GM23762*B

Certificate of Analysis

Product description	Human Fibroblast reprogrammed with five factors (OCT4, SOX2, KLF4, CMYC, LIN28) using lentiviral vectors	
Publication(s) describing iPSC establishment	Brennand, Gage, et al, **Nature.** 2011 May 12;473(7346):221-5	
Parent cell line and cell type	GM02497	Fibroblast
Diagnosis	SCHIZOPHRENIA; SCZD	
Passage of iPSC reported at submission	15	
Number of passages at Coriell	12	
Media	KO DMEM + 20% KOSR + 50ng/ml FGF	
Feeder	CF1 MEFs on 0.1% Gelatin	
Passage method	TrypLE Express	
Split ratio	1:6 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	46,XY	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	Pass
Pluripotency	Illumina Array and PluriTest Software (www.pluritest.org)	Pluripotency Score greater than 20 and a Novelty Score 1.67	Pluripotency: 32.37 Novelty: 1.546

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.

Day 4	284 µm
Day 9	676 µm

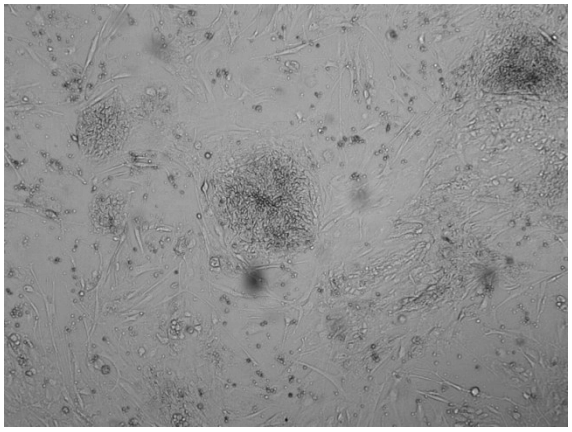

Figure 1A. Colony observed post thaw

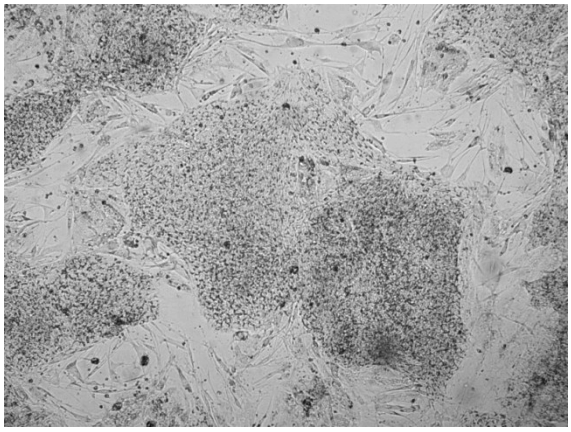

Figure 1B. Colony 5 days after first observation

Karyotype Analysis

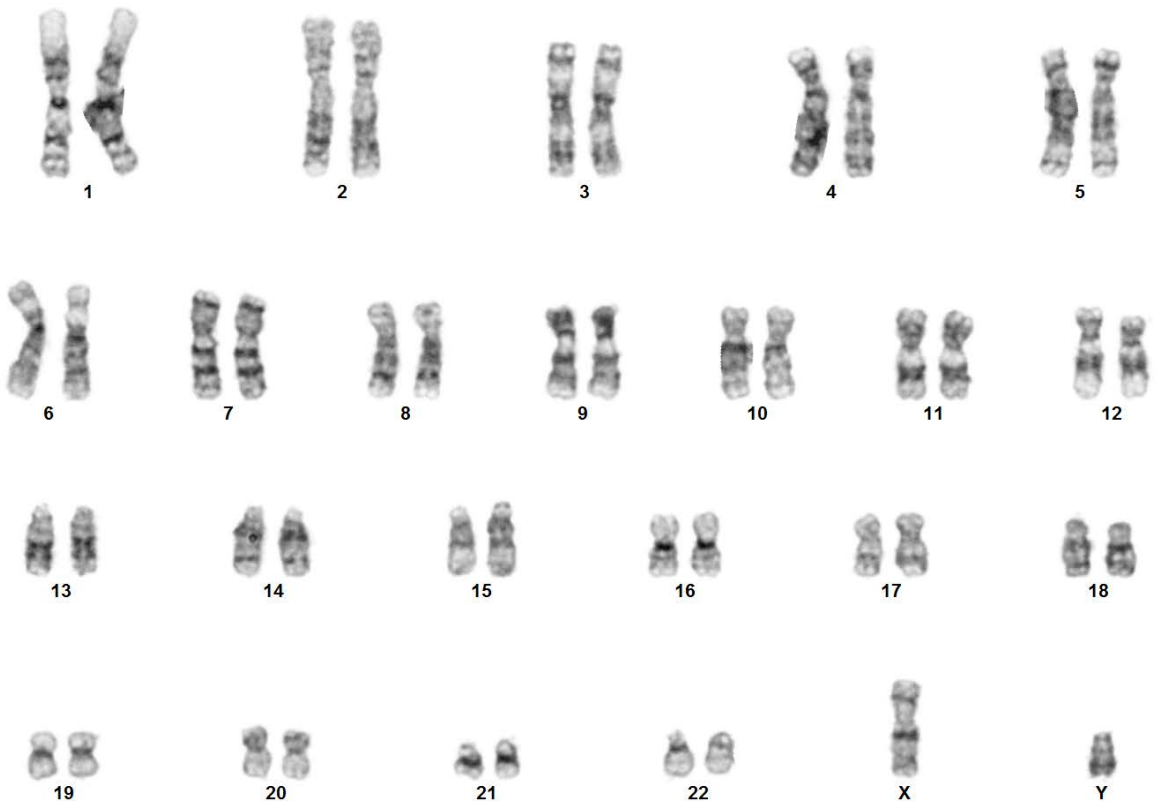

Figure 2 : G-banded karyotype showing 46,XY

Surface Antigen Expression of Stem Cell Markers

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

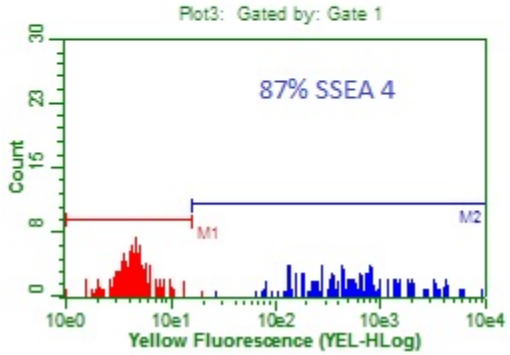

Figure 3A: Representative histogram of SSEA-4 positive population. Histogram is an overlay of negative control (red) and SSEA-4 positive population (blue).

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

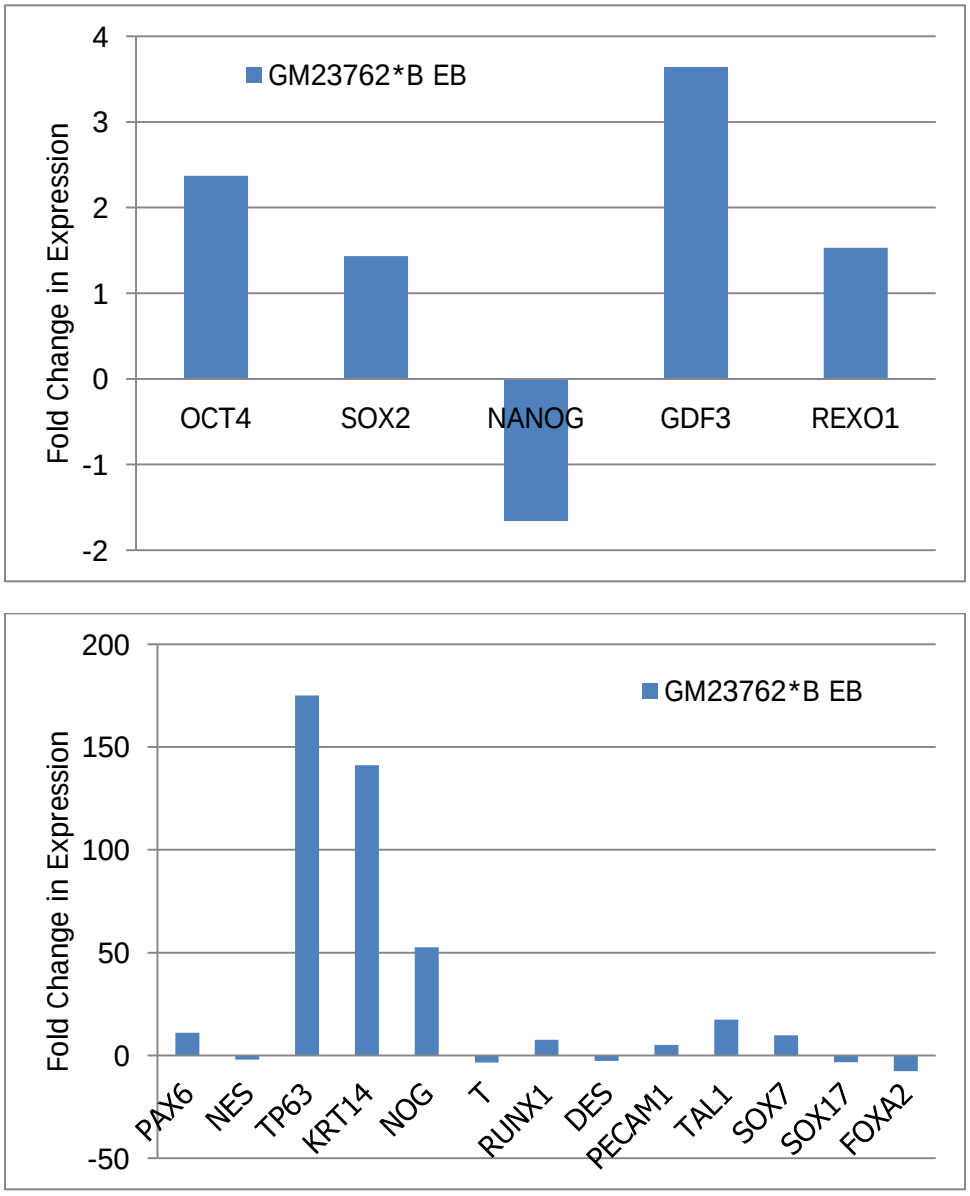

Figure 4. Gene expression following EB differentiation. Fold difference is shown relative to undifferentiated iPS cell line.

Pluripotency Markers

	OCT4	SOX2	NANOG	GDF3	REXO1
GM23762*B EB	2	1	-2	4	2

Ectoderm

	PAX6	NES	TP63	KRT14	NOG
GM23762*B EB	11	-2	175	141	53

Mesoderm

	T	RUNX1	DES	PECAM1	TAL1
GM23762*B EB	-3	8	-3	5	17

Endoderm

	SOX7	SOX17	FOXA2	AFP
GM23762*B EB	10	-3	-8	143902

Table 1. Fold difference values of gene expression of EB. Fold difference is shown as fold difference to undifferentiated cells. Ct values are normalized to that of GAPDH.

☒ Pass
☐ Fail
☐ Other: _____

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