



ANTIBODY (SEROLOGY) TESTING FOR COVID-19 (SARS-CoV-2)

Several antibody tests for Covid-19 have recently appeared in the market and are becoming more widely available. They are NOT FDA approved, but allowed under an Emergency Use Authorization waiver.

- What is the utility of these tests?
- What are the performance characteristics of these tests and how can they be used?

Comparison of multiple serologic assays by Whitman et al

(Preprint-not yet peer-reviewed)

- > 12 serologic tests for SARS-CoV-2 are now available. Whitman et al compared the results on these 12 assays on a variety of clinical specimens.
 - 108 stored samples from blood donors, from before the virus was circulating in the U.S.
 - ~2% of the specimens were (false)+ according to >3 assays, defining a specificity of 85-100%
 - ~50 specimens from symptomatic patients with negative RT-PCR for SARS-CoV-2 and some with + or neg PCR results for other respiratory viruses.
 - ~10% were + by >3 assays → nonspecific or cross-reactivity OR missed PCR Covid-19 diagnosis.
 - 130 specimens from 80 patients with PCR+ SARS-CoV-2 infection (mostly hospitalized; few asymptomatic or ambulatory symptomatic patients)
 - Increasing antibody quantity with time after symptom onset; reached high percentage by ~2 weeks and 80-100% + by 21 d.
 - Antibody quantities tended to be higher with more severe disease.
 - IgM results were more variable than IgG
 - **Concordance between assays ranged from 75-95%**
- **Diazyme (offered by Tuft Medical Center, Boston Heart Diagnostics) not included in above study**

Potential uses

- Population prevalence studies (May be accurate enough for public health use for this now)
- **Individual patient use: Not covered by most payers, not recommended by professional societies**
 - Diagnosis (Insufficient by itself; combined with PCR, improves sensitivity, though often retrospective given time course of antibody appearance)
 - Immunity testing protective immunity conferred by infection has not yet been proven; and if it exists, antibody may or may not be the protective immune response, and may or may not correlate with protection)

For the most up-to-date COVID-19 information please visit:

Centers for Disease Control * Massachusetts Department of Public Health * New England Quality Care Alliance