# *Certificate of Analysis - Amended*

| | | |
|---|---|---|
| Product Description | iPS IMR90-1 | |
| Cell Line Provider | University of Wisconsin – Laboratory of Dr. James Thomson | |
| Lot Number | iPS(IMR90)-1-MCB-01 | |
| Date Vialed | 01-July-2008 | |
| Passage Number | p33 | |
| Culture Platform | Feeder Independent | |
| | Media: mTeSR™1 | Matrix: Matrigel® |

The following testing specifications have been met for the specified product lot:

| 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 | Apptec | 30055 | No contamination detected | Pass |
| Karyotype by G-banding | WiCell | SOP-CH-003 | Normal karyotype | Pass |

[1] These cells were cultured for 32 passages post reprogramming, at least 5 of them in mTeSR™1/Matrigel®. WiCell adds +1 to the passage number to best represent the overall passage number of cells at thaw. Fibroblasts were reprogrammed at p18.

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.

| Date of Lot Release | Quality Assurance Approval |
|---|---|
| 10-September-2008 | 3/12/2018<br>X HEB<br>HEB<br>Quality Assurance<br>Signed by: Bruner, Haley |

UW Health

University of Wisconsin
Hospital and Clinics

**Histocompatibility/Molecular Diagnostics Laboratory**

# Short Tandem Repeat Analysis*

**Sample Report: WiCell 4825** UW HLA#: 59289 Sample Date: 08/11/08
iPS(IMR90)-1-MCB-1 clone1 Received Date: 08/11/08

Requestor: WiCell Research Institute

Test Date: 08/11/08 File Name: 080812 Report Date: 08/20/08

**Sample Name:** (label on tube) **DNA 194**
**4825-STR**

**Description:** DNA Extracted by WiCell

252.35ug/mL; 260/280 > 1.9

| 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 194 4825 STR submitted dated and received on 08/11/08 from WiCell, this sample (UW HLA# 59289) matches exactly the STR profile of the human stem cell line iPS(IMR90) comprising 16 allelic polymorphisms across the 8 STR loci analyzed. No STR polymorphisms other than those corresponding to the human iPS(IMR90) 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 WiCell 4825 DNA sample submitted corresponds to the iPS(IMR90) 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%. A preliminary copy of this report was issued via electronic mail to the WI Cell Research Institute on Friday, August 22, 2008.**

HLA/Molecular Diagnostics Laboratory

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.

File: Final STR Report

WuXi AppTec



WiCell Research Institute

August 11, 2008
P.O. #:

# STERILITY TEST REPORT

**Sample Information:** 2: iPS(IMR90)-1-MCB-1 Lot 1, iPS cells

**Date Received:** July 23, 2008
**Date in Test:** July 25, 2008
**Date Completed:** August 08, 2008

**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 |

**QA Reviewed:** Page 1 Signed

**Reviewed:** Page 1 Signed

*Testing conducted in accordance with current Good Manufacturing Practices.*

Mycoplasma Testing Services

Safe Cells

MYCOPLASMA TESTING SERVICES

BIONIQUE TESTING LABORATORIES, INC

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 # **54002** **M-250** Date Rec'd: **08/05/2008** P.O. #

Indicator Cells Inoculated: Date/Initials: 8/7/08 / JA

Fixation: Date/Initials: 8/11/08 / JA

Staining: Date/Initials: 8/11/08 / JA

TEST/CONTROL ARTICLE:

**IPS(IMR90) 1-MCB-1**

LOT# **NA**

**Wicell QA**
**WiCell Research Institute**

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**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: 8/11/08 Results Read by: JA Date of Review: 8/11/08 Reviewed by: SSA

# WiCell Cytogenetics Report: 000718-090308

**Report Date:** September 10, 2008

## Case Details:

***Cell Line:*** *iPS(IMR90)-1-MCB-1 (2982-KAR)*

***Passage #:*** *18+35(8)*

***Date Completed:*** *9/9/2008*

***Cell Line Gender:*** *Female*

***Investigator:*** *MW*

***Specimen:*** *iPS cells on Matrigel*

***Date of Sample:*** *9/3/2008*

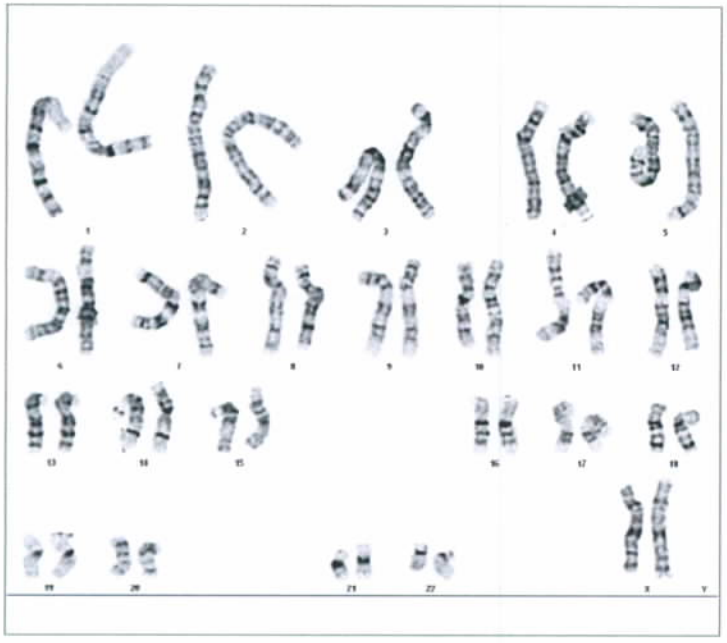
***Tests,Reason for:*** *Lot release*

***Results:*** *46,XX*

*Completed by ST , CLSp(CG), on 9/9/2008*

*Reviewed and interpreted by KDM, PhD, FACMG, on 9/9/2008*

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



***Cell:*** *S01-01*

***Slide:*** *A*

***Slide Type:*** *Karyotyping*

***Cell Results:*** *Karyotype: 46,XX*

***# of Cells Counted:*** *40*

***# of Cells Karyotyped:*** *4*

***# of Cells Analyzed:*** *8*

***Band Level:*** *500-550*

**Results Transmitted by Fax / Email / Post** **Date:**_____

**Sent By:**_____ **Sent To:**_____