

# Method Validation Report

ISO 21527



Enumeration of yeast and mold following ISO 21528; Comparing manual and automated counts.

# **Key Findings**

The preliminary evaluation of the Reshape platform for yeast and mold enumeration revealed that the automated counting system offers significant advantages over the traditional manual method (ISO 21527). The automated process demonstrated superior speed and accuracy, providing a more efficient and reliable alternative for critical food and environmental safety testing.

# Introduction & Background

The presence of yeasts and molds in food, animal feed, and environmental samples is a key indicator of quality degradation, potential spoilage, and, in some cases, the presence of mycotoxins. Accurate and reliable enumeration is therefore essential for quality control and regulatory compliance. Traditionally, this is achieved through manual counting of colonies on selective agar plates, as outlined in ISO 21527. However, this method is labor–intensive and presents unique challenges, as fungal colonies can grow large, spread across the plate, and often overlap, leading to significant counting errors and reduced reproducibility. To enhance efficiency and standardize microbial enumeration, new technologies, such as automated colony counters, have emerged. This report compares the performance of a trained human technician against the Reshape automated imaging device for the enumeration of yeasts and molds, with a focus on its ability to overcome the challenges of manual counting.

## Materials, Methods & Protocols

This study involved the comparative enumeration of yeast and molds from various food and environmental samples. All samples were prepared and inoculated onto selective agar media in accordance with the ISO 21527 standard. The plates were then incubated for the specified duration (typically 3–7 days at 25°C) to allow for colony formation. To prevent overgrowth and facilitate counting, plates were prepared using specific media such as Dichloran Rose–Bengal Chloramphenicol (DRBC) agar or Dichloran 18% Glycerol (DG18) agar, depending on the water activity of the sample matrix. Manual counting was performed by a group of trained personnel, with each plate being counted independently to account for inter–observer variability. Subsequently, all plates were processed using the Reshape automated imaging device, which uses sophisticated software to identify and enumerate yeast and mold colonies, even in cases of overlapping growth. Both the final count and the time required for each method were recorded for a direct comparative analysis.

## Results

A total of 39 jobs with 119 plates where analyzed. For mold, the agreement between manual and RID counts was 97.48% and for yeast it was 92.75% (See Figure 1).

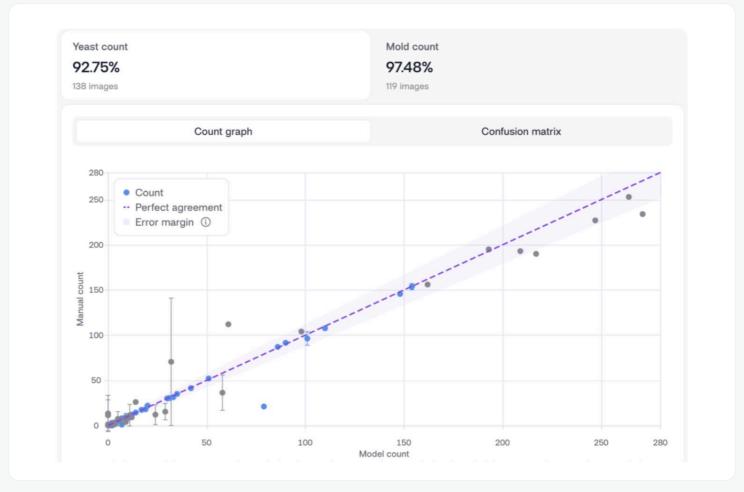


Figure 1: Performance of the model count versus the manual count. Each point represents a plate.

## **Discussion**

The preliminary findings indicate that the Reshape automated counting system provides a significant advantage in both speed and accuracy for the enumeration of yeasts and molds. The automated system's ability to precisely identify and count colonies, even those that have spread or overlapped, addresses a major challenge inherent to manual counting and ensures greater accuracy. This improved reliability is crucial for food safety and quality assurance, where consistent results are paramount. The reduced time required for plate enumeration also suggests that the automated system can substantially increase laboratory throughput, allowing for more frequent and rapid testing. By minimizing the subjective element of human counting and providing a robust, repeatable methodology, the Reshape device is poised to standardize procedures and improve overall data quality in food microbiology.

#### **Conclusions**

In conclusion, the Reshape automated imaging device represents a significant advancement in the field of yeast and mold enumeration. The system's ability to provide faster and more accurate counts positions it as a superior method for replacing traditional manual counting. Its adoption can lead to increased laboratory efficiency, improved data reliability, and enhanced compliance with international food safety standards. Future research should focus on a broader application of this technology to other types of fungal species and a larger dataset to further validate its performance across different food matrices and processing environments.