Put It on the Board

High-sensitivity troponin I assay available in the U.S.

Beckman Coulter Diagnostics received 510(k) clearance from the Food and Drug Administration for its new high-sensitivity troponin assay, Access hsTnI, for use on the Access 2, DxI, and the entire Access family of immunoassay systems.

Access hsTnI demonstrates less than 10 percent CV at the upper reference limits for men and women and detects troponin in more than 50 percent of the healthy population. In an independent study, Access hsTnI detected more than 99 percent of troponin values for healthy men and women (Pretorius CJ, et al. *Clin Biochem.* 2018;55:49–55).

"Beckman Coulter's high-sensitivity cardiac troponin I assay can measure very low cardiac troponin concentrations with excellent precision. This test may help physicians with both the early diagnosis of myocardial infarction and future risk stratification in and outside the acute coronary syndrome setting," Peter Kavsak, PhD, associate professor, Department of Pathology and Molecular Medicine, McMaster University, said in a statement.

FDA clears Afinion HbA_{1c} Dx for diagnosing diabetes

The Food and Drug Administration cleared Abbott's Afinion HbA_{1c} Dx assay for use with the Afinion AS100 analyzer. It's the first point-of-care test to help diagnose diabetes mellitus and assess risk of developing the disease. It will be available in the U.S. late this year.

The Afinion HbA_{1c} assay on the Afinion AS100 analyzer was cleared in 2005 for rapid delivery of hemoglobin A_{1c} results for patient management of diabetes at the point of care. The FDA granted CLIA waiver for the system in 2006. The recent clearance for the expanded diagnostic indication is specific to laboratories with CLIA certification to perform tests that are moderate complexity or higher and does not extend to those that can perform only CLIA waived tests.

The Afinion AS100 analyzer is a compact, rapid, multi-assay analyzer that provides near-patient testing of HbA_{1c} and albumin to creatinine ratio.

Roche, Foundation Medicine reach merger agreement

Roche and Foundation Medicine entered into a definitive merger agreement for Roche to acquire the outstanding shares of FMI's common stock not already owned by Roche and its affiliates at a price of $137 per share in cash. The transaction is expected to close in the second half of this year, with FMI operating as an independent company.

Daniel O'Day, CEO Roche Pharmaceuticals, said in a statement: "This is important to our personalised health care strategy as we believe molecular insights and the broad availability of high-quality comprehensive genomic profiling are key enablers for the development of, and access to, new cancer treatments. We will preserve FMI's autonomy while supporting them in accelerating their progress."

Abbott introduces Alinity

Abbott has introduced the Alinity family of diagnostic systems in the United States. The portfolio of screening systems consists of immunoassay, clinical chemistry, point of care, hematology, blood and plasma screening, and molecular diagnostics.

The company will kick off its introduction of Alinity with the Alinity c clinical chemistry system and Alinity i immunoassay system, which can operate individually or as an integrated system.

Among the features of Alinity are a compact design; flexibility and scalability; proprietary lock-and-key reagent

bottles that fit only in designated positions; an integrated, common interface across instruments; and continuous accessibility, which allows the lab to run any test at any time and replace reagents without stopping the instrument.

The Alinity family of systems features AlinIQ, "a first-of-its-kind, holistic suite of professional services that combines expertise with process analysis and informatics," Abbott said in a statement.

FDA clears Lumipulse G Brahms PCT assay

Fujirebio Diagnostics received Food and Drug Administration clearance of its Lumipulse G Brahms PCT assay for testing on its Lumipulse G1200 immunoassay platform.

Fujirebio says the Lumipulse G Brahms PCT assay offers excellent precision with a CV of ≤4.7 percent and helps in conforming to guidelines for antibiotic stewardship released by the Infectious Diseases Society of America and Society for Healthcare Epidemiology of America.

Study: blood tests effective in screening for sleep apnea

Beckman Coulter announced in June the results of a clinical trial suggesting that blood tests may offer key benefits in the initial screening for obstructive sleep apnea. The study, which involved 264 male adult patients from six institutions, found that screening for changes in three specific biomarkers—HBA_{1c}, CRP, and erythropoietin—may be useful (Fleming WE, et al. *Nature and Science of Sleep.* 2018;10:159–167).

Beckman Coulter offers this panel of three assays on its fully automated platforms.

"The study results demonstrate that sleep apnea induces a characteristic signature cluster of blood biomarker changes," principal investigator and lead author Wesley Elon Fleming, MD, Sleep Center Orange County, Irvine, Calif., said in a statement. "Concurrent elevations of HbA_{1c}, CRP, and EPO levels should generate a high index of suspicion of obstructive sleep apnea, and thus may be useful as an initial screening tool in adult males."

Jon-Erik Holty, MD, MS, of Stanford University School of Medicine and the VA Palo Alto Health Care System, said, "The combination of these three blood tests correlates with the severity of disease and may assist sleep centers in identifying and triaging patients for diagnosis and treatment."

"Important to note," Rohit Budhiraja, MD, of Harvard Medical School and Brigham and Women's Hospital, said in the statement, "is that the blood tests were superior to standard screening methods, such as the Epworth Sleepiness Scale and Stop-Bang questionnaire, in identifying obstructive sleep apnea." The blood tests also demonstrated superiority over the use of body mass index as an indicator in non-obese patients.

Research points to NHS savings with greater use of in vitro diagnostics

Research commissioned by Innovate UK and the British In Vitro Diagnostics Association reveals that the UK's National Health Service could save significant sums within five years through quick adoption of new diagnostic tests as they come on the market.

Patients would benefit from three new tests—for heart attack, preeclampsia, and inflammatory bowel disease—by reducing unnecessary procedures and medication while delivering NHS savings.

The research says the tests are used now in only a handful of clinics and hospitals but that many health experts predict they would save large sums if used more widely. They are high-sensitivity cardiac troponin, placental growth factor, and calprotectin.

Doris-Ann Williams, BIVDA's chief executive, said, "Whilst the shakeup of NHS services and funding so often takes the headlines, simply making the most of the tests we already have would result in dramatic savings."

The report calls on health care leaders and policymakers to reassess how these three high-impact examples, along

with many other diagnostic technologies available now, could be better deployed within the NHS.

BIVDA represents manufacturers and distributors active in the UK. Innovate UK is part of UK Research and Innovation, a nondepartmental public body funded by a grant-in-aid from the UK government.