MRSA STUDY RESULTS WITH APAS® INDEPENDENCE PRESENTED AT ECCMID

The largest global conference for clinical microbiology and infectious diseases taking place in Amsterdam, Netherlands, 13 - 16 April 2019

Adelaide, Australia, 15 April 2019: 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 APAS® Independence German reference site, Labor Dr Wisplinghoff, presented a poster presentation on Saturday 13 April 2019 at the European Congress of Clinical Microbiology and Infectious Diseases (**ECCMID**) in Amsterdam.

The poster presented data from Labor Dr Wisplinghoff's performance evaluation of the APAS® Independence in combination with MRSA Analysis Module for detection of Methicillin-resistant Staphylococcus aureus (**MRSA**). The poster, attached with this ASX announcement and available through the LBT and CCS websites, is titled *"Introduction of artificial intelligence for high throughput culture-based MRSA screening".*

Summary of the MRSA Study and Results

The study evaluated more than 17,000 routine specimens over a 6-month period to evaluate the accuracy of the APAS® Independence AI-based detection of MRSA on chromogenic culture plates when compared to conventional reading by an experienced microbiologist. The results were extremely positive with the APAS® Independence, with the study concluding that:

- In a clinical setting, the APAS® Independence performed with a sensitivity of 100%, and specificity of 98.1%
- The accuracy was at least comparable to conventional microbiologist interpretation, while the system was able to maintain an average throughput of 200 plates per hour.

This study, run in a high throughput routine clinical setting, demonstrated the clinical utility of the APAS® Independence to reliably screen for MRSA and significantly reduce the time to report allowing for technician and microbiologist time to be reprioritised.

The evaluation and study by Labor Dr Wisplinghoff formed an integral part of the development of the MRSA Analysis Modules. LBT is now progressing a clinical study to formally validate the performance of the modules before regulatory clearance can be achieved and the module can be released to market. The Company is on track to have MRSA Analysis Modules available in the EU and Australia in the second half of 2019 under a self-certification process. The MRSA module will be available in the US after FDA clearance is obtained *(for more detail refer ASX Announcement of 2 April 2019)*.

Dr Hilmar Wisplinghoff commented on the study:

"The results of the study demonstrate the speed and reliability of the APAS® Independence to screen for MRSA."

Brent Barnes CEO and Managing Director said:

"Clinical evaluations are important milestones in demonstrating the utility of new medical technologies. In this study the APAS® Independence has consistently delivered excellent results, achieving high sensitivity and specificity, whilst operating in a high throughput laboratory environment."

"I'd like to thank Dr Hilmar Wisplinghoff and his team for their support in conducting this evaluation over the last 6 months."

About ECCMID

ECCMID is the world's premier clinical microbiology and infectious diseases conference, bringing together over 12,000 industry experts, scientists and health professionals. This year's conference is taking place in Amsterdam, Netherlands, 13 – 16 April 2019. As part of the event CCS will be hosting a dinner with talks from LBT's Scientific Director, Dr Steve Giglio,

as well as key opinion leaders from each of the Company's global reference sites. This will provide an opportunity to further showcase the APAS® Independence to an audience of microbiology laboratory directors.

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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.

CONTACTS

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Introduction of artificial intelligence for high throughput culture-based MRSA screening

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Background

- Automating routine procedures in medical laboratories has become a key feature of modern diagnostics in part due to the potential increase in precision and traceability.
- In medical microbiology, automation has – in addition to ID/AST testing – so far largely focused on inoculation.
- In the laboratory, AI-based systems that aid in the plate-reading process may increase the overall sample throughput, and can also improve the workflow and the overall quality by reducing subjectivity and increasing precision of reads.
- The APAS® Independence (APAS ®, Clever Culture Systems, Figure 1) in combination with MRSA Analysis Module was developed and evaluated using over 17,000 routine specimens over a 6 month period. MRSA screening was performed using chromID® MRSA (bioMerieux). Samples were processed using the AutoPlak® (Beckman Coulter), Previ Isola, and evaluated after 24 and 48 hours of incubation. Results of APAS ® AI-based classification were compared to conventional plate reading by experienced medical technicians and microbiologists to determine sensitivity and specificity.

Materials and Methods

- The development of the classifiers is an interactive and iterative process incorporating microbiologist feedback into software development (Figure 2).
- For this study, the MRSA algorithm (classifier) was developed for chromID® MRSA. Samples were processed using the AutoPlak®, Previ Isola, and manual streaking and also imaged by APAS® after 24 and 48 hours.
- Plates inoculated from liquid based microbiology swaps (LBMS, Copan) and from enrichment broth (Thioglycollate, bioMerieux) were used. All samples in this part of the study were read after 18-24 hours, and at 36-48 hours total incubation time by conventional methods (Labtech and microbiologist, plate in hand) and the APAS® system. Results of whether growth was suspicious of MRSA were independently recorded and compared. Discordant results were reviewed by another experienced microbiologist. The study included over 200 unique MRSA strains to challenge the system.
- An average of 400 samples per day were processed in order to determine whether this new automated system could cope with a larger number of samples.

Results

- Improvement of the classifier through the development process is displayed in Figure 3. APAS® AI-based classification results were compared to the microbiologist to estimate sensitivity and specificity.
- Figures 4 shows the analysis of sensitivity and specificity of the APAS system in comparison with conventional plate reading by experienced technicians and microbiologists during routine testing.
- Analysis of discrepant samples resolved all of the initial APAS® false negatives, achieving a sensitivity of 100%.
- A low number of false positives occurred predominantly due to confusion with organisms that were pigmented.
- For known MRSA positive strains, the sensitivity and specificity of MRSA detection using APAS® is 100%.

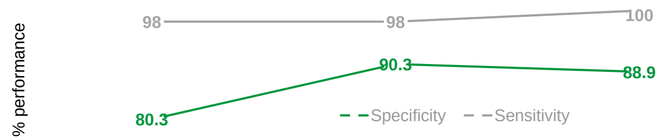

Figure 3: Improvement of the sensitivity of the classifier during the development phase

Figure 1: APAS® Independence

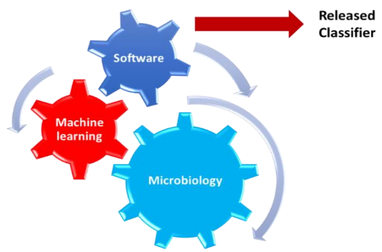

Figure 2: Schematic of machine learning iterations

Conclusions

- ✓ AI-based APAS® was at least comparable to conventional reading, maintaining an average read rate of 200 plates / hour.
- ✓ APAS® reliably screens for MRSA and would significantly reduce time to report and would reprioritize technician/microbiologist time.
- ✓ AI-based systems may provide a great addition to current practices in cultural microbiology.

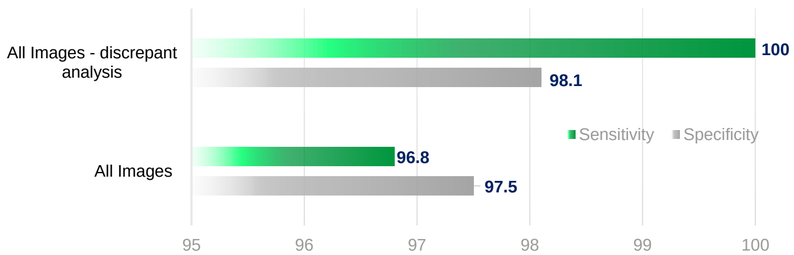

Figure 4: Performance of MRSA classification using APAS ® Independence

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