Antibodies and COVID-19

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Intended to present the latest science to policymakers

Serology testing provides important disease prevalence information

• Serology tests are a type of blood test that detects an immune response to SARS-CoV-2.

• The presence of **antibodies** in the serum can indicate if a person was once infected with the virus, even if they have cleared the virus.

**IgM**: The early responders (5-10 days post symptom onset)

**IgG**: Emerge later, but are more specific (10+ days symptom onset)

Sigma Aldrich
What serology can tell us

Serology results can be used to understand the true prevalence of an infection.

- Individuals with no symptoms have antibodies to the virus, but may not have been tested using molecular methods
- Serology testing can capture all individuals, no matter the type or range of symptoms, who were infected
- Seroprevalence studies may be used to determine the case fatality rate
- Fill in gaps left by contact tracing
Limits of serology test results

Serology test results alone cannot tell us if a person is immune to reinfection

• We do not know what levels or longevity of antibodies are necessary for protective immunity to SARS-CoV-2
• Serology tests cannot tell us if a person’s immune system has memory, or the immune system’s ability to recognize a previously encountered pathogen and produce a rapid, strong response
• Depending upon the seroprevalence, may be less useful for individual decision making (assuming durable immunity)
What makes a good serology test?

✓ The test must have high **sensitivity** and **specificity** to prevent false negatives or positives
✓ The test must be validated by independent, unbiased sources (such as the NCI)
✓ The FDA is currently regulating test development in the US, with recent policies providing more stringent approval criteria

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**NCI Part of Federal Effort to Evaluate Antibody Tests for Novel Coronavirus**

**FDA Sets Standards for Coronavirus Antibody Tests in Crackdown on Fraud**

At least 160 antibody tests for Covid-19 entered the U.S. without prior FDA scrutiny

Dozens of coronavirus antibody tests on the market were never vetted by the FDA, leading to accuracy concerns
Sensitivity and specificity can have large impacts on test accuracy

Seemingly high sensitivities and specificities can lead to false negatives and positives depending on disease prevalence.
Serology test types

**RDT**
- **Rapid Diagnostic Test**
  - Takes 10-30 minutes
  - Qualitative (yes/no)
  - Small and portable
  - Requires a fingerstick
  - Quick yes or no results

**ELISA**
- **Enzyme-Linked Immunosorbent Assay**
  - Takes 2-5 hours
  - Quantitative (antibody levels)
  - Requires lab space and trained personnel
  - Requires blood sample
  - Levels, but not efficacy

**NA**
- **Neutralization Assay**
  - Takes 3-5 days
  - Quantitative (antibody levels)
  - Requires lab space and trained personnel
  - Requires blood sample and live virus
  - Levels of effective antibodies

*What it provides*
The Global Serology Testing Tracker

- The Center for Health Security has created a **serology test tracker** to provide information on available serology tests around the world
- Tests are categorized by health agency approval status
- Updated twice weekly