

Certificate of Analysis (CoA) for induced Pluripotent Stem Cells

This product is for research only

ECACC Catalogue No: 66541178

Cell Line Name	CHDIi027-A	Batch Number	M001
Donor ID	MTM#27		
Disease Association	No Disease Association	Phenotype of Donor	Unaffected Control
Tissue of Origin	Fibroblasts	Sex	Female
Reprogramming Method	CytoTune™ 2.0 Sendai		
Passage Number	Passage 10	Cell number / vial	1.63 x 10 ⁶
Culture Matrix	Matrigel	Culture Medium	mTESR™1
O ₂ Concentration	21%	CO ₂ Concentration	5%
Passaging Method	EDTA	Additional Culture Information	N/A
Cryopreservation Medium	Cryostor® CS10		
Recommendation for thawing	Recommended to thaw 20% of vial contents into 1 well of a 6-well plate and 80% of vial contents into a second well of a 6-well plate Refer to cell line user protocols for further guidance at www.EBiSC.org		
Additional Comments	Typical recovery after thaw, typical growth to confluency		
Associated Publications	PubMed ID: N/A		

Please see www.EBiSC.org for further information on Quality Control 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
	qPCR for Mycoplasma	Not Detected	Pass
	Virology (HBV, HCV, HIV1, HIV2, HTLV1 & HTLV2)	Not Detected	Pass
Cell Line Identity	Short Tandem Repeat analysis using PCR	N/A	Allele data recorded and available upon request. Profile match to donor fibroblast
Viability	Visual Assessment	Growth to confluence post-thaw	Acceptable

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Test	Assay	Acceptance Criteria	Result
Phenotype	Continuous visual assessment of iPSC colony morphology	Recorded	Typical iPSC colonies with low differentiation levels
Phenotype	Flow Cytometry	SSEA-4 > 70% TRA-1-60 > 70% SSEA-1 < 10% POU5F1 > 70%	Pluripotency markers within specification except for SSEA-1 (11.35%)
Differentiation Potential	Directed differentiation and qPCR for trilineage markers	Up-regulation of germ layer markers	Endoderm : Detected Mesoderm : Detected Ectoderm : Detected
Karyotype	G-Banding	Normal karyotype	Diploid female karyotype 46, XX
Clearance of Reprogramming Factors	qPCR for Sendai backbone	Not detected	Not detected

The following guidance can be found in the Instructions for Use

Intended use	Expiry Date
Product Format	Recommended storage conditions
Volume	Hazardous Information

Approved CoA

Signature



Date

19 Sep 2019