Certificate of Analysis - Amended

Product Description	WA23	
Cell Line Provider	WiCell Research Institute	
Parent Material	This material descended from derivation.	
Lot Number	WB0069	
Date Vialed	13-November-2010	
Passage Number	p10	
Culture Platform	Feeder Free	
	Medium: Conditioned Medium	Matrix: Matrigel

The following testing specifications have been met for the specified product lot[1]:

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 1.2 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

[1]This cell line, but not this particular lot of material, was also tested for human virsues via Charles River's Comprehensive Human Virus Panel.

Cells distributed by WiCell are intended for research purposes only and are not intended for use in humans.

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.

Amendment(s):

Reason for Amendment	Date
CoA updated to include copyright information and update logo.	See signature
Original CoA	14-March-2012

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

©2012 WiCell Research Institute The material provided under this certificate has been subjected to the tests specified and the results and data described herein are accurate based on WiCell's reasonable knowledge and belief. Appropriate Biosafety Level practices and universal precautions should always be used with this material. For clarity, the foregoing is governed solely by WiCell's Terms and Conditions of Service, which can be found at http://www.wicell.org/privacyandterms.

UW Health
University of Wisconsin
Hospital and Clinics

Histocompatibility/Molecular Diagnostics Laboratory
D4/231; (608) 263-8815
600 Highland Avenue
Madison, WI 53792-2472

Short Tandem Repeat Analysis*

Sample Report: 10209-STR UW HLA#: 65915 Sample Date: 08/26/11
Received Date: 08/26/11

Requestor: WiCell Research Institute
Test Date: 08/30/11 File Name: 110830_cln Report Date: 09/02/11

Sample Name: (label on tube) **10209-STR**

Description: WiCell Research Institute provided genomic DNA
116.1 ug/mL; 260/280 = 1.88

Locus	Repeat #	STR Genotype
D16S539	5, 8-15	12,13
D7S820	6-14	8,10
D13S317	7-15	12,12
D5S818	7-15	11,13
CSF1PO	6-15	11,11
TPOX	6-13	8,9
Amelogenin	NA	X,Y
TH01	5-11	9,9.3
vWA	11, 13-21	17,17

Comments: Based on the 10209-STR DNA dated and received on 08/26/11 from WiCell Research Institute, this sample (UW HLA# 65915) exactly matches the STR profile of the human stem cell line WA23 comprising 13 allelic polymorphisms across the 8 STR loci analyzed. No STR polymorphisms other than those corresponding to the human WA23 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 10209-STR DNA sample submitted corresponds to the WA23 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%.

9/7/11
Keith Challoner, Manager Date
Molecular Diagnostics Laboratory

09/06/11
William M. Rehrauer, PhD, Director Date
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:
1265 Kennestone Circle
Marietta, GA 30066

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.

WuXi AppTec

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

Attn: Jessica Martin

December 12, 2011
P.O. #: 12-0225

STERILITY TEST REPORT

Sample Information:

1: WA07-CB-01 10297
2: WA14-WB0022 10298
3: WA13.C-CB-01 10299
4: WA23-WB0099 10300
5: WA23-WB0101 10301
6: WA23-WB0069 10302
7: Pt2K-CS011 10303

Date Received: November 17, 2011
Date in Test: November 22, 2011
Date Completed: December 06, 2011

Test Information:

Test Codes: 30744, 30744A
Immersion, USP / 21 CFR 610.12
Procedure #: BS210WCR.201

TEST PARAMETERS	PRODUCT	
Number Tested	14	14
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	14 NEGATIVE	14 NEGATIVE

(continued)

Test Facility:
1265 Kennestone Circle
Marietta, GA 30066

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.

WuXi AppTec

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

Attn: Jessica Martin

December 12, 2011
P.O. #: 12-0225

STERILITY TEST REPORT

PRODUCT	APPROXIMATE VOLUME TESTED (each media)
1	0.5 / 0.5 mL
2	0.3 / 0.45 mL
3	0.5 / 0.5 mL
4	0.5 / 0.5 mL
5	0.5 / 0.5 mL
6	0.4 / 0.4 mL
7	0.45 / 0.45 mL
8	0.5 / 0.5 mL
9	0.5 / 0.5 mL
10	0.4 / 0.4 mL
11	0.4 / 0.4 mL
12	0.4 / 0.4 mL
13	0.35 / 0.35 mL
14	0.5 / 0.5 mL

Grace Arnott 12-13-11
QA Reviewer Date

Lynda Barnes 12-13-11
Technical Reviewer Date

Testing conducted in accordance with current Good Manufacturing Practices.

bionique Testing Laboratories
MYCOPLASMA TESTING SERVICES

BIONIQUE® TESTING LABORATORIES, INC.
156 FAY BROOK DRIVE
SARANAC LAKE, NY 12983
PHONE: 518-891-2356 FAX: 518-891-5753

APPENDIX

Document ID #:	DCF9002F
Title:	QUALITY ASSURANCE REPORT - GMP
Effective Date:	9/7/11
Edition #:	02

QUALITY ASSURANCE REPORT – GMP

TEST PERFORMED	PROCEDURAL REFERENCE	TEST PERFORMED	PROCEDURAL REFERENCE
☒ 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) 666467

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: 9/21/11

Reviewed By Tracy M. Roth, QA Assistant: Tracy M. Roth

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

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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

505 S. Rosa Rd., Suite 120
Madison, WI 53719
PHONE#: **608-441-8019** FAX#: **608-441-8011**

BTL SAMPLE ID#: **66467** P.O.#: **DE0601** DATE REC'D: **08/23/2011**

TEST/CONTROL ARTICLE:

WA23-WB0069 10209

LOT#: **NA**

DIRECT CULTURE SET-UP (DAY 0) DATE: **08/24/2011**

INDICATOR CELL LINE (VERO) SEE DNA FLUOROCHROME RECORD SHEET

				DATE
THIOGLYCOLLATE BROTH	DAY 7	+	⊖	**08/31/2011**
	DAY 28	+	⊖	**09/21/2011**
BROTH-FORTIFIED COMMERCIAL				
0.5 mL SAMPLE	DAY 7	+	⊖	**08/31/2011**
6.0 mL BROTH	DAY 28	+	⊖	**09/21/2011**
BROTH-MODIFIED HAYFLICK				
0.5 mL SAMPLE	DAY 7	+	⊖	**08/31/2011**
6.0 mL BROTH	DAY 28	+	⊖	**09/21/2011**
BROTH-HEART INFUSION				
0.5 mL SAMPLE	DAY 7	+	⊖	**08/31/2011**
6.0 mL BROTH	DAY 28	+	⊖	**09/21/2011**

(See Reverse)

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

SAMPLE ID#: **66467**		AEROBIC	MICROAEROPHILIC	DATE
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ ⊖	+ ⊖	**08/31/2011**
	DAY 14	+ ⊖	+ ⊖	**09/07/2011**
	DAY 21	+ ⊖	+ ⊖	**09/14/2011**
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ ⊖	+ ⊖	**08/31/2011**
	DAY 14	+ ⊖	+ ⊖	**09/07/2011**
	DAY 21	+ ⊖	+ ⊖	**09/14/2011**
AGAR PLATES-HEART INFUSION	DAY 7	+ ⊖	+ ⊖	**08/31/2011**
	DAY 14	+ ⊖	+ ⊖	**09/07/2011**
	DAY 21	+ ⊖	+ ⊖	**09/14/2011**
BROTH SUBCULTURES (DAY 7)		DATE: **08/31/2011**		
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ ⊖	+ ⊖	**09/07/2011**
	DAY 14	+ ⊖	+ ⊖	**09/14/2011**
	DAY 21	+ ⊖	+ ⊖	**09/21/2011**
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ ⊖	+ ⊖	**09/07/2011**
	DAY 14	+ ⊖	+ ⊖	**09/14/2011**
	DAY 21	+ ⊖	+ ⊖	**09/21/2011**
AGAR PLATES-HEART INFUSION	DAY 7	+ ⊖	+ ⊖	**09/07/2011**
	DAY 14	+ ⊖	+ ⊖	**09/14/2011**
	DAY 21	+ ⊖	+ ⊖	**09/21/2011**

RESULTS: No detectable mycoplasmal contamination

9/21/11
Date

Shayn Armstrong
Laboratory Director
Shayn E. Armstrong, Ph.D.

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

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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 # **66467** **M-250** Date Rec'd: **08/23/2011** P.O. # **DE0601**

Indicator Cells Inoculated: Date/Initials: 8/25/11 / MK

Fixation: Date/Initials: 8/29/11 / HS

Staining: Date/Initials: 8/29/11 / HS

TEST/CONTROL ARTICLE:

WA23-WB0069 10209

LOT# **NA**

WiCell QA
WiCell Research Institute

505 S. Rosa Rd., Suite 120
Madison, WI 53719

Phone: **608-441-8019**
Fax #: **608-441-8011**

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: 8/29/11 Results Read by: HS Date of Review: 8/29/11 Reviewed by: SM

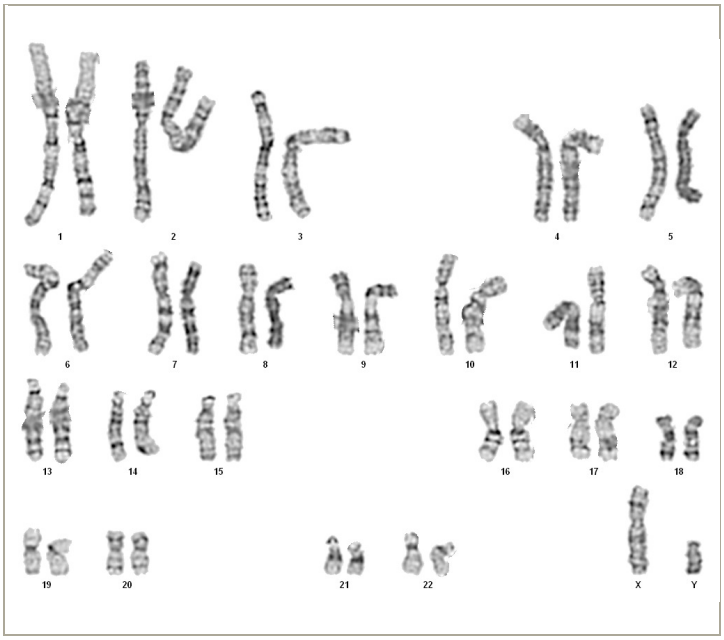
WiCell Cytogenetics Report: 006451

Report Date: September 14, 2011

Cell Line: WA23-WB0069 10210
Passage #: 13
Date of Sample: 8/22/2011
Date Completed: 9/14/2011

Specimen: hESC on Matrigel
Cell Line Gender: Male
Reason for Testing: pre-freeze
Investigator: Jeff Jones, WiCell Derivation

Results: 46,XY



Cell: S02-18
Slide: 2-R1 (11) KARYOTYPE
Slide Type: Karyotyping

# of Cells Counted: 20
# of Cells Karyotyped: 4
# of Cells Analyzed: 8
Band Level: 475-525

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

Completed by Seth Taapken MS, CG(ASCP), on 9/14/2011

Reviewed and interpreted by Karen Dyer Montgomery, PhD, FACMG, on 9/14/2011

Results Transmitted by Fax / Email / Post
Sent By:_____
QC Review By: _____

Date:_____
Sent To:_____
Results Recorded: _____