FDA OKs marketing of AKI risk-assessment test, 11/14

November 2014—The Food and Drug Administration is allowing the marketing of the NephroCheck test, a first-of-a-kind laboratory test to help determine if certain critically ill hospitalized patients are at risk of developing moderate to severe acute kidney injury in the 12 hours following administration of the test. Early knowledge that a patient is likely to develop AKI may prompt closer patient monitoring and help prevent permanent kidney damage or death, according to the agency.

NephroCheck detects the presence of insulin-like growth-factor binding protein 7 (IGFBP7) and tissue inhibitor of metalloproteinases (TIMP-2) in the urine, which are associated with acute kidney injury. Within 20 minutes, the test provides a score based on the amount of the proteins present that correlates to the patient's risk of developing AKI within 12 hours of the test being performed. No other tests currently on the market are FDA-approved or cleared to assess the risk of developing AKI in at-risk patients.

The FDA reviewed the data for NephroCheck through the de novo premarket review pathway, a regulatory pathway for some low- to moderate-risk medical devices that are not substantially equivalent to an already legally marketed device.

The FDA's review included two clinical studies evaluating the test's safety and effectiveness. The studies compared the clinical diagnoses of more than 500 critically ill patients at 23 hospitals to NephroCheck test results. NephroCheck accurately detected 92 percent of AKI patients in one study and 76 percent in the other. In both studies, NephroCheck incorrectly gave a positive result in about half of patients without AKI.

The NephroCheck Test System is manufactured by San Diego-based Astute Medical.