

SARS-CoV-2 IgG Serology FACT SHEET FOR HEALTH CARE PROVIDERS

Mid America Clinical Laboratories

Use of Serology:

- Current data shows that IgG is detected in 98% of known PCR positives at 14 days of symptom onset.
- Not to be used to diagnose COVID-19 infection.
- Use for public health purposes should focus primarily on HCPs, public servants and other workers directly involved in the pandemic response.
- The CDC is still evaluating evidence-based approaches for optimal use and interpretation.

Suggested Clinical Utility of Antibody Testing:

- Provide additional information for assessment of true rate of infection
- Confirm prior infection or exposure with development of immune response
- Aid in creation of return to work protocols
- Support future vaccine development and convalescent plasma donor screening

Positive Results:

- Indicative of an immune response to SARS-CoV-2 infection
- Positive for IgG and Negative PCR for return to work with reduced risk of transmission
- Most likely exposed to COVID-19 with some chance of false positive due to previous exposure to other common coronavirus.
- Suggests unlikely re-infection due to immune response

Negative Results:

- SARS-CoV-2 specific antibodies were not detected
- Does not rule out COVID-19 and should be used along with molecular diagnostic evaluation

Unanswered Questions:

- It is unknown if the presence of IgG antibodies are indicative of protective immunity.
- At this time, there are no formal guidelines on return to work protocols using IgG testing.
- It is unknown when someone is no longer infectious even if they have an IgG immune response.
- At this time, there are no formal guidelines on the use of IgM vs. IgG vs. Total Antibody except to provide additional information regarding the status of infection.

MACL COVID IgG Testing:

- We are currently using the Abbott SARS-CoV-2 IgG Assay.
- Sensitivity is 100% at 14 days post symptom onset
- Specificity is 99.6%

References:

FDA Serology/Antibody Test FAQs <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2> accessed 4.21.2020

ACLA Serologic Testing White Paper <https://www.acla.com/acla-serologic-testing-white-paper/> accessed 4.21.2020

Abbott Diagnostics SARS-CoV-2 IgG Qualitative Assay Instructions for Use. April, 2020