THREE-DAY PHENEOTYPIC STERILITY TESTING FOR CGT MANUFACTURING:

VALIDATION OF THE CALSCREENER+ PLATFORM

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INTRODUCTION

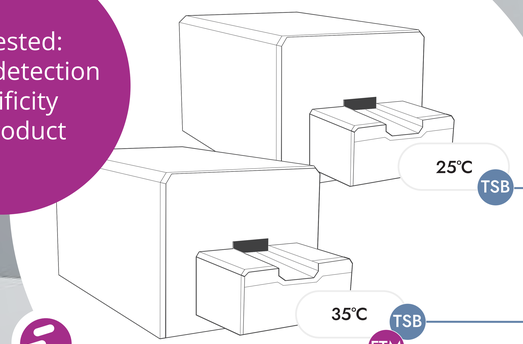
Sterility testing is a critical quality control process for cell and gene therapy products (CGTs), where rapid and reliable detection of microbial contaminants is essential to meet regulatory standards and ensure patient safety. Traditional methods take up to 14 days, delaying batch release and increasing costs.

This study evaluates the calScreener+ platform for **three-day, non-destructive** isothermal microcalorimetry based sterility testing as a **growth-based method** employing direct inoculation. Detection time, specificity, and robustness in small volumes and cell-rich matrices were assessed.

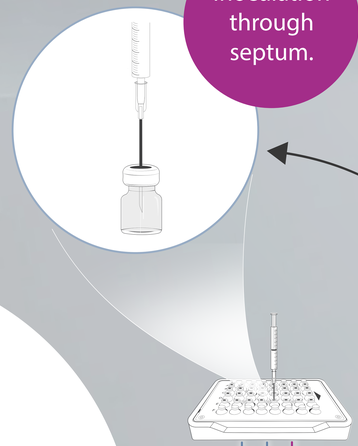
Real-time readings & alerts

We tested: time to detection specificity on-product

calScreener+ Sterility

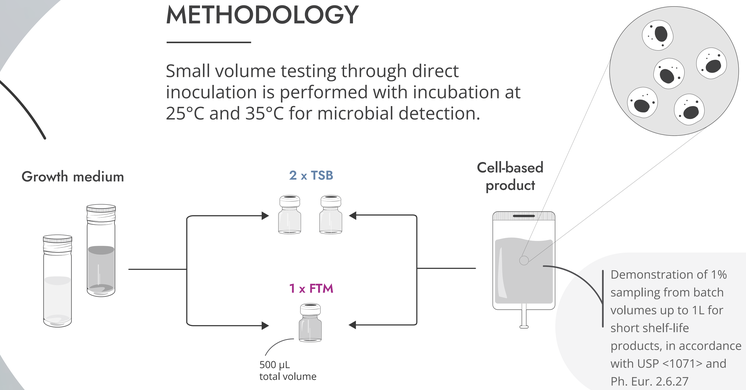


Inoculation through septum.



METHODOLOGY

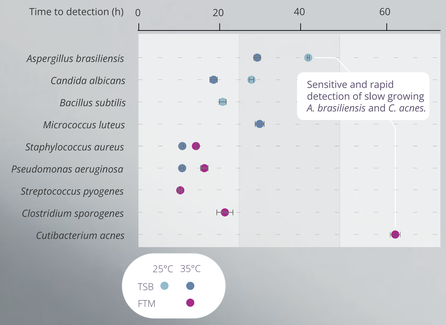
Small volume testing through direct inoculation is performed with incubation at 25°C and 35°C for microbial detection.



Demonstration of 1% sampling from batch volumes up to 1L for short shelf-life products, in accordance with USP <1071> and Ph. Eur. 2.6.27

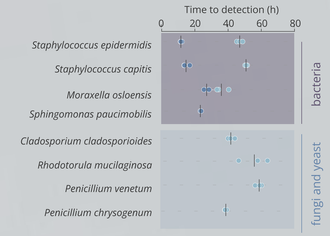
DETECTION < 3 DAYS OF 9 EP STRAINS

Growth promotion of 9 EP strains <10 CFU shows rapid detection within 3 days. (n = 3)



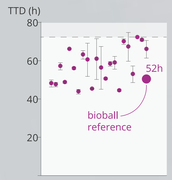
EFFECTIVE DETECTION <3 DAYS FOR WIDER RANGE OF ORGANISMS

Detection at <10 CFU in replicates of bacterial and fungal and yeast species. (n=3)



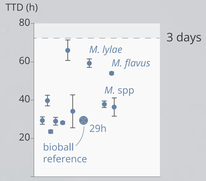
CHALLENGING BACTERIA ARE DETECTED <3 DAYS

22 unique low-passage clinical *Cutibacterium acnes* isolates (n=1-6, <50 CFU) were detected between 41 and 72 hours.



22 unique isolates of *C.acnes* (<50 CFU)

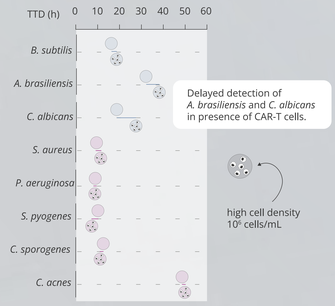
7 *Micrococcus luteus*, 2 *Micrococcus* spp, *Micrococcus lylae*, *Micrococcus flavus* isolates (n=3, ≤10 CFU) were detected between 21 and 72 hours.



12 unique isolates of *Micrococcus* (≤10 CFU)

DETECTION ON COMMERCIAL CAR-T CELL PRODUCT

Time to detection of reference strains (<10 CFU) with and without product. (n=2-3).



CONCLUSIONS

- **Fast and sensitive detection** of diverse microbes within days through direct inoculation, eliminating the need for enrichment.
- **Low sample volume enables** testing of limited CGT batches with minimal material loss.
- Strong performance data supports achieving **reliable time to negative results within 3 days.**

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