Product Information and Testing - Amended

Product Information

Product Name	iPS(Foreskin)-1
Alias	iPS(foreskin) clone (#1)
Lot Number	iPS(Foreskin)1-DL-01
Parent Material	iPS(Foreskin)1-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	p32(17) These cells were cultured for 31 passages prior to freeze, 17 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 Vialed	22-August-2008
Vial Label	iPS(FORESKIN)-1-DL-1 p32(17) MW 22 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 the tables.	28-Jun-2013
CoA updated for clarification of test specifications 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	19-Aug-2010
Original CoA	17-Nov-2008

Product Information and Testing - Amended

Date of Lot Release	Quality Assurance Approval
17-November-2008	12/31/2013 X AMC AMC Quality Assurance Signed by: [redacted]

UW Health
University of Wisconsin
Hospital and Clinics

Histocompatibility/Molecular Diagnostics Laboratory

Short Tandem Repeat Analysis*

Sample Report: 4070-STR
iPS(Foreskin)-1-DL-1

UW HLA#: 59720

Sample Date: 10/21/08
Received Date: 10/21/08

Requestor: WiCell Research Institute

Test Date: 10/23/08

File Name: 081024

Report Date: 10/28/08

Sample Name: 4070-STR

Description: DNA Extracted by WiCell 260 ug/mL; 260/280 = 2.02

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 4070-STR dated and received on 10/21/08, this sample (UW HLA# 59720) 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 4070-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%. 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.

* 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:

WuXi AppTec

WiCell Research Institute

September 15, 2008
P.O. #:

STERILITY TEST REPORT

Sample Information: hES Cells

1: iPs (IMR90)-1-DL-1
2: ES02-DL-2
3: iPs (Foreskin)-1-DL-1
4: WA14-DL-2
5: ES06-DL-3
6: TE04-FTDL-1
7: WA13.C-DL-2
8: iPS(IMR90)-4-MCB-1
9: BG01-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

QA Reviewed: _____ **Reviewed:** _____

Testing conducted in accordance with current Good Manufacturing Practices.

Test Facility:

WuXi AppTec

WiCell Research Institute

September 15, 2008
P.O. #:

STERILITY TEST REPORT

Sample Information: hES Cells
3: iPs (Foreskin)-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

Testing conducted in accordance with current Good Manufacturing Practices.

Mycoplasma Testing Services

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 # **54817** **M-250** Date Rec'd: **10/07/2008** P.O. #

Indicator Cells Inoculated: Date/Initials: 10/9/08 / BMS

Fixation: Date/Initials: 10/13/08 / KG

Staining: Date/Initials: 10/13/08 / KG

TEST/CONTROL ARTICLE:

IPS (Foreskin) 1DL1 p34 (19)

LOT# **NA**

Wicell QA
WiCell Research Institute

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: 10/13/08 Results Read by: KG Date of Review: 10/13/08 Reviewed by: SM

Mycoplasma Testing Services

Safe Cells

BIONIQUE TESTING LABORATORIES, INC.

APPENDIX IV

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

116

PHONE#:

BTL SAMPLE ID#: **54817** P.O.#: DATE REC'D: **10/07/2008**

TEST/CONTROL ARTICLE:

IPS (Foreskin) 1DL1 p34 (19)

LOT#: **NA**

DIRECT CULTURE SET-UP (DAY 0) DATE: **10/08/2008**

INDICATOR CELL LINE (VERO) SEE DNA FLUOROCHROME RECORD SHEET

			DATE
THIOGLYCOLLATE BROTH	DAY 7	+ ⊖	10/15/2008
	DAY 28	+ ⊖	11/05/2008
BROTH-FORTIFIED COMMERCIAL 0.5 mL SAMPLE	DAY 7	+ ⊖	10/15/2008
6.0 mL BROTH	DAY 28	+ ⊖	11/05/2008
BROTH-MODIFIED HAYFLICK 0.5 mL SAMPLE	DAY 7	+ ⊖	10/15/2008
6.0 mL BROTH	DAY 28	+ ⊖	11/05/2008
BROTH-HEART INFUSION 0.5 mL SAMPLE	DAY 7	+ ⊖	10/15/2008
6.0 mL BROTH	DAY 28	+ ⊖	11/05/2008

(See Reverse)

APPENDIX IV

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

SAMPLE ID#: **54817**		AEROBIC	MICROAEROPHILIC	DATE
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ ⊖	+ ⊖	10/15/2008
	DAY 14	+ ⊖	+ ⊖	10/22/2008
	DAY 21	+ ⊖	+ ⊖	10/29/2008
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ ⊖	+ ⊖	10/15/2008
	DAY 14	+ ⊖	+ ⊖	10/22/2008
	DAY 21	+ ⊖	+ ⊖	10/29/2008
AGAR PLATES-HEART INFUSION	DAY 7	+ ⊖	+ ⊖	10/15/2008
	DAY 14	+ ⊖	+ ⊖	10/22/2008
	DAY 21	+ ⊖	+ ⊖	10/29/2008
BROTH SUBCULTURES (DAY 7)		DATE: 10/15/2008		
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ ⊖	+ ⊖	10/22/2008
	DAY 14	+ ⊖	+ ⊖	10/29/2008
	DAY 21	+ ⊖	+ ⊖	11/05/2008
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ ⊖	+ ⊖	10/22/2008
	DAY 14	+ ⊖	+ ⊖	10/29/2008
	DAY 21	+ ⊖	+ ⊖	11/05/2008
AGAR PLATES-HEART INFUSION	DAY 7	+ ⊖	+ ⊖	10/22/2008
	DAY 14	+ ⊖	+ ⊖	10/29/2008
	DAY 21	+ ⊖	+ ⊖	11/05/2008

RESULTS: No detectable mycoplasmal contamination

11/5/08
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 microaerophillically 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.

WiCell Cytogenetics Report: 000749-100608
WISC 4070

Report Date: August 19, 2010

Case Details:

Cell Line: *iPS(Foreskin)-1-DL-1 (WISC#4070)*

Passage #: *34(19)*

Date Completed: *10/9/2008*

Cell Line Gender: *Male*

Investigator: *WiCell Stem Cell Bank*

Specimen: *hESC on Matrigel*

Date of Sample: *10/6/2008*

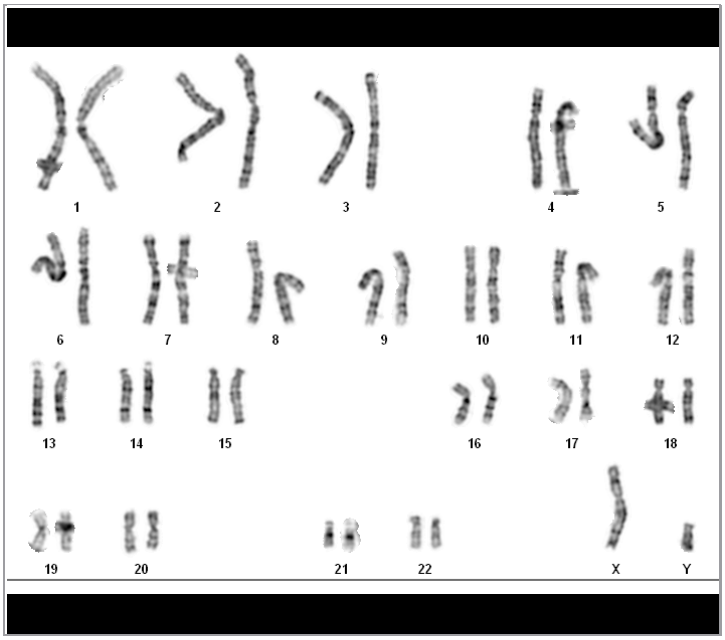
Tests,Reason for: *WISC Bank- iPS cell Dist. Lot Testing*

Results: *46,XY*

Completed by KL, CLSp(CG), on 10/9/2008

Reviewed and interpreted by KDM, PhD, FACMG, on 10/9/2008

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



Cell: *S01-03*

Slide: *A*

Slide Type: *Karyotyping*

Cell Results: *Karyotype: 46,XY*

# of Cells Counted: *20*

# of Cells Karyotyped: *4*

# of Cells Analyzed: *8*

Band Level: *450-550*

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

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