




Thaw and Culture Details

Cell Line Name	SA02
WiCell Lot Number	SA02-FTDL-01
Provider	Cellartis
Banked By	WiCell
Thaw and Culture Recommendations	WiCell recommends thawing 1 vial into 1 well of a 6 well plate.
Culture Platform	Feeder Dependent
	Medium: hESC Medium (KOSR)
	Matrix: MEF
Protocol	WiCell Feeder Dependent Protocol
Passage Number	p27 These cells were cultured for 26 passages prior to freeze . WiCell adds +1 to the passage number to best represent the overall passage number of the cells at thaw.
Date Viald	31-March-2009
Vial Label	SA02-FTDL-1 p27 MW 31 MAR 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
Karyotype by G-banding	WiCell	SOP-CH-003	Expected karyotype	Pass
	<i>Result from report: This is an abnormal karyotype, with trisomy 13 as the only clonal aberration detected. Trisomy 13 was found in all cells examined. The finding of trisomy 13 in this culture is consistent with previous reports of inherent trisomy 13 in this cell line.</i>			
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

Approval Date	Quality Assurance Approval
27-August-2009	<div style="text-align: right;">8/9/2017</div>  <small>AMK Quality Assurance Signed by: Klade, Anjelica</small>

Report Date: June 10, 2009

Case Details:

Cell Line: SA02-FTDL-1 (8909)

Passage #: 31

Date Completed: 6/9/2009

Cell Line Gender: female

Investigator: National Stem Cell Bank

Specimen: hESC on MEF feeder

Date of Sample: 6/1/2009

Test, Reason for: FTDL Release Testing

Results: 47,XX,+13

Completed by _____, CLSp(CG), on 6/9/2009

Reviewed and interpreted by _____, PhD, FACMG, on 6/9/2009

Interpretation: This is an abnormal karyotype, with trisomy 13 as the only clonal aberration detected. Trisomy 13 was found in all cells examined. The finding of trisomy 13 in this culture is consistent with previous reports of inherent trisomy 13 in this cell line.



Cell: S01-01

Slide: B

Slide Type: Karyotyping

Cell Results: 47,XX,+13

of Cells Counted: 20

of Cells Karyotyped: 4

of Cells Analyzed: 8

Band Level: 450-550

Results Transmitted by Fax / Email / Post
Sent By: _____
QC Review By: _____

Date: _____
Sent To: _____
Results Recorded: _____

Short Tandem Repeat Analysis*

Sample Report: 8909-STR

UW HLA#: 61156

Sample Date: 06/18/09

Received Date: 06/18/09

Requestor: WiCell Research Institute

Test Date: 06/23/09

File Name: 090624

Report Date: 06/25/09

Amended Report: 07/24/09

Sample Name: (label on tube)

8909-STR

Description: DNA Extracted by WiCell

242.61 ug/mL; 260/280 = 1.87

Locus	Repeat #	STR Genotype
D16S539	5, 8-15	12,14
D7S820	6-14	10,12
D13S317	7-15	9,11,14
D5S818	7-15	12,12
CSF1PO	6-15	11,12
TPOX	6-13	8,9
Amelogenin	NA	X,X
TH01	5-11	9,9.3
vWA	11, 13-21	14,16

Comments: Based on the 8909-STR DNA submitted by WI Cell dated 06/18/09 and received on 06/18/09, this sample (UW HLA# 61156) matches the STR profile of the human stem cell line SA02 comprising 16 allelic polymorphisms across the 8 STR loci analyzed (Josephson, R. et al., BMC Biol. 2006 Aug 18;4:28). Consistent with published results on the human embryonic stem cell line SA02 (Josephson, R. et al., BMC Biol. 2006 Aug 18;4:28), the 7755-STR DNA sample displays the tri-allelic genotype (9,11,14) at the D13S317 loci with each allele having approximately equal amplification strengths. No STR polymorphisms other than those corresponding to the human SA02 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 8909-STR DNA sample submitted corresponds to the SA02 stem cell line and it does not appear to be 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%.

7-27-09

Manager Date

HLA/Molecular Diagnostics Laboratory

07/24/09

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.

STERILITY TEST REPORT

Sample Information: hES Cells
2: SA02-FTDL-1, #2974

Date Received: April 07, 2009
Date in Test: April 08, 2009
Date Completed: April 22, 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 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 OA

BTL SAMPLE ID#: 57734 P.O.#: DATE REC'D: 06/16/2009

TEST/CONTROL ARTICLE:
SA02-FTDL-01-H #8909

LOT#: NA

DIRECT CULTURE SET-UP (DAY 0) DATE: 06/17/2009

INDICATOR CELL LINE (VERO) SEE DNA FLUOROCHROME RECORD SHEET

			DATE
THIOGLYCOLLATE BROTH	DAY 7	+ ⊖	<u>06/24/2009</u>
	DAY 28	+ ⊖	<u>07/15/2009</u>
BROTH-FORTIFIED COMMERCIAL <u>0.5</u> mL SAMPLE	DAY 7	+ ⊖	<u>06/24/2009</u>
	DAY 28	+ ⊖	<u>07/15/2009</u>
BROTH-MODIFIED HAYFLICK <u>0.5</u> mL SAMPLE	DAY 7	+ ⊖	<u>06/24/2009</u>
	DAY 28	+ ⊖	<u>07/15/2009</u>
BROTH-HEART INFUSION <u>0.5</u> mL SAMPLE	DAY 7	+ ⊖	<u>06/24/2009</u>
	DAY 28	+ ⊖	<u>07/15/2009</u>
<u>6.0</u> mL BROTH	DAY 7	+ ⊖	<u>06/24/2009</u>
	DAY 28	+ ⊖	<u>07/15/2009</u>

(See Reverse)

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

SAMPLE ID#:	57734	AEROBIC	MICROAEROPHILIC	DATE
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ ⊖	+ ⊖	06/24/2009
	DAY 14	+ ⊖	+ ⊖	07/01/2009
	DAY 21	+ ⊖	+ ⊖	07/08/2009
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ ⊖	+ ⊖	06/24/2009
	DAY 14	+ ⊖	+ ⊖	07/01/2009
	DAY 21	+ ⊖	+ ⊖	07/08/2009
AGAR PLATES-HEART INFUSION	DAY 7	+ ⊖	+ ⊖	06/24/2009
	DAY 14	+ ⊖	+ ⊖	07/01/2009
	DAY 21	+ ⊖	+ ⊖	07/08/2009

BROTH SUBCULTURES (DAY 7)

DATE: 06/24/2009

AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ ⊖	+ ⊖	07/01/2009
	DAY 14	+ ⊖	+ ⊖	07/08/2009
	DAY 21	+ ⊖	+ ⊖	07/15/2009
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ ⊖	+ ⊖	07/01/2009
	DAY 14	+ ⊖	+ ⊖	07/08/2009
	DAY 21	+ ⊖	+ ⊖	07/15/2009
AGAR PLATES-HEART INFUSION	DAY 7	+ ⊖	+ ⊖	07/01/2009
	DAY 14	+ ⊖	+ ⊖	07/08/2009
	DAY 21	+ ⊖	+ ⊖	07/15/2009

RESULTS: No detectable mycoplasmal contamination

7.15.09

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 mycoplasma 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 mycoplasma 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 mycoplasma 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.



APPENDIX I

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

DNA-FLUROCHROME ASSAY RESULTS
Procedures 3008, 3009, 3011

Sample ID # 57734 M-250 Date Rec'd: 06/16/2009 P.O. # RP2752

Indicator Cells Inoculated: Date/Initials: 6/18/09 / NS

Fixation: Date/Initials: 6/22/09 / KG

Staining: Date/Initials: 6/22/09 / KG

TEST/CONTROL ARTICLE:

SA02-FTDL-01-H #8909

LOT# NA

Wicell QA
WiCell Research Institute

505 S. Rosa Rd., Suite 120
Madison, WI 53719

Phone: 608-441-8019

Fax #: 608-441-8028

DNA FLUROCHROME 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: 6/22/09 Results Read by: KG Date of Review: 6/22/09 Reviewed by: U