Certificate of Analysis (CoA) for induced Pluripotent Stem Cells



This product is for research only

ECACC Catalogue No: 66540021

| Cell Line Name | UNEWi019-A Alternative name: UNEW019Ai | Batch Number | P001 |
|------------------------------|--|-----------------------------------|---------------------|
| Donor ID | F12/437 | | |
| Disease Association | Aplastic anaemia | Phenotype of Donor | Affected |
| Tissue of Origin | Fibroblast | Sex | Male |
| Reprogramming Method | Non-integrating Sendai Virus (POU5F1, SOX2, KLF and MYC) | | |
| Passage Number | Passage 29 | Cell number / vial | 1-2x10 ⁶ |
| Culture Matrix | Matrigel/Geltrex | Culture Medium | mTeSR-1 |
| O ₂ Concentration | 20% | CO ₂ Concentration | 5% |
| Passaging Method | EDTA | Additional Culture Information | N/A |
| Cryopreservation Medium | Cryostor | | |
| Recommendation for thawing | Recommended thaw into 2 wells of a 6-well plate or per 10cm ² | | |
| | 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 |
|--------------------|--|--------------------------------|--|
| | Inoculation for microbiological growth | Not Detected | Pass |
| Sterility | qPCR for Mycoplasma | Not Detected | Pass |
| | Virology (HBV, HCV, HIV1, HIV2) | Not Detected | Pass |
| Cell Line Identity | Short Tandem Repeat analysis using PCR | N/A | Allele data recorded and available upon request. Gender match to donor |
| Viability | Visual Assessment | Growth to confluence post-thaw | Acceptable |
| Phenotype | Continuous visual assessment of iPSC colony morphology | Recorded | Typical iPSC morphology with low level of differentiation |



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

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| Test | Assay | Acceptance Criteria | Result |
|------------------------------|--|--|---|
| Phenotype | Flow Cytometry | SSEA-4 > 70% + TRA-1-60 > 70% + SSEA-1 < 10% + POU5F1 > 70% + | Pass |
| Differentiation Potential | Spontaneous EB differentiation and qPCR for trilineage markers | Up-regulation of germ layer markers | Endoderm : Detected Mesoderm : Detected 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 15-OCT-2016

| Test | Assay | Result |
|---------------------------------------|--|--|
| | PCR for mycoplasma | Not Detected |
| Sterility | Visual assessment for microbiological growth | Not Detected |
| Identity | CytoSNP Analysis | Parental fibroblasts and clones are identical |
| Phenotype | Flow cytometry | Positive for markers TRA-1-60, SSEA4, NANOG, low expression of SSEA1 |
| Differentiation Potential | Teratoma generation Immunohistochemistry | Formed all germ lineages |
| Karyotype | Cytosnp | No clinically significant imbalance was detected |
| Clearance of Reprogramming Factors | RT-PCR Sendai Virus | Clearance of Sendai virus |

| 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





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