



## Product Information and Testing - Amended

### Product Information

Product Name	iPS(IMR90)-1
Alias	iPS(IMR90) clone (#1)
Lot Number	iPS(IMR90)-1-DL-01
Parent Material	iPS(IMR90)-1-MCB-01
Depositor	University of Wisconsin – Laboratory of Dr. James Thomson
Banked by	WiCell
Thaw Recommendation	Thaw 1 vial into 2 wells of a 6 well plate
Culture Platform	Feeder Independent
	Medium: mTeSR™1
	Matrix: Matrigel®
Protocol	WiCell Feeder Independent Protocol
Passage Number	p39 These cells were cultured for 38 passages post reprogramming, at least 11 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 cultured for 18 passages prior to post reprogramming.
Date Viald	01-July-2008
Vial Label	iPS(IMR90)-1-DL-1 P18+39(12) DF 07 AUG 2008 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

Date of Lot Release	Quality Assurance Approval
17-November-2008	<div>2/26/2018</div> <div>X HEB</div> <div>HEB Quality Assurance Signed by: Bruner, Haley</div>

## Short Tandem Repeat Analysis\*

Sample Report: 0872-STR

UW HLA#: 59559

Sample Date: 09/23/08

iPS(IMR90)-1-BL-1

Received Date: 09/23/08

Requestor: WiCell Research Institute

Test Date: 09/29/08

File Name: 080930

Report Date: 10/02/08

Sample Name: (label on tube) 0872-STR

Description: DNA Extracted by WiCell  
205 ug/mL; 260/280 = 1.91

Locus	Repeat #	STR Genotype
D16S539	5, 8-15	Identifying information has been redacted to protect donor confidentiality. If more information is required, please, contact <a href="#">WiCell's Technical Support</a> .
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 0872-STR DNA dated and received on 09/23/08 from WiCell, this sample (UW HLA# 59559) 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 0872-STR 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, October 3, 2008.

HLA/Molecular Diagnostics Laboratory

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.

Report Number

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WiCell Research Institute

September 15, 2008

P.O. #:

**STERILITY TEST REPORT**

**Sample Information:** hES Cells  
1: iPs (IMR90)-1-DL-1

**Date Received:** August 26, 2008  
**Date in Test:** August 28, 2008  
**Date Completed:** September 11, 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



## APPENDIX IV

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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 QA  
Wicell Research Institute

19 FAX#:

BT SAMPLE ID#: 54778

P.O.#:

DATE REC'D: 10/02/2008

TEST/CONTROL ARTICLE:

IPS(IMR90) 1DL1 p18 + 46 (19)

LOT#: NA

DIRECT CULTURE SET-UP (DAY 0)

DATE: 10/02/2008

INDICATOR CELL LINE (VERO)

SEE DNA FLUOROCHROME RECORD SHEET

			DATE
THIOGLYCOLLATE BROTH	DAY 7	+ ⊖	10/09/2008
	DAY 28	+ ⊖	10/30/2008
BROTH-FORTIFIED COMMERCIAL			
0.5 mL SAMPLE	DAY 7	+ ⊖	10/09/2008
6.0 mL BROTH	DAY 28	+ ⊖	10/30/2008
BROTH-MODIFIED HAYFLICK			
0.5 mL SAMPLE	DAY 7	+ ⊖	10/09/2008
6.0 mL BROTH	DAY 28	+ ⊖	10/30/2008
BROTH-HEART INFUSION			
0.5 mL SAMPLE	DAY 7	+ ⊖	10/09/2008
6.0 mL BROTH	DAY 28	+ ⊖	10/30/2008

(See Reverse)



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

SAMPLE ID#:	54778	AEROBIC	MICROAEROPHILIC	DATE
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+	⊖	10/09/2008
	DAY 14	+	⊖	10/16/2008
	DAY 21	+	⊖	10/23/2008
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+	⊖	10/09/2008
	DAY 14	+	⊖	10/16/2008
	DAY 21	+	⊖	10/23/2008
AGAR PLATES-HEART INFUSION	DAY 7	+	⊖	10/09/2008
	DAY 14	+	⊖	10/16/2008
	DAY 21	+	⊖	10/23/2008
BROTH SUBCULTURES (DAY 7)		DATE: 10/09/2008		
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+	⊖	10/16/2008
	DAY 14	+	⊖	10/23/2008
	DAY 21	+	⊖	10/30/2008
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+	⊖	10/16/2008
	DAY 14	+	⊖	10/23/2008
	DAY 21	+	⊖	10/30/2008
AGAR PLATES-HEART INFUSION	DAY 7	+	⊖	10/16/2008
	DAY 14	+	⊖	10/23/2008
	DAY 21	+	⊖	10/30/2008

RESULTS: No detectable mycoplasmal contamination

10/30/08  
 Date

Laboratory Director

A

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 Scientific Director/Study 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:** August 20, 2010

### Case Details:

**Cell Line:** IMR90-1-DL-1 (7145)

**Passage #:** 18+42(15)

**Date Completed:** 9/11/2008

**Cell Line Gender:** Female

**Investigator:** WiCell Stem Cell Bank

**Specimen:** iPSC on Matrigel

**Date of Sample:** 9/5/2008

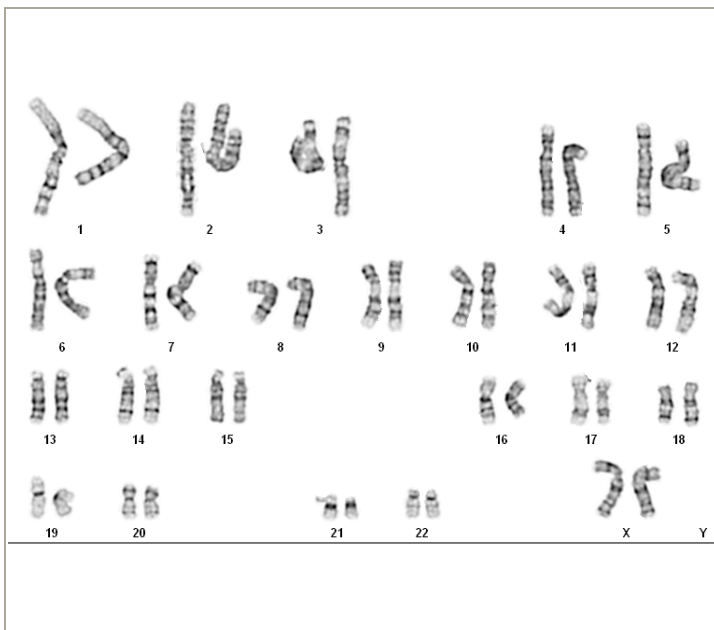
**Tests, Reason for:** WiCell Bank Testing

**Results:** 46,XX

Completed by KL, CLSp(CG), on 9/11/2008

Reviewed and interpreted by KDM, PhD, FACMG, on 9/11/2008

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



**Cell:** S01-02

**Slide:** A

**Slide Type:** Karyotyping

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

**# of Cells Counted:** 20

**# of Cells Karyotyped:** 4

**# of Cells Analyzed:** 8

**Band Level:** 400-500

**Results Transmitted by Fax / Email / Post**  
**Sent By:** \_\_\_\_\_

**Date:** \_\_\_\_\_  
**Sent To:** \_\_\_\_\_