

Certificate of Analysis (CoA) for induced Pluripotent Stem Cells

This product is for research only

ECACC Catalogue No: 66540269

Cell Line Name	BIONI010-C-3	Batch Number	M001
Donor ID	CC-2511		
Tissue of Origin	Dermal fibroblast	Phenotype of Donor	Unaffected control
Cell Line Disease Association	Alzheimer's disease	Sex	Male
Gene Editing Method	CRISPR/Cas-9	Gene Editing Target	ApoE chr19:44905754- 44909393
Type of Modification	Isogenic Modification	Parental Line	BIONI010-C
Details of Gene Edit	Deletion of the ApoE gene by insertion of a frame shift in exon 1		
Reprogramming Method	Non-integrating episomal (POU5F1, SOX2, KLF4, MYC, Lin28 and shP53)		
Passage Number	Passage 34	Cell number / vial	1.4 x 10 ⁶
Culture Matrix	Geltrex/Matrigel	Culture Medium	E8 Flex
O ₂ Concentration	18%	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	Slow recovery after thaw, slow growth to confluence		
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

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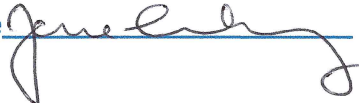
Test	Assay	Acceptance Criteria	Result
Viability	Visual Assessment	Growth to confluence post-thaw	Low, slow recovery
Phenotype	Continuous visual assessment of iPSC colony morphology	Recorded	Typical iPSC colonies with low differentiation levels
	Flow Cytometry	SSEA-4 > 70% + TRA-1-60 > 70% + SSEA-1 < 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 21-FEB-2017

Test	Assay	Result
Sterility	Mycoplasma Broth Sterility	Not detected
Karyotype	G-Banding	19/20 46,XY 1/20 45, XY,-19
Clearance of Gene Editing Plasmid	PCR for CRISPR plasmid	Transient – Weak positive for DNA plasmid no longer active
	Puromycin culture for plasmid	Cells sensitive to puromycin Plasmid no longer active
Genotyping	Southern blot for ApoE gene	ApoE Knocked out

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 23 Feb 2017