Claros Diagnostics Receives CE Mark Approval for Point-of-care PSA System

I-Micronews

The approved system consists of a small portable analyzer and credit card-sized disposable.

Claros is preparing for the European launch of its urology product and continuing the process to attain regulatory clearance in other markets, including the U.S. *“This approval represents a significant milestone of our overall strategy to create a suite of products for the point-of-care market,”* said **Michael J. Magliochetti**, Ph.D., President and CEO of Claros. *“We will continue to expand the menu within urology and leverage the differentiation of our platform technology across other verticals as a vehicle to transition virtually any complex immunoassay from the reference laboratory to the point-of-care. This CE Mark approval will facilitate the commercial rollout of the system in all of the major world markets that we will pursue.”*

This approval follows the announcement late last year of the receipt of corporate ISO 13485 and CMDCAS certificates of registration by Claros subsequent to its establishment of a new manufacturing facility in 2009 for its microfluidic disposable test cassettes to support clinical trials and market launch. The Claros point-of-care system for PSA provides physicians and patients with accurate, laboratory-quality rapid results during their clinical visit. Healthcare providers experience more efficient clinical workflows and direct reimbursement, while stakeholders enjoy lower total cost of operation and enhanced customer experience.

About Claros Diagnostics Point-of-care System
Claros Diagnostics point-of-care system consists of disposable test cassettes and a small (desktop or handheld) analyzer, which delivers high performance quantitative laboratory blood test results with significant ease-of-use allowing the transition of complex immunoassays and other tests from the centralized reference laboratory to the point-of-care (bedside, physician’s office, etc.). Attractive attributes of the technology include the ability to use a finger-stick of whole blood, automation of all assay steps, multiplexing, on-board controls, cost effectiveness and the delivery of results in minutes. The urology market has been the initial focus to validate the technology, while also serving as a bridge to the true platform nature of the technology encompassing infectious disease, women’s health, cardiology, companion diagnostics, and beyond, with applications in settings throughout the world.

About Claros Diagnostics, Inc.
Claros Diagnostics, Inc. is creating innovative products to transition in vitro medical diagnostic tests from the laboratory to the point-of-care, such as a physician's office or bedside. Claros is a venture-financed company located in Woburn, MA.

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