UNIVERSITY OF
PENNSYLVANIA
HEALTH SYSTEM

Department of Pathology and Laboratory Medicine

To: All UPHS Providers

From: Irving Nachamkin, DrPH, MPH, Director, Division of Laboratory Medicine
Michael Feldman, MD, PhD, Vice Chair for Clinical Services

Date: May 5, 2020

Re: CORRECTED VERSION: SARS-CoV-2 Antibody Testing at the William Pepper lab at HUP

Effective Wednesday, May 5, the HUP Core Laboratory is offering anti-SARS-CoV-2 antibody testing. The current assay is the SARS-CoV-2 IgG assay from Abbott Diagnostics, a chemiluminescent microparticle immunoassay for qualitative detection of IgG antibodies in human serum. The assay detects antibodies against the nucleocapsid protein of the virus.

The antibody response to SARS-CoV2 is fairly typical for a viral illness, with antibody levels rising during the course of infection and maximal detection beginning 10-14 days after the onset of symptoms. According to the company validation study, the assay had a sensitivity of 25% from 3-7 days after the onset of symptoms, 86% between day 8-13, and near 100% after 14 days. The specificity of the assay appears to be approximately 99%. Our own in-house validation studies performed on serum samples from patients are consistent with the company performance data. Using patient serum samples collected at least 14 days after a positive SARS-CoV-2 molecular test, there was 98% agreement with molecular results. We observed approximately 99% specificity in pre-COVID-19 era banked serum samples. Additional validation studies are currently in progress to further verify the specificity of the assay using sera from patients with non-SARS-CoV-2 coronavirus infections.

At the current time, there are no guidelines from the FDA, CDC or PA Department of Health about the use of antibody testing for individual patient management during the COVID-19 epidemic. Therefore, refer to the **PENN MEDICINE GUIDANCE ON ANTIBODY TESTING FOR SARS-CoV-2 - APRIL 30, 2020** before ordering this antibody test

Ordering Information: In EPIC: **COVID-19 (SARS-COV-2), ANTIBODIES**
Preferred specimen: serum separator tube
For more information, please call Client Services 1-800-PENNLAB

Antibody Testing for SARS-CoV-2/COVID-19

PENN MEDICINE GUIDANCE ON ANTIBODY TESTING FOR SARSCoV-2 – April 30,2020

- At this time, we do not recommend the use of antibody testing for the diagnosis of COVID-19 disease.
- A positive antibody test should not be interpreted as evidence of protective immunity at this time.
- We do not recommend the routine use of antibody testing of healthcare personnel to determine immunity, inform staffing decisions, make assessments about safety of the organization, or to guide decisions around personal protective equipment.
- Antibody testing should be reserved for:
    - the assessment of seroprevalence in specific populations
    - identification of appropriate convalescent plasma donors
    - unusual clinical circumstances in conjunction with other diagnostic modalities
    - to detect seroconversion following vaccination when a vaccine becomes available

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GENERAL INFORMATION

Currently, Penn Medicine is finalizing validation of three different commercial serologic tests for SARS-CoV-2 virus. These antibody-based tests will be orderable in Penn Chart. However, unlike the molecular tests for SARS-CoV-2 that are used to diagnosis COVID-19 infection, SARS-CoV-2 antibody tests are better suited for public health surveillance and vaccine development than for diagnosis. SARS-CoV-2 antibody tests should not be used as the sole test for diagnostic decisions. Furthermore, until more evidence about protective immunity is available, SARS-CoV-2 serology results should not be used to make staffing decisions or decisions regarding the need for personal protective equipment.

BACKGROUND ON ANTIBODY TESTING FOR SARS-CoV-2 INFECTION

- The antibody response in infected patients remains largely unknown, and the clinical values of antibody testing have not been demonstrated. Performing antibody testing in specific populations will be important in understanding the scale of the pandemic and future vaccine utility.
- Potential utility of serology in SARS-CoV-2:
    - Detection of PCR-negative cases, especially for patients who present late with a very low viral load below the detection limit of RT-PCR assays, or when lower respiratory tract sampling is not possible (this is a very limited diagnostic category);
    - Identification of convalescent plasma donors;
    - Epidemiologic studies of COVID-19 prevalence in the community;
    - Verification of vaccine response once antibody correlate(s) of protection identified.
- Potential drawbacks:
    - A positive serology does not determine whether or not a patient may still be infectious/capable of transmission of the virus;
    - There are false negative risks if performed early in disease course, especially in mild disease;
    - Patients on immunosuppressive drug therapies, or who have low immunoglobulin levels, may also generate a false negative result;
    - False positive risks, particularly with tests for Immunoglobulin M (IgM) and potential cross-reactivity with the four “common cold” human coronaviruses (e.g. HKU1, NL63, OC43, 229E);
    - Some FDA-authorized COVID-19 antibody tests are estimated to have 96%-98% specificity (true negative rate), which means that a positive antibody test result is more likely a <u>false-positive</u> result than a true positive result if the prevalence or pretest probability is 5% or less.