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SmartNotes

New perspectives on the automated lab: The productivity boosting potential of plate reading AI

By streamlining workflows and freeing up microbiologists to concentrate on what matters most, artificial intelligence (AI) holds the key to many of the field's biggest challenges. Yet despite the technology being ubiquitous in many areas of our everyday lives, laboratories have been slow to adopt it.

Traditionally, there has been a lack of awareness among technicians and early systems had a poor reputation, but all that is starting to change. Now, with the evidence base building for next-generation solutions such as the Clever Culture Systems Automated Plate Assessment System (APAS®), it could be full steam ahead for the AI-driven lab.

Increasing pressures

It's no secret that clinical microbiologists face huge challenges. Requests for "on demand" tests with rapid turnaround times are on the rise, and workforce shortages are rife.

In 2019, the American Society for Clinical Pathology, for example, reported a 10.14% vacancy rate in microbiology laboratories.[1] In addition, it's worth noting that the COVID-19 pandemic, and the associated "Great Resignation", has only served to exacerbate the issue.

In short, laboratories are increasingly being asked to do more with less. It means that ways to drive efficiencies without compromising on quality results have huge value.

Currently, microbiologists spend large amounts of their precious time screening negative cultures and reporting the results. In fact, almost 60%[2,3] of urine culture and more than 90% of MRSA/VRE culture plates are negative.[4] Machine learning (ML), a subtype of AI where computer algorithms are trained to quickly spot patterns within large datasets, could help.

AI in microbiology

AI covers a broad range of machines that seek to emulate human intelligence, from driverless cars to smart speakers. ML is an AI approach that solves specific tasks by learning from datasets and making predictions.

ML aims to augment rather than replace human intelligence. Most machine learning relies on having a human expert annotate data as part of the learning processes. These annotations are used to generate a complex model, with aims to replicate the annotations on unseen data.

In essence, models are programmed to find patterns, and then use what they have learned to make informed decisions.

It delegates repetitive tasks to a computer, allowing the human experts to direct their energies elsewhere and yielding more consistent results for the laboratory. Advanced ML imaging analysis techniques, for example, can screen culture plates to identify negative samples, freeing microbiologists up to focus on the positive results.

Despite the potential benefits of such technology, it's been slow to reach the microbiology laboratory. Roadblocks include a general lack of awareness around the workflow-efficiency benefits, and existing solutions have tended to be challenging to implement and prohibitively complex to integrate with laboratory information systems (LIS).

Steve Giglio, Scientific Director at Clever Culture Systems, explains: "AI uptake has been slow for a number of reasons. At first there was concern around whether it could work, then there was a concern around whether it would replace skilled jobs. After that, the pendulum swung to people expecting it to do absolutely everything, which it cannot do."

Luckily, a new wave of AI technology, designed by microbiologists for microbiologists, is promising to upset the status quo and finally unleash the lab AI revolution.

"I think people now have a better understanding of what AI is and what it can do. There's a greater awareness of its benefits – from a quality, technical, and staff satisfaction perspective – and of its constraints.

"We now understand that it is primarily a screening tool that can eradicate some of the mundane, high-volume work, such as analysis of high negative-specimen tests like urine and infection control samples," said Giglio.

[1]**Garcia et al., 2019.** *The American Society for Clinical Pathology's 2018 Vacancy Survey of Medical Laboratories in the United States*

[2]**Millán-Lou et al., 2018.** *Comparing Two Automated Techniques for the Primary Screening-Out of Urine Culture.*

[3]**Mejuto et al., 2017.** *Automated Flow Cytometry: An Alternative to Urine Culture in a Routine Clinical Microbiology Laboratory*

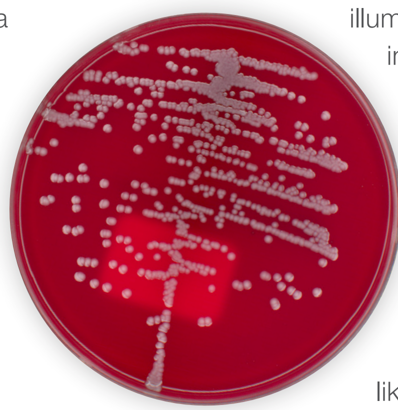
[4]**Hassoun et al, 2017.** *Incidence, prevalence, and management of MRSA bacteremia across patient populations-a review of recent developments in MRSA management and treatment.*

Clever system

One such example is Clever Culture's Automated Plate Assessment System (APAS), known as the APAS® Independence instrument, the first FDA-cleared system for automated culture plate reading and interpretation*.

It uses image recognition technology and ML algorithms to automatically read, interpret, and sort incubated culture plates into those with no significant growth, significant growth, and those needing further review by a microbiologist, said Rhys Hill, Research Director at Clever Culture System's parent company, LBT Innovations.

The system, which the FDA categorizes as a Class II medical device, works by imaging plates and having the computer annotate each pixel as a category of growth or as no growth. Sophisticated algorithms, which have been trained and extensively tested on a datasets of many thousands of plates, then analyze the colonies to determine if they are significant or not.



Hill explained that analysis was a two-stage process that took just 18 seconds. "The first part identifies any growth and decides what type of growth it is (or if it is background agar, debris, or artifacts). The second part then takes that output and converts it into an approximate colony count and morphology designation for the plate.

*For more information, see special use conditions.

"Once you know the type of growth and the number of colonies, you can then run the relevant decision rules to determine the screening result for that particular plate."

Plates marked as negative by the system can be disregarded without the need for manual intervention, freeing up technicians to focus on higher-value tasks.

The whole system is founded, Hill said, on capturing the highest quality image possible. This minimizes variability and drives up reproducibility, making automation as easy and reliable as possible.

"We have put a lot of effort into making sure the illumination is even, and that there is very little interference between the imaging apparatus and the plate itself.

"There is a three-pronged gripper that suspends the plate under the camera and a two-light illumination system, all of which is aligned to within plus- or minus-1mm of the plate to ensure everything is perfectly symmetrical. The images look just like someone is holding the plate," explained Hill.

It means the system can read culture plates in much the same way as a human would, regardless of which way round the plate is entered, whether there are colonies at the edge of the plate, or if labels or marks cause obstructions.

By microbiologists, for microbiologists

In the past, there has often been a gulf between technological capabilities and laboratory requirements – what works well in the controlled development environment doesn't always meet the needs of those working on the front line of microbiological testing, day in day out.

The APAS Independence instrument has been built with this in mind, said Giglio and Hill.

"We have always had a very strong partnership between engineering and microbiology. It's a collaborative approach with an emphasis on engineering out the problems technicians may experience in the laboratory," said Hill.

The system has been trained by a team of microbiologists, for example, and tested according to real-world workflows. As such the Analysis Modules (AI-software) of the APAS Independence have the capability to detect growth with around 98% sensitivity and high specificity in a wide range of common scenarios.

"We tried to replicate every possible thing that could change with the plate in our on-site laboratory," said Hill. "We have tested with a wide range of different stickers from different manufacturers, for example, with different pen writing, different amounts of incubation, and streaking patterns. We have tested with mechanical streaking versus manual streaking, with different transport media, cotton swabs versus polyester swabs."

Its modular design means it can easily be integrated with existing laboratory infrastructure, making it easy to implement, something that many technicians have been calling for. It is also lightweight, meaning it requires minimal footprint allocation.

"AI is often a trade-off between different aspects of performance but having that partnership between engineering and microbiology means we can develop a system based on what really matters on the ground," said Hill.

The evidence base

With plate reading accounting for almost a third of the culture testing workflow, automated reading systems have the potential to significantly boost productivity. But streamlining processes is only worth doing if the quality of results is maintained. It's worth noting, then, that APAS technology is backed by more than 25 publications and posters.

One study compared the results for 2,163 urine cultures read by a reference panel of microbiologists, by the routine laboratory process, and by an APAS, recording a sensitivity rate of up to 99.2% and a specificity rate of up to 99.3%.[5]

"APAS demonstrated high performance in the detection, enumeration, and colony classification of isolates compared with that for conventional plate-reading methods. The device found all cases reported by the laboratory and detected the most commonly encountered organisms found in urinary tract infections," said the authors.

Another submitted 9,224 urine samples to three laboratories. Cultures were prepared on sheep blood and MacConkey agar plates, read by a panel of three microbiologists, then presented to the APAS instrument for image capture and analysis. Where there were discrepant results, the de-identified clinical laboratory reports were also compared with the data generated by APAS and the reference panels.

A pivotal study by Johns Hopkins investigated the use of APAS Independence for the screening of 5,525 MRSA specimens. Positive and negative percent agreements (PPA, NPA) were 100% and 97.3%, respectively. The APAS Independence detected 5 MRSA-positive cultures that were missed by manual reading and determined to be true positives.[6]

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[5] *Glasson, et al., 2016. Evaluation of an Image Analysis Device (APAS) for Screening Urine Cultures*

[6] *Gammel, N., Ross, T.L., Lewis, S., Olson, M., Henciak, S., Harris, R., Hanlon, A. and Carroll, K.C. 2021. Comparison of an Automated Plate Assessment System (APAS Independence) and Artificial Intelligence (AI) to Manual Plate Reading of Methicillin-Resistant and Methicillin-Susceptible Staphylococcus aureus CHROMagar Surveillance Cultures. Journal of clinical microbiology, 59(11), pp.e00971-21.*

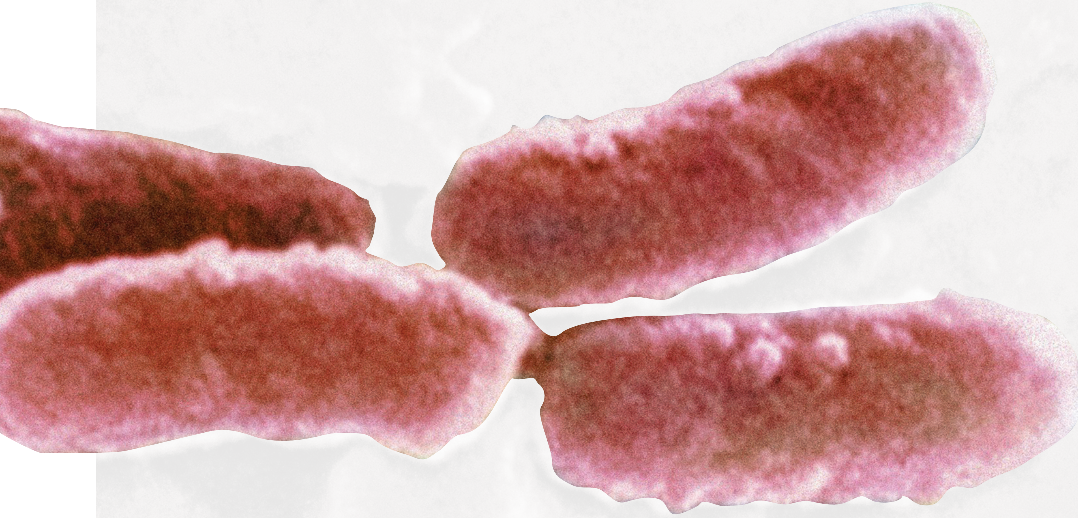
Now is the time

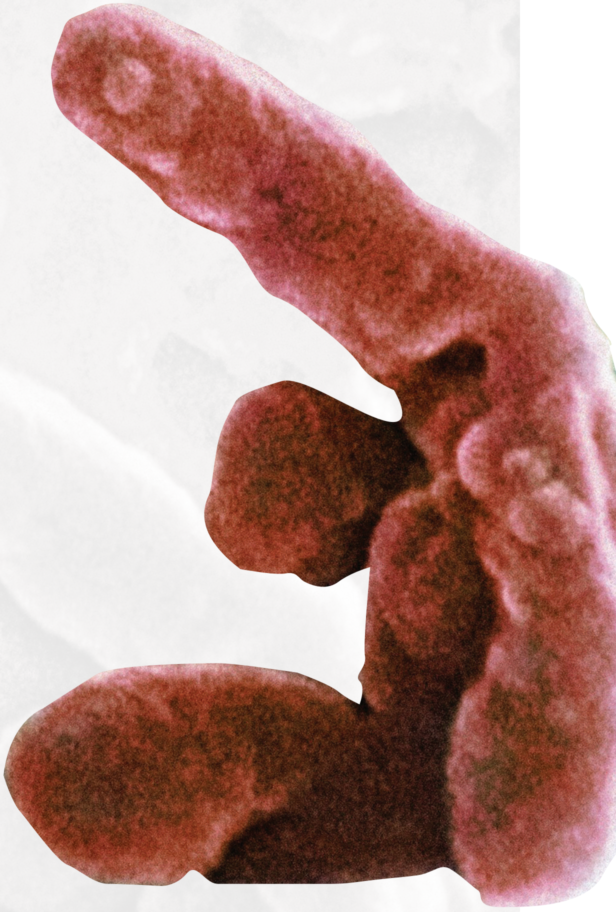
Microbiology has been trailing other sectors in its adoption of productivity-boosting AI technologies, such as ML. But, with sophisticated evidence-backed, laboratory-centric systems such as APAS instrument, the tide is finally turning.

“We have the technology, we have the supporting data, and, with microbiologists in short supply, we have a growing need. That puts us at the right inflection point to bring all of that together,” said Giglio.

The APAS Independence instrument:

- FDA-cleared class II medical device for urine and MRSA analysis modules. For more information, see special use conditions.
- Screens and sorts plates into no growth, significant and non-significant growth at a rate of 200 per hour
- Standalone system built on “plug and play” principles for easy integration with existing laboratory infrastructure
- Lightweight design requires minimal footprint considerations
- System installed and staff trained in just two days
- No manual intervention on negative plates
- Real-time analysis allows plates to be accessed and triaged at any time





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