PARTNERSHIP for the ACCURATE TESTING of HORMONES

STEERING COMMITTEE NEWSLETTER December 12, 2019

PATH UPDATES

- **Save the Date: PATH Steering Committee Meeting –** The annual PATH in-person meeting is scheduled for **Thursday, April 30, 2020** from 8:30 am – 3:30pm and will take place at the Endocrine Society Headquarters in Washington, DC. Additional information and logistics will be distributed in January. We look forward to seeing everyone there!
- **2020 Meeting Dates for Steering Committee Organizations –** We have compiled a list of the available dates for 2020 meetings of Steering Committee organizations below. These meetings provide an opportunity to share information about PATH and accurate testing of hormones through educational sessions and networking. Please review and help us identify specific opportunities at your organization's meeting or others:

PATH Partner	Annual Mtg Date	Location	Abstract Deadline
AACC	July 26-30, 2020	Chicago, IL	February 12, 2020 6pm
APHL	June 8-11, 2020	Portland, OR	January 17, 2020
ASBMR	September 11-14, 2020	Seattle, WA	
ATA	Satellite Symposium Prior to ENDO March 27, 2020	San Francisco, CA	
AUA	May 15-18, 2020	Washington, DC	Late Breaking Abstracts Due January 2, 2020
CAP	October 10-13, 2020	Las Vegas, NV	March 5, 2020 5pm CT
International Society of Andrology	December 9-12, 2020	Munster, Germany	
NAM	September 30-October 3, 2020	Denver, CO	
PES	April 24-27, 2020	Fort Worth, TX	
Endocrine Society	March 28-31, 2020	San Francisco, CA	Late Breaking Abstract Submission Opens January 9, 2020

- **Workshop on Normal Ranges for Estradiol –** PATH helped support the September 23-24 Workshop on Normal Ranges for Estradiol organized by the North American Menopause Society (NAMS). The aim of this workshop was to review existing analytical methodologies for measuring estradiol in postmenopausal women and to assess existing data and study cohorts of postmenopausal women for their suitability to establish postmenopausal reference ranges for estradiol and estrone. The Workshop participants are currently finalizing a White Paper to detail their recommendations and plan to submit to Menopause once completed. For additional details, please contact Dr. Santen or PATH Steering Committee members Alvin Matsumoto, JoAnn Pinkerton, Nanette Santoro, Frank Stanczyk, and Hubert Vesper who led sessions during the Workshop.

NEWS FROM STEERING COMMITTEE MEMBERS

- **CAP –** The College of American Pathologists (CAP) has developed several programs for proficiency testing (PT) to help laboratories measure the absolute accuracy of their assays, including those for testosterone and estradiol.

  A high level of accuracy is clinically important, especially for analytes such a serum creatinine, lipids, hemoglobin A1c, and bilirubin in neonates. Testing accuracy is especially important to patients who are managed using national guidelines. These guidelines require clinical laboratory test results to be very similar to the reference methods that were used to develop national guidelines.

  By participating successfully in a CAP Accuracy-Based Program, a laboratory can easily determine how well its assay results compare with reference methods.

  "Accuracy-Based Programs use genuine pooled human specimens that are free from matrix effects and have target values traceable to certified reference material," said Gary L. Horowitz, MD, FCAP, chair, CAP Accuracy Based Programs Committee. "Thus, these programs are designed for laboratories that want to establish not only that their values match their peers' values but that they match the true values, this is especially important for tests whose values are compared to national or international guidelines rather than local reference intervals. Perfect examples of such tests are Hemoglobin A1c, 25-OH Vitamin D, and testosterone."

  PT and accuracy-based programs have slightly different purposes. While PT measures the proficiency with which a laboratory uses its test systems and enables the laboratory to satisfy regulatory and accreditation requirements, accuracy-based programs both measure

proficiency and enable a laboratory to determine the "trueness" of assays for situations in which a high level of testing accuracy is clinically important.

As PT challenge specimens that are not tested using these reference methods and may contain stabilizers that can impact instrument performance, they cannot be used for measuring an assay's absolute accuracy. PT should, in fact, be used in conjunction with accuracy-based programs to ensure the highest level of accuracy.

Only the CAP's accuracy-based programs allow laboratories to compare their test results with international reference method results. The CAP's accuracy-based programs are:

ABL	Accuracy Based Lipids
ABVD	Accuracy Based Vitamin D
ABS	Accuracy Based Testosterone and Estradiol
ABU	Accuracy Based Urine
ABTH	Harmonized Thyroid
ABGIC	Accuracy Based Glucose, Insulin and C-Peptide
LN24	Creatinine Accuracy Calibration Verification/Linearity
LN15	Hemoglobin A1c Calibration Verification/Linearity
GH5, GH2	Hemoglobin A1c
NB, NB2	Neonatal Bilirubin

- **CDC –**CDC continues to update the lists of certified laboratories for Vitamin D, estradiol, and testosterone procedures. These are available on the PATH website.

If your organization has news to share about what it is doing related to hormone testing, please send to mbecker@endocrine.org so we can post it on the PATH website, forward to the PATH Steering Committee and/or include in our next newsletter.

VISIT THE PATH WEBSITE WWW.HORMONEASSAYS.ORG