SeptiCyte Rapid receives 510(k) clearance

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Dec. 3, 2021—Biocartis announced that the FDA granted 510(k) clearance for its SeptiCyte Rapid test, which was developed under partnership with Immunexpress.

The fully automated, host-response test distinguishes sepsis from infection-negative systemic inflammation in patients suspected of having sepsis.

"The 510(k) clearance for SeptiCyte Rapid comes at the right moment in the COVID-19 pandemic, specifically as winter approaches and various respiratory viruses proliferate," Rolland D. Carlson, PhD, CEO of Immunexpress, said in a press statement. "The burden of unceasing COVID-19–related hospitalizations emphasizes the importance of an early and accurate diagnosis of sepsis, especially in intensive care settings where quick action is needed. Moreover, our recent clinical validation study demonstrates that SeptiCyte Rapid continues to be more efficient and effective than traditional methods, which is needed now more than ever."

The test runs on Biocartis' molecular diagnostics Idyll platform and provides results in about one hour.