Certificate of Analysis - Amended

Product Description	WA09 Distribution Lot	
Cell Line Provider	WiCell Research Institute	
Parent Material	WA09-MCB-01	
Lot Number	WA09-DL-10	
Date Vialed	15-June-2009	
Passage Number	P25	
Culture Platform	Feeder Dependent - MEFs	
	Media: hES Medium	Matrix: MEFs

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	Positive Identity	Pass
Sterility - Direct transfer method	Apptec	30744	No contamination detected	Pass
Mycoplasma	Bionique	M250	No contamination detected	Pass
Karyotype by G-banding	WiCell	SOP-CH-003	Normal karyotype	Pass
Flow Cytometry for ESC Marker Expression	UW Flow Cytometry Laboratory	SOP-CH-101 SOP-CH-102 SOP-CH-103 SOP-CH-105	Report - no specification	See report

Distribution Lot cells are expanded from vials of Master Cell Bank (MCB) cells. MCB cells are thoroughly tested and known to be free of many viruses and pathogens. These cells have undergone extensive testing and are not known to harbor any human pathogens or adventious agents of murine, bovine, or porcine origin. Cells distributed by WiCell are intended for research purposes only and are not intended for use in humans.

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.

Please contact technical service via the website to request test methods and other assistance with your cells. The knowledgeable technical support staff can assist with cell culture concerns, training, and any other customer service concerns.

Amendment(s):

Reason for Amendment	Date
CoA updated to include copyright information and update logo.	See signature
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	17-AUG-10
Original CoA	12-NOV-2009

Date of Lot Release	Quality Assurance Approval
12-November-2009	1/3/2014 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: 1524-STR | UW HLA#: 61562 | Sample Date: 08/25/09, Received Date: 08/25/09

Requestor: WiCell Research Institute

Test Date: 09/04/09 | File Name: 090905 | Report Date: 09/11/09

Sample Name: (label on tube) **1524-STR**

Description: DNA Extracted by WiCell
201.26 ug/mL; 260/280 = 1.92

Locus	Repeat #	STR Genotype
D16S539	5, 8-15	12,13
D7S820	6-14	9,11
D13S317	7-15	9,9
D5S818	7-15	11,12
CSF1PO	6-15	11,11
TPOX	6-13	10,11
Amelogenin	NA	X,X
TH01	5-11	9.3,9.3
vWA	11, 13-21	17,17

Comments: Based on the DNA 1524-STR dated and received on 08/25/09 from WI Cell, this sample (UW HLA# 61562) matches exactly the STR profile of the human stem cell line H9 comprising 12 allelic polymorphisms across the 8 STR loci analyzed. No STR polymorphisms other than those corresponding to the human H9 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 1524-STR DNA sample submitted corresponds to the H9 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%.

Date
HLA/Molecular Diagnostics Laboratory

09/13/09
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

Test Facility:

WuXi AppTec

Report Number
817768
Page 1 of 1

WiCell Research Institute

September 23, 2009
P.O. #:

STERILITY TEST REPORT

Sample Information: hES Cells
1: WA09-DL-10 NSCB #1524
2: ES03-DL-3 NSCB # 9440

Date Received: September 03, 2009
Date in Test: September 04, 2009
Date Completed: September 18, 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	4	4
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	4 NEGATIVE	4 NEGATIVE

QA Reviewer

09-23-09
Date

Technical Reviewer

09-23-09
Date

Testing conducted in accordance with current Good Manufacturing Practices.

Mycoplasma Testing Services

Safe Cells

BIONTOUE 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

BTL SAMPLE ID#: **58233** P.O.#: DATE REC'D: **08/04/2009**

TEST/CONTROL ARTICLE:

WA09-DL-10 #1524

LOT#: **NA**

DIRECT CULTURE SET-UP (DAY 0) DATE: **08/05/2009**

INDICATOR CELL LINE (VERO) SEE DNA FLUOROCHROME RECORD SHEET

			DATE
THIOGLYCOLLATE BROTH	DAY 7	+	08/12/2009
	DAY 28	+	09/02/2009
BROTH-FORTIFIED COMMERCIAL			
0.5 mL SAMPLE	DAY 7	+	08/12/2009
6.0 mL BROTH	DAY 28	+	09/02/2009
BROTH-MODIFIED HAYFLICK			
0.5 mL SAMPLE	DAY 7	+	08/12/2009
6.0 mL BROTH	DAY 28	+	09/02/2009
BROTH-HEART INFUSION			
0.5 mL SAMPLE	DAY 7	+	08/12/2009
6.0 mL BROTH	DAY 28	+	09/02/2009

(See Reverse)

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

SAMPLE ID#: 58233		AEROBIC	MICROAEROPHILIC	DATE
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+	+	08/12/2009
	DAY 14	+	+	08/19/2009
	DAY 21	+	+	08/26/2009
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+	+	08/12/2009
	DAY 14	+	+	08/19/2009
	DAY 21	+	+	08/26/2009
AGAR PLATES-HEART INFUSION	DAY 7	+	+	08/12/2009
	DAY 14	+	+	08/19/2009
	DAY 21	+	+	08/26/2009
BROTH SUBCULTURES (DAY 7)		DATE: 08/12/2009		
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+	+	08/19/2009
	DAY 14	+	+	08/26/2009
	DAY 21	+	+	09/02/2009
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+	+	08/19/2009
	DAY 14	+	+	08/26/2009
	DAY 21	+	+	09/02/2009
AGAR PLATES-HEART INFUSION	DAY 7	+	+	08/19/2009
	DAY 14	+	+	08/26/2009
	DAY 21	+	+	09/02/2009

RESULTS: No detectable mycoplasmal contamination

9/2/09
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 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 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.

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 # **58233** **M-250** Date Rec'd: **08/04/2009** P.O. #

Indicator Cells Inoculated: Date/Initials: 8/6/09 / BNS

Fixation: Date/Initials: 8/10/09 / JA

Staining: Date/Initials: 8/10/09 / JA

TEST/CONTROL ARTICLE:

WA09-DL-10 #1524

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: 8/10/09 Results Read by: JA Date of Review: 8-10-09 Reviewed by: Self

WiCell Cytogenetics Report: 001237-072009
NSCB 1524

Report Date: July 28, 2009

Case Details:

Cell Line: *WA09-DL-10 (1524)*

Passage #: *27*

Date Completed: *7/28/2009*

Cell Line Gender: *female*

Investigator:

Specimen: *hESC on MEF feeder*

Date of Sample: *7/20/2009*

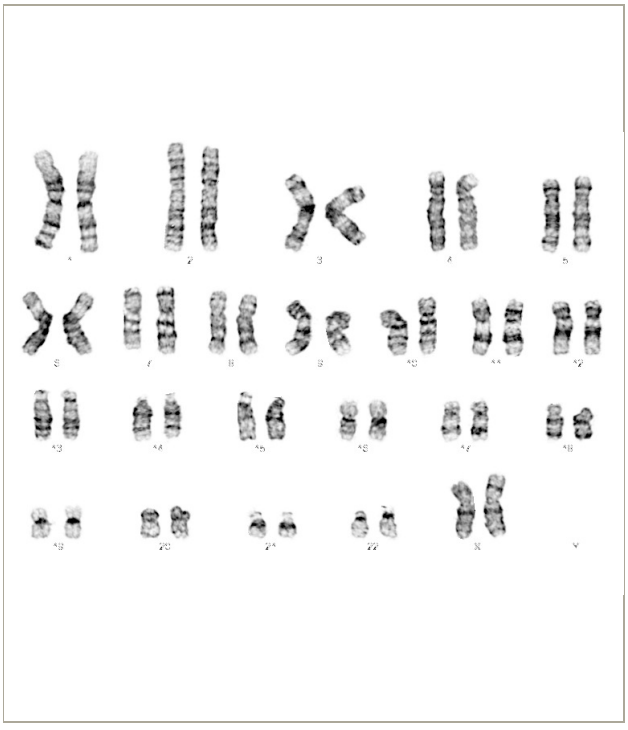
Test, Reason for: *DL release testing*

Results: *46,XX*

Completed by *CLSp(CG), on 7/28/2009*

Reviewed and interpreted by *PhD, FACMG, on 7/28/2009*

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



Cell: *S01-01*

Slide: *B*

Slide Type: *Karyotyping*

Cell Results: *46,XX*

# of Cells Counted: *20*

# of Cells Karyotyped: *4*

# of Cells Analyzed: *8*

Band Level: *450-550*

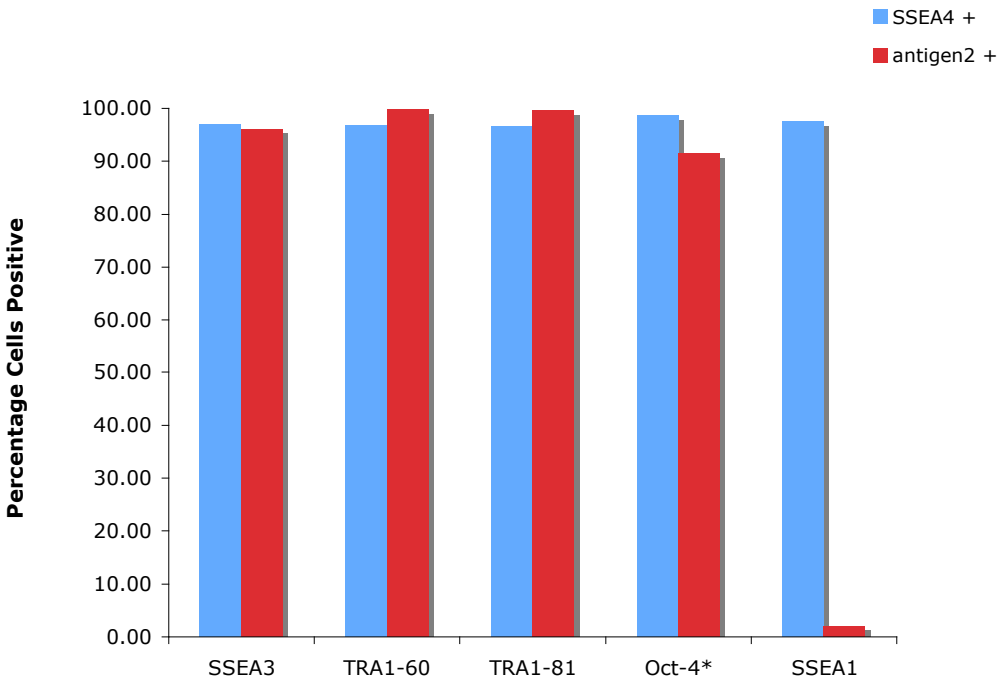
Results Transmitted by Fax / Email / Post **Date:**_____
Sent By:_____ **Sent To:**_____
QC Review By: _____ **Results Recorded:** _____

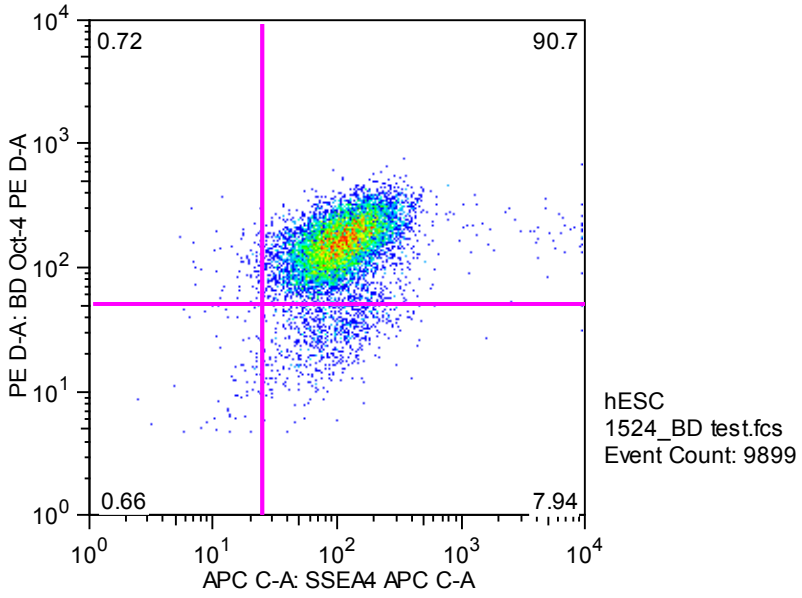
Procedures performed:
SOP-CH-101 SOP-CH-102
SOP-CH-103 SOP-CH-105

Cell Line: WA09-DL-10
Passage 32
Sample ID: 1524-FAC

Date of: *(mm/dd/yy)*
acquisition: 08/10/09
file creation: 08/10/09
file submission: 08/14/09

antigen2:	SSEA4 - antigen2 +	SSEA4 + antigen2 +	SSEA4 + antigen2 -	SSEA4 - antigen2 -	ALL SSEA4 +	ALL antigen2 +
SSEA3	1.50	94.6	2.4	1.46	97.00	96.10
TRA1-60	2.93	96.8	0.03	0.27	96.83	99.73
TRA1-81	2.99	96.5	0.08	0.46	96.58	99.49
Oct-4*	0.72	90.7	7.94	0.66	98.64	91.42
SSEA1	0.07	2.03	95.6	2.33	97.63	2.10





*PE-conjugated Oct-3/4 from BD Biosciences was used (cat #560186).