



SYMCEL^o

RAPID STERILITY TESTING

- Results in less than 3 days
- Continuous phenotypic detection
- Direct inoculation of product
- Non-destructive measurement
- Small test volume requirement

calScreener+
Sterility



NEXT-GENERATION STERILITY TESTING

Isothermal microcalorimetry detects heat with extreme sensitivity. We have further developed and optimized a microcalorimeter specifically for the easy, accurate and fast detection of metabolically active organisms.

The calScreener™+ Sterility biocalorimeter system performs tests directly in vials containing the growth medium, with no need for preparatory steps or the addition of costly reagents. The test provides continuous, phenotypic detection, delivering decisive, positive/negative results within three days.

calScreener+
Sterility



Dual system growth assay

- Twin calScreener system
- 20 - 40°C temperature range

Streamlined workflow

- Easy workflow with low training requirements
- Minimum test volume required: 50 µl

Parallel testing

- 32-position calPlate™ sampling
- Integrated solid references

Reliable and cost-effective

- No moving parts for minimal risk of downtime
- Disposable glass calVial™

Regulatory compliance

- 21 CFR pt. 11-data integrity
- Minimized human error risks with calView™ automated readout



RAPID, SAFE AND EFFICIENT RELEASE OF CELL AND GENE THERAPY PRODUCTS

Two key demands for the efficacy of cell and gene therapies is that they need to be delivered quickly and safely to the patients. Traditional sterility tests' long turnaround times and complex procedures contribute to overly long vein-to-vein times, unnecessarily high development costs, and increased patient risks.



The Symcel calScreeners+, an isothermal microcalorimeter, is designed specifically to address these issues. It provides accurate growth-based test results within three days. It requires a minimal sample volume and, since it detects only viable organisms, delivers decisive, positive/negative results. The system is highly sensitive (LOD <5 CFU), provides continuous measurements and is extremely easy to operate. Of course, it is fully compliant with industry standards*.

Welcome to next-generation sterility testing.

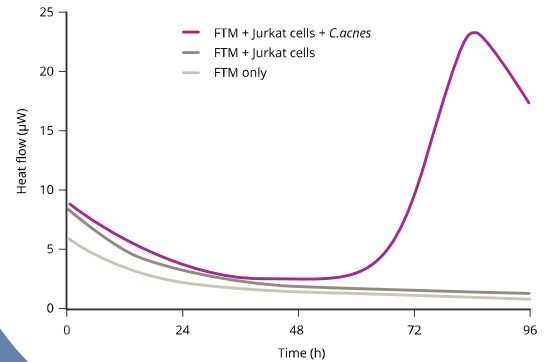
THE SYMCEL DIFFERENCE

MINIMIZED RISK OF FALSE RESULTS

CONTINUOUS PHENOTYPIC DETECTION

There are no second chances in sterility testing. The calScreener+ growth-based method measures continuously and since it works phenotypically, detects only viable microorganisms.

It offers exceptional sensitivity, with a limit of detection (LOD) below 5 CFU, and minimizes the risk of false results caused by debris, residual genetic material, or components of the cellular product.



FAST, CONFIDENT & SAFE PRODUCT RELEASE

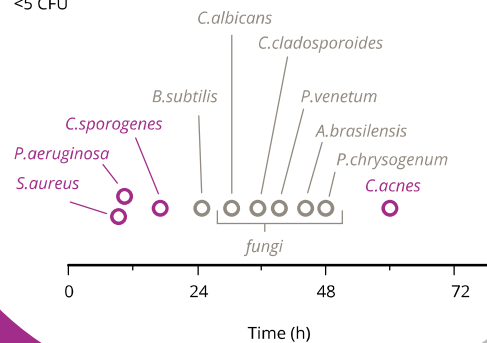
DECISIVE RESULTS IN LESS THAN THREE DAYS

Release times are critical for life-saving therapies. Novel biocalorimetry technology enables faster, continuous, and more actionable results.

- Majority of bacteria detected in less than 24 hours
- Fungi, including in *A.brasilensis* in less than 48 hours
- *C.acnes* assay rate limiting organism detected within 60 hours

Time to detection growth promotion <5 CFU

○ FTM, 35°C
○ TSB, 25°C



TEST COMPLEX PRODUCT MATRICES

DIRECT INOCULATION OF PRODUCT

Sterility testing of living cell therapy products is particularly challenging, as terminal sterilization cannot be applied. Biocalorimetry allows direct inoculation, detecting contamination even in highly complex sample matrices.

- No filtering,
- No sample concentrations
- No intermediate steps



EASIER CONTAMINATION INVESTIGATION

NON-DESTRUCTIVE MEASUREMENT

Root cause analysis is critical if contamination is detected. The calScreener+ method is non-destructive with no manipulation steps or interfering reagents. If a sample is found positive, inoculated samples can immediately be analyzed further using standard methods.

- No reagents
- No dyes
- No lysing



PRESERVE MORE PRODUCT FOR THE PATIENT

SMALL TEST VOLUME REQUIREMENT

Traditional sterility testing methods require sample volumes that many advanced therapy products simply can't spare. The calScreener+ system requires only a minimal volume, enabling testing even when product availability is critically low.

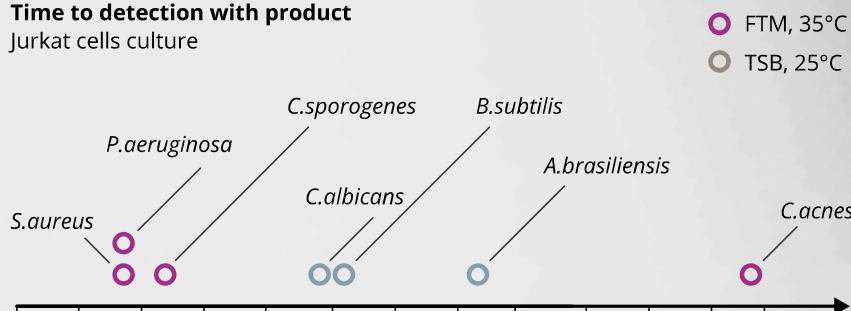


3-DAY CAR-T THERAPY STERILITY TESTING

DETECTION OF C.ACNES AND ALL USP <71> RECOMMENDED STRAINS

Case study using a Jurkat CAR-T cell line. Study performed at <5 CFU in TSB and FTM growth media with direct inoculation in the presence of 10⁶ CAR-T cells/ml. Data is representative of more than 10 different autologous cell therapy products tested, with fast and accurate detection, regardless of the product matrix

Time to detection with product
Jurkat cells culture



WE MEASURE LIFE^o

OUR EXPERTISE AT YOUR SERVICE

At Symcel, we're redefining rapid microbial testing. We are partnering with leading therapy developers, contract manufacturers, test labs and hospitals implementing next-generation sterility testing using our biocalorimetry technology.

Validation and regulatory approval

The calScreen^{er}+ Rapid Microbial Method (RMM) follow the US and EU standards*. Primary validation package is conducted on method limit of detection (LOD), comparability, specificity, ruggedness and robustness, with data package availability before conducting method validation.

Support when you need it

- Feasibility testing and pre-method validation
- Instrument Qualification (IQ/OQ)
- Maintenance and service
- Premium application support

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