

Certificate of Analysis (CoA) for induced Pluripotent Stem Cells

This product is for research only

ECACC Catalogue No: 66540322

Cell Line Name	PFIZI013-A	Batch Number	M001
Donor ID	TDP43		
Disease Association	Amyotrophic Lateral Sclerosis	Phenotype of Donor	Affected
Tissue of Origin	Fibroblast	Sex	Female
Reprogramming Method	Non-integrating Sendai Virus (POU5F1, SOX2, KLF4, MYC)		
Passage Number	Passage 26	Cell number / vial	1.35 x 10 ⁶
Culture Matrix	Geltrex / Matrigel	Culture Medium	E8
O ₂ Concentration	21%	CO ₂ Concentration	5%
Passaging Method	EDTA	Additional Culture Information	N/A
Cryopreservation Medium	40% FBS* / 50% medium / 10% DMSO *Serum of Zone 1 origin		
Recommendation for thawing	Recommended thaw into 2 wells of a 6-well plate or per 10cm ² Refer to cell line user protocols for further guidance at www.EBiSC.org		
Additional Comments	Typical recovery after thaw, typical growth to confluency		
Associated Publications	PubMed ID: N/A		

Please see www.EBiSC.org for further information on Quality Control 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
Sterility	Inoculation for microbiological growth	Not Detected	Pass
	qPCR for Mycoplasma	Not Detected	Pass
	Virology (HBV, HCV, HIV1, HIV2)	Not Detected	Pass
Cell Line Identity	Short Tandem Repeat analysis using PCR	N/A	Allele data recorded and available upon request. Match to donor fibroblast
Viability	Visual Assessment	Growth to confluence post-thaw	Acceptable
Phenotype	Continuous visual assessment of iPSC colony morphology	Recorded	Typical iPSC colonies with low to medium level differentiation

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Test	Assay	Acceptance Criteria	Result
Phenotype	Flow Cytometry	SSEA-4 > 70% + TRA-1-60 > 70% + SSEA-1 < 10% + POU5F1 > 70% +	Pass
Differentiation Potential	Spontaneous EB differentiation and qPCR for trilineage markers	Up-regulation of germ layer markers	Endoderm : Detected Mesoderm : Detected Ectoderm : Detected

Additional cell line characteristics have been determined by original reprogramming centres and have not been independently verified by EBiSC. Historical cell line data displayed here is accurate according to data provided by depositors on 02-NOV-2016

Test	Assay	Result
Karyotype	KaryoLite BoBs	No autosomal or sex chromosome aneuploidies detected in this sample
	G-Banding	10/20 46,XX 7/20 46,XX,add(13)(q32) 1/20 47,XX,+7,add(13)(q32),?del(20)(p12) 1/20 45,XX,?add(5)(p15.3),-10 1/20 44,XX,-13,-13
Clearance of Reprogramming Factors	qPCR for Sendai backbone	Not Detected

The following guidance can be found in the Instructions for Use	
Intended use	Expiry Date
Product Format	Recommended storage conditions
Volume	Hazardous Information

Approved CoA

Signature

[Handwritten Signature]

Date

24 Jan 2017