ACHC U®
EDUCATIONAL RESOURCES

RENAL DIALYSIS

COVID-19 Testing for Dialysis Patients

Welcome

- Jeff Vizethann
- Executive Vice President, Ascend

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

- ✓ Findings from Ascend/Stanford Study published in *The Lancet Sept. 26, 2020.*
- ✓ COVID-19 seroprevalence in the United States confirms herd immunity remains out-of-reach.
- ✓ 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.

PCR Viral Testing

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

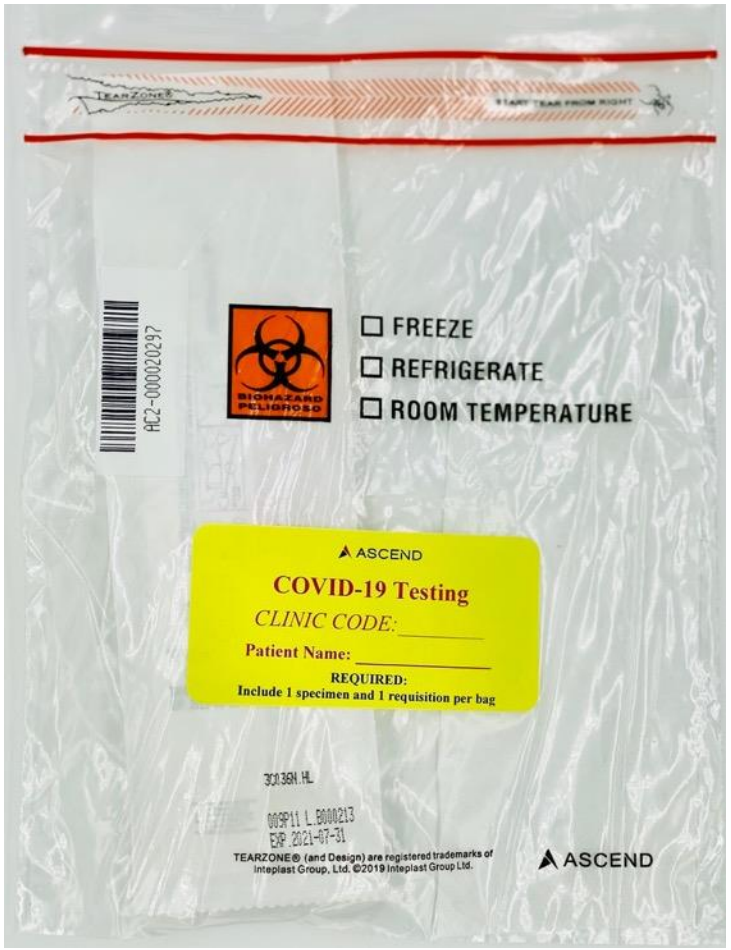
Nares Swab in Plastic Sheath*

DISCARD sheath after removing swab

Liquid Transport Media*

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

Biohazard Bag

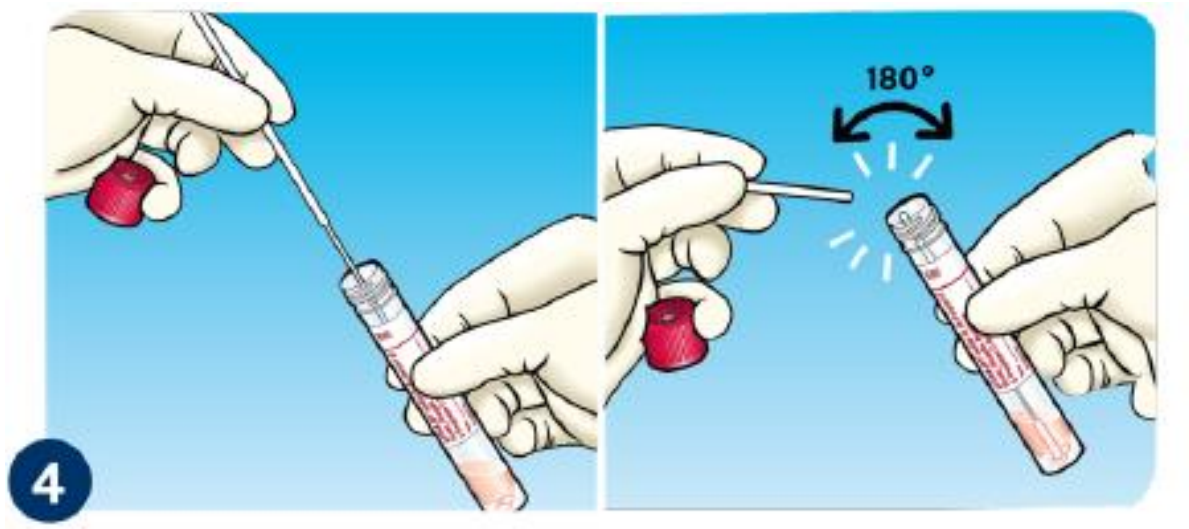


Collection Instructions – Anterior Nares

- 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

Discard plastic sheath
DO NOT label or send

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

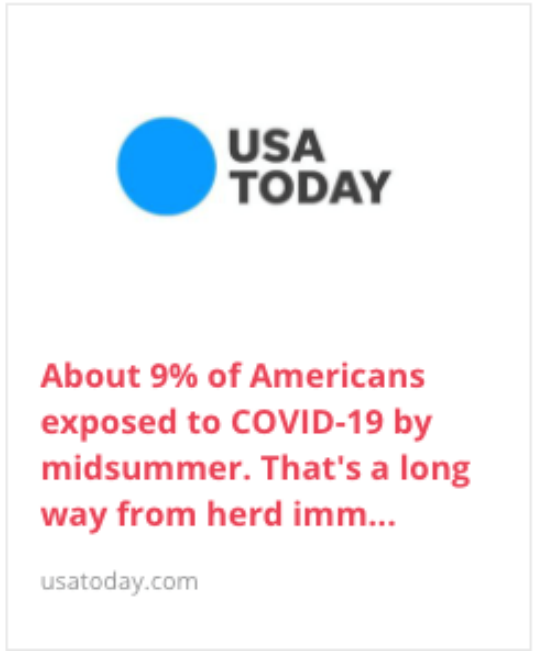
- Blood specimen
- Use Lithium Heparin Plasma, Tall Green top tube
- Separate specimen collection is not required if immunochemistry tests are ordered
- If COVID-19 total antibody screen is Reactive, IgG will be performed
- If COVID-19 total antibody screen is Non-Reactive, IgG will not be performed
- 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

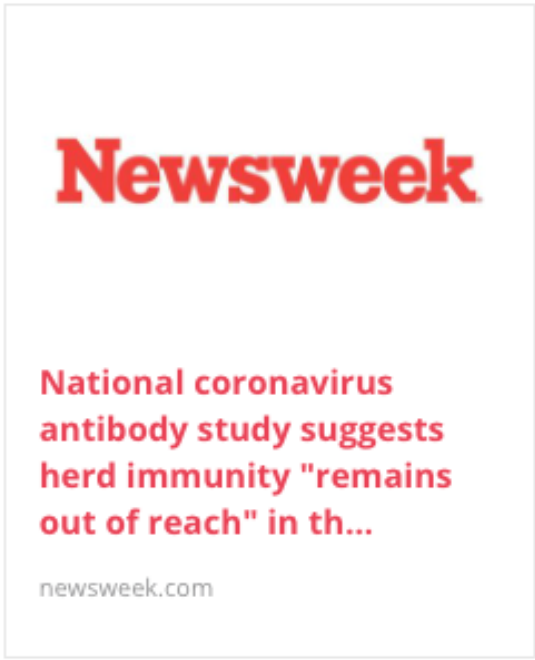
Leading the Way in COVID-19 Testing & Research

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





Research Study in Collaboration with Stanford University

Stanford MEDICINE

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

Research Study in Collaboration with Stanford University

Stanford MEDICINE

SARS-CoV-2 Vaccine Antibody Response and Breakthrough Infection in Patients Receiving Dialysis

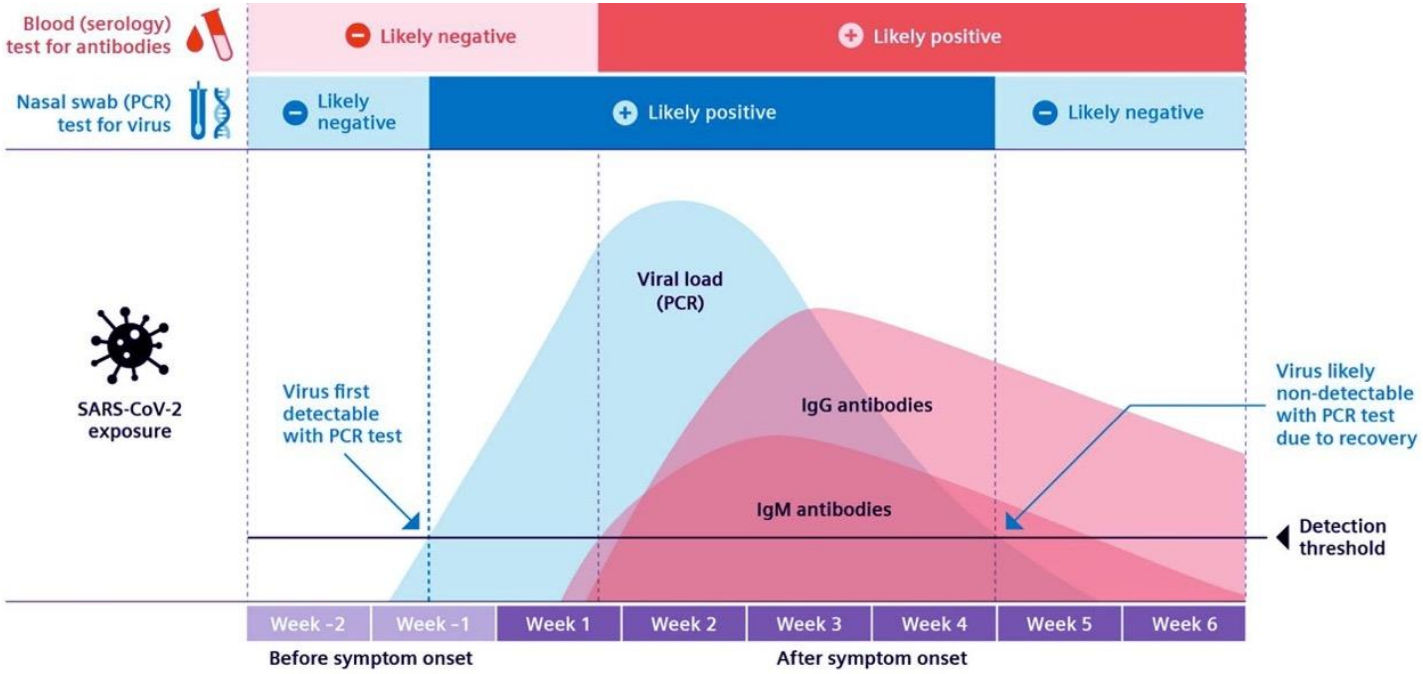
Study Findings

- 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?



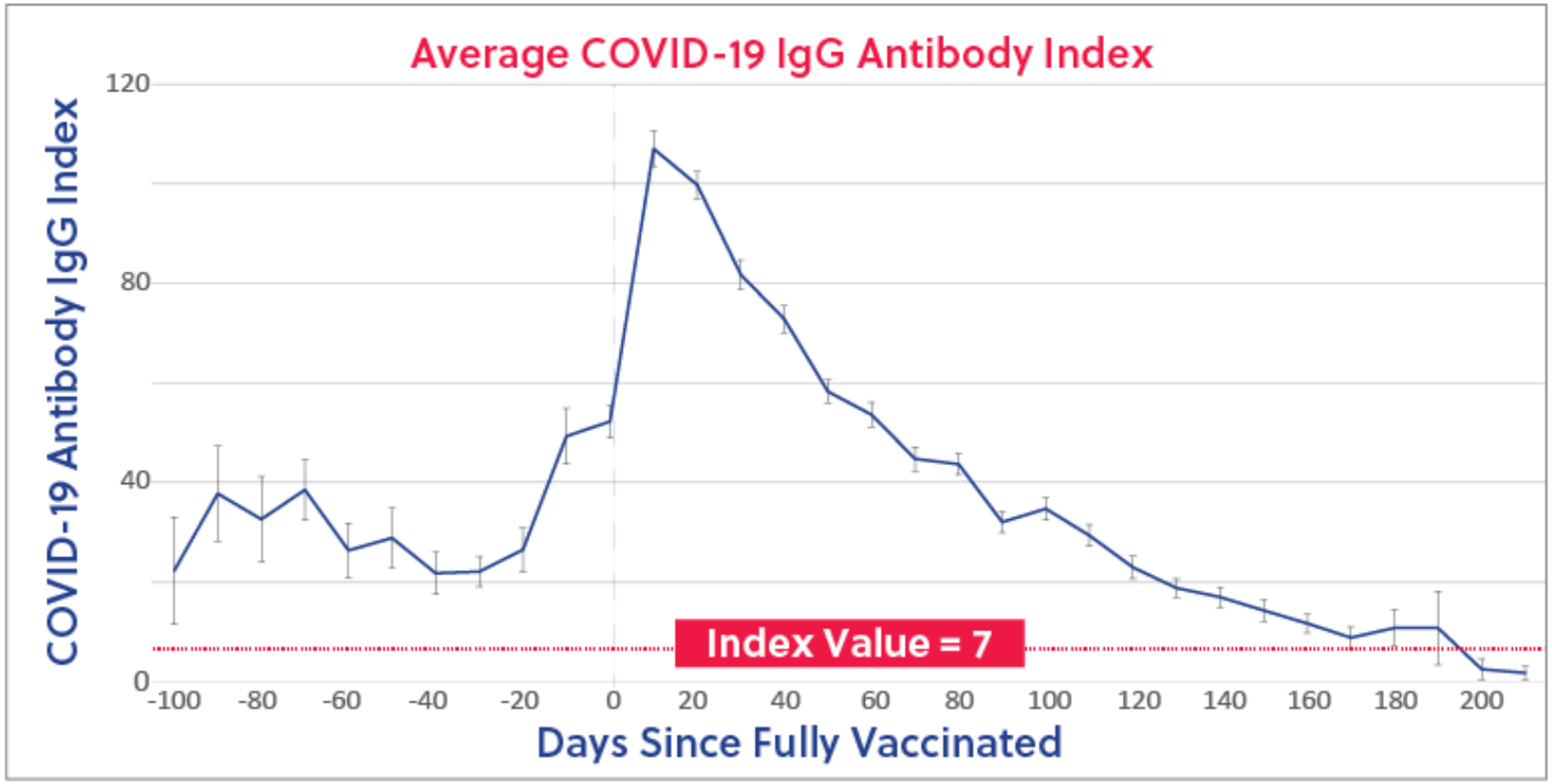
Antibody Tests Complement PCR Tests

- 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?



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.

Antibody Index

- 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.

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Thank you

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