

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

*This product is for research only*

Cell Line Name	BIONI010-C-2	Batch / Lot Number	M001
Reprogramming Method	Episomal vector (POU5F1, SOX2, MYC, LIN28, SHP53 and KLF4)		
Genetic Modification	CRISPR-Cas9		
Passage Number	Passage 39	Cell number / vial	1.2 x 10 <sup>6</sup>
Culture Matrix	Matrigel™ / Geltrex™	Culture Medium	E8-Flex
O <sub>2</sub> Concentration	21%	CO <sub>2</sub> Concentration	5%
Passaging Method	EDTA	Additional Culture Information	None
Cryopreservation Medium	40% FBS* / 50% medium / 10% DMSO *Serum of Zone 1 origin		
Recommendation for thawing	Recommended thaw into 2 wells 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 [www.ebisc.org/](http://www.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	Pass
<b>Cell Line Identity</b>	STR / Fingerprinting	N/A	Allele data recorded and available upon request. 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
	Flow Cytometry	SSEA-4 > 70% + TRA-1-60 > 70% + SSEA-1 < 10% + POU5F1 > 70% +	Pass
<b>Differentiation Potential</b>	Spontaneous EB differentiation and qPCR for trilineage markers	Up-regulation of germ layer markers	Endoderm : Fail Mesoderm : Pass Ectoderm : Pass

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Test	Assay	Acceptance Criteria	Result
<b>Genomic Stability</b>	G-Banding	Sex match to donor. 20 successful karyotypes recorded.	No chromosomal abnormalities detected.
<b>Genetic Modification</b>	Sanger sequencing at locus	Match to reported modification	Hemizygous APOE3/E3, see PMID: 32971461.

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

Approved CoA      Signature       Date: 19<sup>th</sup> June 2024