ST VINCENT'S HOSPITAL MELBOURNE

Towards smarter diagnostics: AI-assisted technology for routine urine cultures

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Better and fairer care. Always.

The APAS® Independence

- The APAS® (**A**utomated **P**late **A**ssessment **S**ystem) Independence (Clever Culture Systems) is a stand-alone in-vitro diagnostic instrument that automates culture plate imaging and interpretation using artificial intelligence algorithms
- In 2024, the APAS was introduced as the primary means of reading urine culture plates at St Vincent's Hospital, Melbourne

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The Technology

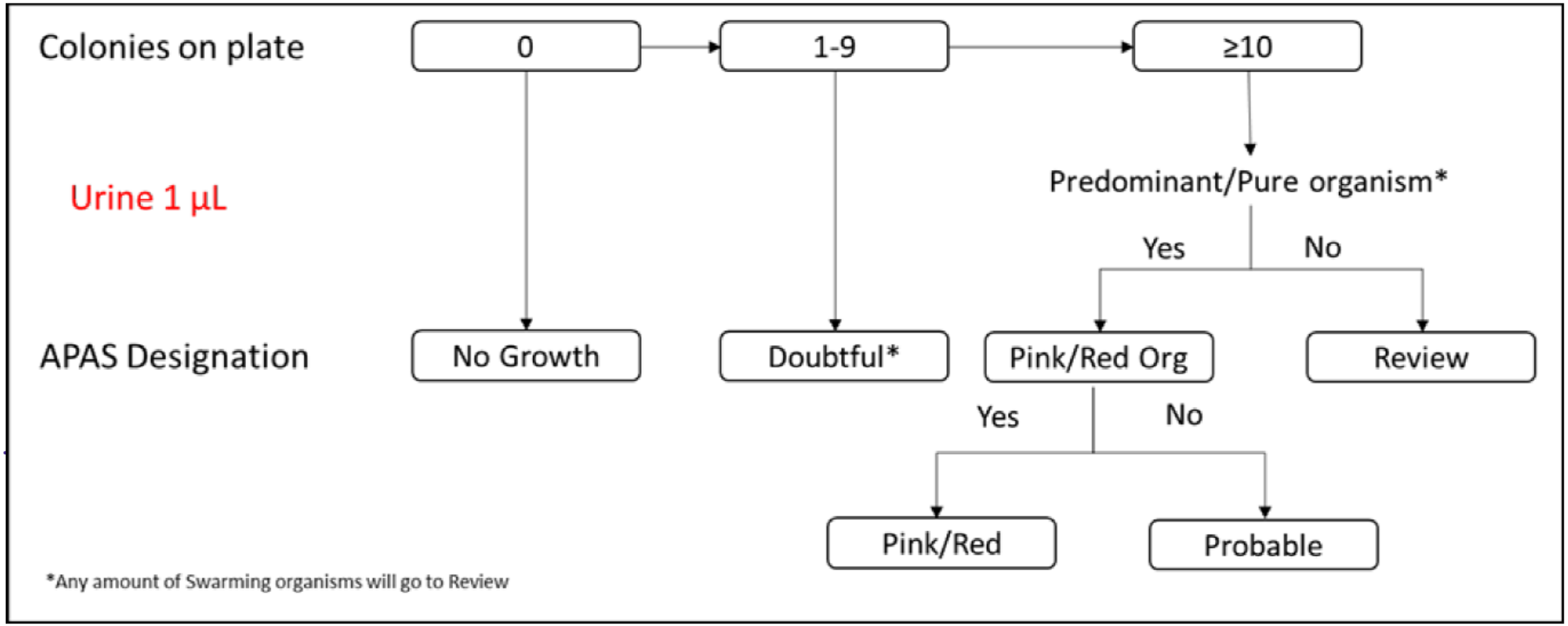
- The instrument utilises AI machine learning to sort urine culture plates into five designation categories, based on the likely significance of the culture
- It uses colony enumeration as the primary decision-making driver

Colonies detected on plate	Enumeration category
≥100	≥10^5 CFU/L or ≥10^8 CFU/L
10-99	10^4 CFU/mL or 10^7 CFU/L
1-9	10^3 CFU/mL or 10^6 CFU/L
0	No growth detected

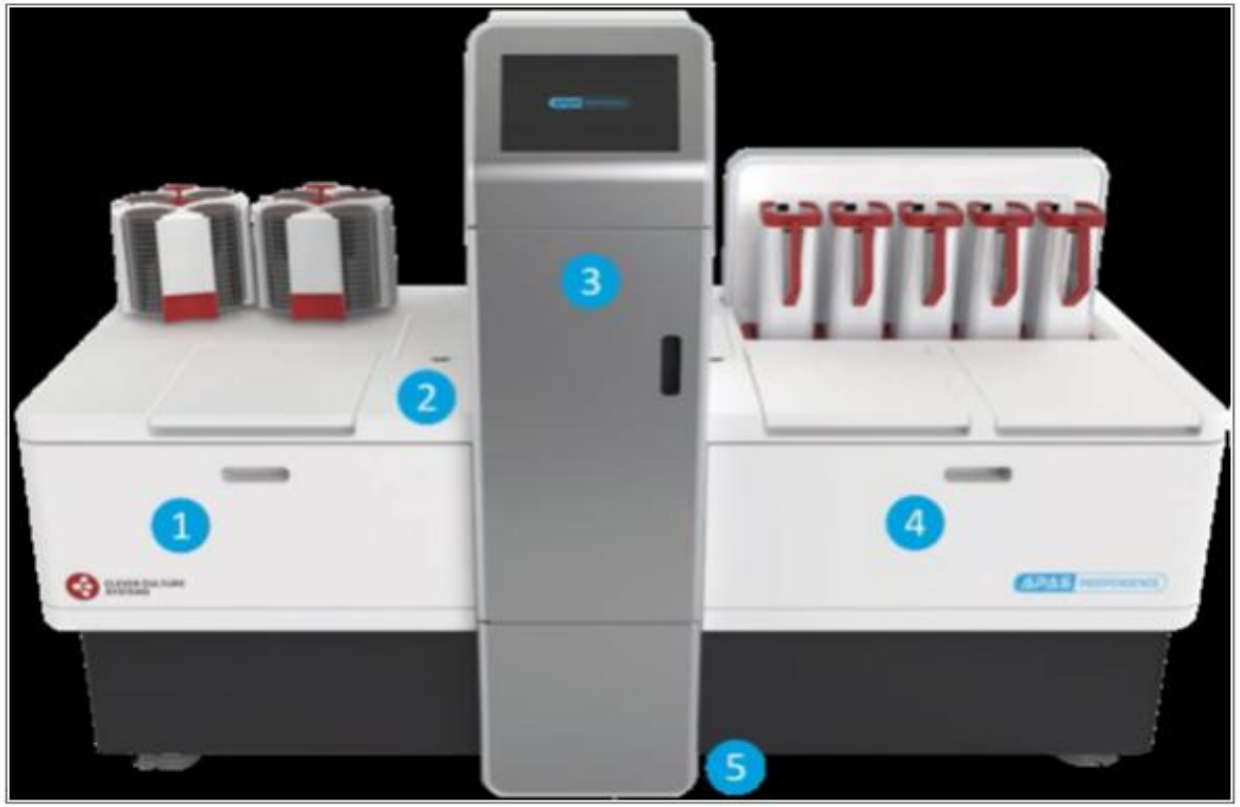
The Technology

- Further categorises microbial growth into colony morphologies
- In a mixed culture, the APAS will report predominance if one colony morphology is significantly more numerous than others
- Predominance exists if the most numerous organism is at least 4x that of the next most numerous organism

Decision Tree for Urinalysis Module

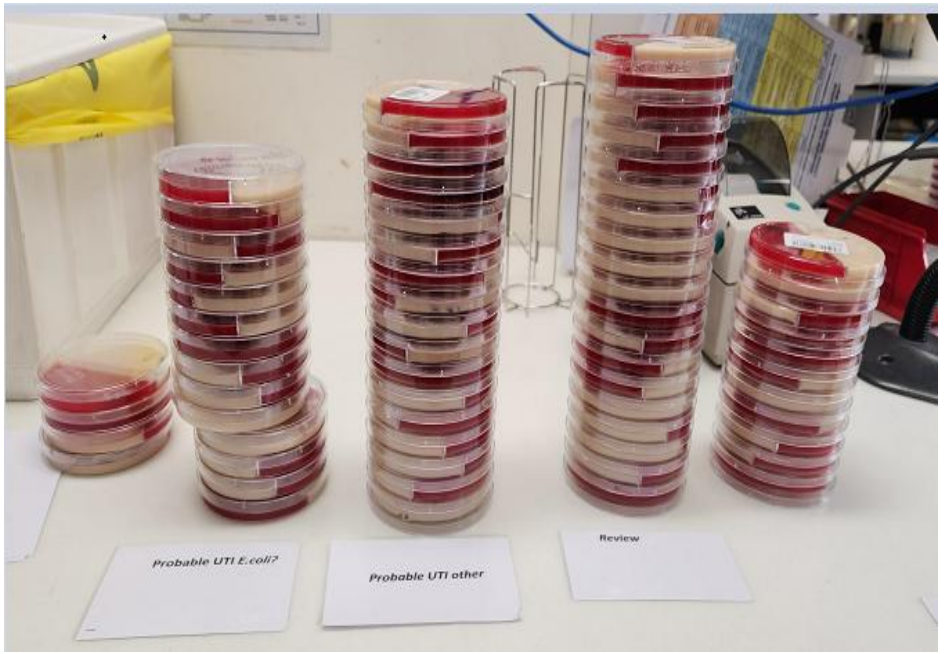


The Technology



1. Input Module
2. Transfer Module (internal of instrument)
3. Imaging Module
4. Output Module
5. Power Switch

Workflow



Plates set up between	Run in APAS at:
7:30am and 3:00pm	7:00am
3:01pm and 8:00pm	12:00pm
After 8:00pm	Bench to read after 16hrs incubation

Workflow

APAS Designation Category	Enumeration Category	Action
Probable UTI (*E.coli*)	≥10^8 CFU/L	Action by scientist Spot indole > Vitek AST N246 card
Probable UTI (Other)	≥10^8 CFU/L	Action by scientist MALDI-TOF identification > susceptibility testing
Review	10^7 CFU/L	Action by scientist Read, interpret & report
Doubtful/No Significant Growth	10^6 CFU/L	None (Auto-authorised by LIS)
No Growth	0 CFU/L	None (Auto-authorised by LIS)

Interfacing

- Interfaced via middleware (DI, Instrument Manager)
- Middleware relays information from the Atellica and from LIS to APAS
- Custom flags block auto-authorisation in LIS & force plate to be sent to review category when:
  - Atellica generates a UTI flag (WBC ≥50 x 10^6/L)
  - Patient demographic determined to require manual review (children <5yrs, pregnant women, haematology/oncology patients, ICU, renal transplant patients)
  - Specific request for culture for fastidious organisms/sterile pyuria

Changes in Workflow

1. Change in Laboratory Assistant shift times (7:30am start to a 7am start)
2. Change in urine bench duties:
   - Action E.coli positive cultures > spot indole > VITEK (before 8:30am)
   - Action Other positive cultures > MALDI-ToF > VITEK
   - Action Review cultures
3. Validated the APAS for a 16hr read to allow for 2 plate batches (versus 4 batches at 18hrs)

18hr incubation verification: Manual v APAS Performance

		APAS Independence		
		NG/NSG	PROBABLE/REVIEW	Total
Manual	NG/NSG	193	2	195
	PROBABLE/REVIEW	5	95	100
		198	97	**295**

Validation of 16hr read

- Acceptance criteria: the APAS must provide the same results at 16hrs incubation as at a minimum of 18hrs incubation
- 206 samples incubated for 16hrs, read by the APAS instrument, re-incubated for another 2 hrs. Plate-in-hand results were compared by viewing the APAS images captured after 16hrs incubation.
- There were no instances of changes in the amount of growth
- 2 discrepant results (tiny pinpoint colonies 10^7 CFU/L/ 10^6 CFU/L)

Advantages

- 40% saving in lab assistant time
- Urine bench scientist time redirected to alternate tasks
- Easy review of cultures using APAS image
- Increased number of urine *E.coli* susceptibility results being issued the same day
- Standardisation of interpretative results
- *L.Brenton, M.Waters, T.Stanford, S.Giglio. Clinical evaluation of the APAS® Independence: Automated imaging and interpretation of urine cultures using artificial intelligence with composite reference standard discrepant resolution. Journal of Microbiology Methods, September 2020, Vol.177.*

Keys to Successful Change Management

Key Learnings	Action
Plan, plan and then plan more	Identify roadblocks & resolve before “go-live”
Communication (regular and transparent)	*Explain* the why, when & how Consult
Data and metrics	*Show* the why, when & how using metrics What’s in it for me?
Stakeholder engagement	Engage as many staff as possible in lived experiences (evaluation, verification, validation, projects) Involve staff in workflow decisions Engage informal leaders
Training, development and resources	Training, seminars, presentations
Flexibility & Adaptability	Be open to continuously adapting Change the workflow, shift times, technology
Psychological Safety & Trust	Bedrock of achieving all of the above. Work harder on all of the above if this isn’t already in place

With thanks to the Microbiology team at St Vincent's Hospital, Melbourne