Certificate of Analysis - Amended

Fast Track Distribution Lot

Product Description	ES06 (HES-6) NSCB FT Distribution lot
Cell Line Provider	ES Cell International
Distribution Lot Number	ES06-FTDL-1
Date Vialed	230-Jan-2008
Passage Number	36
Culture Method	SOP-CC-020B, SOP-CC-030B
Cryopreservation Method	SOP-CC-035D

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
Sterility	SOP-CH-304A	No contamination detected	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.

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 and electronic signature. Links updated.	See signature
Original CoA	24-March-2008

Date of Lot Release	Quality Assurance Approval
24-March-2008	12/30/2013 X AMC AMC Quality Assurance Signed by: [redacted]

UW Health
University of Wisconsin
Hospital and Clinics

Histocompatibility/Molecular Diagnostics Laboratory
D4/231; (608) 263-8815
600 Highland Avenue
Madison, WI 53792-2472

Short Tandem Repeat Analysis*

Sample Report: 0295-STR (ES06-FTDL-1)

UW HLA#: 58208

Sample Date: 03/10/08
Received Date: 03/10/08

Requestor: WiCell Research Institute

Test Date: 03/16/08

File Name: 080317

Report Date: 03/21/08

Sample Name: **(label on tube)**
0295-STR

Description: DNA Extracted by WiCell

118ug/mL; 260/280 = 1.84

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

Comments: Based on the 0295-STR DNA submitted by WI Cell dated 03/10/08 and received on 03/10/08, this sample (UW HLA# 58208) matches exactly the STR profile of the human stem cell line ES06 comprising 13 allelic polymorphisms across the 8 STR loci analyzed. No STR polymorphisms other than those corresponding to the human ES06 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 DNA sample submitted corresponds to the ES06 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%. A preliminary copy of this report was issued via electronic mail to WI Cell Research Institute on Sunday, March 23, 2008.

HLA/Molecular Diagnostics Laboratory

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:
1265 Kennestone Circle
Marietta, GA 30066

WiCell Research Institute

February 28, 2008
P.O. #: RP1680

STERILITY TEST REPORT

Sample Information: Human embryonic stem cell line on mouse feeder layer
3: ES06-FTDL-1

Date Received: February 06, 2008
Date in Test: February 13, 2008
Date Completed: February 27, 2008

Test Information: Test Codes: 30744, 30744A
Immersion, USP / 21 CFR 610.12
Procedure #: BS210WCR.02

TEST PARAMETERS	PRODUCT	
Approximate Volume Tested	0.4 mL	0.4 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 Reviewed: Page 1 Signed

Reviewed: Page 1 Signed

Testing conducted in accordance with current Good Manufacturing Practices.

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 # **51757** **M-250** Date Rec'd: **02/19/2008** P.O. # **RP1695**

Indicator Cells Inoculated: Date/Initials: 2/21/08 / JA

Fixation: Date/Initials: 2/25/08 / JA

Staining: Date/Initials: 2/25/08 / JA

TEST/CONTROL ARTICLE:

ES06-FTDL-1

LOT# **NA**

Wicell QA
WiCell Research Institute

Phone:

Fax #:

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: 2/25/08 Results Read by: JA Date of Review: 2/25/08 Reviewed by: CM

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: **Wicell QA**
WiCell Research Institute

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BTL SAMPLE ID#: **51757** P.O.#: **RP1695** DATE REC'D: **02/19/2008**

TEST/CONTROL ARTICLE:

ES06-FTDL-1

LOT#: **NA**

DIRECT CULTURE SET-UP (DAY 0) DATE: **02/20/2008**

INDICATOR CELL LINE (VERO) SEE DNA FLUOROCHROME RECORD SHEET

			DATE
THIOGLYCOLLATE BROTH	DAY 7	+ ⊖	02/27/2008
	DAY 28	+ ⊖	03/19/2008
BROTH-FORTIFIED COMMERCIAL			
0.5 mL SAMPLE	DAY 7	+ ⊖	02/27/2008
6.0 mL BROTH	DAY 28	+ ⊖	03/19/2008
BROTH-MODIFIED HAYFLICK			
0.5 mL SAMPLE	DAY 7	+ ⊖	02/27/2008
6.0 mL BROTH	DAY 28	+ ⊖	03/19/2008
BROTH-HEART INFUSION			
0.5 mL SAMPLE	DAY 7	+ ⊖	02/27/2008
6.0 mL BROTH	DAY 28	+ ⊖	03/19/2008

(See Reverse)

APPENDIX IV

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

SAMPLE ID#: **51757**

		AEROBIC	MICROAEROPHILIC	DATE
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ ⊖	+ ⊖	02/27/2008
	DAY 14	+ ⊖	+ ⊖	03/05/2008
	DAY 21	+ ⊖	+ ⊖	03/12/2008
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ ⊖	+ ⊖	02/27/2008
	DAY 14	+ ⊖	+ ⊖	03/05/2008
	DAY 21	+ ⊖	+ ⊖	03/12/2008
AGAR PLATES-HEART INFUSION	DAY 7	+ ⊖	+ ⊖	02/27/2008
	DAY 14	+ ⊖	+ ⊖	03/05/2008
	DAY 21	+ ⊖	+ ⊖	03/12/2008

BROTH SUBCULTURES (DAY 7) DATE: 02/27/2008

AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ ⊖	+ ⊖	03/05/2008
	DAY 14	+ ⊖	+ ⊖	03/12/2008
	DAY 21	+ ⊖	+ ⊖	03/19/2008
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ ⊖	+ ⊖	03/05/2008
	DAY 14	+ ⊖	+ ⊖	03/12/2008
	DAY 21	+ ⊖	+ ⊖	03/19/2008
AGAR PLATES-HEART INFUSION	DAY 7	+ ⊖	+ ⊖	03/05/2008
	DAY 14	+ ⊖	+ ⊖	03/12/2008
	DAY 21	+ ⊖	+ ⊖	03/19/2008

RESULTS: No detectable mycoplasmal contamination

3/19/08
Date

Director Technical Services
Carolyn Kay Lincoln, 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.

WiCell Cytogenetics Report: 000422-022108
NSCB 0295

Report Date: February 29, 2008

Case Details:

Cell Line: *ES06*

Passage #: *37*

Date Completed: *2/27/2008*

Cell Line Gender: *female*

Investigator: *National Stem Cell Bank*

Specimen: *hESC on MEF feeder*

Date of Sample: *2/21/2008*

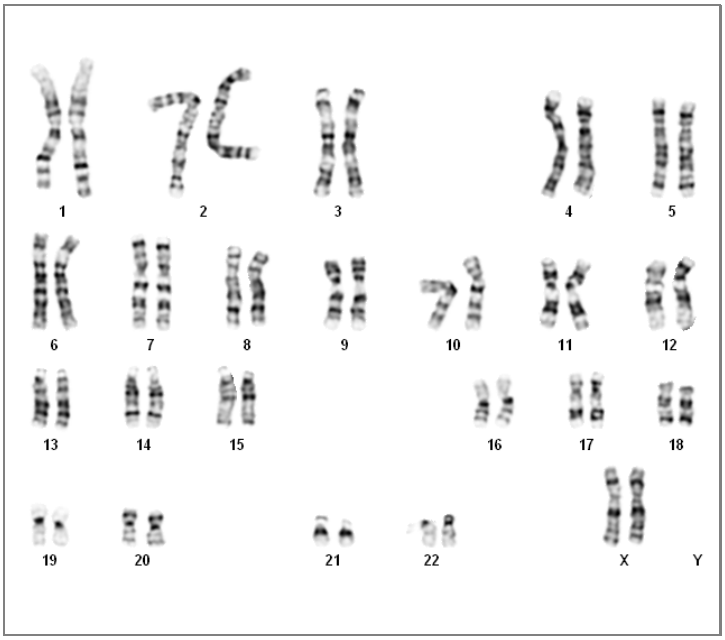
Tests,Reason for: *NSCB# 0295, fast-track distribution lot testing*

Results: *46,XX*

Completed by ST, CLSp(CG), on 2/27/2008

Reviewed and interpreted by KDM, PhD, FACMG, on 2/27/2008

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: 5

# of Cells Analyzed:9

Band Level: *450-550*

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

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