LBT INNOVATIONS
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ASX Limited

AUSTRALIAN CULTURE PLATE ANALYSIS TECHNOLOGY 'EXCEEDS EXPECTATIONS' IN KEY U.S. CLINICAL TRIALS

- *Over 98% sensitivity recorded in detection of pathogenic bacteria in 5,500 urine samples*
- *APAS® software matches findings of team of three independent qualified microbiologists*
- *Pioneering Australian invention on track for submission to FDA by the end of 2015*

Adelaide, 7 October 2015: Australian medical technology company LBT Innovations Limited (ASX: LBT) has received successful results from a pivotal clinical trial of its pioneering culture plate analysis technology, the Automated Plate Assessment System (APAS®), at TriCore Reference Laboratories in the United States.

The trial at the major medical laboratory in Albuquerque, New Mexico, tested the APAS technology against a panel of three microbiologists. The trial protocol and targets for the primary and secondary endpoints were set after consultation with the US Food and Drug Administration (FDA). The results showed that APAS achieved 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 5,500 patients. Blood agar and MacConkey agar are a standard two-plate protocol for culturing urine specimens in US laboratories.

The Albuquerque trial analysed samples from this broad cohort of patients over 10 weeks between June and August 2015. Following incubation, the culture plates were processed by APAS and simultaneously assessed by a panel of three independent qualified microbiologists.

The results of the APAS trial included:

- **Greater than 98% sensitivity in the detection of microbial growth on blood agar**, with a 95% confidence interval width in the order of 1%. The study successfully met the set target of 96%
- **Greater than 99% sensitivity in the detection of microbial growth on MacConkey agar**, with a 95% confidence interval width in the order of 0.5%. The study successfully met the set target of 96%
- **Greater than 98% sensitivity in the detection of microbial growth for the whole sample**, with a 95% confidence interval width of around 0.5%. The study successfully met the set target of 96%
- **Greater than 96% sensitivity for the segmentation of cases with microbial growth typical for urinary tract infections (UTIs)**, with a 95% confidence interval width in the order of 1%. The overall specificity was around 90%, and when there was no growth at all the specificity was around 98%
- **Greater than 98% sensitivity for the detection of microbial growth typical of *E. coli*,** the cause of up to 86% of UTIs in the US and Europe.

All of the primary endpoints were exceeded in the trial, which forms part of LBT's 510(k) *de novo* submission to the FDA. APAS achieved an overall sensitivity of more than 96% in its ability to combine the results from blood agar and MacConkey agar in assessing the presence of bacteria commonly associated with UTIs.

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 laboratory and hospital information systems.

LBT has adopted a two-stage regulatory strategy to de-risk APAS's journey to commercialisation. The company is seeking FDA clearance for a manual version of the technology, while a robotic plate-handling system is simultaneously developed in Europe. The integration of APAS with the robotic plate-handling system – to create an automated plate reader that will be known as APAS Independence® – is considered to be relatively straightforward. The final FDA hurdle for clearance of APAS for the US market will be a much simpler 510(k) supplement to demonstrate that the culture plates are being correctly sorted.

"The results of this major trial far exceeded our expectations and confirm that our ground-breaking technology can match the performance of a highly trained microbiologist," said LBT's CEO, Lusia Guthrie. "The fact that APAS rated so well shows that LBT's technology can be relied upon to replace a repetitive process that accounts for thousands of man-hours in laboratories around the world."

Having completed earlier trials in Australia, LBT is currently awaiting the results of a small trial in Sydney, which will provide the final series of clinical results required by the FDA for consideration of a Class 2 Medical Device. LBT will complete its 510(k) *de novo* submission to the FDA for the manual version of APAS by the end of 2015.

APAS will be brought to market by Clever Culture Systems AG (CCS), a 50:50 joint venture established by LBT with Hettich AG Switzerland. APAS has been licensed exclusively to CCS. Hettich is making good progress in the development of the APAS Independence®, an automated plate-reader which will be the first commercial instrument to incorporate APAS. The 510(k) supplement for APAS Independence is expected to be filed by CCS in mid-2016.

Urine samples represent an estimated 55% of all human samples tested by microbiology laboratories worldwide. Common urinary tract infections such as cystitis and urethritis are one of the most cited reasons for visiting a doctor about an infection and usually necessitate a series of time-consuming culture tests. Globally, millions of agar plates are incubated and assessed each day for the presence of clinically significant bacteria.

However, depending on the source population, the proportion of samples with no microbial growth or no significant growth can be as high as 60-70%. By automating this part of the laboratory workflow, LBT's scientists have developed a screening mechanism that efficiently segments samples with no significant growth and enables microbiologists to focus on the plates with significant growth that hold the key to disease diagnosis. APAS will improve laboratory efficiency and enable results to be delivered to patients and their physicians with much greater speed.

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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

About Clever Culture Systems
Clever Culture Systems AG is the Zurich-based joint venture between LBT Innovations and Hettich AG Switzerland, a world-class laboratory equipment manufacturer based in Switzerland. Clever Culture Systems brings the complementary skills and expertise of both parties to bear in an area of laboratory medicine, microbiology, which is in need of automation.

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