infection	Detection Coronavirus infection
Specimens	Sputum, naso-pharyngeal smears	Blood/Serum/Plasma
Turnaround Time	Approximately 30 minutes	15 Minutes
Facility Requirement	PCR Laboratory Operation	No special facilities needed, test can be anywhere
Operation	Requires trained technicians	No specialized training required
	Requires expensive equipment	No equipment required, visual test result
	Complicated operation	Simple and Easy operation
	Prone to False Negatives	Results are clear and easy to read
Transport/Storage	Requires cold-chain	Room Temperature
Clinical Value	Commonly used, gold standard	Highly specific, can detect “silent infections”

The test was validated using 602 clinically positive and negative patient samples. The overall test sensitivity of QuikPacII™ COVID-19 IgG/IgM is 89.4% and specificity is 97.7%. • For Rx use only. • This test has not been reviewed by the FDA. For use in clinical laboratories by health care professionals following FDA guidance “Policy for Diagnostic Tests for Coronavirus Disease-2019 (COVID-19) during the Public Health Emergency”. • Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic assay should be considered to rule out infection in these individuals. • Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status. • Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E. • Not for the screening of donated blood.

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