RESULTS OF EVALUATION OF APAS® INDEPENDENCE BY JOHNS HOPKINS

APAS® Independence performance: No false negative results and identification of non-diagnosed positive results

Adelaide, Australia, 30 June 2020: 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 the results of an independent evaluation of the APAS® Independence with MRSA analysis module by researchers and laboratory professionals at the Johns Hopkins Hospital and School of Medicine. These results are progressively released as an ePoster at the American Society of Microbiology's (**ASM**) 2020 conference ASM Microbe Online commencing from 22 June 2020. The presentation is titled:

Comparison of an Automated Plate Assessment System (APAS Independence) and Artificial Intelligence (AI) to Manual Plate Reading of Methicillin-resistant *Staphylococcus aureus* Chromagar Surveillance Cultures

The Johns Hopkins MRSA Study and Results

In 2020, The Johns Hopkins Hospital and School of Medicine, Maryland, United States conducted a clinical evaluation of the APAS® Independence to detect the presence of Methicillin-resistant *Staphylococcus aureus* or MRSA as part of their routine infection control surveillance program. The study, using patient samples, assessed the ability of the APAS® Independence with MRSA analysis module to identify culture plates for the presence of MRSA, and compared the results with the current manual plate reading of those same patient samples by a trained microbiologist.

During the three-month study, 4,603 patient samples were read in parallel by both the APAS® Independence and Johns Hopkins microbiologists. The study results demonstrated both the accuracy of the APAS® Independence to identify MRSA as well as its ability to deliver efficiencies within a routine clinical setting. Key findings from the study included:

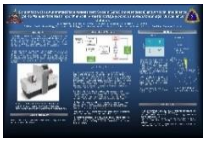
- No false negatives: APAS® Independence achieves 100% Positive Percent Agreement
- APAS® Independence identified a further 3 positive MRSA samples, previously missed by the microbiologists

These results provide a clear demonstration of the technical capability of the APAS® Independence and how the implementation of artificial intelligence and image analysis within laboratories can assist in the management of antimicrobial resistance.

LBT CEO and MD, Brent Barnes said:

"Building independent clinical data from industry leading laboratories such as The Johns Hopkins Hospital is important to support the commercialisation of the APAS® technology and provide a valuable reference for our customers. The findings of this evaluation demonstrate the clinical benefits that can be delivered by the APAS® Independence, not only through workflow efficiencies for laboratories, but also to improve patient care through greater accuracy of culture plate reading. I would like to thank the team at Johns Hopkins for conducting the evaluation."

For full access to the poster please click on the icon below, or the full text can be read in the attached document.



About ASM Microbe Online

The American Society of Microbiology annual ASM Microbe conference is the leading microbiology conference held in the United States, bringing together key laboratory decision makers from around the country. The physical conference in 2020 has been cancelled due to the impact of the COVID-19 global pandemic. Instead the conference will be delivered virtually, bringing new and breaking scientific developments to all ASM members via an online platform. ASM Microbe Online will be accessible from 22 June 2020.

Approved for release by the Chair of the LBT Board.

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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. 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.

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- Comparison of an Automated Plate Assessment System and Artificial Intelligence (ai) to Manual Plate Reading of Methicillin Resistant *Staphylococcus Aureus* Chromagar Surveillance Cultures

January 1, 0001, 12:00 AM - 12:00 AM | ASM Microbe Online

Authors

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Disclosures

N. Gammel: None. **T. Ross:** None. **S. Lewis:** H. Research Contractor; Self; BD Diagnostics, Inc, LBT Innovations, OpGen, MeMed. **M. Olson:** None. **S. Henciak:** None. **R. Harris:** None. **K.C. Carroll:** A. Board Member; Self; Pattern Diagnostics, Inc. H. Research Contractor; Self; BD Diagnostics, Inc, MeMed, LBT Innovations.

Abstract

Background: The Automated Plate Assessment System (APAS) [Clever Culture Systems©, Baech, Switzerland] is an automated imaging station linked with interpretive software that detects pigmented colonies on chromogenic media and triages samples into categories of negative or presumptive positive. We evaluated the APAS instrument's ability to triage Methicillin Resistant *Staphylococcus aureus* (MRSA) cultures accurately compared to human interpretation. **Methods:** Patient samples collected from the nares using Eswabs were plated to BD BBL CHROMagar MRSA II and were incubated for 20-24 h at 37° C in non-CO2. On this medium, a mauve colony is suggestive of MRSA. All mauve colonies are confirmed as ***S. aureus*** by latex agglutination. Following incubation, plates were run on the APAS instrument. The APAS instrument software utilizes AI to interrogate colonies for size, pigment and granularity and analyzes 200 plates/h. Times were recorded as plates were loaded onto the instrument and when all plates had been sorted as negative or presumptive positive. Plates were then scrambled by the operator and handed off to a trained technologist independent of the study. The technologist measured the time to sort plates into positive vs negative and recorded the time to work up presumptive positives. Discrepant analysis was performed by a third reader following confirmatory testing. **Results:** 4,603 BBL Chromagar MRSA plates were read in parallel between the APAS and manual reading. Of these 4603 samples, 261 samples were called presumptive positive by APAS. Manual reading confirmed 170 of these to be true positives, while 92 required discrepant analysis. Discrepant analysis revealed that greater than 50% of APAS false positives were caused by inoculum effect, 13% were caused by agar thinning or breaking, and 27% were due to non-MRSA microbes producing mauve-like pigment. Interestingly, 3% of the discrepant presumptive positives called by APAS were true MRSA missed by manual reading. The PPA and NPA after discrepant analysis were 100% and 98%, respectively. The time motion studies determined a 10% reduction in technologist time per week. **Conclusion**: Compared to manual reading, the APAS demonstrates high accuracy and detected low-level positives missed by manual reading. In a laboratory with a moderate volume of plates (~ 70 per day), modest gains in technologist time are realized. In a laboratory with high throughput MRSA cultures and/or a larger menu of chromagar cultures (e.g. VRE, MSSA), greater efficiencies may be realized.