

# Certificate of Analysis (CoA) for induced Pluripotent Stem Cells

*This product is for research only*

ECACC Catalogue No: 66540366

Cell Line Name	BIONI010-C-4	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	ApoE 112 modified from C/T to C/C		
Reprogramming Method	Non-integrating episomal (POU5F1, SOX2, KLF4, MYC, Lin28 and shP53)		
Passage Number	Passage 31	Cell number / vial	1.3 x 10 <sup>6</sup>
Culture Matrix	Geltrex/Matrigel	Culture Medium	E8 Flex
O <sub>2</sub> Concentration	18%	CO <sub>2</sub> 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 <sup>2</sup> Refer to cell line user protocols for further guidance at <a href="http://www.EBiSC.org">www.EBiSC.org</a>		
Additional Comments	Typical recovery after thaw typical growth to confluence		
Associated Publications	N/A		

Please see [www.EBiSC.org](http://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
<b>Sterility</b>	Inoculation for microbiological growth	Not Detected	Pass
	qPCR for Mycoplasma	Not Detected	Pass
	Virology (HBV, HCV, HIV1, HIV2)	Not Detected	Pass
<b>Cell Line Identity</b>	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
<b>Viability</b>	Visual Assessment	Growth to confluence post-thaw	Acceptable
<b>Phenotype</b>	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
<b>Differentiation Potential</b>	Spontaneous EB differentiation and qPCR for trilineage markers	Up-regulation of germ layer markers	Endoderm : Not 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
<b>Sterility</b>	Mycoplasma Broth Sterility	Not detected
<b>Karyotype</b>	G-Banding	19/20 46,XY 1/20 45,XY,-4
<b>Clearance of Gene Editing Plasmid</b>	PCR for CRISPR plasmid	Not Detected
<b>Genotyping</b>	Sequencing of target locus	ApoE 112 C/T modified to C/C
<b>Differentiation Potential</b>	Directed differentiation to endoderm	Upregulation of CXCR4, FoxA2, GATA6, GSC, PITX1 and SOX17 detected by qPCR

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

Approved CoA

Signature

*Jane Kirby*

Date

*03 feb 2017*



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