

EM Plate Reading Using the APAS Independence

Comprehensive analysis
of automated plate
reading system



Juan Diego González Moreno
Sr. Scientist
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Agenda

- Concept introduction, Study Overview and Objectives
- System Description and Measurement Principles
- Plate Selection and Sample Categories
- Performance Results
- Lessons learned
- Conclusion

Concept introduction

EM program



Current



Manual plate counting with manual entry in LIMS

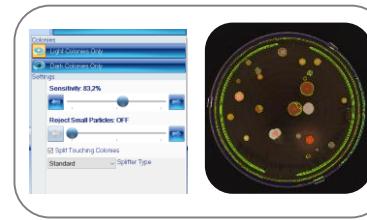
Manual count under magnifier
Count performed by 2 analysts
Manual recording of result
(Some sites take a picture of the plate)

Proposed

Automated Image acquisition



High resolution camera
Keeps every picture in a folder



Automated plate counting with numeric records and automatic entry in LIMS

Image Analysis
Colony localization
Colony counting

Purpose and Scope of the Pilot Study

- Study Objective

- The pilot study aims to evaluate the performance and capabilities of the APAS Independence system.

- Testing Environment

- Tests were conducted at PGS Melbourne focusing on reading 90 mm petri dishes.

APAS Independence System and Software

- Automated Plate Imaging
 - The system automates the imaging of microbiological culture plates, improving efficiency and accuracy in environmental monitoring.
- AI-Driven Analysis
 - Uses artificial intelligence to analyze and interpret microbial growth on culture plates, enhancing detection capabilities.



APAS Independence

Specs from the vendor

Available for 55mm and 90 mm plates.

Capacity: 240 plates ~240 plates/hour

FDA cleared--> The FDA approved the equipment's performance after they sent 5000 plates to 3 different labs

Can it scan codes on labels?-->yes

Vendor is working on identifying the microorganism from the picture (not in scope for Pfizer pilot/validation)

Connection to LIMS/MODA



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 Humidity: 20%-80% (non-condensing indoor use)	15°C-27°C 59°F-81°F	
	Altitude: Sea level to 2000m	9562ft	
Noise Specifications Noise level shall not exceed:	Continuous: 58dBA at 1m Peaks: 70dBA at 1m	3.3ft	
Electrical Input	100-240VAC, 50-60Hz, 6 Amps		
Warranty	12 months from date of commissioning		
Regulatory Cleared	United States (FDA) Europe (CE mark, UKCA) Australia (TGA)		

APAS pilot in Melbourne



Pilot Testing Design



Variety in Organism Growth and Plate Defects

- Microbial Growth Patterns

- Organism growth varies in colony size, color, shape, and plate location, highlighting diverse microbial characteristics.

- Agar Plate Defects

- External plate defects include cracks, ripples, dried agar, and variations in agar color from different batches or brands.

- Interferents on Plates

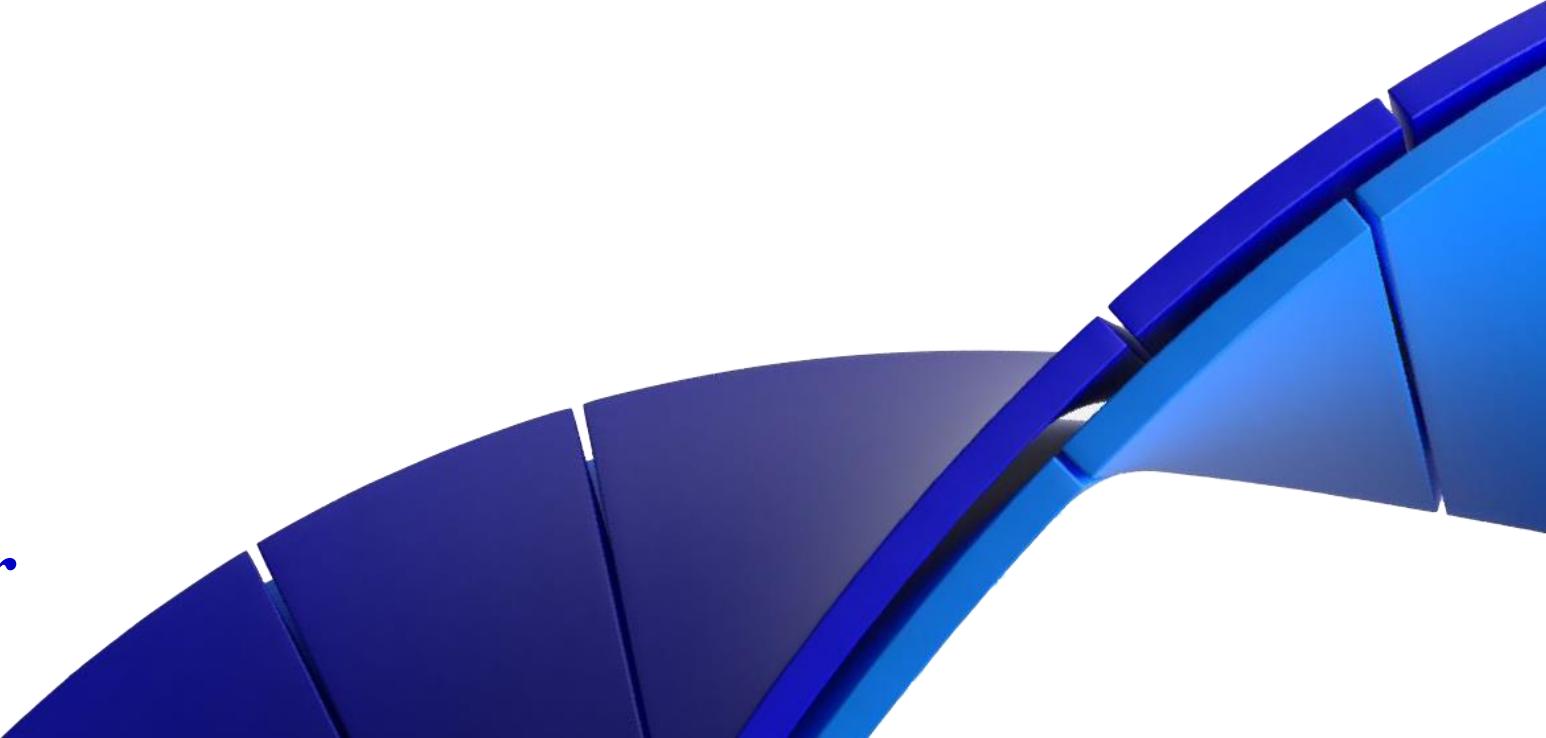
- Interferents such as bubbles, particles, labels, writing, scratches, and grids can impact plate observation and analysis.



Types of Plates Tested and Examples

Type of plates	Picture	Type of plates	Picture	Type of plates	Picture
With no growth		Colony size: overgrown		Colony shape: tentacular	
Colony size: small		Colony shape: fuzzy edges		Colony location: edges	
Colony size: small Colony colour: translucent		Colony shape: rounded		Defects in the agar	

Performance Results



Measurement Approach and Data Sources

Data Sources Overview

- Data was collected from MODA, logbook for contrived plates, and APAS reports for comprehensive analysis.
- 6267 plates of 90mm with TSA or SCDA media were read with the system.
 - 5786 plates came from the normal EM process
 - 481 plates of the same characteristics were contrived in the Microbiology Laboratory at the site
 - From the positive plates, around 14 K total CFU

Colony Detection Principles and Challenges

- Addressing False Negatives

- Colony-level analysis helps detect undetected colonies that would cause false negatives if analyzed only at plate level.

- Growth vs No-Growth Limitations

- Growth vs no-growth method is incomplete as it may miss colonies when multiple colonies are present together.

- Merging Colonies Challenge

- Merging or touching colonies complicate counting, and detection systems accept recognition of contamination presence instead of exact counts.

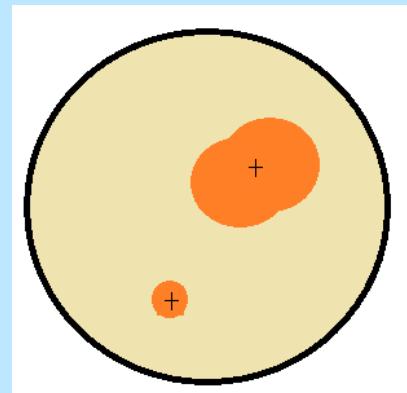
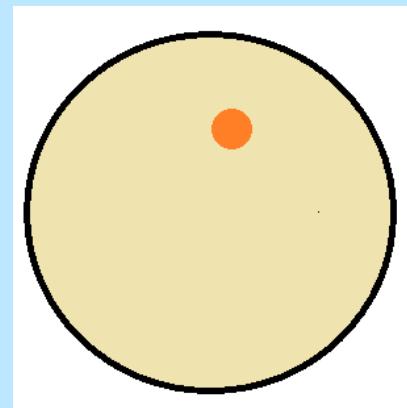
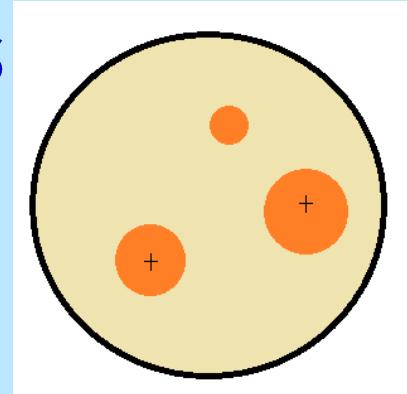


Plate level summary

		APAS		TOTAL
		Growth	No Growth	
Reference Results	Growth	537	2	539
	No Growth	802	4926	5728
Total		1339	4928	6267

STATISTIC	PLATE TYPE	NEW MODULE
PPA (Positive Percent Agreement)	All	99,63%
	Native	100,00%
	Contrived	99,58%
FNR (False negative rate)	All	0,37%
	Native	0,00%
	Contrived	0,42%
FPR (False positive rate)	All	14,00%
	Native	14,00%
	Contrived	0,00%

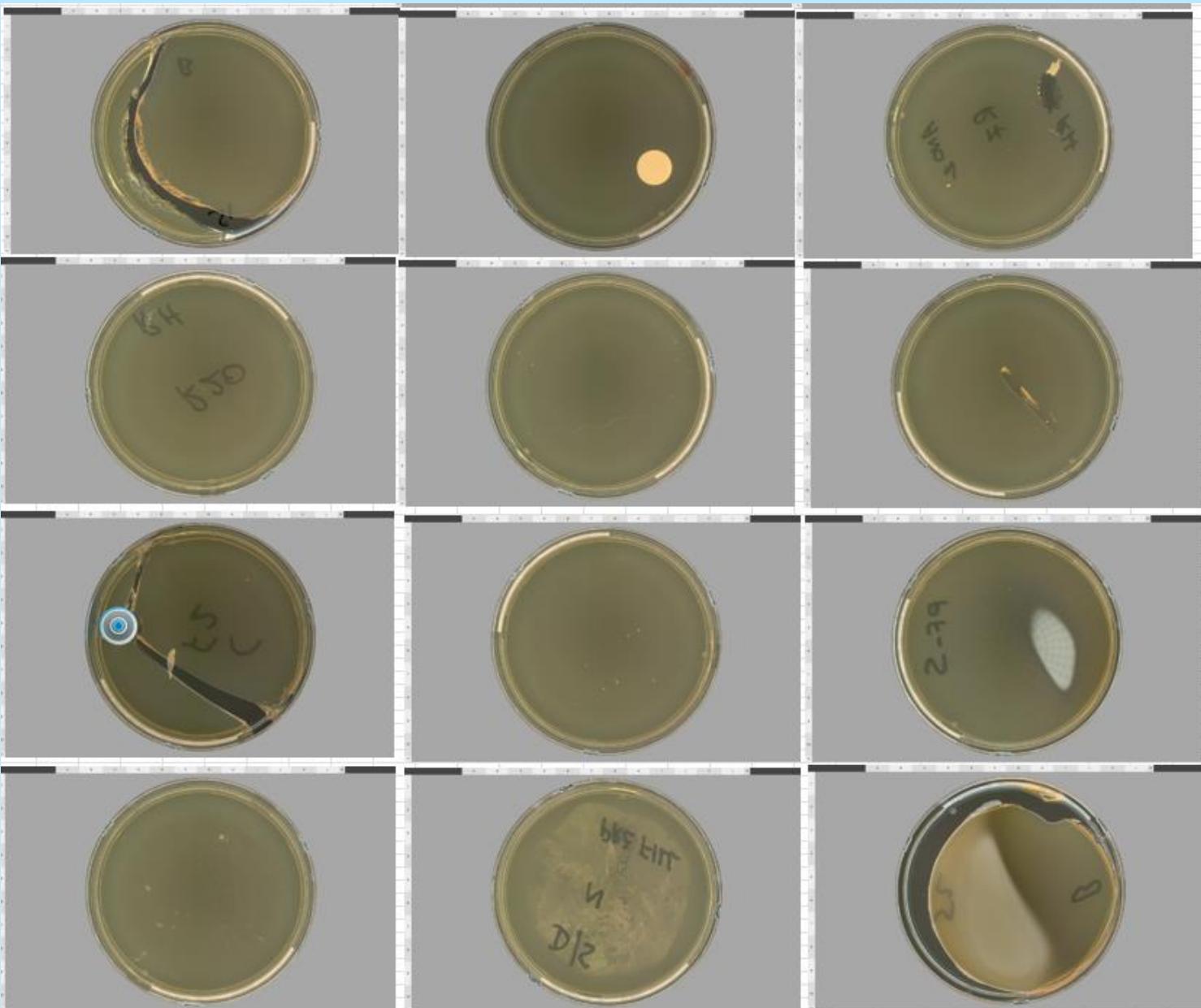
Plate level analysis is part of the pilot but the validation has to be addressed at a colony level

Types of Defects Leading to False Positives

TYPE OF DEFECT	PERCENTAGE OF THE FALSE POSITIVE PLATES
Labels	<3%
Tape	≈ 40%
Damaged agar	≈ 7%
Process interference (material on the agar that is not a microorganism: product, cleaning product, etc)	≈ 36%



Examples of false positives



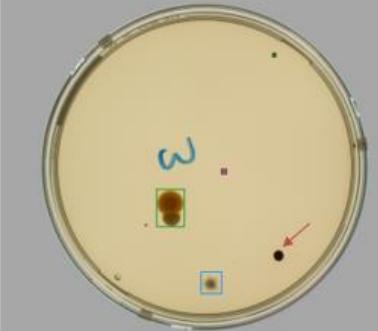
100 positive plates were analysed at a colony level

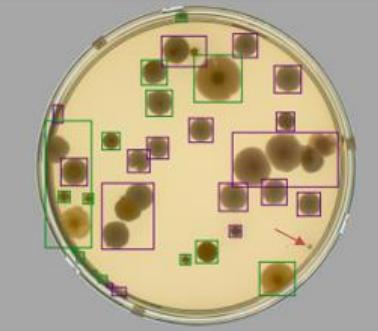
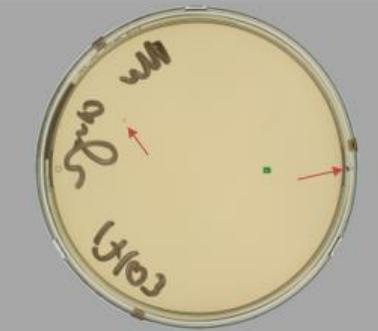
- Current Module Performance

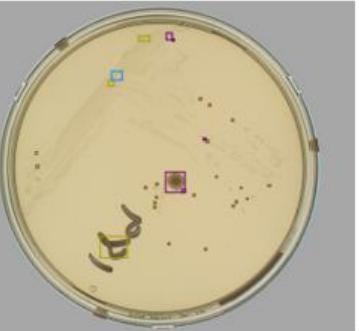
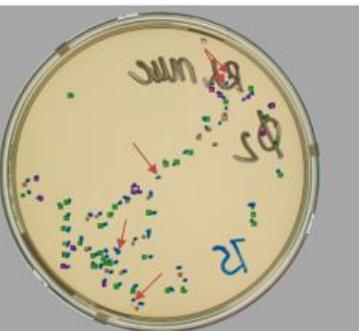
- 9 out of 100 plates in the current module had undetected colonies, mostly small, pale, or translucent.
 - 4 plates had TNTC (small pale/translucent)
 - 5 had isolated CFU: 9 in total

Note: The plates come from a contrived dataset designed to test detection limits, not typical real-world samples.

Example of CFU missed

Undetected CFU	Picture
2	
TNTC (small pale)	

Undetected CFU	Picture
1	
2 (edge)	

Undetected CFU	Picture
TNTC (small pale)	
5	

Lessons learned

- Timing is really important!

You don't want to wait too long to assess your suspicious samples (specially if they are natural plates): As time passes, samples could become impossible to assess



This is product residue.
Had there not been an investigation, it could've been interpreted as a missed CFU by the human eye

Conclusion

- The pilot was successful in evaluating the instrument's performance against human plate reading capabilities. No hardware issues were recorded
- The instrument is robust, user-friendly, and had a 1.19% error rate for label reading, likely due to a batch issue.
- The study affirmed the instrument's strong performance under challenging conditions, indicating its potential to meet future validation criteria.

Thank you!