

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

Cell Therapies

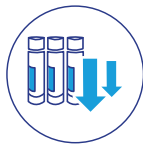
COMPLIANT, FASTER, ANIMAL-FREE



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

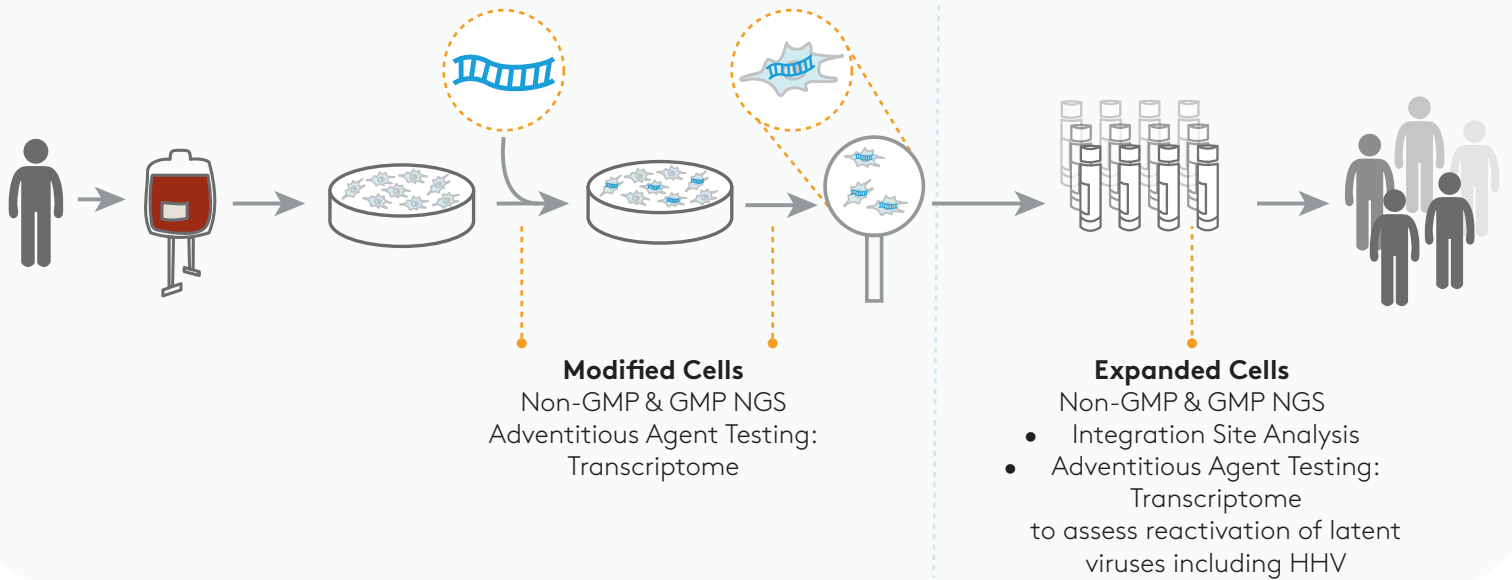


Paris



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- FDA draft guidance documents - Safety testing of human allogeneic cells expanded for use in cell-based medical product (April 2024)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

UPSTREAM PROCESSING (USP)
DOWNSTREAM PROCESSING (DSP)

ASSAY SPECIFICATIONS

	Assay	GMP	Sample Requirements	Turnaround Time (Calendar Days)	Deliverables to Client
VIRAL SAFETY	iDTECT® Transcriptome	✓	Min. 3×10 ⁵ cells	28 days (Standard) 21 days (Fast Track)	<ul style="list-style-type: none"> Certificate of Analysis Expert virologist report Raw data
GENETIC CHARACTERIZATION	iDTECT® Integration Site Analysis		5×10 ⁶ cells (≥10 µg DNA per sample)	35 days (per round)	<ul style="list-style-type: none"> Report Raw Data

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


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