Product Information and Testing - Amended

Product Information

Product Name	WA27
Lot Number	WB0138
Parent Material	WB0130
Depositor	WiCell
Banked by	WiCell
Thaw Recommendation	Thaw 1 vial into 1 well of a 6 well plate. WiCell recommends thawing using ROCK Inhibitor for best results.
Culture Platform	Feeder Independent
	Medium: E8 plus PVA
	Matrix: Recombinant Human Vitronectin
Protocol	WiCell Feeder Independent E8 Medium Protocol
Passage Number	p13 These cells were cultured for 12 passages prior to freeze. 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	20-April-2012
Vial Label	WB0138 WA27 P13 20APR12 JJ
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.

Lot Specific Testing Performed by WiCell

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	Pass
Identity by STR	UW Molecular Diagnostics Laboratory	PowerPlex 16 HS System by Promega	Consistent with known profile	Pass
Sterility - Direct transfer method	Apptec	30744	Negative	Pass
Mycoplasma	Bionique	M250	No contamination detected	Pass
Karyotype by G-banding	WiCell	SOP-CH-003	Normal karyotype	Pass

Product Information and Testing - Amended

General Cell Line Testing Performed by WiCell

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

Test Description	Test Provider	Test Method
Differentiation Potential by Teratoma	WiCell	SOP-CH-213 SOP-CH-214
HLA	UW Histocompatibility Laboratory	High resolution sequencing method with Celera reagents on the ABI 3100 instrument
ABO	New York Blood Center	For ABO: Olsson ML, Chester MA. A rapid and simple ABO genotype screening method using a novel B/O2 versus A/O2 discriminating nucleotide substitution at the ABO locus. Vox Sang 1995; 69(3):242-7. For RHD: Singleton BK, Green CA, Avent ND, Martin PG, Smart E, Daka A, Narter-Olaga EG, Hawthorne LM, Daniels G. The presence of an RHD pseudogene containing a 37 base pair duplication and a nonsense mutation in Africans with the Rh D-negative blood group phenotype. Blood 2000; 95(1): 12-8.
Growth Curve (Doubling Time)	WiCell	Varies by culture platform
Flow Cytometry for ESC Marker Expression	WiCell	SOP-CH-024
Comprehensive Human Virus Panel	Charles River	ID 91/0

Amendment(s):

Reason for Amendment	Date
CoA updated to include copyright information.	See Signature
CoA amended to include additional product information and removal of foonotes.	09-July-2013
Amended STR test method and HLA test provider and test method.	05-October-2012
Original CoA.	16-August-2012

Date of Lot Release	Quality Assurance Approval
16-August-2012	1/3/2014 X AMC AMC Quality Assurance Signed by: [redacted]

UW Health

University of Wisconsin
Hospital and Clinics

Histocompatibility/Molecular Diagnostics Laboratory

[redacted]

Short Tandem Repeat Analysis*

Sample Report: 10459-STR Label on Tube: 10459-STR Sample Date: 05/11/12
Lab Received 05/11/12

Requestor: WiCell Research Institute

Test Date: 05/16/12 File Name: 120517 Report Date: 05/21/12

Sample Name: (label on tube) 10459-STR

Description: WI Cell Research Institute provided genomic DNA
262 ug/mL 260/280=1.97

Locus	Repeat #	STR Genotype
D16S539	5, 8-15	12,13
D7S820	6-14	10,10
D13S317	7-15	11,11
D5S818	7-15	11,12
CSF1PO	6-15	11,13
TPOX	6-13	8,10
Amelogenin	NA	X,X
TH01	5-11	6,8
vWA	11, 13-21	16,18

Comments: Based on the 10459-STR DNA submitted by WI Cell dated and received on 05/11/12, this sample (Label on Tube Cap only: 10459-STR) exactly matches the STR profile of the human stem cell line WA27 comprising 14 allelic polymorphisms across the 8 STR loci analyzed. No STR polymorphisms other than those corresponding to the human WA27 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. This result suggests that the 10459-STR DNA sample submitted corresponds to the WA27 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%.

[redacted]
Molecular Diagnostics Laboratory

[redacted]
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

Test Facility:
[redacted]

WuXi AppTec

Report Number
900594
Page 1 of 1

WiCell Research Institute
[redacted]

June 12, 2012
P.O. #: [redacted]

STERILITY TEST REPORT

Sample Information: Stem Cells

1: WA27-WB0130 10504
2: WA26-WB0131 10505
3: WA25-WB0132 10506
4: WA25-WB0127 10507
5: WA26-WB0128 10508
6: WA27-WB0138 10509
7: WA26-WB0152 10514
8: WA25-WB0151 10512
9: WA09-WB0143 10521
10: WA09-WB0139 10520
11: WA27-WB0150 10522
12: H9 hOct4-pGZ-WB0140 10518
13: MIRJT6i-mND1-4-WB0142.10519

Date Received: May 23, 2012
Date in Test: May 29, 2012
Date Completed: June 12, 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	26	26
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	26 NEGATIVE	26 NEGATIVE

[redacted]
QA Reviewer **Date**

[redacted]
Technical Reviewer **Date**

Testing conducted in accordance with current Good Manufacturing Practices.

[redacted]

Document ID #:	DCF9002F
Title:	QUALITY ASSURANCE REPORT - GMP
Effective Date:	11/2/11
Edition #:	03

QUALITY ASSURANCE REPORT – GMP

TEST PERFORMED	PROCEDURAL REFERENCE	TEST PERFORMED	PROCEDURAL REFERENCE
[X] M-250	SOP's 3008, 3011, 3013	[ ] M-700	SOP's 3008, 3009, 3010
[ ] M-300	SOP's 3008, 3014	[ ] M-800	SOP's 3008, 3011, 3016
[ ] M-350	SOP's 3008, 3014, 3015		

Bionique Sample ID #(s) 69816

This testing procedure was performed in compliance with the FDA's Current Good Manufacturing Practice (cGMP) standards (to the extent that the regulations pertain to the procedures performed) as specified in the Code of Federal Regulations, Title 21 Parts 210 and 211 [21 CFR 210 & 211]. All related records derived from the test procedures have been reviewed by the Quality Assurance Department. The individual's signature below verifies that the methods and procedures referenced above have been followed and that the Final Report accurately reflects the raw data generated during the course of the procedures. All records, including raw data and final reports are archived on site for a minimum of seven years.

The specified test's procedures determine the intervals at which samples are inspected. The medium used for testing must pass quality control mycoplasmal growth promotion testing and sterility testing. Traceability of all of the components used is assured and supporting documentation can be supplied upon request.

Quality Assurance Review Date: 6/6/12

Reviewed By [redacted] QA Assistant: [redacted]

NOTE:

1. Prior to receipt at Bionique® Testing Laboratories, Inc., the stability of the test article is the responsibility of the company submitting the sample. Bionique Testing Laboratories Inc. will assume responsibility for sample stability following receipt and prior to being placed on test.
2. This test is for the detection of microbiological growth and does not require statistical validation.

REFERENCES

Regulatory:

1. Department of Health and Human Services, Food and Drug Administration (USA) [FDA]. Code of Federal Regulations [CFR], Title 21 CFR Part 210, Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General. FDA. Office of the Federal Register, National Archives and Records Department.
2. Department of Health and Human Services, Food and Drug Administration (USA) [FDA]. Code of Federal Regulations [CFR], Title 21 CFR Part 211, Current Good Manufacturing Practice for Finished Pharmaceuticals. FDA. Office of the Federal Register, National Archives and Records Department.
3. Department of Health and Human Services, Food and Drug Administration (USA) [FDA]. Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals, Director, Center for Biologics Evaluation and Research, FDA. May, 1993. Docket No. 84N-0154.
4. Department of Health and Human Services, Food and Drug Administration (USA) [FDA]. Code of Federal Regulations [CFR], Title 21 CFR Part 610.30, General Biological Products Standards; Subpart D, Test for Mycoplasma. FDA. Office of the Federal Register, National Archives and Records Department.

General:

1. Barile MF, Kern J. Isolation of Mycoplasma arginini from commercial bovine sera and its implication in contaminated cell cultures. Proceedings of the Society for Experimental Biology and Medicine, Volume 138, Number 2, November 1971.
2. Chen, T.R. In situ detection of mycoplasma contamination in cell cultures by fluorescent Hoechst 33258 stain. Experimental Cell Research, 104: 255-262, 1977.
3. Carolyn K. Lincoln and Daniel J. Lundin. Mycoplasma Detection and Control. U. S. Fed. for Culture Collections Newsletter, Vol. 20, Number 4, 1990.
4. Fetal Bovine Serum; Proposed Guideline. National Committee For Clinical Laboratory Standards (NCCLS), Vol. 10, Number 6, 1990. (NCCLS publication M25-P).
5. McGarrity GJ, Sarama J, Vanaman V. Cell Culture Techniques. ASM News, Vol. 51, No. 4, 1985.
6. Tully JG, Razin S. Methods in Mycoplasmology, Volumes I and II. Academic Press, N.Y., 1983.
7. Barile MF, Razin S, Tully JG, Whitcomb RF. The Mycoplasmas, Volumes 1-4. Academic Press, N.Y., 1979.
8. http://www.bionique.com/ - Safe Cells Insights

bionique Testing Laboratories

MYCOPLASMA TESTING SERVICES

BIONIQUE TESTING LABORATORIES, INC

[redacted]

APPENDIX IV

Document#: DCF3013D
Edition#: 10
Effective Date: 07/15/2003
Title: **M-250 FINAL REPORT SHEET**

M-250 FINAL REPORT

Direct Specimen Culture
Procedure 3008, 3011, 3013

TO: **WiCell QA**
WiCell Research Institute

[redacted]

BTL SAMPLE ID#: **69816** P.O.#: [redacted] DATE REC'D: **05/08/2012**

TEST/CONTROL ARTICLE:

WA27-WB0138 #10459

LOT#: **NA**

DIRECT CULTURE SET-UP (DAY 0) DATE: **05/09/2012**

INDICATOR CELL LINE (VERO) SEE DNA FLUOROCHROME RECORD SHEET

			DATE
THIOGLYCOLLATE BROTH	DAY 7	+ (−)	05/16/2012
	DAY 28	+ (−)	06/06/2012
BROTH-FORTIFIED COMMERCIAL			
0.5 mL SAMPLE	DAY 7	+ (−)	05/16/2012
6.0 mL BROTH	DAY 28	+ (−)	06/06/2012
BROTH-MODIFIED HAYFLICK			
0.5 mL SAMPLE	DAY 7	+ (−)	05/16/2012
6.0 mL BROTH	DAY 28	+ (−)	06/06/2012
BROTH-HEART INFUSION			
0.5 mL SAMPLE	DAY 7	+ (−)	05/16/2012
6.0 mL BROTH	DAY 28	+ (−)	06/06/2012

(See Reverse)

Document#: DCF3013D
Edition#: 10
Effective Date: 07/15/2003
Title: M-250 FINAL REPORT SHEET

SAMPLE ID#: **69816**		AEROBIC	MICROAEROPHILIC	DATE
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ (−)	+ (−)	05/16/2012
	DAY 14	+ (−)	+ (−)	05/23/2012
	DAY 21	+ (−)	+ (−)	05/30/2012
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ (−)	+ (−)	05/16/2012
	DAY 14	+ (−)	+ (−)	05/23/2012
	DAY 21	+ (−)	+ (−)	05/30/2012
AGAR PLATES-HEART INFUSION	DAY 7	+ (−)	+ (−)	05/16/2012
	DAY 14	+ (−)	+ (−)	05/23/2012
	DAY 21	+ (−)	+ (−)	05/30/2012
BROTH SUBCULTURES (DAY 7)		DATE: **05/16/2012**		
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ (−)	+ (−)	05/23/2012
	DAY 14	+ (−)	+ (−)	05/30/2012
	DAY 21	+ (−)	+ (−)	06/06/2012
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ (−)	+ (−)	05/23/2012
	DAY 14	+ (−)	+ (−)	05/30/2012
	DAY 21	+ (−)	+ (−)	06/06/2012
AGAR PLATES-HEART INFUSION	DAY 7	+ (−)	+ (−)	05/23/2012
	DAY 14	+ (−)	+ (−)	05/30/2012
	DAY 21	+ (−)	+ (−)	06/06/2012

RESULTS: No detectable mycoplasmal contamination

6/6/12
Date

[redacted]

ADDITIONAL COMMENTS:

M-250 Procedural Summary: The objective of this test is to ascertain whether or not detectable mycoplasmas are present in an in vitro cell culture sample, be it a primary culture, hybridoma, master seed stock or cell line. This procedure combines an indirect DNA staining approach to detect non-cultivable mycoplasmas with a direct culture methodology utilizing three different mycoplasmal media formulations. The indirect approach involves the inoculation of the sample into a mycoplasma-free VERO (ATCC) indicator cell line and performing a DNA fluorochrome assay after 72-120 hours of incubation. The direct culture aspect of the test utilizes three different mycoplasmal media including both broth and agar formulations. The sample is inoculated into each of the 3 broth formulations and also onto duplicate plates (0.1 mL/plate) for each of the 3 agar formulations. Subculture from broth to fresh agar plates is carried out after 7 days incubation. Agar plates are incubated aerobically and microaerophillically in order to detect any colony forming units morphologically indicative of mycoplasmal contamination. Issuance of the final report with signature of the Laboratory Director signifies that the required controls were performed concurrently with the test sample(s) as detailed in the referenced SOPs and that all test conditions have been found to meet the required acceptance criteria for a valid test, including the appropriate results for the positive and negative controls.

bionique Testing Laboratories

MYCOPLASMA TESTING SERVICES

BIONIQUE® TESTING LABORATORIES, INC.

[redacted]

Document ID #:	DCF3008A
Title:	**DNA FLUOROCHROME ASSAY RESULTS**
Effective Date:	3/24/10
Edition #:	07

DNA-FLUOROCHROME ASSAY RESULTS

Procedures 3008, 3009, 3011

Sample ID # **69816** **M-250** Date Rec'd: **05/08/2012** P.O. # [redacted]

Indicator Cells Inoculated: Date/Initials: 5/10/12 / MK

Fixation: Date/Initials: 5/14/12 / HS

Staining: Date/Initials: 5/14/12 / HS

TEST/CONTROL ARTICLE:

SM 5/10/12

WA27-~~WB0130~~ W130138 #10459

LOT# **NA**

WiCell QA
WiCell Research Institute

[redacted]

[redacted]

DNA FLUOROCHROME ASSAY RESULTS:

X **NEGATIVE:** A reaction with staining limited to the nuclear region, which indicates no mycoplasmal contamination.

_____ **POSITIVE:** A significant amount of extranuclear staining which strongly suggests mycoplasmal contamination.

_____ **INCONCLUSIVE:**

_____ A significant amount of extranuclear staining consistent with low - level mycoplasmal contamination or nuclear degeneration.

_____ A significant amount of extranuclear staining consistent with bacterial, fungal or other microbial contaminant or viral CPE. Morphology not consistent for mycoplasmal contamination.

COMMENTS:

Date: 5/14/12 Results Read by: HS Date of Review: 5/17/12 Reviewed by: SM

Updated Chromosome Analysis Report: 008095

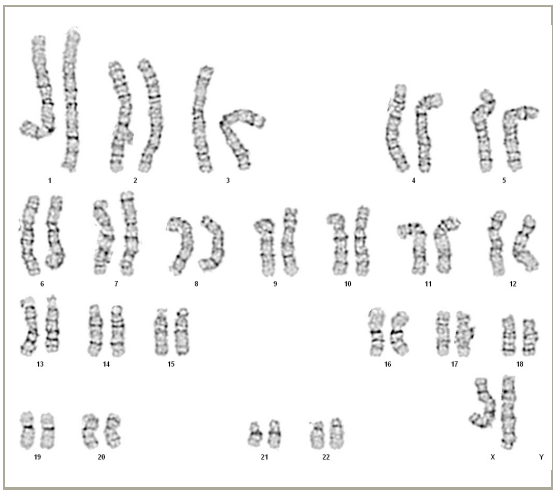
This report is updated to include the results of counting an additional twenty cells in this analysis, as requested by [redacted]

Report Date: May 25, 2012
Updated Report Date: June 26, 2012

Cell Line: *WA27-WB0138 10459*
Passage #: *15*
Date of Sample: *5/7/2012*
Date Completed: *5/25/2012*

Specimen: *hESC on Vitronectin*
Cell Line Gender: *Female*
Reason for Testing: *lot release testing*
Investigator: *[redacted], Core*

Results: *46,XX*



Cell: *S02-22*
Slide: *2-R1(19)KARYOTYPE*
Slide Type: *Karyotyping*

# of Cells Counted: *20; an additional 20 cells were counted for this update*
# of Cells Karyotyped: *4*
# of Cells Analyzed: *8*
Band Level: *450-550*

Interpretation:
No abnormalities were detected at the stated band level of resolution.
Updated Interpretation: ***Chromosomes from an additional twenty cells were counted; there were no abnormalities found.***

Completed by [redacted], CG(ASCP), on 5/21/2012
Reviewed and interpreted by [redacted], PhD, FACMG, on 5/25/2012

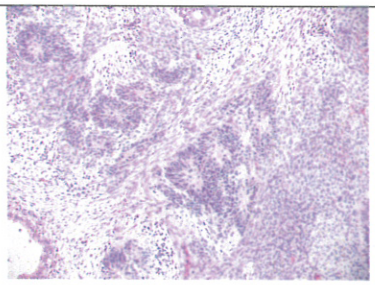
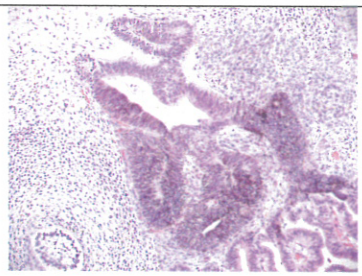
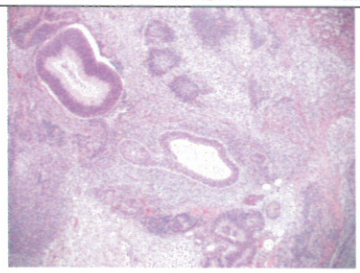
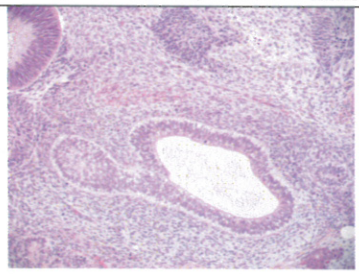
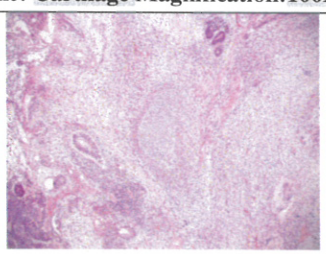
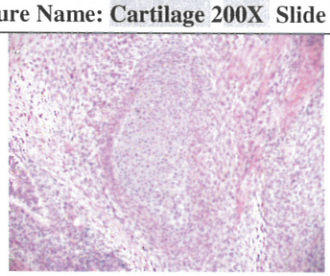
A signed copy of this report is available upon request.

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.

Cell Line: WA27 **Cell Lot Number: NA** **Sample Number: 10447-A**

ECTODERM	
Structure Name: Neural tubules Magnification:200X Slide ID: A	**Structure Name: Pigmented neuroectoderm Magnification: 200X Slide ID: A**
	
ENDODERM	
Structure Name: Respiratory Magnification:100X Slide ID: A	**Structure Name: Respiratory Magnification:200X Slide ID: A**
	
MESODERM	
Structure Name: Cartilage Magnification:100X Slide ID: A	**Structure Name: Cartilage 200X Slide ID: A**
	

Comments: Structures identified include Ectoderm (2), Mesoderm (1) and Endoderm (1)

Sample(s) were assessed for the presence of differentiation into cell types characteristic of the three embryonic germ layers, which, if present in the sample(s) examined, are represented in the photographs above. The individual's signature below verifies that this report accurately reflects the pathology observed.

Pathologist (By/Date): 6/27/2012

[redacted]

QA Review (By/Date): [redacted] 03JUL12 X error 03JUL12 JKT

①SOP ID SOP-CH-214. Error 03JUL12 JKT

UW Health

University of Wisconsin
Hospital and Clinics

Name: WICELL, 10406_HLA
MRN: OS000184
DOB:
HLA#: WICELL

Hospital:
Physician: ,
Category:

Bone Marrow Case Histocompatibility Summary
301417-DT

HLA Typing Results

Patient	Relation	Hap	A*	B*	C*	DRB1*	DRB3*	DRB4*	DRB5*	DQB1*	DPB1*	Tested Date / Collect Date
WICELL, 10406_HLA			02:01	41:02	05:01	03:01						03/12/12
OS000184 / WICELL	Patient		66:01	44:02:01G	17:01:01G	04:01						03/01/12

HLA typings performed by sequencing, SSO, SSP or a combination. For low-resolution testing, results are reported by Serologic Equivalents. A "+" in the HLA allele designation indicates that the typing was performed by low/mid-resolution molecular method and that additional alleles are possible. Only the most frequent allele is listed.

HLA DNA-Based Typing

Name / HLA / MR# / Received	Method / Test Date	A*	B*	C*	DRB1*	DRB3*	DRB4*	DRB5*	DQB1*
WICELL, 10406_HLA		02:01							
OS000184 / WICELL	SEQ	66:01							
03/01/2012	03/20/2012								
		HLA Allele database: IMGT 3.7.0 2012-01-12							
			41:02						
	SEQ		44:02:01G						
03/01/2012	03/20/2012								
		HLA Allele database: IMGT 3.7.0 2012-01-12 The reported allele group B*44:02:01G includes the following alleles, which share identical sequences in the antigen recognition site of exons 2 and 3: B*44:02 B*44:19N							
				05:01					
	SEQ			17:01:01G					
03/01/2012	03/20/2012								
		HLA Allele database: IMGT 3.7.0 2012-01-12 The reported allele group C*17:01:01G includes the following alleles, which share identical sequences in the antigen recognition site of exons 2 and 3: C*17:01 C*17:02 C*17:03 The following allele combination(s), in which both alleles are listed by the ASHI CWD review committee as rare or not well defined, cannot be excluded: C* 05:29.17:05.							
					03:01				
	SEQ				04:01				
03/01/2012	03/20/2012								
		HLA Allele database: IMGT 3.7.0 2012-01-12 Cannot rule out the rare allele DRB1*03:68N, first identified in August 31, 2011.							

Comments

UW Health

University of Wisconsin
Hospital and Clinics

Name:	WICELL, 10406_HLA	Hospital:	
MRN:	OS000184	Physician:	,
DOB:		Category:	
HLA#:	WICELL		

Bone Marrow Case Histocompatibility Summary

301417-DT

This test was developed and its performance characteristics determined by this laboratory. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity clinical laboratory testing.

Electronically signed by
Kathleen J. Meuer, MT(ASCP), CHT(ABHI) 03/25/2012 12:18

Director or Delegate, HLA Laboratory — Date/Time

Histocompatibility Laboratory, Room D4/231, 600 Highland Ave., Madison, WI 53792-2472
Teresa Darcy, MD, Medical Director :: Thomas M. Ellis, PhD, D(ABHI) Laboratory Director
Lab: 608.263.8815 (option 3); Fax: 608.263.9610
ASHI: 01-4-WI-03-2, CLIA: 52DO661997

New York *Blood Center*
Laboratory of Immunohematology and Genomics
45-01 Vernon Blvd., Long Island City, N.Y. 11101
718-752-4771 • Fax 718-752-4747

March 20, 2012

WiCell Research Institute
Attn: Quality Assurance
[redacted]

SAMPLE: DNA WA27 #10406 (MA#168-12)

Date Received: 03/08/12
Sample Date: 03/01/12

HISTORY: DNA from cell line.

TESTING REQUESTED: Genotype for *ABO* and common *RH*

TESTING PERFORMED: *ABO:* Polymerase chain reaction-restriction fragment length polymorphism (PCR-RFLP) testing for nucleotide (nt) positions 261 (O^1), 467 (A^2), 703 (B), and 1096 (B and O^2). *RH:* Multiplex PCR-RFLP for *RHD* and *RHCE*C/c*. PCR-RFLP for RHCE Exon 5 (676C>G for E/e).

DNA MOLECULAR RESULTS: *ABO:* PCR-RFLP testing indicates the presence of a nt261 deleted G, characteristic of O^1 alleles, and the presence of nt703A and nt1096A, characteristic of B alleles. *RH: RHD* exons 4 and 7 are present. Negative for the inactivating *RHD* pseudogene. *RH*Cc* and *RH*ee.*

	Genotype	Predicted Phenotype
WA27 #10406:	*ABO*BO^1; RH*D, RH*Cc, RH*ee*	**Group B; RhD**+, C+E–c+e+

[redacted]
Manager, Genomics

[redacted]
Director of Immunohematology and Genomics

These *in vitro* diagnostic tests were developed and their performance characteristics established in the Molecular Analysis Laboratory. The tests have not been submitted to the Food and Drug Administration (FDA) for clearance or approval and; therefore, are not FDA-licensed tests. The Molecular Analysis Laboratory is certified under the Clinical Laboratory Improvement Amendment (CLIA) of 1988 as qualified to perform high complexity clinical testing. The New York Blood Center has been approved by the New York State Department of Health to perform these tests under its current Clinical Laboratory Permit.

These results are intended to predict a blood group antigen profile in a patient or donor, and are not intended for clinical diagnosis or as the sole means for patient management decisions. There are situations where testing DNA of a person may not reflect the red cell phenotype and not all performance characteristics have been determined. Nucleotide changes that inactivate gene expression or rare new variant alleles may not be identified in these assays. In addition, test results obtained from DNA isolated from leucocytes and other hematopoietic cells may differ from DNA isolated from other tissues in persons with a history of transplantation.

NewYork BloodCenter

Immunohematology
Telephone: 718-752-4771
Genomics
Telephone: 718-752-4637

Sample: MA168-12; WA27 #10406

Test: ABO and RH - GF

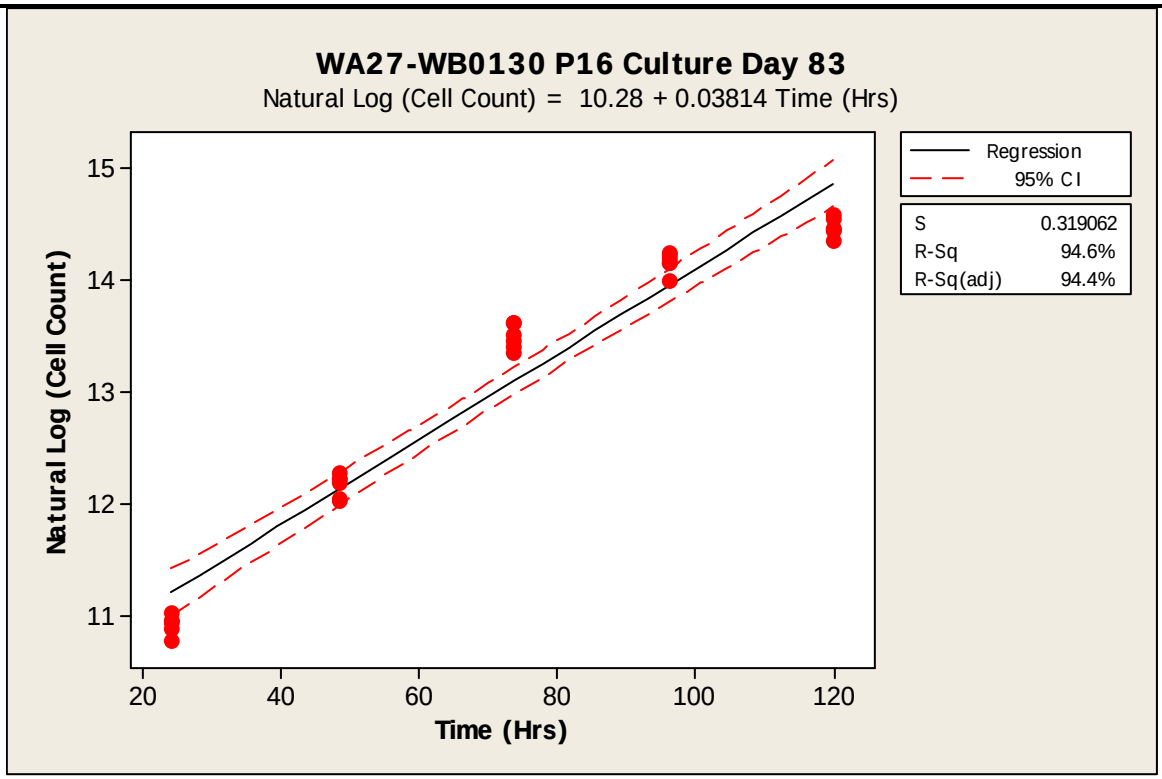
CPT CODE	Description/Molecular Testing	ABO/RH
83892	Enzymatic digestion	X2
83894	Separation by electrophoresis	x3
83898	Amplification each nucleic acid seq	x3
83912	Interpretation and report	X1

Characterization Report- Growth Characteristics

Sample ID	Cell Line	Cell lot #	Passage	Culture Day	Medium	Matrix	Passaging Additive
10450	WA27	WB0130	16	83	E8 + PVA	rh-Vitronectin	Rho-kinase Inhibitor Y-27632

Documentation of Growth Assay Data	Notebook #	Page(s)	Date Initiated
	148	73-81	02MAY12

Growth Assay Performed by	Report Prepared by	Date	QA Reviewed by	Date
WiCell Derivation Laboratory	LAN	14AUG12	JKT	15Aug12



Regression Analysis:
Natural Log (Cell Count) versus Time (Hrs)

The regression equation is Natural Log (Cell Count) = 10.3 + 0.0381 Time (Hrs)

Predictor	*Coef*	*SE Coef*	*T*	*P*
Constant	10.2842	0.1371	75.00	0.000
Time (Hrs)	0.038136	0.001715	22.24	0.000

S = 0.319062 **R-Sq** = 94.6% **R-Sq(adj)** = 94.4%

Analysis of Variance

Source	*DF*	*SS*	*MS*	*F*	*P*
Regression	1	50.331	50.331	494.41	0.000
Residual Error	28	2.850	0.102		
Total	29	53.181			

Slope ± 95% C.I

0.0381 ± 0.0035

Apparent Doubling Time (hours) ± 95% C.I.

18.18 ± 2.05

Apparent Doubling Time (95% C.I.)

16.64 hours – 20.02 hours

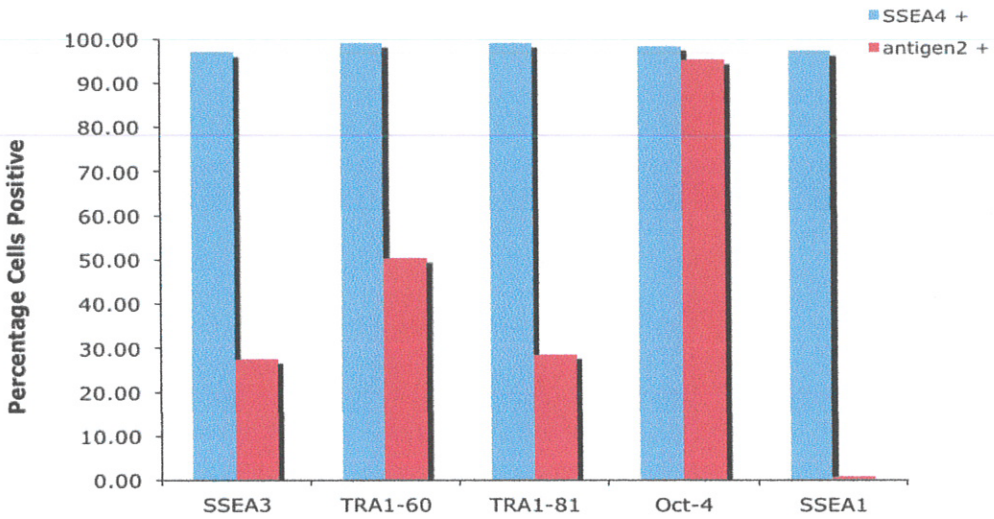
Procedure performed: **Cell line: WA27**
Passage P15
Sample ID: 10450

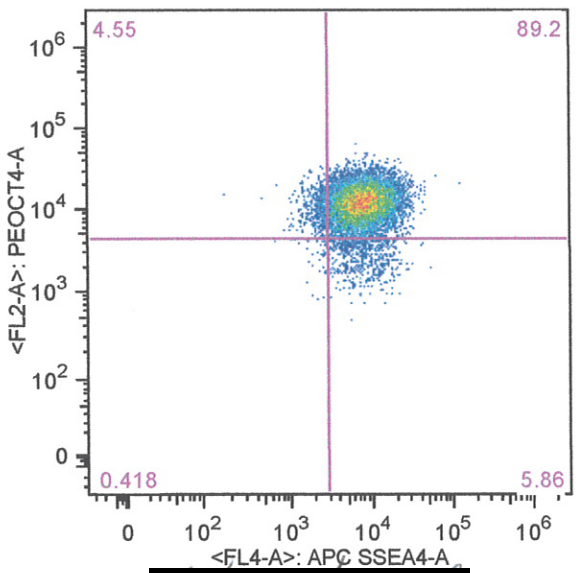
Date of: *(05/05/12)*
acquisition:
file creation:
file submission:

PERCENTS

antigen2:	SSEA4 - antigen2 +	SSEA4 + antigen2 +	SSEA4 + antigen2 -	SSEA4 - antigen2 -	ALL SSEA4 +	ALL antigen2 +
SSEA3	0.37	10.30	78.80	10.50	89.10	10.67
TRA1-60	3.00	64.00	30.60	2.36	94.60	67.00
TRA1-81	2.26	44.00	50.00	3.79	94.00	46.26
Oct-4	4.57	89.2	5.85	0.42	95.05	93.77
SSEA1	0.31	3.08	89.10	7.51	92.18	3.39

Percent analyzable events: 27.9
#wells submitted: 6
Total # cells analyzed: 10.7 X 10^6





prepared by [redacted]
10450 *(signature)*

Charles River Research Animal Diagnostic Services

[redacted]

Sponsor: WiCell Research Institute **Accession #: 2012-015912**

Diagnostic Summary Report

[redacted]

Received: 20 Mar 2012
Approved: 27 Mar 2012, 13:11

Bill Method: [redacted]
Test Specimen: Human

Sample Set	Service (# Tested)	Profile	Assay	Tested	+	+/-	?	PDG
#1	Infectious Disease PCR (3)	All Results Negative						

+ = Positive, +/- = Equivocal, ? = Indeterminate, PDG = Pending

Service Approvals

Service	Approved By*	Date
Infectious Disease PCR	[redacted]	27 Mar 2012, 13:11

To assure the SPF status of your research animal colonies, it is essential that you understand the sources, pathobiology, diagnosis and control of pathogens and other adventitious infectious agents that may cause research interference. We have summarized this important information in infectious agent **Technical Sheets**, which you can view by visiting http://www.criver.com/info/disease_sheets.

**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.*

Charles River Research Animal Diagnostic Services
[redacted]

Sponsor: WiCell Research Institute **Accession #: 2012-015912**

Product: Not Indicated **Test Specimen:** Human **Received:** 20 Mar 2012

Molecular Diagnostics Infectious Disease PCR Results Report

Department Review: Approved by [redacted] 27 Mar 2012, 13:11*

Human Comprehensive Virus Panel

Sample #: / Code :	1 WA25-WB0132 10429	2 WA26-WB0131 10430	3 WA27-WB0130 10431
John Cunningham virus	-	-	-
BK virus	-	-	-
Herpesvirus type 6	-	-	-
Herpesvirus type 7	-	-	-
Herpesvirus type 8	-	-	-
Parvovirus B19	-	-	-
Epstein-Barr Virus	-	-	-
Hepatitis A virus	-	-	-
Hepatitis B virus	-	-	-
Hepatitis C virus	-	-	-
HPV-16	-	-	-
HPV-18	-	-	-
Human T-lymphotropic virus	-	-	-
Human cytomegalovirus	-	-	-
HIV-1	-	-	-
HIV-2	-	-	-
Adeno-associated virus	-	-	-
Human Foamy Virus	-	-	-
LCMV PCR	-	-	-
Hantavirus Hantaan PCR	-	-	-
Hantavirus Seoul PCR	-	-	-
Mycoplasma Genus PCR	-	-	-
DNA Spike	**PASS**	**PASS**	**PASS**
RNA Spike	**PASS**	**PASS**	**PASS**
NRC	**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.

**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.*