85th in a series of calls, initiated by CDC as a forum for information sharing among frontline clinicians caring for patients with COVID-19. This call is not intended for the media.

The views and opinions expressed here are those of the presenters and do not necessarily reflect the official policy or position of the CDC or IDSA. Involvement of CDC and IDSA should not be viewed as endorsement of any entity or individual involved.

This webinar is being recorded and can be found online at www.idsociety.org/cliniciancalls.
Update on Serology Testing

**CDC Update & Setting the Stage: The Use of Serology Testing to Guide Clinical Decision-Making**

Adi Gundlapalli, MD, PhD  
CDC COVID-19 Response Team  
Chief Public Health Informatics Officer, Center for Surveillance, Epidemiology, and Laboratory Services  
U.S. Centers for Disease Control and Prevention

**The Clinical Perspective: Using Serology Test To Guide Clinical Decision-Making**

Ghady Haidar, MD  
Director of Research, Bone Marrow Transplant and Hematological Malignancy Infectious Diseases  
Program Director, Transplant Infectious Diseases Fellowship Program  
University of Pittsburgh

**FDA Update**

Ryan Karsner, MD  
Medical Officer, Division of Microbiology Devices  
Office of In Vitro Diagnostics and Radiological Health  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration

**Key Considerations & Future Directions in Serology Testing**

Florian Krammer, PhD  
Mount Sinai Professor in Vaccinology  
Icahn School of Medicine at Mount Sinai

**Patterns of Testing at Mayo Clinic**

Elitza S. Theel, PhD, D(ABMM)  
Director, Infectious Diseases Serology Laboratory  
Professor, Laboratory Medicine and Pathology  
Mayo Clinic
Question?
Use the “Q&A” Button

Comment?
Use the “Chat” Button
CDC Update & Setting the Stage: The Use of Serology Testing to Guide Clinical Decision-Making

Adi Gundlapalli, MD, PhD

Disclosures:
Nothing to Disclose
FDA Update

Ryan Karsner, MD

Disclosures:
Nothing to Disclose
EMERGENCY USE AUTHORIZATION OF COVID-19 SEROLOGY TESTS

February 26, 2022
Ryan Karsner, MD
Medical Officer, Division of Microbiology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
U.S. Food & Drug Administration
EUA LAW AND SEROLOGY INTENDED USE

• Federal Food, Drug, and Cosmetic Act section 564(b)(1)(A-C):
  • “The product may be effective…” AND
  • “…the known and potential benefits of the device when used for that purpose outweigh the known and potential risks of the device.”

• SARS-CoV-2 serology intended use statements:
  • “an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.”
COVID SEROLOGY TESTS OVERVIEW

85 Serology tests including

• 13 Point-of-care
• 2 Neutralizing antibody tests
• 1 Quantitative
• 17 Semi-quantitative
CURRENT LIMITATIONS OF SARS-COV-2 SEROLOGY TESTING

• Circulation of antigenically distinct viruses with ongoing viral mutation — likely impacts immune protections and limits any current data being applied to new mutations and variants

• Lack of traceability to a standardized reference material — only one test reports out in BAU or IU and most studies do not use this assay
SEROLOGY

Antibody concentration over time (weeks)

PCR or antigen

Cutoff Test 1

Cutoff Test 2

MI Test 3

MI Test 4
CURRENT LIMITATIONS OF SARS-COV-2 SEROLOGY TESTING (CONTINUED)

- Clinical validation studies
  - No standard molecular reference test which test developers can use as a comparator test
  - Relatively wide confidence intervals around performance point estimates
  - Lack of prospective studies where retrospective studies introduce biases by subject enrollment that artificially inflate performance point estimates

- Correlates of protection & clinically relevant thresholds are lacking

- Role of other components of the adaptive immune system such as T cells
FDA RESOURCES

- In Vitro Diagnostics EUAs
  - (templates with validation recommendations and authorized tests)

- Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations for Medical Devices

- FAQs on Testing for SARS-CoV-2
Patterns of Testing at Mayo Clinic

Elitza S. Theel, PhD, D(ABMM)

Disclosures: Serviced on Advisory Boards for: Euroimmun US Oxford Immunotec Roche Diagnostics Serimmun Inc
SARS-CoV-2 Serologic Testing Patterns
An Academic Medical Center and National Reference Laboratory Perspective

Elitza (Elli) S. Theel, PhD, D(ABMM)
Director, Infectious Diseases Serology Laboratory
Professor, Laboratory Medicine and Pathology
Mayo Clinic
Rochester, MN
@ElliTheelPhD
February 26, 2022
DISCLOSURES

• Advisory Board
  • Euroimmun US
  • Oxford Immunotec
  • Roche Diagnostics
  • Serimmun Inc.
LEARNING OBJECTIVES

- Summarize local and national serologic testing patterns over the past 2 years
- Discuss current (limited) role of serologic test for clinical decision purposes at Mayo Clinic
- Provide perspective on the ideal SARS-CoV-2 serologic testing state
SARS-CoV-2 Serologic Testing at Mayo Clinic

• Our SARS-CoV-2 serologic testing journey
  • Started testing April 10, 2020
  • Implemented 6 different high-throughput assays for serum and/or dried blood spots
  • February 2021: Standardized to offer 2 SARS-CoV-2 serologic assays
    • Semi-quantitative, anti-spike total antibody electrochemiluminescent immunoassay (ECLIA)
    • Qualitative, anti-nucleocapsid total antibody ECLIA

• Testing available to the Mayo Clinic practice and through Mayo Clinic Laboratories
General Testing Patterns – Birds Eye View at the National Level

Weekly Volumes

- Expanded Access Program for COVID-19 Convalescent Plasma
- Serologic Testing Guidelines
- First vaccines

No. of Tests Performed

Anti-NC ECLIA (Feb '21-Feb '22)

- ~5X higher rate of anti-spike vs. anti-NC orders

Anti-Spike ECLIA (Feb '21-Feb '22)
Local Seroprevalence Study

Serologic Testing Guidelines
- Internal education efforts

Weekly Volumes

Anti-NC ECLIA
(Feb '21-Feb '22)

Anti-Spike ECLIA
(Feb '21-Feb '22)

~2X higher rate of anti-spke vs. anti-NC orders

No. of Tests Performed

- Anti-Spike ECLIA implemented
Use of Serologic Testing at Our Institution

• Currently performing <100 tests/week
  • Anti-spike > Anti-nucleocapsid testing

• Limited use for clinical decision-making purposes
  • Evaluation of late complications of COVID-19
  • Diagnosis of COVID-19 in PCR-negative patients presenting later in disease course
  • Not used for pre- or post-exposure prophylaxis decisions

• Ordered for clinical interest in immunosuppressed patients and/or patient request
The Ideal SARS-CoV-2 Serologic Testing State for Clinical Laboratories

• Serologic result leads to an actionable, clinical decision point
• Identification of serologic correlate(s) of protection
• Assay Standardization
  • Ig class detected
  • SARS-CoV-2 target antigen
  • Reporting, particularly for quantitative assays
    • Calibration to international Ig standard (e.g., WHO/NIBSC 20/136)
    • Calibration of quantitative assays to the protective correlate
Thank You
The Clinical Perspective: Using Serology Test to Guide Clinical Decision-Making

Ghady Haidar, MD

Disclosures: Research Support
Karius, Inc
Allovir, Inc
The Clinical Perspective: Using Serology Tests to Guide Clinical Decision Making (?)

Ghady Haidar MD
Assistant Professor of Medicine
Division of Infectious Diseases
Transplant ID Program
February 26, 2022
Disclosures (research support)

• Karius, Inc
• Allovir, Inc
Pre-exposure prophylaxis (PrEP) of COVID-19 using monoclonal antibody
• 1271 participants (April – July 2021)
  • 1099 immunocompromised
    • SOT, cancer, autoimmune, persons with HIV
  • 172 non-immunocompromised UPMC HCW

• Blood **2+ weeks** after “full vaccination”
  • Seropositivity (Beckman, IgG to SARS-CoV-2 Spike RBD (≥ 1))
    • Available in EMR, **free**
  • Factors associated with + IgG
  • Comparison with **Bio-Rad** (IgG to RBD)
  • Pseudovirus **neutralization**

Haidar et al, Clin Infect Dis 2022
## What the Antibody Results Might Mean

<table>
<thead>
<tr>
<th>Reactive &gt;0.99</th>
<th>Equivocal 0.80-0.99</th>
<th>Non-reactive 0.00-0.79</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Your body is producing enough antibodies for us to find them in your blood.</td>
<td>• Your body might be producing some antibodies, but the levels are somewhat low.</td>
<td>• Your body either produced very low levels of antibodies or did not produce any antibodies to the vaccine.</td>
</tr>
<tr>
<td>• It suggests that you have some protection against COVID-19 from the vaccine. However, if you have a weak immune system, this level of protection may not be the same as that of a person with a healthy immune system.</td>
<td>• We do not know if you have the same protection against COVID-19 from the vaccine as that of a person with a healthy immune system.</td>
<td>• It suggests that you do not have the same protection against COVID-19 from the vaccine as that of a person with a healthy immune system.</td>
</tr>
<tr>
<td>• We do not know what the different numbers mean. We do know that any result greater than 0.99 is reactive.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

**It is IMPORTANT for everyone, regardless of antibody result, to:**

- Protect yourself and others by masking and physical distancing.
- Encourage those around you to protect YOU by getting vaccinated, masking, and physical distancing.
<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
<th>Sample Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare workers</td>
<td>92.4%</td>
<td>N= 172</td>
</tr>
<tr>
<td></td>
<td>79.8%</td>
<td>N= 94</td>
</tr>
<tr>
<td></td>
<td>79.1%</td>
<td>N= 163</td>
</tr>
<tr>
<td></td>
<td>78.7%</td>
<td>N= 136</td>
</tr>
<tr>
<td></td>
<td>50.0%</td>
<td>N= 156</td>
</tr>
<tr>
<td></td>
<td>30.7%</td>
<td>N= 450</td>
</tr>
</tbody>
</table>

Andrew Bilderback, MS
Statistician, UPMC Wolff Center

Haidar et al, Clin Infect Dis 2022
<table>
<thead>
<tr>
<th>HCW</th>
<th>SOT</th>
<th>Autoimmune</th>
<th>Cancer</th>
<th>HIV</th>
</tr>
</thead>
</table>
| Longer interval from vaccination | • Age > 45  
• BNT162b2 (vs mRNA-1273)  
• Lung transplant  
• Within 1 year of SOT  
• On 2+ immunosuppressive drugs (regardless of class) | • BNT162b2 (vs mRNA-1273)  
• Longer interval from vaccination  
• Anti-CD20 mAB | • Age > 60  
• BNT162b2 (vs mRNA-1273)  
• Anti-CD20 mAB | CD4 < 200 |

*Analyses adjusted for confounders

Haidar et al, Clin Infect Dis 2022
Antibody levels decline over time

1.55 level decline per month since vax

Haidar et al, Clin Infect Dis 2022
• Levels with Moderna >>>>> levels with other vaccines, after adjusting for age, time since vaccination, and underlying conditions

• All subgroups
• Dose?
• Interval?

Haidar et al, Clin Infect Dis 2022
Retesting with 2nd assay (N=245)

- 87% concordant
- 13% discordant

Haidar et al, Clin Infect Dis 2022
Antibody level vs NT50 (N=100)

- Excellent correlation between level and NT50
- Overall, higher antibody level = greater neutralization of virus

Spearman correlation of antibody level to neutralization titer

Haidar et al, Clin Infect Dis 2022
Antibody level vs NT50

- Neutralization ability LOWER in IC vs HCW with antibody levels 1-10

Haidar et al, Clin Infect Dis 2022
• Pre/post samples (serum, PBMC for subset)
  • 509 immunocompromised
  • 47 HCW

• Most “homologous” (Moderna-to-Moderna or Pfizer-to-Pfizer)

• Among IC:
  • **29.9%: levels still < 1**
  • 54.2%: levels still 1-10

• T-cell responses underway
Utility of checking antibody levels

Antibody Testing Is Not Currently Recommended to Assess Immunity After COVID-19 Vaccination: FDA Safety Communication

Date Issued: May 19, 2021
What are we doing?

• Not routinely checking
• Using data COVICS for counseling
• Cutoffs of protection in a changing pandemic?
  • Worried that patients will modify behavior
• Which lab to “trust”?
• “Snapshot” in time
• Insurance coverage
the expert in these matters, I will ask you: Am I correct it reading the test as telling me that the titers have gone from 16.20 to 1627.0 since I stopped my immunosuppressive meds and received a 50% 4th dose of Moderna?
Pre-exposure prophylaxis (PrEP) of COVID-19
Medical conditions or treatments that may result in moderate to severe immune compromise and an inadequate immune response to COVID-19 vaccination include but are not limited to:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm³, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell depleting agents)

Expectation (EUA)

Reality!

> 130,000 IC patients across 46 UPMC sites

Anticipated 456 doses in 12/2021!
• Ethical lottery
• Christmas 2021
• **Tier system** based on risk
• **Informed by COVICS data**
• NOT checking antibodies
  • Logistics of mandating (already complex to give PrEP!)
  • How to interpret?
    • Just for “negative”?
    • Just for “low”? (how low?)
    • Serial testing?
    • What lab to use/trust?
    • $$ $$

Erin K. McCreary, PharmD, BCPS, BCIDP
Infectious Diseases
Clinical Assistant Professor of Medicine
Director of Stewardship Innovation, Infectious Disease Connect
Infectious Diseases Pharmacist, UPMC
Email: mcreary3@upmc.edu
Tier 1

- Anti-CD20/CD52/B-cell depleting therapy (e.g., rituximab, ocrelizumab, ofatumumab, alemtuzumab)
  - Add belimumab
- Bruton Tyrosine Kinase Inhibitor (BTKi) therapy (e.g., ibrutinib, acalabrutinib)
- Add fingolimod, Siponimod, ozanimod, ponesimod therapy
- Chimeric antigen receptor (CAR-T) therapy
- Hematopoietic cell transplant (HCT) within one year of transplant
  - Allos on immunosuppression should be priority 1 even if > 1 year out
- Graft versus host disease (GVHD) on therapy
- Multiple myeloma on therapy
- Chronic Lymphocytic Leukemia (CLL)/acute myeloid leukemia (AML)/acute lymphocytic leukemia (ALL)/Myelodysplastic Syndrome (MDS) on therapy
  - Move MDS and MPD to priority 2
- Solid organ transplant AND within one year of transplant or rejection treatment with thymoglobulin or alemtuzumab
- Solid organ transplant AND aged 65 years or older
- Lung transplant recipient
- Severe primary immunodeficiency (i.e., common variable immunodeficiency disease (CVID), agammaglobulinemia, chronic granulomatous disease (CGD), severe combined immunodeficiency (SCID), Wiskott-Aldrich, DiGeorge, Dock 8 or Stat 3 deficiency, hypogammaglobulinemia requiring intravenous immunoglobulin (IVIG) replacement)
- Acquired immunodeficiency syndrome (AIDS) with CD4 <200 or <15%

• Rationale:
  • Highest risk to not “respond” to vaccines
  • Most efficient: contact all and offer PrEP

“Living Tier”

• Modified based on clinician feedback (red)

Erin McCreary
@ErinMcCreary
Tier 1: highest risk

- 12/27/2021 – 2/1/2022
- ~ 17,000 Tier 1 patients contacted
- ~ 1,110 patients treated as of 2/25/2022
Tiers 2 and 3: lower risk

Tier 2
- All other solid organ transplant patients
- All other stem cell transplant patients
- All other hematological malignancies
  - Move CML to priority 3
  - Move AML patients not on treatment to priority 3
- Aplastic anemia
- Age 65 years of age or older and two or more impairments of activities of daily living

Tier 3
- All solid tumor on chemotherapy
- All other immunosuppressive conditions receiving immunotherapy
  - Consider moving RA patients on MMF/AZA and pred +/-MTX to priority 2 (total burden of IS drugs)
- Functional or anatomic asplenia
- Add sickle cell anemia
- All other primary/acquired immunodeficiency states

- “Living Tier”
- Modified base don clinician feedback (red)
- Delegating to patient’s physician (Tix-cil orderable in EMR)

Erin McCreary
@ErinMcCreary
Subject: pt eligibility and need for Evusheld

Hi,
I have 83 yo patient, woman with hx of a.fib, pulmonary fibrosis 2/2 radiation, hx of lung cancer treated with chemo that was finished 2 months ago.
She also received 4th dose of Covid vaccine within a month or so.
Does she need Evusheld?
Can she take it safely, considering cardiac hx?
My feeling is she does not need MAB if she got 4th vaccine
• Learning much about immune responses to vaccines
• SOT, anti-CD20 mAB, age, non-mRNA-1273 vaccines: poorer antibody response
• Neutralization lower in IC vs HCW
• Clinical use still controversial
• “Precision medicine” approach in the future?
Acknowledgements

• STUDY PARTICIPANTS
• UPMC/Wolff Center/Office of Healthcare innovation
  • Mounzer Agha MD
  • Andrew Bilderback MS
  • Amy Lukanski DNPc
  • Kelsey Linstrum Balish MS
  • Rachel Troyan MBA
  • Scott Rothenberger PhD
  • Deborah K. McMahon MD
  • Melissa D. Crandall MHA
  • Michele D. Sobolewski MS
  • P. Nathan Enick BS
  • Jana L Jacobs PhD
  • Kevin Collins MBA
  • Cynthia Klamar-Blain
  • Bernard JC Macatangay MD
  • Urvi M. Parikh PhD
  • Amy Heaps MS
  • Lindsay Coughenour BSN
  • Marc B. Schwartz MD
  • Jeffrey M. Dueker MD
  • Fernanda P. Silveira MD
  • Mary E. Keebler MD
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  • John F. McDyer MD
  • Bhanu Pappu PhD
  • Robert L. Ferris MD
  • Stanley M. Marks MD
  • John Mahon
  • Katie Mulvey
  • Sundaram Hariharan MD,
  • Glenn M. Updike MD
  • Lorraine Brock MSN
  • Robert Edwards MD
  • Richard H. Beigi MD
  • Paula L. Kip PhD
  • Alan Wells MD
  • Tami Minnner MSN
  • Derek C. Angus MD
  • John W. Mellors MD

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@cleverwebber
Acknowledgements

- Wolff Center
- OPTIMISE-C19 team.
- Jordan Bartlow, Logan Baylor, Sarah Behr, Shannon Buono, Lori Caruso, Vibha Chauhan, Charles Chilleo, Maddie Chrisman, Shawna Chylinski, Cathy Cochran, Kate Codd-Palmer, Nicole Czolba, Celeste Duprey, Kelly Friday, Megan Fritz, Dr. Mark Gladwin MD, Dr Ken Ho MD, Kailey Hughes, Dr. Naudia Jonnasaint MD, David Jordan, Trevor Katich, Jenna Keeling, Kristin Kerfoot, Joshua Kohl, Dr. Fadi Lakkis MD, Elaine Lander, Michelle Lucas, Aimee Majeski, Dr. Rachel Marini PharmD, Oscar Marroquin MD, Susan Martin, Traci McGaha, Rachel McGargle, Stephanie Montgomery, Dr. Alison Morris MD, Ben Morris, Audrey Paul, Dr. Barbara Postol PhD, Dr. Sharon Riddler MD, Nicole Radulovich, Jennifer Roscher, Margherita Sciullo, Amber Shaffer, Jordan Shayer, Lisa Sheehan, Kristin Shoemaker, Lori Snyder, Courtney Starrett, Dr. Mindi Styn PhD, Colleen Sullivan, Abbey Sung, Christina Tedesco, Jeffrey Tischler, Dr Peter Veldkamp MD, Jamie Voyten, Mary K Wisniewski.
Key Considerations & Future Directions in Serology Testing

Florian Krammer, PhD
Key Considerations & Future Directions in Serology Testing

Florian Krammer
Mount Sinai Professor in Vaccinology
Icahn School of Medicine at Mount Sinai

CDC/IDSA COVID-19 Clinician Call: Update on Serology Testing
February 26th, 2022
From a scientific perspective both neutralizing as well as spike binding antibodies correlate with protection from symptomatic disease (mechanistically, it is likely mostly neutralizing antibody).

Gilbert et al., Science, 2021

Goldblatt et al., Vaccine, 2022
Use cases for a correlate of protection

• Vaccine licensure can be facilitated by immuno-bridging

• Serology can be used to determine what percentage of the population is protected

• Serology can be used for patient management
  • Especially important for immunocompromised patients
Hurdles

• Targets of serological assays not unified

• Not all serological assay are quantitative

• Implementation of standards/international units is not widespread

• Variants make everything more complicated

• What endpoints are used? Protection from infection? From disease? From severe disease?
Variants make everything more complicated

Cromer et al., Lancet Microbe, 2022
Variants make everything more complicated

Binding and neutralization titers to wild type SARS-CoV-2 correlate well

Neutralizing titers against variants drop much more than binding titers

Zak et al., Heliyon, 2021

Carreño et al., Nature, 2022
Variants make everything more complicated
Protection from infection

• Mechanistically, this can really only be achieved by neutralizing antibodies
• Antibodies need to be present on mucosal surfaces of the upper and lower respiratory tract
• For SARS-CoV-2 vaccination this is IgG which ends up on mucosal surfaces
  • Good protection of the lower respiratory tract
  • Little in the URT, and levels may decline rapidly
• After natural infection locally produced sIgA may be the main mechanism of protection in the upper respiratory tract
• Virus dose and viral fusogenicity may be factors here as well
Mucosal antibodies matter!

Seropositive before vaccination

Seronegative before vaccination

https://www.medrxiv.org/content/10.1101/2021.12.06.21267352v1
Mucosal antibodies matter!

Mucosal IgG correlates with serum IgG, sIgA does not

Krammer, Nature, 2020

https://www.medrxiv.org/content/10.1101/2021.12.06.21267352v1
Protection from disease

- The virus infects cells but replication is significantly reduced
- Potential contributing factors
  - Neutralizing antibodies at suboptimal levels
  - Non-neutralizing antibodies via effector functions
  - T-cells
  - Memory B cells which differentiate into plasmablasts and quickly increase (neutralizing) antibody levels
- The effect of T-cells and memory B cells likely depends strongly on incubation time – which is already very short for the recent Delta and Omicron variants
Protection from severe disease

• The virus infects cells, spreads, causes symptoms but replication is significantly slowed/attenuated, especially in the lower respiratory tract

• Potential contributing factors:
  • Neutralizing antibodies at suboptimal levels, but high enough IgG titers to protect the lower respiratory tract
  • Non-neutralizing antibodies via effector functions
  • T-cells
  • Memory B cells which differentiate into plasmablasts and quickly increase (neutralizing) antibody levels

• T-cells and memory B cells have significantly more time to respond since disease progression takes time
Conclusions

• Serum neutralizing antibodies are expected to correlate well with protection from infection and disease
• Protection from severe disease is much more complicated
• Variants increase complexity
• Standardization is still not available
• Nevertheless, serology is a great tool to
  • Aid in vaccine licensure through immuno-bridging studies
  • Help manage immunocompromised patients
  • Try to determine infection/vaccination histories
Q&A
Selected Resources

Dr. Karsner

FDA Resources


Dr. Krammer

- [https://www.medrxiv.org/content/](https://www.medrxiv.org/content/)

Program Links:

- This webinar is being recorded and can be found with the slides online at [https://www.idsociety.org/cliniciancalls](https://www.idsociety.org/cliniciancalls)
An online community bringing together information and opportunities for discussion on latest research, guidelines, tools and resources from a variety of medical subspecialties around the world.

Specialty Society Collaborators

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American Academy of Pediatrics
American College of Emergency Physicians
American College of Obstetricians and Gynecologists
American College of Physicians
American Geriatrics Society
American Thoracic Society
Pediatric Infectious Diseases Society
Society for Critical Care Medicine
Society for Healthcare Epidemiology of America
Society of Hospital Medicine
Society of Infectious Diseases Pharmacists

www.COVID19LearningNetwork.org
@RealTimeCOVID19
#RealTimeCOVID19
CDC-IDSA Partnership: Clinical Management Call Support

FOR WHOM?
- Clinicians who have questions about the clinical management of COVID-19

WHAT?
- Calls from clinicians will be triaged by CDC to a group of IDSA volunteer clinicians for peer-to-peer support

HOW?
- Clinicians may call the main CDC information line at 800-CDC-INFO (800-232-4636)
- To submit your question in writing, go to www.cdc.gov/cdc-info and click on Contact Form

cdc.gov/coronavirus
Continue the conversation on Twitter
@RealTimeCOVID19  #RealTimeCOVID19

We want to hear from you!
Please complete the post-call survey.

Next Call
Saturday, March 12th

A recording of this call, slides and the answered Q&A will be posted at
www.idsociey.org/cliniciancalls
-- library of all past calls now available --

Contact Us:
Dana Wollins (dwollins@idsociety.org)
Deirdre Lewis (dlewis@idsociety.org)