

BIOMÉRIEUX

SCANRDI® CELL-BURST

Same-shift sterility testing
for cell & gene therapies



Your Ally in Advancing Quality

PIONEERING DIAGNOSTICS

Is your sterility testing slowing down the release of your cell and gene therapy product?

How do you balance your need for speed with the need to lead responsibly in addressing urgent healthcare challenges?

With SCANRDI® CELL-BURST, you can:

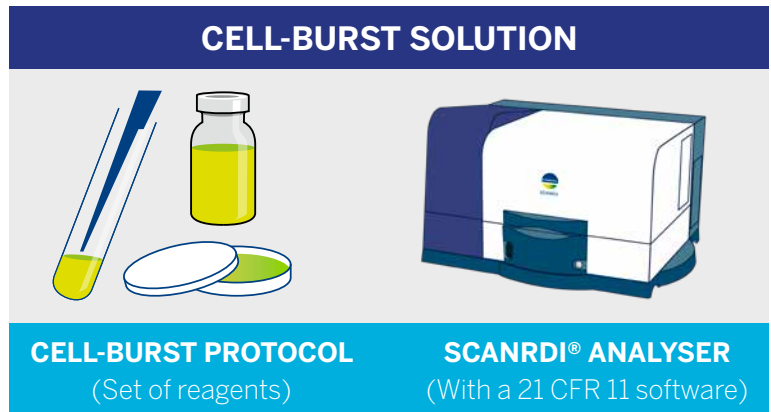
Invest now to future-proof your sterility results and help support long-term leadership in addressing urgent challenges:

- Help drastically reduce the time required to deliver your life-saving therapies to patients in need.
- Rely on a proven method that is broadly applicable to current therapies and intended to support future therapies.

What is CELL-BURST?

CELL-BURST is a CELL-BASED ULTRA RAPID STERILITY TEST

combining the solid-phase cytometry of the SCANRDI® with a patented protocol that renders cell-based matrices easily filterable.



How can you be sure that CELL-BURST solution is right for me?

From feasibility to implementation, we are here for you:

- Feasibility and Customized Studies
- URS Completion Guide
- Installation, Operation and Performance Qualification (IOPQ)
- Primary Validation Data Report (PVR)*
- Suitability Testing Guide
- Drug Master File (DMF)

The microbial stains tested reflect those in the harmonized pharmacopeia as well as those referenced in Ph. Eur, 2.6.27 and Ph. Eur, 2.6.39. For a full list of strains tested, contact your bioMérieux representative.

**Our PVR was built demonstrating equivalency and comparability with both the BACT/ALERT® DUAL-T and traditional testing methods.*

Compatibility with the following cell types has been tested*:



JURKAT



IN-HOUSE CART



DONOR LYMPHOCYTE T-CELLS



DONOR LYMPHOCYTE INFUSION



UNIT CORD BLOOD



MESENCHYMAL STEM (UMBILICAL)

* Non-exhaustive list