



Product Information and Testing

Product Information


Product Name	WA14 Research Bank
Alias	H14
Lot Number	WA14-RB-005
Parent Material	CRM-WA14-MB-001
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	p24 These cells were cultured for 23 passages prior to freeze, 8 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 Viald	31-January-2013
Vial Label	WiCell WA14 Research Cell Bank WA14-RB-005 31JAN2013
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

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	Biotest Laboratories	ST/07	Negative	Pass
Mycoplasma	WiCell	SOP-QU-004	Negative	Pass
Karyotype by G-banding	WiCell	SOP-CH-003	Expected karyotype	Pass
Viable Cell Count at Thaw	WiCell	N/A	Report	Pass
Flow Cytometry	WiCell	SOP-CH-024	Report	Pass

Amendment(s):

Reason for Amendment	Date
Updated CoA to include copyright information	See signature
Original CoA	23-April-2013

Date of Lot Release	Quality Assurance Approval
23-April-2013	<div style="text-align: right;">1/10/2014</div> <div style="text-align: center;">  X AMC AMC Quality Assurance Signed by XXXXXXXXXX </div>

Short Tandem Repeat Analysis*

Sample Report: 10746-STR

Label on Tube: 10746-STR

Sample Date: 03/25/13

Received Date: 03/25/13

Requestor: WiCell Research Institute

Test Date: 03/27/13

File Name: 130328 blb

Report Date: 04/01/13

Sample Name: (label on tube)**10746-STR****Description:** DNA Extracted by WiCell

266.66 ug/mL; 260/280 = 1.97

Locus	Repeat #	STR Genotype
D16S539	5, 8-15	11,13
D7S820	6-14	10,11
D13S317	7-15	11,11
D5S818	7-15	11,13
CSF1PO	6-15	11,12
TPOX	6-13	8,8
Amelogenin	NA	X,Y
TH01	5-11	6,7
vWA	11, 13-21	15,16

Comments: Based on the 10746-STR DNA dated and received on 03/25/13 from WiCell, this sample (UW HLA# Label on Tube: 10746-STR) exactly matches the STR profile of the human stem cell line WA14 (H14) comprising 14 allelic polymorphisms across the 8 STR loci analyzed. No STR polymorphisms other than those corresponding to the human WA14 (H14) 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 10746-STR DNA sample submitted corresponds to the WA14 (H14) 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%.

Molecular Diagnostics Laboratory

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.

Biotest Laboratories, Inc.

FDA Registered
GMP

ISO 13485:2003
www.biotestlabs.com

ISO/IEC 17025:2005
EN/ISO 17665

STERILITY REPORT

WiCell Research Institute, Inc.
WiCell Quality Assurance
505 South Rosa Road
Madison, WI 53719

BIOTEST SAMPLE # 13030760

VALIDATION # NG

TEST PURPOSE NG

PRODUCT NAME Please see packing slip under product name.

PRODUCT LOT NA

STERILE LOT NA

BI LOT NA

STERILIZATION LOT NA

BI EXPIRATION DATE NA

STERILIZATION DATE NA

DATE RECEIVED 2013-03-15

STERILIZATION METHOD NA

TEST INITIATED 2013-03-15

SAMPLING BLDG / ROOM NA

TEST COMPLETED 2013-03-29

REFERENCE Processed according to SOP LAB-003: Sterility Test Procedure.

11 products were divided between 40 mL TSB and 40 mL FTG. The samples were then cultured at 20-25 C and 30-35 C respectively and were monitored for a minimum of 14 days.

- USP
 BI Manufacturers Specifications
 Other

RESULTS	# POSITIVES	# TESTED	POSITIVE CONTROL	NEGATIVE CONTROL
<input checked="" type="checkbox"/> Sterile				
<input type="checkbox"/> Non-Sterile	0	11	NA	2 Negatives
<input type="checkbox"/> NA				

COMMENTS NA

REVIEWED BY

DATE

29 MAR 13

Form: M-002 rev. 10

Effective: 21SEP12

Biotest Laboratories, Inc.

Specific test results may not be indicative of the characteristics of any other samples from the same lot or similar lots.

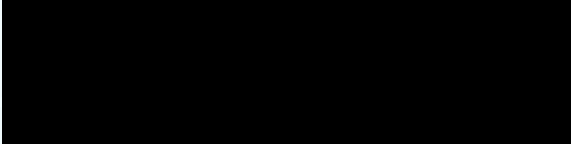
Liability is limited to the costs of the tests.

Page 1 of 1



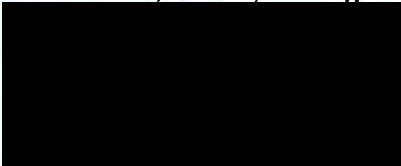
WiCell Research Institute

Packing Slip



Sent to:
Sterility Testing Services
BiotestLabs, Sterility Testing Services

Date:
12Mar13



Product Name	Condition
NSC-H9 #10724 NSC-H14 #10725 NSC-WA0195 #10726 iPS(IMR90)-1-MCB-01-F #10727 WA01-WB0197 #10728 WA01-WB0200 #10729 DF6-9-9T.B-WB0199 #10730 LT2e-H9CAGGFP #10731 WA14-RB-005 #10732 WA07-WB0209 #10733 WIZ01e-H9CAGFP-WB0210 #10734	-80

13030760 suk
MAR 15 2013



Mycoplasma Report

Testing Performed by WiCell

FORM SOP-QU-004.01

Version B

WiCell CDM/LRT #10708 WA14-RB-005-J.1 MWS 02/08/2013

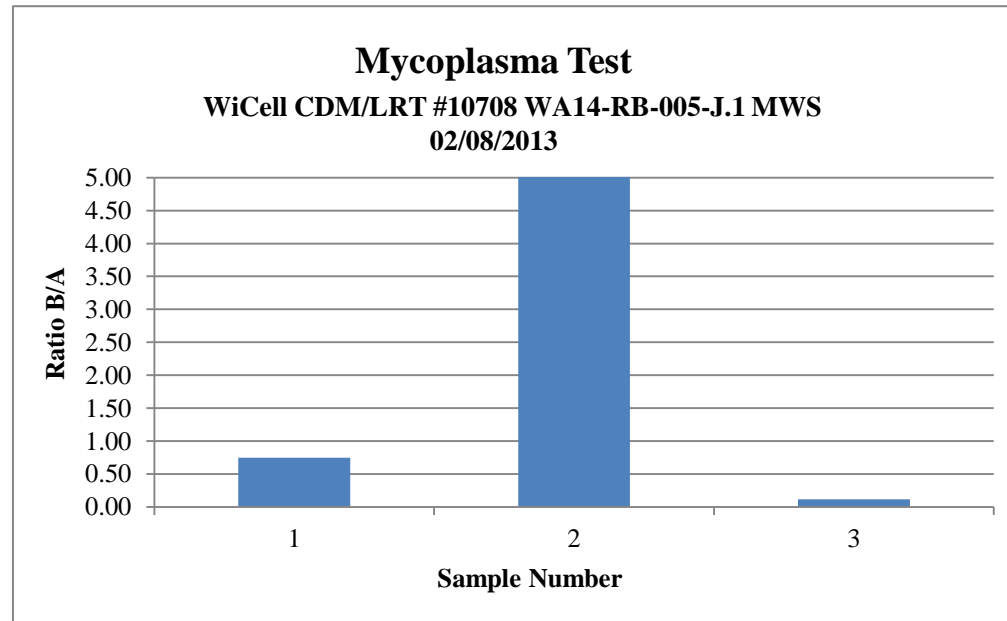
Edition 01

Assay performed and reported by: MWS

Reviewed by: JB

Equipment ID: Berthold 539

Sample Number and ID	Reading A		A Average	Reading B		B Average	Ratio B/A	Mycoplasma Results	Comments/Suggestions
	A1	A2		B1	B2				
1 LRT #10708 WA14-RB-005-J.1 MWS	146	151	148.5	114	108	111	0.75	Negative	
2 Positive (+) Control	166	155	160.5	13264	13211	13237.5	82.48	Positive	
3 Negative (-) Control	284	288	286	37	29	33	0.12	Negative	



Date Reported: Tuesday, February 26, 2013

Cell Line Gender: Male

Cell Line: WA14-RB-005 10708

Reason for Testing: Lot release testing

Passage#: 25

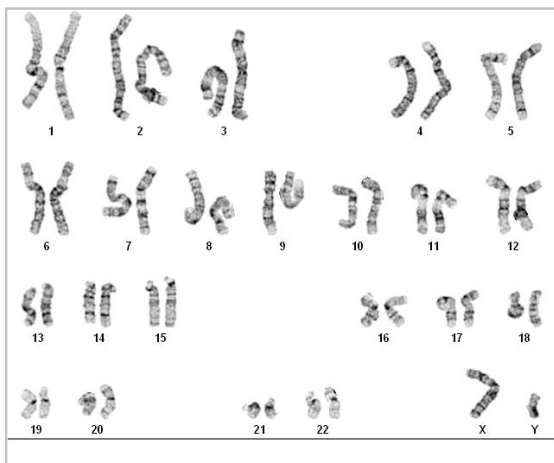
Date of Sample: 2/15/2013

Investigator: [REDACTED], WiCell CDM

Specimen: hESC

Results: 46,XY

Nonclonal findings: 46,XY,der(6)t(6;7)(p21.3;p13) 46,XY,der(4)t(4;14)(p15.2;q24.1)



Cell: 5

Slide: 1

Slide Type: Karyotype

Total Counted: 21

Total Analyzed: 8

Total Karyotyped: 5

Band Resolution: 425 - 500

Interpretation:

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

There are two nonclonal findings, listed above. Nonclonal findings likely result from technical artifact, but may be due to a developing clonal abnormality or to low-level mosaicism. Twenty additional cells were examined with no further evidence of the nonclonal aberrations.

Completed by: [REDACTED], CG(ASCP)

Reviewed and Interpreted by: [REDACTED] 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 for research use only. If the results of this assay are to be used for any other purpose, contact the Director of the WiCell Cytogenetics Laboratory.



Trypan Blue Cell Counts

Goal: Determine the total number of viable cells obtained directly from a thaw of a frozen vial of human pluripotent stem cells.

Date: April 12, 2013

Cell line: WA14-RB-005p24

Sample ID: 10758

Technician: [REDACTED]

Assay in brief:

A total of 2 frozen vials were counted separately, as follows: Thawed cells were resuspended in GMP TeSR and centrifuged at 1000RPM for 5 minutes. After centrifuge, supernatant was aspirated and the pellet was resuspended in TrypLE Select and incubated at 37 degrees for 5 minutes. The cells were then neutralized with DMEM +10%FBS, resuspended, and counted using the ViCell under standardized hES settings. Counts per replicate are indicated below.

Results:

Sample ID	Viability (%)	Total cells/vial (x10 ⁶)	Viable cells/vial (x10 ⁶)	Vial AVG (x10 ⁶)	Vial SD (x10 ⁶)	Lot AVG (x10 ⁶)	Lot SD (x10 ⁶)
WA14-RB-005 V1 #1	97.25	1.0801	1.0504	0.9811	0.0602	1.1164	0.1589
WA14-RB-005 V1 #2	96.94	0.9712	0.9415				
WA14-RB-005 V1 #3	95.05	1.0009	0.9514				
WA14-RB-005 V2 #1	93.24	1.3177	1.2286	1.2517	0.0674		
WA14-RB-005 V2 #2	93.08	1.2880	1.1989				
WA14-RB-005 V2 #3	94.37	1.4068	1.3276				

Conclusions:

WA14-RB-005 cell counts = 1.12 ± 0.16 million cells per vial.

Technician/Date

[REDACTED] 4-23-13

Supervisor/Date

[REDACTED] 4/23/13

QA Review/Date

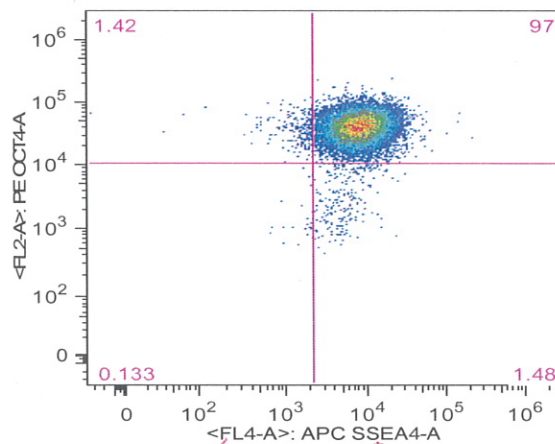
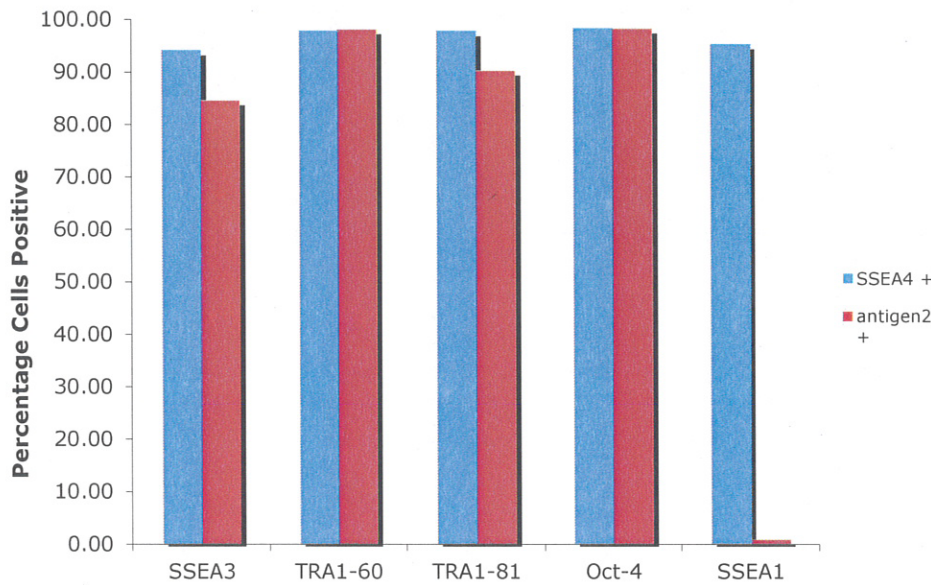
[REDACTED] 23 April 2013

Cell Line: WA14-RB-005
 Passage: 26
 Sample ID: 10746

Date: 3/28/2013
 Acquisition: 3/26/2013
 File Creation: 3/26/2013
 File Submission: 3/28/2013

<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>	Verification: <u>should be 100%</u>
SSEA3	1.95	82.70	11.50	3.89	94.20	84.65	100.04
TRA1-60	1.99	96.20	1.71	0.06	97.91	98.19	99.96
TRA1-81	1.86	88.50	9.43	0.23	97.93	90.36	100.02
Oct-4	1.41	97.00	1.48	0.13	98.48	98.41	100.02
SSEA1	0.07	0.88	94.50	4.60	95.38	0.95	100.05

Percent analyzable events: 54.20%
 #wells submitted: 6
 Total cells recovered: 19.05 X 10⁶



Report prepared By: [Redacted] Date: 03/28/13

QA review By: JLB Date: 03Apr13
 Print Date: 3/28/2013