Alternative methods in microbial QC: Evaluating the use of ATCC MicroQuant™ as a ready-to-use commercial reference microorganism preparation on the Growth Direct® System

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Introduction

In the pharmaceutical industry, microbial quality control (MQC) is critical to ensure product safety. Accurate and reproducible MQC relies on reference microbial standards. Traditional validation methods and routine quality control workflows are often labor intensive and time-consuming, which can slow decision making and introduce variability. ATCC® MicroQuant™ controls are precisely quantitated, ready-to-use reference materials manufactured in an ISO 17034-certified production facility that are designed to simplify workflows, reduce variability, and standardize routine QC processes. The Growth Direct® platform offers a fully automated, high-throughput and secure MQC solution, providing earlier time-to-result (TTR) and accelerating routine MQC workflows. Using MicroQuant™ standards in combination with the Growth Direct® platform can yield further synergies, achieving a robust, efficient, and reliable QC system. Together, this solution is designed to accelerate validation and routine QC testing while minimizing variability.

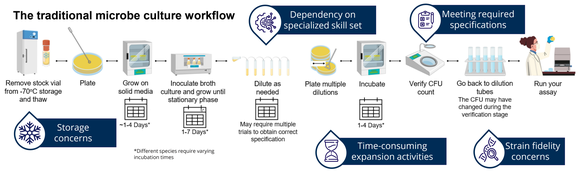


Figure 1: Challenges when using traditional culture workflows.

Study Objectives

The goal of this study is to demonstrate:

1. The integration of MicroQuant™ workflow with Growth Direct® system
2. MicroQuant™ reproducibility on the Growth Direct® System
3. MicroQuant™ accuracy on the Growth Direct® System
4. Growth Direct® System time-to-result (TTR) with MicroQuant™

Growth Direct® System MicroQuant™

Platform Technology

- Growth Direct® System is an automated, non-destructive rapid microbial detection system used for EM, Bioburden, and Sterility testing.
- MicroQuant™ is a precisely quantitated microbial reference material.

Combined Benefits

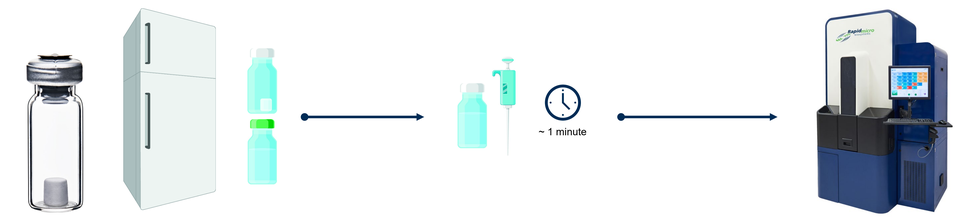
- Faster and more accurate test results
- Enhanced data integrity and sample security
- Fewer repeats
- Reduced hands-on time

Materials and Methods

Strains used in the study: We utilized the ATCC® MicroQuant™ Examination of Nonsterile Products Panel (ATCC® MQ-61™), which includes *Aspergillus brasiliensis*, *Candida albicans*, *Bacillus spizizenii*, *Pseudomonas paraeruginosa*, and *Staphylococcus aureus* subsp. *aureus*. Each vial contains a low quantitation preparation (100 to 1,000 CFU per vial) yielding 10 to 100 CFU per 100 µL upon rehydration, in accordance with USP <61> guidelines.

Growth Direct® system consumables used in the study: The study employed a range of Growth Direct® system consumables to support bioburden testing. These included Bioburden Filtration Funnels (B150-048) and three types of bioburden cassettes: TSA (BTSA-048), R2A (BR2A-048), and SDA (BSDA-048). Each component was selected to align with the specific microbial recovery requirements of the study, ensuring compatibility with the Growth Direct® platform's automated detection and enumeration capabilities.

Integrating the MicroQuant™ workflow with the Growth Direct® system



1. Remove MicroQuant™ vials and rehydration buffer from 2-8°C storage
2. Rehydrate the MicroQuant™ pellet
3. Achieve automated, non-destructive rapid microbial detection 2x faster than traditional methods

Results

MicroQuant™ linearity and correlation on the Growth Direct® System

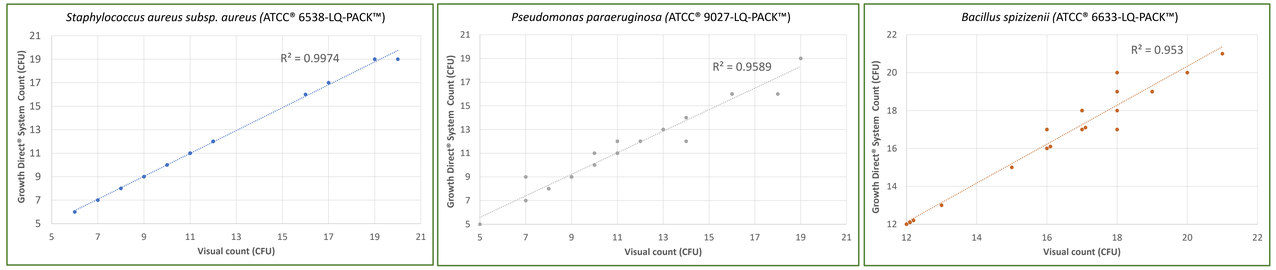


Figure 2: Linearity and correlation of CFU counts on TSA (BTSA-048) cassettes. Regression analysis demonstrating the correlation between Growth Direct® System and visual CFU counts for *S. aureus, P. paraeruginosa,* and *B. spizizenii.*

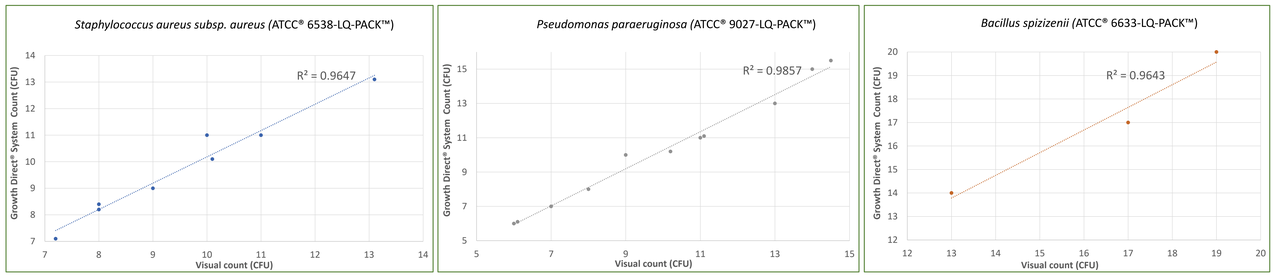


Figure 3: Linearity and correlation of CFU counts on R2A (BR2A-048) cassettes. Regression analysis demonstrating the correlation between Growth Direct® System and visual CFU counts for *S. aureus, P. paraeruginosa,* and *B. spizizenii.*

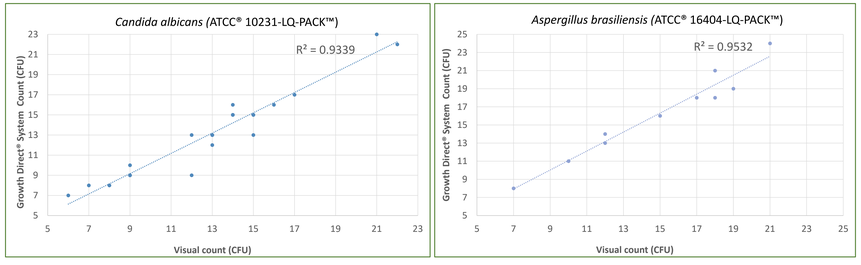


Figure 4: Linearity and correlation of CFU counts on SDA (BSDA-048) cassettes. Regression analysis demonstrating the correlation between Growth Direct® System and visual CFU counts for *C. albicans,* and *A. brasiliensis*,

Growth Direct® System time-to-result (TTR) with MicroQuant™

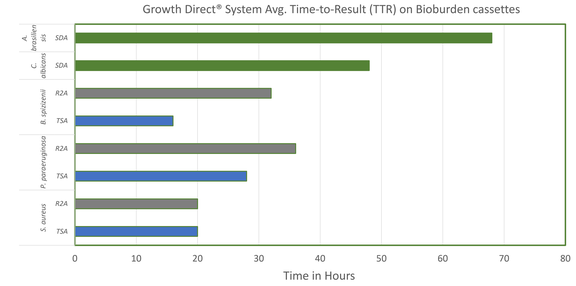


Figure 5: Growth Direct® System time-to-result (TTR) with MicroQuant™ reference materials. TTR (100%) in hours with MicroQuant™ reference materials on Growth Direct® System across Bioburden cassettes

Discussion

Reproducibility and Precision

The MicroQuant™ reference materials demonstrated consistent performance between Growth Direct® counts and visual counts ($R^2 > 0.9$) across all bioburden application media types (TSA, R2A, SDA), with variability within acceptable limits (%CV ≤ 35%).

Growth promotion

The MicroQuant™ reference materials demonstrated recovery within 50-200% across all Bioburden media types.

Accuracy

Linearity plots for all MicroQuant™ reference standards revealed a strong correlation ($R^2 > 0.9$) between visual counts and Growth Direct® counts across all bioburden Growth Direct® media types. This confirms the accuracy and reliability of Growth Direct® system and demonstrates its consistent performance with MicroQuant™ reference standards.

Time-to-result (TTR)

Data revealed that all MicroQuant™ reference materials were detected on Growth Direct® system in <72 hours, with TTR ranging from 16 to 60 hours, depending on the organism and media type. In contrast, traditional microbial QC methods typically require 3-5 days (or 5-7 days depending on incubation requirements). These results highlight the efficiency and rapid decision-making capability of the Growth Direct® system.

Conclusion

Integrating precise MicroQuant™ reference materials with the Growth Direct® platform transforms microbial QC by eliminating multiple manual steps and delivering reproducible, accurate, and rapid results while enabling faster decision making and streamlined workflows.

References

1. U.S. Pharmacopeial Convention, General Chapter <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests. In *USP—NF 2022*, Issue 2; USP: Rockville, MD, 2022.
2. Pharmacopeia, U. S. "Chapter 1223 validation of alternative microbiological methods." USP 39 (2007): 1616-1630.
3. Rapid Micro Biosystems. Achieving Rapid Microbial Method Validation with Precise Reference Standard Quantification. Webinar, 11 June 2025, Rapid Micro Biosystems, https://bit.ly/46ap8N7.