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Utility of COVID-19 Serologic Testing

Recent guidance from the California Department of Public Health has discouraged the use of COVID-19 serologic testing in routine clinical practice. COVID-19 serologic assays are intended to detect antibodies against SARS-CoV-2 in blood samples. It may take one week or longer, following onset of symptoms for antibodies against SARS-CoV-2 to be detected. There is insufficient evidence that the presence of SARS-CoV-2 IgG or IgM represents reliable evidence of immunity. And individuals with positive serologic test results may continue to shed the virus that causes COVID-19. Thus, antibody tests for SARS-CoV-2 currently have limited clinical utility, and none are approved for diagnosing cases of COVID-19. This is true even for serologic assays that have been granted an FDA Emergency Use Authorization (EUA) status.

Any serologic test should be used only in conjunction with molecular methods when evaluating a suspected case of COVID-19. Healthcare Providers using FDA EUA assays are advised to read their accompanying fact sheet.

Within recent weeks, additional serologic assays have been granted Emergency Use Authorization status by the FDA. Several of these are high-throughput enzyme immunoassays. Most detect IgG only and some also detect IgM. Potential uses for these assays include public health surveillance and research but are NOT useful in general clinical practice.

Results of serologic tests must be reported to the Public Health Department. Laboratories and providers should report only the results from serologic tests that have an FDA EUA.

For more information, visit the California Testing Task Force information pages:
https://testing.covid19.ca.gov/