

STAT-Dx announces CE-IVD mark completion for DiagCORE[®] System and Respiratory Panel

BARCELONA – 08 January, 2018 – STAT-Dx, a company specialising in the development of advanced molecular diagnostic systems, announces that it has completed CE-IVD marking for DiagCORE[®], its fully-integrated Syndromic Testing System, and its first assay, the DiagCORE[®] Respiratory Panel 1, following the successful completion of evaluation studies. Clinical data from the evaluation studies will be presented by STAT-Dx at the ECCMID 2018 conference, which will take place on 21-24 April, in Madrid.

STAT-Dx anticipates the full commercial launch of the DiagCORE[®] system in Q2 2018, with an initial focus on the European market. Prior to full commercial release, the Company is undertaking a controlled launch phase during Q1 2018, enabling select customers to evaluate the performance and the differentiated benefits of the DiagCORE[®] platform, such as its clinical performance, safety, ease of use, and unique Point Of Care capabilities.

The DiagCORE[®] Respiratory Panel 1, the system's first application, is able to simultaneously detect and identify up to 21 of the most common viral and bacterial pathogens that cause acute respiratory tract infections, and a clinical picture with nearly indistinguishable signs and symptoms. The Panel, which is intended for use with nasopharyngeal specimen, allows effective decision-making about patient management and care, including antiviral or antimicrobial treatment, hospital admission, infection control measures, based on the timely knowledge of the presence or absence of pathogens.

Further panels are under development, with a focus on clinical microbiology and infectious disease applications. The Company expects to CE mark a Gastrointestinal Panel in Q1 2018.

Jordi Carrera, Chief Executive Officer of STAT-Dx, commented: *"This is a key milestone for STAT-Dx and the DiagCORE[®] system, one which paves the way for commercialisation of the system in Europe, on track for 2018. With its simplicity, its unique Point Of Care capabilities and ability to deliver fast, actionable answers, the DiagCORE[®] system has the potential to revolutionise care, improving outcomes for patients and providing an economic benefit to healthcare systems and the wider community."*

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About Syndromic Testing

Syndromic testing, the ability to test simultaneously for the presence or absence of multiple pathogens which may cause or are associated with clinical syndromes, is becoming increasingly important as the diagnostic strategy of choice, offering benefits in patient care, antimicrobial stewardship, infection control, epidemiology and surveillance. STAT-Dx believes that DiagCORE's syndromic testing capability, as well as its convenience and rapid performance, improves clinical decision making, delivers better patient management and generates significant cost savings to the healthcare system.

About STAT-Dx

Founded in 2010 in Barcelona and backed by leading international healthcare investors, STAT-Dx (formerly STAT-Diagnostica) is focused on the development, manufacturing and commercialisation of 'Closer to Care' diagnostic solutions in areas where fast and accurate diagnostic results are crucial such as infectious diseases and critical care. For further information please visit: www.stat-dx.com/

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