

Press Release

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Marketing Manager Contact Audrey Estampes-Barthélémie Tel:+33 (0)6 16 75 30 01 a.estampes@elitechgroup.com ELITechGroup Molecular Diagnostics announces the CE-IVD marking of the STI ELITe MGB[®] Panel, for the detection of C. trachomatis, N. gonorrhoeae and M. genitalium

Puteaux, France, 9th June 2017 - ELITechGroup Molecular Diagnostics announces the CE-IVD marking of the STI ELITe MGB[®] Panel: a multiplex assay for the detection of Chlamydia *trachomatis* (CT), Neisseria *gonorrhoeae* (NG) and Mycoplasma *genitalium* (MG), three major bacteria involved in Sexually Transmitted Infections. STIs are a global burden with more than 1 million infections acquired every day worldwide. Accurate and specific detection is important to reduce transmission and complications.

In combination with the ELITe InGenius system, the STI ELITe MGB[®] Panel is the first CE-IVD triplex assay available with a sample-to-result solution to simultaneously detect and differentiate in one single reaction Chlamydia *trachomatis*, Neisseria *gonorrhoeae* and Mycoplasma *genitalium*. Patient samples can be directly loaded into the system, which automatically performs all the steps of molecular diagnostics from extraction to result interpretation with minimal hands-on time. The clinical study has demonstrated excellent performance: respectively 96.4%, 100%, and 100% diagnostic sensitivity and 100%, 98.4% and 98.4% specificity with C. *trachomatis*, N. *gonorrhoeae* and M. *genitalium*

"STI ELITE MGB[®] Panel is the 22nd CE-IVD assay of ELITe InGenius' menu and the first one intended to diagnose sexually transmitted infections. This launch is thus an important milestone in our strategy to offer the broadest infectious disease menu on any sample-to-result system and cover the main clinical applications of molecular diagnostics" commented C. Gauer, CEO of ELITechGroup.

Recently identified, M. *genitalium* is highly prevalent in the general population, and share similar symptoms with C. *trachomatis* and N. *gonorrhoeae*, but their specific antibiotic treatments are not fully efficient to cure M. *genitalium* and generate antibiotics resistance strains. Co-detection of Mycoplasma *genitalium*, along with Chlamydia *trachomatis*, Neisseria *gonorrhoeae* improves the efficiency of STI diagnosis and patient management.

ELITe InGenius offers a unique menu with quantitative and qualitative assays for transplant pathogen monitoring, healthcare associated infections, respiratory infections, meningitis, sexually transmitted infections, and the testing of coagulation factors.

Press Release

About ELITechGroup

ELITechGroup is a privately held group of worldwide manufacturers and distributors of in vitro diagnostic equipment and reagents. By bringing together IVD specialty companies that offer innovative products and solutions, ELITechGroup has become a major contributor in advancing clinical diagnostics to laboratories in the proximity market, those operating closer to the patient. The ELITechGroup manufactures and distributes diagnostic products for clinical chemistry, microbiology, and molecular biology though direct sales and a distribution network encompassing more than 100 countries.

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 ELITechGroup (info@elitechgroup.com) or visit our website: www.elitechgroup.com