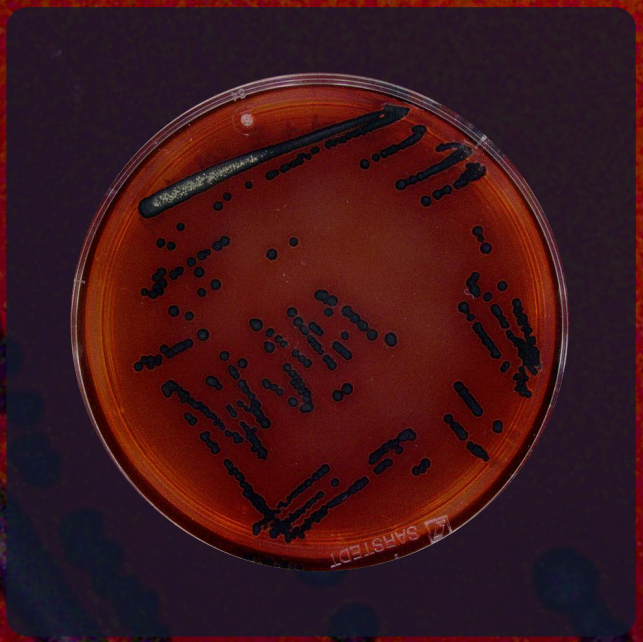
RESHAPE

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 section summarizes the key takeaways from the analysis of food samples for the presence of *Salmonella spp.* The assessment was performed using the internationally recognized ISO 6579 method, a qualitative culture-based technique

The results show and overall agreement between trained personnel and the model of **96.47%**. Based on these findings, quality control laboratories can now switch to automatized methods, without compromising quality of assessment and essentially the safety of their consumers. The use of the automated imaging system for plate analysis significantly streamlined the process, providing a consistent and objective method for colony enumeration and morphology assessment, which improved the overall efficiency and reproducibility of the results.

Introduction & Background

Salmonella is a genus of rod-shaped, Gram-negative bacteria belonging to the family Enterobacteriaceae. It is a major cause of foodborne illness worldwide, leading to a variety of symptoms from mild gastroenteritis to severe typhoid fever. The World Health Organization (WHO) estimates that nontyphoidal 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 study is to perform a qualitative assessment of the presence or absence of Salmonella spp. following the ISO 6579 method. This internationally standardized protocol provides a reliable and reproducible way to detect this pathogen, which is crucial for ensuring food safety and public health. This assessment is necessary to provide a proof of concept for our internal food safety protocols and to demonstrate compliance with relevant regulations.

Materials & Methods

The qualitative detection of *Salmonella spp.* followed the standardized ISO 6579-1:2017 protocol. This method is a five-step process: non-selective pre-enrichment, selective enrichment, plating on selective agar, biochemical confirmation, and serological confirmation, where the focus in this study is on the plating and enumeration on selective agar.

Plating on selective agar: Suspected samples and/or confirmed positive broths where inoculated onto Xylose-Lysine-Deoxycholate (XLD) agar. The XLD agar was incubated at 37 ºC for 24 hours. Suspect colonies of Salmonella spp. on the agar plates were identified based on their characteristic appearance. On XLD, typical colonies are red with or without a black center.

Automated imaging: The agar plates were then imaged using an automated colony counting and imaging system (Reshape imaging device (RID)). This machine captured high-resolution photographs of the plates under controlled lighting conditions. The images were then analyzed by the machine's software to automatically identify and count colonies based on their size, shape, and color. This automated process helped to standardize the assessment of colony morphology and provided an objective basis for the selection of colonies for further testing, minimizing potential human error and improving traceability.

Results

Based on a total of 85 images, the model and manual assessment resulted in 96.47% agreement. Only one false negative in the entire dataset was observed, according to the model.

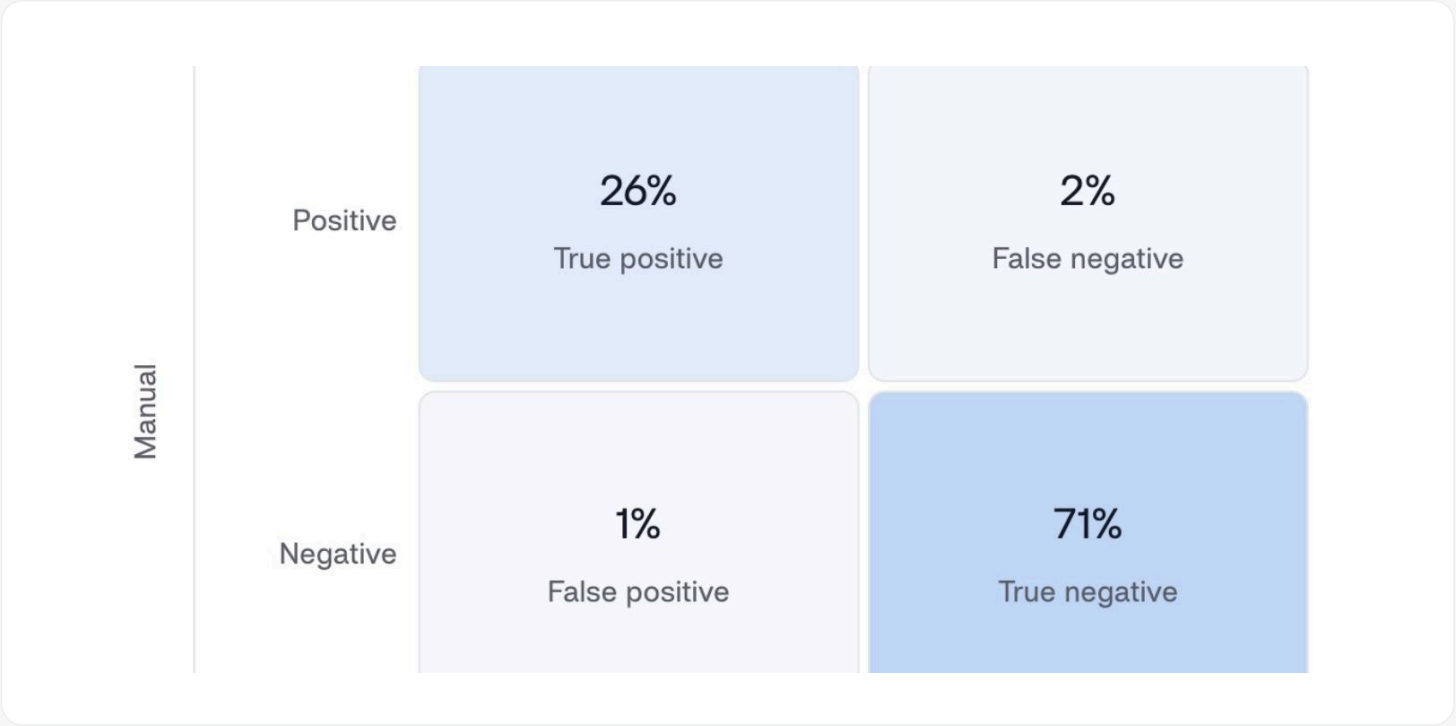


Figure 1: Assessment of all manual versus model counts.

Discussion

The provided confusion matrix offers a compelling snapshot of a machine learning (ML) model's performance against traditional manual assessment for Salmonella detection. The data indicates a very high degree of concordance between the two methods, with the model's classifications matching the manual "gold standard" in 97% of cases (26% True Positive + 71% True Negative). This high level of agreement suggests that machine learning is a highly viable tool in this microbiological context.

The primary advantage of manual assessment—which typically involves culturing, colony morphology, and biochemical or serological testing—is its established reliability. However, these methods are notoriously time-consuming, often requiring 24-72 hours for incubation and confirmation, and are labor-intensive, demanding the expertise of trained microbiologists.

The ML model, in contrast, offers the potential for near-instantaneous, automated, and objective assessment, drastically reducing turnaround time and freeing up expert resources. The key question is whether this speed and efficiency come at the cost of accuracy. According to these results, the trade-off is minimal. The model's 1% False Positive rate is exceptionally low, indicating it rarely flags a negative sample as positive. This is crucial for operational efficiency, as it minimizes costly and unnecessary downstream confirmations or product holds.

More critically, the False Negative rate is only 2%. This represents the most significant risk in Salmonella testing, as it means 2% of contaminated samples (as identified by the manual method) were missed by the model.

While any false negative is a concern for public health or food safety, a 2% rate is remarkably low and may be considered an acceptable tolerance for a high-throughput screening tool, especially when weighed against the significant speed gains.

In conclusion, the data demonstrates that this ML model doesn't just offer a theoretical advantage; it shows practical, high-performance results. It could be confidently deployed as a powerful screening tool to rapidly clear the vast majority (71%) of true negative samples, allowing limited laboratory resources to be focused on the smaller, more ambiguous pool of potential positives.

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 the Reshape imaging device. 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 colonies, thereby reducing the chance of human error and improving the overall integrity of the results.