bioMérieux receives FDA 510(k) clearance for VIDAS® 3, the new generation of VIDAS®

Innovative VIDAS® immunoassays system designed to answer clinical laboratories needs for automation, traceability, quality and optimized workflow

Marcy l'Etoile, France, July 27, 2015 — bioMérieux, a world leader in the field of *in vitro* diagnostics, announces that VIDAS® 3, the new generation of VIDAS®, received FDA 510(k) clearance. This instrument, which further enriches the offering of the VIDAS® immunoassay product range, VIDAS® and mini VIDAS®, is now commercially available in the United States. VIDAS® 3 is CE marked and registered at the Chinese Food and Drug Administration (CFDA) which makes it available to clinical labs on a global scale.

VIDAS® 3 features enhanced automation, in particular the pre-analytical section from the barcoded primary tube including dilution, improved traceability and new software capabilities, as well as a quality control program in compliance with laboratory certification standards. Designed with the help of 1,500 immunoassay laboratories, this new-generation instrument has received an enthusiastic reception by laboratory professionals.

"The VIDAS® 3 analyzer, proved to be a very easy instrument to use with automation, sample handling and intuitive software. Having worked on a study with this analyzer, I have no doubt that the VIDAS® 3 will improve walkaway time and our lab workflow," said Wendy Skinner BS MT(ASCP), Lead Technologist, *BayCare Medical, New Port Richey, FL.*

VIDAS® 3 reinforces the ease of use that has made the VIDAS® range so popular. This low throughput immunoassays platform can perform tests on demand, individually or in series, 24 hours a day and seven days a week. As a result, it is perfectly suited to centralized as well as satellite laboratories, bringing both versatility and reliability to healthcare professionals who are able to optimize their workflows and guarantee the quality of biological testing.

VIDAS® 3 uses the same reagents as the other instruments in the VIDAS® range. At launch in the U.S., VIDAS® 3 menu features specialty and high medical value tests, such as VIDAS® B·R·A·H·M·S PCT™ for the management of septic patients[1]. The single test concept and new features make the VIDAS® 3 particularly well adapted to meet the needs of labs supporting Emergency Departments and Critical Care.

"We are pleased to provide laboratory professionals throughout the world with a best-in-class instrument that combines innovative technology and close to 25 years of solid expertise acquired with the previous generations of our immunoassay platforms, VIDAS® and mini VIDAS®," said François Lacoste, bioMérieux Corporate Vice President, Clinical Unit. "This regulatory clearance will allow us to offer to our U.S. customers the reliability and robustness experience which has already been demonstrated with our European and Asian customers. It is a major step forward in the continuous development of VIDAS® 3 worldwide and an opportunity to fulfill our ambition to make our innovative diagnostic solutions available to as many laboratories as possible."

PRESS RELEASE

[1] VIDAS® B.R.A.H.M.S PCT™ in the U.S. is intended for use in conjunction with other laboratory findings and clinical assessments to aid in the risk assessment of critically ill patients on their first day of ICU admission, for progression to severe sepsis and septic shock

ABOUT VIDAS®

With over 29,000 instruments used by clinical laboratory professionals, VIDAS® has the largest installed base of automated laboratory immunoassay systems in the world[2]. The VIDAS® range makes it possible to meet demand in mature markets for small test series, such as high medical-value, specialty and confirmation tests, while offering the flexibility, reliability and ease of use that are especially well-adapted to needs in emerging countries.
The very broad menu of tests offering 100 clinical parameters allows clinicians to provide diagnosis, monitoring and prognosis for a number of diseases, particularly in the field of infectious diseases and emergency testing.

ABOUT BIOMÉRIEUX

Pioneering Diagnostics

A world leader in the field of *in vitro* diagnostics for 50 years, bioMérieux is present in more than 150 countries through 42 subsidiaries and a large network of distributors. In 2014, revenues reached €1,698 million with 88% of sales outside of France.

bioMérieux provides diagnostic solutions (reagents, instruments, software) which determine the source of disease and contamination to improve patient health and ensure consumer safety. Its products are used for diagnosing infectious diseases and providing high medical value results for cancer screening and monitoring and cardiovascular emergencies. They are also used for detecting microorganisms in agri-food, pharmaceutical and cosmetic products.

bioMérieux is listed on the NYSE Euronext Paris stock market (Symbol: BIM – ISIN: FR0010096479).

Corporate website: www.biomerieux.com - Investors website: www.biomerieux-finance.com

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[2] *CAP Today, July 2015*