Product Information and Testing

Product Information

Product Name	WA01 Cell Bank Produced Under cGMP Conditions
Alias	H1
Lot Number	PACT-ESC-WA01-MB-001
Parent Material	WA01-DL-11
Depositor	WiCell
Banked by	Waisman Biomanufacturing
Thaw Recommendation	Thaw 1 vial into 4 wells of a 6 well plate.
Culture Platform	Feeder Independent
	Medium: mTeSR1
	Matrix: Matrigel
Protocol	WiCell Feeder Independent mTeSR1 Protocol
Passage Number	p29 These cells were cultured for 28 passages prior to freeze, 6 of them in mTeSR1/Matrigel. One number (+1) is added 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	19-May-2010
Vial Label	Waisman Clinical Biomanufacturing Facility WA01 Master Cell Bank Lot #: PACT-ESC-WA01-MB-001 Vialed: 19 May 2010 Store in LN_2
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.

Lot Specific Testing

The following tests were performed on this specific lot.

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
Karyotype by G Band	WiCell	SOP-CH-003	Report Result	No Abnormalities
Sterility – Direct Transfer Method	Apptec	30744	No comtamination detected	Pass
Bacteriostasis & Fungistasis	Apptec	30736	Pass	Pass

General Cell Line Testing

The following tests were performed on the cell line. The tests do not apply to any particular lot.

Test Description	Test Provider	Test Method	Test Specification	Result
HLA profile	UW Molecular Diagnostics Laboratory	AlleleSEQR Kits by Abbott	Consistent with known profile	Pass
Bovine pathogens	BioReliance	032901	No contamination detected	Pass
Porcine pathogens	BioReliance	033901	No contamination detected	Pass
Retrovirus by thin section EM	WuXi Apptec	30610	No contamination detected when cultured without MEFs	Pass
Co-cultivation with Mus Dunni Cells and PG4 S+L- assay	WuXi Apptec	30201	No contamination detected	Pass
HIV 1&2 by PCR	BioReliance	105010	Negative	Pass
HTLV 1&2 by PCR	BioReliance	105013	Negative	Pass
HBV by PCR	BioReliance	105042	Negative	Pass
HCV by PCR	BioReliance	107207	Negative	Pass
CMV by PCR	BioReliance	105012	Negative	Pass
EBV by PCR	BioReliance	105011	Negative	Pass
HHV-6 by PCR	BioReliance	105020	Negative	Pass
HHV-7 by PCR	BioReliance	105029	Negative	Pass
HHV-8 by PCR	BioReliance	105056	Negative	Pass
HP B19 by PCR	BioReliance	105037	Negative	Pass
Comparative Genome Hybridization	WiCell Research Institute	SOP-CH-308 SOP-CH-309 SOP-CH-310	Report - no specification	See report
Gene Expression Profile	UW Gene Expression Center	SOP-CH-321 SOP-CH-322 SOP-CH-333 SOP-CH-311	Report - no specification	See report
ABO and rH typing	American Red Cross	ABO/rH System	Report Blood type	O+

All testing except gene expression was performed on WA01-DDL-13. WA01-DDL-13 is the parent material of WA01-DL-11. Gene expression was performed on WA01-MCB-01.

Date of Lot Release	Quality Assurance Approval
01-October-2015	10/1/2015 X AMK AMK Quality Assurance Signed by: [redacted]

Chromosome Analysis Report: 007078

Report Date: January 20, 2012

Cell Line: PACT-ESC-WA01-MB-001 10369

Passage #: 31

Date of Sample: 1/13/2012

Date Completed: 1/19/2012

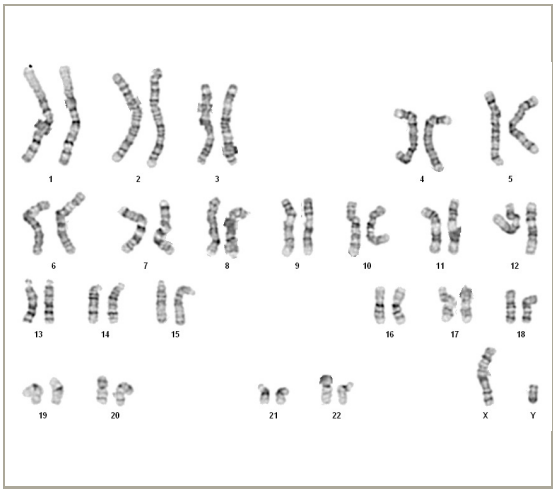
Specimen: hESC on Matrigel

Cell Line Gender: Male

Reason for Testing: Contract testing

Investigator: [redacted], Wisconsin International Stem Cell Bank

Results: 46,XY



Cell: S01-16

Slide: 1-R1 (8) KARYOTYPE

Slide Type: Karyotyping

# of Cells Counted: 20

# of Cells Karyotyped: 4

# of Cells Analyzed: 8

Band Level: 450-525

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

Completed by [redacted], CG(ASCP), on 1/19/2012
Reviewed and interpreted by [redacted], PhD, FACMG, on 1/19/2012

A signed copy of this report is available upon request.

Date:_____ **Sent To:**_____
Sent By:_____ **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.

Test Facility:
1265 Kennestone Circle
Marietta, GA 30066

WuXi AppTec

Waisman Clinical Biomanufacturing Facility
[redacted]

September 20, 2010
P.O. #: [redacted]

STERILITY TEST REPORT

Sample Information: WA01 Master Cell Bank, Lot Number PACT-ESC-WA01-MB-001

Date Received: August 31, 2010
Date in Test: September 02, 2010
Date Completed: September 16, 2010

Test Information: Test Code: 30744
Immersion, USP / 21 CFR 610.12
Procedure #: BS210WSM.204

TEST PARAMETERS	PRODUCT	
Approximate Volume Tested	1.0 mL	1.0 mL
Number Tested	1	1
Type of Media	SCD	FTM
Media Volume	200 mL	200 mL
Incubation Period	14 Days	14 Days
Incubation Temperature	20 °C to 25 °C	30 °C to 35 °C
RESULTS	1 NEGATIVE	1 NEGATIVE

ATTACH TO
F01-QCP-028-13 Dd
LMB
10/14/10

[redacted] 09-21-10
QA Reviewer Date

[redacted] 09-21-10
Technical Reviewer Date

Testing conducted in accordance with current Good Manufacturing Practices.

Test Facility:
1265 Kennestone Circle
Marietta, GA 30066

WuXi AppTec

Waisman Clinical Biomanufacturing Facility
[redacted]

September 08, 2010
P.O. #: [redacted]

GENERAL MICROBIOLOGY TEST REPORT

Sample Information: WA01 Master Cell Bank, Lot Number PACT-ESC-WA01-MB-001

Date Received: August 31, 2010
Date in Test: September 01, 2010
Date Completed: September 05, 2010

Test Information: Test Code: 30736
Sterility Method Suitability (Bacteriostasis / Fungistasis)
Immersion, USP / 21 CFR 610.12
Procedure #: BS210WSM.204
Media Volume: 200 mL
Volume Tested: 1.0 mL

SCD	*B. subtilis* ATCC 6633	*C. albicans* ATCC 10231	*A. brasiliensis* ATCC 16404
Test Sample	Positive	Positive	Positive
Inoculated Control	Positive	Positive	Positive
Inoculum Level (CFU)	12	21	27
RESULTS	PASS	PASS	PASS

FTM	*S. aureus* ATCC 6538	*K. rhizophila* ATCC 9341	*C. sporogenes* ATCC 11437
Test Sample	Positive	Positive	Positive
Inoculated Control	Positive	Positive	Positive
Inoculum Level (CFU)	42	55	9
RESULTS	PASS	PASS	PASS

Conclusion: The above test parameters do not demonstrate bacteriostatic / fungistatic activity. A sterility test performed using a media volume equal to or greater than that shown is acceptable.

Note: Reference Sterility Test Report(s): 846062

ATTACH TO E01-QCR-028-13106 LMB 10/4/10

[redacted] 09-08-10
QA Reviewer Date

[redacted] 9-08-10
Technical Reviewer Date

Testing conducted in accordance with current Good Manufacturing Practices.