

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

*This product is for research only*

ECACC Catalogue No: 66540048

|                              |  |                                |                       |
|------------------------------|--|--------------------------------|-----------------------|
| Cell Line Name               | RCi001-B   | Batch Number                   | P001                  |
| Donor ID                     | EM3  |                                |                       |
| Disease Association          | Familial Erythromelalgia   | Phenotype of Donor             | Affected              |
| Tissue of Origin             | Blood PBMCs  | Sex                            | Male                  |
| Reprogramming Method         | Non-integrating Sendai virus (POU5F1, SOX2, KLF4, C-MYC)   |                                |                       |
| Passage Number               | Passage 14   | Cell number / vial             | 2.0 x 10 <sup>6</sup> |
| Culture Matrix               | Geltrex/Matrigel   | Culture Medium                 | mTeSR-1               |
| O <sub>2</sub> Concentration | 20%  | CO <sub>2</sub> Concentration  | 5%                    |
| Passaging Method             | EDTA   | Additional Culture Information | N/A                   |
| Cryopreservation Medium      | 40% FBS* / 50% medium / 10% DMSO<br>*Serum of Zone 1 origin  |                                |                       |
| Recommendation for thawing   | Recommended thaw into 2 wells of a 6-well plate or per 10cm <sup>2</sup><br>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  |                                |                       |
| Associated Publications      | N/A  |                                |                       |

Please see [www.EBiSC.org](http://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  |
|---------------------------|--|--------------------------------|---|
| <b>Sterility</b>          | Inoculation for microbiological growth                 | Not Detected                   | Pass  |
|                           | qPCR for Mycoplasma                                    | Not Detected                   | Pass  |
|                           | Virology (HBV, HCV, HIV1, HIV2)                        | Not Detected                   | Pass  |
| <b>Cell Line Identity</b> | Short Tandem Repeat analysis using PCR                 | 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                       | Emergence of iPSC colonies with medium differentiation levels   |

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| Test                             | Assay  | Acceptance Criteria                                  | Result  |
|----------------------------------|--|--|---|
|                                  | Flow Cytometry   | SSEA-4 > 70% +<br>TRA-1-60 > 70% +<br>SSEA-1 < 10% + | Pass  |
| <b>Differentiation Potential</b> | Spontaneous EB differentiation and QPCR for trilineage markers | Up-regulation of germ layer markers                  | Endoderm : Detected<br>Mesoderm : Detected<br>Ectoderm : Detected |

Additional cell line characteristics have been determined by original reprogramming centres and have not been independently verified by EBiSC. Historical cell line data displayed here is accurate according to data provided by depositors on 29-JAN-16

| Test                                      | Assay                           | Result   |
|---|---------------------------------|--|
| <b>Phenotype</b>                          | Flow Cytometry                  | Positive Expression of Tra-1-60, POU5F1, SSEA-4, low expression of SSEA-1                            |
| <b>Karyotype</b>                          | G-Banding                       | Acceptable. Modal karyotype in 14 cells showed normal male chromosome complement and banding pattern |
|   | BoBs                            | No autosomal or sex chromosome aneuploidies detected   |
| <b>Clearance of Reprogramming Factors</b> | qPCR for Sendai Virus Clearance | Detected   |

| The following guidance can be found in the Instructions for Use |                                       |
|---|---------------------------------------|
| <b>Intended use</b>   | <b>Expiry Date</b>                    |
| <b>Product Format</b>   | <b>Recommended storage conditions</b> |
| <b>Volume</b>   | <b>Hazardous Information</b>          |

Approved CoA

Signature

Date

01 Apr 2016



In case of queries, please contact [culturecollections.technical@phe.gov.uk](mailto:culturecollections.technical@phe.gov.uk). European Collection of Authenticated Cell Cultures (ECACC), Culture Collections, Public Health England, Tel: +44 (0) 1980 612684