



PRESS RELEASE

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ENIGMA DIAGNOSTICS TO DEVELOP CLINICAL DIAGNOSTICS PLATFORM FOR UK NATIONAL CHLAMYDIA SCREENING PROGRAMME

New DNA-based test produces decisive result within minutes

Porton Down, UK – Enigma Diagnostics, the life sciences company developing rapid molecular diagnostics and detection systems, announces that it has successfully completed a project commissioned by the Defence Science and Technology Laboratory (Dstl) to develop a rapid, point-of-care diagnostic system for screening and diagnosis¹ of Chlamydia infections, the most common treatable sexually transmitted infection (STI) in the UK. The project was designed to meet the needs of the UK National Chlamydia Screening Programme (NCSP), part of the National Strategy for Sexual Health and HIV.

Enigma has developed a specific DNA test (assay), reagents and instrumentation capable of rapidly detecting *Chlamydia trachomatis* DNA from multiple urine and, uniquely, swab samples at the point of care (PoC), i.e. in a clinic or outreach centre. Feasibility of the assay has been proven in the laboratory and the product specifications have been validated with sexual health professionals.

The new system will be based on Enigma's fully-automated diagnostics platform, which uses real-time polymerase chain reaction (PCR) technology to detect bacterial target DNA in samples and provides definitive results in a matter of minutes, enabling immediate treatment as necessary. The system will also be very simple to use, requiring minimal training and experience, and importantly will provide 'gold standard' laboratory quality results thereby reducing the need for samples to be sent to a laboratory for analysis. Other point of care diagnostics products for Chlamydia are known to give unreliable results.

John McKinley, Chairman of Enigma Diagnostics, said: "This successfully completed contract with the UK Government demonstrates the utility of Enigma's innovative molecular diagnostics and detection technology. We will develop a system that rapidly and simply delivers laboratory quality results in a clinical environment and therefore meets the needs of the UK National Chlamydia Screening Programme where speed, sensitivity and simplicity are of crucial importance."

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¹ **Screening** is for people in target group who are at risk but don't have symptoms, while **diagnosis** is for people presenting to a healthcare professional with symptoms, where the cause needs to be identified.

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About Chlamydia and the NCSP

Genital Chlamydia trachomatis is the commonest sexually transmitted infection (STI) in England and a significant proportion of cases, particularly among women, present no symptoms. It is easily treated with antibiotics if detected early enough, but if undetected and left untreated, Chlamydia infection can lead to more serious health problems, such as damage to the fallopian tubes, which can lead to infertility or ectopic pregnancy. In addition, 10-30% of infected women develop pelvic inflammatory disease. Chlamydia infection is also the most common cause of inflammation of the testicles in men under 35.

The National Chlamydia Screening Programme is part of the UK government Department of Health's National Strategy for Sexual Health and HIV. The programme aim is to implement and monitor opportunistic screening for genital Chlamydia trachomatis infection for young women and men in selected programmes in England. Ten opportunistic screening programmes were implemented in 2002, with a further 16 programmes announced in January 2004, covering more than 25% of Primary Care Trusts in England. Phase 3 of the programme saw another 50 sites established bringing the total to approximately 80 sites covering the whole of England. Full screening began across England in April 2006.

About Enigma Diagnostics

Enigma Diagnostics Limited is a private UK based company developing the next generation of rapid diagnostic instrument platforms for the detection and identification of infectious organisms, such as bacteria and viruses, in clinical, environmental and biological samples.

Enigma's innovative and proprietary technology combines the speed and sensitivity of real-time PCR (polymerase chain reaction) with the simplicity needed for field-based and point-of-care tests. The Company is targeting a number of multi-billion pound markets, core among which are the clinical, defence and homeland security, and veterinary markets. Enigma's commercialisation strategy is to maximise revenues from a continuous flow of market leading rapid diagnostic point-of-care and in-field instrument and assay platforms, derived from its broad Intellectual Property portfolio of issued and filed patents. Enigma will build an in-house sales and marketing capability to direct distribution of its bespoke products and partner with market leaders where global penetration of markets is required.

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Enigma has an exclusive licence from the Defence Science Technology Laboratory to a portfolio of patents which represent over 15 years of UK Ministry of Defence funded research. Enigma's own R&D activities have added additional patents and design rights based upon its proprietary technologies to generate a portfolio of over 40-plus worldwide patents and patent applications dedicated to real-time PCR and wider rapid technologies. Over 25 of these patents are granted in a range of core territories such as US, EU and Japan with more extensive filing and grants across a number of other key territories for more information visit www.enigmadiagnostics.com