



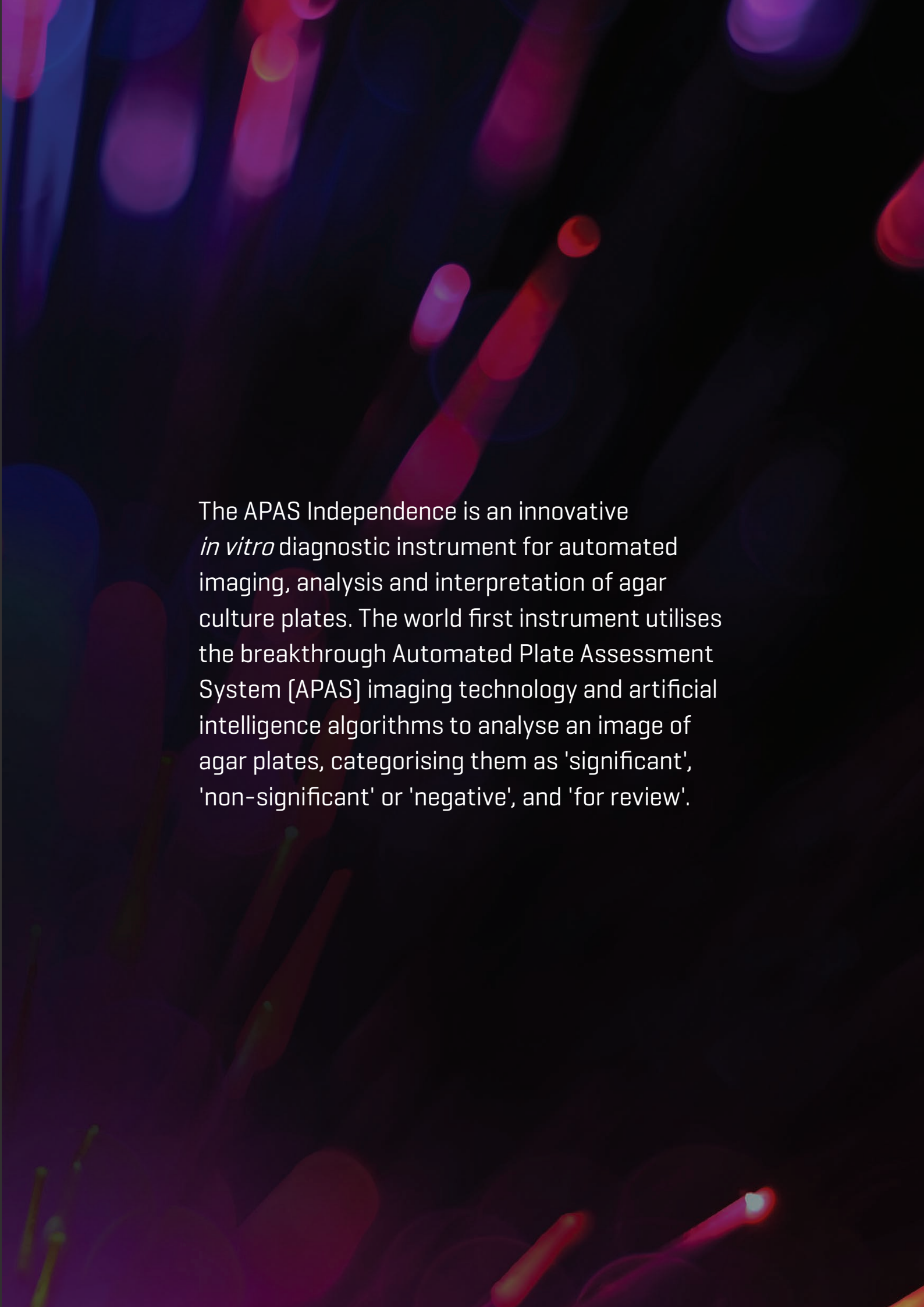
CLEVER CULTURE
SYSTEMS

The first automated culture plate reader

APAS INDEPENDENCE



FDA
CLEARED

A microscopic view of various bacterial colonies on agar plates, showing different shapes and colors like red, purple, and yellow, set against a dark background.

The APAS Independence is an innovative *in vitro* diagnostic instrument for automated imaging, analysis and interpretation of agar culture plates. The world first instrument utilises the breakthrough Automated Plate Assessment System (APAS) imaging technology and artificial intelligence algorithms to analyse an image of agar plates, categorising them as 'significant', 'non-significant' or 'negative', and 'for review'.

Embracing automation in microbiology

With an ageing population and many chronic diseases on the rise, microbiologists are under immense time pressure. Microbiology laboratories 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 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'.

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.



70%

Urine up to 70% negative.²



95%

MRSA up to 95% negative.²



70%

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

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



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

Designed by microbiologists for microbiologists

The APAS Independence 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



1,000s of microbiologist
image annotations



Machine learning



Industry standard
decision rules

Output

Culture plates are sorted into
the following:



Significant growth



Non-significant
growth [negative]



For review

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 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 are transferred in accordance with laboratory protocols.

Incorporating the APAS Independence into your workflow



Cultures



Significant growth



Review



No growth or no significant growth

Better management of resources

The APAS Independence 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.

Its small footprint, compatibility with most 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, 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.



Fast

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



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 for accelerated patient care.



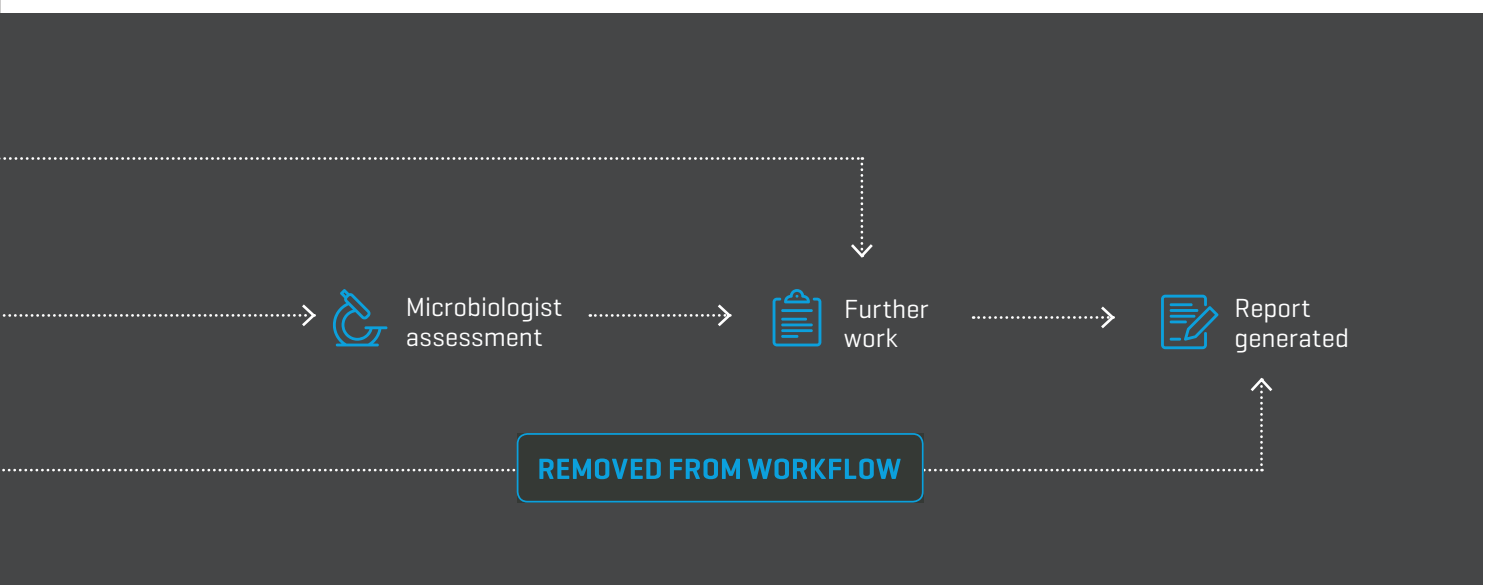
Cost effective

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



Accelerated results

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



Save more than time

The APAS Independence 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.



Increased workload

Adding Analysis Modules allows for optimal throughput.



Process improvement

Reduce manual handling and cross contamination risks.



Quality and consistency

Reduces natural variation in the manual plate reading process.



Staff satisfaction

Utilise highly trained staff on cases that require their expertise.



Time management

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



Workplace injury

Reduces potential RSI risks and staff downtime costs.

Trialled and tested

Don't just take our word for it.

Pilot Study and 10,000 Patient Clinical Trial

An initial pilot study was conducted in Australia demonstrating a high sensitivity, specificity, and clinical utility for the APAS technology.

This was followed up by a 10,000-patient clinical study that was used as the basis for obtaining FDA clearance for the Urine Analysis Module. This trial was conducted at two sites within Australia, and one site in the US.

The results of these studies indicated that APAS delivered a sensitivity of >98% when considering the application within the laboratory, and that APAS was able to perform at least as effectively as a microbiologist. These studies also highlighted the fact that variability exists between microbiologists, and the microbiologists themselves are an imperfect truth.

Several manuscripts have been published in high impact peer reviewed microbiological journals.

St Vincent's Melbourne – Independent Evaluation of the APAS Independence

St Vincent's performed an in-depth evaluation of the APAS Independence instrument that involved over 3,000 urine samples. The results from APAS compared favourably with routine reporting with a sensitivity of 93.2% and specificity of 90.1%. Moreover, implementation of APAS-assisted workflow modifications suggested that efficiencies were possible in specimen processing.

Users of the instrument also reported a high level of engagement and considered the availability of imaged cultures as a key feature. The results of this evaluation were presented at ECCMID in 2018, the premier international conference for microbiology.

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 APAS and reported >98.0% positive and negative agreement. A notable finding of this study was that shorter incubation times combined with APAS did not appear to significantly alter diagnostic utility. In addition, a sensitivity of 94.0% was achieved, and the implementation of APAS LIS flags delivered a >99% sensitivity when compared to routine reporting.

To see what your lab can achieve using the APAS Independence, contact us today.

sales@cleverculturesystems.com

Making a real difference in microbiology

Clever Culture Systems is a joint venture company that brings together experts with experience in medical science, drug and diagnostic product development, and pathology.

The joint venture between LBT Innovations in Australia and Hettich Holding Beteiligungs- und Verwaltungs-GmbH in Germany is focused on delivering products that meet a real need and make a real difference to microbiology labs around the globe.

LBT Innovations

Based in Adelaide, South Australia, LBT Innovations is an Australian developer of clinical and diagnostic technology. The company has so far created two breakthrough products in microbiology automation, including APAS®: a revolutionary automated culture plate reading, interpretation and reporting technology.

Hettich Holding Beteiligungs- und Verwaltungs-GmbH

Located in Germany, Hettich Holding Beteiligungs- und Verwaltungs-GmbH [Hettich Holding Investment and Management] is one of the world's most successful manufacturers of automated laboratory equipment. The company is widely recognised for the introduction of the first microprocessor-controlled and robotically integrated centrifuges.

References

¹College of American Pathologists [CAP] study 2014. ²Journal of Clinical Microbiology Vol 51 No 4 p. 1179-1183. ³The Lewin Group Inc. the value of diagnostics innovation adoption and diffusion into healthcare 2005. ⁴American Society for Clinical Pathology [ASCP] 2016-2017 survey. ⁵CLMA – The Laboratory Personnel Shortage. ⁶Glasson, John, et al. "Multi-center Evaluation of an Image Analysis Device [APAS]: Comparison Between Digital Image and Traditional Plate Reading Using Urine Cultures". Annals of Laboratory Medicine 37.6 [2017]: 499-504.

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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 3000m	9843ft	
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		

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 Urine Analysis Module		
	APAS MRSA Analysis Module [EU/AUS]		
Further Analysis Modules in Development	APAS MRSA Analysis Module [USA]		
	APAS VRE Analysis Module		

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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