

Implementation of the Growth Direct™ System: Driving for Greater Accuracy, Speed, and Efficiency in Microbial Enumeration

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Summary

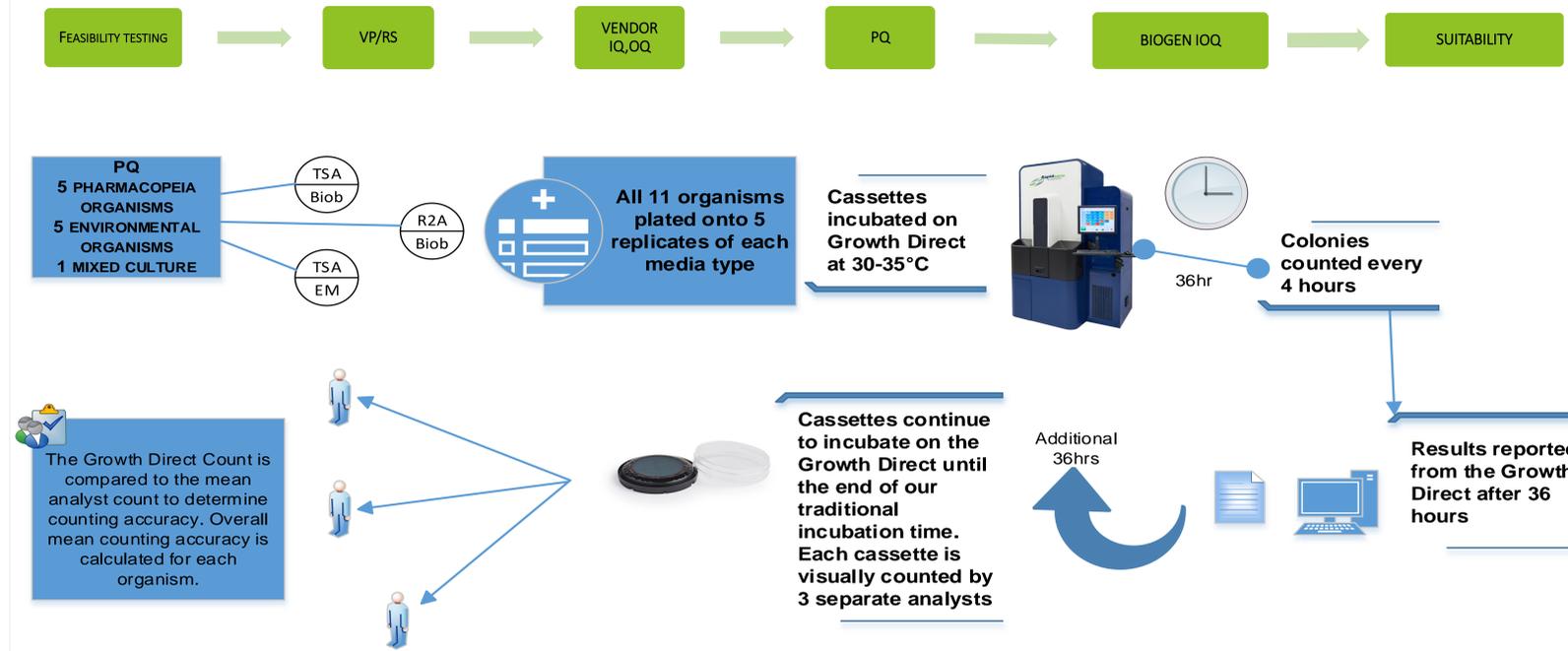
With demand for faster and more accurate results, the Rapid Micro Biosystems Growth Direct™ allows for rapid, automated, and more accurate measurement of microbial colonies. This system was selected to implement automated plate reading in the Biogen QC Microbiology lab.

The current state for testing bioburden is incubation on TSA media for 72 hours and EM for 5 days. Plates are manually counted, entered into our LIMS system, and reviewed. After successful implementation of the Growth Direct™, bioburden and EM incubation will be cut in half, colonies will automatically be counted, results will be migrated to LIMS electronically, and review will be performed on plates that have growth (review by exception). The decreased incubation time, automatic colony counting, and review by exception will decrease our time to result for both bioburden and EM. This rapid microbial method will provide an efficiency gain, cost savings, and allow for earlier detection of microbial contamination in our samples.

The Growth Direct™ instrument has undergone validation and compendial verification (suitability) testing for in-process bioburden. Both the validation and suitability testing met all acceptance criteria.

Biogen is in the process of implementing this technology for all microbial enumeration assays (critical in-process tests, water bioburden, and Environmental Monitoring). The system will also be qualified for drug substance TYMC SDA plate reading. After successful implementation of The Growth Direct™ System at RTP, the System will be implemented at the other Biogen sites globally.

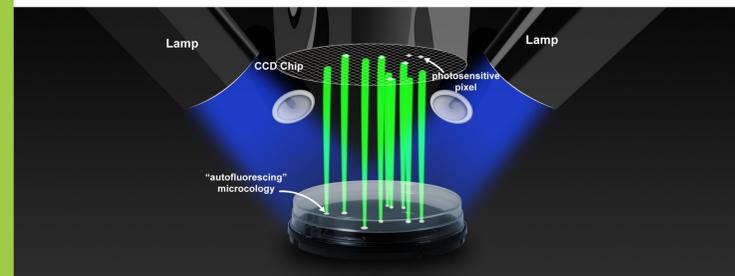
Validation Strategy



What is the Growth Direct System, how does it work, and why do we have it?

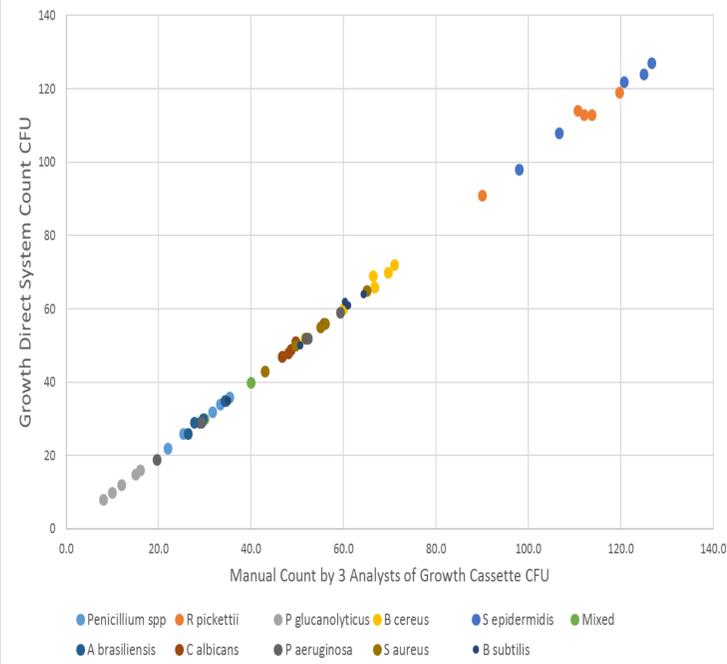
The Growth Direct™ is an automated compendial colony counter and incubator

- System reads cassettes every 4 hours, tracks growing colonies, and immediately reports results which allows for earlier detection of contaminants
- The Growth Direct detects and counts micro colonies in half the time of the traditional culture methods, using the natural auto-fluorescence of all micro-organisms to blue light
- Improves data integrity with automated and validated result interface to LIMS
- Eliminates manual (human) plate counting, data entry (LIMS integration), and data review
- System can send email notification if limits are exceeded or mechanical issues occur
- Supports right time quality/Real Time Right Time

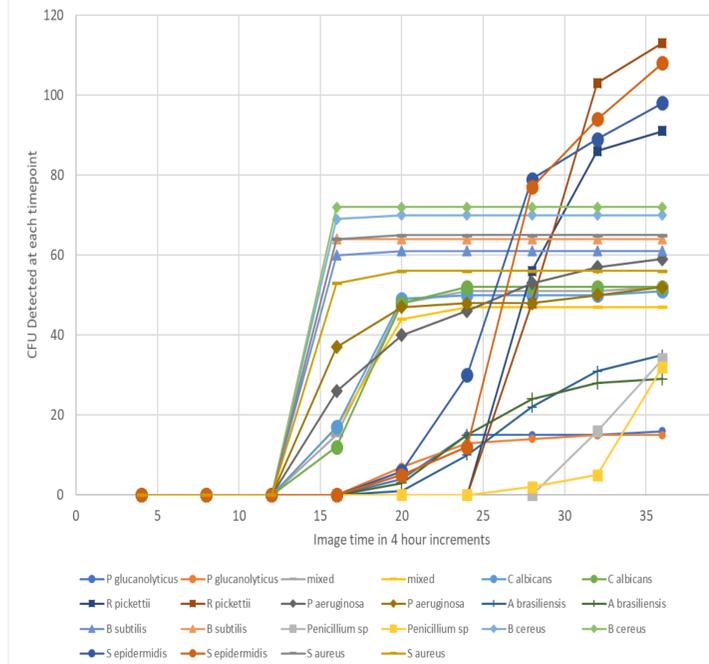


PQ Validation Results

Verification of System Enumeration Accuracy for PQ Organisms



Time To Results Data Curves for all bugs in PQ



Regulatory

The Growth Direct™ System is not an alternative method requiring method validation -USP40/NF35 <1223> states the following, "There are commercially-available enhancements to growth-based methods that allow colonies on solid media to be read more quickly, with substantially less incubation time, than is possible using only the unaided eye. -In the implementation of these enhanced methods for the detection of colony growth, only the detection capability of the method requires verification."

USP General Notices 6, Testing Practices and Procedures states that, "Automated and manual procedures employing the same basic chemistry are considered equivalent." This is also true for systems using the same basic microbiology, i.e. plate counting that counts a CFU earlier than the unaided eye.

The validation of the Growth Direct supports the view of PDA Technical Report No. 33 (Revised) dated September 2013, "Some alternative or rapid technologies may be considered automated traditional or compendial microbiological methods, especially when the results are in colony-forming units (CFU). These technologies may be qualified for their intended use without the need for demonstrating certain method validation requirements...For these technologies, at least accuracy and precision assessments should be performed, in addition to method suitability and equivalence/comparability studies."