

Certificate of Analysis (CoA) for induced Pluripotent Stem Cells

This product is for research only

Cell Line Name	BIONI010-C-42	Batch / Lot Number	P001
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Reprogramming Method	Non-integrating episomal vector (POU5F1, SOX2, KLF4, MYC, Lin28, shP53)		
Genetic Modification	Gene knock-in Doxycycline inducible CRE recombinase		
Passage Number	27	Cell number / vial	1-2x10E6
Culture Matrix	Matrigel™ / Geltrex™	Culture Medium	mTeSR™-1
O ₂ Concentration	20%	CO ₂ Concentration	5%
Passaging Method	Enzyme-free cell dissociation	Additional Culture Information	N/A
Cryopreservation Medium	50% mTeSR1, 40% FBS*, 10% DMSO *Serum of Zone 1 origin		
Recommendation for thawing	Recommended thaw into 2 x 60mm plate(s) 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
Vector clearance	RT-PCR	Not Detected (Episomal)	Pass by depositor
Sterility	Inoculation for microbiological growth	Not Detected	Pass
	Mycoplasma	Not Detected	Pass
	Virology (HBV, HCV, HIV1, HIV2)	Not Detected	Absence of viral pathogens in other cell line clone from same donor
Cell Line Identity	STR / Fingerprinting	85% match to donor Sex match to donor	Allele data recorded and available upon request. First profile recorded for cell line and pass for 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 PSC colonies with low differentiation levels
	Flow Cytometry	SSEA-4 > 70% + SSEA-1 < 10% + POU5F1 > 70% + TRA-1-81 > 70% +	Pass by depositor
Differentiation Potential	Trilineage differentiation and flow cytometry for trilineage markers	Up-regulation of germ layer markers	Endoderm: Pass Mesoderm: Pass Ectoderm: Pass
Genomic Stability	G-Banding (10- 20 successful karyotypes recorded)	Sex match to donor.	No chromosomal abnormalities detected
Genetic Modification	PCR	Match to reported modification	Pass

Additional guidance on storage, safety and usage can be found in the [EBiSC Technical Information](#).

Approved CoA

Signature

P. J. J. J.

Date

07-07-2026