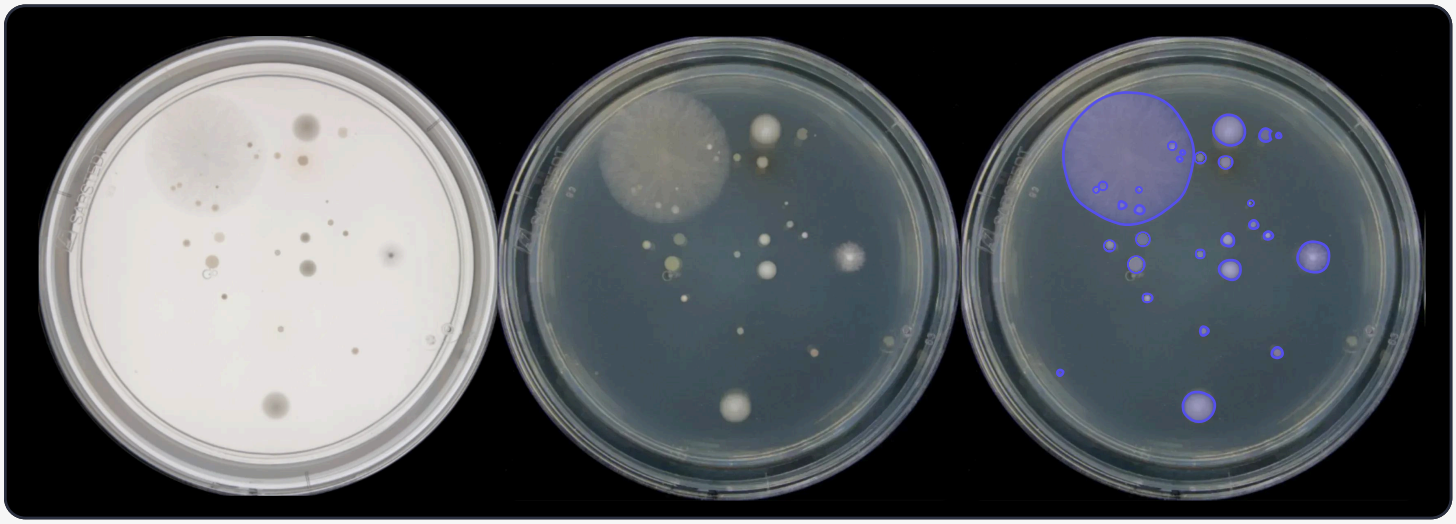
RESHAPE

Method Validation Report

ISO 4833

The aim of this validation is to demonstrate that Reshape Biotech's colony counting machine learning model performs in line with the ISO 4833 standard.

The standard defines how to reliably count colonies of microorganisms growing on agar plates at 30°C, typically used for assessing hygiene and microbial load in food samples.



Example image of a plate with transillumination, epi illumination, and annotation of analysis (from left to right)

Key Findings

Across 242 agar plates representative of ISO 4833 workflows, Reshape Biotech's colony counting machine learning model achieved **90.5%** agreement with technician consensus using ISO-aligned thresholds (±10% above 30 CFU; ±3 CFU at ≤30 CFU).

Precision was confirmed on a subset of 15 plates re-imaged 12 times under rotations, translations, and different devices, yielding a standard deviation of 0.44 CFU for low-count plates and an average coefficient of variation of 5.88% for higher-count plates.

Discrepancies largely coincided with high inter-technician variance, indicating performance within normal human variability. These results support the automated system as an equivalent, traceable alternative to manual counting under ISO 4833.

Introduction & Background

ISO 4833 is a widely adopted standard for enumerating total viable counts of microorganisms at 30 °C using colony-forming unit (CFU) counts on agar plates. In regulated food and environmental microbiology, consistency and traceability are essential, yet manual counting remains time-consuming and operator-dependent. The aim of this report is to assess Reshape Biotech's integrated imaging and machine-learning analysis pipeline for ISO 4833 use, by determining whether automated counts match technician consensus in accuracy and precision.

Materials, Methods & Protocols

A diverse set of agar plates (n = 242) was prepared using surface and pour-plate inoculation methods and included bacterial, yeast, and mold morphologies, as well as common real-world artifacts (e.g., labels and barcodes). Plates were imaged on the Reshape Smart Incubator and analyzed with Microbiology model v1.0.0.

Accuracy was evaluated against the mean of four trained technician counts, with thresholds of ±10% for CFU's greater than 30, and ±3 CFUs for less than 30 total counts (10% for >30 CFU and ±3 CFU for ≤30 CFU). Precision was assessed on 15 plates imaged 12 times each under varied positioning and across devices; standard deviation was reported for ≤30 CFU and coefficient of variation for >30 CFU.

Results

The automated system correctly assessed 219 of 242 plates (90.5%). Among 23 deviations, four were overestimates and nineteen were underestimates relative to the technician counts. Most deviations occurred on plates where technicians showed substantial disagreement, and automated counts frequently fell within the range of at least one technician.

Repeatability testing showed a mean standard deviation of 0.44 CFU for low-count plates and an average CV of 5.88% for higher counts, demonstrating stable performance across orientations and devices.

Discussion

In this study it was found that the automated pipeline performs on par with trained technicians when counting colonies following the method stated in ISO 4833 (See Figure 1 and 2; Correlation between manual and automatic count results across the full range of plates, and correlation plot of the models log10(CFU/mL) with the manual log10(CFU/mL)). Observed discrepancies align with expected human variability, suggesting that remaining edge cases reflect intrinsic plate ambiguity rather than systematic bias of the Reshape Smart Incubator. Moreover, because imaging and analysis are versioned and auditable, the method strengthens traceability and reviewability without altering the underlying microbiological procedure, enabling straightforward implementation in established laboratory workflows.

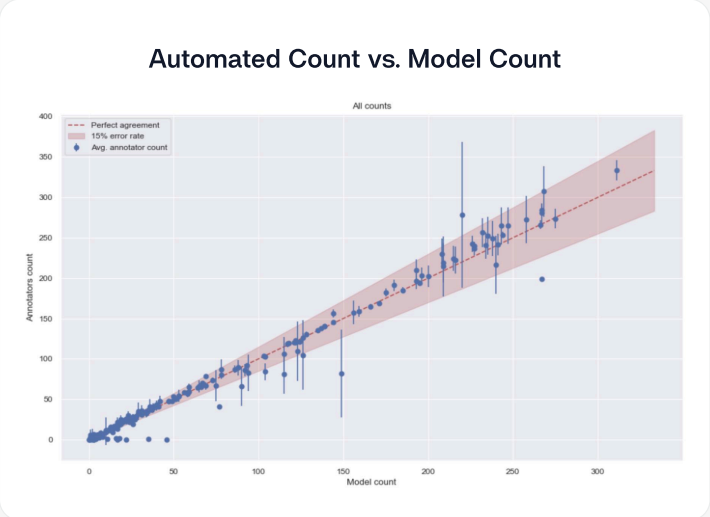


Figure 1: Correlation between manual and automatic results across the full range.

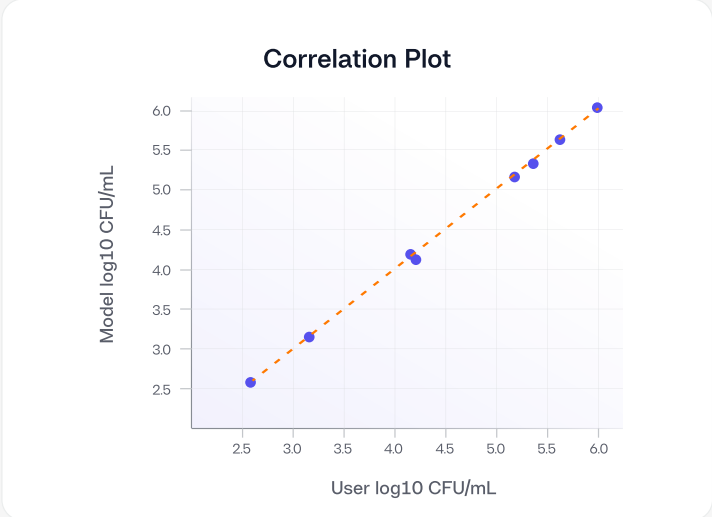


Figure 2: Correlation plot of the model's log10(CFU/mL) counts with the manual log10(CFU/mL) counts.

Conclusions

Reshape's automated colony counting solution meets ISO 4833 expectations for accuracy and precision, providing a reliable, efficient, and traceable alternative to manual counting. The 90.5% agreement rate and strong repeatability support it as an alternative method, which is easily adoptable in regulated quality control (QC) laboratories.

Additionally, ongoing improvements are being made to the models, which should further improve and alleviate the discrepancies seen in this study, with the long term goal of being implementable with more ISO-methods.