Certificate of Analysis - Amended
Fast Track Distribution Lot

Product Description (Cell Line)	WA07 Fast Track Distribution Lot
Cell Line Provider	WiCell Research Institute (Madison, WI, USA)
Lot Number	WA07-FTDL-01
Date Vialed	20-February-2009
Passage Number	P26

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-305C	Viable cells recovered	Pass
Sterility	Apptec Protocol 30744 Rev. 1	Negative	Pass
Identity by STR	SOP-SS-006A	Positive identity	Pass*
Mycoplasma	Bionique Method M250	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.

Cells distributed by the National Stem Cell Bank are intended for research purposes only and are not intended for use in humans. These cells have undergone testing and are not known to harbor pathogens. However, 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. The NSCB is not responsible for damages or injuries that may result from the use of these cells.

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, electronic signature, and WiCell logo. Links updated.	See signature
Original CoA	07-Oct-2009

Date of Lot Release	Quality Assurance Approval
07-October-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: 0282-STR | UW HLA#: 60637 | Sample Date: 03/31/09, Lab Received 03/31/09

Requestor: WiCell Research Institute

Test Date: 04/01/09 | File Name: 090402 | Report Date: 04/03/09

Sample Name: (label on tube) 0282-STR

Description: WI Cell Cytogenetics provided genomic DNA
252.80 ug/mL 260/280=1.85

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

Comments: Based on the 0282-STR DNA submitted by WI Cell dated and received on 03/31/09, this sample (UW HLA# 60637) matches exactly the STR profile of the human stem cell line H7 comprising 14 allelic polymorphisms across the 8 STR loci analyzed. No STR polymorphisms other than those corresponding to the human H7 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 0282-STR DNA samples submitted corresponds to the H7 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%.

_____ , Manager Date
HLA/Molecular Diagnostics Laboratory

_____ , 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.

File: Final STR Report

WuXi AppTec

WiCell Research Institute

March 16, 2009
P.O. #:

STERILITY TEST REPORT

Sample Information: hES Cells
7: WA07-FTDL-1

Date Received: February 26, 2009
Date in Test: March 02, 2009
Date Completed: March 16, 2009

Test Information: Test Codes: 30744, 30744A
Immersion, USP / 21 CFR 610.12
Procedure #: BS210WCR.201

TEST PARAMETERS	PRODUCT	
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

PRODUCT	APPROXIMATE VOLUME TESTED (each media)
1	0.45 mL
2	0.50 mL

Page 1 Signed
QA Reviewer **Date**

Page 1 Signed
Technical Reviewer **Date**

Testing conducted in accordance with current Good Manufacturing Practices.

Mycoplasma Testing Services

BIONIQUE TESTING LABORATORIES, INC.

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#: **56766** P.O.#: DATE REC'D: **03/19/2009**

TEST/CONTROL ARTICLE:

WA07-FTDL-1-N.1 p29

LOT#: **NA**

DIRECT CULTURE SET-UP (DAY 0) DATE: **03/19/2009**

INDICATOR CELL LINE (VERO) SEE DNA FLUOROCHROME RECORD SHEET

			DATE
THIOGLYCOLLATE BROTH	DAY 7	+ (−)	03/26/2009
	DAY 28	+ (−)	04/16/2009
BROTH-FORTIFIED COMMERCIAL			
0.5 mL SAMPLE	DAY 7	+ (−)	03/26/2009
6.0 mL BROTH	DAY 28	+ (−)	04/16/2009
BROTH-MODIFIED HAYFLICK			
0.5 mL SAMPLE	DAY 7	+ (−)	03/26/2009
6.0 mL BROTH	DAY 28	+ (−)	04/16/2009
BROTH-HEART INFUSION			
0.5 mL SAMPLE	DAY 7	+ (−)	03/26/2009
6.0 mL BROTH	DAY 28	+ (−)	04/16/2009

(See Reverse)

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

SAMPLE ID#: 56766		AEROBIC	MICROAEROPHILIC	DATE
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ (−)	+ (−)	03/26/2009
	DAY 14	+ (−)	+ (−)	04/02/2009
	DAY 21	+ (−)	+ (−)	04/09/2009
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ (−)	+ (−)	03/26/2009
	DAY 14	+ (−)	+ (−)	04/02/2009
	DAY 21	+ (−)	+ (−)	04/09/2009
AGAR PLATES-HEART INFUSION	DAY 7	+ (−)	+ (−)	03/26/2009
	DAY 14	+ (−)	+ (−)	04/02/2009
	DAY 21	+ (−)	+ (−)	04/09/2009
BROTH SUBCULTURES (DAY 7)		DATE: 03/26/2009		
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ (−)	+ (−)	04/02/2009
	DAY 14	+ (−)	+ (−)	04/09/2009
	DAY 21	+ (−)	+ (−)	04/16/2009
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ (−)	+ (−)	04/02/2009
	DAY 14	+ (−)	+ (−)	04/09/2009
	DAY 21	+ (−)	+ (−)	04/16/2009
AGAR PLATES-HEART INFUSION	DAY 7	+ (−)	+ (−)	04/02/2009
	DAY 14	+ (−)	+ (−)	04/09/2009
	DAY 21	+ (−)	+ (−)	04/16/2009

RESULTS: No detectable mycoplasmal contamination

4/16/09
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 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.

Mycoplasma Testing Services

Safe Cells

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 # **56766** **M-250** Date Rec'd: **03/19/2009** P.O. #

Indicator Cells Inoculated: Date/Initials: 3/19/09 / KG

Fixation: Date/Initials: 3/23/09 / KG

Staining: Date/Initials: 3/23/09 / KG

TEST/CONTROL ARTICLE:

WA07-FTDL-1-N.1 p29

LOT# **NA**

Wicell QA

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: 3/23/09 Results Read by: KG Date of Review: 3/23/09 Reviewed by: [illegible]

WiCell Cytogenetics Report: 000970-032009
NSCB 0282

Report Date: March 30, 2009

Case Details:

Cell Line: *WA07-FTDL-1 (0282)*

Passage #: *29*

Date Completed: *3/30/2009*

Cell Line Gender: *Female*

Investigator: *National Stem Cell Bank*

Specimen: *hESC on MEF feeder*

Date of Sample: *3/20/2009*

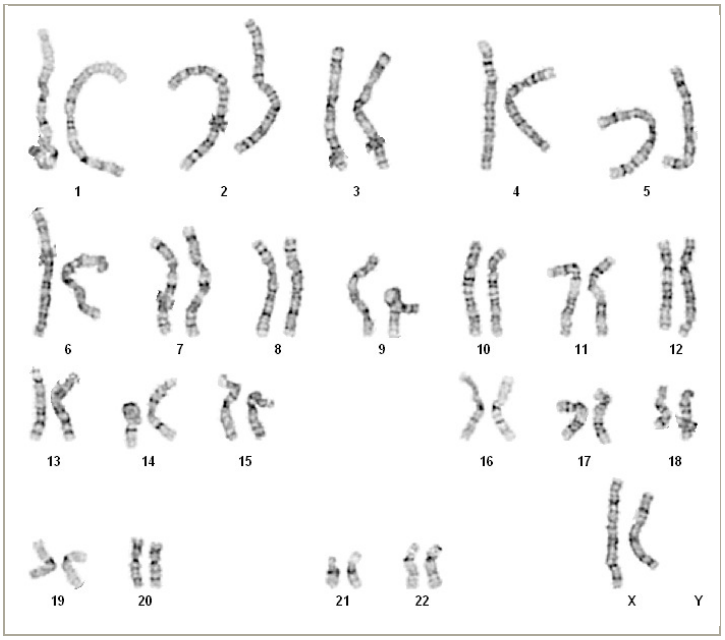
Tests,Reason for: *Not given*

Results: *46,XX*

Completed by , CLSp(CG), on 3/27/2009

Reviewed and interpreted by , PhD, FACMG, on 3/30/2009

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



Cell: *S01-01*

Slide: *A*

Slide Type: *Karyotyping*

Cell Results: *Karyotype: 46,XX*

# of Cells Counted: 20

# of Cells Karyotyped: 4

# of Cells Analyzed: 8

Band Level: 450-600

Results Transmitted by Fax / Email / Post **Date:**_____

Sent By:_____ **Sent To:**_____