US FDA 510(k) CLEARANCE FOR MRSA ANALYSIS MODULE

Increases APAS® Independence value proposition to cover high volume microbiology samples

Adelaide, Australia, 29 October 2021: Australian medical technology company LBT Innovations Limited (ASX: LBT) (**LBT** or the **Company**), a leader in medical technology automation using artificial intelligence, is pleased to announce that the United States Food and Drug Administration (**FDA**) has given 510(k) clearance for the Company's culture plate reading technology, APAS® Independence with associated MRSA analysis module.

Key Points:

- **FDA clearance for APAS® Independence with MRSA analysis module as Class II medical device**
- **APAS® Independence now cleared for sale in the US with both Urine and MRSA analysis modules**
- **MRSA is a major healthcare issue – one of the leading causes of multi-drug resistant infections**
- **APAS® Independence value proposition now significantly enhanced for US customers**

LBT's 50% owned joint venture company, Clever Culture Systems (**CCS**) received 510(k) clearance for the APAS® Independence with MRSA analysis module as a Class II medical device, enabling the module to be sold commercially to customers in the United States.

MRSA, or Methicillin-resistant *Staphylococcus aureus* is one of the leading causes of multi-drug resistant infections and is a significant and growing healthcare issue in the United States and globally[1]. Patients suffering from MRSA infections are 64% more likely to die than people with drug sensitive infections[2].

The Company now has regulatory cleared analysis modules covering the largest two specimen types by volume - Urine and MRSA.

"This FDA clearance for the MRSA analysis module demonstrates that we continue to lead the way in the use of artificial intelligence for clinical microbiology. It is a testament to the ability of our technical and regulatory teams that no one else has been able to achieve what we have delivered with our APAS® technology," LBT CEO and Managing Director, Brent Barnes said.

"This is a significant achievement for the Company and will support the roll out of the APAS® Independence with Thermo Fisher in the US. To date, we have focussed on larger customers and technology leaders, with a second analysis module we will be able to meet the day-to-day needs of many more laboratory customers in the United States," Mr Barnes said.

A study by Johns Hopkins Hospital found the APAS® Independence successfully identified all positive MRSA specimens, including identifying five positive samples previously missed by the microbiologists.

"The availability of the MRSA analysis module to customers in the United States delivers a high degree of efficiency by automatically reading and reporting the negative MRSA plates which typically account for over 95% of total MRSA workflow," Mr Barnes said.

The FDA clearance will enable customers in the United States to process more tests through the APAS® instrument, delivering increased cost savings for the laboratory.

FDA Clearance

CCS submitted its application to the FDA in March 2020, using the previously cleared APAS® Independence with Urine analysis module as a predicate device. This FDA clearance provides two APAS® products available for the screening of MRSA specimens supporting the most prevalent media types in the United States (see attachment to this ASX). The FDA decision followed a detailed review process including the presentation of clinical data, comparing the performance of the

[1] https://www.mayoclinic.org/diseases-conditions/mrsa/symptoms-causes/syc-20375336
[2] https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance

APAS® Independence against a reference panel of three clinical microbiologists reviewing over 1,500 patient specimens per media type supported.

The APAS® technology remains the first and only regulatory cleared device able to automatically read and interpret growth on microbiology culture plates. This second FDA clearance provides further validation for customers of the APAS® technology for culture plate reading helping to further raise awareness of this technology in the market.

MRSA Healthcare Threat & Testing by US Laboratories

MRSA or Methicillin-resistant *Staphylococcus aureus* is one of the leading causes of multi-drug resistant infections and is often the cause of hospital acquired infections that occur within a healthcare setting. As a result, hospitals typically routinely screen and test for MRSA in all new hospital admissions.

In the United States, MRSA is the second largest specimen type by volume tested by clinical microbiology laboratories and together with Urine specimens, accounts for 50% to 70% of all culture plates processed by laboratories. The use of MRSA as a screening test, results in a very low positivity rate, where typically less than 5% of all MRSA specimens tested are positive for MRSA growth. The MRSA test results are also binary with a sample either containing MRSA or not. This compares to the much higher positivity rate of 20-40% for Urine specimens, which in turn may exhibit any one of a number of potential bacteria that the microbiologist needs to diagnose.

Increased US Market Access & Customer Value Proposition

Along with the existing FDA clearance granted in June 2019 for the APAS® Independence with Urine analysis module, there are now two analysis modules cleared for use on the APAS® Independence in the United States. Each analysis module is sold to customers as a separate software licence and available to customers as a software upgrade. This enables laboratory customers to customise the configuration of the APAS® Independence for their laboratory workflow and range of specimens, as well as increasing the revenue opportunity for each APAS® instrument sold.

With over 5,000 clinical laboratories, the United States is the single largest market in the world. LBT estimates that the addressable market for the APAS® Independence in the United States is over 1,500 laboratories, being those laboratories that have sufficient daily culture plate volume to provide a commercial return on investment for purchasing an APAS® Independence instrument. LBT's strategy is to have a selection of regulatory cleared analysis modules available, providing the flexibility for customers to build the system to suit their laboratory volumes and specimen types.

Approved for release by the Chair of the LBT Board.

– ENDS –

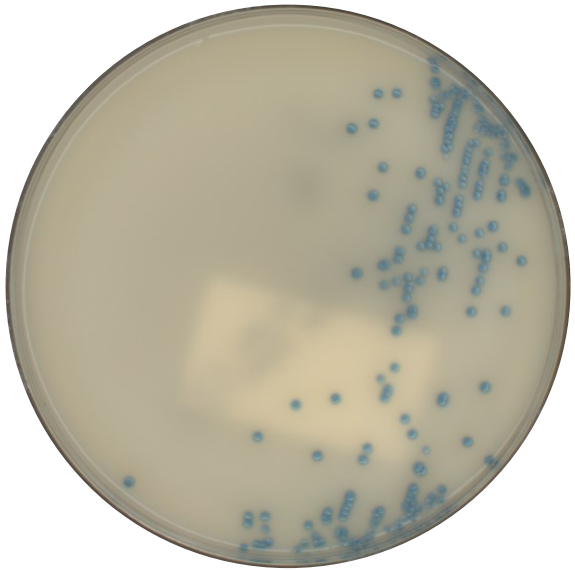
About LBT Innovations
LBT Innovations (LBT) improves patient outcomes by making healthcare more efficient. Based in Adelaide, South Australia, the Company has a history of developing world leading products in microbiology automation. Its first product, MicroStreak®, was a global first in the automation of the culture plate streaking process. The Company's second product, the Automated Plate Assessment System (APAS®) is being commercialised through LBT's 50% owned joint venture company Clever Culture Systems AG (CCS) with Hettich Holding Beteiligungs- und Verwaltungs-GmbH. Beckman Coulter have also been appointed as Marketing Agent in Europe to assist in facilitating sales. The APAS® instrument is based upon LBT's intelligent imaging and machine learning software and remains the only US FDA-cleared artificial intelligence technology for automated imaging, analysis and interpretation of culture plates following incubation.

CONTACTS

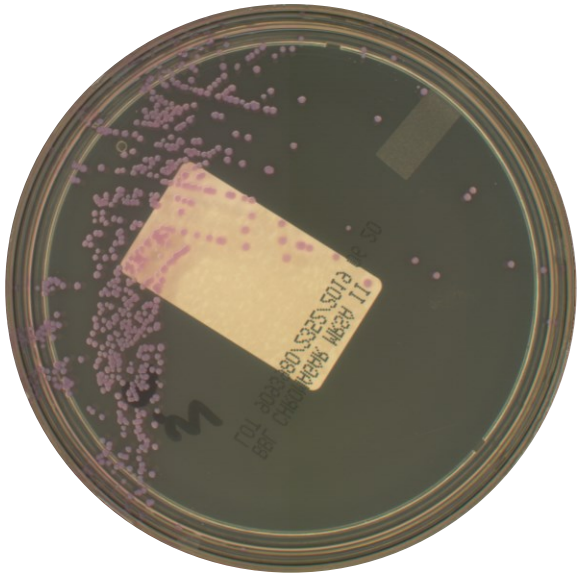
LBT Innovations	Investor Enquiries
Brent Barnes Chief Executive Officer & Managing Director Tel: +61 8 8227 1555 E: info@lbtinnovations.com	**David Allen / John Granger** Hawkesbury Partners Tel: +61 2 9103 9494 E: jgranger@hawkesburypartners.com

APAS® MRSA analysis modules - FDA cleared for use

Two analysis modules supporting the screening of MRSA specimens from two culture media manufacturers



Product Details
Culture Media: Thermo Fisher Scientific Spectra™ MRSA
Description: Detection of blue colonies as Presumptive MRSA



Product Details
Culture Media: BD BBL™ CHROMagar™ MRSA II
Description: Detection of mauve colonies as Presumptive MRSA