



Certificate of Analysis - Amended

Product Description	WA01	
Cell Line Provider	WiCell Research Institute	
Lot Number	WA01-MCB-04 ¹	
Date Viald	04-May-2009	
Passage Number	p21	
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


¹This lot was frozen and labeled as a MCB but it was later determined to release this lot as a DDL lot. Depositor Distribution Lot (DDL) cells are expanded from vials of provider cells.

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.

Amendment(s):

Reason for Amendment	Date
CoA updated to include copyright information. WiCell logo updated.	See Signature
Removed "Released as a DDL" from the lot number and updated footnote for clarity.	18-OCT-2012
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	27-AUG-2010
Original CoA	09-NOV-2009

Date of Lot Release	Quality Assurance Approval
09-November-2009	<div style="text-align: right;">12/31/2013</div> <div style="text-align: center;">  AMC Quality Assurance Signed by ██████████ </div>

Short Tandem Repeat Analysis*

Sample Report: 3293-STR

UW HLA#: 61326

Sample Date: 07/15/09

Received Date: 07/15/09

Requestor: WiCell Research Institute

Test Date: 07/20/09

File Name: 090721

Report Date: 07/23/09

Sample Name: (label on tube) 3293-STR

Description: DNA Extracted by WiCell
234.0 ng/ μ L; 260/280 = 1.86

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

Comments: Based on the 3293-STR DNA submitted by WI Cell dated 07/15/09 and received on 07/15/09, this sample (UW HLA# 61326) matches exactly the STR profile of the human stem cell line H1 comprising 15 allelic polymorphisms across the 8 STR loci analyzed. No STR polymorphisms other than those corresponding to the human H1 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. This result suggest that the 3293-STR DNA sample submitted corresponds to the H1 stem cell line and 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%.

7/22/09

Manager Date
HLA/Molecular Diagnostics Laboratory

07/25/09

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.

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.



Report Number
809720
Page 1 of 1

WiCell Research Institute

June 04, 2009
P.O. #: _____

STERILITY TEST REPORT

Sample Information: hES Cells, WA01-MCB-4, #4465

Date Received: May 19, 2009

Date in Test: May 20, 2009

Date Completed: June 03, 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

QA Reviewer

Date

06-05-09

Technical Reviewer

Date

06-04-09

Testing conducted in accordance with current Good Manufacturing Practices.





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#: 57802 P.O.#: | DATE REC'D: 06/23/2009

TEST/CONTROL ARTICLE:

WA01-MCB-4-L.4 #3293

LOT#: NA

DIRECT CULTURE SET-UP (DAY 0)

DATE: 06/24/2009

INDICATOR CELL LINE (VERO)

SEE DNA FLUOROCHROME RECORD SHEET

			DATE
THIOGLYCOLLATE BROTH	DAY 7	+ ⊖	<u>07/01/2009</u>
	DAY 28	+ ⊖	<u>07/22/2009</u>
BROTH-FORTIFIED COMMERCIAL <u>0.5</u> mL SAMPLE	DAY 7	+ ⊖	<u>07/01/2009</u>
	DAY 28	+ ⊖	<u>07/22/2009</u>
<u>6.0</u> mL BROTH	DAY 28	+ ⊖	<u>07/22/2009</u>
BROTH-MODIFIED HAYFLICK <u>0.5</u> mL SAMPLE	DAY 7	+ ⊖	<u>07/01/2009</u>
	DAY 28	+ ⊖	<u>07/22/2009</u>
<u>6.0</u> mL BROTH	DAY 28	+ ⊖	<u>07/22/2009</u>
BROTH-HEART INFUSION <u>0.5</u> mL SAMPLE	DAY 7	+ ⊖	<u>07/01/2009</u>
	DAY 28	+ ⊖	<u>07/22/2009</u>
<u>6.0</u> mL BROTH	DAY 28	+ ⊖	<u>07/22/2009</u>

(See Reverse)

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

SAMPLE ID#:	57802	AEROBIC	MICROAEROPHILIC	DATE
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ ⊖	+ ⊖	<u>07/01/2009</u>
	DAY 14	+ ⊖	+ ⊖	<u>07/08/2009</u>
	DAY 21	+ ⊖	+ ⊖	<u>07/15/2009</u>
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ ⊖	+ ⊖	<u>07/01/2009</u>
	DAY 14	+ ⊖	+ ⊖	<u>07/08/2009</u>
	DAY 21	+ ⊖	+ ⊖	<u>07/15/2009</u>
AGAR PLATES-HEART INFUSION	DAY 7	+ ⊖	+ ⊖	<u>07/01/2009</u>
	DAY 14	+ ⊖	+ ⊖	<u>07/08/2009</u>
	DAY 21	+ ⊖	+ ⊖	<u>07/15/2009</u>

BROTH SUBCULTURES (DAY 7)DATE: 07/01/2009

AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ ⊖	+ ⊖	<u>07/08/2009</u>
	DAY 14	+ ⊖	+ ⊖	<u>07/15/2009</u>
	DAY 21	+ ⊖	+ ⊖	<u>07/22/2009</u>
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ ⊖	+ ⊖	<u>07/08/2009</u>
	DAY 14	+ ⊖	+ ⊖	<u>07/15/2009</u>
	DAY 21	+ ⊖	+ ⊖	<u>07/22/2009</u>
AGAR PLATES-HEART INFUSION	DAY 7	+ ⊖	+ ⊖	<u>07/08/2009</u>
	DAY 14	+ ⊖	+ ⊖	<u>07/15/2009</u>
	DAY 21	+ ⊖	+ ⊖	<u>07/22/2009</u>

RESULTS: No detectable mycoplasmal contamination

7-22-09

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 # 57802 M-250 Date Rec'd: 06/23/2009 P.O. #

Indicator, Cells Inoculated: Date/Initials: 6/25/09 / BRS

Fixation: Date/Initials: 6/29/09 / KG

Staining: Date/Initials: 6/29/09 / KG

TEST/CONTROL ARTICLE:

WA01-MCB-4-L.4 #3293

LOT# NA

Wicell OA

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: 6/29/09 Results Read by: KG Date of Review: 6-29-09 Reviewed by: Seta

Report Date: September 11, 2009

Case Details:

Cell Line: WA01-MCB-4 (0831)

Passage #: 23

Date Completed: 9/11/2009

Cell Line Gender: Male

Investigator: National Stem Cell Bank

Specimen: hESC on MEF feeder

Date of Sample: 9/4/2009

Tests, Reason for: pre-freeze DL

Results: 46,XY

Completed by MS, CLSp(CG), on 9/11/2009

Reviewed and interpreted by _____, PhD, FACMG, on 9/11/2009

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



Cell: S01-04

Slide: B-19

Slide Type: Karyotyping

of Cells Counted: 20

of Cells Karyotyped: 4

of Cells Analyzed: 8

Band Level: 425-500

Results Transmitted by Fax / Email / Post

Sent By: _____

QC Review By: _____

Date: _____

Sent To: _____

Results Recorded: _____