# COVID-19 Serologic Testing Practices Guide

Introduction

Serology testing for COVID-19 (IgG antibody) is now widely available but many questions remain unanswered. Therefore, the full clinical utility of serologic testing is presently unknown. The purpose of this Guide is to provide clinical context for clinicians who are considering whether or not to order serologic tests on their patients.

COVID-19 Testing Diagram
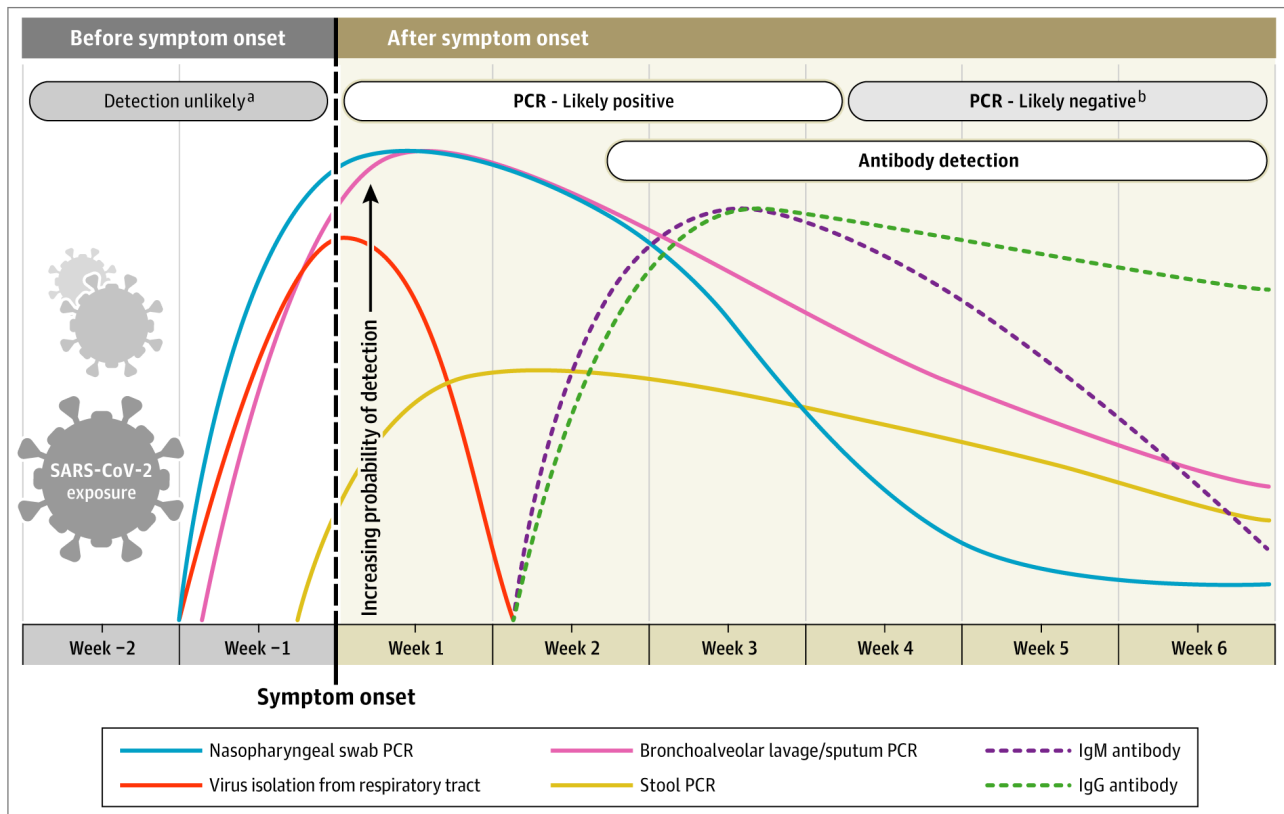
Sethuraman N, Sundararaj Stanleyraj J, Ryo A, Interpreting Diagnostic Tests for SARS-CoV-2, JAMA May 6, 2020;E1-E3.

What is currently known about available serologic tests and results?
1) There are multiple different antibody tests available with variable performance and targeted at different viral antigens.
2) Results are qualitative or semi-quantitative reducing their clinical utility
3) Positive PCR results overlap seroconversion
4) Antibody detection is not yet associated with immune status
5) Average duration of antibody detection is not clear
6) Not a diagnostic test

7) No universal standard for reporting is developed

What does a negative test mean?
1) No antibody to COVID-19 was detected in the sample
2) Does not mean the patient is free of virus
3) Does not mean the patient is not currently infected or infectious
4) Immunosuppressed individuals may test negative despite being exposed to COVID-19

What does a positive test mean?
1) The patient was exposed in the past and developed detectable antibody
2) Does not prove the patient is immune
3) Does not mean the patient is not infectious
4) May be false positive due to SARS-CoV-2 strain

What are the appropriate clinical settings to order serologies?
Testing for individualized care is questionable since patient care is directed by symptom management not serologic results. Once serological science is developed, individual testing may have more utility. Presently, the primary rationale for serology testing is for epidemiological purposes and should be guided by infectious disease specialists. Individual testing should be a rare occurrence at this time.
1) Epidemiological purposes
   a. Evaluating a targeted population
      i. Outbreak investigation directed by the RRH Infection Prevention & Epidemiology team or the NYS/Monroe County Department of Health
      ii. Cohorted population such as LTC
   b. Evaluating a community to assess vaccination benefit
      i. Who might benefit from a vaccination
      ii. Who is immune to the disease (once immunity has been established)
2) Individual purposes
   a. Provide diagnostic confirmation for PCR negative cases or prolonged idiopathic illness
   b. Not useful to determine immune status, therefore, patient care assignments or PPE utilization should not be made based on test results.
   c. Who has responded to vaccination
   d. Identification of convalescent plasma donor

References
Sethuraman N, Sundararaj Stanleyraj J, Ryo A, Interpreting Diagnosit Tests for SARS-CoV-2, JAMA May 6, 2020;E1-E3.

Wajnberg A, Firpo-Betancourt A, Serum Antibody Testing at Mount Sinai: Laboratory and Operational Partnership (webinar 5/20)

Abbasi J, The Promise and Peril of Antibody Testing for COVID-19, Jamanetwork, April 17, 2020;E1-E3

Liu A, etal, Prolonged Virus Shedding Even After Seroconversion in a Patient with COVID-19, JInfection, April 18, 2020;1:48

Xiao A, Gao C, Zhang S, Profile of Specific Antibodies to SARS-CoV-2: The First Report, JInfection, April 18, 2020;11:22

IDSA COVID-19 Antibody Testing Primer, Updated: May 4, 2020