

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

*This product is for research only*

Cell Line Name	BIONi010-C-53	Batch / Lot Number	P001
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Reprogramming Method	Non integrating episomal vector (OCT3/4, SOX2, cMYC, LIN28, SHP53 and KLF4)		
Genetic Modification	Isogenic modification APOE (APOE3/3 homozygous)		
Passage Number	36	Cell number / vial	1-2x10E6
Culture Matrix	Matrigel™ / Geltrex™	Culture Medium	mTeSR™-1
O <sub>2</sub> Concentration	21%	CO <sub>2</sub> Concentration	5%
Passaging Method	EDTA	Additional Culture Information	Rho kinase inhibitor used at thaw
Cryopreservation Medium	40% FBS* / 50% medium / 10% DMSO *Serum of Zone 1 origin		
Recommendation for thawing	Recommended thaw into 60mm plate(s) 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 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
<b>Sterility</b>	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
<b>Cell Line Identity</b>	STR / Fingerprinting	85% match to donor Sex match to donor	Allele data recorded and available upon request. First profile recorded for cell line, match to donor.
<b>Viability</b>	Visual Assessment	Growth to confluence post-thaw	Acceptable
<b>Phenotype</b>	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% + TRA-1-60 > 70% + SSEA-1 < 10% + POU5F1 > 70% +	Pass
<b>Differentiation Potential</b>	Trilineage differentiation and qPCR for trilineage markers	Up-regulation of germ layer markers	Endoderm : Pass Mesoderm : Pass Ectoderm : Pass
<b>Genomic Stability</b>	G-Banding (10- 20 successful karyotypes recorded)	Sex match to donor.	No chromosomal abnormalities detected confirmed by depositor
<b>Genetic Modification</b>	Sanger sequencing at locus	Match to reported modification	Pass

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

Approved CoA

Signature

D. J. J. J. J.

Date

06.03.2024