2022 PASCV Fall Meeting
Quantitative Molecular Virology Testing
September 22-23 | Chicago, IL

Overview
The 2022 PASCV Fall Meeting will bring together molecular virology laboratory experts for informal, interactive discussions of quantitative viral molecular testing.

Organizers
Randall T. Hayden, MD
St. Jude Children’s Research Hospital

Heba Mostafa, MD, PhD, D(ABMM)
Johns Hopkins School of Medicine

Program

Thursday, September 22

8:00am - 1:00pm
Registration
Atrium Alcove

9:00am - 12:00pm
Innovation Theater: Understanding the New PreP Guidelines and its Implications for Laboratorians, Clinicians, and Patients
Abricot Ballroom

Sponsored by Roche

Moderator:
Kwaku Tawiah, PhD; Scientific Partner, Medical Affairs, Roche Diagnostics Corporation, Indianapolis, IN

At the end of 2021, the Centers for Disease Control and Prevention released updated HIV PrEP Guidelines. Some of the major changes included: expansion of eligible patients and prescribing providers, inclusion of injectable PrEP (i.e. Cabotegravir), and new laboratory monitoring guidelines. Central to the lab changes were the introduction of two separate PrEP testing algorithms that present significant workflow alterations within the clinical microbiology laboratory. In this session, we will explore the why behind these guideline changes, the challenges that they place on clinicians, patients, and laboratorians, and potential solutions to these laboratory implementation challenges.
Speakers:
Rachael Liesman, PhD, D(ABMM); Director of the Clinical Microbiology Laboratory and Director of the Molecular Microbiology Laboratory, University of Kansas Health System, Kansas City, KS

Meghan W. Starolis, MS, PhD, HCLD(ABB); National Science Director, Infectious Disease, Quest Diagnostics, Chantilly, VA

Caitlin Otto, PhD, D(ABMM); Director of Microbiology, NYU Langone Health, New York City, NY

Ben La Brot, MD; Roche Molecular Solutions, Indianapolis, IN

12:00pm - 1:00pm  Lunch on Own

1:00pm - 1:50pm  Verification of IVD Quantitative Molecular Assays
   Abricot Ballroom

   Moderator:
   Randall T. Hayden, MD; St. Jude Children’s Research Hospital, Memphis, TN

   This presentation will focus on key requirements for verification of quantitative molecular infectious disease assays. Highlights will be the major differences between a validation and verification, a detailed description and protocol for the required studies, and how to analyze the data. Lastly, the speaker will share a tried-and-true “go live” checklist for preparedness for launching an assay.

   Speaker:
   Meghan Starolis, MS, PhD; Quest Diagnostics, Chantilly, VA

1:50pm - 2:05pm  Break

2:05pm - 2:55pm  Validation of LDT Quantitative Molecular Assays
   Abricot Ballroom

   Moderator:
   Randall T. Hayden, MD; St. Jude Children’s Research Hospital, Memphis, TN

   This presentation will review the differences between FDA-approved and laboratory-developed procedures (LDP) assay verification and describe the patient centric and strategic approach to defining the limitations and allowable error for your LDP. The speaker will define which data assessment and graphing approaches are best for your quantitative LDP assays.
2:55pm - 3:55pm
Atrium Alcove

Poster Session, Exhibits, and Networking Break

P1: Quality Assessment of HSV and VZV Specimen Adequacy Using RT-PCR for Endogenous RNAseP
Andrew Cameron, PhD D(ABMM); University of Rochester Medical Center, Rochester, NY

P2: "Making a Monkey Out of You!" – Validation of a Real-Time PCR Typing Assay for the Qualitative Detection of Monkeypox and Non-Monkeypox Orthopoxviruses
Kenneth Gavina, PhD, M(ASCP); Indiana University School of Medicine and Indiana University Health, Indianapolis, IN

P3: Performance Evaluation of the High-Throughput Quantitative Alinity m CMV Assay
Julie Hirschhorn, PhD; Medical University of South Carolina, Charleston, SC

P4: Performance Evaluation of the High-Throughput Quantitative Alinity m EBV Assay
Julie Hirschhorn, PhD; Medical University of South Carolina, Charleston, SC

P5: Whole Genome Sequencing of Human Monkeypox Virus From Two Cases in Western New York
Mondraya Howard, PhD; University of Rochester, Rochester, NY

P6: Evaluation of a Laboratory-Developed PCR Assay for the Detection and Quantitation of Human Adenovirus From Plasma
Joel Maki, PhD; University of Rochester Medical Center, Rochester, NY

P7: Auto Versus Manual Baseline and Their Impact on the Reproducibility of Real-Time PCR Results
Mikayla Quinton, Bachelors of Science in Medical Lab Science; Johns Hopkins Hospital, Baltimore, MD
**P8: Development and Validation of Genital Ulcer Disease PCR Panel**

Keith Tardif, PhD; ARUP Laboratories, Salt Lake City, UT

**P9: Validation and Implementation of an Orthopoxvirus Qualitative Real-Time PCR for Detection of Monkeypox Virus**

Katharine Uhteg, Masters in Biotechnology; Johns Hopkins Hospital, Baltimore, MD

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<th>Time</th>
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<tr>
<td>3:55pm - 5:15pm</td>
<td>Interactive Breakout Session: Challenges in Verification and Validation of Quantitative Molecular Assays</td>
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<td>Abricot Ballroom</td>
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<td>Moderator:</td>
<td>Heba Mostafa, MD, PhD, D(ABMM); Johns Hopkins School of Medicine, Baltimore, MD</td>
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<tr>
<td>Speakers:</td>
<td>Amy B. Dean, PhD; Wadsworth Center, New York State Department of Health, David Axelrod Institute, Albany, NY</td>
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<td>Andrew Cameron, PhD; University of Rochester Medical Center, Rochester, NY</td>
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<td>David C. Gaston, MD, PhD; Vanderbilt University Medical Center, Nashville, TN</td>
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<td>Rebecca Yee, PhD, D(ABMM), M(ASCP); The George Washington University School of Medicine and Health Sciences, Washington, DC</td>
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<tr>
<td>5:15pm - 6:30pm</td>
<td>Exhibits and Networking Reception</td>
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<td>Atrium Alcove</td>
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### Friday, September 23

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<tr>
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<tr>
<td>8:00am - 9:00am</td>
<td>Networking Breakfast</td>
<td>Atrium Alcove</td>
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<tr>
<td>9:00am - 9:50am</td>
<td>Quantitative Assays for Hepatitis B &amp; C: Technical Aspects and Clinical Practice</td>
<td>Abricot Ballroom</td>
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<td><strong>Moderator:</strong> <a href="#">Randall T. Hayden, MD</a>; St. Jude Children’s Research Hospital, Memphis, TN</td>
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<td>This presentation will review the current state of HBV and HCV viral load testing in clinical practice, comparison of available assays, and cases illustrating some common pitfalls of these assays.</td>
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<td><strong>Speaker:</strong> <a href="#">Joseph D. Yao, MD</a>; Mayo Clinic, Rochester, MN</td>
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<td>9:50am - 10:05am</td>
<td>Break</td>
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<tr>
<td>10:05am - 10:55am</td>
<td>Quantitative Assays for Transplant Viruses: Technical Aspects and Clinical Practice</td>
<td>Abricot Ballroom</td>
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<td>This presentation will discuss the clinical significance of accurate quantification, international standards, and relevance of fragment sizes of select viruses in plasma cell-free DNA.</td>
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<td><strong>Speaker:</strong> <a href="#">Alex Greninger, MD, PhD, MS, MPhil</a>; University of Washington, Seattle, WA</td>
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<td>11:00am - 12:00pm</td>
<td>Exhibits and Networking Lunch</td>
<td>Atrium Alcove</td>
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<td>12:00pm - 1:20pm</td>
<td>Interactive Breakout Session: Esoteric Requests for Quantitative Testing</td>
<td>Abricot Ballroom</td>
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<td><strong>Moderator:</strong> <a href="#">Heba Mostafa, MD, PhD, D(ABMM)</a>; Johns Hopkins School of Medicine, Baltimore, MD</td>
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This interactive session will use clinical cases to understand the thought-process behind approving esoteric requests and identify other diagnostic recommendations that may be warranted for different clinical scenarios. Clinical interpretations of test results from esoteric requests will be reviewed.

**Speakers:**

Amy B. Dean, PhD; Wadsworth Center, New York State Department of Health, David Axelrod Institute, Albany, NY

Andrew Cameron, PhD; University of Rochester Medical Center, Rochester, NY

David C. Gaston, MD, PhD; Vanderbilt University Medical Center, Nashville, TN

Rebecca Yee, PhD, D(ABMM), M(ASCP); The George Washington University School of Medicine and Health Sciences, Washington, DC

1:20pm - 1:30pm  
Closing Remarks  
Abricot Ballroom

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