

Product Information

| | |
|-------------------------------|--|
| Product Name | iPS DF6-9-9T.B |
| Alias | iPS-DF6-9-9T |
| Lot Number | DF6-9-9T.B-MCB-01 |
| Depositor | University of Wisconsin – Laboratory of Dr. James Thomson |
| Banked by | WiCell |
| Thaw Recommendation | Thaw 1 vial into 1 well of a 6 well plate |
| Culture Platform | Feeder Independent |
| | Medium: mTeSR1 |
| | Matrix: Matrigel |
| Protocol | WiCell Feeder Independent Protocol |
| Passage Number | p23 These cells were cultured for 22 passages prior to freeze. WiCell adds +1 to the passage number at freeze so that the number on the vial best represents the overall passage number of the cells at thaw. |
| Date Viald | 03-June-2009 |
| Vial Label | DF6-9-9T.B P23 JY EDTA 03 JUNE 2009 SOPCC038A |
| 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 |
|------------------------------------|-------------------------------------|---------------------------------|--|--------|
| Post-Thaw Viable Cell Recovery | WiCell | SOP-CH-305 | ≥ 15 Undifferentiated Colonies, ≤ 30% Differentiation | Pass |
| Identity by STR | UW Molecular Diagnostics Laboratory | PowerPlex 1.2 System by Promega | Consistent with known profile | Pass |
| Sterility - Direct transfer method | Apptec | 30744 | Negative | Pass |
| Mycoplasma | Bionique | M250 | No contamination detected | Pass |
| Karyotype by G-banding | WiCell | SOP-CH-003 | Normal karyotype | Pass |

Amendment(s):

| Reason for Amendment | Date |
|---|---------------|
| CoA updated to include copyright information. | See signature |
| CoA updated for format changes, including adding fields of thaw recommendation, vial label, protocol, and banked by. | 01-JUL-2013 |
| CoA updated for clarification of test specifications, lot number, and product description, and removed text regarding technical services and iPS cells | 05-OCT-2010 |
| CoA updated for format changes, clarification of test specifications, test method, addition of test provider, culture platform, and electronic signature, and reference to WiCell instead of the NSCB | 20-AUG-2010 |
| Original CoA | 02-NOV-2009 |

| Date of Lot Release | Quality Assurance Approval |
|---------------------|--|
| 02-November-2009 | <p style="text-align: right;">12/31/2013</p> <p>X AMC _____ AMC Quality Assurance Signed by [REDACTED]</p> |

Short Tandem Repeat Analysis*

Sample Report: 5611-STR

UW HLA#: 61565

Sample Date: 08/25/09

Received Date: 08/25/09

Requestor: WiCell Research Institute

Test Date: 09/04/09

File Name: 090905

Report Date: 09/14/09

Sample Name: (label on tube) 5611-STR

Description: DNA Extracted by WiCell

331.6 ug/mL; 260/280 = 1.93

| Locus | Repeat # | STR Genotype |
|------------|-----------|---|
| D16S539 | 5, 8-15 | Identifying information has been redacted to protect donor confidentiality. If more information is required, please, contact WiCell's Technical Support . |
| D7S820 | 6-14 | |
| D13S317 | 7-15 | |
| D5S818 | 7-15 | |
| CSF1PO | 6-15 | |
| TPOX | 6-13 | |
| Amelogenin | NA | |
| TH01 | 5-11 | |
| vWA | 11, 13-21 | |

Comments: Based on the DNA 5611-STR dated and received on 08/25/09 from WI Cell, this sample (UW HLA# 61565) matches exactly the STR profile of the human stem cell line iPS FORESKIN comprising 15 allelic polymorphisms across the 8 STR loci analyzed. No STR polymorphisms other than those corresponding to the human iPS FORESKIN 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. These results suggest that the 5611-STR DNA sample submitted corresponds to the iPS FORESKIN stem cell line and it was not contaminated with any other human stem cells or a significant amount of mouse feeder layer cells. Sensitivity limits for detection of STR polymorphisms unique to either this or other human stem cell lines is ~5%.

11

9-20-09

09/14/09

Manager Date
HLA/Molecular Diagnostics Laboratory

PhD, Director Date
HLA/Molecular Diagnostics Laboratory

* Testing to assess engraftment following bone marrow transplantation 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.

Test Facility:

This report is confidential. No part may be used for advertising or public announcement without written permission. Results apply only to the sample(s) tested.



Report Number
815300
Page 3 of 7

WiCell Research Institute

August 27, 2009
P.O. #:

STERILITY TEST REPORT

Sample Information: hES Cells
2: DF6-9-9T.B WISC #1152

Date Received: August 04, 2009
Date in Test: August 05, 2009
Date Completed: August 19, 2009

Test Information: Test Codes: 30744, 30744A
Immersion, USP / 21 CFR 610.12
Procedure #: BS210WCR.201

| TEST PARAMETERS | PRODUCT | |
|---------------------------|----------------|----------------|
| Approximate Volume Tested | 0.5 mL | 0.5 mL |
| Number Tested | 2 | 2 |
| Type of Media | SCD | FTM |
| Media Volume | 400 mL | 400 mL |
| Incubation Period | 14 Days | 14 Days |
| Incubation Temperature | 20 °C to 25 °C | 30 °C to 35 °C |
| RESULTS | 2 NEGATIVE | 2 NEGATIVE |

Page 1 Signed

QA Reviewer

Date

Page 1 Signed

Technical Reviewer

Date

Testing conducted in accordance with current Good Manufacturing Practices.





APPENDIX I

Document #: DCF3008A
 Edition #: 06
 Effective date: 9/17/2003
 Title: DNA FLUOROCHROME ASSAY RESULTS

DNA-FLUOROCHROME ASSAY RESULTS
 Procedures 3008, 3009, 3011

Sample ID # 58170 M-250 Date Rec'd: 07/29/2009 P.O. # RP2890

Indicator Cells Inoculated: Date/Initials: 7/30/09 / HS

Fixation: Date/Initials: 8/3/09 / JA

Staining: Date/Initials: 8/3/09 / JA

TEST/CONTROL ARTICLE:

DF6-9-9T.B-A

LOT# #5611

Wicell OA

DNA FLUOROCHROME ASSAY RESULTS:

X **NEGATIVE:** A reaction with staining limited to the nuclear region, which indicates no mycoplasmal contamination.

 POSITIVE: A significant amount of extranuclear staining which strongly suggests mycoplasmal contamination.

 INCONCLUSIVE:
 A significant amount of extranuclear staining consistent with low - level mycoplasmal contamination or nuclear degeneration.

 A significant amount of extranuclear staining consistent with bacterial, fungal or other microbial contaminant or viral CPE. Morphology not consistent for mycoplasmal contamination.

COMMENTS:

Date: 8/3/09 Results Read by: JA Date of Review: 8-3-09 Reviewed by: SAH



Document#: DCF3013D
 Edition#: 10
 Effective Date: 07/15/2003
 Title: **M-250 FINAL REPORT SHEET**

M-250 FINAL REPORT

Direct Specimen Culture
 Procedure 3008, 3011, 3013

TO: **Wicell OA**

BTL SAMPLE ID#: **58170** P.O.#: DATE REC'D: **07/29/2009**

TEST/CONTROL ARTICLE:

DF6-9-9T.B-A

LOT#: **#5611**

DIRECT CULTURE SET-UP (DAY 0)
 INDICATOR CELL LINE (VERO)

DATE: **07/29/2009**

SEE DNA FLUOROCHROME RECORD SHEET

| | | DATE |
|-----------------------------|------------|--------------------------|
| THIOGLYCOLLATE BROTH | DAY 7 + ⊖ | <u>08/05/2009</u> |
| | DAY 28 + ⊖ | <u>08/26/2009</u> |
| BROTH-FORTIFIED COMMERCIAL | | |
| <u>0.5</u> mL SAMPLE | DAY 7 + ⊖ | <u>08/05/2009</u> |
| <u>6.0</u> mL BROTH | DAY 28 + ⊖ | <u>08/26/2009</u> |
| BROTH-MODIFIED HAYFLICK | | |
| <u>0.5</u> mL SAMPLE | DAY 7 + ⊖ | <u>08/05/2009</u> |
| <u>6.0</u> mL BROTH | DAY 28 + ⊖ | <u>08/26/2009</u> |
| BROTH-HEART INFUSION | | |
| <u>0.5</u> mL SAMPLE | DAY 7 + ⊖ | <u>08/05/2009</u> |
| <u>6.0</u> mL BROTH | DAY 28 + ⊖ | <u>08/26/2009</u> |

(See Reverse)

Document#: DCF3013D
 Edition#: 10
 Effective Date: 07/15/2003
 Title: M-250 FINAL REPORT SHEET

| SAMPLE ID#: | 58170 | AEROBIC | MICROAEROPHILIC | DATE |
|-------------------------------------|--------|-------------------------|-----------------|-------------------|
| AGAR PLATES-FORTIFIED COMMERCIAL | DAY 7 | + ⊖ | + ⊖ | <u>08/05/2009</u> |
| | DAY 14 | + ⊖ | + ⊖ | <u>08/12/2009</u> |
| | DAY 21 | + ⊖ | + ⊖ | <u>08/19/2009</u> |
| AGAR PLATES-MODIFIED HAYFLICK | DAY 7 | + ⊖ | + ⊖ | <u>08/05/2009</u> |
| | DAY 14 | + ⊖ | + ⊖ | <u>08/12/2009</u> |
| | DAY 21 | + ⊖ | + ⊖ | <u>08/19/2009</u> |
| AGAR PLATES-HEART INFUSION | DAY 7 | + ⊖ | + ⊖ | <u>08/05/2009</u> |
| | DAY 14 | + ⊖ | + ⊖ | <u>08/12/2009</u> |
| | DAY 21 | + ⊖ | + ⊖ | <u>08/19/2009</u> |
| <u>BROTH SUBCULTURES (DAY 7)</u> | | DATE: <u>08/05/2009</u> | | |
| AGAR PLATES-FORTIFIED COMMERCIAL | DAY 7 | + ⊖ | + ⊖ | <u>08/12/2009</u> |
| | DAY 14 | + ⊖ | + ⊖ | <u>08/19/2009</u> |
| | DAY 21 | + ⊖ | + ⊖ | <u>08/26/2009</u> |
| AGAR PLATES-MODIFIED HAYFLICK | DAY 7 | + ⊖ | + ⊖ | <u>08/12/2009</u> |
| | DAY 14 | + ⊖ | + ⊖ | <u>08/19/2009</u> |
| | DAY 21 | + ⊖ | + ⊖ | <u>08/26/2009</u> |
| AGAR PLATES-HEART INFUSION | DAY 7 | + ⊖ | + ⊖ | <u>08/12/2009</u> |
| | DAY 14 | + ⊖ | + ⊖ | <u>08/19/2009</u> |
| | DAY 21 | + ⊖ | + ⊖ | <u>08/26/2009</u> |

RESULTS: No detectable mycoplasmal contamination

8/26/09
 Date

Laboratory Director
 Ph.D.

M-250 Procedural Summary: The objective of this test is to ascertain whether or not detectable mycoplasmas are present in an *in vitro* cell culture sample, be it a primary culture, hybridoma, master seed stock or cell line. This procedure combines an indirect DNA staining approach to detect non-cultivable mycoplasmas with a direct culture methodology utilizing three different mycoplasmal media formulations. The indirect approach involves the inoculation of the sample into a mycoplasma-free VERO (ATCC) indicator cell line and performing a DNA fluorochrome assay after 72-120 hours of incubation. The direct culture aspect of the test utilizes three different mycoplasmal media including both broth and agar formulations. The sample is inoculated into each of the 3 broth formulations and also onto duplicate plates (0.1 mL/plate) for each of the 3 agar formulations. Subculture from broth to fresh agar plates is carried out after 7 days incubation. Agar plates are incubated aerobically and microaerophilically in order to detect any colony forming units morphologically indicative of mycoplasmal contamination. Issuance of the final report with signature of the Laboratory Director signifies that the required controls were performed concurrently with the test sample(s) as detailed in the referenced SOPs and that all test conditions have been found to meet the required acceptance criteria for a valid test, including the appropriate results for the positive and negative controls.

Report Date: July 22, 2009

Case Details:

Cell Line: DF6-9-9T.B (5611)

Passage #: 25

Date Completed: 7/22/2009

Cell Line Gender: male

Investigator: WiCell Stem Cell Bank

Specimen: iPSC on Matrigel

Date of Sample: 7/17/2009

Tests, Reason for: MCB Testing

Results: 46,XY

Completed by CLSp(CG), on 7/22/2009

Reviewed and interpreted by PhD, FACMG, on 7/22/2009

Interpretation: No abnormalities were detected at the stated band level of resolution.



Cell: S01-03

Slide: C

Slide Type: Karyotyping

Cell Results: Karyotype: 46,XY

of Cells Counted: 20

of Cells Karyotyped: 4

of Cells Analyzed: 8

Band Level: 425-550

Results Transmitted by Fax / Email / Post

Sent By: _____

QC Review By: _____

Date: _____

Sent To: _____

Results Recorded: _____