Specific Diagnostics Gearing Up for Commercial Launch of Rapid AST System

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NEW YORK – After spending 2018 and 2019 developing its rapid antibiotic susceptibility testing platform, Specific Diagnostics is readying itself for its first commercial launch later this year.

Specific is beginning its commercial activities in Europe starting in the fourth quarter of 2021 and plans to expand to the US next year, according to its CEO Paul Rhodes. With the addition of former GenMark Diagnostics CFO Johnny Ek to its executive team and Romney Humphries, former CSO of Accelerate Diagnostics, on its scientific advisory board, as well as study results and regulatory clearances, the firm hopes to become a major competitor in the AST space.

Its flagship platform called Reveal uses a proprietary volatile organic compound metabolomic signature technology to provide drug susceptibility information for bloodstream infections directly from positive blood cultures within five to seven hours. The technology has stayed "fundamentally the same" since 2019, with only refinements and product enhancements, such as an information dashboard so customers can monitor trends inside their sample flows, Rhodes said.

The instrument detects small volatile compounds that are byproducts of bacteria's metabolic activity. Those compounds diffuse out of the cell and evaporate, collecting into sensors that change color to detect the presence and kind of bacteria.

Most other AST systems use microscopy to look at bacteria dividing and require optical access into the blood, necessitating the removal of red blood cells from the sample. Reveal, however, doesn't need red blood cells to be removed to run, which can be a difficult process.

The platform is also able to respond to a signal before cell division, allowing for a faster result, Rhodes said.

The Reveal platform received CE marking last October, and earlier this year Specific entered into an evaluation agreement to perform two studies with the French National Reference Centre for Antibiotic Resistance. The first of two evaluations has been completed, validating the accuracy of Reveal with clinical samples.

The second is ongoing and focused on confirmation and characterization of Reveal's sensitivity in detecting and quantitatively characterizing carbapenem resistance.

Meantime, results from five other clinical studies are being reported out, including two additional studies conducted at other hospitals of the Assistance Publique-Hôpitaux Paris that found overall 97 percent concordance versus the current standard of care within approximately five hours. The "same strong performance" has been seen across all of the studies completed so far, Rhodes said.

In June, Specific signed an agreement with BioMérieux to distribute the Reveal system in Europe, and the French firm also invested $10 million in Specific to support commercial activities.

With BioMérieux's help and supporting clinical data, Specific plans to launch its AST test in France and England in Q4, then proceed with a launch in Spain next year. In 2022, BioMérieux plans to expand distribution of the Reveal system to more than 20 countries across Europe.

As Europe prepares to implement new regulations called the IVD Regulation next May, Jeff Holman, the firm's VP of global marketing, said the company is engaged with a notified body and "is well prepared to meet all IVDR requirements within the timeline specified."

Specific's reason for emphasis on the French market is its prominence in AST testing. France is "a very exacting market" with "world-leading" microbiology diagnostics communities and research, as well as demand for AST products, Rhodes said.

"If we can make a real impact in Paris, it would be clear that we could equally successfully … present our product to the key opinion leader lab directors in any city in the world," he added.

In addition, Europe's regulatory clearance process is less burdensome than going through the US Food and Drug Administration's approval pathway. US clearance "takes much more time to put all the pieces in place," Rhodes said.

The Mountain View, California-based firm is running two parallel commercialization efforts across Europe — one with the BioMérieux distribution partnership across all of Europe, including the UK, and a direct effort using Specific's own sales team and the European sites that have been testing the system. Those sites will be pivoting to commercial use of the platform in the fourth quarter, Rhodes said.

US intentions

The firm is also planning entry into the US market. Clinical trials for Reveal are intended to begin in the US in October at five sites: the Cleveland Clinic, Indiana University, Vanderbilt University, Henry Ford Health System, and University Hospitals Cleveland Medical Center. Internal analytical studies at the company will be starting in the second half of September, and the studies are expected to finish within four months, Rhodes said.

Linoj Samuel, the division head of clinical microbiology at Henry Ford Health System, has evaluated the instrument and noted that the benefits of Reveal include its ease of use, while also allowing for a full profile of the bacteria and its susceptibility, enabling clinicians to narrow down the potential treatments for a patient.

While the Reveal platform shares some similarity to Accelerate's Pheno system, Samuel said that the advantage of Reveal is its potential for higher throughput testing. Specific's platform is modular and units can be stacked with a relatively small footprint, allowing for more than one sample to be run at a time. Four samples can be loaded per module.

John Meduri, Accelerate's chief strategy officer, noted via email that Accelerate offers a "stacking stand" that holds up to eight Pheno modules, which "normally exceeds the positive blood culture capacity and throughput requirements for healthcare institutions at any given time point." The Pheno system runs one sample at a time.

He added that "the vast majority of laboratories only need two to three modules for their daily [positive blood culture] sample volumes."

The key for any new technology for AST is to "make sure you're not sacrificing accuracy" for speed, Samuel said, and "so far, what we've seen is promising."

Samuel said real world data is needed to further evaluate the system, which Specific plans to gather with its clinical studies beginning later this year.

Following those studies, Specific intends to submit Reveal to the FDA for 510(k) clearance at the end of January. After the trials begin, Rhodes said the company will consider US distribution partners for the test and platform. He added that the internal sales team already has appointments with US customers, and an early access program in the US will begin in the first quarter of 2022.

While the company isn't releasing US pricing yet, Holman said it will be "less than half" of Accelerate's current pricing.

As for US reimbursement, Rhodes said Specific intends to follow Accelerate's model for rapid multiplex susceptibility testing, although he noted that Specific will have a bigger menu than Accelerate. European reimbursement is slightly trickier, as it is determined by country, he said.

Accelerate's Meduri noted that since the Reveal system isn't cleared by the FDA and specific claims haven't been established, "it's not possible for us to compare antibiotic test menus at this point."

However, he said Accelerate's PhenoTest BC Kit for blood culture is offered in two configurations, one offering microbial identification and AST results directly from a positive blood culture and the other combining labs' existing rapid identification methods with Accelerate's susceptibility testing.

He added that the firm offers "very flexible purchase options" and the customer base "is extremely pleased with our antimicrobial coverage and assay performance."

Further development

Specific's current test menu is for blood infections, with plans to launch rapid tests for time-sensitive isolates in the future, such as pneumonia isolates for patients in the intensive care unit, Rhodes said.

Trials for the isolate dilution test will begin in the first quarter of 2022 after the blood culture test and platform are submitted to the FDA, Rhodes said. "We are nearly ready for" the next menu, he added, but "we want to focus on one at a time." Trials for the new menu will start after the blood test has been submitted to the FDA.

The launch of the isolate test will follow the framework laid out by the blood test, with an introduction in the EU first, then a submission to the FDA next year. The isolate dilution test will have the same five-hour average turnaround time.

Beyond 2022, the firm's road map is laid out. Menu additions are on the table, including other sample types and testing in other drug categories, such as those for fungal infections. In addition, Rhodes said the platform is simple enough that it is "suited actually for any market" in the world and will likely be expanded globally.

He added that the firm has already had preliminary discussions with nongovernmental organizations about the AST test and its applicability across the world.

There are also intentions for a "next-generation" of the system that would introduce more automation and complete integration, as well as products that "go beyond susceptibility testing," Rhodes said.

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