



Certificate of Analysis

Thaw and Culture Details

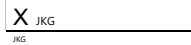
Cell Line Name	WA01	
Lot Number	DL-11	
Parent Material	WA01-DDL-13	
Provider/Client	WiCell	
Banked By	WiCell	
Thaw and Culture Recommendations	WiCell recommends thawing 1 vial into 1 well of a 6 well plate using mTeSR™ 1 and Matrigel®.	
Protocol	WiCell Feeder Independent Pluripotent Stem Cell Protocol	
Culture Platform Prior to Freeze	Medium: mTeSR™ 1	Matrix: Matrigel®
Passage Number	p26 Cells were cultured for 25 passages prior to freeze. Plated cells at thaw should be labeled passage 26.	
Date Vialied	09March2010	
Vial Label	WA01-DL-11 P26 LD 09 MAR 2010 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.	



Certificate of Analysis

Results

Test Description	Test Provider	Test Method	Test Specification	Result
Karyotype	WiCell	G-T-L Banding performed on 20 metaphase cells	Expected karyotype	See Report
	Results: 46,XY Interpretation: No clonal abnormalities were detected at the stated band level of resolution.			
Post-Thaw Viable Cell Recovery	WiCell	Thaw using specified Thaw & Culture Recommendations	≥ 15 Undifferentiated Colonies prior to passage, ≤ 30% Differentiation prior to passage, and recoverable attachment after passage	Pass
Identity by STR	UW Molecular Diagnostics Laboratory	PowerPlex 1.2 System by Promega™	Consistent with STR profile of deposited cell line	See Report
Mycoplasma	Charles River	PCR	Amplification of mycoplasma specific DNA detected with negative result	Pass
Sterility	Apptec	30744	Negative for growth following 14 days of culture	Pass

Approval Date	WiCell Quality Assurance Approval
25-July-2025	 5/29/2025 JKG WiCell Quality Assurance Signed by: Gay Jemma

Report Date: April 06, 2010

Case Details:

Cell Line: WA01-DL-11 (8656)

Passage #: 27

Date Completed: 4/6/2010

Cell Line Gender: Male

Investigator: WiCell Stem Cell Bank

Specimen: hESC on Matrigel

Date of Sample: 3/29/2010

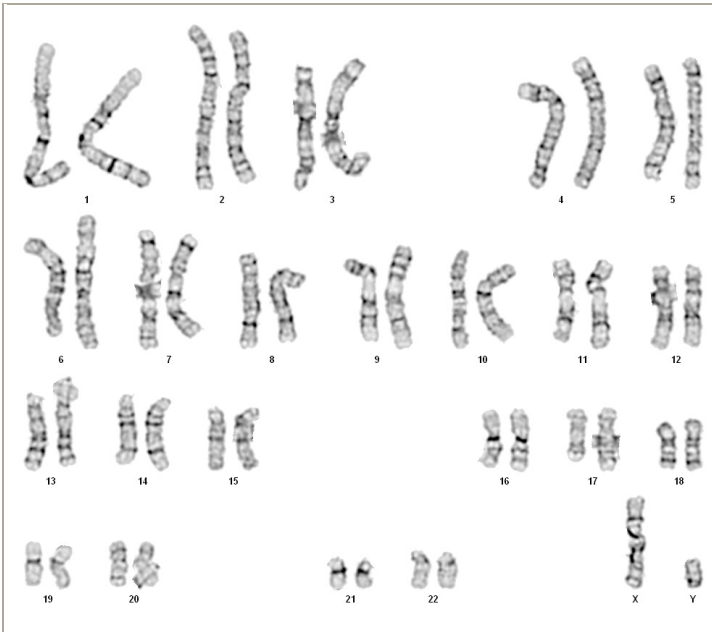
Tests, Reason for: DL testing

Results: 46,XY

Completed by Kim Leonhard, CG(ASCP), on 4/1/2010

Reviewed and interpreted by Karen Dyer Montgomery, PhD, FACMG, on 4/6/2010

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



Cell: S01-01

Slide: A-4

Slide Type: Karyotyping

of Cells Counted: 40

of Cells Karyotyped: 4

of Cells Analyzed: 8

Band Level: 475-550

Results Transmitted by Fax / Email / Post

Sent By: _____

QC Review By: _____

Date: _____

Sent To: _____

Results Recorded: _____

Short Tandem Repeat Analysis*

Sample Report: 8656-STR

UW HLA#: 62867

Sample Date: 04/02/10

Received Date: 04/02/10

Requestor: WiCell Research Institute

Test Date: 04/06/10

File Name: 100407

Report Date: 04/09/10

Sample Name: (label on tube) 8656-STR

Description: DNA Extracted by WiCell
526.8 ng/ μ L; 260/280 = 1.93

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
CSFIPO	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 8656-STR DNA dated and received on 04/02/10 from WI Cell, this sample (UW HLA# 62867) 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. These results suggest that the 8656-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%.


 4-12-10

David F. Lorentzen, Manager Date
HLA/Molecular Diagnostics Laboratory


 04/09/10

William M. Rehauer, 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.

Molecular Diagnostics Infectious Disease PCR Results Report**Sponsor: WiCell Research Institute****Accession #: 2010-020961**505 South Rosa Rd.
Suite 120
Madison, WI 53719
USA**Received:** 26 Mar 2010
Department: Approved by Alison L. Kelleher, 01 Apr 2010, 15:52***Attn:** Jessica Martin
Tel: 608-441-8019**Bill Method:** Purchase Order
Test Specimen: hES Human**Human Comprehensive Viral PCR Panel**

Sample #: Code :	<u>1</u> WA01-DL-11 5446	<u>2</u> WA17-pMCB -02 9243	<u>3</u> WA17-pMCB -03 9778
<i>John Cunningham virus</i>	-	-	-
<i>BK virus</i>	-	-	-
<i>Herpesvirus type 6</i>	-	-	-
<i>Herpesvirus type 7</i>	-	-	-
<i>Herpesvirus type 8</i>	-	-	-
<i>Parvovirus B19</i>	-	-	-
<i>Epstein-Barr Virus</i>	-	-	-
<i>Hepatitis A virus</i>	-	-	-
<i>Hepatitis B virus</i>	-	-	-
<i>Hepatitis C virus</i>	-	-	-
<i>HPV-16</i>	-	-	-
<i>HPV-18</i>	-	-	-
<i>Human T-lymphotropic virus</i>	-	-	-
<i>Human cytomegalovirus</i>	-	-	-
<i>HIV-1</i>	-	-	-
<i>HIV-2</i>	-	-	-
<i>Adeno-associated virus</i>	-	-	-
<i>Human Foamy Virus</i>	-	-	-
<i>LCMV PCR</i>	-	-	-
<i>Hantavirus Hantaan PCR</i>	-	-	-
<i>Hantavirus Seoul PCR</i>	-	-	-
<i>Mycoplasma Genus PCR</i>	-	-	-
<i>DNA Spike</i>	PASS	PASS	PASS
<i>RNA Spike</i>	PASS	PASS	PASS
<i>NRC</i>	PASS	PASS	PASS

Remarks: - = Negative; I = Inhibition, +/- = Equivocal; + = Positive.

Sample Suitability/Detection of PCR Inhibition:

Sample DNA or RNA is spiked with a low-copy number of a exogenous DNA or RNA template respectively. A spike template-specific PCR assay is used to test for the spike template for the purpose of determining the presence of PCR inhibitors. The RNA spike control is also used to evaluate the reverse-transcription of RNA. Amplification of spike template indicates that there is no detectable inhibition and the assay is valid.

NRC:

The nucleic acid recovery control (NRC) is used to evaluate the recovery of DNA/RNA from the nucleic acid isolation process. The test article is spiked with a low-copy number of DNA/RNA template prior to nucleic acid isolation. A template-specific PCR assay is used to detect the DNA/RNA spike.

Molecular Diagnostics Infectious Disease PCR Results Report

Sponsor: WiCell Research Institute

Accession #: 2010-020961

**This report has been electronically signed by laboratory personnel. The name of the individual who approved these results appears in the header of this service report. All services are performed in accordance with and subject to General Terms and Conditions of Sale found in the Charles River Laboratories-Research Models and Services catalogue and on the back of invoices.*

Report Number
833787
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WiCell Research Institute
505 S. Rosa Road
Suite 120
Madison, WI 53719

April 26, 2010
P.O. #: RP3426

Attn: Jessica Martin

STERILITY TEST REPORT

Sample Information:

hES Cells
1: WA17-pMCB-03 # 9794
2: WA17-pMCB-04 # 2169
3: TE04-MCB-02 # 9051
4: ES01-DL-02 # 0431
5: ES06-DL-06 # 0142
6: WA01-DL-09 # 2852
7: WA01-DL-10 # 4205
8: WA01-DL-11 # 7858
9: WA01-DL-12 # 6048

Date Received:

April 02, 2010

Date in Test:

April 07, 2010


Date Completed:

April 21, 2010

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	18	18
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	18 NEGATIVE	18 NEGATIVE


QA Reviewer Date


Technical Reviewer Date

Testing conducted in accordance with current Good Manufacturing Practices.

