FDA clears Streck MDx-Chex for BCID2

Jan. 31, 2022—Streck's MDx-Chex for BCID2, a quality control designed to meet the standards for verifying the performance of the BioFire BCID2 panel assay for sepsis, has been granted FDA clearance for in vitro diagnostics use.

MDx-Chex for BCID2 evaluates the entire analytical process of the assay, including cell lysis, DNA extraction, purification, and removal of PCR inhibitors, as well as qPCR amplification, detection, and analysis. It can be used for assay verification, to track lot-to-lot performance of the BCID2 assay, and to reduce the occurrence of incorrect results due to instrument or assay failures.

The control kit contains 43 bacteria, yeasts, and antimicrobial resistance gene targets packaged in two vials, one for Gram-negative bacteria and one for Gram-positive bacteria and yeasts. The microorganisms are intact, inactivated, and suspended in a matrix of stabilized red blood cells, white blood cells, and blood culture media components.