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Articles, announcements, and news briefs are welcome and will be edited and published at the discretion of the editors.

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PRESIDENT'S MESSAGE:

FOCUS AND PROGRESS IN 21ST CENTURY MOLECULAR PATHOLOGY



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Three decades ago, life seemed a lot simpler.

We shopped in our neighborhoods, bought telephone service from "the phone company", and our entertainment media options included books, radio, TV, LPs (a term that may be unfamiliar to younger AMP members!), and the occasional movie at the local one-screen theatre.

Today, catalogs arrive by the armful and we buy on-line. Families are discarding land-line phones because everyone has their own cellular device purchased from one of dozens of local vendors. Books are e-books or audio books. Radio is personalized into Podcasts. TV is TiVo'ed. MP3s are downloaded. Movies are available on DVD, on demand viewing at home, or stadium seating at the local 12-screen cinema.

Science is no different. Three decades ago, there was no PCR, no Human Genome Project, no desktop computing. There were 3 restriction enzymes and you could not

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2006 RECIPIENT OF AMP LEADERSHIP AWARD



The Nominating Committee has elected **Mark Sobel, MD, PhD** to receive the AMP Leadership Award for 2006. Mark was one of the members of the Action Committee that formally established the Association for Molecular Pathology and created the framework for the future growth and development of this organization. Along with Fran Pitlick, PhD, he took on the task of forming Bylaws for this organization and was the first in a long line of Secretary-Treasurers, before he became President-Elect in 1998 and subsequently President in 1999. One of his nominators commented: "as a 'political pathologist' in the finest sense of the term (he's actually a pediatrician!), Mark pursued multiple advocacy roles without complaint and with true passion for AMP."

The AMP Leadership Award is AMP's highest award given to a member. This is one means for the membership to publicly honor the exceptional accomplishments and notable contributions of an individual who has demonstrated vision and direction for both AMP and the field of molecular pathology. It is presented to someone who has demonstrated exceptional leadership in the accomplishment of the mission and goals of this organization. The award, supported by Abbott Molecular, is bestowed each year during the Business and Awards Session of the Annual Meeting. Last year's recipient was **Jeffrey A. Kant, MD, PhD**.

REPORT OF THE CHIEF OPERATING OFFICER AND DIRECTOR OF SCIENTIFIC PROGRAMS



Mary Steele Williams, MT(ASCP)SM
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Have you ever been so busy that you cannot adequately answer the question, “So what have you been up to?” This is the situation at AMP. Molecular diagnostics is the fastest growing area of laboratory services and some say of health care itself. The number of challenges and opportunities presented to us is growing at an enormous rate. At AMP, we are not just busy, we are productive.

The Clinical Practice Committee continues to produce manuscripts from existing working groups and to create new groups. The Professional Relations Committee is addressing numerous issues regarding reimbursement and regulatory requirements. The Program Committee worked like athletes running a marathon at a full sprint to narrow the many topics of importance to your practice to the fabulous few that are on this year’s program. The Publications Committee is shepherding several manuscripts that are the work product of committees through the publications review process and working to continually review and help update the content of our website. The more molecular diagnostics grows, the more we talk about it on CHAMP and **Shuji Ogino**, our tireless CHAMP Moderator, keeps this high traffic flowing smoothly. **Mark Sobel** and Audra Cox, JMD’s Scientific Editor, are hard at work with the JMD CME Committee to promote and oversee the JMD CME Program. The Strategic Planning Committee continues to assist Council and the membership by addressing areas important to our future such as financial planning and strategic priorities. In addition to their usual tasks involving education, the Training & Education Committee has taken on the new task this year of managing AMP’s outreach to non-molecular laboratory professionals. Leading the premier professional association that represents the fastest growing area of laboratory services is a wildly exciting life! The Nominating Committee keeps us manned for the future with members who are willing to step up to the plate. In addition to all of this, some of our leaders travel to represent AMP at the table where important discussions regarding recertification and other issues are taking place.

For the first time this year, the AMP Subdivision leaders are meeting together in quarterly conference calls to address areas that are specific to their specialty. At the top of their discussions is how they can help AMP members in your day-to-day practice. They are all beefing up their sections of the AMP Website (www.amp.org) to provide more information

and resources, Infectious Diseases (ID) is updating the ID section of the AMP *Test Directory*, and Hematopathology is reaching out to new volunteers. Your Committees and Subdivisions are very proactive on your behalf. Please read their reports carefully. If you find a current area or want to propose a new project in which you would like to get involved, please contact the respective Chairs.

I would like to highlight an important event that is taking place on November 16 in Orlando. The Training & Education (T&E) Committee has organized “**Molecular Diagnostic Applications in Pathology: A Case-Oriented Approach**,” an outreach effort to non-molecular laboratory professionals. The program for this course as well as the full annual meeting is on our website at www.amp.org. We are responding to numerous requests from community pathologists, who want to understand more about the tests they send out to reference labs and to gain a better foundation for eventual in-house molecular testing. This event is co-sponsored by the Florida Society of Pathologists (FSP). Credit is due to **Patty Gregg**, FSP President, for her hard work to help promote the event to pathology residents and laboratories in Florida. Credit is also due to the entire T&E Committee, who focused the first third of their year on planning the course. As of the end of May, commitments for educational grants have been received from Abbott Molecular, Beckman Coulter, Cepheid, Labcorp, Luminex, Osmetech Molecular Diagnostics, Roche Diagnostics, and the Intersociety Council for Pathology Information (ICPI). We are very grateful for these groups, who are willing to help laboratory professionals enter the field of molecular diagnostics. If you would like to promote this event to your reference laboratory clients or other laboratory colleagues who have little or no molecular testing experience, please contact me. I will be happy to send you brochures or HTML content for use in e-mails.

New AMP Listservs to Launch in June

Trainee Listserv - moderated by **Karen Rasmussen** and **Mike Rhode**. All AMP members who will soon enter, are currently in, or have recently graduated from molecular pathology graduate or fellowship programs are invited to join.

Technologist Listserv - moderated by **Kim Moses**. All AMP member non-doctoral technologists are invited to join.

If you would like to join either listserv, please contact **Mary Williams** (mwilliams@asip.org) with your name and the e-mail address that you plan to use to address the listserv.

CLINICAL PRACTICE COMMITTEE REPORT



By Elaine Lyon, PhD
Chair, Clinical Practice Committee
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Busy! That's the word to describe the working groups of the Clinical Practice Committee.

There is a search underway for a new *Test Directory* Editor. This was announced via CHAMP asking for those interested to send their CV's. We thank those who have applied. We will be accepting applications only into June, so please hurry and let us know if you are interested in being considered. This position is high visibility, is great for Trainees or technologists, and takes only about four hours per month. The most important qualification is general familiarity with the molecular tests currently in use for hematopathology, infectious diseases, and solid tumors. The requirements and description of the position were sent out on CHAMP. The full position description is in the Clinical Practice Committee section of the AMP Website (www.amp.org). Also see the announcement in this issue of the *Newsletter* (page 9).

The Fragile Xperts under **Jean Amos Wilson's** direction are on target with testing quality control material for Fragile X cell lines. Data was collected from nine laboratories and is now in

the hands of our statistician. We are anxious to see how well we did among these laboratories in sizing pre-mutations. Along these lines, I appreciate the support from the Committee and AMP members for the webcast presentation, "Fragile X Laboratory Testing: Background and Quality Improvement Opportunities." I have received requests for the availability of the presentation and/or slides. The presentation (audio and visual) will be archived and available through *DNAMedEdCafe.com*. Slides are also posted in AMP's *Web Library*.

Thanks to all who responded to the survey regarding calibrators for CMV quantification that was sent through CHAMP. **Kathy Stellrecht** is summarizing the data and will be asking some AMP members to participate in the working group. We are impressed (as always) with the willingness of AMP members to volunteer their time and expertise for these working groups.

Two new projects will soon be underway. One is molecular monitoring for minimal residual disease in leukemias with **Dan Jones** from the Clinical Practice Committee, working with **Nina Longtine** from the Hematopathology Subdivision. This will be a practical based study, having clinicians involved in discussing the utility of the data. The other project, headed by **Antonia Sepulveda** is assessing methods and needs for gene methylation assays for solid tumors. She has posted a survey for those of you who do (or will soon be offering) this type of testing in your laboratory. Please support her in responding to the survey. Thanks to all for their incredible work!!

PROFESSIONAL RELATIONS COMMITTEE REPORT



By Wayne W. Grody
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The Professional Relations Committee (PRC) has continued to work on a number of urgent issues of importance to the daily practice of AMP members. Some in fact represent fundamental threats to the continued viability of molecular diagnostics, and countering them requires constant surveillance and effort. Fortunately we have the support of the AMP Council, the AMP President, and several other organizations with allied interests in these initiatives.

"Medically Unbelievable Edits"

This issue has probably occupied the greatest amount of time and effort by the PRC since our last report, because of the magnitude of the economic threat and the time-sensitive nature of

the response. To review, medically unbelievable edits (MUE) is Centers for Medicare and Medicaid Services' (CMS) designation for any use of CPT billing codes that is deemed implausible and therefore fraudulent, such as using the code for oophorectomy in a male or using the code for appendectomy twice in the same patient. At issue for laboratory medicine and pathology was the announcement from CMS earlier this year that similar repeated use of technique or methods codes would also be considered fraudulent. As we all know, many tests in molecular pathology are of a multiplex nature, requiring repeated use of the same amplification, hybridization, or sequencing techniques. The same thing applies to repeated use of antibody applications in immunohistochemistry and similar procedures in other areas of anatomic pathology. For that reason, the College of American Pathologists (CAP) reacted as strongly to this announcement as did we, as did also the American Society of Clinical Pathology, the American College of Medical Genetics, the American Clinical Laboratory Association, the American Medical Association and other groups. Along with other groups, we co-signed the CAP response and

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NOMINATING COMMITTEE REPORT



By Andrea Ferreira-Gonzalez, PhD
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By the time you read this issue of the *AMP Newsletter*, the election for AMP officers should be completed! Online voting for officers and bylaws changes occurred throughout the month of May. We certainly had an outstanding slate of candidates willing to volunteer their time for AMP. The members of the Nominating Committee worked very hard in putting together this year's list of candidates. They will be notified as soon as electronic tabulation of results is completed. This will allow ample time for the newly elected officers to make travel plans to sunny Orlando. The election results will be announced in the October issue of the *AMP Newsletter*.

We are delighted to announce that **Mark Sobel, MD, PhD** has

been selected by the Nominating Committee as the second recipient of the AMP Leadership Award for 2006. The AMP Leadership Award is bestowed each year upon an AMP member who has demonstrated exceptional leadership in the accomplishment of the mission and goals of this organization. Mark contributed prodigiously to AMP over a period of ten years. He was a member of the Action Committee, which organized the 1992-1994 workshops, and then the Association itself. Mark played a critical role in the development of the constitution and bylaws, which now govern AMP. He was President in 1999, where he played a major role as the functional precursor to the Professional Relations Committee, amongst other accomplishments. Mark pursued multiple advocacy roles without complaint and with true passion for AMP. He provided instrumental leadership that allow for successful partnering with the American Society for Investigative Pathology (ASIP) to launch *The Journal of Molecular Diagnostics*. He will be honored during the AMP Business/Awards Session at our Annual Meeting in November in Orlando. The Committee thanks all members who nominated their colleagues and provided gracious and eloquent homage to them.

PROGRAM COMMITTEE REPORT



By S. Terence Dunn, PhD
Chair, Program Committee
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As you saw in the very colorful "Call for Abstracts" brochure that was distributed recently to the membership, the Program Committee is well on its way to finalizing the program for the 12th Annual AMP Meeting to be held from November 16th to the 19th, 2006 at the Gaylord Palms Resort & Convention Center in Orlando, Florida. Topics for each of the Plenary and Workshop Sessions have been finalized. We have most speakers confirmed although there remain a few outstanding "To Be Determined (TBD)" speaker items; however, since the time of publication of the preliminary program in the Call for Abstracts brochure, the Program Committee has further reduced those outstanding "TBD" items to a meager few. Check the Preliminary Program link on the AMP Annual Meeting page of the AMP Website (www.amp.org) for updated program information. I think that you will agree that we have lined-up some fabulous topics and speakers for you this year. Realizing the popularity and success of the Early Bird Sessions, we have decided to continue with the theme for this year and have expanded the selection of topics for our early-riser audience. There is always time to sleep on the plane on the way home,

right? In concert with the Training and Education (T&E) Committee and AMP Council, we recognized the need to provide our members with some basic "nuts-and-bolts" talks on test validation principles and so we have included several Early Bird and Technical Topics talks to cover some commonly adopted approaches to this extremely important and occasionally neglected element of clinical testing. If you missed Shuji's "Bayesian Risk Analysis" talk last year (or need a refresher) he is up again, with an additional Early Bird Session on "Mutation Nomenclature." With three different Early Bird talks to choose from each morning, I am sure there is something of interest for all. As a reflection of how nanotechnology is making large strides into all aspects of molecular diagnostics we have a timely addition to the program in the form of a Technical Topics Plenary scheduled for Saturday afternoon that will consider this issue. We anticipate a record number of abstracts for posters to be submitted this year. The size requirements for the posters will remain the same as last year so that we can accommodate two posters on each side of a board.

It seems that each year there are more topics to discuss in our Plenary and Workshop Sessions and more specialty group and other meetings within the meeting to accommodate. It is certainly no easy task to organize our Annual Meeting, the bulk of which must happen within the first four months of each new year. It takes a team of truly motivated and committed individuals to pull it off. So, finally, I would like to recognize the

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TRAINING AND EDUCATION COMMITTEE REPORT



By Thomas W. Prior, PhD
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Committee
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The Training and Education (T&E) Committee's major activity has been planning the Community Pathology Education Day, which will be targeted to non-molecular laboratory professionals to be held on Thursday, November 16, 2006 in Orlando. The one-day course titled "**Molecular Diagnostic Applications in Pathology: A Case-Oriented Approach,**" will provide an update on the current developments through actual case studies covering the four major clinical molecular pathology disciplines: solid tumors, hematopathology, infectious diseases, and human genetics. Most of our speakers are members of our T&E Committee and will highlight how molecular testing impacts disease management. We have also recruited AMP member speakers **Greg Tsongalis** and **Jennifer Hunt**. **Mary Williams** has worked out a co-promotional agreement with the

Florida Society of Pathologists and we are pleased to also have received corporate involvement.

This T&E Committee continues to work on our educational sessions at the Annual Meeting. **Shuji Ogino** will be ready to conduct another stellar Early Bird Session on Bayesian Risk Analysis and another one on Mutation Nomenclature. If only I had that kind of energy? **Marsha Speevak** will be moderating a Friday morning Early Bird Session on Validation and Maintenance of ASRs and Lab Developed Assays.

I have enjoyed working with the T&E Committee because, like a good sports team, we have displayed a strong sense of teamwork. Everyone has contributed and in a very short period of time we have accomplished a great deal. I thank **Marsha Speevak, Jerald Gong, Shuji Ogino, Ted Schutzbank, Michael Rhode, Karen Rasmussen** and **Mary Williams** for their constant efforts and enthusiasm in putting together the Community Pathology Education Day. It has been as much fun as coaching my daughter's basketball team, without the parent involvement.

PUBLICATIONS COMMITTEE REPORT



By Karen Mann, MD, PhD
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Website

We are close to completing a full review and updating of the AMP Website (<http://www.amp.org>) which was begun last year. The final sections, Training and Education and the Infectious Diseases Subdivision, are in the process of being reviewed by the Training and Education Committee and the Infectious Diseases Subdivision respectively. Any updates or changes will be implemented by our web gurus. In addition, there is a new emphasis on yearly review of the website by the appropriate Subdivisions and Committees. Thanks to **Vivianna Van Deerlin, MD, PhD** for continuing to act as our Website Editor.

Newsletter

Our newsletter co-editors **Terry Redondo, MD** and **Marlene Sabbath-Solitare, PhD** continue to do an excellent job producing our attractive and informative newsletter.

ADVANCE Articles

Keep your eyes open for the next AMP sponsored article in

ADVANCE for Administrators of the Laboratory. The topic is Pharmacogenetics and it is co-authored by Gwen McMillin, PhD and **Elaine Lyon, PhD**, Medical Directors, Pharmacogenetics, ARUP Laboratories. This edition will have a special distribution at the AACC's Annual Meeting thereby continuing to improve AMPs visibility to laboratorians.

CHAMP

CHAMP continues to be a handy source of information and consultation with our colleagues around the world. It would not work without our moderator **Shuji Ogino, MD, PhD**. Several of you have expressed an interest in having the CHAMP postings in a searchable archive. We are looking into options and hope that this can be achieved in the near future.

The AMP Test Directory continues to be one of laboratories' greatest resources. Gauging by the traffic on the site, people in laboratories worldwide are saying every day, "Let's check the AMP Test Directory to see who offers the test we need."

Access www.amptestdirectory.org to locate appropriate laboratories when you need to send out a test. If your laboratory is not yet listed, do so! The new online submission format makes updates easy.

SUBDIVISION REPORTS

GENETICS SUBDIVISION



By Vicky M. Pratt, PhD
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Greetings again from Washington D.C! Spring is in full swing as well as planning for our Annual Meeting in the Fall.

The Meeting

We have an exciting Meeting planned in Orlando. The Genetics Plenary Session will be on Fragile X. **Annette Taylor** will be speaking on the clinical aspects of *FMRI* disorders while **Ben Roa** will be speaking on the laboratory aspects of *FMRI* disorders. Can you believe that we have never had a Plenary Session on Fragile X at AMP? Our esteemed colleagues from Infectious Diseases are geneticists in disguise and have planned their Plenary Session on the Genetics of Susceptibility to Infection. Our first Workshop will be a panel discussion concerning Quality Control Material with **Lisa Kalman, Kasinathan (Murali) Muralidharan, C. Sue Richards, Jean Amos Wilson**, and David Barton. We hope this will be a lively and interactive session. Our second Workshop will be Prior's Puzzlers by **Tom Prior**. This is always one of my favorite sessions. So do not forget to bring those problem cases to this session so that we all can benefit. Heck if you still don't have that problem case figured out, bring it any way and we will all help find a solution (hopefully the right one)! We have two early morning sessions planned. Thanks to **Shuji Ogino** who will be presenting Bayesian Risk Analysis (we remember how much fun you had at the last one) as well as one on Mutation Nomenclature. I am looking forward to seeing you all at Chez Mickey.

The Validators

Lack of validated control material continues to be problematic, especially as new assays are developed. **Lisa Kalman** has been leading the efforts along with several AMP members to obtain and validate control material for Fragile X, Huntington disease, Ashkenazi Jewish disorders and others. We plan to review all the validation efforts made both here and in Europe during our first Workshop on Friday, November 17. If you are interested in further information check out the following website <http://www.phppo.cdc.gov/dls/genetics/qcmaterials/default.aspx>

The End (for now)

Have a great summer. I plan on seeing you in Orlando.

HEMATOPATHOLOGY SUBDIVISION



By Janina A. Longtine, MD
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Lynne Abruzzo and I have been working hard to develop an interesting and informative program for the 2006 AMP Annual Meeting. We decided to join forces with **Karin Berg** and **Deborah Dillon** of the Solid Tumors Subdivision and have joint Plenary Sessions on topics that are of interest to the members of both Subdivisions. Carlo Croce will discuss the role of microRNAs in both hematolymphoid and solid tumor development and diagnosis. Stephen Baylin will discuss epigenetic events in cancer. We think this is an exciting opportunity to look at common events related to the pathogenesis, diagnosis and potential treatment in both fields. For the workshops, the Hematopathology Subdivision will test using one of the workshops as a venue for platform presentations of submitted abstracts. This should be a highly interactive session (especially knowing the personalities of many of the hematopathology members!) and allow us to highlight some of the great work done by our members. We have high expectations! Gary Gilliland of Harvard Medical School will lead the other Hematopathology workshop on the genetics and related targeted therapies of myeloproliferative disorders. Finally, in response to requests by members in last year's survey, **Jerry Gong** will give a clear, practical and interesting introduction to molecular hematopathology at an Early Bird Session.

Your elected representatives in the Hematopathology Subdivision, **Dan Sabath** and **Tim O'Leary** of the Nominating Committee, **Jerry Gong** of the Training and Education Committee, **Dan Jones** of the Clinical Practice Committee, **Lynne Abruzzo**, Chair-Elect, and I, have been having conference calls to address issues important to the Subdivision. To date, we have discussed or made plans to address: updating the webpage, enhancing opportunities for academic members to intellectually engage with industry members, optimal utilization of volunteers and the negative impact of patents on diagnostic molecular hematopathology. Have a great summer and see you in Orlando!

Are you considering Molecular Hematopathology for your career and need advice?

Jerry Gong (gong0001@mc.duke.edu), the hematopathology representative to the Training & Education Committee, is willing to answer questions from residents and students.

SUBDIVISION REPORTS

INFECTIOUS DISEASES SUBDIVISION



By James Versalovic, MD, PhD
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As we say farewell to another respiratory virus season and look ahead to West Nile virus season, it is time to pause and consider relevant highlights. The results for the 2005-2006 season in the USA indicate a relatively mild winter with respect to respiratory virus infections. The vaccine formulated for 2005-2006 was an effective match for the circulating viruses, especially the type A viruses. As of April 29, 2006, 12.7% of samples tested in WHO and National Respiratory and Enteric Virus Surveillance System (NREVSS) laboratories were positive, and activity sharply tapered downward during the month of April (for reference, see <http://www.cdc.gov/flu/weekly/>). More than 82% of the influenza viruses detected were type A viruses. As more laboratories implement molecular diagnostic strategies for respiratory viruses, all of the possible type A and type B viral target sequences should be considered for effective testing. An outbreak of type B infections of children in Houston included type B Victoria, a subtype that was not included in this past year's vaccine and exposed the importance of coverage gaps in the vaccination strategy. With all of the attention on pandemic influenza, we remain wary in North America as we ponder when and where H5/N1 viruses will strike this continent. On February 3, 2006, the FDA approved the clearance of a primer-probe set for real-time RT-PCR-based detection of influenza A/H5 (Asian lineage) (see *MMWR* Feb 10, 2006;55:127).

In Houston, we were rudely reminded again of West Nile virus (WNV) with our first possible case during the first week of May. It is also time to consider the upcoming WNV season and diagnostic strategies. Although serologic testing remains the standard approach for primary screening, new molecular assays offer promise as additional tests for WNV evaluation (see Tang Y, et al. *J. Clin Virol* May 1, 2006; epub ahead of print).

The drama related to Hurricane Katrina last year illustrated the

importance of molecular diagnostics for the diagnosis of outbreak-associated enteric virus infections. The sudden relocation of thousands of Hurricane Katrina survivors to Houston last summer resulted in a norovirus outbreak that was first reported in October (see *MMWR* October 14, 2005;54:1016-1018). During a 3-day period beginning on August 31, 2005, approximately 27,000 evacuees were relocated from New Orleans to the Reliant Park Complex in Houston. Of approximately 6,500 people who visited the on-site medical clinic, 18% of patients reported symptoms of acute gastroenteritis. The bottom-line is that only molecular testing by RT-PCR yielded the diagnosis of a large outbreak of norovirus infections. Alternative global methods such as transmission electron microscopy failed to visualize any norovirus-like particles in stool specimens. Norovirus was found in 22 of 44 stool specimens (50%) tested by RT-PCR, and no other enteric pathogen including rotavirus was identified. Rapid diagnosis by RT-PCR resulted in important adjustments regarding patient isolation and handwashing/hygiene procedures so that the outbreak was contained in a short time frame. This recent experience helps to prepare us for another hurricane season and serves as a useful reminder regarding the importance of molecular diagnostics for public health purposes in crisis situations.

On the AMP front, several efforts should be highlighted. The Program Committee has finalized the program for the 2006 Annual Meeting in Orlando, and the call for abstracts has been announced. Please see the meeting schedule on the AMP website for details (<http://www.amp.org/Meetings/2006/amp2006.htm>) and in this issue of the Newsletter.

The Infectious Diseases Subdivision leadership has been working together to make progress regarding several issues. We communicated recently about the structure of the infectious diseases portion of the AMP Website and ways to improve it by adding more links and up-to-date information for diagnostic laboratories. We are also reviewing the *Test Directory* and examining ways in which we can improve its structure and utility. Thirdly, educational opportunities will be provided to laboratorians in the Orlando area at the 2006 AMP Meeting, and this AMP community outreach effort will include infectious diseases. Finally, our Clinical Practice Committee is working on collaborative opportunities to improve proficiency testing and standards for molecular diagnostics of cytomegalovirus (CMV).

Please send any ideas or feedback to me, **Mary Williams**, your Chair-Elect (**Alexandra Valsamak**) and Subdivision representatives who are serving on various AMP committees: **Kathleen A. Stellrecht** of the Clinical Practice Committee, **Ted E. Schutzbank** of the Training and Education Committee and **Betty A. Forbes** and **Stephen P. Day** of the Nominating Committee.

Best wishes to all.

The AMP Jobs Board (www.PathologyJobsToday.org) is a great place for employers and job seekers to connect! Job seekers can post their resumes anonymously, view currently available jobs and create a personal account. Employers can view resumes, post jobs and create an employer account.

SUBDIVISION REPORTS

SOLID TUMORS SUBDIVISION

The late winter and spring have been a very busy time for Solid Tumors' representatives to the various AMP Committees, as you can see by the letters from the Chairs of these committees. **Deborah Dillon** and I have been busy with the Program Committee, working to generate a timely and educational set of presentations for the 2006 meeting in Orlando. During our early discussions regarding the program, we noticed that there were significant overlaps in subjects the Solid Tumors membership had proposed as interesting with those proposed by the Hematopathology leadership. Because of the overlap, we have moved forward with a slightly different approach to our sessions this year, in which we will have several talks aimed at both the Solid Tumors and Hematopathology audiences.

Our first Plenary topic will be regarding the new and rapidly advancing topic of microRNA (miRNA). Our esteemed colleagues from the Hematopathology Subdivision, Drs. **Nina Longtine** and **Lynn Abruzzo**, have enlisted the services of Dr. Carlo Croce to address this topic in a joint Hematopathology/Solid Tumors Plenary Session. He is well published in the field of miRNA in the solid and liquid tumor fields. We are thrilled to have Dr. Croce speak and are indebted to our hematopathology colleagues, Nina and Lynn, in their effort in obtaining his services. The second Plenary Session is also a team effort with Hematopathology (...such a deal!!) and will involve epigenetic changes in cancer. This topic has certainly been addressed from a research perspective at AMP previously, but in this presenta-

tion we hope to see information regarding the bridging of research advances into clinical application.

For the Solid Tumors Workshops, we will have the privilege of hearing about the work of Dr. Frederic Waldman on the topic of array CGH. Dr. Waldman, a patent holder of this technology, is excited to present its application to the assessment of a variety of solid and hematologic neoplasms. We are very thrilled that Dr. Waldman has agreed to speak and look forward to hearing him. Our second workshop will be a review of recent advances in the molecular pathology of urologic malignancies and the speakers for this presentation are in the final phases of negotiation.

To finish up, let me say that I am indebted to our incoming Solid Tumor Subdivision Chair, **Deborah Dillon**, for all of her time and hard work developing this program and trying to keep me in line! We thank **Nina Longtine** and **Lynn Abruzzo** for their collegial and collaborative help in stepping a little out of the box on programming this year, to make this a top-notch program. I hope all my colleagues are well, old friends and the new ones I hope to meet soon. I look forward to seeing everyone at the meeting in Orlando. I believe it is Deborah's year to wear the tiara...

By Karin D. Berg, MD
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Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) Molecular Genetics Reference Guidelines

- MM10-A Genotyping for Infectious Diseases: Identification and Characterization; Approved Guideline
- MM11-P Molecular Methods for Bacterial Strain Typing; Proposed Guideline – Available May 2006
- MM12-A Diagnostic Nucleic Acid Microarrays; Approved Guideline
- MM13-A Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods; Approved Guideline
- MM14-A Proficiency Testing (External Quality Assessment) for Molecular Methods; Approved Guideline
- MM16-P Uses of External RNA Controls in Gene Expression Assays; Proposed Guideline

See www.clsi.org or call 610-688-0100 or e-mail customerservice@clsi.org for more information.

PRECLINICAL VALIDATION OF FISH ASSAYS FOR CLINICAL PRACTICE

By Editors' invitation: a report from an Early Bird Session of the 2005 Annual Meeting.

Fluorescence *in situ* hybridization (FISH) assays must be validated prior to use in clinical practice, as required by the Clinical Laboratory Improvement Amendments (CLIA), Food and Drug Administration (FDA), and the College of American Pathologists (CAP) before reporting any patient results. The pre-clinical validation should encompass evaluation of accuracy, analytical sensitivity and specificity, normal values, precision, reportable reference ranges, safety, and assessment of equipment of the FISH assay. It is not sufficient to rely on a manufacturer's package insert.

There are only a few published examples that describe the validation process (1, 2, 3). However, the requirements or procedures to validate FISH probes can be met in a stepwise fashion. The steps are similar for commercial or home brew probes and for metaphase cells or interphase nuclei from suspensions or for sectioned material (4, 5). The process can begin with familiarization of probe performance on metaphase cells from five PHA-stimulated blood specimens from karyotypically normal males. This experiment is useful to measure analytical sensitivity and specificity and to define scoring criteria and guidelines. The second step is analysis of a series of normal and abnormal specimens, using the intended tissue type(s), to establish the preliminary normal cutoff and analytical sensitivity of the FISH assay. Each intended tissue type should be validated independently. Tissue-specific validation statistics can be pooled if not significantly different. The third step is a more extensive clinical evaluation experiment which tests the forgoing parameters in a simulation of daily clinical practice. This allows establishment of the normal cutoff and abnormal reference ranges. A written standard operating procedure can be based on the validation experience thus far. The fourth step involves analytic precision or testing the reproducibility of the new assay. At this point, the new FISH assay is ready for clinical use.

Validation of an FDA approved FISH assay may only require preclinical testing to set the normal cutoff and abnormal reference ranges, assuming the procedure is followed as written by the manufacturer. The assay must be used only for the clinical application for which the regulatory agency has approved the product. If the FDA-approved method or clinical application is not followed exactly, or for an off-label purpose, it is necessary to validate the procedure and establish performance criteria before testing patients in clinical practice.

The process of validation is a continuous process in clinical practice. It is up to the laboratory to ensure that the FISH assay works as expected over time and consistently achieves the intended results which include expectations of adequate clinical sensitivity and specificity and review of the abnormal reference range. In addition to internal and external proficiency testing,

ongoing employee competency can be assessed by evaluating inter-observer variation in scoring and consistency of applying the scoring criteria over time.

Control specimens are not required during preclinical validation because known (albeit blinded) normal and abnormal specimens serve as their own controls. In clinical practice, however, CLIA standards do require control specimens to detect immediate errors as well as long-term changes and drift in the testing system. FISH tests should include control probes or control specimens that are designed to detect errors, assess performance of the assay, and assure the accuracy of scoring criteria.

References:

1. Dewald G. Interphase FISH studies for chronic myeloid leukemia. In: Fan YS, ed. *Methods in Molecular Biology: Molecular Cytogenetics: Protocols and Applications*. Vol 204. Totowa, NJ:Humana Press; 2002:311-342.
2. NCCLS. *Fluorescence In Situ Hybridization (FISH) Methods for Medical Genetics; Approved Guideline NCCLS Document MM7-A*; 2004.
3. Schad CR, Dewald GW. Building a new clinical test for fluorescence in situ hybridization. *Applied Cytogenetics* 1995;21:1-4.
4. Vance G, Van Dyke DL. Validation of FISH Probes in Clinical Testing. AMP Annual Meeting, Scottsdale, AZ, November 2005.
5. Wiktor AE, Van Dyke DL, Stupca PJ, Ketterling RP, Thorland EC, Shearer BM, Fink SR, Stockero KJ, Majorowicz JR, Dewald GW. Preclinical Validation of FISH Assays for Clinical Practice. *Genet Med* 2006;8(1):16-23

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WANTED: AMP TEST DIRECTORY EDITOR

There is an opening for a volunteer *AMP Test Directory* Editor. This position is high visibility, is great for trainees or technologists and takes very little time per month. The most important qualification is general familiarity with the molecular tests currently in use for hematopathology, infectious diseases and solid tumors. The Editor will not be responsible for maintaining the database; the AMP office has a programmer who handles database programming. Please send an e-mail to learn more about the position or to express your interest (include your current *curriculum vitae*) to **Elaine Lyon**, Chair of the Clinical Practice Committee at lyone@aruplab.com.

PRESIDENT'S MESSAGE

(Continued from page 1)

buy them from a catalog - you made them yourself. "Cloning" referred to inserting fragments of DNA from bacteria into plasmids. Control of the recombinant bacteria was a huge concern and stopped many studies while appropriate biocontainment levels were debated by leading scientists of the day. We needed exactly one reference book at the bench - "Maniatis" - to get the work done.

The "good" news is that many graduate student projects from the 70's - mine included - can be performed today by a talented 8th grader with commercially available kits and access to a few instruments.

The "bad" news is that while the 8th grader can program every new electronic device, those of us working in the lab face a bewildering array of tasks and tools, demands and responsibilities, challenges and opportunities. My month of April included laboratory inspections and certification requirements. Manuscripts, chapters, meeting presentations, lectures. Standards and guidelines. New methods, instruments, reagents, controls. Cost-effectiveness. Patient privacy. Gene patents and exclusive licensing. MUEs, reimbursements and modifier codes. Lots of discussion about personalized medicine. My guess is that you, the membership of AMP, find yourselves running just as hard, just to keep up.

Sure, you may have attended medical school or graduate school, you may have done postdocs or a residency, you may even have specialty training and board certification. But none of that addressed the real-life responsibilities of mentoring, technical supervision, certification, compliance, billing, human resources, accounting, business and related skills that are currently required to be effective in the laboratory. And someone - I will bet it is you - has to know what to do when the plate gets stuck in the reader, the freezer alarm goes off and the safety officer shows up for an unscheduled inspection.

With all this "stuff" competing for our time and attention, how do we move our careers - and the discipline of molecular pathology forward?

Here's one approach.

1. **Focus.** Have a clear idea about what molecular pathology means locally, nationally and professionally. Set aside time each week to focus on moving the frontier forward, such as at least reading the latest issue of our journal. Make sure that what you do, who you serve, who you train is recognized by those around you.
2. **Leverage.** AMP members are unique, but the problems they face are not. Use the AMP collaborative to find effective and workable solutions to the emerging challenges. **Mary Williams** has directed your attention to the new feature at the AMP website for initiating

collaborations with commercial or academic institutions. Other professional organizations have similar posting forums (HumMolGen is one) for alerting members to these possibilities. Of course, CHAMP is indispensable for many of us and suggestions to organize the archive into discussion topics or threads should help reduce some duplication.

3. **Extend.** There are other individuals and organizations with complementary interests and goals. Earlier this year a Pathology Coalition formed by the College of American Pathologists (CAP) included AMP in a protest to the Centers for Medicare and Medicaid Services (CMS) requesting the withdrawal and reconsideration of the medically unbelievable edits that would severely restrict recommended standards of medical practice and adversely affect most pathology procedures and reimbursement. This collective advocacy did garner attention from the federal agency and congressional leaders to facilitate a process for review and comment by the medical community of the need for such edits. AMP responded both as part of the coalition and with our Professional Relations Committee. AMP members also represent our interests with SACGHS considering pharmacogenetic guidelines and gene patent issues that continue to restrict diagnostic testing. With our colleagues in AACC we continue to develop educational programs of molecular diagnostics for mutual interest and benefit of members of both organizations. Pharmacogenetics is one good example in which the collaboration of the toxicologist, clinical chemist, pharmacologist, molecular geneticist and pathologist will bring a better understanding of this laboratory data for implementation by the physician.
4. **Imagine.** Hockey great Wayne Gretzky credits his father with the best piece of advice he ever received: "Don't skate to where the puck is, Son; skate to where the puck is going to be." The wonderful thing about AMP is that we can imagine together. Use the listserv, come to the meetings, participate and contribute.

The goal is not just about making sense of the present. It's about sharing a vision and building a future. Ours.

Got ideas? Want to get more involved? Write to me at zahnbauer_b@wustl.edu.

It is time to make your hotel reservations at the
Gaylord Palms & Convention Center
Orlando, Florida
for the 2006 AMP Annual Meeting.

PROGRAM COMMITTEE REPORT

(Continued from page 4)

hard labors of our Subcommittee Chairs and Chairs-to-be, our Technical Topics Representatives and the Staff of the AMP Executive Office who constitute our outstanding Program Committee.

Karen Weck - Program Chair-Elect (*University of North Carolina at Chapel Hill*)

Vicky Pratt - Genetics Chair (*Quest Diagnostics-Nichols Institute*)

Paul Rothberg - Genetics Chair-Elect (*University of Rochester Medical Center*)

Janina Longtine - Hematopathology Chair (*Brigham & Women's Hospital*)

Lynn Abruzzo - Hematopathology Chair-Elect (*UT-MD Anderson Cancer Center*)

Jim Versalovic - Infectious Diseases Chair (*Texas Children's*

Hospital)

Alexandra Valsamakis - Infectious Diseases Chair-Elect (*Johns Hopkins School of Medicine*)

Karin Berg - Solid Tumors Chair (*Gastrointestinal Pathology Partners*)

Deborah Dillon - Solid Tumors Chair-Elect (*Brigham & Women's Hospital*)

Gladys Garrison - Technical Topics Rep (*Vanderbilt University Medical Center*)

Malinda Butz - Technical Topics Rep (*Mayo Foundation*)

Mary Steele-Williams - Director of Scientific Programs

Maricel Herrera - Director, Meetings and Membership Services

I look forward to seeing you all in Florida!

PROFESSIONAL RELATIONS COMMITTEE REPORT

(Continued from page 3)

provided CAP with a number of documented case examples illustrating how proper performance of a molecular pathology test requires repeated use of certain codes. Because of this unified outcry, which included a letter from the PRC crafted for submission under the AMP letterhead, CMS withdrew the scheduled July implementation of the restrictions and agreed to extend the external comment period for a few months. While this was welcome news, we must keep our guard up because there is still a good possibility that CMS may come back with essentially the same proposal again. The PRC is monitoring these developments and is ready to continue our efforts both alone and in partnership with other professional associations.

CFTR FDA Guidance Document

In October 2005 the Food and Drug Administration (FDA) issued for public comment a draft guidance document aimed at manufacturers of cystic fibrosis mutation detection systems. The intent was to advise manufacturers on features the FDA would be scrutinizing in submissions, in order to facilitate clearance of additional CFTR (cystic fibrosis transmembrane conductance regulator) mutation products. Our response, spearheaded by **Jean Amos Wilson**, was generally supportive of the document, but we did express two areas of concern. One was the apparent blurring of analytic and post-analytic aspects of the testing, in which too much responsibility for results interpretation was placed on the manufacturer. We stressed that this phase is the responsibility of the laboratory director, not the device or manufacturer. Second, we recommended that FDA use caution in evaluating platforms containing expanded CFTR mutation panels, since the additional mutations will not have been vetted by knowledgeable professional organizations, and genotype-phenotype correlations (and hence clinical utility) may be uncertain.

AdvaMed Test Pricing Proposal

The PRC was invited to participate in some conference calls with this organization (Advanced Medical Technology Association) to evaluate its intent to introduce legislation to obtain support for evidence-based surveys of molecular diagnostic test costs, the ultimate goal being an improvement in reimbursements to levels that are more reasonable and realistic. While the intent is admirable, we had some concerns about the strategy of going through the legislative route for something that has already been recommended to the HHS Secretary by SACGHS (in which our AMP member **Debra Leonard** participated). We also needed to explore further what impact this proposal might have on technique-based CPT codes as opposed to disease-specific codes. And we were concerned about the potential downside of focusing exclusively on the costs of molecular testing in such a high-profile way. We have decided to neither support nor oppose the proposal at this time, but to watch as the activity progresses.

Point-of-Care Testing

The rapidity of PCR- and real-time PCR-based tests makes them obvious candidates for implementation at the point of care, and a number of manufacturers are continuing to come forward with devices to meet this need. However, an impediment has been noted based on a restrictive CMS/CLIA policy excluding these assays from alternative QC measures, thus requiring additional controls. A response has been formulated by **Michele Schoonmaker** and **Angie Caliendo**.

2006 ANNUAL MEETING PRELIMINARY PROGRAM

WEDNESDAY, NOVEMBER 15, 2006

12:00 pm - 6:00 pm Registration
1:00 pm - 7:30 pm AMP Council Meeting (Part I)
8:00 pm - 9:00 pm AMP Committee Meetings

THURSDAY, NOVEMBER 16, 2006

8:00 am - 6:00 pm Registration
9:00 am - 5:00 pm **Corporate Workshops**
6:00 pm - 7:00 pm MGP Fellowship Program Directors Meeting

FRIDAY, NOVEMBER 17, 2006

7:00 am - 6:00 pm Registration
7:00 am - 7:50 am Continental Breakfast
6:50 am - 7:40 am **EARLY BIRD SESSIONS**
Validation and Maintenance of ASRs and Lab Developed Assays
*Moderators: Marsha Speevak, PhD, Credit Valley Hospital, Mississauga, ON
Wayne W. Grody, MD, PhD, UCLA School of Medicine, Los Angeles, CA
Margaret L. Gulley, MD, University of North Carolina, Chapel Hill, NC*

Entrée to Molecular Hematopathology

Jerald Z. Gong, MD, Duke University Medical Center, Durham, NC

Competency and Training of Molecular Technologists

Jeanne Carr, PhD, St. Jude Children's Research Hospital, Memphis, TN

7:50 am - 8:00 am

Opening Remarks

S. Terence Dunn, PhD, University of Oklahoma Health Sciences Center, Oklahoma City, OK

8:00 am - 9:15 am

AMP AWARD FOR EXCELLENCE IN MOLECULAR DIAGNOSTICS LECTURE
(Supported by Roche Diagnostics Corporation)

9:15 am - 10:30 am

Break/Visit Posters and Exhibits

10:30 am - 12:00 p.m.

PLENARY SESSION I - INFECTIOUS DISEASES

Genetics of Susceptibility to Infection

Moderator: James Versalovic, MD, PhD, Baylor College of Medicine and Texas Children's Hospital, Houston, TX

Host Genetics and Recovery from Chronic Viral Hepatitis Infections

Chloe Thio, MD, Johns Hopkins Medicine, Baltimore, MD

Immunogenetic Studies of Toll-Like Receptors and Susceptibility to Pulmonary Infections

Thomas R. Hawn, MD, PhD, University of Washington School of Medicine, Seattle, WA

12:00 pm - 1:15 pm

Lunch/Visit Posters and Exhibits
General and Subdivision Business Luncheons

1:15 pm - 2:45 pm

PLENARY SESSION II - HEMATOPATHOLOGY AND SOLID TUMORS

Moderator: Janina Longtine, MD, Brigham & Women's Hospital, Boston, MA

MicroRNA Expression Profiling

Carlo M. Croce, MD, Ohio State University, Columbus, OH

- 2:45 pm - 4:00 pm Break/Visit Exhibits and Posters (even-numbered posters manned)
- 4:00 pm - 5:15 pm **SOLID TUMORS WORKSHOP I**
Moderator: Karin Berg, MD, Gastrointestinal Pathology Partners, Memphis, TN
Array CGH
Frederic M. Waldman, MD, PhD, UCSF, San Francisco, CA
- GENETICS WORKSHOP I**
*Supported by the Genetic Testing Quality Control Materials Program (GTQC)
Centers for Disease Control and Prevention*
Quality Control in Genetic Testing
Moderator: Vicky Pratt, PhD, Quest Diagnostics, Chantilly, VA
Fragile X
Jean Amos Wilson, PhD, Focus Diagnostics, Cypress, CA
Ashkenazi Jewish Diseases
Kasinathan Muralidhara, PhD, Emory University School of Medicine, Atlanta, GA
Cystic Fibrosis
Lisa Kalman, PhD, Centers for Disease Control, Atlanta, GA
Huntington Disease
Carolyn Sue Richards, PhD, Oregon Health Science University, Portland, OR
European QC Initiatives
David Barton, PhD, National Center for Medical Genetics, Dublin, Ireland
- 5:15 pm - 6:30 pm **HEMATOPATHOLOGY WORKSHOP I**
Moderator: Janina Longtine, MD, Brigham & Women's Hospital, Boston, MA
**Genetics and Therapy of Myeloproliferative Disorders:
The Search for Disease Alleles and Drug Targets**
D. Gary Gilliland, MD, PhD, Harvard Medical School, Boston, MA
- INFECTIOUS DISEASES WORKSHOP I**
Supported by Roche Diagnostics Corporation
Immuno-PCR: Marriage of Antibodies and DNA
*Moderator: James Versalovic, MD, PhD, Baylor College of Medicine and
Texas Children's Hospital, Houston, TX*
Immuno-PCR: Maximizing Immunoassay Sensitivity
Ron Wacker, PhD, Chimera Biotec GmbH, Dortmund, Germany
Immuno-PCR as a Unique Molecular Tool for Detection of Infectious Diseases
Niel Constantine, PhD, University of Maryland School of Medicine, Baltimore, MD
- 6:30 pm - 7:30 pm **WELCOME RECEPTION** (*Supported by Roche Diagnostics Corporation*)
- 7:30 pm - 10:00 pm *The Journal of Molecular Diagnostics (JMD)* Editorial Board Meeting
- SATURDAY, NOVEMBER 18, 2006**
- 7:00 am - 6:00 pm Registration
- 7:00 am - 7:50 am Continental Breakfast
- 7:00am - 7:50 am **EARLY BIRD SESSIONS**
Bayesian Risk Analysis
Shuji Ogino, MD, PhD, Brigham & Women's Hospital, Boston, MA
MSI Testing
Speaker TBD
Principles and Validation of Quantitative Lab Tests
David R. Hillyard, MD, ARUP Laboratories, Salt Lake City, UT

- 8:00 am - 9:30 am **PLENARY SESSION III - GENETICS**
Moderator: Vicky Pratt, PhD, Quest Diagnostics, Chantilly, VA
Fragile X: A Clinical Perspective
Annette Taylor, PhD, Kimball Genetics, Denver, CO
Fragile X: A Practical Perspective
Benjamin Roa, PhD, Baylor College of Medicine, Houston, TX
- 9:30 am - 10:30 am Break/Visit Posters and Exhibits (odd-numbered posters manned)
- 10:30 am - 12:00 pm **PLENARY SESSION IV - SOLID TUMORS AND HEMATOPATHOLOGY**
Moderator: Deborah Dillon, MD, Brigham & Women's Hospital, Boston, MA
Epigenetic Events in Cancer
Stephen B. Baylin, MD, Johns Hopkins Medicine, Baltimore, MD
- 12:00 pm - 1:15 pm Lunch/Visit Posters and Exhibits
General and Subdivision Business Luncheons
Trainee Luncheon
- 1:15 pm - 2:30 pm **TECHNICAL TOPICS WORKSHOP**
*Moderators: Gladys Garrison, MS, MT(ASCP), Vanderbilt University Medical Center
Nashville, TN and Malinda Butz, CLSp(MB), Mayo Foundation, Rochester, MN*
Validation and QC of Sequencing Arrays
Matthew Ferber, PhD, Mayo Clinic, Rochester, MN
Friederike Gedge, ARUP Laboratories, Salt Lake City, UT
Kathryn Gumper, MT(ASCP)I, Myriad Genetics Laboratory, Salt Lake City, UT
- 1:15 pm - 2:30 pm **HEMATOPATHOLOGY WORKSHOP II**
Moderator: Lynn V. Abruzzo, MD, PhD, UT-MD Anderson Cancer Center, Houston, TX
Platform Presentations of Selected Hematopathology Abstracts
- 2:30 pm - 3:30 pm Break/Visit Posters and Exhibits
- 3:30 pm - 4:45 pm **TECHNICAL TOPICS PLENARY**
Moderator: Kenneth Bahk, PhD, Nanosphere, Northbrook, IL
The Impact of Nanotechnology on Molecular Diagnostics
Speakers TBD
- 4:45 pm - 6:00 pm **AMP BUSINESS/AWARDS SESSION**
- 6:00 pm - 7:00 pm **AMP AWARDS RECEPTION** (*Supported by Third Wave Technologies*)
7:00 pm - 10:00 pm AMP Council Meeting (Part II)
7:30 pm - midnight Canadian AMP Members' Reception

SUNDAY, NOVEMBER 19, 2006

- 7:00 am - 7:50 am Continental Breakfast
- 7:00 am - 7:50 am **EARLY BIRD SESSIONS**
Mutation Nomenclature
Shuji Ogino, MD, PhD, Brigham & Women's Hospital, Boston, MA
Patent Law and Genes
Roger Klein, MD, JD, Mayo Clinic, Rochester, MN
To Type or not to Type HPV: Liquid Bead Arrays
(*Supported by Luminex Corporation*)
German Pihan, MD, Beth Israel Deaconess Medical Center, Boston, MA

8:00 am - 9:30 am

GENETICS WORKSHOP II*Moderator: Paul G. Rothberg, PhD, University of Rochester Medical Center, Rochester, NY***Puzzlers by Prior***Thomas W. Prior, PhD, Ohio State University, Columbus, Ohio***INFECTIOUS DISEASES WORKSHOP II***Moderator: Alexandra Valsamakis, MD, PhD, Johns Hopkins Medicine, Baltimore, MD***Molecular Diagnosis of Pathogens in Tissue: Clinical Utility and Practical Considerations***Jennifer L. Prentice, MS, MT(ASCP), University of Washington Medical Center, Seattle, WA**Brent Seaton, PhD, Focus Diagnostics, Cypress, CA***SOLID TUMORS WORKSHOP II***Moderator: Deborah Dillon, MD, Brigham & Women's Hospital, Boston, MA***Advances in Urothology***Speaker TBD*

9:30 am - 10:00 am

Break

10:00 am - 11:30 am

SPECIAL TOPICS WORKSHOP*Moderator: Karin Berg, MD, Gastrointestinal Pathology Partners, Memphis, TN***Reimbursement Issues in Molecular Diagnostics***Speakers TBD*

11:30 am - 11:45 am

Closing Remarks*S. Terence Dunn, PhD, University of Oklahoma Health Sciences Center, Oklahoma City, OK***EARN CME CREDIT****WHILE UPDATING YOUR KNOWLEDGE IN THE LATEST ADVANCES IN MOLECULAR DIAGNOSTICS**

The *JMD* CME Program in Molecular Diagnostics provides *The Journal of Molecular Diagnostics (JMD)* readership with a unique opportunity to earn CME credit while renewing and updating their knowledge in the latest advances in molecular diagnostics. This program consists of a series of questions based on selected articles in the 2006 issues of *JMD*.

Visit <http://www.amp.org/CME/jmdCME.htm>: for complete information.

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William Beaumont Hospital

DNA TECHNOLOGY

IN THE

CLINICAL LABORATORY15th Annual Symposium on Molecular Pathology

September 13-15, 2006

Somerset Inn, Troy, Michigan

This three-day symposium will begin Wednesday morning, September 13th, with a *Flow Cytometry Workshop* followed by the *Introduction to Molecular Diagnostics Workshop* in the afternoon. Corporate Workshops will be on Thursday morning, September 14th, with the *New Technology in Molecular Pathology* session held Thursday afternoon. The Friday, September 15th morning session on *Hematology-Oncology* will be followed by the *Molecular Microbiology* session in the afternoon. Lunch Break-out sessions and vendor exhibits will be held each day of the symposium. CME credit is available.

For more information, contact Domnita Crisan, MD, PhD:
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