

Certificate of Analysis (CoA) for induced Pluripotent Stem Cells

This product is for research only

ECACC Catalogue No: 66540022

Cell Line Name	BIONI010-A	Batch Number	P001
Donor ID	CC-2511		
Disease Association	No disease association	Phenotype of Donor	Unaffected Control
Tissue of Origin	Dermal Fibroblasts	Sex	Male
Reprogramming Method	Non-integrative episomal vectors, hOSKUL + SHP53		
Passage Number	Passage 17	Cell number / vial	1-2 x 10 ⁶
Culture Matrix	Geltrex/Matrigel	Culture Medium	mTeSR-1
O ₂ Concentration	5%	CO ₂ Concentration	5%
Passaging Method	EDTA	Additional Culture Information	Cells were previously cultured using ROCK inhibitor
Cryopreservation Medium	90% medium / 10% DMSO		
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 growth after initial thaw but stable growth pattern after first post-thaw passage. After passage 1, cells grew in a three day growth cycle		
Associated Publications	PubMed ID: 25241739		

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 23-MAR-2016

Test	Assay	Result
Phenotype	qPCR	Typical expression of ZFP42, POU5F1, SOX2, NANOG, DMNT3B
	Flow Cytometry	Positive expression of markers SSEA4, TRA1 -60, SSEA3, TRA 1-81, low expression of SSEA1
	Immunocytochemistry	Positive expression of TRA-1-60, NANOG, TRA-1-81, POU5F1, SSEA-4 and SSEA-3
Karyotype	G-Banding	Normal: 46, XY
Cell Line Identity	Microsatellite PCR	Match to donor tissue
Clearance of Reprogramming Factors	qPCR analysis of DNA and RNA	Not detected
Differentiation Potential	PluriTest	Distributed with previously referenced PSCs
	EB Spontaneous Differentiation	Endoderm : AFP positive Mesoderm : SMA positive Ectoderm : TUJ1 positive
	Directed Differentiation	Production of Neurons (positive for NESTIN, VIMENTIN, TUJ1, vGLUT1)

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 mar 2016