

Certificate of Analysis (CoA) for induced Pluripotent Stem Cells

This product is for research only

ECACC Catalogue No: 66540017

Cell Line Name	UNEWi004-A	Batch Number	P001
Donor ID	F119		
Disease Association	Retinitis pigmentosa	Phenotype of Donor	Affected
Tissue of Origin	Dermal fibroblasts	Sex	Male
Reprogramming Method	Cytotune 2.0 Sendai virus (POU5F1, SOX2, KLF4, MYC)		
Passage Number	Passage 28	Cell number / vial	1-2 x 10 ⁶
Culture Matrix	Geltrex/ Matrigel	Culture Medium	mTeSR-1
O ₂ Concentration	20%	CO ₂ Concentration	5%
Passaging Method	EDTA	Additional Culture Information	N/A
Cryopreservation Medium	Cryostor		
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	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
Viability	Visual Assessment	Growth to confluence post-thaw	Acceptable
Phenotype	Continuous visual assessment of iPSC colony morphology	Recorded	Typical iPSC colonies with low differentiation levels

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Test	Assay	Acceptance Criteria	Result
	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 28-JAN-2016

Test	Assay	Result
Genetic Defect	Sequencing	Confirmation of mutation
Phenotype	Flow cytometry	Positive for markers TRA-1-60, SSEA4, NANOG, low expression of SSEA1
Karyotype	CytoSNP analysis	No clinically significant imbalance was detected
Cell Line Identity	CytoSNP analysis	Parental fibroblasts and clone are identical
Clearance of Reprogramming Factors	PCR for Sendai virus clearance	Not detected
Differentiation Potential	EB spontaneous trilineage differentiation	Formed all germ layers

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 

Date 03 Feb 2016