



**Company** Epistem Plc  
**TIDM** EHP.L (AIM)  
**Headline** Epistem Tuberculosis test gains CE-IVD registration  
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**Epistem Plc**  
("Epistem" or "the Company")

### **Epistem Tuberculosis test gains CE-IVD registration**

MANCHESTER, UNITED KINGDOM – (Marketwire: July 9th 2012) - Epistem plc (London AIM:EHP), the biotechnology and personalised medicine company, is pleased to announce the registration of its rapid molecular test for Tuberculosis (TB) test as a CE Marked in vitro diagnostic medical device (CE-IVD). The registration enables Epistem and/or its authorised representatives to place its TB test and Genedrive™ units for sale in the EEA member state markets.

Genedrive™ provides a major advance in next generation molecular diagnostic testing by providing a rapid (30 minute), low cost, simple to use 'Point of Care' device with high sensitivity and specificity. Genedrive™ has applications across a wide range of bacterial, viral and fungal and somatic mutation disease status. Genedrive™ will be targeted at providing 'gold standard' identification of *Mycobacterium tuberculosis* and antibiotic resistance testing and will be priced competitively with traditional less reliable methods of diagnosis such as microscopy and culturing. The World Health Organisation (WHO) has publicly recommended that nations incorporate new rapid molecular tests for tuberculosis into their disease testing programs.

On the back of this CE-IVD registration, Epistem is now preparing regulatory submissions for India in advance of the anticipated launch of its first molecular TB test including patient assessment for antibiotic resistance towards the end of this year.

Commenting on the successful registration of Epistem's first Genedrive™ test, Matthew Walls, CEO said "This is an important milestone for the Company as we move towards our first significant revenue stream in the commercialization of Genedrive"

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#### **Notes for editors**

Epistem is a biotechnology company commercialising its expertise in stem cells in the areas of epithelial (oncology, gastrointestinal and dermatological) and infectious diseases. Epistem develops innovative therapeutics, biomarkers and diagnostics (Genedrive™) alongside contract research services to drug development companies. The Group's core expertise is focused around the regulation of adult stem cells



located in epithelial tissue including the gastrointestinal tract, skin, hair follicles, breast and prostate and utilizing novel and proprietary next generation molecular biology for use in personalised medicine.

[www.epistem.co.uk](http://www.epistem.co.uk)