



## About us

Hennepin Healthcare's clinical and forensic toxicology laboratory has been providing laboratory testing/processing services for toxicology needs across the Midwest for the past 50 years. Our toxicology laboratory provides testing for clinical, emergency, and forensic toxicology, as well as alcohol testing, therapeutic drug monitoring, and medicolegal services. We have been certified by the College of American Pathologists Forensic Drug Testing since 1997.

In addition to the services provided to the hospital, we also provide drugs of abuse testing for city, county and state agencies, public and private industry, and several emergency departments in the Twin Cities.

# Hennepin Healthcare Clinical Laboratory

## SARS-CoV-2 (COVID-19) ANTIBODY TESTING

- Serology tests detect evidence of the body's immune response to an infection, which can provide information on both current and prior infection and on vaccine-induced immune responses.
- Qualitative and quantitative antibody testing can provide information on an individual's adaptive immune response to SARS-CoV-2
- May assess immune response to a known diagnosis from a previous SARS-CoV-2 (COVID-19) infection or may assist in identifying individuals who have been exposed to the virus but may have not been tested
- Tests determine presence of antibodies to SARS-CoV-2, the virus which causes COVID-19
- Antibody tests should not be used to diagnose acute COVID-19 infection or symptomatic individuals; testing should be conducted 14 days or more following exposure or onset of COVID-19 symptoms
- Assays utilized have been authorized by the FDA under an Emergency Use Authorization (EUA) for use by CLIA certified laboratories
- Results from various antibody assays should not be compared

## COVID-19 antibodies

- Qualitative; reported as "Non-Reactive" or "Reactive"
- Includes a quantitative result with interpretive comment
- Detects high affinity antibodies to the SARS-CoV-2 nucleocapsid protein
- Preferentially detects IgG but also IgM and IgA antibodies
- Serum or plasma (Lithium Heparin or EDTA)
- Analytical specificity: 99.5%
- Clinical specificity: 99.8%
- Clinical sensitivity: 88% and 100% at 7-13 days and >14 days post-PCR detection of COVID-19
- Turnaround time: Same day/ <24 hours



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[hennepinhealthcare.org/lab](https://hennepinhealthcare.org/lab)

## COVID-19 spike antibodies

- Quantitative and qualitative; reported as “Non-Reactive” or “Reactive” with a quantitative value (U/mL)
- Detects antibodies against receptor binding domain (RBD) of the spike protein
- Spike protein is the target of many COVID-19 vaccines and candidate vaccines
- Serum or plasma (Lithium Heparin or EDTA)
- Analytical specificity: 100%

- Clinical specificity: 99.9%
- Clinical sensitivity: 93.4% and 96.6% at 7-14 days and  $\geq 15$  days post-PCR detection of COVID-19
- No decline in titers up to 126 days following a detectable COVID-19 result
- If an individual has been vaccinated against SARS-CoV-2, with no history of natural infection, the antibodies they develop are to the spike protein receptor binding domain

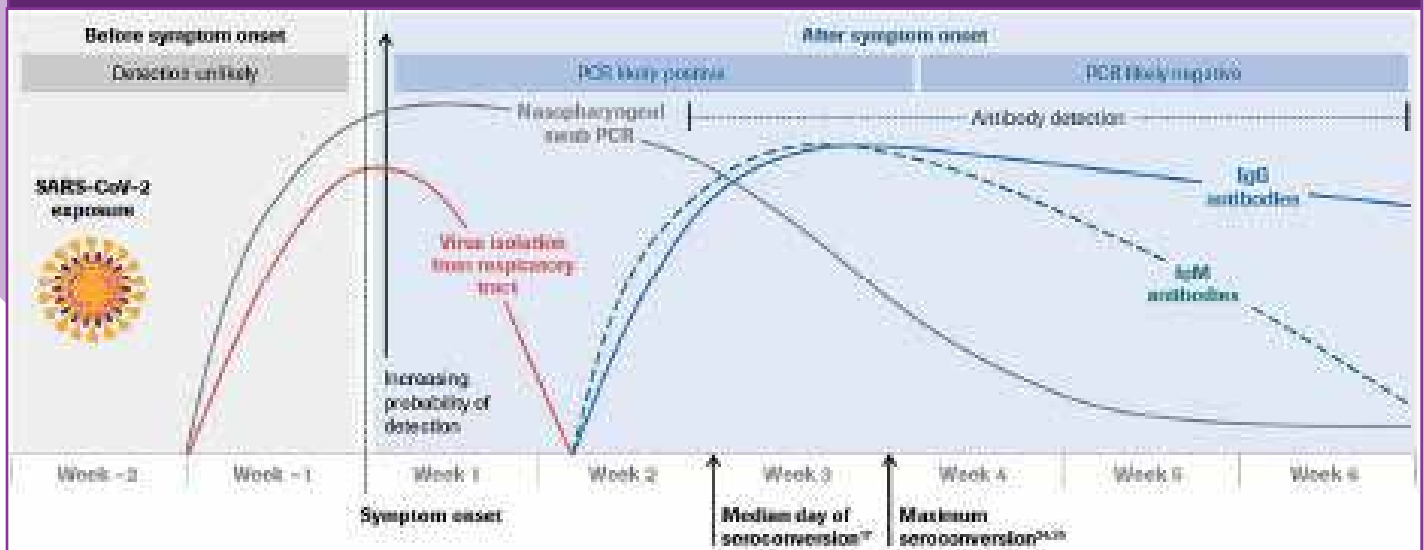
- Determining the levels of these antibodies could play a role in establishing vaccine efficacy and vaccine-induced immune response
- Turnaround time: Same day/ <24 hours
- It is unknown how long antibodies persist following infection and/or vaccination

### Contact us

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### Estimated Course of Markers in SARS-CoV-2 Infection



Source: Roche Diagnostics

### Viral & Antibody Testing

Test	Result	Interpretation
Viral (PCR) Testing	Positive	Current active COVID-19 infection
	Negative	No active COVID-19 infection
Antibody Testing	Positive	Likely had infection or response to the COVID-19 vaccine
	Negative	Likely never had (or not yet developed antibodies to) COVID-19
Viral and Antibody Testing	Viral + Antibody +	Current active infection
	Viral + Antibody -	Current active infection
	Viral - Antibody +	Past/recovered from infection or positive immune response post-vaccination
	Viral - Antibody -	Never infected and/or no immune response

Source: Roche Diagnostics