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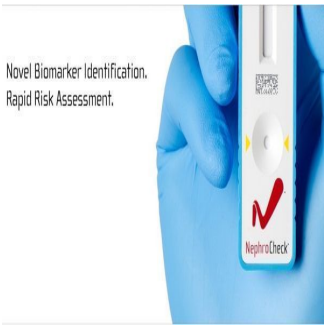
AKI Diagnostic Test Gets FDA Marketing Nod



A new laboratory test to gauge severe acute kidney injury (AKI), developed by Astute Medical (San Diego, CA, USA), has been approved for marketing by the US Food and Drug Administration.

The manufacturer said its new "NephroCheck" test is intended to be used in critically ill, hospitalised patients. The urine-based test can detect whether a patient pool that largely consists of diabetics, the elderly, and those with hypertension are at risk of developing moderate to severe forms of AKI in the 12 hours following the test, the company explained.

AKI can cause fluid build-up, muscle weakness, chest pain, and permanent kidney damage. Current tests can only determine whether a patient has acute kidney injury, and it is important to have a predictive test that could help head off serious and permanent kidney damage, or even death, according to the FDA.

Test Provides Instant Feedback

The NephroCheck test, designed to detect the presence of insulin-like growth-factor binding protein 7 (IGFBP7) and tissue inhibitor of metalloproteinases (TIMP-2), can provide a feedback score within 20 minutes, Astute Medical said.

“Early assessment and timely treatment for AKI can help prevent kidney damage and potential associated complications,” said Alberto Gutierrez, director of the Office of In Vitro Diagnostics and Radiological Health at the FDA’s Center for Devices and Radiological Health. As the NephroCheck test provides clinicians with a fast, validated method of evaluating a patient’s AKI risk status, physicians will be able to make informed decisions for effective management of the patient, he added.

Astute Medical's new diagnostic test went through a de novo premarket review pathway, which is available to low- to moderate-risk medical devices that stand unique from legally marketed devices, the FDA said. Upon completion of two clinical studies involving more than 500 critically ill patients, the NephroCheck was found to be 92 percent effective. However, the diagnostic test gave false positives in about half the patients that did not have acute kidney injury, the FDA noted.

Protein Biomarkers

Astute Medical identifies protein biomarkers found in blood and urine as the basis of its diagnostic tests. In addition to AKI, the company is developing tests for acute coronary syndromes, cerebrovascular injury, abdominal pain, and - more notably - sepsis. As a leader in novel biomarkers research, the company attends and often organises biomarker conferences.

The FDA approval for NephroCheck comes right after a big fundraiser for Astute Medical that brought in about $20 million in July. The well-capitalised company has raised many millions — it brought in $40.2 million in a Series C round in 2012, for example.

Source: MedCityNews.com
Image Credit: Astute Medical

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