



Applied StemCell

PRODUCT DATA SHEET

ActiCells™ GMP hiPSCs

(CD34⁺ Cord Blood Cells, Normal, Male)

Catalog No. ASE-9280 GMP • Rev. 1 | August 2026

Product Overview

ASE-9280 is a GMP-grade human induced pluripotent stem cell (hiPSC) line reprogrammed by an episomal (footprint-free) method from male CD34⁺ umbilical cord blood cells. Manufactured under an ISO 13485:2016 quality system and released against compendial (USP) specifications with full in vitro adventitious virus and agent testing, it provides a clinically-oriented, well-characterized starting material for translational and therapeutic cell development.

Key Features & Benefits

Feature	Benefit
GMP-manufactured, ISO 13485:2016	A clinically-oriented starting material with a documented quality pedigree.
Episomal (footprint-free) reprogramming	Transgene-free iPSCs with no integrated reprogramming vectors.
Compendial release testing	USP sterility, mycoplasma, and endotoxin methods plus in vitro adventitious virus and agent testing.
Neonatal CD34 ⁺ cord blood source	Fewer somatic mutations than adult-cell-derived iPSCs.
Fully characterized pluripotency	≥70% OCT3/4, SOX2, NANOG, SSEA-4, and TRA-1-60 by flow cytometry, with confirmed tri-lineage differentiation.

Product Specifications

Product Type	GMP Grade
Cell Type	Human induced pluripotent stem cells (hiPSCs)
Parental Line / Background	CD34 ⁺ umbilical cord blood cells (Male)
Clinical Information	Normal
Reprogramming Method	Episomal (footprint-free)
Format	1 vial (1 × 10 ⁶ cells / 0.5 mL)
Storage / Shipping	-135 °C (liquid nitrogen vapor phase)
Shelf Life / Retest	~2.5 years from manufacture (see lot-specific CoA)
Quality System	ISO 13485:2016; compendial (USP) release testing

Applications

- Translational and clinical iPSC-derived cell therapy development
- GMP master and working cell bank generation
- Substrate for GMP genome engineering and differentiation
- Allogeneic (off-the-shelf) cell product development

Quality Control Summary

Each lot is released against the following quality criteria. Lot-specific results are provided on the accompanying Certificate of Analysis (CoA).

- Pluripotency markers $\geq 70\%$ by flow cytometry: TRA-1-60, SSEA-4, SOX2, OCT3/4, NANOG
- Tri-lineage directed differentiation into ectoderm, mesoderm, and endoderm
- Morphology: round, tightly packed colonies with well-defined edges
- Karyotype: normal human male chromosomes (G-banding); Viability $\geq 70\%$ (NC-202)
- Identity: STR (PCR) – match to CD34+ cell donor
- Sterility USP <71> (no growth); Mycoplasma USP <63> (negative); Endotoxin USP <85> (≤ 5.0 EU/mL)
- In vitro adventitious virus (Vero, MRC-5, HeLa) and 30+ agent PCR panel: negative

Supporting Data

Morphology Analysis

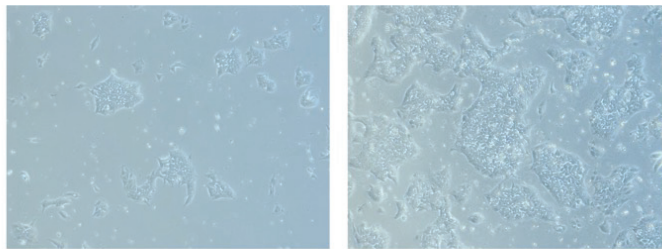


Figure 1. Morphology images of the iPSCs captured at 24 hours and 72 hours after thawing. The control human iPSCs were generated from normal CD34⁺ umbilical cord blood cells using an episomal method. The image of the hiPSCs on the left was taken 24 hours after thawing, and the image on the right was captured 72 hours after thawing.

Expression of Pluripotency Markers

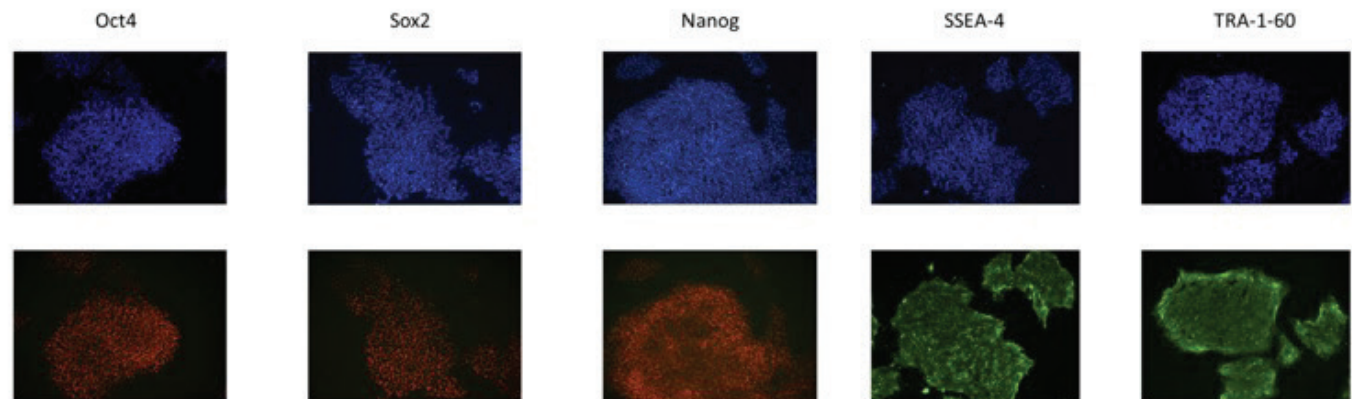


Figure 2. Expression of pluripotency markers. The hiPSC line, derived from male CD34⁺ umbilical cord blood cells, expresses pluripotency markers Oct4, Sox2, Nanog, SSEA-4, and Tra-1-60, indicating pluripotency of the hiPSC line. The corresponding DAPI staining is shown above each image.

Alkaline Phosphatase (AP) Analysis

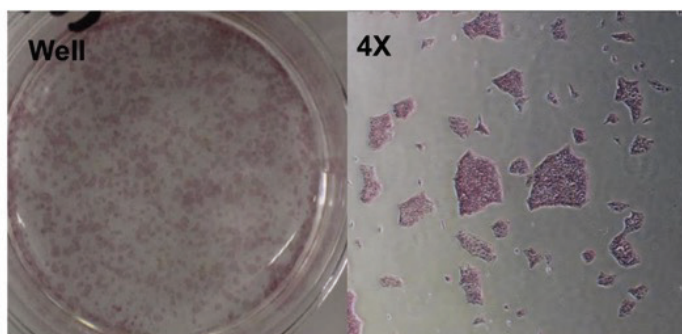


Figure 3. Alkaline phosphatase (AP) staining. The hiPSC line stained positive for alkaline phosphatase.

Supporting Data

Directed Differentiation to the Three Germ Layers

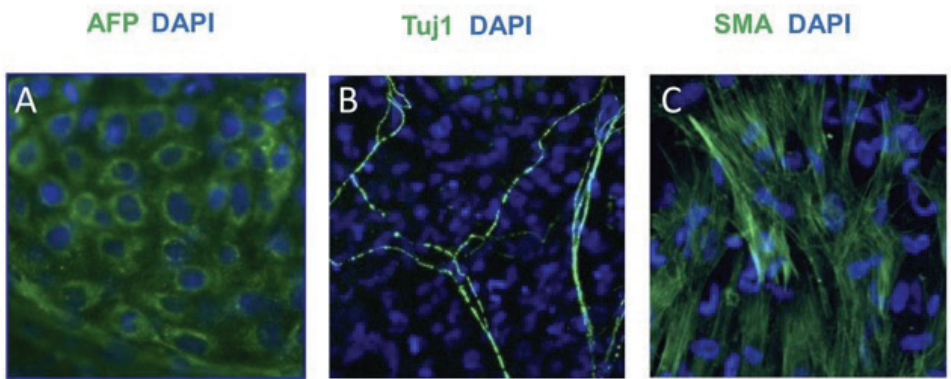


Figure 4. Directed differentiation of three germ layers. Immunofluorescent staining for the three germ layers after directed differentiation of hiPSC line. A) Endoderm is demonstrated by alpha-fetoprotein (AFP) immunofluorescence (IF, green), (B) ectoderm by Neuron-specific class III β -tubulin (Tuj1) IF, and (C) mesoderm by smooth muscle actin (SMA) IF. DAPI staining in blue.

STR Profile

Amelogenin	X	Y	D18S51	14	
vWA	16		Penta E	7	11
D8S1179	13	14	D5S818	11	
TPOX	8		D13S317	9	11
FGA	18	25	D7S820	10	11
D3S1358	15		D16S539	11	13
THO1	6	9.3	CSF1PO	12	
D21S11	31.2	33.2	Penta D	11	13

Figure 5. STR profiling of the hiPSC line. The DNA STR profile of the cell line is consistent with the presence of a single cell line.

Ordering Information

Catalog No.	ASE-9280
Description	Human iPSC Line, GMP Grade (CD34+ cord blood, male; episomal)
Format	Cells
Pack Size	1.0 $\times$ 10 ⁶ cells/vial

Related Products

- ASE-9250 – Human iPSC Line, Research Grade (CD34+ cord blood, male)
- TARGATT™ GMP hiPSC Knock-in Kit (AST-9480)
- Custom GMP iPSC engineering, banking & differentiation services

Contact & Ordering

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