Vitros NephroCheck test for AKI gets CE mark, 8/17

August 2017—Ortho Clinical Diagnostics launched its Vitros NephroCheck test, a fully automated risk assessment tool for predicting acute kidney injury. The test has received CE mark clearance and is available for purchase in Europe and for use on Ortho's Vitros Systems.

Previously available for testing only on the Astute 140 meter, the NephroCheck test can now run on Ortho's fully automated Vitros 3600/5600 Immunodiagnostic Systems. The urine test provides lab results in 16 minutes, allowing clinicians to assess the risk of AKI and proactively treat at-risk patients.

The Vitros NephroCheck was developed under license from Astute Medical. The test was discovered and validated as an AKI risk assessment tool for the development of moderate to severe AKI in two international clinical trials across 29 sites with more than 1,200 patients combined. It is the only test that can accurately measure two biomarkers of kidney stress, TIMP-2 and IGFB-7, according to a company statement. When these proteins are elevated, which can happen without any signs or symptoms, it indicates kidney stress before kidney damage has occurred and is highly predictive of which patients are most likely to develop AKI, if interventions are not started quickly, according to the company.

Ortho Clinical Diagnostics, 800-828-6316