bioMérieux strengthens its *Clostridium difficile* offer with the launch of VIDAS® *C. difficile* GDH

VIDAS® *C. difficile* GDH is the 100th assay for use on VIDAS® range

VIDAS® *C. difficile* GDH is the only FDA-approved automated immunoassay parameter for GDH* detection

Marcy l'Étoile, France, February 26, 2014 - bioMérieux, a world leader in the field of *in vitro* diagnostics, is pleased to announce that the launch of VIDAS® *C. difficile* GDH makes it the only company with the width to provide solutions for *C. difficile* according to different laboratory settings, patient conditions and medical needs.

Clostridium difficile is a bacterium recognized as the chief infectious cause of healthcare and antibiotic-associated diarrhea, mainly in elderly patients. In this context, diagnosing *C. difficile* infections is key to improve patient outcome and avoid complications and septicemia. In addition, an accurate and rapid diagnosis enables to stop contaminations at hospitals and reduce high financial expenses associated with such infections.

As the leader in clinical microbiology testing, bioMérieux's ambition is that every infectious disease laboratory will find a solution adapted to its need within bioMérieux *C. difficile* range of products. bioMérieux's offering already includes chromID® *C. difficile* culture media and VIDAS® *C. difficile* Toxin A&B assay for the detection of *C. difficile* Toxins A&B secreted by the bacteria. In line with this long-standing expertise in *C. difficile* control and detection, bioMérieux recently launched VIDAS® *C. difficile* GDH, for the automated detection of GDH, a specific enzyme produced by *C. difficile*. This innovative, qualitative assay will be used as an aid in the diagnosis and treatment of *C. difficile* infections in complement to other *C. difficile* assays. The combination of tests based on GDH, then toxin detection, is recommended by leading international experts as the most valuable *C. difficile* diagnosis solution.[1] VIDAS® *C. difficile* GDH has received CE marking and is the only automated immunoassay cleared by the U.S. Food and Drug administration (FDA).

VIDAS® *C. difficile* GDH was developed and is produced by bioMérieux in France at its Marcy l'Etoile site, where the Company's global headquarters are located. VIDAS® *C. difficile* GDH is used on the VIDAS®, mini VIDAS® and VIDAS® 3 automated immunoassay platforms, providing clinical laboratories with a fully automated, accurate, standardized and cost-effective solution for *C. difficile* diagnosis and infection control. With a reputation for quality and reliability, VIDAS® is the world's largest installed base of automated immunoassay systems in clinical laboratories.

*"*C. difficile *infections are a major concern for both health professionals and hospitalized patients, and are a leading cause of healthcare-associated infections",* said Mark Miller, bioMérieux's Chief Medical Officer. *"We are extremely pleased to enrich our VIDAS® menu with this new test, a welcome addition for our existing offer. Many clinical laboratories will now be able to perform the complete* C. difficile *detection, based on bioMérieux's solutions. With this new launch, bioMérieux shows its commitment to the fight against* C. difficile *infections, providing clinical laboratories with a global offer for* C. difficile *infection diagnosis and management."*

** Glutamate dehydrogenase*

bioMérieux now offers a full solution for *C. difficile*, from identification to epidemiology, in order to answer to all customer needs in all infectious disease laboratories: chromID® *C. difficile* culture media for identification, VIDAS® *C. difficile* GDH and VIDAS® *C. difficile* Toxin A&B for automated and cost-effective identification, Etest® for antibiotic susceptibility testing and DiversiLab®, an epidemiological tool for strain typing. This range should soon be enlarged by the FilmArray® Gastrointestinal (GI) Panel, a molecular diagnostics system enabling to rapidly identify pathogens responsible for infectious diarrhea, including *C. difficile*, in emergency or critical situations. This panel has just been submitted to the U.S. Food and Drug Administration (FDA) for 510(k) clearance.

About *Clostridium difficile*

C. difficile is the main infectious cause of healthcare-associated diarrhea, and can lead to extremely serious and incapacitating pseudomembranous colitis. *C. difficile* is highly contagious, due to its oral-fecal route of transmission and the persistence of spores on inert surfaces. It requires drastic measures involving patient isolation, hygiene and disinfection. It is currently ranked by the CDC (Centers for Disease Control and Prevention) as an "urgent public health threat" requiring immediate and aggressive action.[2]

- In the U.S., *C. difficile* is responsible for an estimated 250,000 illnesses and 14,000 deaths per year[2]
- In Europe, *C. difficile* causes 5% of all healthcare-associated infections, leading to 185,000 infections per year.[3]
- The annual economic burden of CDI is estimated to be $3 billion per year in the US[4] and €3 billion in Europe.[5]
- In 2000, a hyper-virulent strain of *C. difficile*, known as type 027, emerged in Canada and many North American states, and has since spread widely in Europe. This strain type causes more severe infections and is associated with high morbidity and mortality rates (7 to 22% during epidemics in Canada). Between 2000 and 2007, deaths related to *C. difficile* increased 400% in the US, partly due to the increasing spread of the 027 strain.[2]

[1] Planche T D, Davies KA, Coen PG, Finney JM, Monahan IM, Morris KA, O'Connor L, Oakley SJ, Pape CF, Wren MW, Shetty NP, Crook DW, Wilcox MH.; Differences in outcome according to Clostridium difficile testing method: a prospective multicenter diagnostic validation study of C difficile infection. Lancet Infect Dis. 2013;13:936-45
[2] Antibiotic Resistance Threats in the United States, CDC Report 2013
[3] ENVI 2013-04-10 European Report on Patient Safety
[4] Guide to preventing *C. difficile infections*, APIC implementation guide, 2013
[5] Bouza, E. Consequences of *Clostridium difficile* infection. Clin Microbiol Infect. 2012 Dec;18 Suppl 6:5-12

About VIDAS®

With about 28,000 VIDAS®, mini VIDAS® and VIDAS® 3 systems used by clinical laboratory professionals, bioMérieux has the largest installed base worldwide of automated immunoassay systems. Around the world, three VIDAS® tests are performed each second. These systems offer multi-parameter instruments using ELFA (Enzyme Linked Fluorescent Assay) technology, based on a ready-to-use single-sample test concept. The analyses may be run in a series or individually. Launched in 1992, the VIDAS® product range has earned a reputation for quality and reliability. The VIDAS® menu includes 100 parameters covering a wide range of human pathologies: identification and quantification of bacteria, viruses and parasites, antibodies measuring the immunological response to an infection and different proteins circulating in the blood, markers for selected cardiovascular diseases and certain cancers, inflammatory response and hormonal dysfunction.

VIDAS® 3, the new generation of VIDAS®, was granted CE marking in June 2013. VIDAS® 3 features enhanced automation, improved traceability and new software capabilities, as well as a quality control program in compliance with laboratory certification standards. This instrument is commercially available in Europe and the countries that recognize the CE marking. The Company plans to progressively obtain regulatory approval for commercialization in other countries, particularly the United States and China.

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 41 subsidiaries and a large network of distributors. In 2013, revenues reached €1,588 million with 87% 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 market. (Symbol: BIM - ISIN: FR0010096479). Corporate website: www.biomerieux.com - Investor website: www.biomerieux-finance.com.

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