

PHENOTYPIC STERILITY TESTING FOR ATMPs WITH DETECTION <3 DAYS WITH CALSCREENER+

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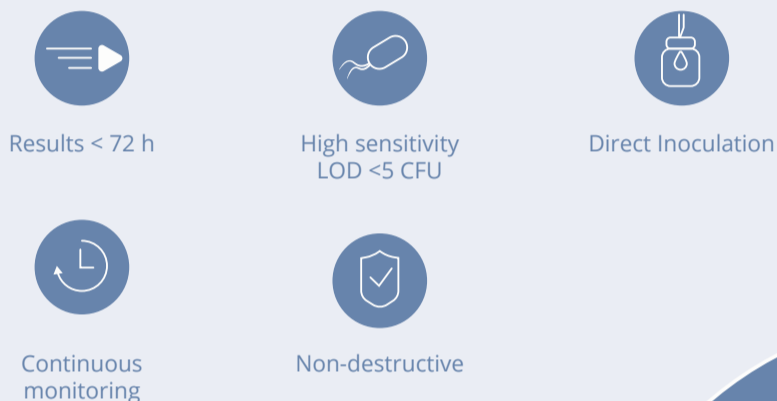
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CALSCREENER+ STREAMLINED WORKFLOW

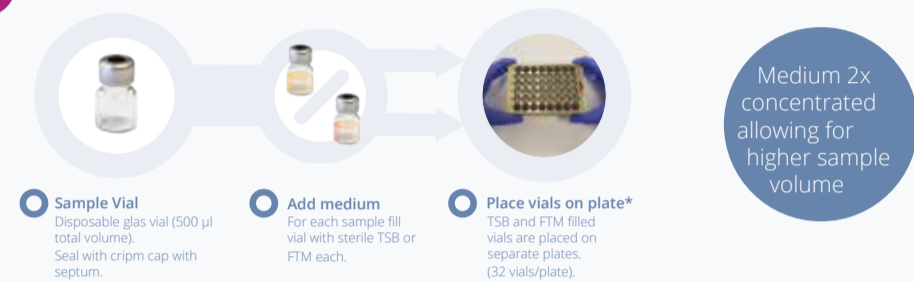
The need for rapid sterility testing in Advanced Therapy Medicinal Products (ATMPs) is critical to ensure patient safety and product efficacy. We present a novel instrument on isothermal microcalorimetry, enabling **continuous monitoring** of metabolic activity from a broad range of microorganisms in a **non-destructive and product matrix independent** manner.

With minimal sample input and maximum sensitivity (LOD <5 CFU), our method detects a wide range of organisms even in presence of high cell backgrounds. Most organisms tested in product are detected within 24 hours, while molds and slow-grower *C. acnes* are detected within 72 hours.



CALSCREENER+ STREAMLINED WORKFLOW

1 PLATE PREPARATION



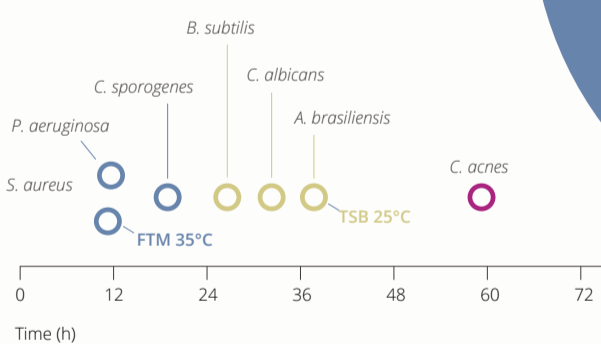
2 DIRECT INOCULATION



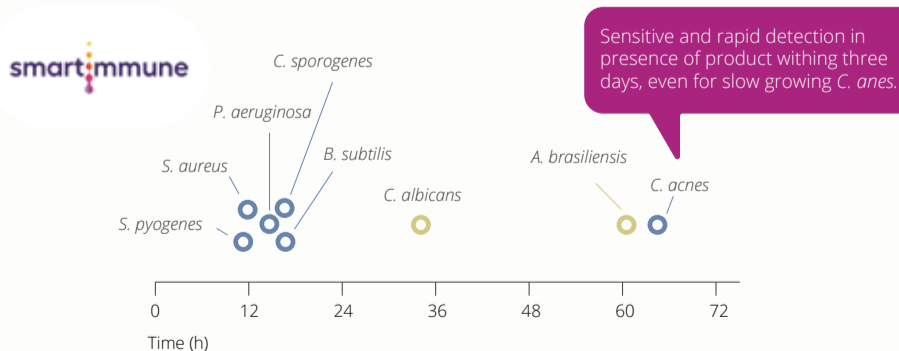
CALSCREENER+ FOR RAPID STERILITY TESTING

RAPID AND SENSITIVE DETECTION < 72 H

A Growth promotion assay shows fast detection of compendial organisms (USP) with low inoculum (CFU <5).

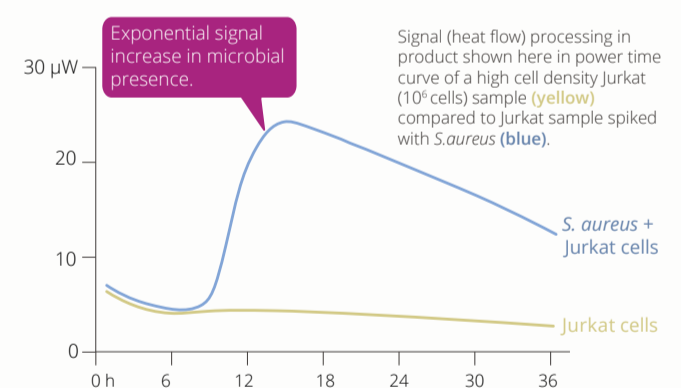


B Case study using a T-cell progenitor therapy product. Product SMART101-DP from SmartImmune was spiked with CFU < 5 in a 1:1 product to media ratio.



REDUCED RISK OF FALSE POSITIVES

Clear distinction between background signal from cells and product components and microbial signal.



SYSTEM HIGHLIGHTS

- The calScreener+ system provides a biocalorimetry based **phenotypic sterility assay** as describe in USP1071 and EP 5.1.6).
- Detection of microbial activity within **three days** in presence of cell based products with a low risk for false positive signal.
- Real-time result through continuous and automated reading for **yes/no** result

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