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AMPlifications™

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MP EVENT NEWS AND DEADLINES



AMP2016 Annual Meeting
Big World. Molecular Medicine. One Community.
November 10-12, 2016
Charlotte, North Carolina

Corporate Workshop Day
November 9, 2016

2016 Award for Excellence Lecture
Secrets of the Human Genome: The 35-year Journey of Genomic Medicine
Eric S. Lander, PhD, Broad Institute, Cambridge, MA, USA

Preliminary Program Highlights

[Detailed program information](#) will be available on the AMP website as it becomes available!

- Genomic Medicine: Molecular Tests, Validation, Quality Control, Test Utilization for Precision Medicine
- Integrating Informatics for Interpretation and Clinical Applications
- Emerging Technologies to Revolutionize Molecular Diagnostics
- Immunologics and Check-Points for Clinical Cancer Management
- Microbiome in Health and Disease, Global Molecular Infectious Disease Testing and Technologie

The [Abstract Submission Site](#) is now open! **Deadline Tuesday, May 31, 2016** (11:59pm U.S. Eastern). NEW this year: Review the Submission Checklist, Submission Guide, and Style Guide while you prepare your abstract!

NEW!!! AMP 2017 Global Congress on Molecular Pathology

AMP is excited to announce that in 2017 we will host the inaugural Global Conference on Molecular Pathology (GCMP). Are you interested in attending, presenting, exhibiting, or just receiving information about GCMP program developments? Tell Me More About GCMP!
<https://www.surveymonkey.com/r/AMP2017GCMPinterest>

INNOVATION & IMPROVED PATIENT CARE



The AMP Board of Directors approved the “**Standardization of Clinically Relevant Pharmacogenetic Alleles**” project to be led by Lisa Kalman and Vicki Pratt.

The CAP/IASLC/AMP Molecular Testing Guideline for Lung Cancer - Revision project team met at the AMP headquarters in Bethesda on February 26-27, 2016 to finalize both their reaffirmed and new draft recommendations.

An open public comment period is anticipated in Spring 2016 - *stay tuned to CHAMP for updates!*

The recent call for volunteers to serve as a 2016 CPC Junior Member received 14 applications. The CPC is currently reviewing the applications and a decision will be announced shortly. Thank you to all applicants for your willingness to serve!

The Clinical Practice Committee and Subdivision leadership have been discussing several interesting and exciting project ideas that impact the field of molecular pathology. If you have an idea for a new project that AMP can help with, please let us know!

EDUCATION



Zika Virus: Diagnostic Testing and Front-Line Management - An Educational Event Collaboration Between the Association for Molecular Pathology and the Pan American Society for Clinical Virology will be presented on April 29 at 12:00pm Eastern. The speakers are Benjamin Pinsky from Stanford University and Cecilia Perret from Pontificia Universidad Catolica de Chile. Register today at http://www.amp.org/Webinars/future_webinars.cfm

The online education series, “**Emerging Fronts in Molecular Pathology**” is now under way. Go to http://www.amp.org/Webinars/future_webinars.cfm to register for:

- Building Synthetic Immunity to Cancer Using Chimeric Antigen Receptors, presented by Michael C. Milone on April 27 at 2:00pm Eastern.
- The Role of Immunobiology and PD-1/PD-L1 Directed Therapy in Oncology, presented by Margaret A. Shipp on May 9 at 1:00pm Eastern.
- Clinical Utilization of 16S Bacterial Sequencing, presented by Lynn Bry on May 27 at 2:00pm Eastern.

Prepping for a test, need a refresh, or looking for an introduction to Molecular Genetic Pathology? **The AMP MGP Online Self-Study Review Course** is available through December 31, 2016! Go to <http://www.amp.org/2015OnlineMGPRReviewCourseReq.cfm> for more information.

ADVOCACY



Dear AMP members,

Mosquito season is arriving in the U.S. and laboratories across the country are working hard to develop accurate diagnostic procedures as soon as possible. In March, Texas Children’s Hospital and Houston Methodist created a laboratory developed procedure (LDP), which by identifying virus-specific RNA sequences, is able to provide a diagnosis in a few hours. Immediately after the announcement,

FDA sent the AMP-member physicians who developed this test an “It Has Come to Our Attention Letter” asking to review the LDP’s design, validation, and procedure information. As of April 12, there are no FDA-approved tests for Zika. Further, the only Emergency Use Authorizations (EUA) have been solely provided to CDC, who, to date, have only authorized state public health laboratories and the domestic and international laboratories belonging to the Laboratory Response Network. CDC’s announcement noted that no U.S. hospitals would receive authorization on their RT-PCR assay. The public health laboratory network, while important and necessary, is not sufficient to provide patient care on the scale or turn-around time needed. Clinical laboratories that have the necessary expertise should be able to develop their own Zika LDPs. These LDPs need to exist beyond testing from the public health laboratories, and must be available to all Americans across the country, particularly in Southern states.

During the H1N1 outbreak a few years ago, AMP leaders [Karen Kaul](#) and [Jan Nowak](#) wrote an editorial in JMD titled “[The Role of Community Molecular Diagnostics Laboratories in the H1N1 Pandemic](#),” where they describe the important role of community diagnostics laboratories during the H1N1 pandemic and issued a call for better planning in the future. Their points reverberate today as the importance of a community molecular diagnostic laboratory continues.

FDA has stated their intention to finalize the guidance on LDPs in 2016. Under FDA’s proposed framework, laboratories will likely experience FDA correspondence similar to the Texas hospitals recent letter and be forced to comply in order to avoid enforcement action for the LDPs they provide. AMP continues to monitor FDA and Congressional activity related to LDP regulatory oversight very closely and will continue to update the membership as things progress. The emergence of widespread Zika infection and its devastating co-morbidities, plus the recent activity by FDA reminds us that FDA oversight of LDPs would be a very bumpy road! We will soon distribute a survey to members to obtain feedback on what services AMP should provide to assist in a possible new reality of FDA regulation.

Sincerely,
Charles E. Hill, MD, PhD
AMP President

Public Policy and News you can Use: Read The ChAMPion

Hot off the presses is the second edition of the AMP policy newsletter, **The ChAMPion!** This policy-focused newsletter provides in depth updates on important policy issues. Links to the most recent ChAMPion are provided in each AMPlifications newsletter and are also delivered to members via the ChAMP listserv.

Click on the link below to read the latest AMP advocacy news, which results from the hard work of the Professional Relations and Economic Affairs Committees. Recent news includes submission of multiple comments to FDA and CMS, and a recently-published *JMD* paper that summarizes the results of AMP’s cost and value models for genomic sequencing procedures. Additionally, [Eric Konnick](#) provides his perspective on the value of advocating for molecular professionals and patients on Capitol Hill.

The link to **The ChAMPion** is available here: <http://www.amp.org/chAMPion/May2016-1.cfm>

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