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LABORATORY

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HIGHLIGHTS

TOP OF THE NEWS

T2 Biosystems Has Strong Diagnostic Tool in Fight Against Sepsis 1

Quest Acquires Hartford HealthCare Outreach Business 1

UCSF Launches Center to Focus on Genomic Medicine 2

INSIDE THE LAB INDUSTRY

Outlook for Medium-Size Labs Continues to Show Promise 4

INDUSTRY BUZZ

FDA Releases Report Listing 20 Potentially Dangerous Lab Tests 8

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Lab Revolution

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T2 Biosystems Has Strong Diagnostic Tool in Fight Against Sepsis

A small laboratory company in Massachusetts is taking on one of the biggest killers in the hospital setting.

That would be sepsis, a bloodstream infection that typically evolves from lung, skin or urinary tract infections. Hospital stays for sepsis cases are about 75 percent longer than average, according to data from the Centers for Disease Control and Prevention. And while sepsis can be fought off with antibiotics, its mortality rate hovers around 50 percent.

One of the biggest obstacles to treating sepsis is identifying its presence rapidly, and that is the issue T2 Biosystems is trying to address. The company received approval from the U.S. Food and Drug Administration in September 2014 to market its test, called T2Candida, and its T2Dx platform.

Continued on page 7

Quest Acquires Hartford HealthCare Outreach Business

Quest Diagnostics has made another dip into hospital laboratory outreach, acquiring those specific assets from Connecticut's largest health care system.

The New Jersey-based Quest announced the acquisition of the outreach business of Clinical Laboratory Partners (CLP) earlier this month. CLP is an affiliate of Hartford HealthCare, which operates five hospitals within Connecticut.

The deal is one of several Quest has made for hospital outreach operations in recent years, both in the eastern and western United States. The latest transaction will actually take advantage of a previous outreach deal it made in Massachusetts in 2013 involving University of Massachusetts Memorial Medical Center.

“Over the past decade, many health systems have expanded their outreach lab businesses to service physicians in their area. Now that pattern is shifting, as these same systems reconsider their outreach lab

Continued on page 2

■ T2 BIOSYSTEMS HAS STRONG DIAGNOSTIC TOOL IN FIGHT AGAINST SEPSIS, from page 1

The platform uses magnetic resonance imaging to analyze blood samples based on how water molecules react in the presence of magnetic fields. In the presence of *Candida*, the fungal virus that is among the leading causes of sepsis, the behavior of water in the blood samples is a tip-off. Blood samples are run through a worktop device that is about the size of a dormitory refrigerator. It can process up to seven samples simultaneously and test for five different forms of *Candida*. Test results are usually available within three to five hours.

Sandy Estrada, a Lee Memorial pharmacist with expertise in infectious diseases, said that use of the platform has cut the initiation of anti-fungal drug regimens from 40 hours to just six, and has eliminated use of the medication on sepsis patients who won't respond to such treatment.

Sepsis testing typically requires blood culturing, and if a case is fungal in nature it can take at least a couple of days to lead to a positive diagnosis. The mortality rate for candida-related sepsis cases is about 35 percent when it takes 48 hours or longer to make an accurate diagnosis. That drops to 11 percent if the diagnosis is made in less than 12 hours after a case is suspected.

A strong economic case can also be made for a quicker sepsis diagnosis. A rapid diagnosis cuts treatment costs by about \$30,000, a roughly 23 percent decrease, and reduces the average hospital and intensive care unit stay by about nine days, according to studies made on the subject.

That the platform costs \$150,000—not including the costs of supplies—is apparently not an obstacle for some larger health care systems, according to T2 Biosystems Chief Executive Officer John McDonough. “We are seeing cases where it is literally paying for itself in the first week of operation,” he said.

Although the T2 platform is considered a point-of-care diagnostic that required FDA approval, Medicare has shifted payments for most hospitals treating sepsis to a bundled payment tied to existing DRG codes. McDonough said that meant T2 would not have to go through a long process with Medicare fiscal intermediaries in order to obtain coverage.

At present, 19 of the largest 450 hospitals and health care systems in the U.S. have purchased the testing platform, according to McDonough, with nine occurring during the third quarter of this year.

Among them is the Lee Memorial Health System, which operates four hospitals in Florida. It has run 60 tests since it began using the platform two months ago, six of which tested positive for sepsis caused by candida.

Sandy Estrada, a Lee Memorial pharmacist with expertise in infectious diseases, said that use of the platform has cut the initiation of anti-fungal drug regimens from 40 hours to just six, and has eliminated use of the medication on sepsis patients who won't respond to such treatment.

“We've implemented this pathway and it's working,” Estrada said.

Takeaway: T2 Biosystems' sepsis testing platform could be a game-changer regarding one of the costliest maladies in the hospital setting. 