

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

*This product is for research only*

ECACC Catalogue No: 66540268

|                               |  |                                |                                 |
|-------------------------------|--|--------------------------------|---------------------------------|
| Cell Line Name                | BIONI010-C-2   | Batch Number                   | M001                            |
| Donor ID                      | CC-2511  |                                |                                 |
| Tissue of Origin              | Dermal fibroblast  | Phenotype of Donor             | Unaffected control              |
| Cell Line Disease Association | Alzheimer's disease  | Sex                            | Male                            |
| Gene Editing Method           | CRISPR/Cas-9   | Gene Editing Target            | ApoE<br>chr19:44905754-44909393 |
| Type of Modification          | Isogenic Modification  | Parental Line                  | BIONI010-C                      |
| Details of Gene Edit          | ApoE 112 modified from C/T to T/T  |                                |                                 |
| Reprogramming Method          | Non-integrating episomal (POU5F1, SOX2, KLF4, MYC, Lin28 and shP53)  |                                |                                 |
| Passage Number                | Passage 39   | Cell number / vial             | 1.2 x 10 <sup>6</sup>           |
| Culture Matrix                | Geltrex/Matrigel   | Culture Medium                 | E8 Flex                         |
| O <sub>2</sub> Concentration  | 18%  | 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 confluence   |                                |                                 |
| 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.<br>Match to donor |

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| Test                             | Assay  | Acceptance Criteria  | Result  |
|----------------------------------|--|--|---|
| <b>Viability</b>                 | Visual Assessment  | Growth to confluence post-thaw   | Acceptable  |
| <b>Phenotype</b>                 | Continuous visual assessment of iPSC colony morphology         | Recorded   | Typical iPSC colonies with low differentiation levels                 |
|                                  | Flow Cytometry   | SSEA-4 > 70% +<br>TRA-1-60 > 70% +<br>SSEA-1 < 10% +<br>POU5F1 > 70% + | Pass  |
| <b>Differentiation Potential</b> | Spontaneous EB differentiation and qPCR for trilineage markers | Up-regulation of germ layer markers                                    | Endoderm : Not 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 21-FEB-2017

| Test                                     | Assay                                | Result   |
|--|--------------------------------------|--|
| <b>Karyotype</b>                         | G-Banding                            | 46,XY  |
| <b>Clearance of Gene Editing Plasmid</b> | PCR for CRISPR plasmid               | Not Detected   |
| <b>Genotyping</b>                        | Sequencing of target locus           | ApoE 112 C/T modified to T/T   |
| <b>Differentiation Potential</b>         | Directed differentiation to endoderm | Upregulation of CXCR4, FoxA2, GATA6, GSC, PITX1 and SOX17 detected by qPCR |

| 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

23 feb 2017