



Product Information and Testing - Amended

Product Information

Product Name	iPS(IMR90)-4
Alias	iPS(IMR90) clone (#4)
Lot Number	iPS(IMR90)-4-DL-01
Parent Material	iPS(IMR90)-4-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: mTeSR1
	Matrix: Matrigel
Protocol	WiCell Feeder Independent Protocol
Passage Number	p18+34(9) These cells were cultured for 51 passages prior to freeze. Fibroblasts were cultured 18 passages prior to reprogramming, and 33 passages post transformation, at least 9 of them in mTeSR1/Matrigel. 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 Vialied	29-August-2008
Vial Label	iPS(IMR90)-4-DL-1 p18+34(9) MW 29 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

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, and incorporation of footnotes into the tables.	01-JUL-2013
CoA updated to remove technical services and iPS cells text, for clarification of test specifications, product description, and passage number	05-OCT-2010
CoA footnote 1 updated	16-SEPT-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	26-AUG-2010
Original CoA	16-MAR-2009



Product Information and Testing - Amended

Date of Lot Release	Quality Assurance Approval
16-March-2009	<div>12/31/2013</div> <div>X AMC</div> <div>AMC</div> <div>Quality Assurance</div> <div>Signed by [REDACTED]</div>

Short Tandem Repeat Analysis*

Sample Report: 6488-STR

UW HLA#: 59724

Sample Date: 10/21/08

iPS(IMR90)-4-DL-1

Received Date: 10/21/08

Requestor: WiCell Research Institute

Test Date: 10/23/08

File Name: 081024

Report Date: 10/29/08

Sample Name: (label on tube) 6488-STR

Description: DNA Extracted by WiCell
253 ug/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 6488-STR DNA dated and received on 10/21/08 from WiCell, this sample (UW HLA# 59724) 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 6488-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%. These results were communicated via phone to the Cytogenetics laboratory of the WiCell Research Institute on Monday, October 27, 2008. A preliminary copy of this report was issued via electronic mail to the WI Cell Research Institute on Friday, October 31, 2008.

Date

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.

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.

WuXi AppTec

Report Number
788629
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WiCell Research Institute

October 07, 2008
P.O. #: RP2149

STERILITY TEST REPORT

Sample Information: hES Cells / iPS Cells
4: iPS(IMR90)-4-DL-1

Date Received: September 17, 2008
Date in Test: September 22, 2008
Date Completed: October 06, 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.



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 # 54938 M-250 Date Rec'd: 10/14/2008 P.O. #

Indicator Cells Inoculated: Date/Initials: 10/16/08 / JA

Fixation: Date/Initials: 10/20/08 / JA

Staining: Date/Initials: 10/20/08 / JA

TEST/CONTROL ARTICLE:

IPS(IMR90)4DC1

LOT# NA

Wicell QA

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: 10/20/08 Results Read by: JA Date of Review: 10/20/08 Reviewed by: SCH



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

BTL SAMPLE ID#: **54938** P.O.#: DATE REC'D: **10/14/2008**

TEST/CONTROL ARTICLE:

IPS (IMR90) 4DC1

LOT#: **NA**

DIRECT CULTURE SET-UP (DAY 0)

DATE: **10/15/2008**

INDICATOR CELL LINE (VERO)

SEE DNA FLUOROCHROME RECORD SHEET

			DATE
THIOGLYCOLLATE BROTH	DAY 7	+ ⊖	<u>10/22/2008</u>
	DAY 28	+ ⊖	<u>11/12/2008</u>
BROTH-FORTIFIED COMMERCIAL			
<u>0.5</u> mL SAMPLE	DAY 7	+ ⊖	<u>10/22/2008</u>
<u>6.0</u> mL BROTH	DAY 28	+ ⊖	<u>11/12/2008</u>
BROTH-MODIFIED HAYFLICK			
<u>0.5</u> mL SAMPLE	DAY 7	+ ⊖	<u>10/22/2008</u>
<u>6.0</u> mL BROTH	DAY 28	+ ⊖	<u>11/12/2008</u>
BROTH-HEART INFUSION			
<u>0.5</u> mL SAMPLE	DAY 7	+ ⊖	<u>10/22/2008</u>
<u>6.0</u> mL BROTH	DAY 28	+ ⊖	<u>11/12/2008</u>

(See Reverse)

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

SAMPLE ID#:	54938	AEROBIC	MICROAEROPHILIC	DATE
AGAR PLATES-FORTIFIED	DAY 7	+	⊖	10/22/2008
COMMERCIAL	DAY 14	+	⊖	10/29/2008
	DAY 21	+	⊖	11/05/2008
AGAR PLATES-MODIFIED	DAY 7	+	⊖	10/22/2008
HAYFLICK	DAY 14	+	⊖	10/29/2008
	DAY 21	+	⊖	11/05/2008
AGAR PLATES-HEART	DAY 7	+	⊖	10/22/2008
INFUSION	DAY 14	+	⊖	10/29/2008
	DAY 21	+	⊖	11/05/2008
BROTH SUBCULTURES (DAY 7)		DATE: 10/22/2008		
AGAR PLATES-FORTIFIED	DAY 7	+	⊖	10/29/2008
COMMERCIAL	DAY 14	+	⊖	11/05/2008
	DAY 21	+	⊖	11/12/2008
AGAR PLATES-MODIFIED	DAY 7	+	⊖	10/29/2008
HAYFLICK	DAY 14	+	⊖	11/05/2008
	DAY 21	+	⊖	11/12/2008
AGAR PLATES-HEART	DAY 7	+	⊖	10/29/2008
INFUSION	DAY 14	+	⊖	11/05/2008
	DAY 21	+	⊖	11/12/2008

RESULTS: No detectable mycoplasmal contamination

11/12/08
 Date

Laboratory Director

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: October 15, 2008

Case Details:

Cell Line: iPS(IMR90)4-DL-1 (6488)

Passage #: 18+37(12)

Date Completed: 10/15/2008

Cell Line Gender: Female

Investigator: WiCell Stem Cell Bank

Specimen: hESC on Matrigel

Date of Sample: 10/13/2008

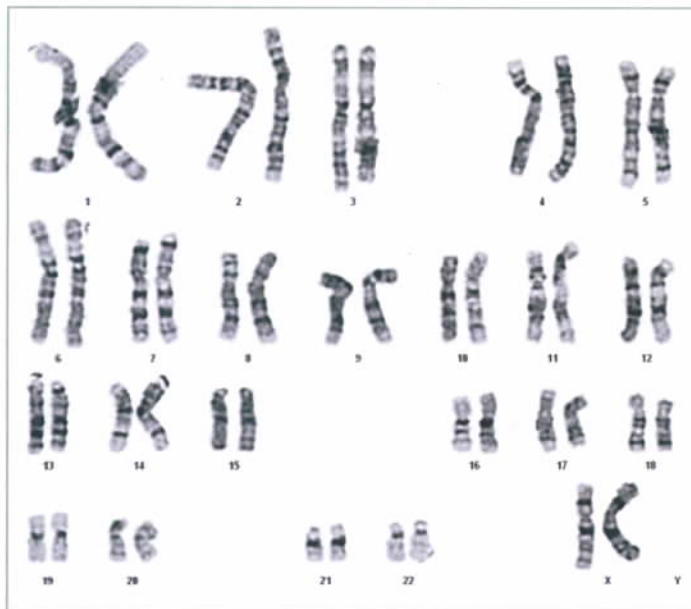
Tests, Reason for: WISC Banking

Results: 46,XX

Completed by: CLSp(CG), on 10/15/2008

Reviewed and interpreted by: PhD, FACMG, on 10/15/2008

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



Cell: S01-04

Slide: B

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: _____