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Sepsis Test Developers Progress on Commercialization, Market Approvals of Rapid Tests During 2024

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NEW YORK – In 2024, firms in the sepsis testing space made big moves to begin or expand the commercialization of tests that could help reduce the time-to-results, while many also secured funding to compete in an increasingly crowded space.

The emergence of rapid risk stratification tests, including molecular assays, has the potential to give hospitals a new option to determine how aggressively they can treat patients who have suspected sepsis or other severe infections.

Just in the past month, Chicago-based startup Prenosis said that it was preparing for clinical implementation of its AI-developed Sepsis ImmunoScore Software that is used to analyze biomarkers and clinical data to generate a risk score of patients' likelihood of developing sepsis.

Interest in the sepsis testing space was borne out by investments to companies developing tests to get faster results and improvement management of sepsis patients.

For example, San Francisco-based Cytovale received $184 million from its two most recent funding rounds to support the expanded commercialization of its IntelliSep prognostic test that uses high-speed imaging and machine learning for the analysis of cell morphology and immune cell activation. The blood-based semiquantitative test is used to help emergency departments stratify patients by their sepsis risk and provides results in less than 10 minutes,

According to Cytovale officials, the test results were being used at its leading partner hospital in Louisiana, Our Lady of the Lake Regional Medical Center, to save an average of one life per week. The company expects to publish in early 2025 the results of a study with Johns Hopkins University on the impact of serial testing.

Meanwhile, Stanford University spinout Inflammatix has been preparing to launch a 30-minute test for the simultaneous determination in a blood sample of infection type and severity. By September, the firm had raised more than $200 million in private capital, including $57 million from a recent Series E funding round, as well as more than $50 million in grants and contracts. The firm said that it would use the proceeds of its most recent funding round to support regulatory filings and commercialization of the test.

The outlook for 2025

According to Craig Steger, managing director at Outcome Capital, 2024 saw more activity in the sepsis testing space, and he noted the significant financial backing secured by test developers who are pursuing commercialization. He added that the emerging tests that are used to stratify patients by risk scores will impact the market, allowing healthcare providers to more easily determine when to pursue additional testing as well as whether to start treatments more quickly.

Steger said that he expects new tests will emerge in the next few years to quickly identify the pathogens and drug resistances for the patients who are likely to develop sepsis, but those tests likely will be deemed too costly for their use in all patients with suspected sepsis. If risk scoring tests are used first, doctors can better identify which patients should receive the more expensive tests, he said.

He noted, however, that downstream healthcare economic costs are not always considered when providers are comparing the costs of a test, and identifying which patients have sepsis or are likely to develop sepsis could reduce the durations of hospital stays, resulting in healthcare cost savings.

Approvals and clearances

2024 also saw numerous regulatory approvals and clearances that paved the way for new sepsis testing technology to hit the market. Molecular diagnostics firm Immunexpress received expanded FDA clearance in December 2023 for its SeptiCyte Rapid sample-to-answer test, and regulatory clearance from Australia's Therapeutic Goods Administration in January 2024. More recently, the firm announced that study results published in the *Journal of Clinical Medicine* show that SeptiCyte Rapid was able to consistently discriminate between sepsis and systematic inflammatory response syndrome and to stratify patients by clinical severity.

Company officials said early this year that they were focused on the hospital market although elder care and long-term care providers have expressed interest in using the system.

Also, this fall Accelerate Diagnostics secured US FDA 510(k) clearance for its automated blood culture sample preparation platform that is used to shorten the time to result for microbial identification tests and aid the treatment of sepsis. The firm's Accelerate Arc System is used to eliminate the need for overnight culture and lab developed test-related sample preparation methods.

Accelerate also said that it is conducting clinical trials to support an FDA 510(k) submission for its Accelerate Wave antimicrobial susceptibility testing system, which would be used with the Accelerate Arc System to deliver same-shift antimicrobial susceptibility test results.

Meantime, T2 Biosystems nabbed FDA clearance in early 2024 for an extended version of its T2Bacteria syndromic panel for the detection of pathogens that cause bloodstream infections. The test uses the firm's magnetic resonance technology and PCR and is performed on its T2Dx Instrument, with results in three to five hours.

Swiss diagnostics firm Abionic announced in October that it had received FDA 510(k) clearance for its IVD Capsule PSP point-of-care test for the early detection of sepsis. The test is used to measure levels of pancreatic stone protein (PSP) in capillary whole blood or venous whole blood, and it is performed on the company's AbioScope nanofluidics testing platform, with results provided in five minutes.

The company said at the time that study results show that levels of PSP, which is produced by the pancreas and immune cells in response to infections and inflammation, rise days before patients develop symptoms of sepsis. The firm has focused on commercializing its test and platform in Europe, but it has distribution channels around the world and it has been forming a commercialization strategy for the US market.

DeepUll also recently received breakthrough device designation from the US FDA for a sepsis test that is used to detect pathogens directly from blood. The firm unveiled the UllCore BSI Test this spring along with the company's flagship UllCore molecular testing platform. UllCore BSI is a one-hour direct-from-blood multiplex PCR test that targets 95 percent of sepsis-causing pathogens and multiple antimicrobial resistance genes.

The firm also said that it had raised more than €40 million since 2020 and was preparing for a fundraising round.

Even more tests are coming into view as startup firms lay the foundations for the commercialization of new technologies for faster sepsis testing.

Over the summer, Bluejay Diagnostics closed an $8.75 million public offering and said that the company would use the proceeds to fund clinical studies that are needed to obtain FDA approvals for its tests, among other things. The company, which went public in 2021, has been developing its Symphony IL-6 test that is used to measure the interleukin-6 biomarker for the triage and monitoring of patients with suspected sepsis, with results provided in about 20 minutes.

South Korean researchers also reported in July that they had developed a culture-free testing method that could reduce by 40 to 60 hours from the time to treatment of patients with suspected sepsis. The scientists from Seoul National University and the diagnostics firm QuantaMatrix said that their whole-blood-based pathogen identification and antimicrobial susceptibility profiling test uses a synthetic peptide to recover bacterial pathogens and provides results in about 13 hours.

Seoul-based QuantaMatrix has licensed the technologies and plans to develop a fully automated instrument that will integrate pathogen detection, identification, and drug susceptibility profiling.

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