DiaSorin gets FDA clearance for PCT assay

April 6, 2018—DiaSorin received clearance from the Food and Drug Administration to market the Liaison Brahms PCT II Gen assay for the quantitative determination of procalcitonin.

“I am pleased to announce the addition of the Brahms PCT II Gen assay to our growing specialty menu in the U.S. market”, John Walter, president of DiaSorin, said in a statement. “I’m proud of the great collaboration between various DiaSorin groups that allowed for the rapid clearance of the product. In addition to the assay, the PCT controls and cal verifiers have been cleared for use on the Liason family of instruments.”

Procalcitonin can be used for the diagnosis of sepsis, severe sepsis, and septic shock, the differential diagnosis of clinically relevant bacterial infections and sepsis, the evaluation of the severity of a bacterial infection and systemic inflammatory reactions, the monitoring of the course of treatment of patients with sepsis, and the evaluation of the progression and control of antibiotic treatment.

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