Certificate of Analysis (CoA) for induced Pluripotent Stem Cells



This product is for research only

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Reprogramming Method	Integrating R	etrovirus (KLF4, MYC, PO	U5F1, SOX2)
Genetic Modification	lso	ession Dox inducible NGN Dogenic modification MAP Dozygous; EX10 + 16 bp =	T
Passage Number	27	Cell number / vial	1-2 x10E6
Culture Matrix	Matrigel™	Culture Medium	mTeSR™-1
O ₂ Concentration	21%	CO ₂ Concentration	5%
Passaging Method	EDTA	Additional Culture Information	Rho kinase inhibitor used at thaw
Cryopreservation Medium	50% mTeSR1, 40% FCS*, 10% DMSO *Serum of Zone 1 origin		
Recommendation for thawing	Recommended thaw into 60mm plates Refer to cell line user protocols for further guidance at www.EBiSC.org		
Additional Comments	Typical recovery after thaw, typical growth to confluency		

Please see https://cells.ebisc.org for further information on Quality Control and characterisation applied to lines released by EBiSC. The following standard testing criteria have been determined within EBiSC, prior to release of this product:

Test	Assay	Acceptance Criteria	Result
	Inoculation for microbiological growth	Not Detected	Pass
Sterility	Mycoplasma	Not Detected	Pass
	Virology (HIV1, HIV2, HBV, HCV)	Not Detected	Absence of viral pathogens in other cell line clone from same donor
Cell Line Identity	STR / Fingerprinting	85% match to donor Sex match to donor	Allele data recorded and available upon request. First profile recorded for cell line, match to donor.
Viability	Visual Assessment	Growth to confluence post-thaw	Acceptable



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Cell Line Name SIGi001-A-15 Batch / Lot Number P001	Cell Line Name	SIGi001-A-15	Batch / Lot Number	P001
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Test	Assay	Acceptance Criteria	Result
Phenotype	Continuous visual assessment of iPSC colony morphology	Recorded	Typical PSC colonies with low to medium differentiation levels
	Flow Cytometry	SSEA-4 > 70% positive SSEA-1 < 10% positive POU5F1 > 70% positive	Pass
Differentiation Potential	Trilineage differentiation and flow cytometry for trilineage markers	Up-regulation of germ layer markers	Endoderm : Pass Mesoderm : Pass Ectoderm : Pass
Genomic Stability	G-Banding (10 -20 successful karyotypes recorded)	Sex match to donor.	No chromosomal abnormalities detected
Genetic Modification	Sanger sequencing at locus MAPT 17q21.31	Match to reported modification	Pass
	Induction of transgene NGN2	Match to reported modification	Pass

Additional guidance on storage, safety and usage can be found in the EBISC Technical Information.

Approved CoA	Signature	Date
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