Building the business case for the introduction of APAS Independence

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ABSTRACT

Introduction of automation into laboratories is a multi-faceted consideration requiring several stakeholders to inform decisions. Building the business case is sometimes complex and at the core of the business case is a return-on-investment (ROI) proposition to justify expenditure, whether it be re-utilisation of staff on other and current tasks, or availing time for additional revenue-generating tasks. When considering the implementation of APAS Independence across multiple labs globally, a ROI of 4 years or less was demonstrated in 96% of studies, with 88% of studies delivering a ROI within 2-4 years, and 46% of studies demonstrating a ROI within 3 years. All of the US sites included in this study delivered a ROI of less than 3.5 years. Notwithstanding the demonstrated clinical performance of the APAS Independence, these data demonstrate the adoption of APAS Independence provides financial benefit to most laboratories.

INTRODUCTION

Challenges in microbiology laboratories

The art of microbiological plate reading has remained unchanged for many years and remains an essential task for any infectious disease laboratory. Competency is achieved through the repetition of culture plate reading, and astute observations of colony morphology, haemolysis, and size are required for the reliable delineation of genera and species. Not only must the microbiologist make an assessment of the growth on a plate, but they must also be able to interpret the growth according to a sometimes-complex algorithm of significance dependent on sample type and clinical history. This takes time, persistence, commitment, and several years to achieve full competency.

A shortage of microbiologists is apparent, where close to 6% of vacancies remain unfilled in the US, with a decline in education enrolments observed even pre-COVID pandemic (1). Couple this with an already ageing workforce and the post-COVID resignation increases, the microbiology industry is struggling to retain skilled staff at a time where there is an expected increased staffing requirement of 11% between 2020-30 (2). Those staff that remain have typically been cross-skilled in non-plate reading tasks or in other departments, such as running molecular platforms and serology. The redeployment of staff to molecular duties during the pandemic also significantly delayed the ongoing training and development of plate reading staff. This flux of staff movements impacts the core plate reading task, possibly introducing errors, but can also be dissatisfying for the plate reading purists.

Table 1. Automation considerations

Consideration	Comments
Laboratory vision	Is my laboratory a leader, innovator, or follower? What does the laboratory look like in 5 years?
Staffing and expertise to execute automation adoption, overhead management costs	Is there sufficient stakeholder availability across academic, IT, engineering, routine staff to plan, cost, and execute and automation project? Is the expertise for project management available? What budget exists for project management and incidentals for project implementation?
Modality	What does my future laboratory look like with respect to testing menu and automation requirements? Can I automate reading plates today, streaking tomorrow (or at all)? What is the risk appetite for large scale projects?
Physical Space	What does the lab have space for? Is there capacity for expansion? Is engineering required to support heavy instruments?
Maintenance requirements	Is a high level of support needed for day to day, or scheduled preventative maintenance visits?
Quality	Quality of results, quality of staff, quality of suppliers.
Safety	Staff safety, patient safety through using platforms with high clinical sensitivity.
Procedure enhancement	Does the implementation of automation facilitate the end-to-end testing of a sample? What other procedures have touchpoints with automation and are additional benefit possible?
Improved audit trail and compliance	Considering automation to improve compliance with auditing system and improve sample testing traceability.
Turnaround time (TAT)	Can automation help my laboratory decrease TAT through improved processes?
Flexibility	Utilising more staff, more often, across multiple platform to ensure automation continuity Participating in R&D.
Staff satisfaction, engagement, and retention	Providing opportunities for all staff to participate and champion the investigation of value-add automation solutions. Engaging staff in exciting technologies and staff retention impact.
Addressing staff shortages	Using automation to fill gaps, refresh/rethink overall laboratory and personnel function.
Cost/Return of investment (ROI)	Is this important to the lab? What does the ROI need to be? Is ROI purely financial/transactional, or are there other non-financial returns availed? Is future revenue opportunity considered in ROI?
Future growth of the laboratory	What are the future challenges associated with increase in sample loads? Are there any laboratory acquisition considerations that will impact a central laboratory? What is the laboratory considering for resource increase V automation initiatives?
Cost	Does the laboratory have budget? Capital v Leasing options?
Performance & Regulatory requirements	Does the technology have evidence of clinical performance – peer reviewed, FDA, CE, TGA?
Administration Influence	Is management supportive of automation? When is capital available and how should you compete with capital budget with other departments? How is microbiology positioning the discussion of capital purchases with management?

Only recently have error rates in microbiology plate reading been published, as studies focusing on automation have challenged the status quo. Even at the basic level of counting colonies, there can be <65% agreement in consensus counts for some agars (3) and as little as 87.5% agreement on colony morphologies (4). Laboratories are looking to automation to address these and other challenges.

Adoption of automation considerations

The last decade has seen a rise in the consideration and adoption of automated platforms in microbiology. Typically, microbiology labs have been under-funded when compared to Chemistry and Haematology departments when positioning for capital budget, except during the pandemic response where many microbiology laboratories had to implement automated COVID testing platforms in an unprecedented and rapid manner. Implementation of automation in laboratories is always dependent on several factors for strategic consideration, which can be prioritised differently depending on the laboratory function and risk appetite. Considerations include, but are not limited to, the items listed in Table 1.

Laboratory managers must be forward thinking to future proof their laboratories as there are now many options for automation. The larger the automation project, the longer the planning and implementation phase (typically years), the higher the investment and maintenance cost, and the higher the implementation risk. A more modular and de-risked approach is a low burden alternative as implementation times are usually low and utility of the system can be realised in a much timelier manner (typically months), notwithstanding typical implementation challenges with IT integration and workflow modification.

APAS Independence – Proven clinical performance

The APAS® Independence[1] (Clever Culture Systems, Switzerland) is a stand-alone in-vitro diagnostic instrument that fully automates culture plate imaging and interpretation. The APAS Independence differs from other imaging systems such as those found in the Kiestra (BD Life Sciences—Integrated Diagnostic Solutions, USA) and WASP Lab (Copan Italia, Italy) in that it offers a plate reading function using artificial intelligence and does not include additional robotics to process or incubate specimens. With a processing rate of 200 plates per hour, the APAS Independence reads and interprets microbial cultures using proprietary algorithms for enumeration and classification, and in the case of urine samples, an expert decision system based on international reporting guidelines (3). For screening of Vancomycin Resistant Enterococci (VRE) and Methicillin Resistant Staphylococcus aureus (MRSA), the algorithms are designed to comply with media specifications for the determination of presumptive target organisms. A key difference between the APAS Independence and other automation systems is that negative results can be reported without user intervention, facilitating improved turnaround time and therefore patient care. Non-negative results can also be sent to the Laboratory Information System (LIS), reducing operator touch time and transcription errors. Over 25 scientific publications (https://cleverculturesystems.com/scientific-library) have demonstrated clinical efficacy with very high sensitivity and specificity across multiple applications

[1] Products are distributed in the U.S. and Europe so uses, applications, and availability of product in each country depend on local regulatory marketing authorisation status. Clever Culture Systems is the legal manufacturer of the APAS® Independence. APAS® is a trademark of Clever Culture Systems. The APAS Independence is distributed in the U.S. and Europe by Thermo Fisher Scientific.

Table 2. APAS performance for MRSA screening

Region	Laboratory	Agar	Sample Size	Sensitivity / PPA	Specificity / NPA
UK	William Harvey	TFS Brilliance MRSA	1319	100%	97.90%
UK	Health Services Laboratory	TFS Brilliance MRSA	3719	100%	94.10%
Germany	Labor Dr Wisplinghoff	bioMérieux chromID	17,000	100%	98.10%
Germany	LADR	Brilliance MRSA	816	100%	96.55%
Australia	SA Pathology	bioMérieux chromID	500	100%	94.81%
US	Johns Hopkins Hospital	BD BBL CHROMagar MRSA	5913	100%	97.30%

Table 3. APAS performance on urine samples

Region	Laboratory	Agar	Sample Size	Sensitivity / PPA	Specificity / NPA
AU	ACL	Blood Agar and Mac CV	2163	99.4%	99.30%
US and AU	Global Clinical Trial	Blood Agar and Mac CV	9224	99.00%	84.50%
US	UCSD	Blood Agar and Mac CV	1519	95.13%	NA
US	Hennepin	Blood Agar and Mac CV	6200	98.00%	NA
Germany	LADR	Brilliance UTI Clarity	382	98.30%	64.34%
UK	William Harvey	Brilliance UTI Clarity	1974	98.80%	NA
UK	Health Services Laboratory	Brilliance UTI Clarity	1085	100.00%	76.00%
FR	BioMed21, Dijon	CPSE	1520	100.00%	NA
AU	ACL	HBA/UTI Brilliance	1477	97.0-99.5%	NA
AU	St. Vincent's Hospital Melbourne	HBA/UTI Brilliance	3,000	91.9-99.8%	87.70%

and media types which are summarised in Table 2 and Table 3.

The APAS Independence allows for the standardisation of culture reading through the use of standardised interpretive software (algorithms) with the consistency and accuracy expected from automation. The production of clinically useful algorithms is not a trivial task, and much consideration is needed when developing and deploying algorithms for IVD use. Recently DeYoung et al (5) detailed these considerations and this information is important in providing a baseline understanding of what an algorithm is, and more importantly, what an algorithm can and cannot do. The APAS Independence with its associated algorithms is the only IVD medical device to achieve FDA clearance as a class II medical device for multiple plate reading applications. In addition to CE Marking and TGA approval for use, a high burden of proof with regulatory clearances supports autonomous decision making which underpins patient safety.

Return on Investment (ROI) Considerations

ROI continues to be a significant driver for many procurement processes, and in

some cases remains a firm go/no-go decision point based on financial modelling alone. Typically, administrators look for a low ROI (2-4 years) as this provides financial justification for capital through increased returns during the life of an instrument, which is notionally 7 years.

ROI determination is complex and is best determined in consultation with laboratory management, automation champions, and financial administrators at any given site or network of sites. Investigation of workflow practices, and detailed assessments of specific tasks are needed. When considering implementation of APAS, information detailed in Table 4 is what typically feeds into ROI modelling.

Specialist workflow consultants from automation companies may be used to facilitate this process and have an ability to objectively measure impact on staffing and processes, and to determine how automated systems can add value, efficiencies, and benefit to the laboratory. It is critical that any changes to existing staffing levels, staffing function, and workflow are the result of extensive consultation and collaboration between all stakeholders to gain acceptance of the model, as this will reduce any inertia moving forward in the procurement and implementation process.

APAS Independence ROI retrospective analysis

Methodology and key baseline metrics

A total of 24 workflow studies from across the globe were included in this retrospective analysis, which included 14 sites from the US, 4 from Australia (AU), 3 from the UK, 2 from France (FR), and 1 from Germany (DE). As well as diverse geographies, the workflow studies included a diverse range of laboratories, including public, private and reference laboratories both small (<400 plates per day, n=9), medium (>400 and <1000 plates per day, n = 11), and large (>1000 plates per day, n=4). The number of plates per day was dependant on the sample type being processed and the number of plates inoculated per sample,

Table 4. ROI Considerations for APAS implementation

Information for ROI modelling	Comments
Staffing	Number of staff assigned Staff mix required (lab assistants vs microbiologists) Salaries Typical shifts rostered
Staff overheads/ongoing costs	Statutory requirements e.g., superannuation, pension, 401k. Discretional e.g., training, PPE, health insurance.
Media usage and costs	What is the impact on consumables with automation changes? Move from whole plate to bi-plate, bi-plate to whole plate? Media supplier change? Reduced re-work through automation?
Volume of specimens and process mapping over 24 hours	Flow of specimens through the lab. Peak times, staffing level equivalents. Timing of plate reading and impact on TAT.
Percent positive rate for a sample / Number of samples to be handled by staff	Defining what a positive sample for microbiology review is and determining impact on workflow and staff handling of plates.
Percent negative rate for a sample / Number of samples to be handled by staff	Defining what a negative sample for auto verification is and determining impact on workflow and staff handling of plates.
Opportunity for increase in revenue	Determine the ability to absorb growth in testing numbers concurrently with staff reduction or at same staffing levels and realising the benefits, financially. The opportunity for additional revenue through redeployment of FTE.

as well as the number of samples. For example, 400 plates per day for a urine protocol could mean 200 specimens with a two whole plate protocol, or 400 specimens for a single bi-plate or single whole plate protocol. Detailed assessment of this was carried out and presented to participating laboratories for review and approval. Included in the ROI calculation was the capital cost of the APAS Independence, annual software licence fees, and an annual maintenance fee commencing in year 2 (1 year warranty period with included preventative maintenance for the first year). Salaries were normalised to USD and staffing represented by FTE[2]. The ROI calculation considered all these costs in addition to any potential FTE reallocations availed by implementation of the APAS Independence, laboratory mishandling error rates and resultant re-work, any laboratory growth projections, any change in media costs, and any additional costs (or benefits) as a result of APAS implementation.

Figure 1 shows the variability of routine microbiology salaries[3] by region and by seniority. The differences of salary in the US when compared to rest of world is likely due to the high vacancy rate in the US and the necessity to retain licenced staff in some regions. There is also a generally higher indirect costs for staff, such as benefits, pensions, and insurance.

When examining staffing levels for urine culture reading and reporting, significant variability occurred. The average plate reads per FTE (per day) in the UK was 418, 328 in France, 179 in Australia and 122 in the US. The MRSA/VRE reads per FTE ranged between 400 and 1100. No German based urine workflows were included in this analysis. However, one German lab has reported a reduction in manual reviews of urine cultures of 51.9% (6).

Impact of APAS implementation on staffing allocations

When looking at the APAS-assisted process and the impacts APAS could provide to workflow and staff allocations, those tests in the infection control suite (MRSA and VRE) demonstrated an almost linear relationship (Figure 2) between staffing impact and volume of tests, primarily due to the large negativity rate

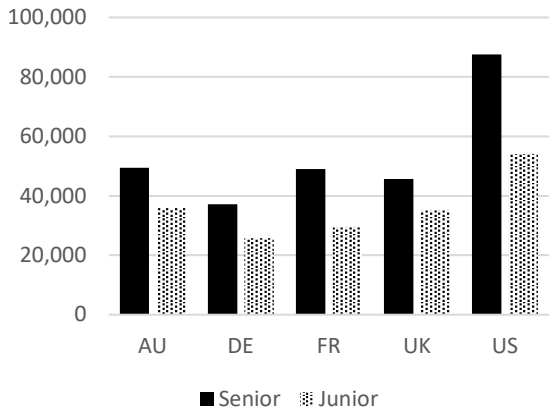

Figure 1. Average employee salary by region

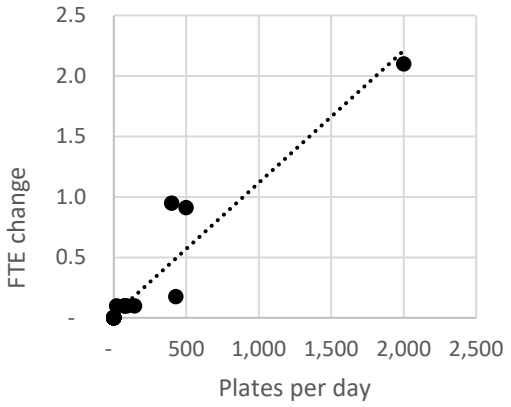

Figure 2. APAS-assisted FTE staffing reductions for MRSA reading

[2] FTE = A full-time equivalent, is a unit to measure employed persons in a way that makes them comparable although they may work a different number of hours per week.
The unit is obtained by comparing an employee's average number of hours worked to the average number of hours of a full-time worker. A full-time person is therefore counted as one FTE, while a part-time worker gets a score in proportion to the hours he or she works. For example, a part-time worker employed for 20 hours a week where full-time work consists of 40 hours, is 0.5 FTE.
[3] Microbiology salaries take into account regional differences in nomenclature of staff, and are ranked by junior and senior in terms of experience and tasks performed.

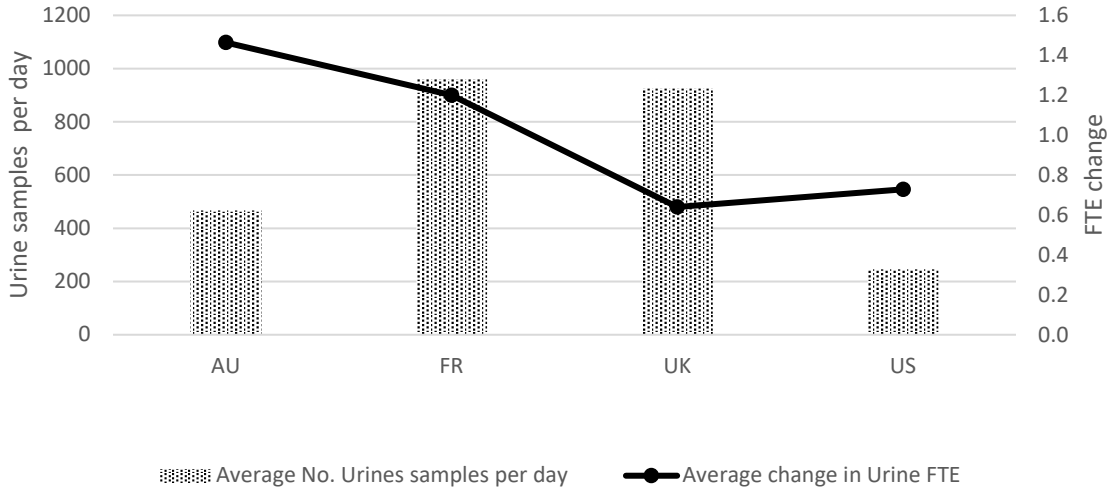

Figure 3. Change in FTE, per region, based on average urine volume

of these samples. For example, a laboratory performing 2000 MRSA tests per day (using a single plate protocol) demonstrated a reallocation of 2 FTEs, with the FTE performing additional value-add tasks. For a laboratory performing 400 or 500 MRSA tests per day an FTE reduction of 0.95 and 0.9 respectively was demonstrated. Low volume of MRSA/VRE testing is typically absorbed by microbiologists on other benches and so the impact at low volumes is less.

Examining the same impact on urine plate readings availed much more variability by regions. This is not unexpected as practices, media usage, positive and negative rates, LIS usage, and laboratory type (e.g., reference v hospital v private) all contribute to urinalysis workflow variation. Significant variability in reading rate has already been discussed, and when compounded with the other variables described above, FTE changes were less predictable than those seen in MRSA analysis. Therefore, implementation of APAS for urine analysis is not necessarily a 1:1 relationship between any volume, practice, or single laboratory workflow feature. Rather, the impact of APAS will depend on many facets of laboratory practices and workflow investigations. As with any implementation of automation, the workflow needs to be considered in a detailed, systematic, and objective manner.

Figure 3 shows the variability observed. When comparing UK and FR, the average number of urines processed was similar at 925-960 per day, but the FTE reduction availed by APAS in FR was 1.2 FTE whereas in the UK it was 0.64. In contrast, the US had a low average of urine samples processed (245 per day), but the FTE reduction was 0.73. Similarly, the average AU FTE reduction was 1.46 with an average daily urine sample volume of 467, which is an almost liner relationship with US urine/FTE reduction. These data highlight the necessity to understand each laboratory's financial and operational considerations for any adoption of automation, and that the ROI delivery could by variable by region, but also within region.

ROI analysis of APAS Independence - Summary

When taking a global perspective and examining all the data from the workflow and ROI analyses performed, the average global ROI for the APAS Independence is 2.95 years. Figure 4 demonstrates that 96% of studies returned a ROI of 4 years or less, with 88% of studies delivering a ROI within 2-4 years. 46% of studies demonstrated a ROI within 3 years and the US data clustered with the change of FTE when compared to the rest of world

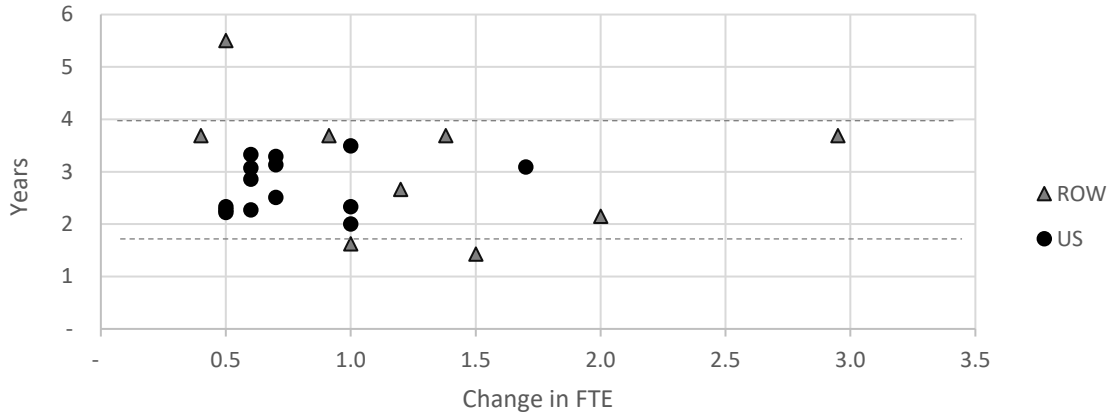

Figure 4. Global ROI for APAS Independence

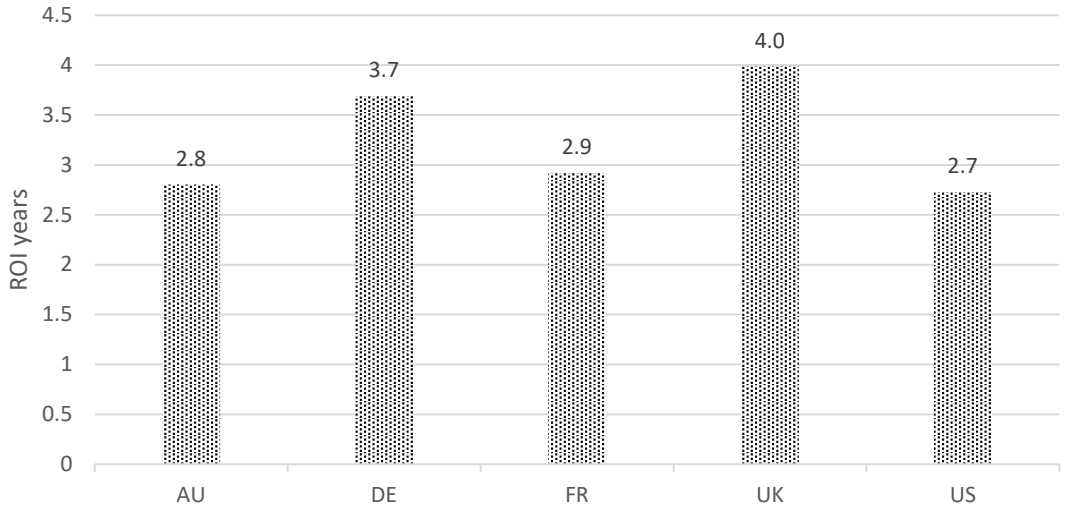

Figure 5. Average ROI for APAS Independence by region

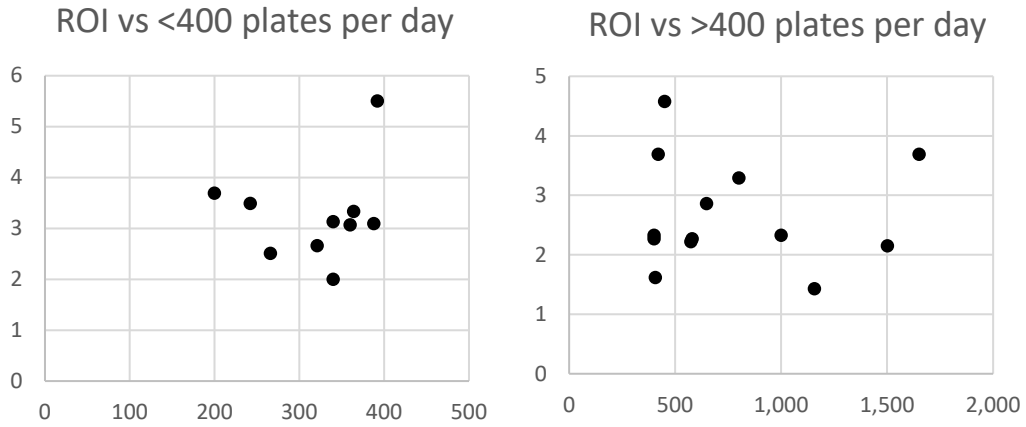

Figure 6. ROI segregated by plates per day available for APAS

(ROW), as well as highlighting that 100% of ROI in the US was less than 3.49 years. These data were achieved through a collaborative process between CCS and key decision makers within institutions and accepted as accurate.

Average ROI by region is detailed in Figure 5 where regional variation of 2.7-4.0 years payback is demonstrated. The average ROI is lowest in the US at 2.7 years, with AU and FR close to that figure also. Both DE and UK were higher at 3.7 and 4.0 years respectively.

When segregating laboratories by plate numbers that can be run on the APAS Independence, where a small laboratory is defined as <400 plates, the ROI clusters more tightly between 2-4 years when compared to >400 plates (Figure 6).

It's not just ROI driving APAS Independence adoption.

Machine Learning. Artificial intelligence. Deep Learning. Neural networks. ChatGPT. It's hard to avoid these buzz words in modern society and it has certainly become common vernacular in the laboratory. Naturally, those laboratory managers looking to be early adopters of new automation are interested in the science and prestige behind the APAS Independence and ROI isn't the only consideration. These early adopters are the innovators of the field, and the validators of the technology. Aside from the obvious utility and workflow benefits, these laboratories are the first to publish new and exciting scientific literature in an emerging field and become key reference points for technology adoption whilst raising laboratory and individual profiles.

Due to the simplicity of use of the APAS Independence, any staff can load samples and run the instrument. This means that reporting of negative samples can occur at any hour of the day with a high degree of confidence. In a large German 24/7 reference laboratory, Labor Dr Wisplinghoff, the laboratory has implemented two APAS Independence instruments and analysis modules for MRSA and VRE screening, leading to an improved TAT for patient reports. Due to the ease and short training time, several staff have been trained and there is a broad coverage of users at all hours. This has allowed staff to be trained in other areas, such as molecular, and many of the operational shifts are multi-tasking on various platforms, including the APAS Independence. The ability to multitask creates opportunities to maximise utility of staff and thus absorb natural growth in a lab without the requirement for additional FTE resources.

In another example, the APAS Independence was purchased to enable the laboratory to re-deploy staff across other priority activities within the laboratory without the need for additional headcount. The Health Services Laboratory (HSL) operate a private laboratory in central London where access to experienced and qualified staff is competitive. Servicing many hospitals across the UK, their focus is on operational efficiency and continuous improvement. Implementing the APAS Independence has enabled them to reduce the time spent on manual plate reading and free up resources to focus on value-added tasks. These benefits are often hard to quantify directly and may not be visible in an ROI calculation but add to the strategic rationale and benefit of implementing automation so should not be overlooked in the laboratory business case.

Staff shortages and licencing requirements in some US states is a major driver in the procurement process. While the ROI presented in this article is generally favourable in the US, the APAS Independence has also been demonstrated to be favourable in smaller laboratories that may not be able to attract trained staff. In one such instance, Albany Medical Centre (Albany, NY) has implemented the APAS Independence without ROI consideration and the decision has been driven predominantly on addressing staff shortages. In this case, APAS Independence demonstrated at least a

33% automatic release of negative urine results (7), and this time was utilised by staff across other value add tasks within the laboratory, in addition to absorbing approximately a 10% expected growth from additional specimens from an affiliate hospital. The small footprint and ease of implementation of the APAS Independence also contributed significantly to the decision.

As technologies continue to emerge and test laboratories continue to respond, implementation of APAS Independence creates additional capacity in the laboratory. This enables the ability to onboard additional revenue-generating testing such as automated microscopy platforms for ova and parasite detection, genetic sequence analysis, or molecular panels for respiratory and central nervous system pathogens.

It's not APAS Independence or TLA, but APAS Independence and TLA

Instinctively, one might think that committing to a TLA (Total Laboratory Automation) system precludes any other automation solutions for plate reading. TLA systems offer advantages for complex samples that require multiple media types and incubation conditions. The digital toolboxes available are powerful and nicely present all plates on a single screen, allowing the digital images to be investigated thoroughly. This facilitates decision-making, minimises plate handling, and allows tagging of colonies for downstream ID/AST to proceed easily. However, these are generally high-cost installations (several million dollars), and the addition of smart incubators during laboratory growth, for example, is an expensive exercise, and presents issues with expanding footprints due to the defined availability of plate locations in the incubators.

The APAS Independence can be installed side-by-side with these systems, utilising existing incubator infrastructure and processing procedures. This has been demonstrated at HSL where two full TLA lines have been operating for several years. APAS Independence offered a solution for MRSA and urine samples, which are inoculated on the TLA system, but then incubated routinely and run on the APAS Independence. In this case APAS is used in parallel to TLA where APAS, with its faster throughput, has been dedicated to the workflows having the highest samples per day and the highest negative rate, while TLA is dedicated to the other sample types. The MRSA negative rate for this laboratory was >98% and the urine negative rate >50%, ultimately freeing up a combined 79.8% of total plates for these tests, resulting in thousands of plates not taking up space within the smart incubators (8). This has allowed laboratory growth to occur, without additional TLA infrastructure, increase in footprint, or staffing required.

Additionally, digital image interpretation may present some challenges for discrete colony identification during routine reads. In a head-to-head automation comparison for MRSA, APAS Independence results and Kiestra digital MRSA read results were compared using plate-in-hand (and Maldi-ToF identification) as the gold standard (9). In this study the authors demonstrated that the APAS Independence delivered higher sensitivity and specificity than the digital reads on the Kiestra system and concluded there is inherent human error when reading plate in hand and digitally. Combined, APAS Independence automated reading provided superior results.

Conclusion

Building the business case for any automation is multi-faceted. Many challenges exist and continue to emerge, and automation is part of the suite of tools available to improve business continuity and patient safety. While the ROI remains an important part of any automation consideration strategy, laboratories have become more holistic in presenting business cases and the adoption of automation is largely driven by laboratory management, with

administration sign off. This article provides some meaningful data around ROI which is generally not available, but also presents other strategic considerations. It is by no means a complete list or template, instead it should guide the business case preparation and positioning.

As technology advances in the field of microbiology, there is an emerging trend to gravitate to solutions that target highly skilled staff. It seems that fears of “AI taking my job” have largely been allayed and the assistive value-add properties of AI-based solutions are being recognised. What is abundantly clear is that AI technologies serve to augment skilled staff, in any industry, and microbiology is no different. It makes sense that skilled staff look at complex microbial flora and not negative samples, and the APAS Independence is leading the way in this field.

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