

# Evaluating the APAS Independence System for Automated Microbial Detection in Environmental Monitoring

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## Abstract

Automated microbial detection systems are becoming increasingly beneficial in pharmaceutical manufacturing to enhance efficiency, accuracy, and compliance with Good Manufacturing Practice (GMP) standards. The APAS Independence System, developed by Clever Culture Systems, was evaluated at Bristol Myers Squibb (BMS) to assess its suitability for environmental monitoring applications. The APAS system is capable of automated plate counting of both 55 mm and 90 mm plates, following an offline incubation at routine EM parameters. The study compared APAS automated colony counts to traditional manual counts for compendial strains and environmental monitoring samples across multiple weeks of EM sampling. Performance metrics for both plate sizes were analyzed, such as accuracy, precision, false negative and false positive rates, and robustness. The APAS system demonstrated high accuracy ( $\geq 70\%$ ) and reliability for most tested organisms. Therefore, the system is being implemented for GMP use, with a validation approach that combines vendor validation of the Artificial Intelligence with site specific instrument qualification. This evaluation provides insight into the capabilities and limitations of automated colony detection, informing future digitalization strategies in microbiological quality control.

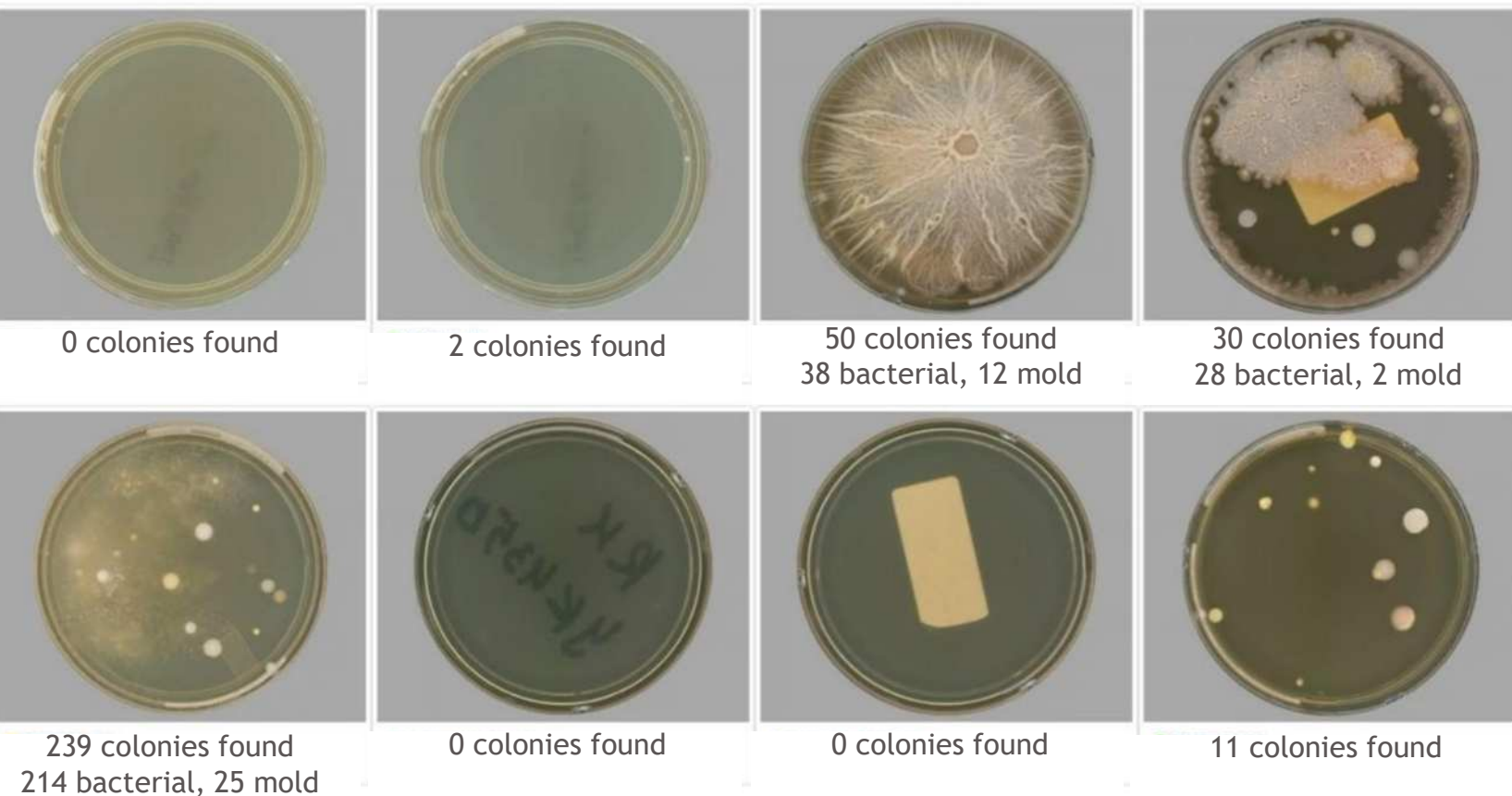
Figure 1. APAS Independence<sup>1</sup>



## APAS Independence

APAS Independence is an advanced automated instrument developed for imaging, analyzing, and interpreting microbiology culture plates in environmental monitoring (EM). Utilizing advanced imaging technology and artificial intelligence (AI), APAS Independence automatically detects and quantifies microbial growth, including mold colonies, on culture media. Specialized analysis modules enable fully automated plate reading and direct reporting of results to the laboratory information system (LIS), enhancing the efficiency and accuracy of laboratory workflows.

Figure 2. APAS Plate Counts



## Study Design

The APAS Independence system was assessed for accuracy by comparing its colony counts to manual counts performed by trained analysts across a range of organisms ( $\leq 100$  CFU), using the ratio of automated to manual counts. Precision was evaluated through repeatability and reproducibility studies, measuring intra- and inter-operator/instrument variability. Sensitivity was determined by comparing APAS results to manual counts on tested organisms and routine environmental monitoring plates, focusing on the false negative rate. Ruggedness was tested by examining the impact of variations in operators, consumable lots, and media types on results, while robustness was assessed by introducing deliberate changes in test parameters such as incubation times and temperatures (i.e. 3 days at 30-35°C and 2 days at 30-35°C then 5 days at 20-25°C).

Table 1. Manual vs APAS Plate Counting for 90mm Plates

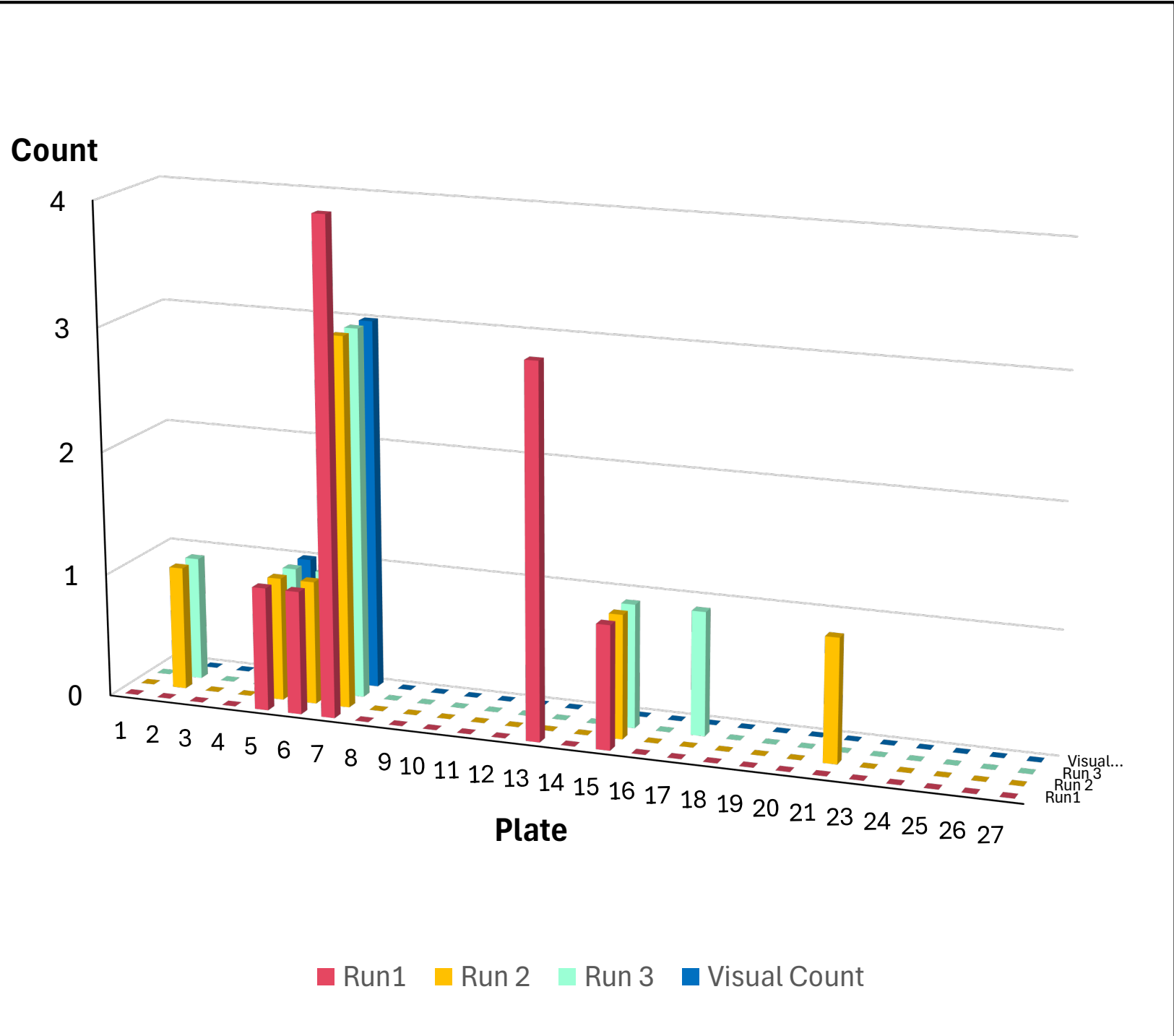
Sample ID	Manual			APAS		
	Bacteria	Mold	Total CFU	Bacteria	Mold	Total CFU
B. spizizenii	16	0	16	55	0	55
	12	0	12	83	0	83
	10	0	10	276	1	277
	12	0	12	264	0	264
A. brasiliensis	0	19	19	77	5	82
	0	23	23	115	6	121
	0	14	14	52	49	101
	0	16	16	57	52	109
P. paraeruginosa	8	0	8	12	0	12
	12	0	12	18	0	18
	9	0	9	10	0	10
	14	0	14	15	0	15
S. aureus	22	0	22	23	0	23
	27	0	27	28	0	28
	48	0	48	48	0	48
	32	0	32	35	0	35
S. epidermidis	13	0	13	19	0	19
	14	0	14	17	0	17
	10	0	10	10	0	10
	14	0	14	14	0	14
C. albicans	15	0	15	15	0	15
	19	0	19	19	0	19
	29	0	29	29	0	29
	19	0	19	18	0	19
M. luteus	27	0	27	23	0	23
	17	0	17	14	0	14
	20	0	20	19	0	19
	16	0	16	16	0	16

Table 2. Manual vs. APAS Plate Counting for 55mm Plates#

Sample ID	Manual			APAS		
	Bacteria	Mold	Total CFU	Bacteria	Mold	Total CFU
B. spizizenii	11	0	11	21	0	21
	13	0	13	27	2	29
A. brasiliensis	0	8	8	1	1	2
	0	12	12	0	10	10
P. paraeruginosa	13	0	13	13	0	13
	16	0	16	25	0	25
S. aureus	32	0	32	33	0	33
	30	0	30	unable to read barcode	0	0
S. epidermidis	8	0	8	7	0	7
	6	0	6	5	0	5
C. albicans	15	0	15	15	0	15
	10	0	10	10	0	10
M. luteus	26	0	26	17	0	17
	14	0	14	8	0	8

#During testing, software and equipment upgrades resulted in a temporary pause in the study, which limited the time available for additional data collection.

Graph 1. APAS Multiple Run Count Accuracy for 90mm EM Plates



Twenty-seven environmental monitoring plates were processed through the APAS system in triplicate (each of the 27 plates was read three times, indicated as "Run 1", "Run 2" or "Run 3") to assess count accuracy. Nineteen plates had no growth reported by both APAS and manual visual counts. The remaining eight plates, which exhibited growth detected by APAS, visual inspection, or both, are highlighted in the graph above.

After upgrading the software and equipment, 512 uninoculated and incubated 55 mm plates were processed through the system. Of these, 52 plates were incorrectly identified as having "growth," resulting in a false positive rate of 10.16%, which is within the acceptable limit of  $\leq 15\%$ . Additional evaluation is recommended for 55 mm plates to further assess system performance.

Table 3. Negative Plate Runs on APAS for 55mm Plates

	Number of plates	% Accuracy
Negative plates	512	89.84
False positive	52	10.16

## Results

- The APAS system consistently achieved  $\geq 70\%$  accuracy compared to manual counts with low deviation across replicates.
- False negative rate remained below the 1% acceptance criteria.
- False positive rate remained below the 15% acceptance criteria.
- Inconsistency between manual counts and APAS were observed specifically for spreading colonies and molds.
- System performance was unaffected by media, operator changes, or minor environmental fluctuations.

## Conclusion

The results demonstrated that the system met acceptance criteria for count accuracy, with counts reported at  $\geq 70\%$  of the visual counts performed by analysts. In alignment with GMP compliance, the APAS system can serve as the initial count for plates used in environmental monitoring testing, requiring only one analyst to verify all observed growth. This approach streamlines the workflow by eliminating the need for two individuals to review every plate.

## Acknowledgements

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## References

- <https://www.rapidmicrobiology.com/news/apas-independence-delivers-automated-culture-plate-reading-for-your-lab>