Certificate of Analysis - Amended Distribution Lot

Product Description	H1 (WA01) WiCell Distribution Lot
Cell Line Provider	WiCell Research Institute (Madison, WI, USA)
Distribution Lot Number	H1-WCDL-12 (lot 12)
Date Vialed	23 April 2007
Passage Number	29
Culture Method	SOP-CC-030B, SOP-CC-020B
Cryopreservation Method	SOP-CC-034A

The following testing specifications have been met for the specified product lot:

Test Description	Test Method	Test Specification	Result
Post-Thaw Viable Cell Recovery	SOP-CH-305A	Viable cells recovered	Pass
Identity by STR	SOP-CH-302B	Positive identity	Pass
Mycoplasma	SOP-SS-002A	No contamination detected	Pass
Karyotype by G-banding	SOP-CH-003B	Normal karyotype	Pass

Electronic versions of this certificate of analysis (CoA) complete with electronic copies of individual reports, results, and procedures are available on our website, www.wicell.org. There are also archived CoAs for past cell lots.

Please visit the technical service portion of the website for assistance with your human ES Cells. The knowledgeable technical support staff can assist with embryonic stem cell culture concerns, training, and any other customer service concerns you may encounter.

Amendment(s):

Reason for Amendment	Date
CoA updated to include copyright information and electronic signature, and update to WiCell logo. Links updated.	See signature
Original CoA	21-Aug-2007

Date of Lot Release	Quality Assurance Approval
21-August-2007	1/3/2014 X AMC AMC Quality Assurance Signed by: [redacted]

UW Health
University of Wisconsin
Hospital and Clinics

Histocompatibility/Molecular Diagnostics Laboratory
Madison, WI 53792-2472

Short Tandem Repeat Analysis*

Sample Report: H1 (lot12) p29 UW HLA#: 56874 Sample Date: 08/13/07
Received Date: 08/13/07

Requestor: WiCell Research Institute

Test Date: 08/13/07 File Name: 070814 Report Date: 08/16/07

Sample Name: (label on tube) WiCell DNA042 STR **Description:** DNA Extracted by WiCell

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

36 ng/µL; 260/280 = 2.1

Comments: Based on the H1 (lot12) p29 DNA submitted by WI Cell dated 08/13/07 and received on 08/13/07, this sample (UW HLA# 56874) 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 DNA sample submitted corresponds to the H1 stem cell line and was not contaminated with any other human stell 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 to CS of the Cytogenetics group of WiCell Research Institue on Thursday, August 16, 2007. A preliminary copy of this report was issued via electronic mail to both CS and JJ of WI Cell Research Institute on Friday, August 17, 2007.

***** 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.

Mycoplasma Testing Services
Safe Cells

MYCOPLASMA
TESTING SERVICES

BIONIQUE TESTING LABORATORIES, INC
156 Fay Brook Drive
Saranac Lake, NY 12983
Phone: 518-891-2356 FAX: 518-891-5753

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 # **48644** **M-250** Date Rec'd: **05/24/2007** P.O. # **RP1330**

Indicator Cells Inoculated: Date/Initials: 5/24/07 / [redacted]

Fixation: Date/Initials: 5/28/07 / [redacted]

Staining: Date/Initials: 6/28/07 / [redacted]

TEST/CONTROL ARTICLE:

Hlp33

LOT# **12**

Distribution
WiCell Research Institute

505 S. Rosa Rd., Suite 20
Madison, WI 53719

Phone: **608-441-2719**

Fax #: **608-441-2766**

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: 5/29/07 Results Read by: ____ Date of Review: 5/29/07 Reviewed by: ____

Mycoplasma Testing Services
Safe Cells

BIONIQUE TESTING LABORATORIES, INC.
156 FAY BROOK DRIVE
SARANAC LAKE, NY 12983
PHONE: 518-891-2356 FAX: 518-891-5753

QUALITY ASSURANCE REPORT - GMP

Catalog #: M-250

Procedural Reference Numbers: 3008, 3011, 3013

Bionique Sample ID # 48644

This testing procedure was performed in compliance with Current Good Manufacturing Practice (cGMP) standards as specified under 21 CFR parts 210 and 211 to the extent to which these regulations pertain to the procedures performed. All records pertaining to the test/procedure have been reviewed by the Quality Assurance/Quality Control individual whose signature below verifies that the methods and procedures referenced above have been followed, and that the Final Report accurately reflects the raw data generated during the course of these procedures.

Date of full data review by Quality Assurance: 6/21/07

[illegible] 6/21/07
Date

All records, including raw data and final reports, are maintained by:

Quality Assurance
Bionique Testing Laboratories, Inc.
156 Fay Brook Drive
Saranac Lake, NY 12983

Procedures specified in individual protocols are inspected at appropriate intervals according to a pre-determined schedule. Each lot of medium used for testing is examined for mycoplasmal growth-promoting properties, and must meet with required Quality Control performance criteria. Traceability of all of the components used in these protocols is assured, and documentation for individual lots will be supplied upon request.

Additional Comments:

I. The stability of the test and/or control sample material is the responsibility of the company submitting the sample prior to receipt at Bionique Testing Laboratories. Bionique Testing Laboratories will assume responsibility for sample stability following receipt and prior to being placed on test.

II. This test is for the detection of microbiological growth and does not require statistical validation.

Mycoplasma Testing Services
Safe Cells

BIONIQUE TESTING LABORATORIES, INC.
156 FAY BROOK DRIVE
SARANAC LAKE, NY 12983
PHONE: 518-891-2356 FAX: 518-891-5753

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: Distribution
WiCell Research Institute

505 S. Rosa Rd., Suite 20
Madison, WI 53719
PHONE#: **608-441-2719** FAX#: **608-441-2766**

BTL SAMPLE ID#: **48644** P.O.#: **RP1330** DATE REC'D: **05/24/2007**

TEST/CONTROL ARTICLE:

Hlp33

LOT#: **12**

DIRECT CULTURE SET-UP (DAY 0) DATE: **05/24/2007**

INDICATOR CELL LINE (VERO) SEE DNA FLUOROCHROME RECORD SHEET

			DATE
THIOGLYCOLLATE BROTH	DAY 7	+ ⊖	**05/31/2007**
	DAY 28	+ ⊖	**06/21/2007**
BROTH-FORTIFIED COMMERCIAL			
0.5 mL SAMPLE	DAY 7	+ ⊖	**05/31/2007**
6.0 mL BROTH	DAY 28	+ ⊖	**06/21/2007**
BROTH-MODIFIED HAYFLICK			
0.5 mL SAMPLE	DAY 7	+ ⊖	**05/31/2007**
6.0 mL BROTH	DAY 28	+ ⊖	**06/21/2007**
BROTH-HEART INFUSION			
0.5 mL SAMPLE	DAY 7	+ ⊖	**05/31/2007**
6.0 mL BROTH	DAY 28	+ ⊖	**06/21/2007**

(See Reverse)

APPENDIX IV

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

SAMPLE ID#: **48644**

		AEROBIC	MICROAEROPHILIC	DATE
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ (−)	+ (−)	05/31/2007
	DAY 14	+ (−)	+ (−)	06/07/2007
	DAY 21	+ (−)	+ (−)	06/14/2007
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ (−)	+ (−)	05/31/2007
	DAY 14	+ (−)	+ (−)	06/07/2007
	DAY 21	+ (−)	+ (−)	06/14/2007
AGAR PLATES-HEART INFUSION	DAY 7	+ (−)	+ (−)	05/31/2007
	DAY 14	+ (−)	+ (−)	06/07/2007
	DAY 21	+ (−)	+ (−)	06/14/2007
BROTH SUBCULTURES (DAY 7)		DATE: 05/31/2007		
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ (−)	+ (−)	06/07/2007
	DAY 14	+ (−)	+ (−)	06/14/2007
	DAY 21	+ (−)	+ (−)	06/21/2007
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ (−)	+ (−)	06/07/2007
	DAY 14	+ (−)	+ (−)	06/14/2007
	DAY 21	+ (−)	+ (−)	06/21/2007
AGAR PLATES-HEART INFUSION	DAY 7	+ (−)	+ (−)	06/07/2007
	DAY 14	+ (−)	+ (−)	06/14/2007
	DAY 21	+ (−)	+ (−)	06/21/2007

RESULTS: No detectable mycoplasmal contamination

6/21/07
Date

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: 000137-051807

Report Date: May 27, 2007

Case Details:

Cell Line: *H1 lot 12*

Passage #: *31*

Date Completed: *5/27/2007*

Cell Line Gender: *Male*

Investigator: *NSCB*

Specimen: *hESC on MEF feeder*

Date of Sample: *5/18/2007*

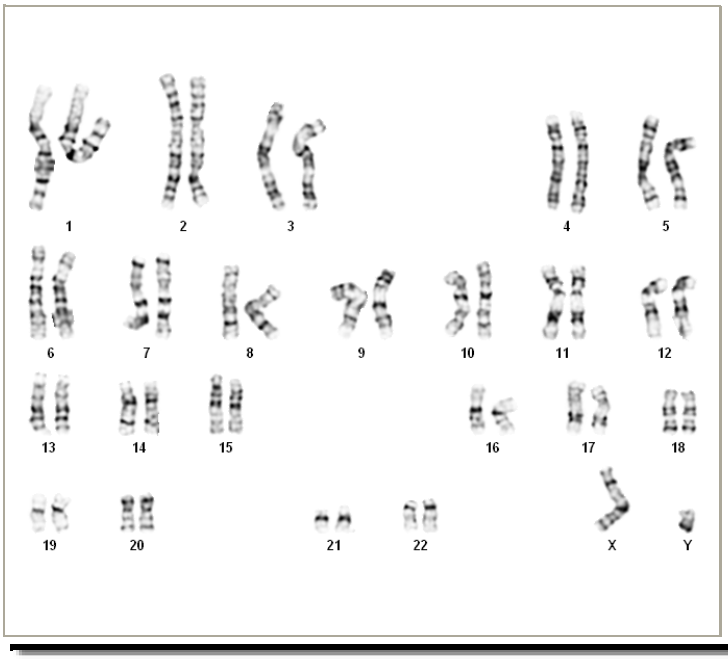
Tests,Reason for: *Karyotype for distribution lot*

Results: *46,XY*

Completed by CS on 5/27/2007

Reviewed and interpreted by KDM on 5/27/2007

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



Cell: *S01-05*

Slide: *C*

Slide Type: *Karyotyping*

Cell Results: *Karyotype: 46,XY*

# of Cells Counted: *20*

# of Cells Karyotyped: *6*

# of Cells Analyzed: *8*

Band Level: *450-575*

WiCell Cytogenetics Report: