

# EM Plate Reading Using the APAS Independence

Comprehensive analysis  
of automated plate  
reading system



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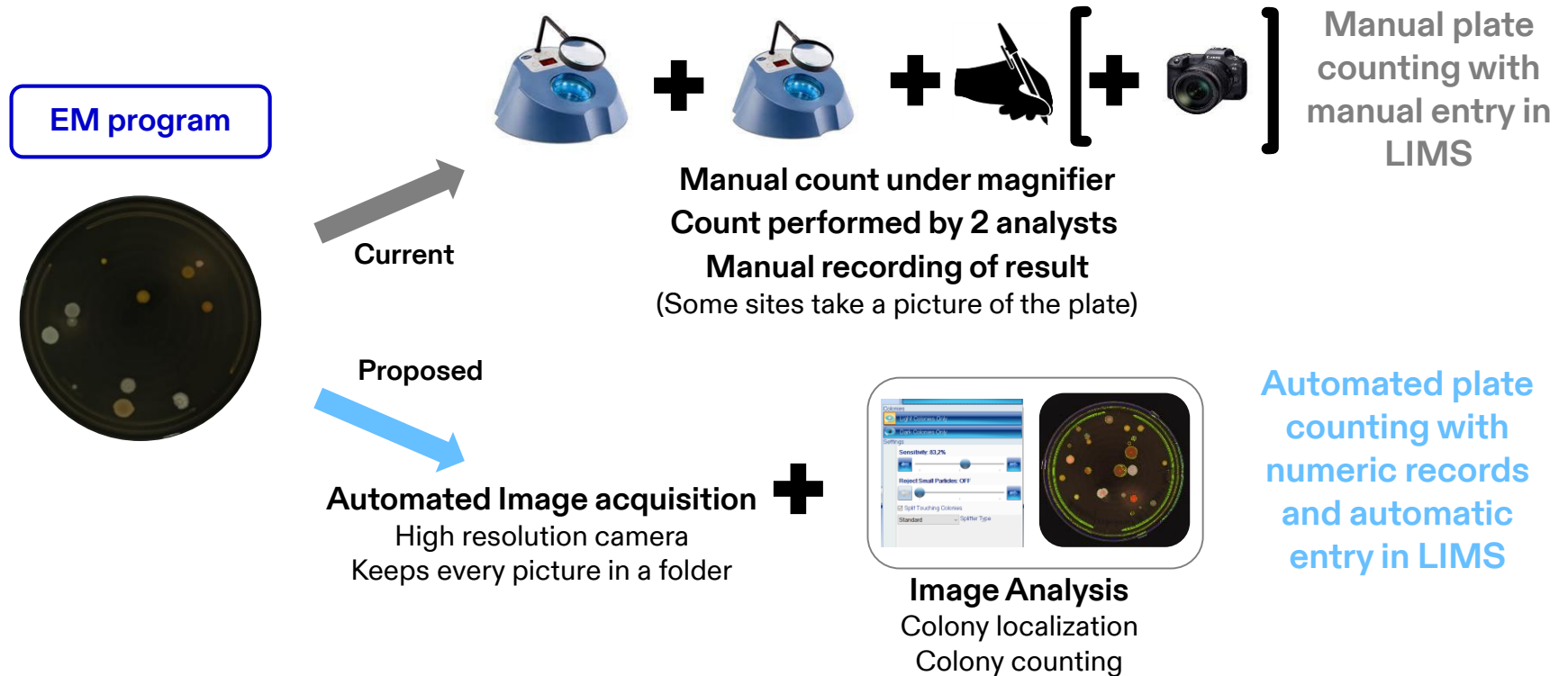
November 2025

# Agenda

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



# Concept introduction



# 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	15°C -27°C	59°F- 81°F
	Humidity: 20%-80% (non-condensing indoor use)		
	Altitude: Sea level to 2000m	9562ft	
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		
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

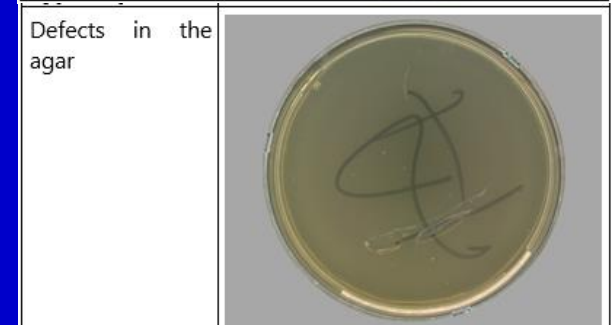
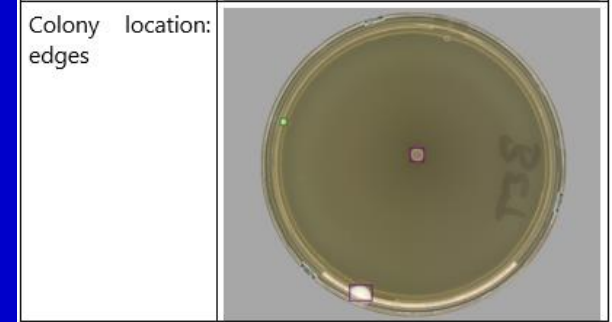
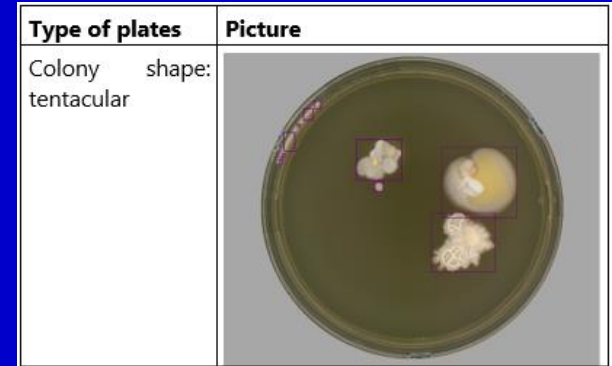
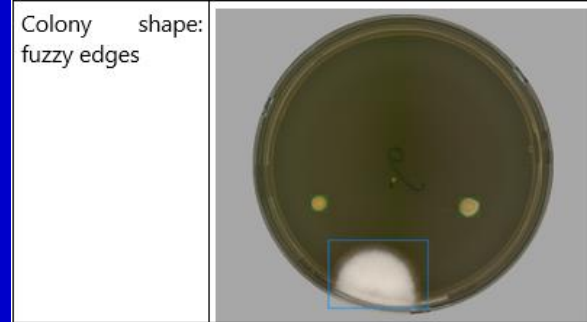
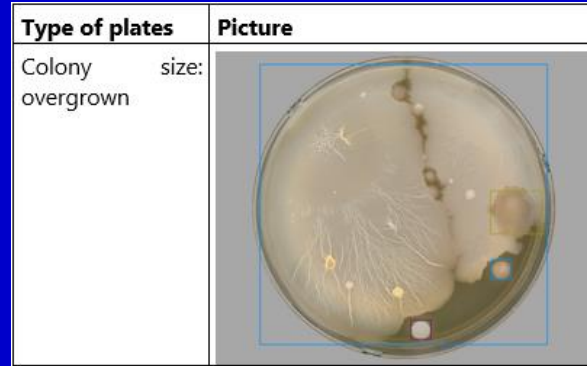
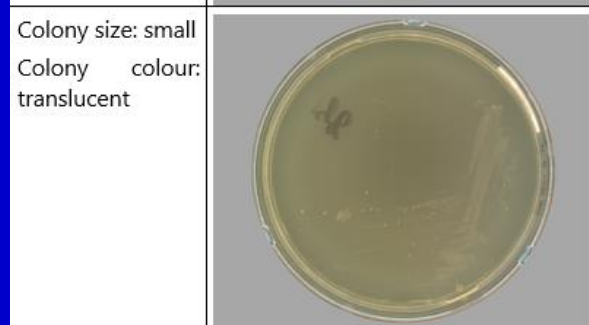
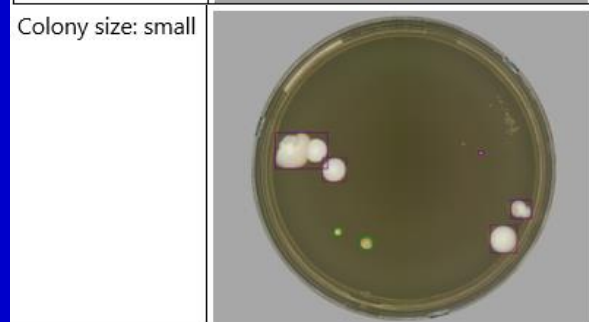
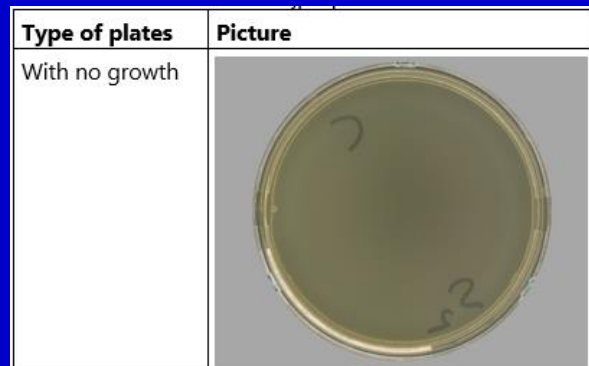
- External plate defects include cracks, ripples, dried agar, and variations in agar color from different batches or brands.

- 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



# Performance Results



# Measurement Approach and Data Sources

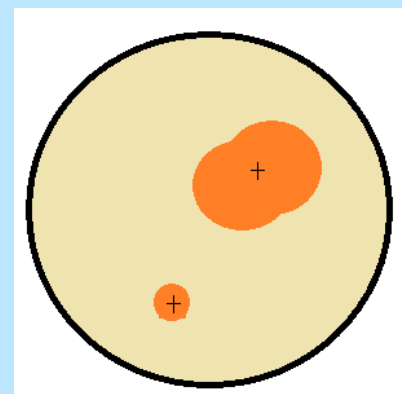
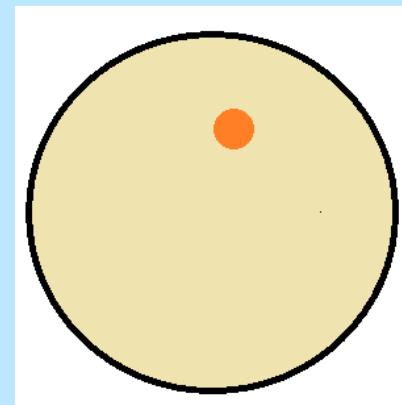
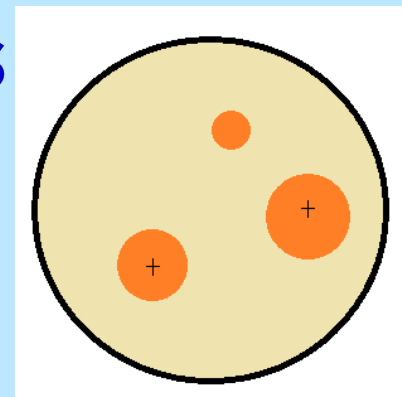
## Data Sources Overview

- 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*

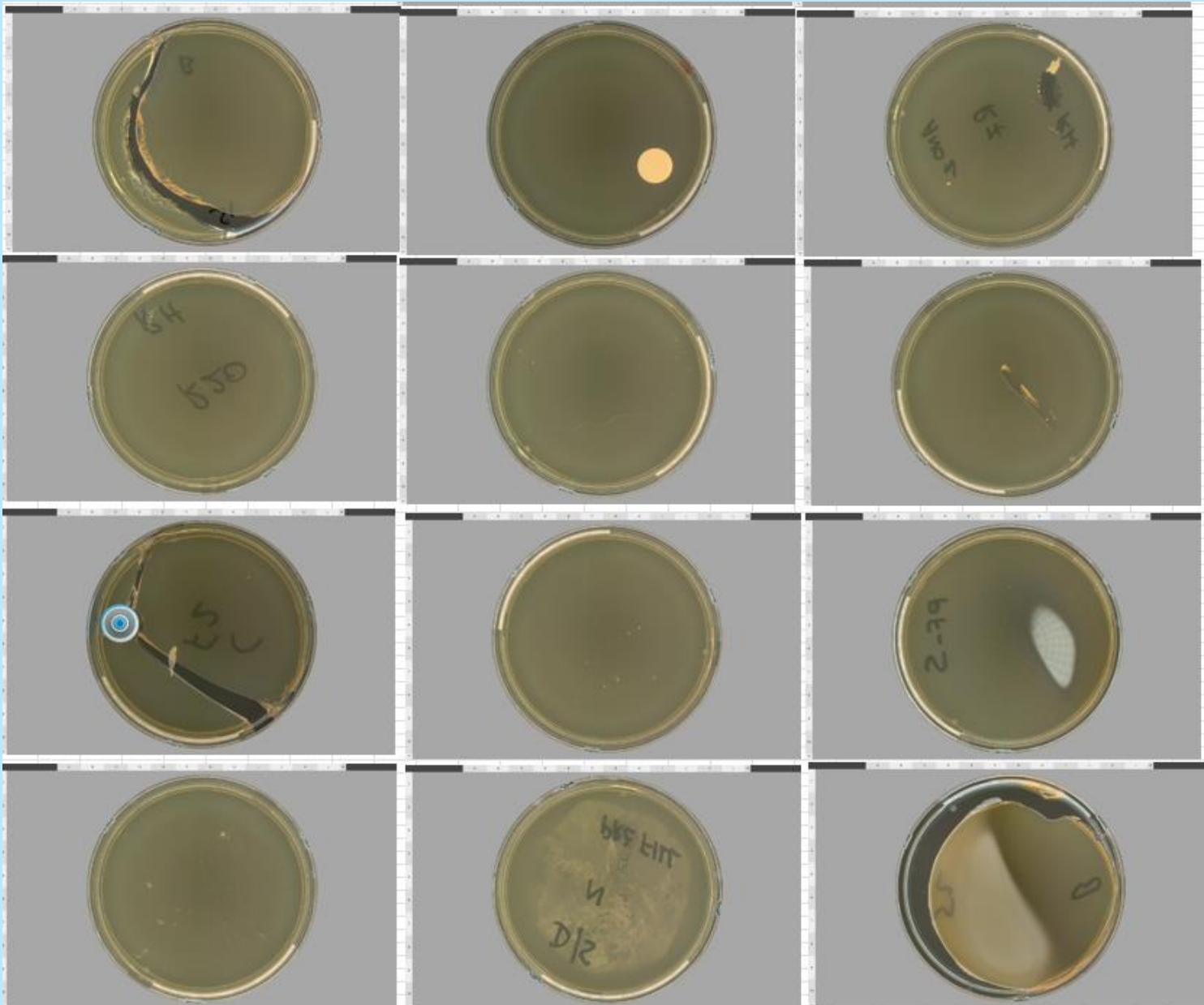


# Types of Defects Leading to False Positives

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





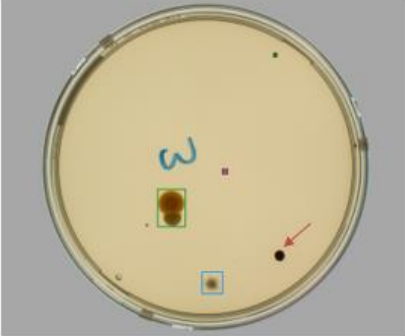
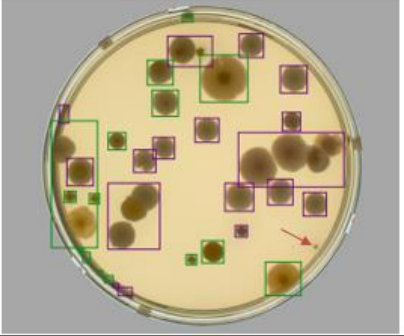
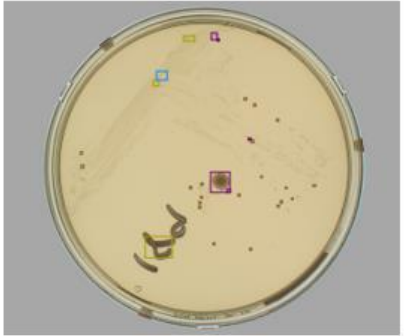


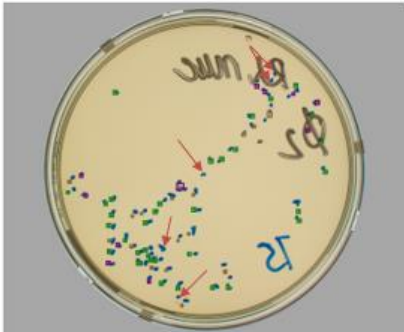
# 100 positive plates were analysed at a colony level

- 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.*

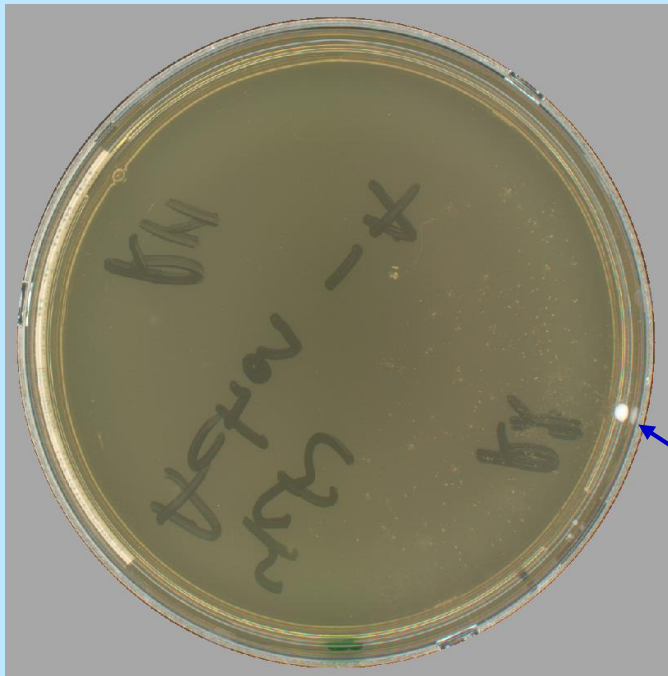
# Example of CFU missed

Undetected CFU	Picture	Undetected CFU	Picture	Undetected CFU	Picture
2		1		TNTC (small pale)	
TNTC (small pale)		2 (edge)		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!