



## Thaw and Culture Details

|                                  |                                                                                                                                                                                                                                                                                                                                                                                                            |
|----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Cell Line Name                   | LUEL5748i-2                                                                                                                                                                                                                                                                                                                                                                                                |
| WiCell Lot Number                | WB66878                                                                                                                                                                                                                                                                                                                                                                                                    |
| Provider                         | Luebeck University, Dr. Christine Klein                                                                                                                                                                                                                                                                                                                                                                    |
| Banked By                        | WiCell                                                                                                                                                                                                                                                                                                                                                                                                     |
| Thaw and Culture Recommendations | WiCell recommends thawing 1 vial into 3 wells of a 6 well plate.                                                                                                                                                                                                                                                                                                                                           |
| Culture Platform                 | Feeder Independent                                                                                                                                                                                                                                                                                                                                                                                         |
|                                  | Medium: mTeSR™1                                                                                                                                                                                                                                                                                                                                                                                            |
|                                  | Matrix: Matrigel®                                                                                                                                                                                                                                                                                                                                                                                          |
| Protocol                         | WiCell Feeder Independent mTeSR™1 Protocol                                                                                                                                                                                                                                                                                                                                                                 |
| Passage Number                   | p26<br>These cells were cultured for 25 passages prior to freeze and post colony picking. WiCell adds +1 to the passage number at freeze to best represent what the overall passage number of the cells at thaw. Plated cells at thaw should be labeled passage 26.                                                                                                                                        |
| Date Vialied                     | 05-August-2018                                                                                                                                                                                                                                                                                                                                                                                             |
| Vial Label                       | LUEL5748i-2<br>p26<br>WB66878                                                                                                                                                                                                                                                                                                                                                                              |
| 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.<br>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                                                                                | See Report |
| Post-Thaw Viable Cell Recovery | WiCell                                                        | SOP-CH-305                        | ≥ 15 Undifferentiated Colonies,<br>≤ 30% Differentiation and recoverable attachment after passage | Pass       |
| Identity by STR                | UW Translational Research Initiatives in Pathology Laboratory | PowerPlex 16 HS System by Promega | Defines profile                                                                                   | Pass       |
| Sterility                      | Steris                                                        | ST/07                             | Negative                                                                                          | Pass       |
| Mycoplasma                     | WiCell                                                        | SOP-QU-004                        | Negative                                                                                          | Pass       |

## Testing Reported by Provider

The provider has provided the following testing and results for this cell line. If available, a link to the relevant publication is provided on the cell line specific web page on the WiCell website.

| Test Description            | Result   | Report               |
|-----------------------------|----------|----------------------|
| HIV, HBV, and HCV Screening | Negative | Report not available |



| Approval Date   | Quality Assurance Approval                                                                                          |
|-----------------|---------------------------------------------------------------------------------------------------------------------|
| 11-October-2018 | <div>10/11/2018</div> <div>X JKG</div> <div>JKG</div> <div>Quality Assurance</div> <div>Signed by: Gaj, Jenna</div> |



## Chromosome Analysis Report: 073295

**Date Reported:** Wednesday, September 26, 2018

**Cell Line Sex:** Male

**Cell Line:** LUEL5748i-2-WB66878 13989

**Reason for Testing:** Lot Release Testing

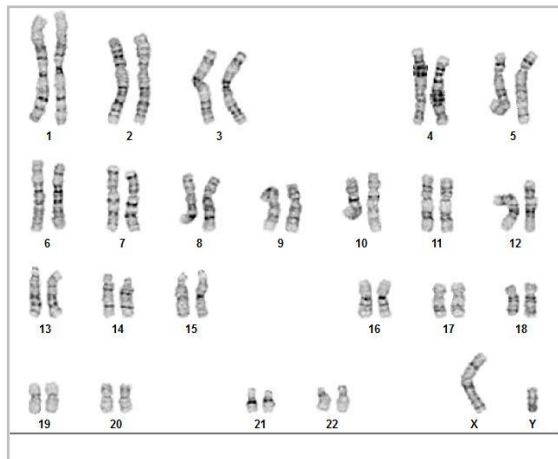
**Passage#:** 26

**Date of Sample:** 9/18/2018

**Investigator:** [REDACTED], WiCell

**Specimen:** Human IPS

**Results:** 46,XY



**Cell:** 43

**Slide:** G03

**Slide Type:** Karyotype

**Total Counted:** 20

**Total Analyzed:** 8

**Total Karyogrammed:** 4

**Band Resolution:** 450 - 500

### Interpretation:

**This is a normal karyotype; no clonal abnormalities were detected at the stated band level of resolution.**

**Completed by:** [REDACTED], CG(ASCP)

**Reviewed and Interpreted by:** [REDACTED], PhD, FACMG

**Date:** \_\_\_\_\_ **Sent 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 of this assay are for research use only. Unless otherwise mutually agreed in writing, the services provided to you hereunder by WiCell Research Institute, Inc. ("WiCell") are governed solely by WiCell's Terms and Conditions of Service, found at [www.wicell.org/privacyandterms](http://www.wicell.org/privacyandterms). Any terms you may attach to a purchase order or other document that are inconsistent, add to, or conflict with WiCell's Terms and Conditions of Service are null and void and of no legal force or effect.*



HISTOLOGY - IHC - MOLECULAR - IMAGING

Department of Pathology and Laboratory Medicine

TRIP Laboratory (Molecular)

<http://www.pathology.wisc.edu/research/trip>

# Short Tandem Repeat Analysis



WiCell®

[info@wicell.org](mailto:info@wicell.org)

(888) 204-1782

## Sample Report:

13989-STR

Sample Name on Tube: 13989-STR

138.4 ng/μL, (A260/280=1.89)

Sample Type: Cells

Cell Count: ~2 million cells

## Requestor:

WiCell Research Institute

Quality Department

Sample Date: N/A

Receive Date: 09/24/18

Assay Date: 09/25/18

File Name: STR 180926 wmr

Report Date: 10/01/18

| 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 been redacted to protect donor confidentiality. If more information is required, please, contact <a href="#">WiCell's Technical Support</a> . |
| TPOX       | 6-13                                                                                                          |                                                                                                                                                                           |
| D8S1179    | 7-18                                                                                                          |                                                                                                                                                                           |
| vWA        | 10-22                                                                                                         |                                                                                                                                                                           |
| Amelogenin | X,Y                                                                                                           |                                                                                                                                                                           |
| Penta_D    | 2.2, 3.2, 5, 7-17                                                                                             |                                                                                                                                                                           |
| CSF1PO     | 6-15                                                                                                          |                                                                                                                                                                           |
| D16S539    | 5, 8-15                                                                                                       |                                                                                                                                                                           |
| 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                                                                                                         |                                                                                                                                                                           |

**Results:** Based on the 13989-STR cells submitted by WiCell QA dated and received on 09/24/18, this sample (Label on Tube: 13989-STR) defines the STR profile of the human stem cell line LUEL5748i-2 comprising 26 allelic polymorphisms across the 15 STR loci analyzed.

**Interpretation:** No STR polymorphisms other than those corresponding to the human LUEL5748i-2 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 13989-STR sample submitted corresponds to the LUEL5748i-2 stem cell line and was not contaminated with any other human stem cells or a significant amount of mouse feeder layer cells.

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

X<sub>RMB</sub>

Digitally Signed on 10/01/18

\_\_\_\_\_, BA  
TRIP Laboratory, Molecular

X<sub>WMR</sub>

Digitally Signed on 10/01/18

\_\_\_\_\_, 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  
504 S Rosa Rd, Rm 101  
Madison, WI 53719

SAMPLE #: 18081822  
DATE RECEIVED: 23-Aug-18  
TEST INITIATED: 29-Aug-18  
TEST COMPLETED: 12-Sep-18

SAMPLE NAME / DESCRIPTION: UCSD027i-9-2 WB57332 13953  
WA07 CY66889 13954  
LUEL7159i-16 WB66875 13955  
UCSD028i-9-3 WB66873 13956  
CREM003i-BU3C2 WB66874 13957  
CREM018i-SS24-1 WB66883 13958  
LUEL5748i-2 WB66878 13959  
WC036i-0498-1 WB66882 13960  
WC036i-0498-1 WB66884 13961  
CREM024i-SS36-1 WB66886 13962  
LUEL8360i-2 WB66888 13963  
LUEL7991i-1 WB66891 13964  
LUEL5748i-3 WB66894 13965  
LUEL7153i-1 WB66895 13966  
LUEL7673i-2 WB66898 13967  
LUEL7149i-1 WB66899 13968  
CREM029i-SS44-1 DB48061 13969  
CREM030i-SS45-1 DB48064 13970  
JHU012i-2 DB36196 13971  
JHU017i DB36203 13972

UNIQUE IDENTIFIER: NA  
PRODUCT REGISTRATION: Other: Human iPS cells

## TEST RESULTS:

| # Tested | # Positives<br>(Growth) | - Control   |
|----------|-------------------------|-------------|
| 20       | 0                       | 2 Negatives |

## TEST SUMMARY:

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

REFERENCE: Processed according to LAB-003: Sterility Test Procedure  
METHOD VALIDATION / PD #: 000053

# Native Product Sterility Report



TEST METHODOLOGY: USP - Direct Transfer

COMMENTS: NA

REVIEWED BY

A handwritten signature in blue ink, appearing to read "G. Malinski", written over a horizontal line.

DATE

17SEP18

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

Lot Release Testing

September 20, 2018

FORM SOP-QU-004.01

Version G Edition 02

Reported by: AP

Reviewed by: JB

BD Monolight 180

| # | Sample Name               | Reading A |      | A<br>Ave | Reading B |       | B<br>Ave | Ratio<br>B/A | Result   | Comments/Suggestions |
|---|---------------------------|-----------|------|----------|-----------|-------|----------|--------------|----------|----------------------|
|   |                           | RLU1      | RLU2 |          | RLU1      | RLU2  |          |              |          |                      |
| 1 | LUEL5748i-2-WB66878 13989 | 225       | 226  | 225.5    | 108       | 110   | 109      | 0.48         | Negative |                      |
| 2 | Positive (+) Control      | 343       | 347  | 345      | 46171     | 46330 | 46251    | 134.06       | Positive |                      |
| 3 | Negative (-) Control      | 701       | 711  | 706      | 93        | 89    | 91       | 0.13         | Negative |                      |

