

iPSC Testing

Induced pluripotent stem cells (iPSCs) hold immense potential for regenerative medicine, cell therapy, and drug discovery, but ensuring their safety, identity, and potency is essential at every stage of development. At Avance Biosciences, we offer comprehensive iPSC testing, including regulatory-compliant release assays as well as in-depth characterization and analytical support, to help you advance your programs with confidence.

Our Expertise

Leveraging state-of-the-art analytical platforms, we provide comprehensive iPSC assessment, including genomic integrity, sterility and mycoplasma testing, pluripotency validation, and residual reagent profiling. With expertise in GLP- and GMP-compliant testing, we help you confidently advance iPSC-based therapies from early research through clinical development.

Identity Testing

Assays that confirm the genetic and phenotypic identity of iPSCs and their derivatives. These studies ensure cell lineage fidelity and provide confidence that each product matches its intended profile.

Assay	Platform
Pluripotency Surface Marker Profiling	Flow
Pluripotency Marker Panel Gene Expression	qPCR
STR-Based Genetic Identity Profiling	qPCR
HLA Genotyping	Sanger

Potency Testing

Assay	Platform
Ectoderm Marker Expression	qPCR
Mesoderm Marker Expression	qPCR
Endoderm Marker Expression	qPCR

Functional assays that demonstrate the biological activity and therapeutic relevance of iPSC-derived products. These data establish consistency of performance across batches and support regulatory expectations for efficacy.

Purity Testing

Analyses that detect unwanted cell populations, contaminants, or residual undifferentiated cells. Purity testing safeguards product quality and reduces risks associated with off-target effects.



Assay	Platform
Residual Episomal Plasmid Detection (EBNA1)	ddPCR
Residual Episomal Plasmid Detection (Ori)	ddPCR / qPCR
Residual Reprogramming Vector (Custom)	ddPCR
Residual Reprogramming Vector (Sendai)	ddPCR
Residual Total Collagenase	ELISA
Residual Medium Components	ELISA
Residual ROCK Inhibitor (Y-27632)	LC-MS
Residual Trypsin Activity	Colorimetric
Lineage Marker Exclusion	qPCR

Safety Testing

Assay	Platform
Whole Genome Variant Detection (WGS)	NGS
Whole Exome Variant Detection (WES)	NGS
Bovine-Origin Adventitious Viruses	qPCR (Panel)
Human-Tropic Adventitious Viruses	Cell Culture
Broad-Spectrum Adventitious Viruses	Cell Culture
Avian/Broad-Spectrum Adventitious Viruses	Cell Culture
Human-Origin Adventitious Viruses	qPCR (Panel)
Porcine-Origin Adventitious Viruses	NGS (Panel)
Genetic Integrity – Inherited Disease Panel	NGS (Panel)
Residual Active Collagenase	Fluorometric
Residual DMSO Quantification	Colorimetric
Telomere Length Analysis	qPCR
Endotoxin Testing	LAL Assay
Mycoplasma Testing	qPCR
Sterility Testing	Microbiological

Targeted assays to evaluate genomic integrity, tumorigenicity risk, and microbial sterility. These studies provide assurance that iPSC-based products meet stringent safety requirements for clinical use.

Other (Support Assays)

These methods offer rapid, informative assessments to support routine monitoring and early decision-making.

Assay	Platform
Alkaline Phosphatase Staining	Colorimetric
Trypan Blue Viability Assay	Microscopy
7-AAD Viability Assay	Flow

Scan to learn more.

