




# Product Information and Testing - Amended

## Product Information

Product Name	H1 OCT4-EGFP
Lot Number	WA01(Oct4KI)-DL-02
Parent Material	WA01(Oct4KI)-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 Pluripotent Stem Cell Protocols Supplement Culturing with G418
Passage Number	p69(10)  These cells were cultured for 68 passages prior to freeze, 10 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 Viald	26-March-2009
Vial Label	WA01(OCT4KI)-DL-2 P69(10) JT 26 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
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 STR profile of deposited cell line	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

Date of Lot Release	Quality Assurance Approval
21-September-2009	<div style="text-align: right;">7/14/2020</div> <div style="text-align: center;">             X AA            AA            Quality Assurance            Signed by: Arntz, Andy         </div>

Short Tandem Repeat Analysis\*

Sample Report: 8831-STR

UW HLA#: 61157

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

Sample Name: (label on tube) 8831-STR

Description: DNA Extracted by WiCell  
271.19 ng/ $\mu$ L; 260/280 = 1.89

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 8831-STR DNA submitted by WI Cell dated 06/18/09 and received on 06/18/09, this sample (UW HLA# 61157) 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 8831-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%.

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.

WiCell Research Institute

April 23, 2009  
 P.O. #:

**STERILITY TEST REPORT**

**Sample Information:** hES Cells  
 8: WA01 (Oct 4 KI)-DL-2, 4976

**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
<b>RESULTS</b>	2 NEGATIVE	2 NEGATIVE

Page 1 Signed  
 \_\_\_\_\_  
 QA Reviewer                      Date

Page 1 Signed  
 \_\_\_\_\_  
 Technical Reviewer                      Date



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:

BTL SAMPLE ID#: 57705 P.O.#: DATE REC'D: 06/11/2009

TEST/CONTROL ARTICLE:

WA01 (Oct4K1) -DL-02-G #8831

LOT#: NA

DIRECT CULTURE SET-UP (DAY 0)

DATE: 06/11/2009

INDICATOR CELL LINE (VERO)

SEE DNA FLUOROCHROME RECORD SHEET

			DATE
THIOGLYCOLLATE BROTH	DAY 7	+ ⊖	<u>06/18/2009</u>
	DAY 28	+ ⊖	<u>07/09/2009</u>
BROTH-FORTIFIED COMMERCIAL <u>0.5</u> mL SAMPLE	DAY 7	+ ⊖	<u>06/18/2009</u>
	DAY 28	+ ⊖	<u>07/09/2009</u>
<u>6.0</u> mL BROTH	DAY 7	+ ⊖	<u>06/18/2009</u>
	DAY 28	+ ⊖	<u>07/09/2009</u>
BROTH-MODIFIED HAYFLICK <u>0.5</u> mL SAMPLE	DAY 7	+ ⊖	<u>06/18/2009</u>
	DAY 28	+ ⊖	<u>07/09/2009</u>
<u>6.0</u> mL BROTH	DAY 7	+ ⊖	<u>06/18/2009</u>
	DAY 28	+ ⊖	<u>07/09/2009</u>
BROTH-HEART INFUSION <u>0.5</u> mL SAMPLE	DAY 7	+ ⊖	<u>06/18/2009</u>
	DAY 28	+ ⊖	<u>07/09/2009</u>
<u>6.0</u> mL BROTH	DAY 7	+ ⊖	<u>06/18/2009</u>
	DAY 28	+ ⊖	<u>07/09/2009</u>

(See Reverse)

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

SAMPLE ID#:	57705	AEROBIC	MICROAEROPHILIC	DATE
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ ⊖	+ ⊖	<u>06/18/2009</u>
	DAY 14	+ ⊖	+ ⊖	<u>06/25/2009</u>
	DAY 21	+ ⊖	+ ⊖	<u>07/02/2009</u>
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ ⊖	+ ⊖	<u>06/18/2009</u>
	DAY 14	+ ⊖	+ ⊖	<u>06/25/2009</u>
	DAY 21	+ ⊖	+ ⊖	<u>07/02/2009</u>
AGAR PLATES-HEART INFUSION	DAY 7	+ ⊖	+ ⊖	<u>06/18/2009</u>
	DAY 14	+ ⊖	+ ⊖	<u>06/25/2009</u>
	DAY 21	+ ⊖	+ ⊖	<u>07/02/2009</u>
<b><u>BROTH SUBCULTURES (DAY 7)</u></b>		DATE: <u>06/18/2009</u>		
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ ⊖	+ ⊖	<u>06/25/2009</u>
	DAY 14	+ ⊖	+ ⊖	<u>07/02/2009</u>
	DAY 21	+ ⊖	+ ⊖	<u>07/09/2009</u>
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ ⊖	+ ⊖	<u>06/25/2009</u>
	DAY 14	+ ⊖	+ ⊖	<u>07/02/2009</u>
	DAY 21	+ ⊖	+ ⊖	<u>07/09/2009</u>
AGAR PLATES-HEART INFUSION	DAY 7	+ ⊖	+ ⊖	<u>06/25/2009</u>
	DAY 14	+ ⊖	+ ⊖	<u>07/02/2009</u>
	DAY 21	+ ⊖	+ ⊖	<u>07/09/2009</u>

RESULTS: No detectable mycoplasmal contamination

M-9-09  
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 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 # 57705 M-250 Date Rec'd: 06/11/2009 P.O. #

Indicator Cells Inoculated: Date/Initials: 6/11/09 / JA

Fixation: Date/Initials: 6/15/09 / JA

Staining: Date/Initials: 6/15/09 / JA

TEST/CONTROL ARTICLE:

WA01(Oct4K1)-DL-02-G #8831

LOT# NA

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: 6/15/09 Results Read by: JA Date of Review: 6/15/09 Reviewed by: U

**Report Date:** June 03, 2009

**Case Details:**

**Cell Line:** WA01(Oct4KI)-DL-2 (8831)

**Passage #:** 73(14)

**Date Completed:** 6/3/2009

**Cell Line Gender:** Male

**Investigator:** National Stem Cell Bank

**Specimen:** hESC on Matrigel

**Date of Sample:** 5/29/2009

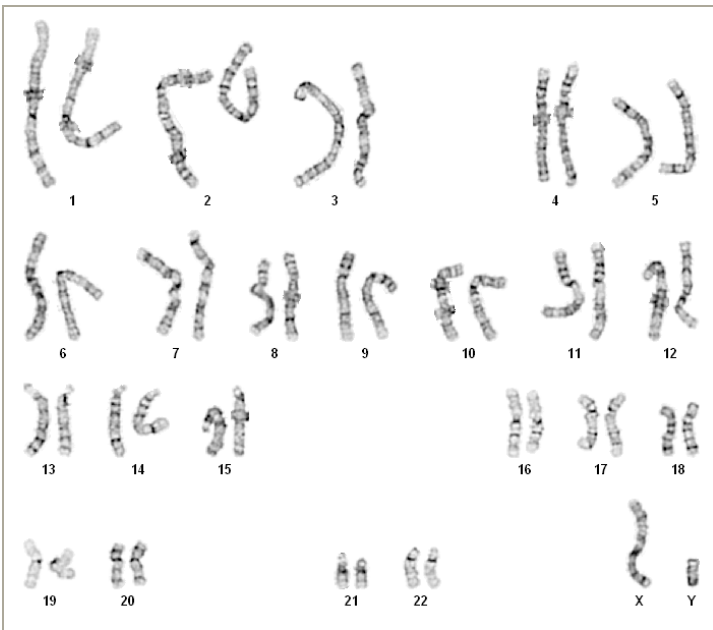
**Tests, Reason for:** FTDL Equivalent

**Results:** 46,XY

Completed by \_\_\_\_\_ on 6/3/2009

Reviewed and interpreted by \_\_\_\_\_ on 6/3/2009

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



**Cell:** S01-01

**Slide:** A

**Slide Type:** Karyotyping

**Cell Results:** Karyotype: 46,XY

**# of Cells Counted:** 20

**# of Cells Karyotyped:** 4

**# of Cells Analyzed:** 8

**Band Level:** 450-600

**Results Transmitted by Fax / Email / Post**

**Sent By:** \_\_\_\_\_

**QC Review By:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Sent To:** \_\_\_\_\_

**Results Recorded:** \_\_\_\_\_