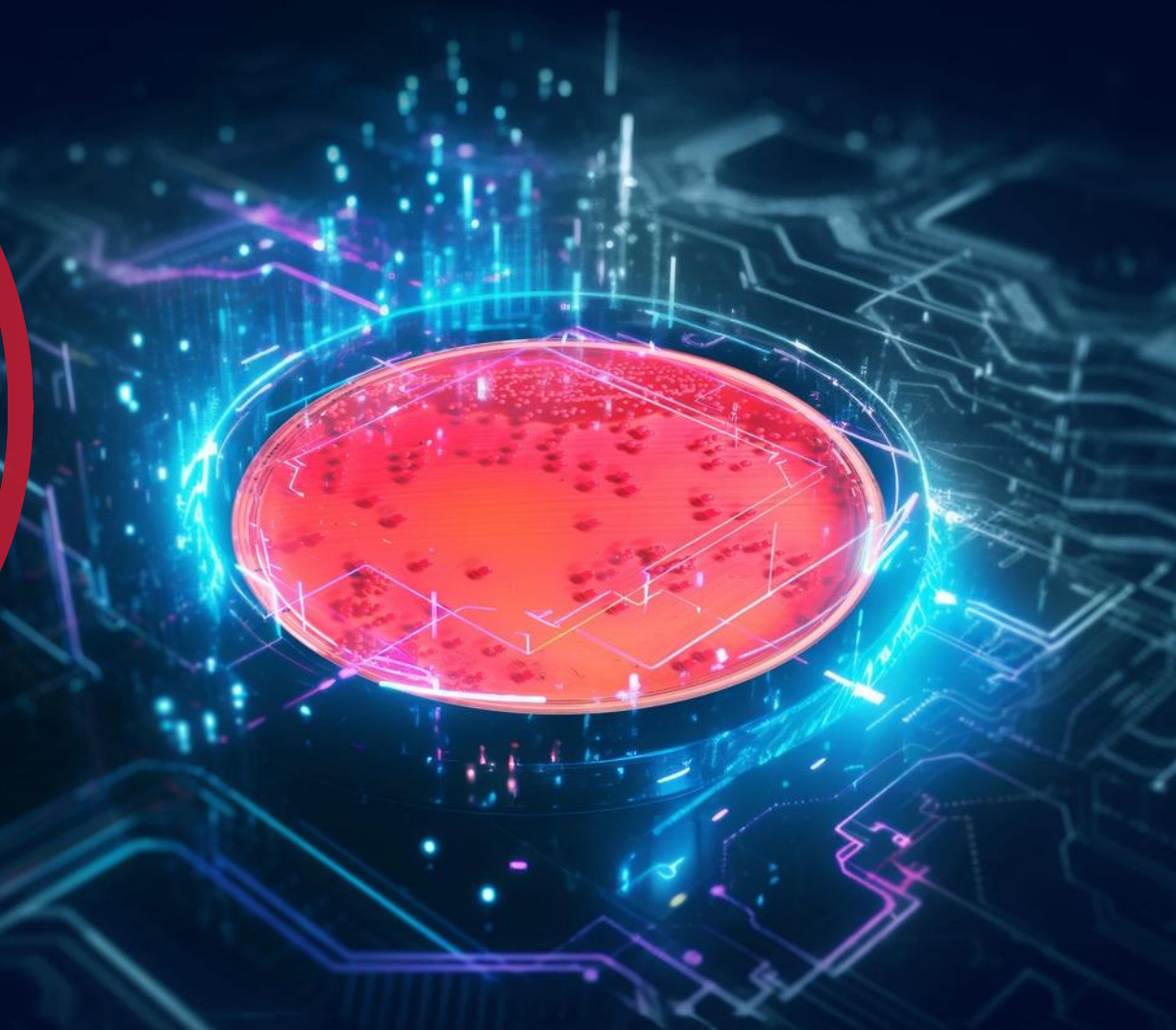
APAS® PharmaQC

Pilot secondary validation study results

July-23



CLEVER CULTURE SYSTEMS

LBT INNOVATIONS

Executive Summary – Pilot Secondary Validation study

Total 1,515 environmental monitoring plates collected during routine production

- 1,477 Environmental monitoring plates collected from Class A (including settle and finger dab plates)
- 38 contrived plates (11 pos, 27 neg) collected to increase positivity rate
- Data collected from LIMS system to provide reference result for each plate

Plates subsequently run through APAS Independence to assess performance using “real-world” data and identify any discrepant results between human and AI

- Measured growth vs no growth performance

Summary of performance

APAS PharmaQC demonstrates 100% sensitivity for microbial growth detection

Discrepant analysis investigations:

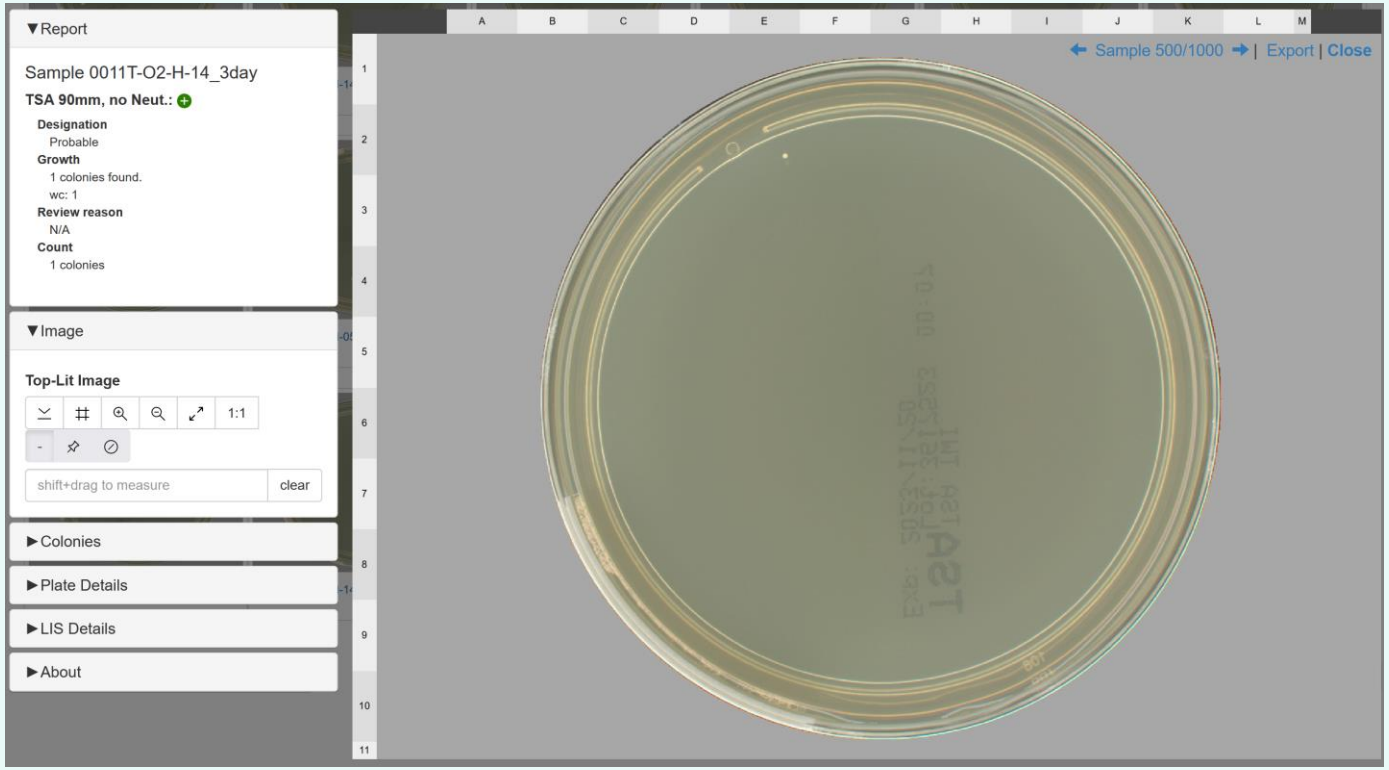
- APAS identified potential additional positive plate(s) missed by normal reading
- Top causes of disagreement between reference count and APAS:
  - Tape applied to plates during processing
  - Labels incorrectly applied to plates
  - Excessive text markings on the plate
  - Product identified on the plate

Results:

	APAS			
AZ		No growth	Growth	Total
	No growth	1390	110	1500
	Growth	0	15	15
	Total	1264	251	1515

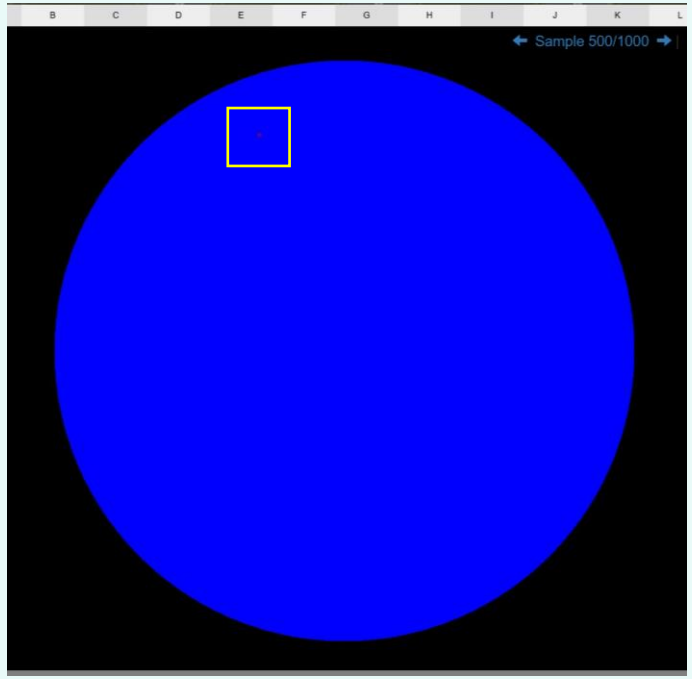
- Positive percent agreement (PPA): 100% (15/15 correct)
- False negative rate (FNR): 0% (0/15 incorrect)
- Negative percent agreement (NPA): 92.6% (1390/1500 correct)
- False positive rate (FPR): 7.3% (110/1500 incorrect)

Example Results – Plate classifier result, single colony detection

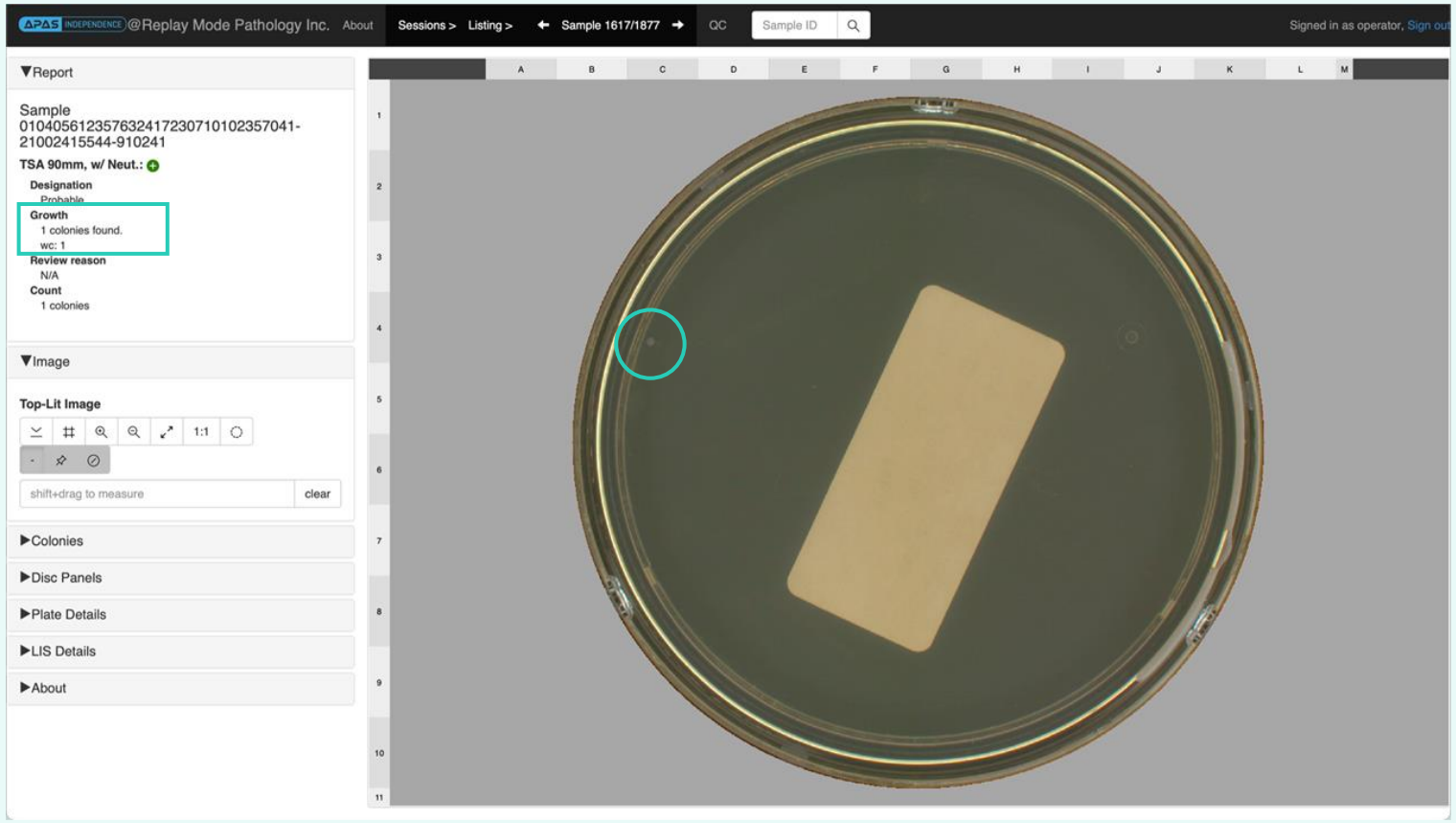


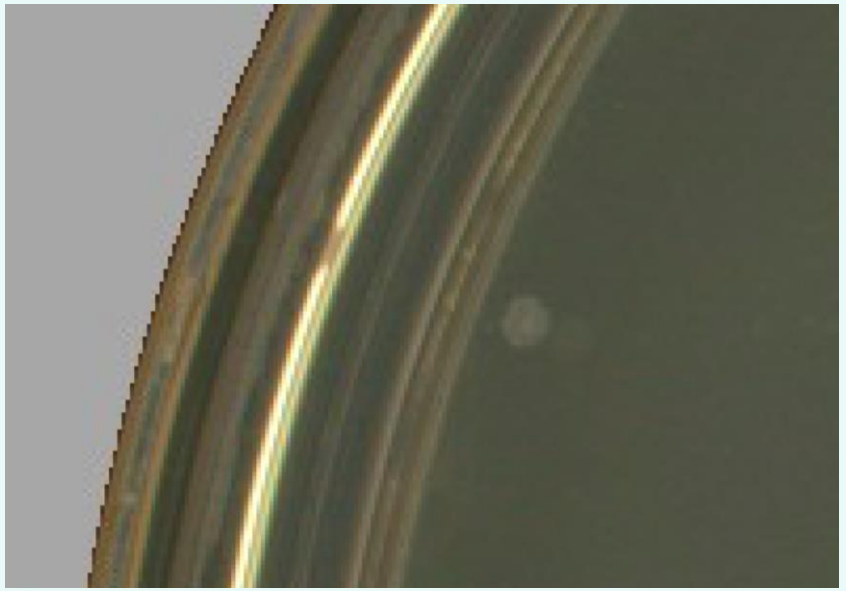
APAS correctly identifies and counts single small colony on plate.

No interference from dish markings or labels



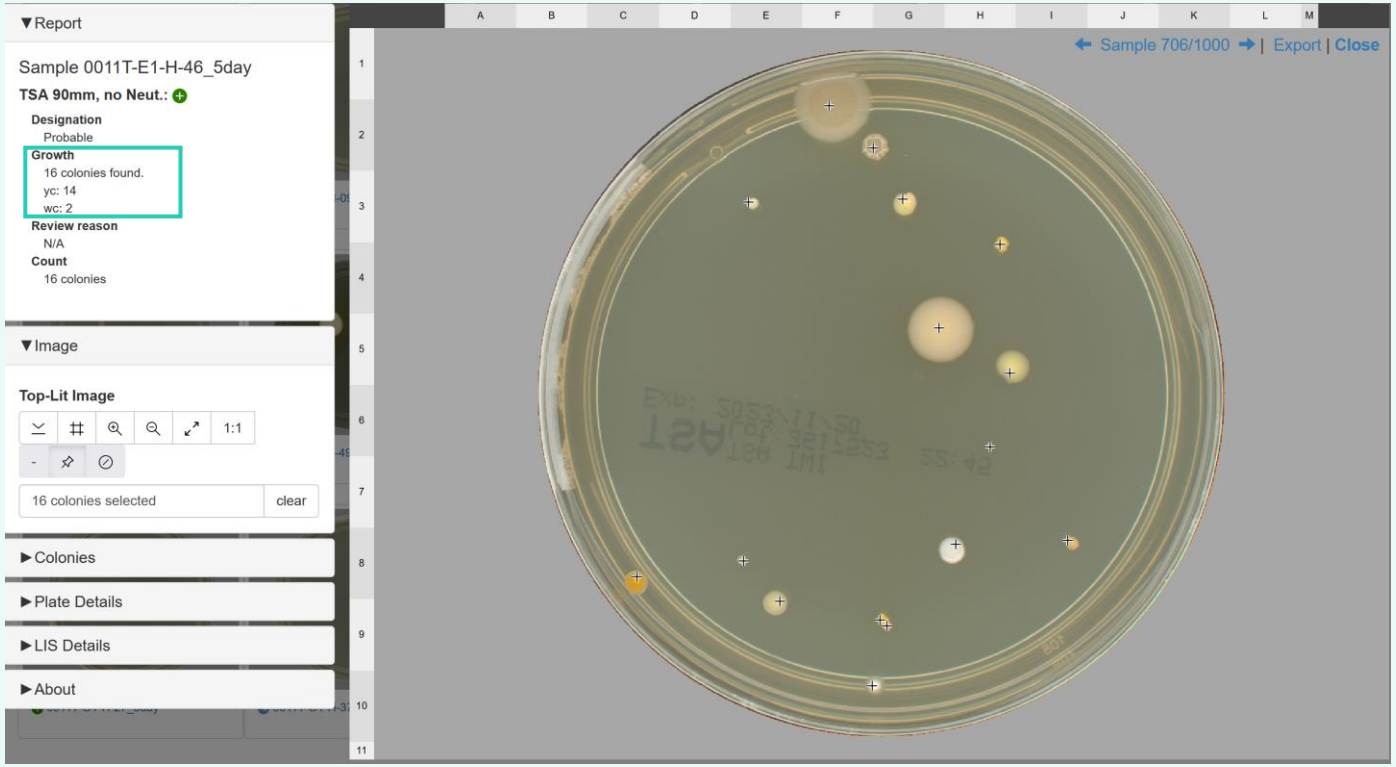
Example Results - APAS PharmaQC detects colonies missed by human reading





Small white colony detected at edge of plate, missed during normal reading.

Example Results – Plate Counting Performance



APAS Count identifies 16 colonies which are confirmed by manual counting

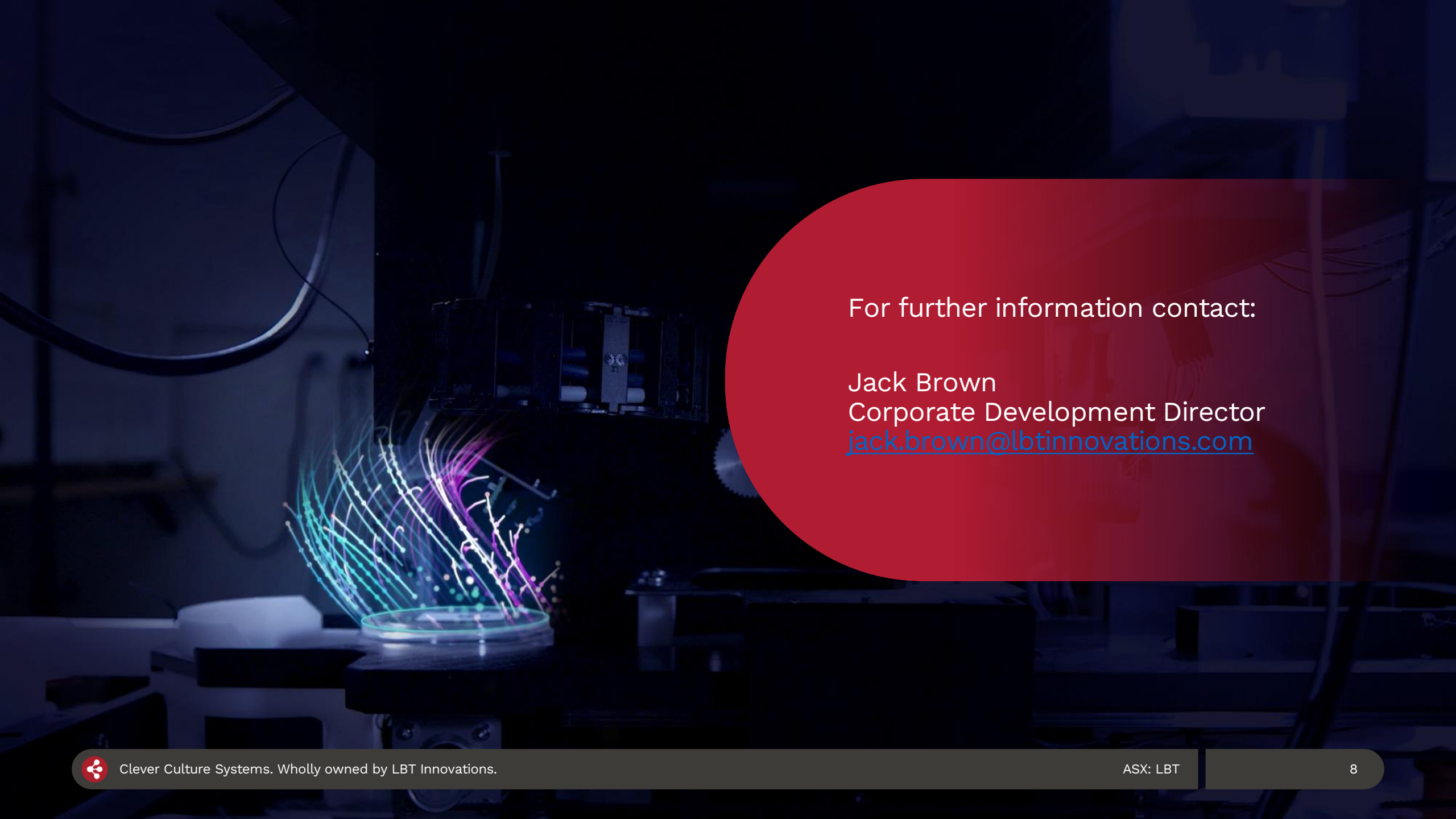
Plate counting tools available in APAS Web-UI assist for human verification of results

Next Steps

Pilot primary validation study underway, testing performance and preliminary methods for formal testing.

Testing scope aligned with Pharmacopeial requirements for:

- Linearity of Count
- Specificity
- Robustness
- Ruggedness
- Limit of Detection
- Precision
- Accuracy
- Operational Range
- Limit of Quantification
- Repeatability



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