



Lab automation

Clever Culture Systems APAS[®] Independence instrument

Maximize efficiency with the first
automated culture plate reader

Making a real difference in microbiology

The APAS Independence instrument is an innovative, FDA-cleared and CE-marked *in vitro* diagnostic instrument for automated imaging, analysis and interpretation of agar culture plates. As the first instrument of its kind, it utilizes the breakthrough Automated Plate Assessment System (APAS) imaging technology and artificial intelligence algorithms to analyze an image of agar plates, categorising them as 'significant', 'non-significant' or 'negative', and 'for review'.



**CLEVER CULTURE
SYSTEMS**

Thermo Fisher Scientific are proud to partner with Clever Culture Systems as the exclusive distributor of the APAS Independence instrument in the U.S. and Europe. The collaboration harnesses Clever Culture System's strengths in laboratory automation and artificial intelligence algorithms with Thermo Fisher's expertise in developing high quality culture media products, to help microbiology laboratories of all sizes work more efficiently.

Embracing automation in microbiology

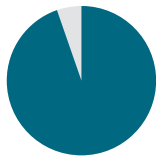
With an aging population and many chronic diseases on the rise, microbiologists are under immense time pressure, and are increasingly expected to do more with less resources.

While advancements have been made in some areas of pathology, with diagnostic materials being screened using image analysis technologies, the reading and reporting of cultures from agar plates remains a manual process.

The APAS Independence instrument is task focused, compact and designed specifically to overcome the bottleneck in manual culture plate reading by automatically triaging plates into three categories: 'significant', 'non-significant' or 'negative', and 'for review'.



Urine up to 70% negative.²



MRSA up to 95% negative.²



% clinical decisions are based on in vitro diagnostic lab results.³



40%
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 next 5 years.⁴

On average, results present a high percentage of non-significant or negative samples². Being able to triage these out of the workflow provides significant efficiencies in time and focuses skilled staff on more complex tasks that require their expertise. With laboratories in the US reporting difficulties finding skilled personnel in this field¹, only a third of the qualified staff required annually graduating each year⁵, and over a fifth of the current workforce due to retire in the next 5 years⁴, using skilled staff wisely is essential to managing workflows.

Unlike large-scale automation solutions, with the APAS Independence you get the benefits of standardization, but in a small, affordable and flexible footprint designed to easily integrate with the majority of laboratories.

Designed by microbiologists for microbiologists

The APAS Independence instrument triages plates using sophisticated machine learning algorithms built on input from real microbiologists and computer vision experts.

The algorithms are specific for specimen type and media used, and can quantify growth and identify organism morphologies. These results are then processed by decision packages based on national and international guidelines. Trials show that the instrument provides consistent reproducible results and is as accurate as a highly experienced microbiologist.⁶

Input: For accurate and reliable results.

- Complex algorithm
- Machine learning
- 1,000s of microbiologist image annotations
- Industry standard decision rules

Output: Culture plates are sorted into the following:

- Significant grow
- Non-significant growth (negative)
- For review

Streamline your workflow

The intuitive nature of the APAS Independence instrument 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

After incubation, 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 instrument takes images of each plate and interprets each one within seconds.

Step 4

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

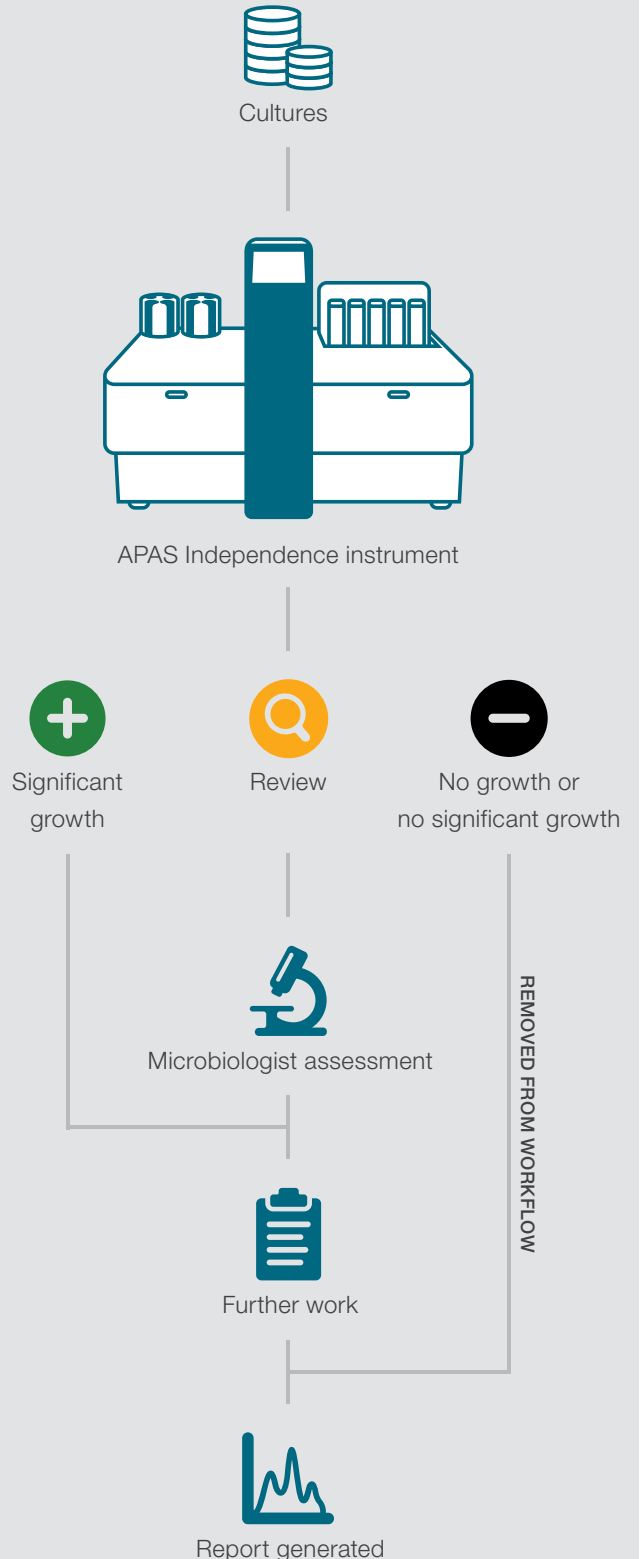
Step 5

Monitor the output stations for actioning as required.

Transfer plates from positive output carriers to microbiologist for further review. The designated plates with no significant growth or no growth are released in accordance with laboratory protocols.



Incorporating the APAS Independence instrument into your workflow



Better management of resources

The APAS Independence instrument brings intelligent plate reading to microbiology labs, providing real efficiencies. By automatically removing negative or non-significant plates out of the workflow, it delivers reliable and consistent results three times faster than a highly skilled microbiologist. This allows microbiologists to turn their attention to more complex plates.

Fast

Improve your team's efficiency and streamline laboratory workflows with technology that is three times faster than a trained microbiologist.*

Cost effective

Only pay for what you need thanks to APAS Independence instrument's modular system, with the option to add additional capabilities via extra modules.

Accurate

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

Accelerated results

Analyze results more swiftly, facilitating faster delivery of patient test results.

Staff satisfaction

Focus microbiologists on complex, significant growth plates that require their expertise for accelerated patient care.

Its small footprint, compatibility with many LIS and simple cleaning protocols ensure it integrates seamlessly in busy laboratories. The technology makes good financial sense, as it works with most media, including split plates, and does not require laboratory remodelling to function effectively. New modules to expand operation are available for a fraction of the cost of a new instrument.

Save more than time

The APAS Independence instrument was designed to alleviate the bottleneck in bench reading culture plates. But it impacts across many aspects of managing an efficient and effective microbiology lab.

Budget management

Helps avoid budget overruns with predictable costs year on year.

Quality and consistency

Reduces natural variation in the manual plate reading process.

Workplace injury

Reduces potential RSI risks and staff downtime costs.

Time management

Improve your team's efficiency with shorter turn around times.

Increased workload

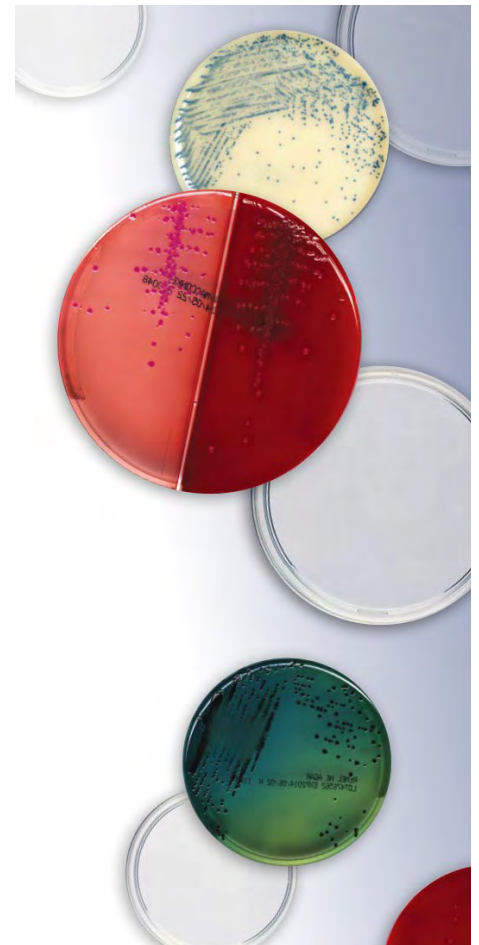
Adding Analysis Modules allows for optimal throughput.

Staff satisfaction

Utilise highly trained staff on cases that require their expertise.

Process improvement

Reduce manual handling and cross contamination risks.



* Based on a timing study conducted in June 2016 at St. Vincent's hospital in Melbourne, Australia.

Tried and tested

Don't just take our word for it.

Over 5,000 MRSA plates analyzed by The Johns Hopkins Hospital

The Johns Hopkins Hospital in Baltimore, USA, evaluated the accuracy of the APAS Independence to triage methicillin-resistant *Staphylococcus aureus* (MRSA) and *S. aureus* cultures using chromogenic media compared to human interpretation.

Five-thousand nine-hundred thirteen MRSA cultures were analyzed by the APAS Independence instrument before being read by a trained technologist who was blinded to the APAS Independence interpretation. The triaging by both the APAS Independence and the technologists were compared for accuracy.

The result of the study showed positive and negative percent agreements (PPA, NPA) of 100% and 97.3%, respectively. The APAS Independence detected 5 positive cultures that were missed by manual reading and determined to be true positives.

This study confirmed the high sensitivity (Negative Predictive Value (NPV) 100%) of digital image analysis by the APAS Independence instrument such that negative cultures can be reliably reported without technologist intervention.⁶

Independent evaluation – Australian Private Pathology

A private pathology company looking at microbiology automation evaluated the APAS Independence with over 3,000 routine urine samples.

In a two-stage study, users evaluated the level of agreement with the designation from the APAS instrument and reported >98.0% positive and negative agreement.

A notable finding of this study was that shorter incubation times combined with the APAS instrument did not appear to significantly alter diagnostic utility.

In addition, a sensitivity of 94.0% was achieved, and the implementation of APAS⁷ LIS flags delivered a >99% sensitivity.

The William Harvey Hospital – time reduction with the APAS Independence instrument

Screening of MRSA samples in routine microbiology is an important service to assist with infection control surveillance. The low prevalence (<2% in the UK) means that significant time is spent by skilled staff to examine and report negative plates. As workload pressures on laboratories increase, there is an increase in demand to investigate technologies to assist with routine plate reading.

A total of 1319 routine surveillance specimens were cultured onto Thermo Scientific™ Brilliance™ MRSA 2 Agar and incubated for 18-24 hours, in accordance with manufacturer's recommendations for MRSA detection.

The study demonstrated that the APAS Independence with MRSA Analysis Module effectively screens out negative MRSA cultures and identifies all positive MRSA cultures. It does this with a significant reduction in time (approximately 90%) and is easily integrated into the MRSA workflow.⁸



Specifications

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	Mono plates		
Dimensions (L x W x H)	2000 mm x 800 mm x 1600 mm	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 2000 m	9843 ft	
Noise specifications	Continuous: 85 dBA at 1 m	3.3 ft	
Noise level shall not exceed:	Peaks: 70 dBA at 1 m	3.3 ft	
Electrical input	100-240 VAC, 50~60 Hz, 6 Amps		
Warranty	12 months from date of commissioning		

Analysis modules	
General description	APAS Independence suite of interpretive software packages of assessing growth in cultures from a range of specimens
Available analysis modules	APAS MRSA Analysis Module
	APAS Urine Analysis Module
	APAS VRE Analysis Module*

Compliant with the following standards ISO 13485:2016; IEC 62304: 2006; UL 61010-1, 3rd Edition, May 11, 2012, Revised July 15, 2015; CAN/CSA- C22.2 No. 61010-1-12, 3rd Edition, Revised July 2015.

*For research use only. Not for use in diagnostic procedures.





References

1. College of American Pathologists (CAP) study 2014.
2. Journal of Clinical Microbiology Vol 51 No 4 p. 1179–1183.
3. The Lewin Group Inc. the value of diagnostics innovation adoption and diffusion into healthcare 2005.
4. American Society for Clinical Pathology (ASCP) 2016-2017 survey.
5. CLMA – The Laboratory Personnel Shortage.
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.
7. L.Brenton, M. Waters, T. Stanford and S. Giglio. 2020, Clinical evaluation of the APAS® Independence: Automated imaging and interpretation of urine cultures using artificial intelligence with composite reference standard discrepant resolution, Journal of Microbiological Methods, Volume 177
8. Sloan, B., Dawson, M. and Arkley, R. 2022. Evaluation of the APAS Independence with Thermo Fisher Brilliance MRSA Analysis Module at NHS William Harvey Hospital. ECCMID 2022. Lisbon

For more information on the APAS Independence instrument, visit thermofisher.com/apas or contact your local Thermo Fisher Scientific Microbiology representative at microbiology@thermofisher.com

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