COVID -19 Antibody Testing

Patricia Slev, PhD, D(ABCC)
Section Chief, Immunology Division, ARUP
Associate Professor, University of Utah
patricia.slev@aruplab.com

APRIL 2020

EuroImmun Anti-SARS-CoV-2 ELISA (IgG)

Intended use
The enzyme immunoassay (ELISA) provides qualitative in vitro determination of human antibodies of the immunoglobulin class IgG against SARS-CoV-2

Samples
Human serum or EDTA, heparin or citrate plasma

TAT
1-5 days

Stability
2 weeks refrigerated
1 month frozen

Regulatory
EUA approved

Validation

Accuracy

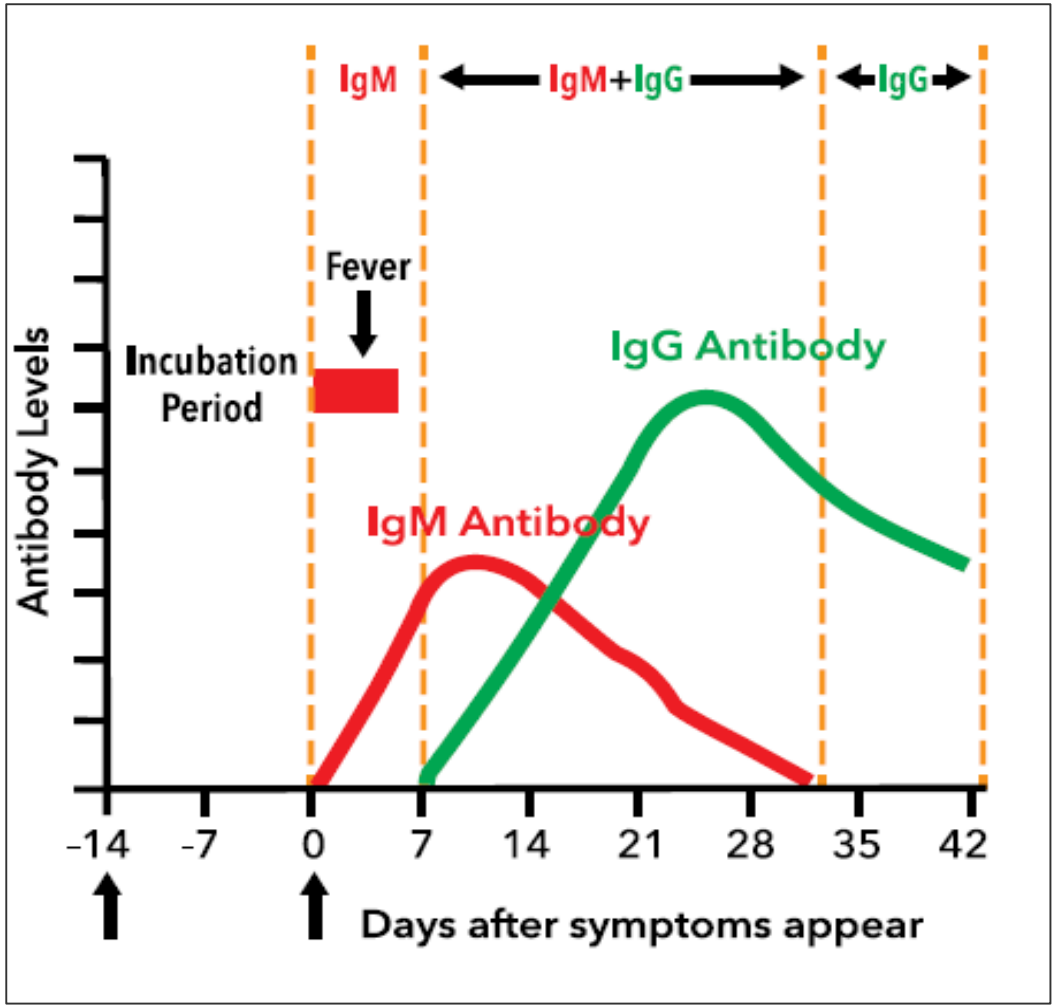
- Negative – specimens obtained prior to the outbreak
  - 126 Adults (20 - 68 yo)
  - 55 Pediatric (0 - 18 yo)

- Positive –patients who tested positive for COVID-19 by PCR at ARUP
  - 43 Adults (24-79 yo)

Other Validation Parameters Assessed

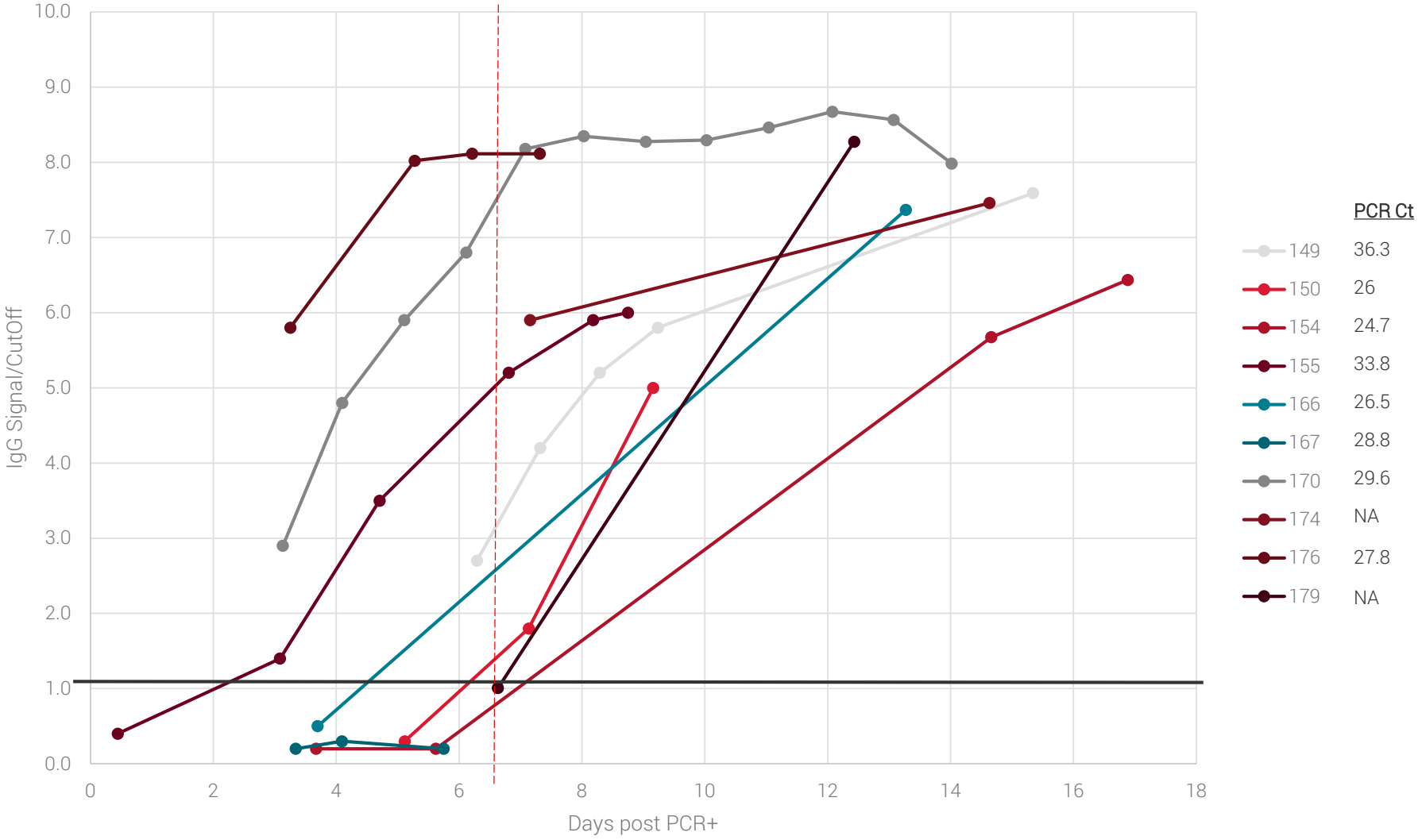
- Precision
- Interference
- Cross-Reactivity
- Stability

Typical Antibody Response to Viral Infection



BioMedomics COVID-19 Brochure

Seroconversion and IgG Antibody Response



Only includes patients with multiple samples tested

Sensitivity and Specificity

	COVID+	Negative
IgG Positive	41	3
IgG Negative	2	178

	Value	95% Confidence Interval
Sensitivity	95.35%	84.19% to 99.43%
Specificity	98.34%	95.23% to 99.66%

Antibody Testing Interpretation

- Presence of IgG antibody
  - Indicates exposure to COVID-19
  - Does not indicate protective immunity – pending ongoing studies
  - Does not inform infection status :
    - patient may have cleared infection
    - patient may still be infectious for several days after seroconversion if IgG test done too early
  - Cannot be used to diagnose acutely ill patients (only molecular tests are to be used to diagnose disease)

Current Recommendations for Use of SARS -CoV -2 Serologic Testing

- Overall consensus among organizations: WHO, ASM, IDSA, FDA, ACLA, ASCP, etc.
- Recommended use for:
  - » Identification of individuals previously infected with SARS-CoV-2
    - ▪ Epidemiology and seroprevalence studies
    - ▪ Facilitate contact tracing
  - » Identification of potential convalescent plasma donors
  - » Evaluation of immune response to candidate vaccines
  - » *Potential* aid for the diagnosis of COVID-19 in RT-PCR negative patients who present later during disease course
- Recommendations against use to:
  - » Diagnose of acute/recent COVID-19
  - » Determine whether or not a patient has developed protective immunity
  - » Guide PPE use

medRxiv
THE PREPRINT SERVER FOR HEALTH SCIENCES

CSH Cold Spring Harbor Laboratory BMJ Yale

Plasma from 175 COVID-19 recovered patients with mild symptoms were screened using a neutralization assay

Neutralizing antibody responses to SARS-CoV-2 in a COVID-19 recovered patient cohort and their implications

Fan Wu, Aojie Wang, Mei Liu, Qimin Wang, Jun Chen, Shuai Xia, Yun Ling, Yuling Zhang, Jingna Xun, Shibo Jiang, Hongzhou Lu, Yumei Wen, Jinghe Huang

doi: https://doi.org/10.1101/2020.03.30.20047365

Relevant results:

- SARS-CoV-2 specific NAbs were identified – no cross-reactive with SARS-CoV virus
- About 30% patients failed to develop high titers of Nabs (~6% below assay threshold) after COVID-19 infection even though disease duration was similar to those with high titers. Suggest that other immune responses, such as T cells/cytokines may contribute to recovery.
- SARS-CoV-2-specific NAbs were detected in patients from day 10-15 after the onset of the disease and remained thereafter.
- The titers of NAbs were variable in different patients. Elderly and middle-age patients had significantly higher plasma NAb titers ($P<0.0001$) than young patients.

A nonprofit enterprise of the University of Utah and its Department of Pathology