Certificate of Analysis (CoA) for induced Pluripotent Stem Cells



This product is for research only

ECACC Catalogue No: 66540606

Cell Line Name	BIONi037-A-4	Batch / Lot Number	M001	
Reprogramming Method	Episomal vector (POU5F1, SOX2, cMYC, LIN28, KLF4)			
Genetic Modification	CRISPR-Cas9			
Passage Number	Passage 31	Cell number / vial	1x10 ⁶	
Culture Matrix	Matrigel [™] / Geltrex [™]	Culture Medium	mTeSR™-1	
O ₂ Concentration	21%	CO ₂ Concentration	5%	
Passaging Method	EDTA	Additional Culture Information	Rho kinase inhibitor used at thaw	
Cryopreservation Medium	Cryostor®			
Recommendation for thawing	Recommended thaw into a 50mm cell culture plate Refer to cell line user protocols for further guidance at www.EBiSC.org			
Additional Comments	Slow recovery after thaw, slow growth to confluency			

Please see https://cells.ebisc.org/ for further information on Quality Control and characterisation 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
ć	Inoculation for microbiological growth	Not Detected	Pass
Sterility	Mycoplasma	Not Detected	Pass
	Virology (HBV, HCV, HIV1, HIV2) Not Detected		Confirmed Pass by depositor
Cell Line Identity	STR / Fingerprinting N/A		Allele data recorded and available upon request. Match to donor
Viability	Visual Assessment Growth to confluence post-thaw		Low, slow recovery
Phenotype	Continuous visual assessment of iPSC colony morphology	Recorded	Typical PSC 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 Pass Mesoderm : Pass Ectoderm : Pass



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Test	Assay	Acceptance Criteria	Result
Genomic Stability	G-Banding	Sex match to donor. 20 successful karyotypes recorded.	No chromosomal abnormalities detected.
Genetic Modification Sanger sequencing at locus		Match to reported modification	ApoE4/E4. NM_000041.4:c.388T>C

Additional guidance on storage, safety and usage can be found in the <u>EBiSC Technical Information</u>.

Approved CoA	Signature	(luse)	Date	28.05.2021

