Certificate of Analysis (CoA)
for induced Pluripotent Stem Cells

This product is for research only

Cell Line Name	BIONi010-C-3	Batch / Lot Number	M001

Reprogramming Method	Non-integrating episomal vector (POU5F1, SOX2, MYC, Lin28, shP53 and KLF4)		
Genetic Modification	CRISPR-associated (CRISPR/Cas) System, ApoE KO by insertion of a frame shift in exon 1		
Passage Number	34	Cell number / vial	1,4x10E6
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 60mm plates 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
Sterility	Inoculation for microbiological growth	Not Detected	Pass
	Mycoplasma	Not Detected	Pass
	Virology (HBV, HCV, HIV1, HIV2)	Not Detected	Confirmed Pass by depositor
Cell Line Identity	STR / Fingerprinting	85% match to donor Sex match to donor	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

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Test	Assay	Acceptance Criteria	Result
	Flow Cytometry	SSEA-4 > 70% positive TRA-1-60 > 70% positive SSEA-1 < 10% positive POU5F1 > 70% positive	Pass
Differentiation Potential	Spontaneous EB differentiation and qPCR for trilineage markers	Up-regulation of germ layer markers	Endoderm: Detected Mesoderm: Detected Ectoderm: Detected
Genomic Stability	G-Banding (10 -20 successful karyotypes recorded)	Sex match to donor.	No chromosomal abnormalities detected
Genetic Modification	Sanger sequencing at locus 19q13.32	Match to reported modification	Pass

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

Approved CoA **Signature** _____ **Date** 14.06.2024