

## Thaw and Culture Details

| Cell Line Name                      | HVRDi001-A  |  |  |  |  |  |  |
|-------------------------------------|---|--|--|--|--|--|--|
| WiCell Lot Number                   | WB66391   |  |  |  |  |  |  |
| Provider                            | Brigham & Women's Hospital – Dr. Tracy Young-Pearse   |  |  |  |  |  |  |
| Banked By                           | Brigham & Women's Hospital – Dr. Tracy Young-Pearse   |  |  |  |  |  |  |
| Thaw and Culture<br>Recommendations | WiCell recommends thawing 1 vial into 1 well of a 6 well plate. WiCell recommends thawing using ROCK Inhibitor for best results.  |  |  |  |  |  |  |
| Culture Platform                    | Feeder Dependent  |  |  |  |  |  |  |
|                                     | Medium: Stem Cell Culture Medium  |  |  |  |  |  |  |
|                                     | Matrix: MEF   |  |  |  |  |  |  |
| Protocol                            | WiCell Feeder Dependent Protocol  |  |  |  |  |  |  |
| Passage Number                      | p29<br>These cells were cultured for 28 passages after colony picking. WiCell adds +1 to the passage<br>number to best represent the overall passage number of the cells at thaw.   |  |  |  |  |  |  |
| Date Vialed                         | 01-July-2017  |  |  |  |  |  |  |
| Vial Label                          | HVRDi001-A<br>p29<br>WB66391  |  |  |  |  |  |  |
| Biosafety and Use Information       | Appropriate biosafety precautions should be followed when working with these cells. The end user is responsible for ensuring that the cells are handled and stored in an appropriate manner. WiCell is not responsible for damages or injuries that may result from the use of these cells. Cells distributed by WiCell are intended for research purposes only and are not intended for use in humans. |  |  |  |  |  |  |

## **Testing Performed by WiCell**

| Test Description                  | Test Provider  | Test Method                             | Test Specification                         | Result |  |  |  |
|-----------------------------------|--|---|--|--------|--|--|--|
| Karyotype by G-banding            | WiCell   | SOP-CH-003                              | Expected karyotype                         | Pass   |  |  |  |
|                                   | Results: 46,XY,t(1;12)(q44;q22)[19]<br>Nonclonal findings: 47,XY,t(1;12)(q44;q22),+5<br>Interpretation: This is an abnormal karyotype. There is an apparently balanced<br>translocation between the long arms of chromosomes 1 and 12 in twenty of twenty<br>cells examined. No other clonal abnormalities were found.<br>There is also one nonclonal change seen in the abnormal clone, as described above.<br>This is not a recurrent acquired abnormality in human pluripotent stem cell cultures.<br>Nonclonal findings may result from technical artifact, but may be due to a<br>developing additional clonal abnormality or to low-level mosaicism. |   |  |        |  |  |  |
| Post-Thaw Viable Cell<br>Recovery | WiCell SOP-CH-305 ≥ 15 Undifferentiated Colonies,<br>≤ 30% Differentiation and<br>recoverable attachment after<br>passage  |   |  |        |  |  |  |
| Identity by STR                   | UW Translational<br>Research Initiatives in<br>Pathology Laboratory  | PowerPlex 16 HS<br>System by<br>Promega | Defines STR profile of deposited cell line | Pass   |  |  |  |
| Sterility                         | Steris   | ST/07                                   | Negative                                   | Pass   |  |  |  |
| Mycoplasma                        | WiCell   | SOP-QU-004                              | Negative                                   | Pass   |  |  |  |

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## **Testing Reported by Provider**

The Provider stated that some or all of the additional analyses listed below may have been performed for this cell line. For more information, publication and dbGaP links, where available, are provided on the cell line specific web page on the WiCell website.

- Expression of MAP2, Tau and TuJ1, markers of upper (Cux1) and lower (Tbr1) layer cortical neurons and synaptic markers synaptophysin (SYP), PSD95 and VGLUT1 by immunostaining
- Embryoid body formation and in vitro differentiation to ectodermal, mesodermal, and endodermal lineage

| Approval Date     | Quality Assurance Approval   |  |  |  |
|-------------------|--|--|--|--|
| 25-September-2017 | 9/28/2021<br>X HEB<br>HeB<br>Quality Assurance<br>Signed by: Bruner, Haley |  |  |  |

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The material provided under this certificate has been subjected to the tests specified and the results and data described herein are accurate based on WiCell's reasonable knowledge and belief. Appropriate Biosafety Level practices and universal precautions should always be used with this material. For clarity, the foregoing is governed solely by WiCell's Terms and Conditions of Service, which can be found at http://www.wicell.org/privacyandterms.



Date Reported: Monday, September 11, 2017 Cell Line: HVRDi001-A-WB66391 12770 Passage#: 31 Date of Sample: 8/27/2017 Specimen: Human IPS Results: 46,XY,t(1;12)(q44;q22)[19] Cell Line Gender: Male Reason for Testing: lot release testing

Investigator:

Nonclonal findings: 47,XY,t(1;12)(q44;q22),+5

Cell: 28 Slide: G01 Slide Type: Karyotype

Total Counted: 20 Total Analyzed: 8 Total Karyogrammed: 4 Band Resolution: 425 - 550

#### Interpretation:

Date:

This is an abnormal karyotype. There is an apparently balanced translocation between the long arms of chromosomes 1 and 12 in twenty of twenty cells examined. No other clonal abnormalities were found.

There is also one nonclonal change seen in the abnormal clone, as described above. This is not a recurrent acquired abnormality in human pluripotent stem cell cultures. Nonclonal findings may result from technical artifact, but may be due to a developing additional clonal abnormality or to low-level mosaicism.

Completed by: Reviewed and Interpreted by:

A signed copy of this report is available upon request.

By:\_\_\_\_ Sent To:

QC Review By:

Limitations: This assay allows for microscopic visualization of numerical and structural chromosome abnormalities. The size of structural abnormality that can be detected is >3-10Mb, dependent upon the G-band resolution obtained from this specimen. For the purposes of this report, band level is defined as the number of G-bands per haploid genome. It is documented here as "band level", i.e., the range of bands determined from the four karyograms in this assay. Detection of heterogeneity of clonal cell populations in this specimen (i.e., mosaicism) is limited by the number of metaphase cells examined, documented here as "# of cells counted".

This assay was conducted solely for listed investigator/institution. The results may not be relied upon by any other party without the prior written consent of the Director of the WiCell Cytogenetics Laboratory. The results of this assay are for research use only. If the results of this assay are to be used for any other purpose, contact the Director of the WiCell Cytogenetics Laboratory.

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Short Tandem Repeat Analysis

Department of Pathology and Laboratory Medicine TRIP Laboratory (Molecular) http://www.pathology.wisc.edu/research/trip

Sample Report: 12770-STR Sample Name on Tube: 12770-STR 45.7 ng/μL, (A260/280=2.15) Sample Type: Cells Cell Count: ~2 million cells **Requestor:** WiCell Research Institute Quality Department WiCell<sup>®</sup> info@wicell.org (888) 204-1782

Sample Date: N/A Receive Date: 09/05/17 Assay Date: 09/12/17 File Name: 170913 STR WMR Report Date: 09/15/17

| STR Locus  | STR Genotype Repeat #   | STR Genotype                          |
|------------|---|---------------------------------------|
| FGA        | 16–18,18.2,19,19.2,20,20.2,21,21.2,22, 22.2, 23, 23.2, 24, 24.2, 25, 25.2, 26–30, 31.2, 43.2, 44.2,45.2, 46.2 | Identifying information has           |
| TPOX       | 6-13  | been redacted to                      |
| D8S1179    | 7-18  | protect donor                         |
| vWA        | 10-22   | confidentiality. If                   |
| Amelogenin | X,Y   | more information                      |
| Penta_D    | 2.2, 3.2, 5, 7-17   | is required,                          |
| CSF1PO     | 6-15  | please, contact<br>WiCell's Technical |
| D16S539    | 5, 8-15   | Support.                              |
| D7S820     | 6-14  |                                       |
| D13S317    | 7-15  |                                       |
| D5S818     | 7-16  |                                       |
| Penta_E    | 5-24  |                                       |
| D18S51     | 8-10, 10.2, 11-13, 13.2, 14-27  |                                       |
| D21S11     | 24,24.2,25,25.2,26-28,28.2,29,29.2, 30, 30.2,31, 31.2,32,32.2,33,33.2, 34,34.2,35,35.2,36-38                  |                                       |
| TH01       | 4-9,9.3,10-11,13.3  |                                       |
| D3S1358    | 12-20   |                                       |

<u>Results:</u> Based on the 12770-STR cells submitted by WiCell QA dated and received on 09/05/17, this sample (Label on Tube: 12770-STR) defines the STR profile of the human stem cell line HVRDi001-A comprising 28 allelic polymorphisms across the 15 STR loci analyzed.

<u>Interpretation:</u> No STR polymorphisms other than those corresponding to the human HVRDi001-A stem cell line were detected and the concentration of DNA required to achieve an acceptable STR genotype (signal/ noise) was equivalent to that required for the standard procedure (~1 ng/amplification reaction) from human genomic DNA. This result suggests that the 12770-STR sample submitted corresponds to the HVRDi001-A stem cell line and was not contaminated with any other human stem cells or a significant amount of mouse feeder layer cells.

<u>Sensitivity</u>: Sensitivity limits for detection of STR polymorphisms unique to either this or other human stem cell lines is ~2-5%.

| X RMB Digitally Signed on 09/15/17 | X WMR | Digitally Signed on         | 09/15/17 |
|------------------------------------|-------|-----------------------------|----------|
|                                    |       | , PhD, Director / Co-Direct | tor      |

TRIP Laboratory, Molecular

, PhD, Director / Co-Director UWHC Molecular Diagnostics Laboratory / UWSMPH TRIP Laboratory

Testing was accomplished by analysis of human genetic polymorphisms at STR loci. This methodology has not yet been approved by the FDA and is for investigational use only. Acknowledge TRIP in your publications, posters & presentations. For details, see: http://www.pathology.wisc.edu/research/trip/acknowledging TRIP agrees to maintain the confidentiality of any information provided to it in connection with its performance of this STR analysis on the same conditions as set forth in paragraph 2 of WiCell's Terms and Conditions of Service (http://www.wicell.org/media.acux/1a429b84-2b54-44a4-8ad8-5c05db93dd8a).

# Native Product Sterility Report



| WiCell<br>504 S Rosa Rd, Rm 101<br>Madison, WI 53719                      |   | SAMPLE #:<br>DATE RECEIVED:<br>TEST INITIATED:<br>TEST COMPLETED: | 17071725<br>27-Jul-17<br>31-Jul-17<br>14-Aug-17 |
|---|---|---|---|
| SAMPLE NAME / DESCRIPTION:<br>UNIQUE IDENTIFIER:<br>PRODUCT REGISTRATION: | HVRDi001-A-WB66391 12659<br>JHU024i-WB66445 12660<br>WA09-WB66444 12661<br>WA09-WB66446 12662<br>UCSD005i-43-1-WB62267 12663<br>UCSD008i-44-1-WB66286 12664<br>UCSD036i-4-5-WB65173 12665<br>UCSD233i-SAD-2-DB26810 12666<br>UCSD235i-SAD2-4-DB26816 12667<br>iPS(IMR90)-2-WB66447 12668<br>NA<br>Human iPS cells |   |   |

| TEST RESULTS: | # Tested | # Positives<br>(Growth) | - Control   |  |  |
|---------------|----------|-------------------------|-------------|--|--|
|               | 10       | 0                       | 2 Negatives |  |  |

**TEST SUMMARY:** 

| # Samples | Media Type | Volume (mL) | Incubation<br>Temperature<br>(° C) | Incubation<br>Duration<br>(Days) |
|-----------|------------|-------------|------------------------------------|----------------------------------|
| 10        | TSB        | 40          | 20-25                              | 14                               |
| 10        | FTG        | 40          | 30 - 35                            | 14                               |

### **REFERENCE:**

METHOD VALIDATION / PD #: TEST METHODOLOGY: Processed according to LAB-003: Sterility Test Procedure 000053 USP - Direct Transfer

COMMENTS: NA REVIEWED BY

DATESAUGO

Specific test results may not be indicative of the characteristics of any other samples from the same lot or similar lots. This test report shall not be reproduced, except in full, without prior written approval. Liability is limited to the costs of the tests.



## Mycoplasma Detection Assay Report Testing Performed by WiCell

Testing Performed by WiCell Lot Release Testing July 12, 2017 FORM SOP-QU-004.01 Version F Edition 02 Reported by: KR Reviewed by: DF 12Jul17 BD Monolight 180

|   |                          | Read | ding A A Reading B |       | В     | Ratio |       |       |          |                             |
|---|--------------------------|------|--------------------|-------|-------|-------|-------|-------|----------|-----------------------------|
| # | Sample Name              | RLU1 | RLU2               | Ave   | RLU1  | RLU2  | Ave   | B/A   | Result   | <b>Comments/Suggestions</b> |
| 1 | HVRDi001-A-WB66391 12606 | 311  | 320                | 315.5 | 142   | 147   | 144.5 | 0.46  | Negative |                             |
| 2 | Positive (+) Control     | 349  | 363                | 356   | 31431 | 31358 | 31395 | 88.19 | Positive |                             |
| 3 | Negative (-) Control     | 543  | 529                | 536   | 53    | 54    | 53.5  | 0.10  | Negative |                             |

