

The Manager
Company Announcements Office
ASX Limited

LBT INNOVATIONS CONCLUDES APAS CLINICAL TRIAL PROGRAM WITH SUCCESSFUL RESULTS IN SYDNEY TRIAL

Adelaide, 16 November 2015: Australian medical technology company LBT Innovations Limited (ASX: LBT) has received further successful results from a clinical trial of its pioneering culture plate analysis technology, the Automated Plate Assessment System (APAS®), at the SydPath pathology laboratory at St Vincent's Hospital in Sydney.

The results represent the conclusion of an extensive international clinical trial program, which will form the basis of a 510(k) *de novo* submission on APAS to the US Food and Drug Administration (FDA) by the end of 2015.

The Sydney results were similar to those of a major trial of APAS at TriCore Reference Laboratories in Albuquerque, New Mexico, which also tested the technology against a panel of three microbiologists in July and August. The SydPath results showed APAS achieving over 98% sensitivity in its detection of disease-causing bacteria on two of the most widely-used culture media – blood agar and MacConkey agar – in urine samples from 2,122 patients.

The trials at SydPath and TriCore followed an initial trial of the APAS technology at Healthscope Pathology in Melbourne in late 2014. In total, the three trials tested the efficacy of APAS in detecting and reporting pathogenic bacteria in urine samples from more than 10,000 patients.

All of the primary endpoints were exceeded. The trial also achieved a number of secondary endpoints regarding APAS's differentiation and classification of clinical results, with important implications for the automated reporting and integration of patient results with modern laboratory and hospital information systems.

LBT will keep the market informed of the progress of APAS through the FDA regulatory process, which holds the key to registration of the technology as a Class 2 Medical Device in the United States.

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About LBT Innovations

LBT Innovations (LBT) is an Australian developer of clinical and diagnostic technology. Based in Adelaide, South Australia, the Company has two breakthrough products in microbiology automation: MicroStreak®, which provides automation of culture plate streaking, and APAS®, a breakthrough in automated culture plate reading, interpretation and reporting. Based on LBT's innovative intelligent image interpretative platform, APAS specifically addresses the automated imaging, analysis and interpretation of culture plates following incubation. LBT has entered into a joint venture with Hettich AG Switzerland to drive the commercialisation of APAS products. LBT also has a third product in development, WoundVue™, a proposed automation solution to assist in the management of chronic wounds.

For more information, see www.lbtinnovations.com

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