Modernising Growth Promotion Testing using APAS Independence

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Amongst all the advancements in cleanroom technologies, the humble agar plate has withstood the test of time as a practical, low-cost method for environmental monitoring. For detection of viable microbes, there is no result more definitive than growth on a plate, and as long as agar is relied on for monitoring, so too is the Growth Promotion Test (GPT) for verifying that every new batch of agar can perform as required.

As laboratories look to modernise their processes to more efficiently utilise skilled personnel, there is potential for agar-based methods to adapt accordingly with minimal disruption to already established procedures. For GPT, the use of freeze-dried organism pellets has streamlined inoculation and greatly improved accuracy over serial dilutions, but interpretation is still largely performed by manual counting. With some tests being performed in duplicate for several organisms and up to 100cfu on each plate, manual interpretation for GPT can be tedious—and after all that time spent counting, how reliable are the results anyway?

Human factors such as time pressure, fatigue, and distraction are the obvious culprits of erroneous counts. However, lighting conditions, backgrounds, and plate features such as embossing and pen markings also contribute significantly to inaccuracy. Clever Culture Systems APAS Independence mitigates these variables by imaging plates with dual lighting modes and a non-interfering background (Figure 1). By providing the ideal optical conditions for colony detection using artificial intelligence (AI) and humans alike, not only does the system give robust automated counts, but it also supports the skills of experienced microbiologists when challenging growth morphologies present themselves.

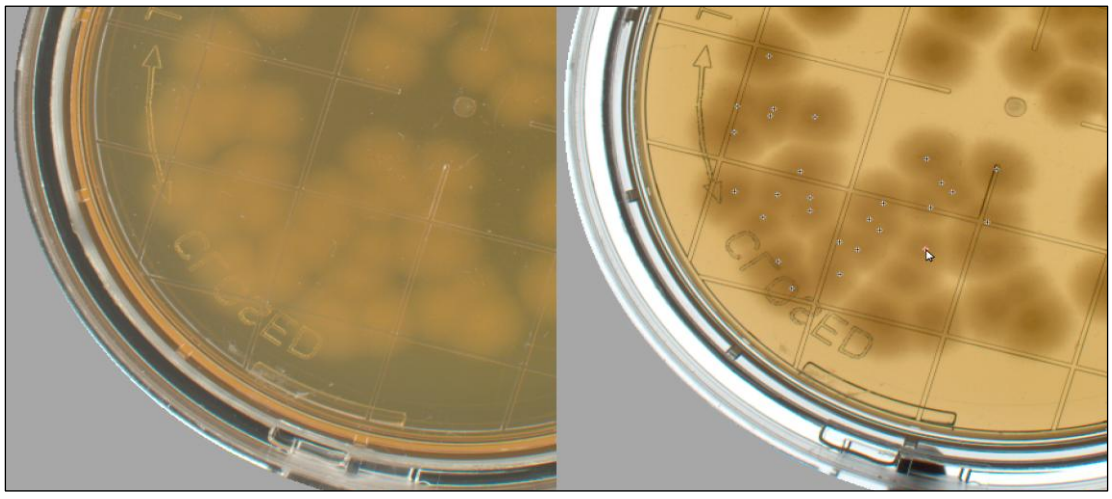

Figure 1: With its hazy, spreading morphology, Pseudomonas paraeruginosa can be challenging, especially with crowded colonies on 55mm plates. APAS Web UI gives users the ability to toggle lighting modes so they can visibly discern colonies and increase counting accuracy.

For GPT, USP <61> and Ph. Eur. 2.6.1 prescribe a generous acceptance range of 50-200% recovery compared to the reference media, so while absolute accuracy is not as essential as for monitoring Grade A environments, the benefits of modernised GPT extend beyond just counting. One problem with the traditional agar workflow is that once plates are interpreted, the results are manually recorded, and the plate is then discarded. Transcription error is yet another source of uncertainty in recorded results, and with the raw 'observation' data now gone there is effectively a dead-end in terms of traceability. The requirements for good record-keeping and data integrity are becoming more stringent from regulators, so by integrating directly with LIMS to store plate images and results, along with all relevant auditable information, APAS enables labs to operate in compliance with 21 CFR Part 11. (Figure 2 shows the APAS result and image which are automatically stored).

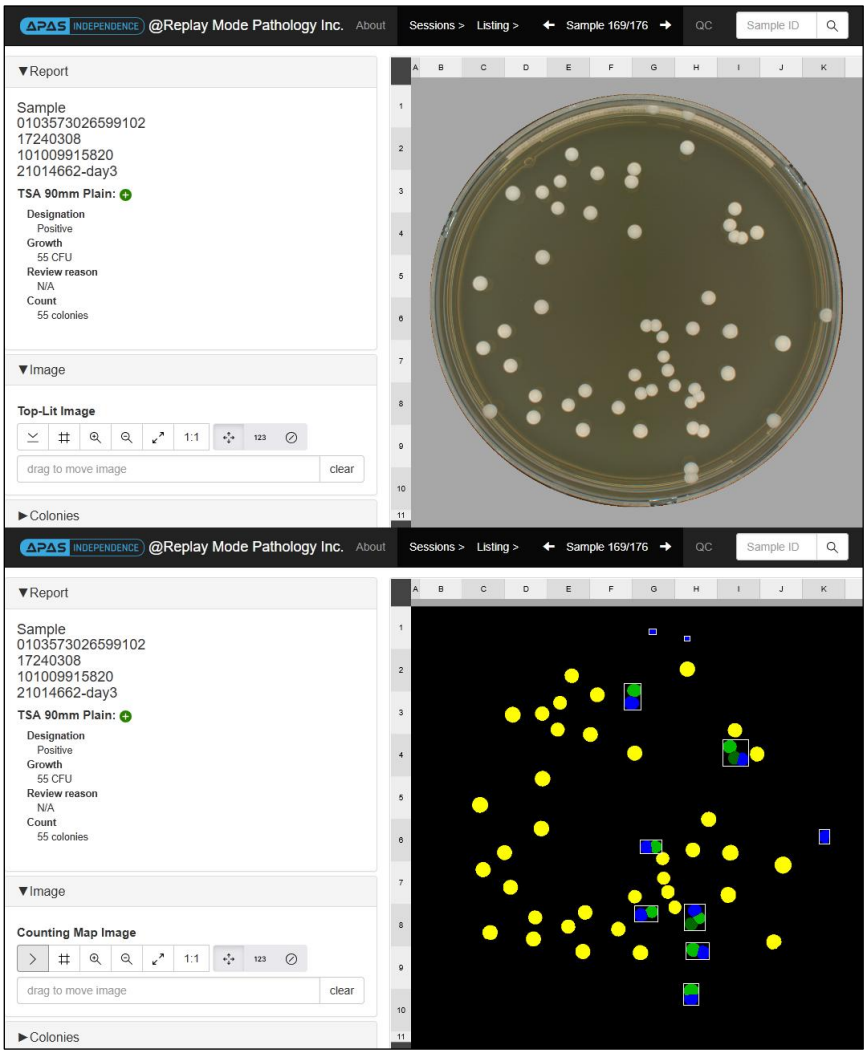

Figure 2: Screen captures of APAS Web UI demonstrate how its AI algorithms effectively detect merged and obscured colonies which may be missed with manual plate-in-hand reading, providing an accurate count that can integrate with any LIMS.

The ability to export data for further dissection is crucial for conducting trend analysis not just for contamination events, but also for monitoring long-term GPT performance. The lower limit of 50% recovery for acceptance allows for a good deal of variation but any gradual decline in agar performance could potentially be

masked unless established trending alert levels are in place. It is therefore incumbent that long-term GPT results are scrutinised in order to identify trends and investigate accordingly—especially if serial dilutions are used for testing as viability of stock cultures could also decline, resulting in a similar trend.

Even as alternative methods of air monitoring such as continuous particle counters are gradually becoming adopted, the versatility of agar and its capacity for organism identification uphold it as a dependable method of sampling, particularly in lower grade clean rooms where instantaneous alerts for single contaminants are not required. For surface sampling, however, contact/RODAC plates firmly remain the gold standard. In any case, whether the plate size is 90mm or 55mm, the GPT is an unavoidable obligation, but one which can be effectively facilitated with some clever use of automation that supports skilled staff, rather than replacing them.

Figure 3: APAS Independence - the only scientifically proven instrument that uses AI to read environmental monitoring culture plates 90mm and contact plates.

For more information about APAS Independence for your growth promotion testing, contact us: sales@cleverculturesystems.com.