



Certificate of Analysis - Amended Distribution Lot

Product Description	WA09 (H9) Distribution Lot
Cell Line Provider	WiCell
MCB Lot Number	(WA09) H9-MCB-1
Distribution Lot Number	WA09 (H9)-DL-7
Date Viald	21-July-2008
Passage Number	p26
Culture Method	SOP-CC-030B, SOP-CC-001B, SOP-CC-022B, SOP-CC-020C, SOP-CC-037A
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-302A	Positive identity	Pass
Sterility - Direct transfer method	SOP-CH-304A	No contamination detected	Pass
Mycoplasma	SOP-CH-320A	No contamination detected	Pass
Karyotype by G-banding	SOP-CH-003A	Normal karyotype	Pass

Comparative Genome Hybridization	SOP-SS-010A SOP-CH-309A SOP-CH-310A SOP-SS-001A	Report copy number variants	Report available on website
Flow Cytometry for ESC Marker Expression	SOP-CH-101B SOP-CH-102B SOP-CH-103B SOP-CH-105B	Report values Oct-4 > 90%	Report available on website
Gene Expression Profile	SOP-CH-321A SOP-CH-322A SOP-CH-333A SOP-CH-311B	Report level of gene expression	Report available on website

Distribution lot cells are expanded from vials of Master Cell Bank (MCB) cells. MCB cells are thoroughly tested and known to be free of many viruses and pathogens. 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 extensive testing and are not known to harbor any human pathogens or adventitious agents of murine, bovine, or



Certificate of Analysis - Amended Distribution Lot

porcine origin. 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.

Electronic versions of the MCB and distribution lot certificates (CoAs) 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	29-September-2008

Date of Lot Release	Quality Assurance Approval
29-September-2008	<div style="text-align: right;">1/3/2014</div> <div style="text-align: center;">X AMC</div> <div style="text-align: center;">AMC Quality Assurance Signed by: XXXXXXXXXX</div>

Short Tandem Repeat Analysis*

Sample Report: 1297-STR
WA09-DL-7

UW HLA#: 59442

Sample Date: 09/04/08
Received Date: 09/04/08

Requestor: WiCell Research Institute

Test Date: 09/10/08, 09/17/08

File Name: 080911, 080918 Report Date: 09/19/08

Sample Name: (label on tube) **1297-STR****Description:** DNA Extracted by WiCell
229 ug/mL; 260/280 = 1.9

Locus	Repeat #	STR Genotype
D16S539	5, 8-15	12,13
D7S820	6-14	9,11
D13S317	7-15	9,9
D5S818	7-15	11,12
CSF1PO	6-15	11,11
TPOX	6-13	10,11
Amelogenin	NA	X,X
TH01	5-11	9.3,9.3
vWA	11, 13-21	17,17

Comments: Based on the DNA 1297-STR dated and received on 09/04/08 from WI Cell, this sample (UW HLA# 59442) matches exactly the STR profile of the human stem cell line **H9** comprising 12 allelic polymorphisms across the 8 STR loci analyzed. No STR polymorphisms other than those corresponding to the human H9 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 1297-STR DNA sample submitted corresponds to the H9 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 the WI Cell Research Institute on Monday, September 22, 2008.

* 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.

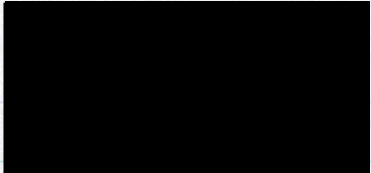
Test Facility:
1265 Kennestone Circle
Marietta, GA 30066

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.

WuXi AppTec

Report Number
783245
Page 1 of 3

August 11, 2008
P.O. #: 

WiCell Research Institute


STERILITY TEST REPORT

Sample Information: hES Cells
1: WA09-DL-6
2: WA09-DL-7

Date Received: July 23, 2008
Date in Test: July 25, 2008
Date Completed: August 08, 2008

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

QA Reviewed:  08-12-08

Reviewed:  08-11-08

Testing conducted in accordance with current Good Manufacturing Practices.

Report Number
783245
Page 3 of 3

August 11, 2008
P.O. #: RP2030

WiCell Research Institute

STERILITY TEST REPORT

Sample Information: hES Cells
2: WA09-DL-7

Date Received: July 23, 2008
Date in Test: July 25, 2008
Date Completed: August 08, 2008

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 Reviewed: _____
Page 1 Signed

Reviewed: _____
Page 1 Signed

Testing conducted in accordance with current Good Manufacturing Practices.

Report Date: June 26, 2013

Case Details:

Cell Line: WA-09-7-U.1

Passage #: 30

Date Completed: 9/3/2008

Cell Line Gender: Female

Investigator: NSCB

Specimen: hESC on MEF feeder

Date of Sample: 8/27/2008

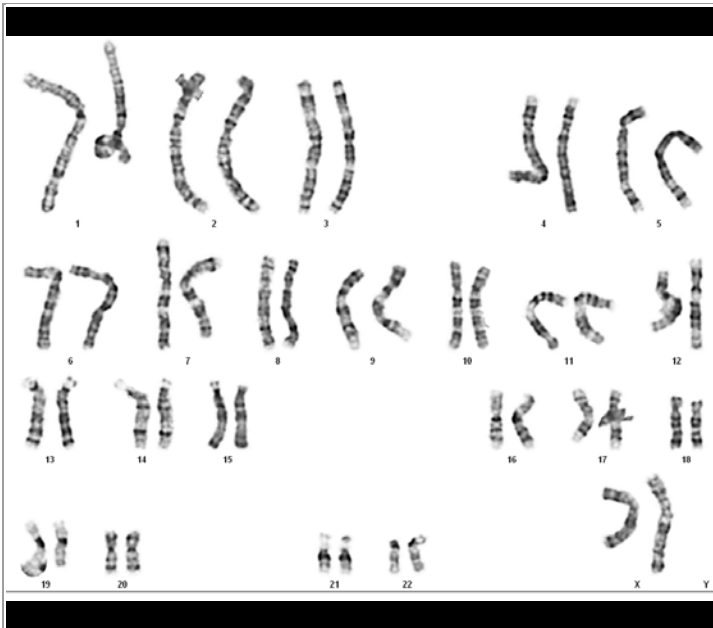
Tests, Reason for: NSCB-DL lot release

Results: 46,XX

Completed by KL, CLSp(CG), on 8/29/2008

Reviewed and interpreted by KDM, PhD, FACMG, on 9/3/2008

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: 4

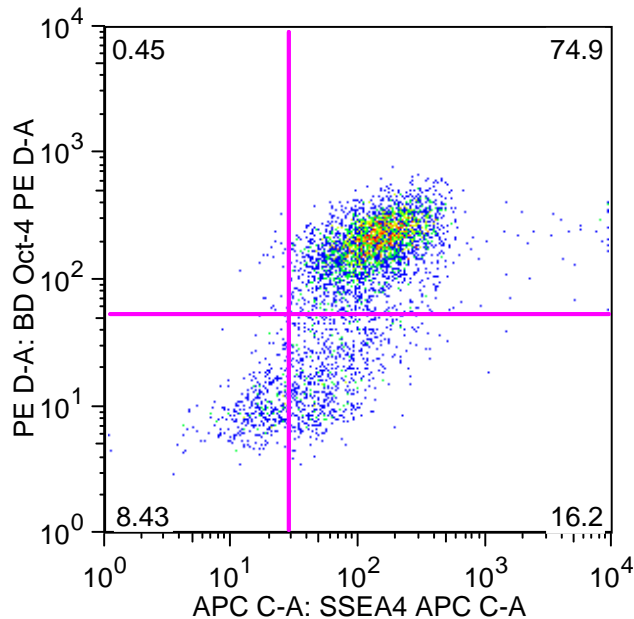
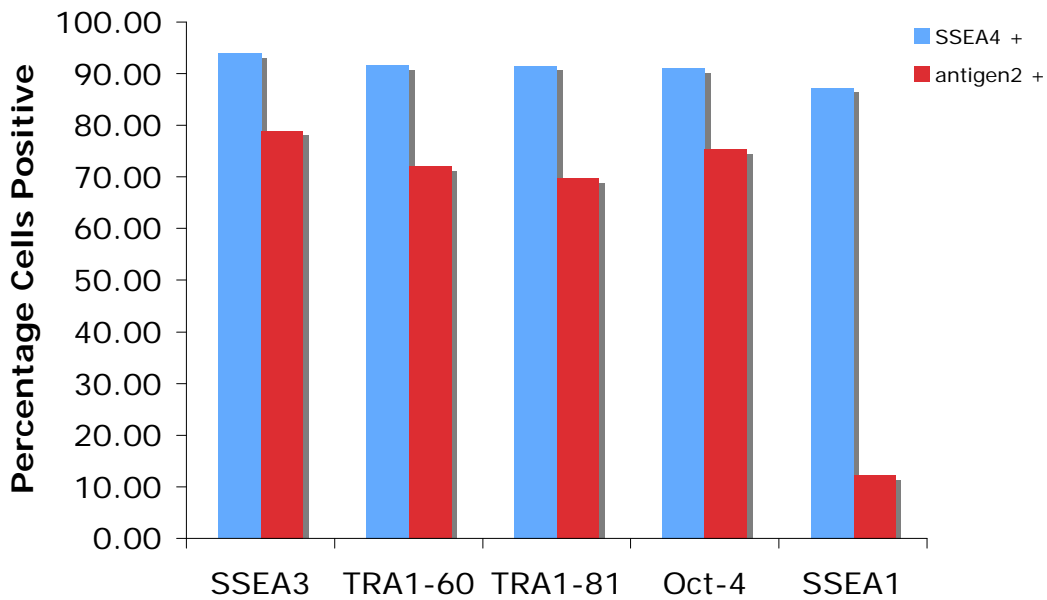
of Cells Analyzed: 8

Band Level: 425-550

Results Transmitted by Fax / Email / Post
Sent By: _____

Date: _____
Sent To: _____

<u>antigen2:</u>	SSEA4 - <u>antigen2 +</u>	SSEA4 + <u>antigen2 +</u>	SSEA4 + <u>antigen2 -</u>	SSEA4 - <u>antigen2 -</u>	ALL <u>SSEA4 +</u>	ALL <u>antigen2 +</u>
SSEA3	0.05	78.80	15.10	5.99	93.90	78.85
TRA1-60	0.18	71.80	19.90	8.10	91.70	71.98
TRA1-81	0.50	69.20	22.40	7.85	91.60	69.70
Oct-4*	0.45	74.90	16.20	8.43	91.10	75.35
SSEA1	4.19	8.01	79.30	8.51	87.31	12.20



*PE-conjugated Oct-3/4 from BD Biosciences was used (cat #560186).