

e Product Information and Testing

Product Information

Product Name	WA01				
Alias	H1				
Lot Number	WB0112				
Depositor	WiCell				
Banked by	WiCell				
Thaw Recommendation	Thaw 1 vial into 3 wells of a 6 well plate.				
Culture Platform	Feeder Independent				
	Medium: mTeSR1				
	Matrix: Matrigel				
Protocol	WiCell Feeder Independent Protocol				
Passage Number	p20				
	These cells were cultured for 19 passages prior to freeze, 3 of them in mTeSR1/Matrigel. WiCell adds +1 to the passage number at freeze so that the number on the vial best represents the overall passage number of the cells at thaw.				
Date Vialed	13-December-2011				
Vial Label	WB0112 WA01 p20 MW 13DEC11				
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.				

Testing Performed by WiCell

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Test Description	Test Provider	Test Method	Test Specification	Result			
Post-Thaw Viable Cell Recovery	WiCell SOP-CH-305		≥ 15 Undifferentiated Colonies, ≤ 30% Differentiation and recoverable attachment after passage	Pass			
Identity by STR	UW Molecular Diagnostics Laboratory	PowerPlex 16 HS System by Promega	Consistent with known profile	Pass			
Sterility	Apptec	30774	Negative	Pass			
Mycoplasma	WiCell	SOP-QU-004	Negative	Pass			
Karyotype by G-banding	WiCell	SOP-CH-003	Expected karyotype	Pass			

Date of Lot Release	Quality Assurance Approval		
28-October-2013	AMC AMC Quality Assurance Signed by:		



Short Tandem Repeat Analysis*

Sample Report: 10849-STR

Label on Tube: 10849-STR

Sample Date: 09/06/13

Received Date: 09/06/13

Requestor: WiCell Research Institute

Test Date: 09/11/13

File Name: 130911 STR CLN

Report Date: 09/13/13

Sample Name: (label on tube) 10849-STR

Description: DNA Extracted by WiCell

 $251.5 \text{ ng/}\mu\text{L}$; 260/280 = 1.98

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

Comments: Based on the 10849-STR DNA dated and received on 09/06/13 from WI Cell, this sample (Label on Tube: 10849-STR) matches exactly the STR profile of the human stem cell line WA01 (H1) comprising 15 allelic polymorphisms across the 8 STR loci analyzed. No STR polymorphisms other than those corresponding to the human WA01 (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 10849-STR DNA sample submitted corresponds to the WA01 (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%.





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

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.



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February 20, 2012 P.O. #:



STERILITY TEST REPORT

Sample Information:

1: WA01-WB0106 10381

6: WA01-WB0111 10386

2: WA01-WB0108 10382

7: WA01-WB0112 10387

3: WA01-pMCB-W.1 10383

8: WA01-WB0113 10388

4: iPS(IMR90)-1-MCB-01-F 10384 5: iPS(IMR90)-4-CB-02 10385

9: MIRJT7i.mND2.0-WB0119 10389

Date Received: Date in Test:

January 31, 2012 February 03, 2012

Date Completed:

February 17, 2012

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		





Testing conducted in accordance with current Good Manufacturing Practices.



Mycoplasma Report

Testing Performed by WiCell RP/LRT 10849 9-6-2013

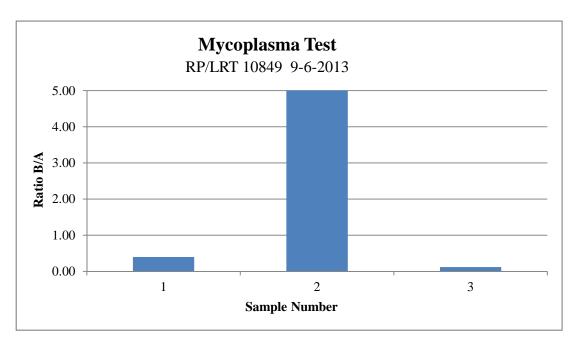
FORM SOP-QU-004.01

Version B Edition 01

Assay performed and reported by: MWS

Reviewed by: JB Equipment: Berthold

	Readi	ng A	Α	Read	ing B	В	Ratio		
Sample Number and ID	A1	A2	Average	B1	B2	Average	B/A	Mycoplasma Results	Comments/Suggestions
1 10849-WA01-WB0112-T.9	173	183	178	70	72	71	0.40	Negative	
2 Positive (+) Control	217	225	221	19030	18980	19005	86.00	Positive	
3 Negative (-) Control	488	469	478.5	55	62	58.5	0.12	Negative	





Chromosome Analysis Report: 011466

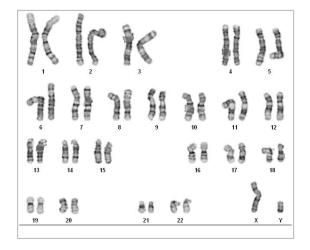
Date Reported: Tuesday, August 20, 2013

Cell Line: WA01-WB0112 10849

Passage#: 21

Date of Sample: 8/14/2013

Specimen: hESC Results: 46,XY



Cell Line Gender: Male

Reason for Testing: Lot release testing

Investigator:

Wi

WiCell CDM

Cell: 17 Slide: 2

Slide Type: Karyotype

Total Counted: 20 Total Analyzed: 8 Total Karyotyped: 4

Band Resolution: 450 - 525

Interpretation:

This is a normal karyotype. No clonal abnormalities were detected at the stated band level of resolution.

Completed by:

Reviewed and Interpreted by:

MS, CG(ASCP)
PhD, FACMG

A signed copy of this report is available upon request.

 Date:______
 Sent By:____
 Sent To:______
 QC Review By: ____

Limitations: This assay allows for microscopic visualization of numerical and structural chromosome abnormalities. The size of structural abnormality that can be detected is >3-10Mb, dependent upon the G-band resolution obtained from this specimen. For the purposes of this report, band level is defined as the number of G-bands per haploid genome. It is documented here as "band level", i.e., the range of bands determined from the four karyograms in this assay. Detection of heterogeneity of clonal cell populations in this specimen (i.e.,mosaicism) is limited by the number of metaphase cells examined, documented here as "# of cells counted".

This assay was conducted solely for listed investigator/institution. The results may not be relied upon by any other party without the prior written consent of the Director of the WiCell Cytogenetics Laboratory. The results of this assay are to be used for any other purpose, contact the Director of the WiCell Cytogenetics Laboratory.