

## Randox FDA-cleared controls, 6/14

June 2014—Randox's Acusera HbA1c received FDA clearance. It is a 100 percent human whole blood, lyophilized control with assayed values provided for high-performance liquid chromatography and a wide range of clinical chemistry analyzers. When reconstituted the control remains stable for four weeks at 2°–8°C. The control is available in levels 1 and 2, and a calibrator is also available.



Also cleared by the FDA are the Aldolase calibrator and controls and the Ammonia Ethanol control.

Acusera Aldolase calibrator and controls are for testing for liver damage and skeletal muscle diseases. The controls are available in levels 2 and 3 and are lyophilized, with a reconstituted stability of five days at 2°–8°C. The Ammonia Ethanol control is liquid ready to use, with an open-vial stability of 30 days at 2°–8°C, and comes in levels 1, 2, and 3.

The company's Immunology CSF control also received FDA clearance. This multianalyte cerebrospinal fluid control is suitable for use on most clinical analyzers, providing method specific target values and ranges for 11 analytes.

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