COVID-19 Testing for Dialysis Patients
Welcome

- Jeff Vizethann
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COVID-19 Response

**February 2020**
- PCR testing available to clinics.
- Provided scarce collection supplies to customers.

**June 2020**
- Partnered with Stanford University to research affects of COVID-19 on dialysis population.
- Offered COVID-19 test reports for clinics to track patient results.

**January 2021**
- Developed Vaccination tracking reports for patients and staff.

**Today**
- 250,000+ COVID-19 Antibody tests performed.

**May 2020**
- First ESRD lab to offer COVID-19 Antibody testing.
- Available as an add-on to other immunochemistry tests.

**October 2020**
- The dialysis population is ideal for studying the general spread of COVID-19 in the U.S.

**May 2021**
- Offered first quantitative antibody test by Siemens.
- Developing testing programs for COVID-19 for 2021 and beyond.
Test Name – COVID-19 SARS-CoV-2 PCR

- For patients displaying COVID-19 symptoms or meet criteria established by CDC
- Methodology - PCR and is a multi-target molecular RNA diagnostic test
- Specimen Type – Anterior Nares swab and viral or universal transport medium (UTM)
- Detects the presence of SARS-CoV-2 and determines if a patient is currently infected
Collection Materials

Nares Swab in Plastic Sheath*

Liquid Transport Media*

*Nares swab and liquid transport media are sourced from multiple vendors and may look slightly different

Biohazard Bag

DISCARD sheath after removing swab
Collection Instructions – Anterior Nares

- Wear appropriate PPE when collecting specimens
- Remove swab and *discard plastic sheath*
- Insert swab into LEFT nostril until slight resistance is met
- Rotate swab in a circular motion for 3-5 seconds
- Remove swab & repeat steps in RIGHT nostril
- Remove swab when finished
Collection Instructions – Anterior Nares

- Remove cap from liquid transport media
- Insert swab immediately into tube containing 2-3 mL of liquid transport media
- Bend swab shaft against side of tube
- Bend back and forth until top of swab breaks off, or cut
- Secure cap tightly to prevent leakage
Total Antibody Testing

Test Name – COVID-19 SARS-CoV-2 Ab, Total
- Use for patients who may have been exposed to COVID-19 to detect earlier and later seroconversion
- Methodology – Chemiluminescent Sandwich Immunoassay IgM/IgG (Serology)
- Specimen Type – Lithium Heparin Plasma (Tall Green top tube)
- Combine with other Immunochemistry tests such as Ferritin, PTH and other infectious diseases
- Detects SARS-CoV-2 antibodies, IgM/IgG with 100% sensitivity and 99.8% specificity
- Siemens received authorization for test by the FDA under an Emergency Use Authorization (EUA)
Antibody Testing - IgG Reflex

Test Name – Enhanced Sensitivity COVID-19 SARS-CoV-2 IgG
- Performed as a reflex test if the Total Antibody Screen is reactive
- Methodology – Chemiluminescent Sandwich Immunoassay IgM/IgG (Serology)
- Specimen Type – Lithium Heparin Plasma (Tall Green top tube)
- Detects SARS-CoV-2 IgG antibody
- Provides qualitative interpretation and a quantitative index to monitor IgG antibody levels
  - Reportable index range: 0.5-150.00
- Siemens received authorization by the FDA under an Emergency Use Authorization (EUA)
Collection Materials - COVID-19 SARS-CoV-2 Ab, Total w/Reflex IgG

- Blood specimen
- Use Lithium Heparin Plasma, Tall Green top tube
- Separate specimen collection is not required if immunochemistry tests are ordered
- If COVID-19 total antibody screen is Reactive, IgG will be performed
- If COVID-19 total antibody screen is Non-Reactive, IgG will not be performed
- Centrifuge immediately or within 2 hours after collection
- Transport – refrigerated, can be packaged with other patient blood specimens
- Stable for 2 days at 2-8°C
Leading the Way in COVID-19 Testing & Research

Major media outlets covered our latest research with Stanford University

"Pioneering a scalable sampling strategy that offers a blueprint for standardized national serosurveillance in the USA and other countries with a large hemodialyzing population."

Barnaby Flower, Christina Atchison, *The Lancet*, September 25, 2020

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Coronavirus Antibodies Found in Small Portion of Americans, Study Says

wsj.com

Under 10 Percent of Americans Have Covid-19 Antibodies, Study Finds

nytimes.com

About 9% of Americans exposed to COVID-19 by midsummer. That’s a long way from herd imm...

usatoday.com

National coronavirus antibody study suggests herd immunity "remains out of reach" in th...

newsweek.com
Research Study in Collaboration with Stanford University

Prevalence of COVID-19 Antibodies in the US Dialysis Population

- Most extensive study of this type
- Includes approximately 30,000 patients
- Using the COVID-19 SARS-CoV-2 Ab, Total w/Reflex IgG from Siemens Healthineers
- Performed on high throughput Atellica® immunoassay instrument

Study Goals
- Estimate the exposure status to COVID-19 in the US dialysis patients
- Understand rates of protective immunity over time
- Highlight in differences between age groups and regional factors
Study Findings

- Among vaccinated patients, 1 in 5 lost detectable antibody response, and over 70% lost protective levels of antibody within 6 months.
- The researchers report a strong link between circulating antibody levels and likelihood of breakthrough infections.
- Levels of circulating RBD below 10 (210 BAU/mL) were associated with a 11-fold higher risk for breakthrough infection, which resulted in hospitalization in over 40% of cases in this study.
- After 5 months dialysis patients are vulnerable to breakthrough infection, stressing the importance of encouraging of booster doses among this high-risk patient population.

Details

- Began in September 2021
- Includes nearly 5,000 recently vaccinated patients receiving dialysis
- Using the COVID-19 SARS-CoV-2 Ab, Total w/Reflex IgG from Siemens Healthineers
- Performed on high-throughput Atellica® immunoassay instrument
Why Use Antibody Testing?

Antibody Tests
Complement PCR Tests

- Support the clinical assessment of patients that test negative while presenting signs and symptoms associated with COVID-19
- Support the assessment of recent or prior infection for patients in clinical settings
- Provide an alternative when swab sample collection is compromised

Antibody Testing Is Vital for Surveillance

- Detecting a patient’s level of IgG antibodies allows clinicians to establish a baseline to:
  - Track the long-term duration of an individual’s immune response
  - Verify the effectiveness of vaccines
Do Patients Need a Vaccine Booster?

Data from a sample of our patient population shows IgG antibody levels decreasing over time.

The Vaccination History Report in LabCheck tracks patients’ vaccine type and test results.

The FDA and CDC recommend a Pfizer vaccine booster for immunocompromised and high-risk individuals (includes dialysis patients and staff) 6 months after their 2nd dose.
Thank you

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