For Immediate Release

News

Novel Abbott Test That Aids in the Early Diagnosis of Acute Kidney Injury (AKI) Receives CE Mark

Protein Marker Test Aids in the Early Diagnosis of Kidney Injury and Reduces Wait Time from Days to Hours

ABBOTT PARK, Ill., Oct. 6, 2009 — Abbott announced today it has received CE Marking (Conformité Européenne) for a new diagnostic test that detects an important protein in urine, neutrophil gelatinase-associated lipocalin (NGAL), an early marker or indicator for patients with, or at risk of, acute kidney injury (AKI).

NGAL is a novel biomarker that can be detected in urine in as little as two hours instead of days. Early detection can aid in the diagnosis of AKI -- a common condition that can quickly progress to kidney failure if left untreated -- and help physicians better manage patient care. Current tests lack the clinical and timely precision that can help physicians intervene quickly and mitigate the effect of any potential injury.

"Earlier and more accurate differential diagnosis of evolving AKI could result in quicker changes in patient management to make potentially life-saving therapeutic interventions and stop harmful progression," said Patrick Murray, M.D., professor, University College Dublin and Mater Misericordiae University Hospital.

Today AKI is diagnosed with a serum test to measure levels of creatinine, a molecule that is generated from muscle metabolism. However, the test is neither sensitive nor specific for detecting kidney injury. As much as half of normal kidney function could be lost before serum creatinine elevations are detected. This delay in diagnosis prevents physicians from intervening to regulate medications or using hydration or blood pressure support in a timely manner to lower the risk of patient harm.

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"Published studies show that NGAL levels in patients with AKI are 30 times higher compared to normal patients, and urine NGAL measurements assist in the specific and rapid diagnosis of AKI while creatinine blood tests are not able to accurately distinguish AKI from chronic kidney disease," said Sudarshan Hebbar, M.D., senior medical director, Abbott Diagnostics. "From as little as a single drop of urine, we obtain vital information when time is critical to improve patient management. Early information provided by the NGAL urine test could make treatments more timely and effective and reduce costs due to early intervention."

A landmark study published in *Annals of Internal Medicine* in May 2008 reported that urine NGAL can aid in distinguishing acute kidney injury from other forms of kidney dysfunction in emergency room patients. The study showed that urine NGAL is a highly sensitive and specific test that assists in the differential diagnosis of AKI that helps distinguish acute injury from normal kidney function, dehydration and chronic kidney disease.

Abbott’s Urine NGAL assay is performed on the company’s flagship automated laboratory instrument, the ARCHITECT system. The test is now available to hospital laboratories in a targeted group of European countries and will be made more broadly available later this year.

**About Acute Kidney Injury**
AKI is a common and often devastating illness that quickly reduces the ability of the kidneys to filter waste, a condition which can then progress to kidney failure. Common causes of AKI include sepsis, major surgery, cardiogenic shock, trauma and medications toxic to the kidneys. Prompt diagnosis of AKI is critical in reducing mortality, which is as high as 80 percent in post-operative settings. In addition, AKI predisposes those surviving to an increased incidence of chronic kidney disease and end-stage renal disease.
About Abbott’s Diagnostics Businesses
Abbott is a global leader in *in vitro* diagnostics and offers a broad range of innovative instrument systems and tests for hospitals, reference labs, molecular labs, blood banks, physician offices and clinics. With more than 69,000 institutional customers in more than 100 countries, Abbott's diagnostic products offer customers automation, convenience, bedside testing, cost effectiveness and flexibility. Abbott has helped transform the practice of medical diagnosis from an art to a science through the company’s commitment to improving patient care. The history of Abbott is filled with examples of first-of-a-kind diagnostic products and significant technological and research advancements.

About Abbott
Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs more than 72,000 people and markets its products in more than 130 countries.

Abbott’s news releases and other information are available on the company’s Web site at [www.abbott.com](http://www.abbott.com).

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