

3 DAY STERILITY TEST FOR CGTs:

DIRECT INOCULATION, NON-DESTRUCTIVE AND CONTINUOUS MONITORING

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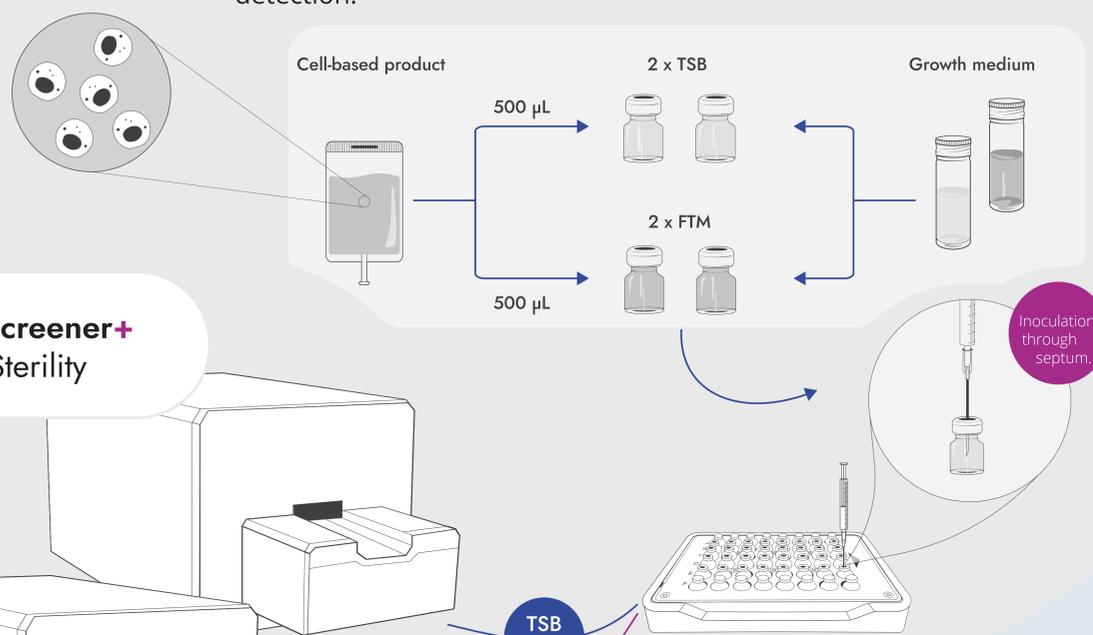
INTRODUCTION

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+, a 3-day, non-destructive sterility test based on isothermal microcalorimetry assessing its detection time, specificity and robustness in small-volume and cell rich-matrices.

METHODOLOGY

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



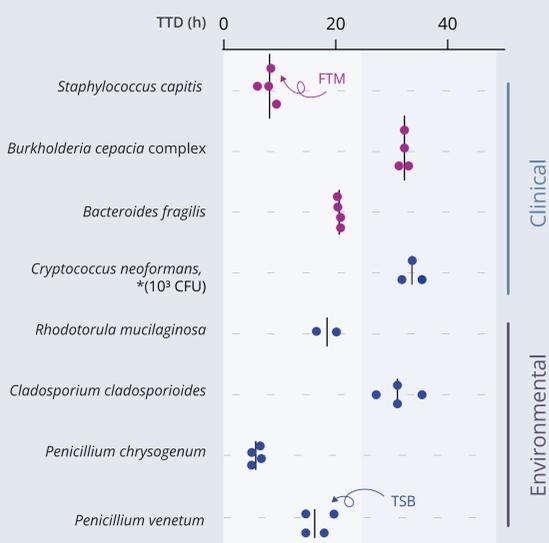
DETECTION < 2 DAYS OF 9 EP STRAINS

Growth promotion of 9 EP strains (CFU <50) shows rapid time to detection (TTD) within 2 days. (n = 4)



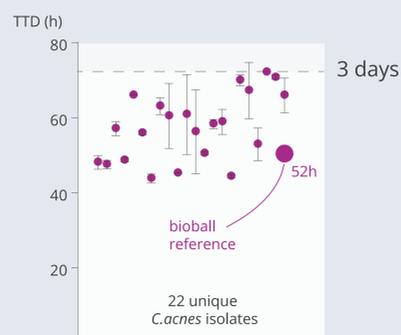
EFFECTIVE DETECTION <2 DAYS FOR WIDER RANGE OF ORGANISMS

Detection at CFU <100* in replicates of clinical-derived and environmental species.



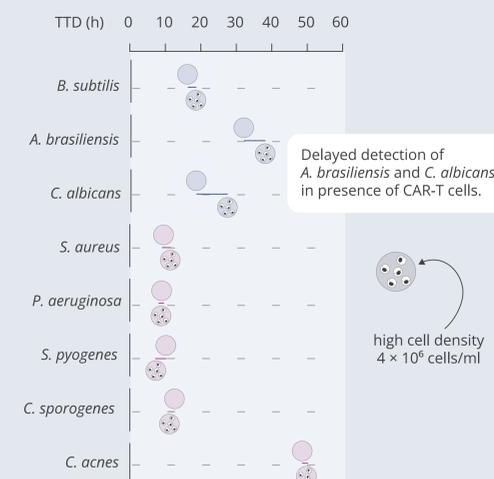
22 CUTIBACTERIUM ACNES ISOLATES DETECTED <3 DAYS

22 low-passage clinical isolates (n=1-6) with <50 CFU were detected within 41-72 hours, all within 3 days.



DETECTION ON COMMERCIAL CAR-T CELL PRODUCT

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



CONCLUSIONS

- Fast and sensitive detection of diverse microbes through direct inoculation within days, 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.

