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Message from the Chair

2020 is here and it has been challenging and will continue to be so for the foreseeable future. The Covid-19 pandemic has affected all our lives. Some of us will have lost family or friends to this disease. We are working from home or with limited on-site appearances. Picking up a “hands-free pizza,” if your local shop is open, may be the highlight of the week. If we do venture out, we see old fabric turned into homemade facemasks everywhere we look (mine has Ninja Turtles). Who knows what vacations will look like this year, as crowded beaches and restaurants will look less enticing? International travel is probably not too appealing, if even possible. But enough gloom, Spring has finally happened and hopefully what we do in the labs can impact the outcome of this pandemic. The doctors and nurses and other frontline personnel get a lot of deserved praise for saving lives, but a greater long-term impact will be the product of laboratories through testing, therapeutics and vaccines that will get the world back to normal. In that regard, planning DACC events has been challenging. You are probably aware that the AACC had shifted the Annual meeting to December 13-17, 2020. Being so close to the end of year holidays it will likely affect attendance, but as of now we are planning to hold our Lunch and Learn and social events. This could all change quickly as organizations may have travel bans in place. Therefore, plans for a Fall meeting are currently on hold until the situation gets more clarity. To keep members connected we will be trying some online discussions on a variety of topics. This concept worked well in person at the last Fall meeting and we will try to transfer that over to an online concept – so stay tuned.

This year I began my third round proudly serving as the Chair of the DACC. In addition to the pandemic we continue to see upheaval in the industry through mergers, consolidations and unfortunately – layoffs. We have seen some of our group move to other careers or retirement, but the DACC remains a vibrant organization with a strong focus on educational opportunities and networking. I believe the DACC members together are the best source of collective knowledge of clinical pathology related pre-clinical laboratory issues. It is common for members to contact the group or individuals to address questions about acquiring new instrumentation and methods, dealing with Validation and Quality Assurance issues, or

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Kay Criswell
Bob Emmons
Doug Neptun

Scientific Program & Long Range Planning
Madhu Sirivelu
Lisa Blankenship
Amy Hudak

Membership
Volunteers Needed!

*Exec Comm Rep
The Division of Animal Clinical Chemistry (DACC) welcomes all persons interested in advancing clinical laboratory science in animals by promoting and encouraging the study, exchanging knowledge, and expanding and improving the practice of clinical laboratory science in animals.

Our division provides a forum for sharing of information relevant to methods of analysis, reference intervals for different animal models, selection of appropriate species for research, and feasibility of transferring relevance of the data to human medicine. The DACC supports the development of methods to detect specific target organ effects and cellular changes associated with xenobiotic agents and/or disease processes.

The Division publishes this newsletter and sponsors regional and national meetings as a means for promoting education, research, and service. We encourage members to pursue professional interactions with AACC as well as within other professional groups. Our membership represents scientists working in interdisciplinary fields, industry, academia, and governmental laboratories.

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  DACC Associate News Editor
2019 DACC Fall Symposium
October 2019
Tarrytown, NY

Meet the Speakers Reception
## 2019 DACC Fall Meeting Program

**Biomarkers - Perspective from the Bench: From Validation in Clinical Laboratory to Regulatory Qualification**

### FRIDAY– OCTOBER 25TH, 2019

**Venue:** Auditorium, Siemens Healthcare Diagnostics, 511 Benedict Avenue, Tarrytown, NY 10591

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tr>
<td>8:00 AM — 8:25 AM</td>
<td>Registration and Continental Breakfast</td>
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</table>
| 8:25 AM — 8:30 AM | **Welcome from the DACC Chair**  
*Madhu Sirivelu*, DACC Chair and Symposium Moderator  
Clinical Pathologist  
Pfizer, Inc, Cambridge, MA                                      |
| 8:30 AM — 9:10 AM | **Regulatory Qualification Of Drug Induced Kidney Injury Biomarkers**  
*Gary S. Friedman*, Clinical Nephrologist  
Global Product Development, Inflammation and Immunology  
Pfizer, Inc, Collegeville, PA                                    |
| 9:10 AM — 9:50 AM | **Biomarker Qualification For Drug-Induced Liver Injury: A Case Example Of Glutamate Dehydrogenase**  
*Kimberly Navetta*, Principal Scientist  
Drug Safety Research & Development  
Pfizer, Inc, Andover, MA                                           |
| 9:50 AM — 10:10 AM | **Coffee Break**                                                         |
| 10:10 AM — 10:50 AM | **Evolution in Veterinary Diagnostic Endocrinology with Immunoassays: Dealing with Validations and Generation Gaps of New Technologies**  
*Stephen V. Lamb*, AHDC Endocrinology Lab Manager  
Animal Health Diagnostic Center (AHDC)  
College of Veterinary Medicine  
Cornell University, Ithaca, NY                                    |
| 10:50 AM — 11:30 AM | **Validation of Quantitative Mass Spectrometry Assays**  
*Jennifer Colangelo*, Sr Manager, Pharmacology  
Drug Safety Research & Development  
Pfizer, Inc, Groton, CT                                             |
| 11:30 AM—12:10 PM | **Industry Perspective: Rat Cytokine Assay Selection - a Case Study**  
*Thomas Philip*, Senior Scientist  
Pathology, Safety Assessment and Laboratory Animal Resources  
Merck Research Laboratories, West Point, PA                         |
| 12:10 PM — 1:20 PM | **Lunch**                                                               |
2019 DACC Fall Meeting Program
Biomarkers - Perspective from the Bench: From Validation in Clinical Laboratory to Regulatory Qualification

FRIDAY– OCTOBER 25TH, 2019

Venue: Auditorium, Siemens Healthcare Diagnostics, 511 Benedict Avenue, Tarrytown, NY 10591

1:20 PM — 2:00 PM
GLP/GCP, CLIA, CAP and ISO: Anchors for Quality in Clinical Testing
Kay Ann Criswell
Laboratory Services Director, Clinical Research
Global Product Development
Pfizer, Inc, New Haven, CT

2:00 PM — 3:00 PM
Open Forum Discussion: Validation and Quality Assurance
Discussions led by DACC colleagues designed to openly discuss ideas and share experiences among peers.
Subtopics include the following:

- Quality Assurance and Assay Validation: What parameters do you consider?
  Differences between GLP versus Non-GLP assays
  Review of validation considerations and evaluations

- Disaster Recovery – Are You Prepared? What Would You Do If...
  Review of important preparation considerations and actions taken when a small or large disaster strikes

- Instrumentation Survey: What Instruments Are in Use Across the Veterinary Clinical Pathology Laboratories?
  Review of recent survey soliciting which instruments are in use across clinical chemistry, hematology, coagulation, and urinalysis

Closing Remarks

The Membership of the DACC Extends a HUGE THANK YOU to Siemens Healthineers for Hosting the DACC Spring Symposium at Tarrytown, NY
Biomarker Qualification For Drug-Induced Liver Injury: A Case Example Of Glutamate Dehydrogenase
Kimberly Navetta, Principal Scientist
Drug Safety Research & Development
Pfizer, Inc, Andover, MA

Drug induced liver injury (DILI) is the single greatest cause for termination of drug candidates and withdrawal of approved drugs from the market. Serum activities of alanine and aspartate aminotransferases (ALT and AST) are used as gold standard biomarkers for the diagnosis of hepatocellular injury in humans. However, considerable amounts of both ALT and AST are also present in muscle. Under conditions of disease or drug-induced muscle injury, aminotransferases cannot be used for the accurate detection of the onset of liver injury. Due to this lack of liver specificity of the standard biomarkers and the challenges with other approaches to the diagnosis of liver injury, glutamate dehydrogenase (GLDH), a mitochondrial enzyme found primarily expressed throughout the liver lobule with only a trace amount found in muscle tissue, was evaluated as a liver specific biomarker of hepatocellular injury. GLDH serum activity was measured in several populations to establish a reference range for GLDH in healthy subjects, to establish GLDH as a marker of hepatotoxicity that strongly correlates with ALT, to establish GLDH serum activity cutoffs of concern, and to assess the capability of GLDH to differentiate liver and muscle injury from human subjects with muscular dystrophies and a variety of myopathies. The results from the above summarized studies, along with supportive data that will be submitted from proposed confirmatory studies, has been proposed for the qualification of GLDH activity as a biomarker of liver injury in human subjects with ALT elevations from suspected extrahepatic sources such as muscle.

Industry Perspective: Rat Cytokine Assay Selection - a Case Study
Thomas Philip, Senior Scientist
Pathology, Safety Assessment and Laboratory Animal Resources
Merck Research Laboratories, West Point, PA

The increase of therapeutic biologics and vaccines in drug development has increased the demand for cytokine measurements in non-clinical species. However, available cytokine assays for animal samples are notoriously lacking in standardization, consist of different antibody pairs, and values vary significantly across vendors. To identify the most reliable assay, we examined six commercial rat multiplex cytokine kits with the intent of finding the best method for measuring frequently requested cytokines. In addition, rat strain (Sprague Dawley or Wistar), sample type (EDTA plasma or serum), collection site (jugular vein, vena cava, tail vein), control and positive samples were investigated.

The performance of the assays varied considerably, and their performance was further influenced by the sample collection site and the sample matrix examined. Our comprehensive evaluation of sample type, collection site, and available cytokine assays demonstrated that the least variable and most reliable data was generated from vena cava EDTA plasma samples. Rat serum resulted in considerably higher and more variable values. The Bio-Plex Pro™ kit provided consistent data for the terminal EDTA plasma samples; however, interim jugular samples were highly variable. The Meso Scale Discovery platform demonstrated the lowest and least variable values, and could be considered if interim sampling (e.g., jugular) is needed. Although our findings suggest guidelines for cytokine measurements in rat samples, careful monitoring of the performance of existing assays is recommended due to the potential variability observed with these cytokine assays.

Evolution in Veterinary Diagnostic Endocrinology with Immunoassays: Dealing with Validations and Generation Gaps of New Technologies

Stephen V. Lamb,
AHDC Endocrinology Lab Manager
Animal Health Diagnostic Center (AHDC)
College of Veterinary Medicine
Cornell University, Ithaca, NY

The immunoassay has been a valuable tool in science since discovered by Rosalyn Yalow and colleagues in the late 1950’s in adult diabetes research with the Insulin assay. The methodology has evolved to be an important component in research with the diagnostic, health, and life sciences today. This talk will discuss the immunoassays used in a veterinary endocrinology lab for clinical and research testing. The changes in reagents and technology over the decades will be reviewed along with application of the validation criteria (accuracy, sensitivity, specificity and precision), in order to maintain assay quality. Several hor-mone assays used in the lab are reviewed including testing using a recently installed Siemens’ IMMULITE 2000 XPi analyzer.
or being reassured they are not the only one having a problem with a bug in an instrument’s software. For the DACC to remain a strong organization it requires members to take the initiative to step into supporting roles within the group. That can be as simple as attending the Executive Committee meeting in person (they are open to all members) at the Fall or Annual meetings to get a first-hand look at how the organization runs. Then one can volunteer for one of the committees listed in this newsletter or run for the Nominating committee. Eventually as you feel the need to give back to the DACC you might feel led to run for an elected Board position - Treasurer, Secretary, Chair-Elect. What I have described is precisely the path I took to my first time being the Chair of the DACC. So please try to get involved with the DACC even in the smallest way. Knowing the organization and membership on a deeper level can expand your professional opportunities.

Now I would like to applaud some of our members who have made that commitment to DACC leadership. First, Samantha Wildeboer our multiple term Treasurer has graciously agreed to remain as our Treasurer through a transition over to Jeff Burns from Boehringer Ingelheim. Next, we have another returning face represented on the Board as Lisa Blankenship from Charles River Laboratories has graciously run and been elected our Chair-Elect. The Board gains the valuable perspective of the contract lab experience. Madhu Sirivelu who did a fine job as Chair now rotates to the Past-Chair position and maintains his position as newsletter editor. Finally, we welcome Roseanne Riley from Johnson and Johnson to the Secretary position as she transitions with the help of our excellent past Secretary Pete Szczerba.

Please try to have an impact on the current situation whether scientifically through your job, socially through personal connections and actions, or monetarily through donations for hunger relief.

Doug

Doug Thudium

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Roseann received a Bachelor of Science in the area of Clinical Laboratory Science (CLS) from Gwynedd Mercy University in 2002. She has been working in the pharmaceutical drug discovery for eighteen years. She was a Research Scientist at Bristol Myers Squibb in Lawrenceville, NJ in the Discovery Toxicology Department for seventeen years. Roseann is currently at Janssen R&D in Spring House, PA as an Associate Senior Scientist in Non-Clinical Safety Department.

She has been active DACC member since 2004. She has authored and co-authored posters in chemistry and hematology technologies over the years that have been presented at the AACC annual meetings. She has also presented at DACC Spring meetings on new maintenance and troubleshooting procedures for the Siemens Advia 1800, Clinical Chemistry Analyzer.

Roseann recognizes the value of the DACC organization and is happy to work with the Executive Committee serving as the DACC secretary. She is excited to learn, grow and share future innovation of new technologies in the area of clinical laboratory science with the DACC community.
Marjory B. Brooks, BS, DVM, Diplomate ACVIM

to Receive the 2020 DACC Award for Outstanding Contributions to Animal Clinical Chemistry

The Division of Animal Clinical Chemistry (DACC) Award for Outstanding Contributions to Animal Clinical Chemistry was established in 1992 and constitutes a major milestone for our professional society. This Award is now in its 28th year of recognizing significant contributions including teaching, training, practicing and research. This award acknowledges activities and achievements of a scientist who has significantly benefited and advanced the science, as well as enhanced the public awareness and understanding of the discipline of animal clinical laboratory medicine.

This recognition reflects Dr. Brooks’ extensive contributions in science, education and leadership in several areas of animal clinical pathology in comparative coagulation and hemostasis, including canine models of hereditary bleeding disorders, biomarkers of hypercoagulability in animals, to evaluation of Russell’s viper venom time as a test of coagulation in red-tailed hawks for rodenticide exposure. Dr. Brooks has been an innovator and leader in veterinary clinical pathology with a wide diversity of valued contributions in animal clinical laboratory medicine and is recognized as an international expert in comparative coagulopathies, hemostasis and thrombosis. Highly experienced and qualified, some of her accomplishments in research include publications in a variety of research and diagnostic applications ranging from mice & rats to horses, dogs, cats, monkeys and manatees including: a rat model of hypercoagulability, equine herpesvirus type I-induced platelet activation, turbidimetric canine plasma fibrinolysis assay, cold stress syndrome in the Florida manatee, PK and PD of an oral formulation of apixaban in horses, and Factor XI deficiency in cats, among numerous others. Her research has encompassed coagulation Factors VIII, IX, Xa, X and XI across species, diseases and drug effects among others.

Dr. Marjory B. Brooks is presently Senior Research Associate, and Director, Coagulation Section in Animal Health Diagnostic Center, College of Veterinary Medicine, Cornell University, Ithaca, NY. Dr. Brooks obtained a BS in Animal Science (1977) and her DVM (1981) with Distinction at the College of Veterinary Medicine, Cornell University, Ithaca, NY. She became a Diplomate, American College of Veterinary Internal Medicine Specialty in 1988. Following her DVM, Dr. Brooks enjoyed veterinary clinical practice (1981-1988) in New York, NY, prior to her joining the Comparative Hematology Laboratory, Wadsworth Center for Laboratories & Research, NY State Dept of Health, in Albany, NY (1988-1994). She subsequently returned to Ithaca to join the Comparative Coagulation Section, Animal Health Diagnostic Center - College of Veterinary Medicine at Cornell University (1994-present). In addition to lecturing, research and mentoring graduate and undergraduate students, Dr. Brooks has authored or co-authored 107 peer-reviewed manuscripts (some cited above), 50 invited articles and books/chapters, over 65 abstracts/presentations, and more than 180 continuing education presentations in the US and abroad. As an invited expert she has presented on the various aspects of animal coagulation and hemostasis at national and international scientific congresses and professional society meetings including the Society of Toxicology, College of Veterinary Internal Medicine, the International Soc of Thrombosis & Hemostasis and the British Small Animal Veterinary Association.

Dr. Brooks has been an established leader in veterinary clinical pathology with a wide diversity of valued contributions in animal clinical pathology. Marjory B. Brooks, DVM is particularly known for her contributions in comparative hemostasis and coagulopathies: including canine models of hereditary bleeding disorders, biomarkers of hypercoagulability in animals, platelet disorders and von Willebrand disease as exemplified in veterinary reference text chapters such as: the 5th, 6th Editions of Schalm’s Veterinary Hematology (2000 & 2010); and Ettinger, et al. Textbook of Veterinary Internal Medicine, 5th, 6th and 8th editions (2000, 2005 & 2017) and Saunders Manual of Small Animal Practice 1st,2nd and 3rd editions (1994, 2000 & 2006).

Marjory B. Brooks DVM, DACVIM has had many career distinctions, including Phi Kappa Phi and Phi Zeta Veterinary Honor Societies, the ACVECC Scientific Achievement Award, and serving as a member of the Cardiac Biomarkers Working Group of the HESI Cardiac Safety Technical Committee. She remains actively engaged in a number of major veterinary professional societies including the the American Society for Veterinary Clinical Pathology (ASVCP), the American Association for Clinical Chemistry/Division of Animal Clinical Chemistry (AACC/DACC), American College of Veterinary Internal Medicine (ACVIM), American Veterinary Medical Association (AVMA), the Association of Veterinary Hematology and Transfusion Medicine, and the Veterinary Cancer Society.

In summary, Dr. Marjory B. Brooks’ career has been exemplary in her accomplishments and contributions to the practice of and education, teaching, training and advancing research in animal clinical laboratory medicine. Please join the DACC Awards and Executive Committee in celebrating Marjory B. Brooks, BS, DVM, DACVIM as the 2020 recipient of the DACC Award for Outstanding Contributions to Animal Clinical Chemistry.

~ JP Kimball, DACC Awards Committee
Thank you to all who were able to attend the first in a long time Fall DACC Meeting. We received a lot of feedback which spurred a survey sent out earlier this year. We received a good number of replies (N19) and the results are in!

When?

Fig 1: Time of Year Preference
Eighty four percent preferred hosting the meeting in the Fall while sixteen percent did not have a preference between Fall and Spring (Fig. 1).

Where?

Fig. 2: Location Preference
Each respondent ranked locations from their top choice (1) to the least favorite (5). New Jersey and Eastern Pennsylvania tied for the top average 1.5. This was followed in order by Southeastern New York (2.3), Connecticut (2.7), and Boston (3.2).

What to include?

Fig. 3: Meeting Attributes Importance
Similarly, respondents were asked to rank (scale 1 to 3) what do they see as the most important attributes of the meeting (Fig. 3). Speakers (1.4) was the top choice followed closely by the Open Forum (1.6) and then Networking (2.3). The average advance notice requested for meeting details was 10 weeks. Finally, it was unanimous that everyone is interested in a Webinar type meeting the opposite time of year from the in-person meeting (e.g. Spring versus Fall).

In summary, the top choice would be a **Fall meeting** located in **New Jersey or Eastern Pennsylvania** with **good speakers and the opportunity for an Open Forum discussion**.

The DACC leadership appreciates your responses and will look to provide at least a 10 week notice if not more and also put together a WebEx in the off-season. We always appreciate your feedback and would appreciate speaker and topic suggestions that interest you.
2019 AACC Annual Meeting
August 2019
Anaheim, CA

2019 DACC Award for Outstanding Contributions to Animal Clinical Chemistry
Reception Hosted by Siemens Healthineers
(The award recipient, Denise Bounous is on the far right)

Fidelis Olumese, BSc, MBBS, PhD
University of Benin, Nigeria
The DACC Membership Extends a HUGE THANK YOU to Siemens Healthineers for Hosting the DACC Spring Symposium 2019 at Tarrytown, NY & to Sysmex America For Hosting the Meet the Speakers Reception 2019