Put It on the Board, 11/17

Study finds biotin interference

A study published Sept. 26 in *JAMA* found that biotin ingestion was associated with potentially clinically important assay interference in some but not all of the biotinylated assays studied.

The study assessed the association of seven days of 10 mg daily biotin ingestion with the performance of 37 assays that measure 11 hormone and non-hormone analytes: TSH, T4, T3, free T4, free T3, intact PTH, prolactin, NT-proBNP, and 25-hydroxyvitamin D in six healthy adults (two women, four men), and ferritin and PSA in the four men, using four assay systems.

"Biotin interference outcomes were significantly different between biotinylated assays (9 of 23 [39%]) and nonbiotinylated assays (none) (Fisher exact test, *P*=.007)," Danni Li, PhD, and colleagues write (318[12]:1150–1160). The study was conducted at the University of Minnesota, Boston Medical Center, Children's Mercy Hospitals in Kansas City, Mo., and Johns Hopkins Medical Institutions.

"Among the 23 biotinylated assays studied," the authors write, "biotin interference was of greatest clinical significance in the OCD

Vitros TSH assay, where falsely decreased TSH concentrations (to

The smaller changes seen in other assays (OCD Vitros PTH; Roche Cobas e602 TSH, total and free T3, free T4, and 25-OHD; and Siemens Vista free T3) primarily produced false results within the reference range. But the authors note that those results could lead to falsely normal or abnormal interpretations for individuals who start from baseline levels closer to the reference range limits.

Biotin interference with clinical laboratory test accuracy is a complex issue, says Dr. Li, assistant professor and director of clinical chemistry, University of Minnesota Medical Center Fairview. "It depends on biotin dose, the clinical test, last dose of biotin, and renal function of a patient as biotin is cleared by kidney. Furthermore," she tells CAP TODAY, "some diagnostic companies' assays are more affected than others. And the million-dollar question remains: What is the oral biotin use prevalence in the United States?"

The FDA is reluctant to tackle this issue, she says, because the prevalence data are not available and it's unclear to the FDA what specific questions it should address. "Should FDA's role only be to make sure whether package inserts state that biotin is one of the interfering substances, or should FDA play a more active role in making sure companies provide clear instructions on what to do with patients who take large doses of biotin?"

The job of the clinical laboratory community, in Dr. Li's view, is "to come up with clear and easy-to-follow recommendations for clinicians regarding what they should do."

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FDA clears Flu A/B/RSV assay on Hologic's Panther Fusion

Hologic received 510(k) clearance from the FDA for its Panther Fusion Flu A/B/RSV assay running on the Panther Fusion system.

The Panther Fusion is available as a full system or the Panther Fusion module can be attached to existing Panther systems in the field to extend testing capabilities. Panther Fusion adds the capacity to run PCR assays in addition to tests based on transcription-mediated amplification, the proprietary Hologic chemistry that powers the company's Aptima brand.

The Panther Fusion system retains all the key benefits of the Panther platform, including full sample-to-result automation, the ability to run multiple tests from a single sample, random-access processing, continuous loading, and stat capabilities. Additional benefits include a higher throughput of up to 335 Panther Fusion tests in eight hours, or up to 500 Fusion and Aptima tests.

Two additional respiratory panels, the Panther Fusion Paraflu assay and the Panther Fusion AdV/hMPV/RV (adenovirus/human metapneumovirus/rhinovirus) assay, are under FDA review.

Once all three Panther Fusion respiratory assays are cleared, the company says, they will offer a modular approach to testing via the ability to run one, two, or all three assays from a single patient specimen. Panther Fusion assays also use ready-to-use reagents, which offer up to 60-day onboard stability.
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FDA clears Abbott's Alinity ci-series

Abbott has secured FDA 510(k) clearance for its Alinity ci-series instruments for clinical chemistry and immunoassay diagnostics.

The Alinity c clinical chemistry system and the Alinity i immunoassay system can operate individually or as an integrated Alinity ci-series unit, allowing for greater productivity in half the footprint of current diagnostics systems. In addition to the instrument clearance, several clinical chemistry and immunoassay tests are now cleared in the U.S. for the system, with a comprehensive menu of tests expected to be available within a year of launch. The Alinity ci-series obtained CE mark earlier this year and is available in Europe, Middle East, Asia, and Latin America.

"Alinity ci was designed using a different approach. We went beyond traditional market research and spent countless hours with our customers, listening to their challenges and observing how they work," said John Frels, vice president, immunoassay and clinical chemistry research and development.
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Sysmex introduces CyFlow Antibodies for flow cytometry

Sysmex America has introduced CyFlow Antibodies, a portfolio of analyte-specific reagent antibodies for use in flow cytometry applications. The ASR antibody product launch marks Sysmex's entrance into the clinical flow cytometry market. The new portfolio of Sysmex ASRs, available directly through Sysmex, can be used on any flow cytometer platform.

With the initial offering of 79 ASR antibodies, the portfolio will be geared toward core and gating markers prevalent in the flow cytometry community. In the upcoming months, more esoteric markers and fluorochromes will be available to support 10 color flow cytometry applications.
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Test approved for screening Zika in blood donations

The FDA approved in October the Cobas Zika test, a qualitative nucleic acid test for the detection of Zika virus RNA in individual plasma specimens obtained from volunteer donors of whole blood and blood components and from living organ donors.

The test's clinical specificity was evaluated by testing individual samples from blood donations at five laboratory sites, resulting in clinical specificity of more than 99 percent.

The Roche Molecular Systems Cobas Zika test is intended for use on the Cobas 6800 and 8800 systems.
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New insights into female reproductive tract development

The embryological origin of the human vagina has remained contested for more than 80 years. The authors of a new study led by Stanley J. Robboy, MD, and published in *Differentiation* (2017;97:9–22), definitively concluded in their analysis that while the vagina's muscular wall is Müllerian in origin, the epithelium that comes to line the wall beginning in the middle of pregnancy consists of cells of endodermal origin that have ingrown from the embryonic urogenital sinus.

"This investigation offers for the first time a mechanism for how the malignancy, clear cell adenocarcinoma, and its precursor and benign condition, vaginal adenosis, could arise in young women several decades after they were exposed in utero to the drug, diethylstilbestrol (DES), that their mothers had taken during their pregnancies," Dr. Robboy tells CAP TODAY.

During his years at Massachusetts General Hospital, he says, he examined a number of the cancer cases.

"I am already in the process of trying to identify those cases and examine them using the new stains developed over these past years to support or disprove the mechanism advanced," says Dr. Robboy, a past president of the CAP.
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