2024 PASCV Annual Meeting
May 17-18 | Clearwater Beach, FL

Agenda

Day One | Friday, May 17

8:00 am - 5:20 pm  
Registration
*Sponsored by Bio-Rad*

8:00 am - 8:55 am  
Breakfast and Exhibits

8:55 am - 9:00 am  
Welcome and Introduction

Speaker
*Esther Babady, PhD, D(ABMM), FIDSA*
Chief, Clinical Microbiology Service, Memorial Sloan Kettering Cancer Center, New York, NY

9:00 am - 10:30 am  
Session 1: Up to Date: What You Need to Know About the Latest Practical Topics in Clinical Virology

Moderator
*Morgan A. Pence PhD, D(ABMM)*
Director, Clinical and Molecular Microbiology, Cook Children’s Medical Center, Fort Worth, TX

At the heart of the Molecular Virology Workshop (now the PASCV Annual Meeting) are practical, everyday topics. This session will focus on topics that span pre- to post-stages of assay implementation.

**Learning Objectives**
- Identify approaches for complying with regulatory standards when verifying an assay’s analytical measurement range
- Define strategies for effective laboratory stewardship
- Discuss the clinical applicability of metagenomic testing

**Speakers**

*Take It to the Limit: How to Verify Your AMR at Both Ends*
*Eleanor Powell, PhD, D(ABMM)*
Technical Director, Microbiology/Molecular Diagnostics Laboratory, UC Health, University of Cincinnati Medical Center, Cincinnati, OH
“You Need to Calm Down”: How to Get Your Providers to Stop Inappropriate Repeat Testing  
**Rebekah Dumm, PhD, D(ABMM)**  
Assistant Professor, Pathology and Immunology, Washington University School of Medicine, St. Louis, MO

**Tell Us Why We Should Still Care About... Clinical Metagenomics**  
**David Gaston, MD, PhD**  
Assistant Professor, Department of Pathology, Microbiology, and Immunology, Vanderbilt University Medical Center, Nashville, TN

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**10:30 am - 11:00 am**  
**Coffee Break and Exhibits**

**Exhibit Presentations**

10:30 am - 10:45 am  
*Sponsored by Copan*

10:45 am - 11:00 am  
*Sponsored by SpeeDx*

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**11:00 am - 12:00 pm**  
**Session 2: How Do We Make Access to Molecular Diagnostics Equitable?**

**Moderator**  
**Stephanie Mitchell, PhD, D(ABMM)**  
Sr. Director, Scientific Affairs, Cepheid, Sunnyvale, CA

It is well-known that 70% of medical decision-making is based on laboratory diagnostic tests. With molecular diagnostics becoming commonplace, in the laboratory and at the point-of-care, it is important to ensure equitable access to these testing methodologies to all patients, regardless of socioeconomic status, race, ethnicity, gender, or geographical location. This session will discuss the challenges in equitable diagnostics and highlight approaches to improve access to molecular diagnostics in under-served regions.

**Learning Objectives**

- Describe the challenges in achieving equity in clinical molecular diagnostics
- List three commonly under-served regions or patient populations
- Identify three approaches to increase access to molecular diagnostics

**Speakers**

**Víctor R. De Jesús, PhD**  
Chief, Quality and Safety Systems Branch, Centers for Disease Control and Prevention, Atlanta, GA

**Dina N. Greene, PhD**  
Clinical Associate Professor, University of Washington, Seattle, WA

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**12:00 pm - 1:00 pm**  
**Lunch and Exhibits**
1:00 pm - 2:00 pm  
**Session 3: Updates on the FDA Proposed Rule**

**Moderator**
**Erin H. Graf, PhD, D(ABMM)**  
Director, Clinical Microbiology and Associate Professor, Mayo Clinic, Phoenix, AZ

This session will provide a background and timeline of the historical to current and future landscape of FDA’s proposed regulation of LDTs. Panelists will discuss their views on the FDA’s proposed rule, which is slated to be final just before the meeting, describing challenges and concerns around implementation. Panelists will represent diverse perspectives including policy analysts, clinical laboratory directors, infectious disease clinicians and government representatives.

**Learning Objectives**
- Describe the historical background of FDA’s proposed regulation of LDTs
- Discuss the implications of the proposed/final rule for clinical laboratories in a variety of settings
- Interpret the timeline of the proposed/final rule

**Speakers**

**Susan Butler-Wu, PhD, D(ABMM), FIDSA**  
Director of Clinical Microbiology, Los Angeles General Medical Center, Los Angeles, CA

**Francesca Lee, MD**  
Associate Professor, Departments of Pathology and Internal Medicine, UT Southwestern Medical Center, Dallas, TX

**Jennifer R. Leib, ScM, CGC**  
Founder, Innovation Policy Solutions, LLC, Washington, DC

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2:00 pm - 2:15 pm  
**Coffee Break**

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2:15 pm - 3:45 pm  
**Session 4: Clinical Virology Debate Session: Laboratories Should be Able to Modify Analytical Measurement Ranges on FDA Cleared Viral Load Assays**

**Moderator**
**Erin H. Graf, PhD, D(ABMM)**  
Director, Clinical Microbiology and Associate Professor, Mayo Clinic, Phoenix, AZ

With the continued advances in ultra-sensitive molecular detection, the clinical interpretation of low levels of viral nucleic acid can be a challenge. Specifically for viruses like HIV and CMV, where low levels of viremia may not necessarily indicate a treatment failure or clinical disease, respectively. Further, guidance documents may be out of date with what is currently commercially available, in terms of actionable cutoffs. This debate panel will discuss both pro and con sides of the controversial topic of modifications of analytical measurement range reporting.

**Learning Objectives**
- Identify viral load assays that may challenge clinical interpretation due to low limits of quantification
Discuss how laboratories may respond to physician/provider complaints about ultra-sensitive detection
Describe examples of guidance documents that do not reflect the current testing landscape

Speakers

David Gaston, MD, PhD
Assistant Professor, Department of Pathology, Microbiology, and Immunology, Vanderbilt University Medical Center, Nashville, TN

Kenneth Gavina, PhD, D(ABMM), SM(ASCP)CM
Assistant Professor of Clinical Pathology and Laboratory Medicine, Indiana University School of Medicine, Indianapolis, IN

D. Jane Hata, PhD, D(ABMM)
Associate Director of Clinical Microbiology Laboratory – Molecular Virology, Parasitology, Mayo Clinic, Jacksonville, FL

Francesca Lee, MD
Associate Professor, Departments of Pathology and Internal Medicine, UT Southwestern Medical Center, Dallas, TX

3:45 pm - 4:15 pm  Coffee Break and Exhibits

Exhibit Presentations

3:45 pm - 4:00 pm  
Sponsored by Delve Bio

4:15 pm - 4:45 pm  Session 5: Updates in Congenital Cytomegalovirus (cCMV) Testing - The Move Towards Universal Screening  
Sponsored by Roche

Approximately 1 in 200 babies are born in the United States with congenital cytomegalovirus (cCMV), which is the leading non-genetic cause of childhood hearing loss. However, screening and diagnostic testing strategies vary widely across the country. This session will review available testing methods, best practices, and challenges to both clinical and public health laboratories when implementing a screening program for cCMV.

Learning Objectives

- Summarize the current state of congenital CMV (cCMV) screening in the United States in 2024
- Describe available testing methodologies, specimen types, and best practices for cCMV screening
- Discuss challenges, lessons learned, and future directions in implementation of cCMV screening in both the clinical and public health arenas
Speakers

**Trenna Lapacinski-Ludens**  
Research Scientist, Newborn Screening Laboratory, Minnesota Department of Health, St. Paul, MN

**Hannah Wang, MD**  
Director, Molecular Microbiology & Virology, Cleveland Clinic Laboratories, Cleveland, OH

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**4:45 pm - 6:00 pm**  
**Networking Reception, Posters and Exhibits**  
*Sponsored by Roche*

Click here to view Poster Presentation Abstracts.

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**6:00 pm - 8:00 pm**  
**Dinner On Own**

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**8:00 pm - 11:00 pm**  
**Back to the 90s Party**  
*Sponsored by Fort Worth Diagnostics*

Let’s party like it’s 1990 something! Break out your fanny packs, dust off your Beanie Babies, and practice your Mario Kart for this totally awesome party. Come dressed in your 90s best and get ready to dance and sing the night away to all your 90s favorite hits. Your RSVP is encouraged, but not required. Click here to RSVP.

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**Day Two | Saturday, May 18**

**9:00 am - 9:30 am**  
**Breakfast and Exhibits**

**9:30 am - 10:30 am**  
**Session 7: How to Successfully Partner with Industry to Meet the Needs of Both Sides**

**Moderator**  
*Stephanie Mitchell, PhD, D(ABMM)*  
Sr. Director, Scientific Affairs, Cepheid, Sunnyvale, CA

The collaboration between industry and clinical laboratories is vital to bringing molecular diagnostics to market. Despite dual interest in forming these partnerships, the roadmap to engaging with industry colleagues is often vague and frustrating. This session will review the various opportunities for lab:industry partnerships and lay a framework for engaging industry colleagues in those opportunities.

**Learning Objectives**

- Identify three types of studies where industry and clinical laboratories can partner
- Discuss the general process of product development and when opportunities arise
- Describe the differences in functions within industry and how they contribute to or influence study partnerships
Speakers

**Ben Svarczkopf, MS, MBA, MT(ASCP)**
Vice President, Product Innovation, Global Product Management, Cepheid, Evanston, IL

**Nathan A. Ledeboer, PhD**
Professor, Medical Director, Clinical Microbiology, Medical College of Wisconsin, Milwaukee, WI

**Jennifer Dien Bard, PhD, D(ABMM), FIDSA**
Director, Clinical Microbiology and Virology, Children’s Hospital Los Angeles, Los Angeles, CA

10:30 am - 11:00 am  
**Coffee Break and Exhibits**

11:00 am - 12:00 pm  
**Session 8: Testing Wastewater and Other Surveillance Strategies That May Create More 🖤 Than You Realize**

**Moderator**
**Morgan A. Pence PhD, D(ABMM)**
Director, Clinical and Molecular Microbiology, Cook Children’s Medical Center, Fort Worth, TX

Wastewater-based epidemiology was first reported in the 1940s, but the COVID pandemic brought increased awareness around wastewater surveillance, including its utility and prevalence. This session will discuss wastewater surveillance strategies, response to detections, and the ethical considerations of surveillance testing.

**Learning Objectives**
- Describe the advancement and expansion of wastewater surveillance
- Discuss the advantages and limitations of pathogen surveillance strategies
- Discuss the ethical considerations of surveillance testing

Speakers

**Alessandro Rossi, PhD, D(ABMM)**
CLIA Director and Infectious Diseases Chief Scientist, Utah Public Health Laboratory, Salt Lake City, UT

**Adelaide Roquet, PhD**
Scientist, Environmental Health Division, Water Microbiology, Wisconsin State Laboratory of Hygiene, Madison, WI

12:00 pm - 1:00 pm  
**Lunch and Exhibits**

1:00 pm - 2:00 pm  
**Session 9: How Do We Come to Consensus on the Right Number and Makeup of Panels for Specific Patient Populations**

**Moderator**
**Erin H. Graf, PhD, D(ABMM)**
Recent changes in molecular panel reimbursement, as well as continued focus on diagnostic stewardship, have augmented the need for smaller, more flexible panels. While that concept seems simple on the surface, the right number of targets that are clinically relevant may differ by patient population and institutional needs, such as epidemiology. In this session, two speakers will discuss this topic of smaller syndromic panels for specific infectious syndromes.

**Learning Objectives**
- Compare the pros and cons of various commercially available syndromic panel options
- Define the unique needs of various patient populations as they relate to multiplex panels
- Describe various examples of ideal molecular panel designs

**Speakers**

Rebekah Dumm, PhD, D(ABMM)
Assistant Professor, Pathology and Immunology, Washington University School of Medicine, St. Louis, MO

Sarah Jung, MS, PhD, D(ABMM)
Scientific Director, Clinical Microbiology, Department of Pathology and Laboratory Medicine, Children’s Hospital Colorado, Aurora, CO

2:00 pm - 2:30 pm  
Coffee Break and Exhibits

2:30 pm - 4:00 pm  
Session 10: Clinical Virology Debate Session: Laboratories Should Be Able to Test Non-Validated Sample Types with a Disclaimer or “Offline”

**Moderator**

Morgan A. Pence PhD, D(ABMM)
Director, Clinical and Molecular Microbiology, Cook Children’s Medical Center, Fort Worth, TX

Prior to implementing new assays or adding additional sample types, laboratories perform verification and validation studies. However, despite thorough preparations, many laboratories receive occasional requests from physicians to test non-validated sample types. Such requests may occur when the sample type has not been validated by any laboratory or when a result is needed sooner than a reference laboratory can provide. This debate will focus on the pros and cons of testing non-validated sample types with a disclaimer or offline.

**Learning Objectives**
- Identify clinical situations where testing may be requested on non-validated sample types
- Describe regulatory standards that govern which sample types can be tested in a laboratory
- Discuss pros and cons of testing a non-validated sample type
Speakers

**Richard E. Davis, PhD, D(ABMM), MLS(ASCP)**
Microbiology Director, Providence Sacred Heart Medical Center and Children’s Hospital, Spokane, WA

**Sarah Jung, MS, PhD, D(ABMM)**
Scientific Director, Clinical Microbiology, Department of Pathology and Laboratory Medicine, Children’s Hospital Colorado, Aurora, CO

**Huanyu Wang, PhD, D(ABMM)**
Director, Molecular Microbiology, Nationwide Children’s Hospital, Columbus, OH

**Eleanor Powell, PhD, D(ABMM)**
Technical Director, Microbiology/Molecular Diagnostics Laboratory, UC Health, University of Cincinnati Medical Center, Cincinnati, OH

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<th>Time</th>
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<tr>
<td>4:00 pm - 5:00 pm</td>
<td>Annual Business Meeting and Award Presentations</td>
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