

SYMCEL<sup>o</sup>

# RAPID STERILITY TESTING

- **Results within 3 days**
- Extreme sensitivity with LOD <5 CFU
- Direct inoculation of product
- Non-destructive
- Continuous monitoring
- Low sample volumes

# RAPID, SAFE RELEASE OF CELL AND GENE THERAPY PRODUCTS



Cell and gene therapies need to be available quickly, and they need to be safe. Yet the long turnaround times and complex procedures of traditional sterility tests can lead to long vein-to-vein times and high development costs. Our method is straightforward and remarkably fast and accurate.

The Symcel calScreener<sup>+</sup>, an isothermal microcalorimeter adapted specifically to biological systems, provides accurate sterility results within three days. It tests the actual product directly, requires only a minimal sample volume, and with continuous monitoring detects with an extreme sensitivity of LOD <5 CFU. It is remarkably user friendly and fully compliant with industry standards\*.

Welcome to next-generation sterility testing.

CALSCREENER<sup>+</sup>

## NEXT-GENERATION STERILITY TESTING

Isothermal microcalorimetry detects heat with extreme sensitivity. We have repurposed a microcalorimeter for biological, metabolically active organisms to create the world's most advanced biocalorimeter, the CalScreener<sup>+</sup>. We deliver previously unattainable results in terms of speed, sensitivity, specificity and methodological simplicity.

### Dual temperature capability

- two calScreener<sup>+</sup> units
- 20-40°C temperature range

### Medium throughput capability

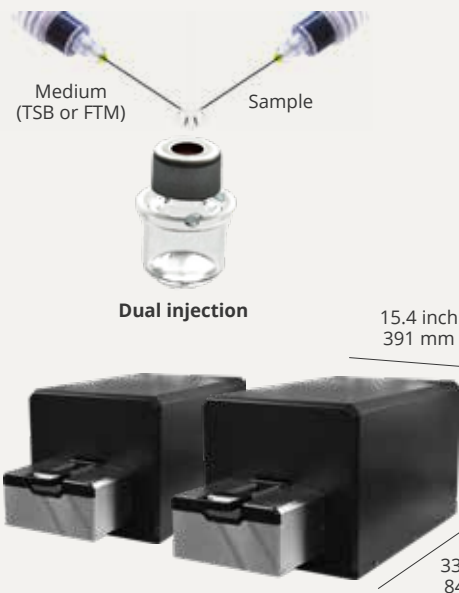
- 32-sample parallel testing
- disposable glass vials (up to 500 µl)

### Meet regulatory compliance

- 21 CFR pt. 11-compliant software
- IQ/OQ

### Premium support plan

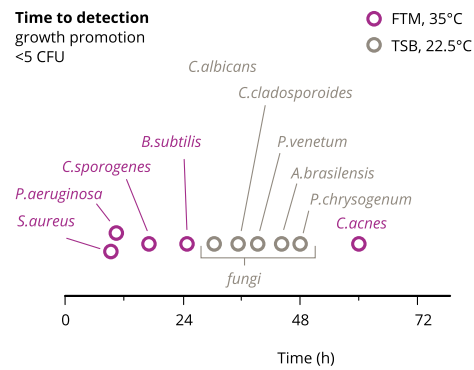
- premium application support
- service support



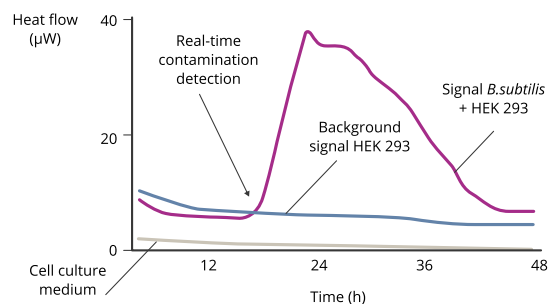
## REAL-TIME DETECTION, EXTREMELY FAST RESULTS

- Detect most organisms < 24 hours
- Environmental organisms < 48 hours
- *C.acnes* and *A.brasilensis* < 72 hours
- Continuous measurement - you can take immediate action

Time to detection  
growth promotion  
<5 CFU



## THE SYMCEL DIFFERENCE



## HIGHLY SENSITIVE AT LOD <5 CFU

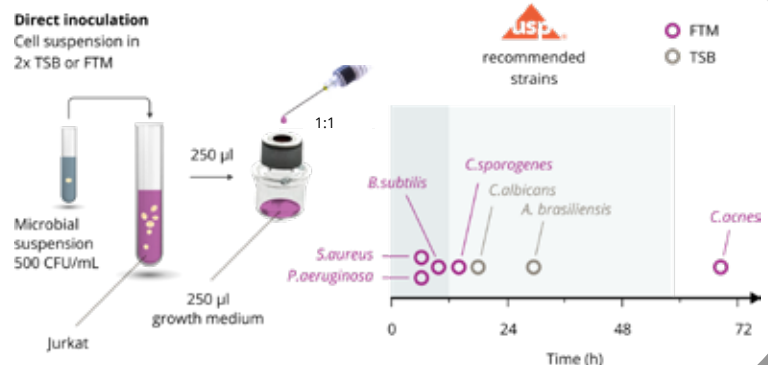
There are no second chances in sterility testing. Non-destructive with LOD <5 CFU, our calScreener+ picks up contaminations in even the most complex matrices.

## RAPID DETECTION IN CAR-T CELL SAMPLE

Growth promotion assay <5 CFU in TSB and FTM growth media with direct inoculation of Jurkat cells. The samples were spiked with USP <71> recommended species plus *C.acnes* in presence of  $10^6$  cells/ml.

The calScreener+ sterility test detected all contaminants within 3 days.

Direct inoculation  
Cell suspension in  
2x TSB or FTM



# WE MEASURE LIFE<sup>o</sup>

## SMALL VOLUME, NO FILTRATION, NO REAGENTS

- Only 1% of final product required for testing
- Add product and medium to vial directly
- No intermediate steps
  - no sample concentration
  - no filtering
  - no lysing
- No dyes, no reagents

## STREAMLINED WORKFLOW, OBJECTIVE READOUT

- Super-easy workflow
- Objective results
- 21 CFR pt. 11-compliant
- Human error risk minimised
- No special training required

## SYMCEL<sup>o</sup>

Tomtebodavägen 6  
171 65, Stockholm  
Sweden



sales@symcel.com  
symcel.com  
rapidsterilitytest.com