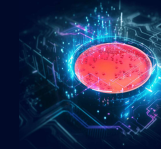


Modernizing Growth Promotion Testing Using APAS Independence

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Clever Culture Systems



Agar's Unrivalled Utility

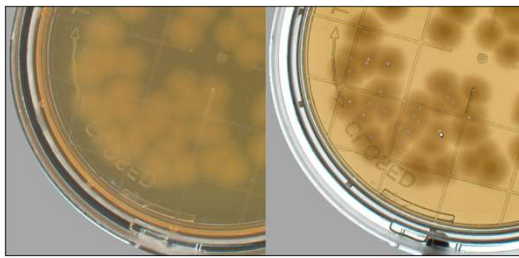
- Agar remains a cornerstone in environmental monitoring.
- Still the most practical, low-cost method for EM.
- Versatile – used for testing of air, water, surfaces, personnel, and products.
- Facilitates organism identification by microbiologists and enables further testing.
- Culturing with agar is venerable, but there is still great potential for modernizing its workflow.



Manual plate interpretation is not just time-consuming and tiresome, but also inaccurate.

The Growth Promotion Test

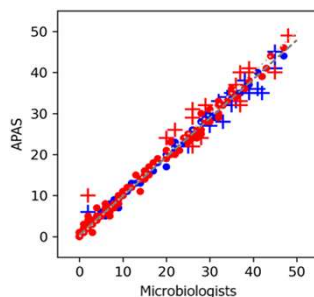
- The cleaner the environment, the more critical it is that any single colony-forming unit will produce a positive result.
- The Growth Promotion Test (GPT) is a regulatory requirement and verifies that each new batch of agar can perform as needed.
- Inoculation has been streamlined with freeze-dried organism pellets, but interpretation is still largely performed manually with plate in hand.
- Counts are performed on new and previously accepted batches for comparison.
- With multiple organisms and up to 100 CFU on each plate, interpretation is highly tedious and error-prone.



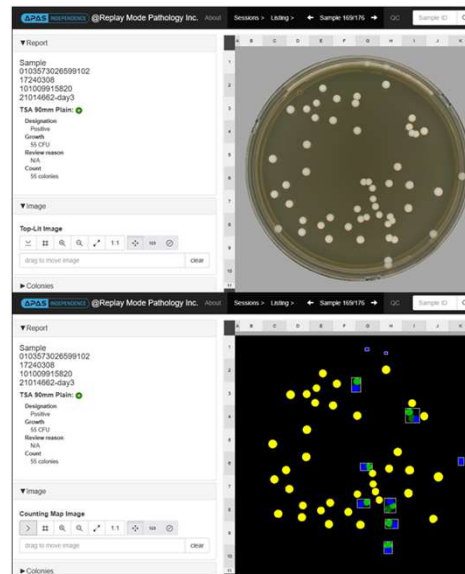
Hazy, transparent colonies can be challenging, especially when crowded on 55mm plates. APAS images provide the ideal base for automated counts as well as assisting users with on-screen counts which are more accurate than plate in hand.

Count Colonies with Confidence Using APAS Independence

- Variation in lighting, background, and plate features contribute to erroneous counts.
- APAS mitigates these variables, producing plate images that are ideal for counting by AI and humans.
- APAS WebUI features lighting toggle, zoom, and count tool which marks and tallies colonies.
- APAS provides accurate counts when compared to microbiologists in less than 18 seconds.



In primary validation, APAS counts were compared with the panel result of three microbiologists. Correlation coefficients were >0.97 for counts of 0-50 CFU.



APAS algorithms effectively detect merged and obscured colonies which may be missed with manual interpretation. Enumeration as well as other relevant plate data is securely stored via direct LIMS integration, enhancing traceability.

Integrated Data Integrity

- Transcription error is yet another common source of uncertainty, but manual methods offer limited traceability.
- Plates are interpreted, the results recorded, then the plates are discarded.
- As labs increasingly adopt digitalized systems, regulatory requirements are becoming more stringent.
- APAS automatically stores plate images, results, and all relevant audit information.
- With direct LIMS integration, compliance with 21 CFR Part 11 is built-in.

Tracking Trends

- US and European Pharmacopoeias prescribe an acceptance range of 50-200% compared to counts on previously accepted batches.
- This allows for pipetting errors if serial dilutions are used, but gradual declines in agar performance or organism viability can be masked.
- Data export enables further dissemination for long-term scrutiny of GPT results.
- Identifying trends for GPT and EM sampling is crucial for early investigation to stay ahead of alerts and potential recalls.

Summary

- Even as alternative methods such as fluorescent particle counters become adopted, agar's versatility and capacity for identification uphold it as a dependable method of sampling.
- This is especially true for surface sampling, where contact/RODAC plates are still the gold standard.
- Regardless of plate size, GPT is a must.
- APAS Independence makes it faster and more accurate, with enhanced record-keeping and data insights.



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