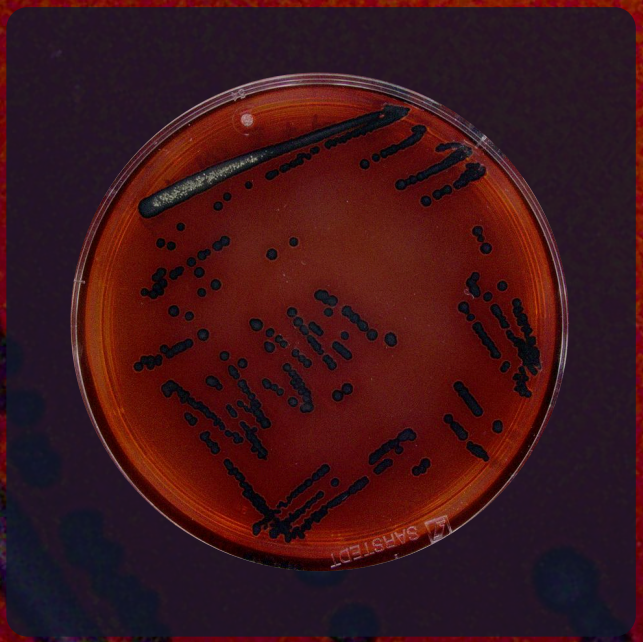
RESHAPE

Method Validation Report

ISO 6579



This study evaluates Reshape Biotech's integrated imaging and analysis system for use in ISO 6579 workflows.

We compared its presumptive *Salmonella* identifications to those of trained technicians, measuring both accuracy and precision, without changing the underlying microbiological process.

Key Findings

This validation study compared an automated detection method (Reshape Biotech) with manual observation for monitoring the presence of *Salmonella* spp. The assessment was performed using the internationally recognized ISO 6579 method, a qualitative culture-based technique.

The results show an overall agreement of 100% between trained personnel and the analysis model used in the automated detection method. Based on these findings, QC laboratories can rely on automated methods without compromising assessment quality, while more readily ensuring consumer safety. The use of Reshape's automated imaging system for plate analysis significantly streamlined the workflow, providing a consistent and objective approach to colony detection and assessment, and improving overall efficiency and reproducibility.

Introduction & Background

Salmonella is a genus of rod-shaped, Gram-negative bacteria belonging to the family *Enterobacteriaceae*. It is a major cause of food-borne illness worldwide, leading to a variety of symptoms from mild gastroenteritis to severe typhoid fever. The World Health Organization (WHO) estimates that non-typhoidal Salmonella causes tens of millions of illnesses and tens of thousands of deaths each year. Sources of contamination are varied but often include raw or undercooked meat, poultry, eggs, and dairy products.

The purpose of this report is to qualitatively assess the presence or absence of *Salmonella* spp. using the ISO 6579 method. This internationally standardized protocol provides a reliable and reproducible approach for detecting *Salmonella* spp., supporting food safety and protecting public health. The assessment also evaluates Reshape's performance for accurate analysis and demonstrates its compliance with relevant regulatory requirements.

Materials & Methods

The qualitative detection of *Salmonella spp.* was performed according to the standardized ISO 6579-1:2017 protocol. This method comprises five steps: non-selective pre-enrichment, selective enrichment, plating on selective agar, biochemical confirmation, and serological confirmation. In the following study, the focus was on the plating step and enumeration on selective agar.

Plating on selective agar: Suspected samples and/or confirmed positive enrichment broths where inoculated onto Xylose-Lysine-Deoxycholate (XLD) agar. Plates were incubated at 37 ºC for 24 hours. Suspected colonies of *Salmonella spp.* were identified based on characteristic morphology; on XLD agar, typical colonies appear red with or without a black center.

Automated imaging: Following incubation, agar plates were imaged using an automated colony counting and imaging system (Reshape Smart Incubator). The system captured high-resolution images under controlled lighting conditions. Images were analyzed using the system's software to automatically detect and count colonies based on size, shape, and color. This automated workflow standardized colony morphology assessment, provided an objective basis for colony selection for downstream confirmation, minimized potential human error, and improved traceability.

Results

Based on a total of 85 images, the model and manual assessment showed 100% agreement. No false negatives or false positives were observed, and all results were correctly classified as either true positives (28%) or true negatives (72%).

Figure 1: Confusion matrix comparing manual assessment and model-based classification results across all samples.

Discussion

The confusion matrix provides a clear snapshot of Reshape's machine learning (ML) model performance relative to traditional manual assessment for *Salmonella* detection. The data show complete concordance between the two methods, with the model matching the manual "gold standard" in 100% of cases (28% true positives and 72% true negatives). This level of agreement supports the suitability of ML-based analysis for this microbiological application.

Manual assessment involving culture-based detection, colony morphology interpretation, and confirmatory biochemical or serological testing, remains widely trusted due to its long-established reliability. However, QC laboratories have often been cautious in adopting AI/ML approaches, in part due to well-founded concerns regarding model robustness and accuracy across different sample types and laboratory conditions. At the same time, manual workflows are time-consuming, often requiring 24–72 hours for incubation and confirmation, and are highly labor-intensive. They depend heavily on trained microbiologists, and outcomes can be influenced by inter-technician variability, fatigue, and differences in experience.

In contrast, Reshape's analysis model enables rapid, automated, and objective assessment, with the potential to substantially reduce turnaround time while freeing expert resources for higher-value tasks. Importantly, these efficiency gains were achieved without compromising performance in this study: the model demonstrated 0% false positives and 0% false negatives across the evaluated dataset. This is operationally significant, as false positives can lead to unnecessary downstream confirmations, product holds, and added costs, while false negatives represent a critical risk in food safety.

Although any validation study must be interpreted within the context of its dataset size and scope, these results indicate that the model performs reliably as a high-throughput screening tool, particularly when combined with established confirmatory testing for positives.

Overall, the data demonstrate that Reshape's automated plate analysis delivers practical value beyond theoretical benefits. The model could be deployed with confidence as a screening step to rapidly clear the majority (72%) of true negative samples, enabling laboratories to focus time and resources on the smaller subset of potential positives requiring confirmatory follow-up.

Conclusions

This qualitative assessment successfully applied the ISO 6579 method for the detection of *Salmonella* spp. and compared it to the assessment of plates using Reshape's automation platform. The results of the study indicate that machine learning and standardized automated imaging can successfully replace manual assessments, without compromising the validity of the data and therefore the safety of the consumers. This information is critical for ensuring high quality of food samples and products.

The use of an automated colony imaging system proved highly effective in standardizing the observation of agar plates. This automation improved the efficiency of the analysis and provided an objective, reproducible method for identifying presumptive *Salmonella* spp. colonies, thereby reducing the chance of human error and improving the overall integrity of the results.