CLEVER CULTURE SYSTEMS

The first automated culture plate reader

APAS INDEPENDENCE

ARTIFICIAL INTELLIGENCE FOR MICROBIOLOGY

"The APAS Independence is the natural progression from mechanical automation to using artificial intelligence for active decision making within the laboratory."

Glen Hansen, Director of Microbiology, Hennepin County Medical Center

"The APAS Independence helps drive consistency in the laboratory through an objective, automated approach to routine laboratory processes."

Alan Williams, Lead Clinical Scientist, Health Services Laboratories

The APAS Independence is an advanced *in vitro* diagnostic instrument for automated imaging, analysis and interpretation of microbiology culture plates. The world first instrument utilises artificial intelligence algorithms to autovalidate plates showing non-significant bacterial growth, freeing up time and resources to focus on clinically actionable data and other value added tasks.

The APAS Independence is designed to alleviate the bottleneck in culture plate reading to provide a greater level of consistency, traceability and reliability.

Embracing automation in microbiology

As the global demand for diagnostic testing grows, driven by a rise in chronic diseases, aging population and infectious diseases, microbiology laboratories are increasingly expected to deliver quality results with fewer resources whilst under immense time pressure.

Automation has become a key feature of modern diagnostic laboratories due to the potential to offer a greater level of consistency, traceability, and reliability. However, automation in the field of clinical microbiology, especially the reading and reporting of cultures plates, has remained, until now, a highly manual process.

The APAS Independence is a stand-alone automated culture plate reading instrument using advanced artificial intelligence algorithms to overcome the bottleneck in manual culture plate reading. By triaging the no growth and non-significant growth samples out of the workflow, the APAS Independence provides real efficiencies in time and focuses skilled staff on more complex tasks that require their expertise.

70%

Urine up to 70% negative.[2]

95%

MRSA up to 95% negative.[2]

66%

Clinical decisions are based on *in vitro* diagnostic lab results.[3]

43%

Clinical laboratories surveyed reported it is difficult to find personnel.[1]

30%

Medical laboratory positions are being filled by graduates from accredited training programs.[5]

20%

Microbiology staff expected to retire in the next 5 years.[4]

Designed by microbiologists for microbiologists

The APAS Independence triages plates using sophisticated machine learning algorithms built on input from experienced microbiologists.

The APAS Independence intelligent imaging platform employs a high-speed classification system for culture plate screening in real time. The APAS Independence images, interprets, and triages plates into three categories: 'significant', 'non-significant' or 'negative', and 'for review'. Plates showing no significant bacterial growth are identified and triaged to remove them from the workflow without any human intervention required, providing efficiencies for microbiology laboratories around the world.

Unlike Total Laboratory Automation (TLA), the APAS Independence delivers the benefits of standardisation with a small footprint and modular design. It offers flexibility to integrate with different laboratory workflows and alongside the laboratory's existing technologies.

Analysis Modules

The APAS Analysis Modules contain the artificial intelligence engine of the image analysis system. They are the suite of interpretive software packages for assessing growth in cultures from a range of specimens. A separate Analysis Module is developed for each of the most common specimen types received, such as urine and infection control (e.g. MRSA and VRE) screening.

Adding additional Analysis Modules increases the functionality and volume of samples the APAS Independence can interpret, in turn increasing the clinical utility of the instrument for microbiologists.

Available – Routine use	Urine [US, EU, UK, Australia] MRSA [US, EU, UK, Australia]
Available – Research use only (RUO)*	VRE AST Disc Diffusion - APAS-AMR
Pipeline – Future development	CRE ESBL Group A Strep. Group B Strep. Candida

Streamline your workflow

The intuitive nature of the APAS Independence means your workflow remains the same no matter what modules are used.

Training on the instrument is easy, and module-specific training can be added when required.

Step 1

Load plates into the quad stack carriers and place into the instrument.

Up to 60 plates per carrier
Up to 4 carriers
= 240 plates

Step 2

Use the touchscreen to start a session.

Step 3

The APAS Independence takes images of each plate and interprets each one within seconds.

Step 4

Sample results are instantly transferred to the LIS as each sample is processed.

Step 5

Monitor the output stations for actioning as required.

Transfer plates from positive output carriers for further review.

What does the APAS Independence do for your lab

Time Management

Improve your team's efficiency with technology faster than a trained microbiologist to deliver accelerated results.

Accurate

Receive consistent and reliable reports from a market-leading, tried and tested instrument.

Staff Satisfaction

Focus microbiologists on complex significant growth plates that require their expertise whilst reducing potential RSI risks (workplace injury).

Cost Effective

Budget management by avoiding overruns with predictable costs year on year. Only pay for what you need, with the option to add additional capabilities via extra Analysis Modules.

Optimise Staff Utilisation

Increase your laboratory's capacity by freeing up microbiologists to focus on value added tasks and emerging critical testing needs, such as COVID-19.

Quality and Consistency

Reduce reader variation in the manual plate reading process.

Increased Workload

Adding Analysis Modules allows for optimal throughput and increases the clinical utility of the instrument.

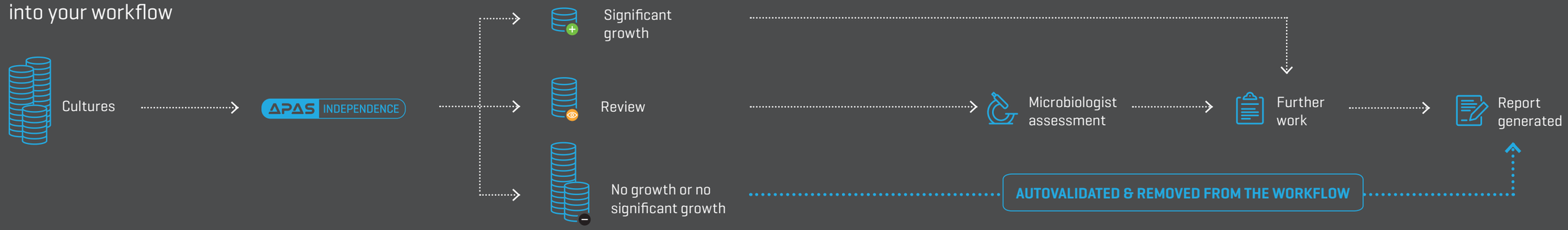
Process Improvement

Optimise laboratory culture plate workflow through automation.

Enhanced Record Keeping

Images and results available for review and easily accessible from workstation.

Incorporating the APAS Independence into your workflow



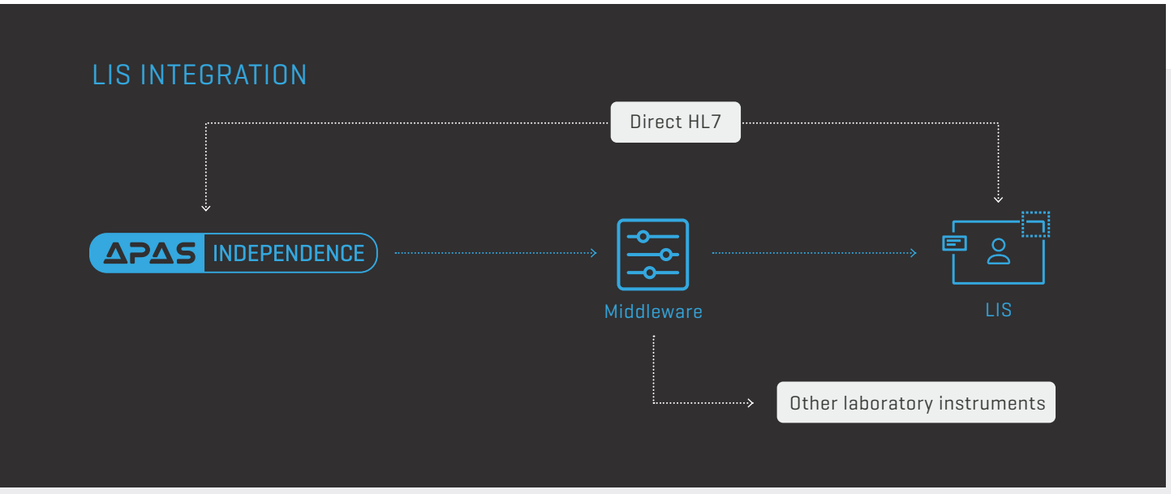
Connectivity and support

Installation
Simple on-site installation which takes less than a day. Instrument has a small footprint, is on wheels and only requires a standard power and ethernet connection to run.

Maintenance
Minimal daily and weekly maintenance schedule.
One preventative maintenance visit required per year.

LIS Connection
Compatible with most Laboratory Information Systems (LIS). Plates with no significant growth can be set by the user to autovalidate, with no human interaction needed.

Easily access reports directly from the workstation for review via the APAS web interface.



Field Support
At Clever Culture Systems we understand that support for your instrument is critical for the continued delivery of quality results. Clever Culture Systems has developed a network of experienced and customer focused support staff on both the software and the hardware aspects of the APAS Independence instrument to ensure quick, reliable, and effective field support.

Australia
LBT Innovations

USA
Thermo Fisher Scientific

UK, Germany, France
oneservice

Proven performance

Read papers in full

The APAS Independence is proven to deliver fast and accurate results that generate real laboratory savings and efficiencies. This has been demonstrated in over 15 clinical studies completed around the world covering over 70,000 specimens across multiple applications.

Evaluation of an image analysis device (APAS) for screening urine cultures[6]

Summary and key outcome

"All cases of clinical infection were detected by APAS and its associated decision algorithm during the study."

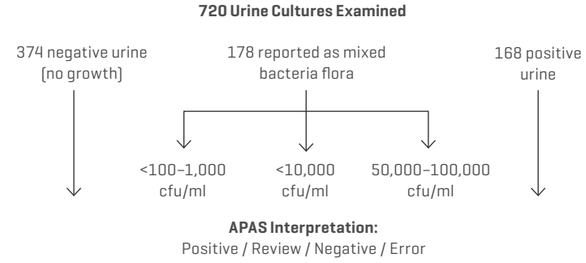
"The morphological identification of colonies showed a high level of performance for the colony types typical of E. coli and other enteric bacilli."

APAS® identification performance by colony type	Sensitivity	Specificity
Blood agar (all)	99.1%	99.3%
MacConkey (all)	99.4%	99.3%
Lactose-fermenters on Blood agar	98.9%	NR
Lactose-fermenters on MacConkey agar	99.2%	98.1%

Intelligent Automation - the first US use of the APAS Independence Delivering Artificial Intelligence for Clinical Microbiology Automation[7]

Summary and key outcome

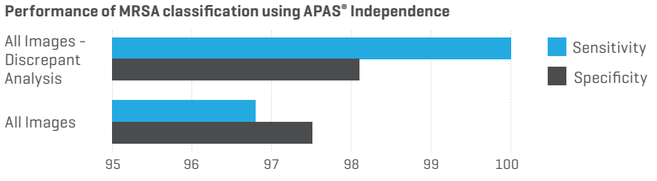
The APAS Independence correctly screened cultures with 100% sensitivity for positive results. A 100% NPV was observed for blood agar analysis. Removing negative and non-significant urine cultures from the workflow reduces laboratory hands-on time with 51.9% reduction in manual review.



Introduction of artificial intelligence for high throughput culture-based MRSA screening[8]

Summary and key outcome

The APAS Independence performed with a sensitivity of 100%, and a specificity of 98.1% for negative identification. The APAS Independence reliably screens for MRSA and would significantly reduce time to report and would reprioritize technician/microbiologist time. Discrepant analysis showed APAS Independence correctly identified positive plates previously missed by microbiologist.



Making a real difference in microbiology

Clever Culture Systems is a leader in clinical microbiology technology, delivering modular automation solutions that maximise laboratory efficiency. Our technologies are designed by microbiologists for microbiologists to ensure our products not only meet the needs of the laboratory but also seamlessly integrate within our customer's workflow. Our team are highly experienced in biotechnology, laboratory automation, diagnostics and microbiology.

Clever Culture Systems is an LBT Innovations company.

LBT INNOVATIONS

References

[1]Bennett, A., Thompson, N.N., Holladay, B., Bugbee, A. and Steward, C.A., 2009. ASCP wage and vacancy survey of US medical laboratories. Laboratory Medicine, 40(3), pp.133-141. [2]Manickam, K., Karlowsky, J.A., Adam, H., Lagacé-Wiens, P.R., Rendina, A., Pang, P., Murray, B.L. and Alfa, M.J., 2013. CHROMagar Orientation medium reduces urine culture workload. Journal of Clinical Microbiology, 51(4), pp.1179-1183. [3]Rohr, U.P., Binder, C., Dieterle, T., Giusti, F., Messina, C.G.M., Toerien, E., Moch, H. and Schäfer, H.H., 2016. The value of in vitro diagnostic testing in medical practice: a status report. PloS one, 11(3), p.e0149856. [4]Garcia, E., Kundu, I., Ali, A. and Soles, R., 2018. The American Society for Clinical Pathology's 2016-2017 vacancy survey of medical laboratories in the United States. American journal of clinical pathology, 149(5), pp.387-400. [5]Cortelyou-Ward, K., Ramirez, B. and Rotarius, T., 2011. The laboratory workforce shortage: a managerial perspective. The Health Care Manager, 30(2), pp.148-155. [6]Glasson, J., Hill, R., Summerford, M. and Giglio, S., 2016. Evaluation of an image analysis device (APAS) for screening urine cultures. Journal of clinical microbiology, 54(2), pp.300-304. [7]Hansen G., Bujold, A., Cox, A., Hanson, K., Wesenburg, E., 2019. Intelligent Automation- the first US Use of the APAS Independence. ASM Microbe. [8]Aurbach U, Wirth S, Gigilo S, Pohl B, Wisplinghoff H., 2019. Introduction of artificial intelligence for high throughput culture-based MRSA screening. ECCMID 2019.

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Physical Specification

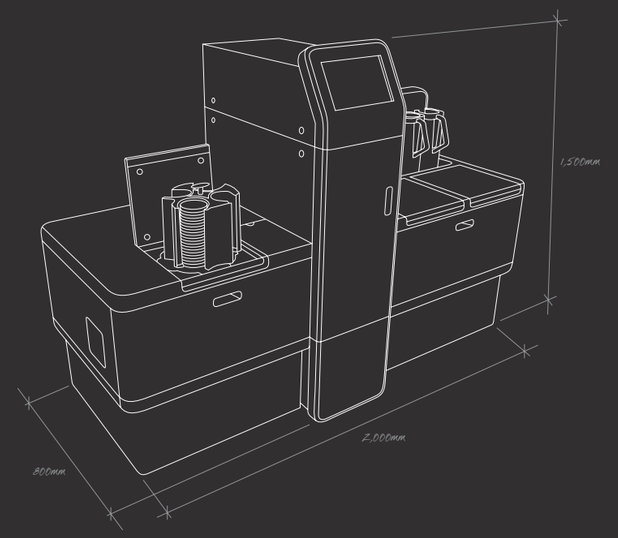
General Description	APAS Independence is an Automated Culture Plate Reader		
Imaging Time	Minimum throughput 200 plates per hour		
Input Stack	4 cassettes / 60 plates per cassette		
Plate Compatibility	Full plates/bi-plates		
Dimensions (L x W x H)	2000mm x 800mm x 1600mm	78.74" x 31.5" x 62.99"	
Configuration	Freestanding		
LIS Interface	HL7 Version 2		
Weight	330kg	727.5lb	
Operating Environment	Ambient temperature range	15°C–27°C	59°F-81°F
	Humidity: 20%-80% (non-condensing indoor use)		
	Altitude: Sea level to 2000m	6562ft	
Noise Specifications Noise level shall not exceed:	Continuous: 58dBA at 1m	3.3ft	
	Peaks: 70dBA at 1m	3.3ft	
Electrical Input	100-240VAC, 50-60Hz, 6 Amps		
Warranty	12 months from date of commissioning		
Regulatory Cleared	United States (FDA)		
	Europe (CE mark, UKCA)		
	Australia (TGA)		

Analysis Modules

General Description	APAS Independence suite of interpretive software packages of assessing growth in cultures from a range of specimens
Available Analysis Modules	Urine (US, EU, UK, Australia)
	MRSA (US, EU, UK, Australia)
Available Analysis Modules (RUO)*	VRE Analysis Module
	AST Disc Diffusion - APAS-AMR Analysis Module

Further Analysis Modules such as CRE, ESBL, Group A & B Strep. and Candida specimens are for potential future developments.

Compliant with the following standards ISO 13485:2003, IEC 62304: 2006, UL 61010-1: 2004; 3rd edition, 2002/96/EC, 2011/65/EU.



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