

Certificate of Analysis (CoA) for induced Pluripotent Stem Cells

This product is for research only

ECACC Catalogue No: 66541171

| | | | |
|------------------------------|--|--------------------------------|-----------------------|
| Cell Line Name | CHDIi016-A | Batch Number | M001 |
| Donor ID | MTM#16 | | |
| 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 12 | Cell number / vial | 1.9 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% | Pass |
| 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 *Jane Ebery* Date 19 Sep 2019