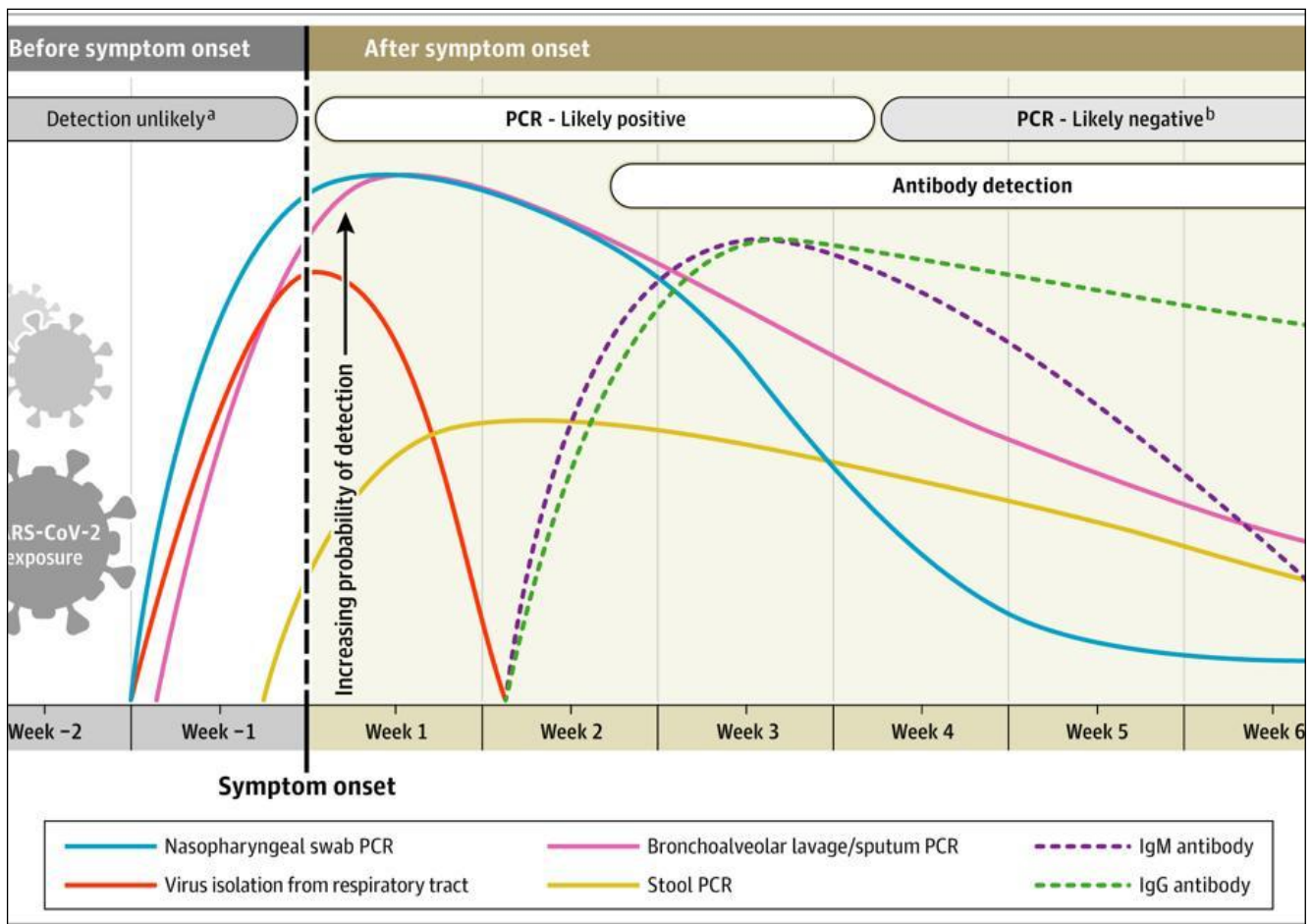


COVID-19 Antibody Test

Roche Elecsys MultiStep ImmunoAssay: IgM and IgG

Automated & Instrumented ~ FDA EUA Authorized ~ 100% Sensitivity ~ 99.8% Specificity

Abrishami Dermatopathology Physician directed laboratory Guidance on policy
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The graph illustrates an approximate conceptual timeline for various Covid-19 tests. After a viral infection, the immune system first produces IgM, followed by IgG Antibodies. It takes about one week to produce enough mature antibodies for detection. In some, it may take longer.

The Roche instrumented Antibody test runs on an e411 immunoanalyzer and is highly accurate for Covid-19 IgM and IgG antibody detection. It is the gold standard in antibody testing.

Roche Elecsys MultiStep ImmunoAssay for IgM and IgG

Abrishami Dermatopathology: Physician directed laboratory offering guidance on policy.

“Antibody testing can play a critical role in the fight against Covid-19”- FDA
“As part of a comprehensive plan, testing for Covid-19 antibodies can help organizations function efficiently, prevent shut-downs, and reduce liability.” -Payam Abrishami, M.D.

FDA EUA data on Roche Antibody test **100% Sensitivity ~ 99.8% Specificity**

Antibody	Performance Measure	Estimate of Performance	95% Confidence Interval
Pan-Ig	Sensitivity (PPA)	100% (29/29)	(88.3%; 100%)
Pan-Ig	Specificity (NPA)	99.8% (5262/5272)	(99.7%; 99.9%)
Pan-Ig	PPV at prevalence = 5%	96.5%	(93.9%; 98.1%)
Pan-Ig	NPV at prevalence = 5%	100%	(99.4%; 100%)

Very High Specificity Means Essentially No False Positive Results

Roche Elecsys Antibody test has the advantage: it is the leading combined IgM and IgG blood test with superb accuracy. Once in our laboratory, testing time is under 20 minutes.

Only two other instrumented antibody tests are available. Point of Care tests lack accuracy.

1-Abbott’s Architect: only detects IgG, NOT the IgM subclass, which is produced initially in the immune reaction pathway and is important for early detection.

2- Bio-Rad’s Platelia has lower sensitivity at 92%.

3- “Point of Care” tests using one drop of blood are generally less reliable than automated pharmaceutical grade tests by Roche, Abbott, and Bio-Rad, run on instrumentation.

Introduction: By July 5, 2020, about 320,000 cases of Covid-19 infection and 7000 deaths were confirmed in California by viral detection. 130,000+ of those cases were in Los Angeles County. The actual incidence is certainly higher. Antibody tests randomly performed suggest 5% of the population may have been infected. An estimated 50% of infections are asymptomatic and are the main driver of the pandemic. Infections occur in waves and ~95% have still not been exposed. The disease is highly contagious, unpredictable and can be fatal.

Because the vast majority are still at risk of infection, institutions and businesses will face outbreaks and waves of infection. We believe early testing is a powerful tool for businesses, schools, hospitals and municipalities. It will permit **early action** to maximize productivity and safeguard health. As part of a comprehensive program, “Antibody testing can play a critical role in the fight against Covid-19” -FDA. Antibody production is an essential function of our immune system and indicates recent or distant exposure to infection. Roche Elecsys detects two classes of antibodies. IgM antibodies rise initially, usually within a week of infection and decline quickly. IgG antibodies rise more slowly and remain elevated.

Highly Accurate Roche Antibody Test to Covid-19 Serves Two Functions:

1- Detection: Clearly, viral swab testing is important for detection in individuals with symptoms or known exposure, during the initial days of infection. But, viral swab test has a narrower window of detection and lower sensitivity. By some estimate, within a week of infection, viral swab sensitivity may drop by about 40%, yielding false negative results.

The detection of recent or distant infection by antibody testing is underutilized. It is complementary to viral swab test, and helpful to identify infected individuals who did not receive a viral swab test in initial days of infection, or may have had a false negative viral swab test. **Antibody testing widens the detection window and improves on the detection sensitivity and specificity.** It has advantages in asymptomatic individuals and for group testing. It can determine accurate infection rates and exposure risk within one’s institution.

2- Assessment of Immunity: While no guarantee can be made about absolute long-term protection offered by antibodies, it is widely accepted that antibodies are protective when detectable. In fact, administering hyperimmune globulin in ill patients and injecting intramuscular immunoglobulin to individuals at risk of infection are two hopeful ways to battle Covid-19 using antibody technology. On a larger scale, antibody detection can help institutions understand their group immunity to the threat of the pandemic.

Abrishami Dermatopathology: A Pathology and Immunology Reference Laboratory

As a physician led clinical and laboratory practice, our role is to aid patients, physicians, and employers make confident decisions about the next steps that affect the health, safety, and economic prosperity of our community. We understand the challenges facing clinics, hospitals, nursing homes, schools, professional sports and other businesses in our community. We believe government policies are in their early stage of development and are not tailored for all organizations. The FDA has advocated for EUA testing and Human and Health Services has approved payment for antibody testing.



In summary, we believe viral swab testing and instrumented IgM/IgG Antibody testing, such as the Roche Elecsys anti-SARS-Cov2, are **BOTH essential for our community's fight against Covid-19 and complementary**. Because the number of active infections at any one point, i.e. the prevalence, is low, viral swab testing has narrower application. For the vast majority of asymptomatic individuals and for organization aiming to stay vibrant and vigilant, incorporating antibody testing can clarify the next set of decisions. There are many applications for antibody testing depending on institutional needs.

Antibody Testing is powerful tool for detection, in asymptomatic individuals or in suspected infections. We believe it should follow viral swab testing (by 1-2 weeks), improving the detection window and to increase sensitivity and specificity of diagnosis. Antibody testing can provide insight into infection rates and risk within your organization.

Antibody testing can map the immunologic progression of individual to complete recovery and probable immunity. The detection of antibodies by the Roche Elecsys test implies presence of “neutralizing antibodies” that impart immunity. The general scientific consensus is that antibodies impart protective immunity in the exposed, based on experience with Covid-19, Sars, other coronaviruses, and based on studies in primates with Covid-19.

Testing should be always be voluntary and by order of a physician or licensed provider. Employment changes should not be tied in any way to results of antibody testing.