

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

*This product is for research only*

Cell Line Name	BIONI037-A-3	Batch / Lot Number	M001
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Reprogramming Method	Episomal vector (OCT3/4, SOX2, cMYC, LIN28, SHP53 and KLF4)		
Genetic Modification	Isogenic modification APOE (APOE3/4 heterozygous)		
Passage Number	Passage 31	Cell number / vial	1x10E6
Culture Matrix	Matrigel™	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	Cryostor		
Recommendation for thawing	Recommended thaw into 1 well of a 6-well plate or per 10cm <sup>2</sup> 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
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	Acceptable
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

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Test	Assay	Acceptance Criteria	Result
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	ApoE3/E4 NM_000041.4:c.388T>C

*Differentiation potential not performed for batch M001.*

*Please refer to historical data from the initial batch P003:*

Differentiation Potential	Trilineage differentiation and qPCR for trilineage markers	Up-regulation of germ layer markers	Endoderm: Pass Mesoderm: Pass Ectoderm: Pass
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Additional guidance on storage, safety and usage can be found in the [EBiSC Technical Information](#).

Approved CoA

Signature

*A. Juwan*

Date

*27.06.2024*



In case of queries, please get in touch via [Contact@EBiSC.org](mailto:Contact@EBiSC.org)

BIONI037-A-3.M001.CoA.v2