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ELITechGroup SAS
13-15 rue Jean Jaurès
92800 Puteaux • France
Tel: +33 (0)1 41 45 07 10
Fax : +33 (0)1 41 45 07 19
info@elitechgroup.com
www.elitechgroup.com

Product Manager Contact
Audrey Estampes-Barthélemie
Tel : +33 (0)6 16 75 30 01
a.estampes@elitechgroup.com

ELITechGroup Molecular Diagnostics announce the CE-IVD marking of the CRE ELITe MGB[®] Kit, for the detection of the Carbapenem Resistance genes of Enterobacteriaceae

Puteaux, France November 8th, 2016 - ELITechGroup Molecular Diagnostics announce today the CE-IVD marking of the **CRE ELITe MGB[®]** kit, a high-performance, qualitative, multiplex assay for the rapid detection of the Carbapenem Resistance genes of Enterobacteriaceae. In combination with the **ELITe InGenius[™]**, the ELITech Group's fully automated sample-to-result system, the assay is intended to detect 150 variants belonging to the 5 main families of Carbapenem-Resistant genes: **KPC, NDM, VIM, IMP, and OXA-48** like and differentiate the main classes.

Identified in the 1990's, the Carbapenem Resistance Enterobacteriaceae recently became a public-health priority and their spread is currently one of the most challenging health issues throughout the world. Resistant Enterobacteriaceae can cause serious infections which can become very difficult to treat and resulting in higher levels of patient morbidity and mortality. A rapid and reliable CRE detection with molecular methods is crucial to quickly identify infected patients, and provide adapted treatments, prevent transmission, and avoid an outbreak in hospital and healthcare settings.

"The **CRE ELITe MGB[®]** Assay is an advanced molecular assay to better and faster identify patients at risk and improve the fight against the antibiotics resistance in hospitals settings. In combination with ELITe InGenius, it provides a high-performance, full automated, and extremely flexible solution to simplify the lab workflow" said Christoph Gauer, CEO of ELITechGroup. "Indeed the **ELITe InGenius** system enables the user to directly load the patient sample in the transport media without pre-treatment, then all the steps of molecular diagnostics are automatically performed by the ELITe InGenius system, including the results interpretation".

The **CRE ELITe MGB[®]** Assay is a monoreagent, ready-to-use, real-time PCR assay, based on the proprietary Minor Groove Binder Technology (**MGB**). The validation study of the system demonstrated superior performance: analytical sensitivity ranging from 99 to 399 CFU/mL depending on strains, 99.33% clinical sensitivity and 100% specificity on rectal swabs samples.

The **ELITe InGenius** menu already covers the main pathogens involved in healthcare associated infection: **MRSA/SA**, and **C. difficile** and will be further broadened before the end of the year with a new real-time PCR assay to detect Extended-Spectrum Beta-Lactamases (**ESBL**) antibiotic resistance.

Press Release

About ELITechGroup

ELITechGroup, headquartered in Paris, is a global leader in targeted segments of the In Vitro Diagnostics (IVD) market. With R&D and manufacturing facilities in Europe as well as the United States, ELITechGroup focuses on specific segments in clinical chemistry and microbiology and has a strong presence in molecular diagnostics. The company has a broad array of proven PCR assays currently in use across the world for in vitro diagnostic analysis on open systems. These assays take advantage of ELITechGroup's intellectual property portfolio which includes the Minor Groove Binder (MGB), modified bases, and novel fluorophores. Recently, ELITechGroup launched ELITe Ingenius™, a sample-to-result molecular diagnostics system.

About ELITe InGenius

ELITe InGenius is the first sample-to-result solution introduced with a quantitative CE-IVD core menu for transplant pathogen monitoring. ELITe InGenius is an ease-of-use and highly flexible solution integrating all the steps of molecular diagnostics: extraction, amplification and result interpretation, in a single platform with best-in-class and proven technologies for nucleic acid extraction and RT-PCR amplification. Built on ELITechGroup expertise to design, optimize and provide efficient PCR solutions for in vitro diagnostic laboratories, the system was CE-IVD marked for IVD applications in Europe in August 2015 and is also available in the US as Laboratory Use Equipment.

For more information:

Contact ELITech Group (info@elitechgroup.com) or visit our website: www.elitechgroup.com