



Lab automation

# Clever Culture Systems APAS<sup>®</sup> Independence instrument

Maximize efficiency and productivity 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**

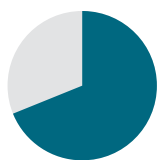
Thermo Fisher Scientific are proud to partner with Clever Culture Systems as the exclusive distributor of the APAS Independence instrument in the U.S. and Europe. The collaboration harnesses Clever Culture System's strengths in laboratory automation and artificial intelligence algorithms with Thermo 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.

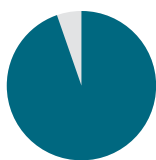
While advancements have been made in some areas of pathology, with diagnostic materials being screened using image analysis technologies, the reading and reporting of cultures from agar plates remains a manual process.

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'.



**70%**

Urine up to 70% negative.<sup>2</sup>



**95%**

MRSA up to 95% negative.<sup>2</sup>



**70%**

% clinical decisions are based on in vitro diagnostic lab results.<sup>3</sup>



**40%**

Clinical laboratories surveyed reported it is difficult to find personnel.<sup>1</sup>



**30%**

Medical laboratory positions are being filled by graduates from accredited training programs.<sup>5</sup>



**20%**

Microbiology staff expected to retire in next 5 years.<sup>4</sup>

On average, results present a high percentage of non-significant or negative samples<sup>2</sup>. 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 field<sup>1</sup>, only a third of the qualified staff required annually graduating each year<sup>5</sup>, and over a fifth of the current workforce due to retire in the next 5 years<sup>4</sup>, 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.<sup>6</sup>

**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.

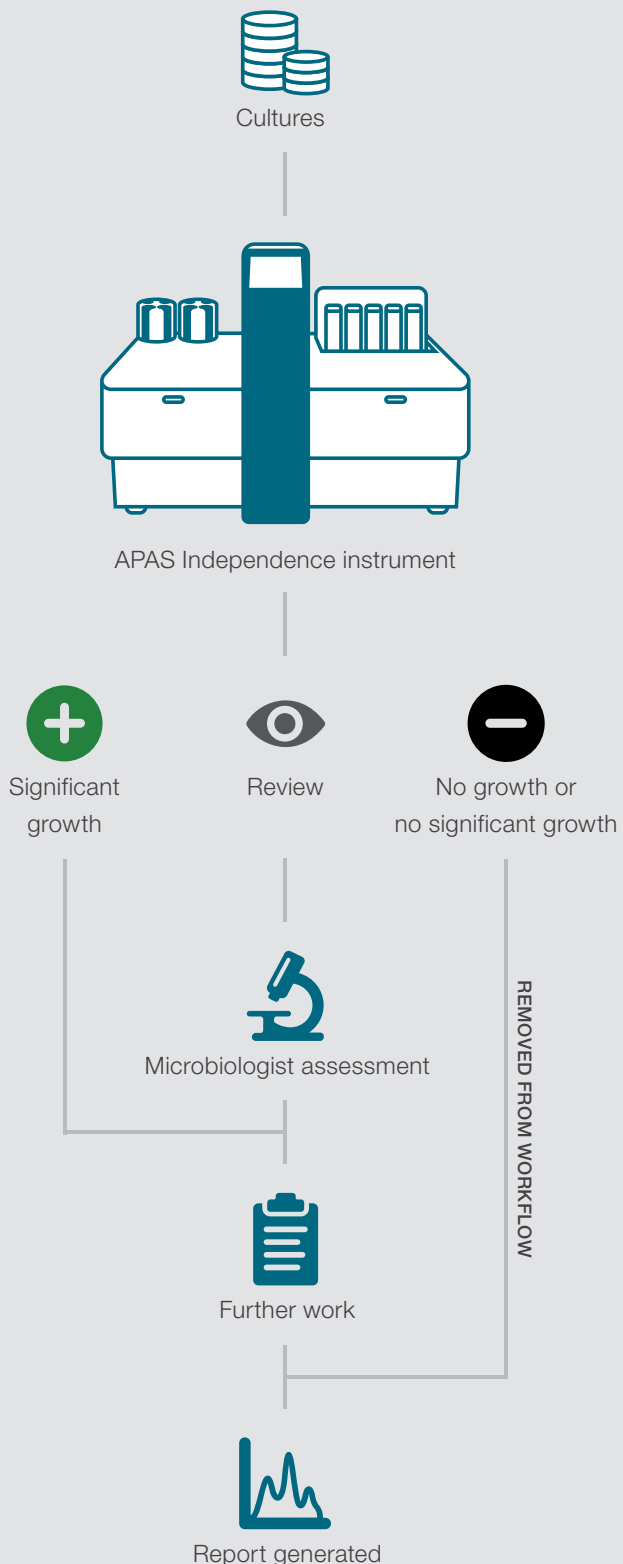
## Step 5

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.

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.

## 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 instrument's modular system, with the option to add additional capabilities via extra modules.

## Accelerated results

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

# 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.

## Increased workload

Adding Analysis Modules allows for optimal throughput.

## Quality and consistency

Reduces natural variation in the manual plate reading process.

## Staff satisfaction

Utilise highly trained staff on cases that require their expertise.

## Workplace injury

Reduces potential RSI risks and staff downtime costs.

## Process improvement

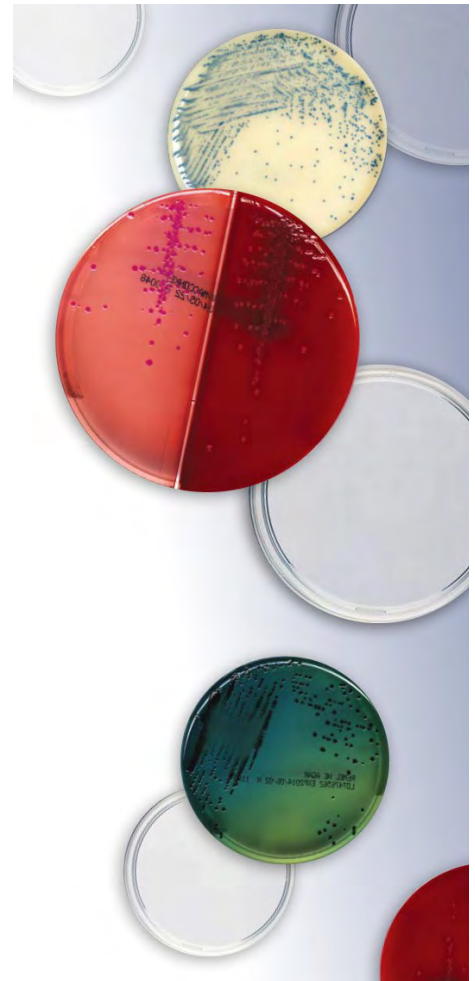
Reduce manual handling and cross contamination risks.

## Time management

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

## Revenue Generation

Increase productivity with new tests that add value to patient care and incremental revenue streams.



\* 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.

### 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 the APAS instrument delivered a sensitivity of >98% when considering the application within the laboratory, and that it was able to perform at least as effectively as a microbiologist. These studies also highlighted the fact that variability exists between microbiologists.

Several manuscripts have been published in high impact peer reviewed microbiological journals.<sup>7</sup>

### 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 the APAS instrument compared favorably 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.<sup>8</sup>

### 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 APAS LIS flags delivered a >99% sensitivity when compared to routine reporting.<sup>9</sup>



# 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)	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	Continuous: 58dBA at 1m	3.3ft	
Noise level shall not exceed:	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

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







## References

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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. Glasson, 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.
7. <https://cleverculturesystems.com/scientific-library/>
8. <https://cleverculturesystems.com/apas-eccmid-2018/>
9. <https://cleverculturesystems.com/clinical-evaluation-of-the-apas-independence/>

For more information on the APAS Independence instrument, visit [thermofisher.com/apas](https://thermofisher.com/apas) or contact your local Thermo Fisher Scientific Microbiology representative at [microbiology@thermofisher.com](mailto:microbiology@thermofisher.com)

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