



CORIELL INSTITUTE
FOR MEDICAL RESEARCH

GM 23937*B

Certificate of Analysis

Product description	Human Fibroblast reprogrammed with seven factors (OCT4, SOX2, KLF4, LMYC, LIN28, NANOG, T-Antigen) using retroviral vectors	
Publication(s) describing iPSC establishment		
Parent cell line and cell type	GM11853	Fibroblast
Diagnosis	Tay-Sachs Disease	
Parent cell line freeze passage		
Passage of iPSC reported at submission	10	
Number of passages at Coriell	6	
Media	mTeSR1	
Feeder	Matrigel	
Passage method	Dispase	
Split ratio	1:8 every 5-7 days	

The following testing specifications have been met for the specified product lot:

Test Description	Test Method	Test Specification	Result
Post-Thaw Viable Cell Recovery	Colony Doubling	Colony formation and diameter doubling within 5 days	Pass
Sterility	Growth on agar	Negative	Pass
Mycoplasma	PCR	Negative	Pass
Karyotype	G-banding	Normal Karyotype	Pass
Identity Match	STR (THO-1, D22S417, D10S526, vWA31, D5S592, and FES/FPS)	Match parent fibroblast line	Pass
Surface Antigen Expression of Stem Cell Markers	Immunostaining	> 80% expression of SSEA-4 < 10% expression of SSEA-1	Pass
Pluripotency	Illumina Array and PluriTest Software (www.pluritest.org)	Pluripotency Score greater than 20 and a Novelty Score < 1.62	Pluripotency: 25.56 Novelty: 1.545

Post-Thaw Viability

One vial of distribution lot was thawed. Cultures were observed daily. Colonies were photographed on the first day of appearance and then 5 days later. Colonies must double in diameter 5 days after first observation.

Days from Recovery to First Colony Observation	Average Colony Diameter (initial)	Average Colony Diameter (post 5 days)
1 Day	310 um	1358 um

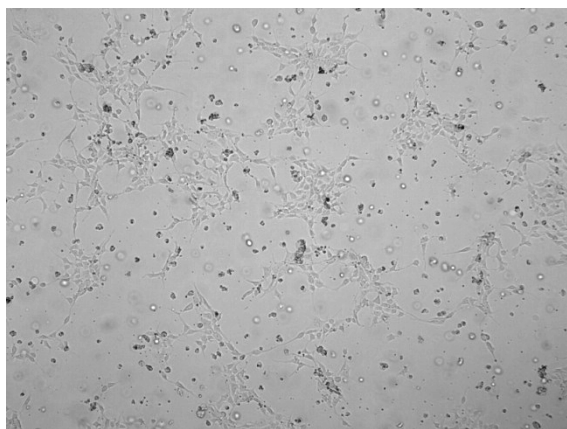


Figure 1A. Colony observed post thaw

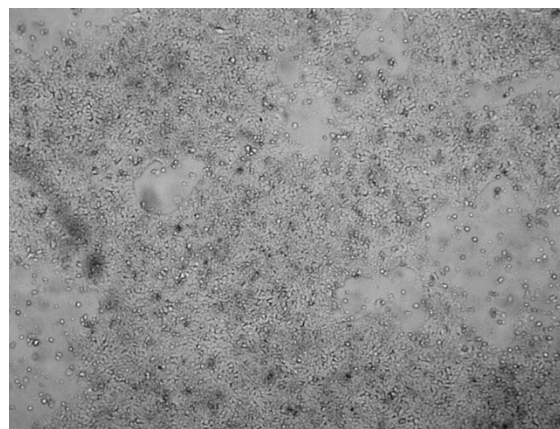


Figure 1B. Colony 5 days after first observation

Karyotype Analysis

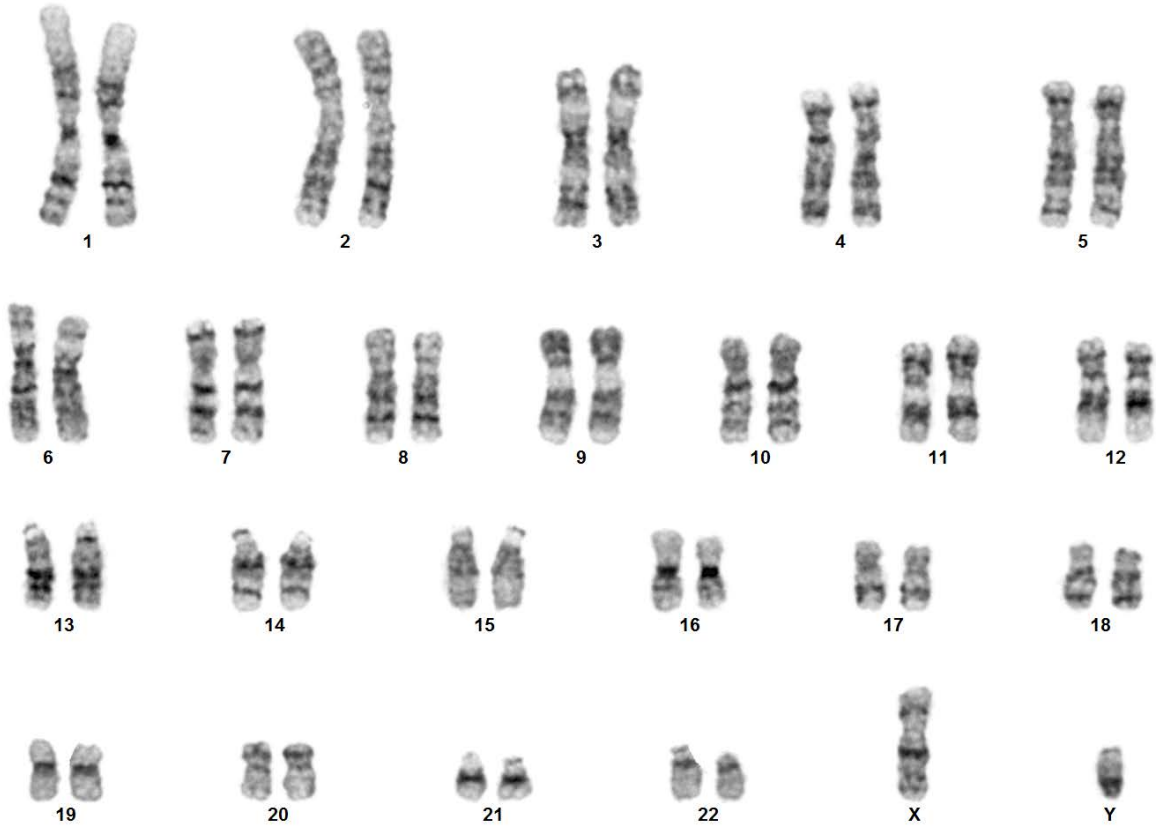


Figure 2 :G-banded karyotype showing 46,XY

Surface Antigen Expression of Stem Cell Markers

Undifferentiated cells are stained for the surface antigens, SSEA4 and SSEA1. SSEA4 (stage specific embryonic antigen 4) is expressed on undifferentiated human stem cells. SSEA1 (stage specific embryonic antigen 1) is expressed on differentiated stem cells.

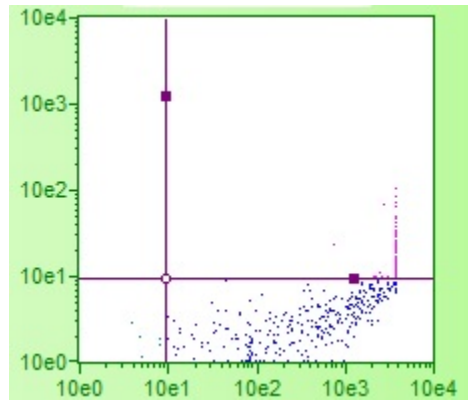


Figure 3A: Scatter plot of SSEA4 stained iPS cells.

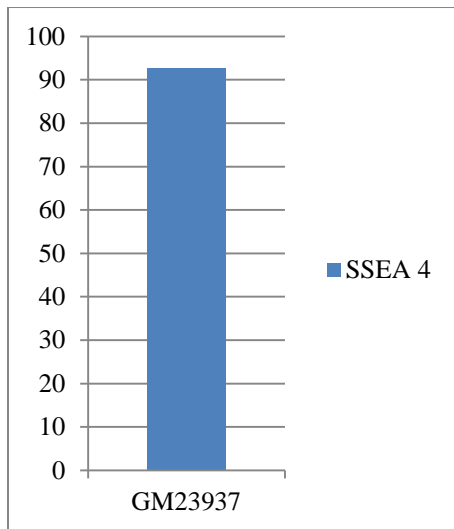


Figure 3B. Graph depicting percent SSEA4 positive cells in an undifferentiated cell culture.

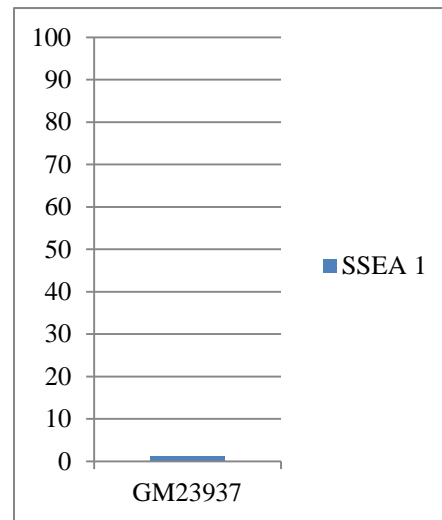


Figure 3C. Graph depicting percent SSEA1 positive cells in undifferentiated cell culture

Assessment of Pluripotency of a Cell Line

Cells are directed to differentiate to assess the pluripotency of the cell line. RNA is harvested and gene expression is analyzed by real-time PCR. Ct values are adjusted for loading using a housekeeping gene. Gene expression is shown as fold difference to undifferentiated cells.

Embryoid Body (EB) Formation Assay

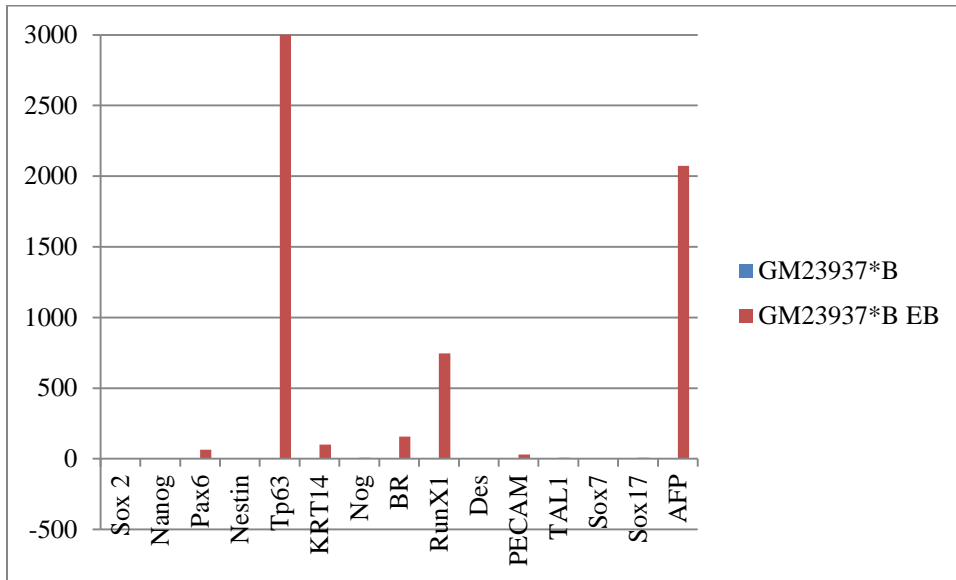
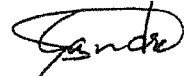


Figure 4. Gene expression following EB differentiation. Fold difference is shown relative to undifferentiated iPS cell line.

	Sox 2	Nanog	Pax6	Nestin	Tp63	KRT1 4	Nog	BR	RunX1	Des	PECAM	TAL1	Sox7	Sox17	AFP
GM23937* B	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
GM23937* B EB	-2	-1	64	2	3290	100	7	156	747	3	31	7	5	7	2074

Table 1. Fold difference values of gene expression of EB. Fold difference is shown as fold difference to undifferentiated cells.

- Pass
- Fail
- Other: _____



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