



PARTNERSHIP for the ACCURATE TESTING of HORMONES

STEERING COMMITTEE NEWSLETTER July 13, 2020

PATH UPDATES

➤ **New: PATH Website –**

- We encourage all Steering Committee members to visit the PATH website at www.hormoneassays.org where we have added a new animated video about the importance of accurate hormone tests, updates from the CDC, and information about the Workshop on Normal Reference Ranges for Estradiol in Postmenopausal Women and its [final report](#).
- We also encourage all Steering Committee members to let us know if your organization has updates for the website.

➤ **PATH Educational Curriculum –** During our annual meeting, the Steering Committee supported the draft proposed outline for an educational curriculum prepared by Dr. Matsumoto and agreed we should move forward with developing online educational modules. We have established a work group and are working with the Endocrine Society's digital education team on developing the modules. The plan is to create the first module as the introduction to the program and then three additional modules, each 1 hour in length. Each module will contain a didactic presentation, examples from the different topic areas of endocrinology, and case-based questions to encourage greater learning. We are planning to release a module every 4 months, starting in November 2020.

➤ **PATH Initiative with Payors -** PATH co-chairs Drs. Alvin Matsumoto and Hubert Vesper, along with CDC, NACDD, and ES project staff, conducted an introductory call with Avalon Healthcare Solutions on June 18. Avalon is a laboratory benefits manager for health insurance companies including BlueCross BlueShield of North Carolina. During the call, Drs. Matsumoto and Vesper provided background information about PATH and discussed the importance of standardized hormone assays for research and patient care. A follow-up call occurred July 6 to learn more about Avalon and to explore potential opportunities for information-sharing and collaboration. Avalon is interested in promoting to its plan members the importance of using CDC-certified tests. We will continue to explore this opportunity and report back to the Steering Committee with additional details.

NEWS FROM STEERING COMMITTEE MEMBERS

➤ CDC –

- CDC has established a FT4 reference measurement procedure and is creating sera with reference values for laboratories and assay manufacturers. At the same time, ATA is working with CDC to review literature on biological variability to verify current analytical performance criteria for fT4 and TSH assays. It is anticipated that standardization of fT4 will require recalibration of fT4 assays. As a result of this recalibration, values of fT4 concentrations in patients and reference intervals for fT4 may change. CDC is working with stakeholders to facilitate this transition.
- Reference intervals for testosterone in women. After establishing reference intervals for testosterone in men that are linked to the CDC Hormones Standardization Program, establishing reference intervals for testosterone in women that are also linked to CDC's programs is a new priority. Under the leadership of PCOS Challenge: The National Polycystic Ovary Syndrome Association, a workplan is being developed to create this urgently needed information.
- Reference Method for Parathyroid Hormone (PTH): CDC is finalizing work for a new parathyroid hormone (PTH) reference measurement procedure. This new method is part of a new program under development at CDC to standardize PTH measurements. CDC collaborates with the Mayo Clinic to assay PTH as well as PTH fragments in patients with different stages of chronic kidney disease.
- CDC continues to offer standardization programs for:
 - Laboratories and assay developers with calibration and assessment of assay performance - Total Testosterone, Estradiol, Total 25-hydroxyvitamin D,
 - Laboratories and investigators to continuously monitor the accuracy of measurements in patient care and research studies over time through CDC Accuracy-based Monitoring Programs (AMP) for Total 25-hydroxyvitamin D, Total Testosterone in Males, Total Testosterone in Females
 - CDC offers up to 120 different samples for more detailed method verification and characterization for Total 25-hydroxyvitamin D, Total Testosterone and Estradiol. It also offers orientation values of additional steroid hormones (17 α -Hydroxyprogesterone, 17-OHP Androstenedione, Progesterone, Testosterone, Estrone, 17 β -Estradiol, Estrone sulfate, and Dehydroepiandrosterone sulfate) and 24,25-Dihydroxyvitamin D. Customization is available upon request.

- **ATA** – The ATA announces its [Webinar Summer Series!](#) Programs available on-demand now and webinar releases through August. Up next: [July 14: Ablative Technologies for Benign and Malignant Thyroid Disease](#)
- **Endocrine Society** – The Endocrine Society submitted [appropriations testimony](#) to the Senate Appropriations Committee requesting at least \$8.2 billion for the CDC in FY 2021 and highlighting the work and value of CDC's Clinical Standardization Programs.

Upcoming 2020 Meeting Dates for Steering Committee Organizations

We have updated our list of dates for 2020 meetings for Steering Committee organizations taking into account changes because of the pandemic.

PATH Member	Annual Mtg Date	Location
ASBMR	September 11-14, 2020	Now virtual
NAM	September 30 – October 3	Now virtual
CAP	October 10-14, 2020	Now virtual
International Society of Andrology	December 9-12, 2020	Munster, Germany
AACC	December 13-17, 2020 [new dates]	Chicago, IL

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