

FDA clearance for hematology workcell solution, 12/14

December 2014—Beckman Coulter Diagnostics received FDA 510(k) clearance for its UniCel DxH v3.0 software, which supports automated connectivity of the UniCel DxH 800 and DxH Slidemaker Stainer Coulter Cellular Analysis Systems. The UniCel DxH Connected Workcell solution is available for in vitro diagnostic use. The clearance enables laboratories to connect up to three DxH 800 analyzers to a DxH Slidemaker Stainer to create a customized, scalable workflow solution.

With its automated sample routing, increased data management capabilities, and proven analytical capabilities, the DxH Connected Workcell provides low review rates and first-pass accuracy in results reporting driven by the company's Automated Intelligent Morphology, a multidimensional, high-definition flow cytometric technology.

In combination with the AIM technology, the workcell's bidirectional sample transport system automatically distributes samples between the analyzers, reducing potential delays in sample testing and the reporting of results. The technology also allows for critical stat samples or body fluids to be added while the system is running, without the need to interrupt routine sample testing.

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