Navios flow cytometer cleared for diagnostic use, 11/13

Beckman Coulter Life Sciences has received 510(k) clearance from the FDA and an import medical device registration certificate from the China Food and Drug Administration for the in vitro diagnostic use of the Navios flow cytometry system. In the U.S., the Navios flow cytometer is intended for immunophenotyping in conjunction with proprietary Navios Tetra software and Cyto-Stat TetraChrome reagents.

The Navios incorporates 10 fluorescence detectors and two light-scattering detectors. Simultaneous measurements of integral, peak, and width are available for all scatter measurements and up to 10 fluorescent parameters. Ready-to-use, optimized Cyto-Stat TetraChrome reagents make sample preparation easy. A no-wash protocol reduces sample handling and increases laboratory safety.

Beckman Coulter's Navios Tetra system, for simultaneous identification and enumeration of T, B, and NK lymphocytes in whole blood, provides an easy-to-use solution for multicolor flow cytometric analysis of lymphocyte subsets as well as CD4+ and CD8+ T cell subset ratios.
Navios software reports cellular characteristics such as size, granularity, and phenotype and combines data in one automated, customized report with plots and formulas. A variety of reporting options are available. Easy integration with a variety of automated preparation devices and LIS-readiness offers secure, high-throughput results, even at the highest volumes.

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