

# SIMPLIFY AND SECURE YOUR BIOSAFETY QUALITY CONTROL WITH **NEXT GENERATION SEQUENCING (NGS)**

## Cell Therapies

**COMPLIANT, FASTER, ANIMAL-FREE**



Adventitious Agent Testing

Integration Site Analysis

### SIMPLIFIED VIRAL SAFETY TESTING



**Reduced sample volume:**  
Only one million cells needed



**Faster:**

One assay replaces *In Vivo* and *In Vitro* Adventitious Agent Testing and Species-Specific Virus Testing



**Safer:**

Comprehensive viral breadth of detection



**Animal-Free:**  
3Rs compliant

### UNMATCHED PRECISION FOR GENETIC CHARACTERIZATION



**Integration Site Analysis:**

- Better understanding of your clones
- Targeted, long-read sequencing analysis to resolve concatemers, truncations and inverted repeats more easily

### 2 GMP MIRROR FACILITIES



Wayne, PA



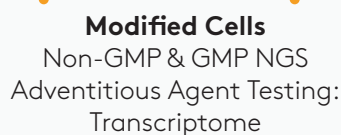
Paris



### REGULATORY GUIDELINES

- WHO Expert Committee on Biological Standardization (80th report) (2025)
- ICH Q5D – Derivation and characterization of cell substrates
- EMA Guideline: EMA/CHMP/BWP/457920/2012 Rev.1
- FDA Guidance for the Industry: Points to consider in the characterization of cell lines (1993)
- FDA draft guidance documents - Safety testing of human allogeneic cells expanded for use in cell-based medical product (April 2024)
- USP <1050> – Viral safety from cell lines of human and animal origin
- Ph. Eur. 2.6.41 - High-throughput sequencing for the detection of viral extraneous agents: New chapter adopted in March 2025

## DOWNSTREAM PROCESSING (DSP)



	Assay	GMP	Sample Requirements	Turnaround Time	Deliverables to Client
VIRAL SAFETY	iDETECT® Transcriptome		Min. 3×10 <sup>5</sup> cells	5 weeks (Standard) 4 weeks (Fast Track)	<ul style="list-style-type: none"><li>• Certificate of Analysis</li><li>• Expert virologist report</li><li>• Raw data</li></ul>
GENETIC CHARACTERIZATION	iDETECT® Integration Site Analysis		5×10 <sup>6</sup> cells (≥10 µg DNA per sample)	5 weeks (per round)	<ul style="list-style-type: none"><li>• Report</li><li>• Raw Data</li></ul>

Back up samples required. BSL1 and BSL2 samples accepted. | Shipment & storage: - 80°C/Dry Ice



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