Certificate of Analysis (CoA) for induced Pluripotent Stem Cells



This product is for research only

ECACC Catalogue No: 66540039

Cell Line Name	UNEWi001-A Alternative name: UNEW001Ai	Batch Number	P001
Donor ID	F255		
Disease Association	Retinitis Pigmentosa	Phenotype of Donor	Affected
Tissue of Origin	Dermal Fibroblasts	Sex	Female
Reprogramming Method	Non-integrating Sendai virus (MYC, SOX2, KLF4, POU5F1)		
Passage Number	Passage 27	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
	Inoculation for microbiological growth	Not Detected	Pass
Sterility	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



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Test	Assay	Acceptance Criteria	Result
	Continuous visual assessment of iPSC colony morphology	Recorded	Typical iPSC colonies with low differentiation levels
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 26-Nov-2015

Test	Assay	Result
Genetic Defect	DNA Sequencing	Deletion 522-27+IVS+1 to +10 in PRPF31 gene
Phenotype	Flow cytometry	Positive expression of TRA-1-60, SSEA4, NANOG. Low expression of SSEA1
Karyotype	CytoSNP analysis	Acceptable, normal karyotype
Cell Line Identity	CytoSNP analysis	Parental fibroblasts and clone are identical
Clearance of Reprogramming Factors	RT-PCR for Sendai Virus	Not detected
Sterility	Mycoplasma qPCR	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





In case of queries, please contact <u>culturecollections.technical@phe.gov.uk</u>. European Collection of Authenticated Cell Cultures (ECACC), Culture Collections, Public Health England, Tel: +44 (0) 1980 612684