Cell Line: WA09
Lot: 9

Table of Contents

This material predates when WiCell produced a certificate of analysis for each lot. Therefore, a certificate of analysis is not available. The following pages are the reports for the testing completed for this lot.

If you have any questions please contact WiCell's technical support staff via our website side at www.wicell.org and we will be happy to assist you.

Thank you,

WiCell

P.O Box 7365 • Madison, WI 53707-7365 • Phone: 888.204.1782 • Fax: 608.441.8011
www.wicell.org

UW Health

University of Wisconsin
Hospital and Clinics

Histocompatibility/Molecular Diagnostics Laboratory

[redacted]

Short Tandem Repeat Analysis*

Sample Report: H9 lot 9 UW HLA#: 53836 Sample Date: 03/20/06

Requestor: WICell Research Institute

Test Date: 03/29/06,03/30/06 File Name: 060330, 060330ok9600 Report Date: 04/05/06

Sample Name: (label on tube) H9 lot 9 Dry, frozen pellet from PBS (~3 million cells)

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

Comments: The concentration of purified DNA isolated from the H9 lot 9 sample required to achieve an acceptable STR genotype (signal/ noise) was ~10-fold greater than that required for the standard procedure (~1 ng/amplification reaction) from human genomic DNA.

[redacted]

* 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

QUALITY ASSURANCE REPORT - GMP

Catalog # : M-250

Procedural Reference Numbers: 3008, 3011, 3013

Bionique Sample ID# 42072, 42073

This testing procedure was performed in compliance with Current Good Manufacturing Practice (cGMP) standards as specified under 21 CFR parts 210 and 211 to the extent to which these regulations pertain to the procedures performed. All records pertaining to the test/procedure have been reviewed by the Quality Assurance/Quality Control individual whose 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 these procedures.

Date of full data review by Quality Assurance: 8/24/05

[redacted]

8/24/05
Date

Manager, QA/QC, Bionique Testing Labs, Inc.

All records, including raw data and final reports, are maintained by:

Quality Assurance
Bionique Testing Laboratories, Inc.
[redacted]

Procedures specified in individual protocols are inspected at appropriate intervals according to a pre-determined schedule. Each lot of medium used for testing is examined for mycoplasmal growth-promoting properties, and must meet with required Quality Control performance criteria. Traceability of all of the components used in these protocols is assured, and documentation for individual lots will be supplied upon request.

Additional Comments:

I. The stability of the test and/or control sample material is the responsibility of the company submitting the sample prior to receipt at Bionique Testing Laboratories. Bionique Testing Laboratories will assume responsibility for sample stability following receipt and prior to being placed on test.

II. This test is for the detection of microbiological growth and does not require statistical validation.

REFERENCES:

REGULATORY:

1. Title 21 CFR Part 210 - CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS, GENERAL and 21 CFR Part 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS. Federal Register, Food and Drug Administration.

2. Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals (May, 1993); Director, Office of Biologics Research and Review, Food and Drug Administration.

3. Title 21 CFR PART 610.30 - General Biological Products Standards, Subpart D; Test for Mycoplasma. Federal Register, Food and Drug Administration.

4. Title 9 CFR PART 113.28 - Detection of Mycoplasma Contamination. Federal Register, Animal and Plant Health Inspection Service, United States Department of Agriculture

GENERAL:

5. Michael Barile and Jerome Kern. 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.

6. Chen, T.R. *In situ* detection of mycoplasma contamination in cell cultures by fluorescent Hoechst 33258 stain. *Experimental Cell Research,* 104: 255-262, 1977.

7. A Guide to MYCOPLASMA DETECTION AND CONTROL. Bionique Testing Laboratories, Inc., 1992.

8. Carolyn K. Lincoln and Daniel J. Lundin. Mycoplasma Detection and Control. *U. S. Fed. for Culture Collections Newsletter*, Vol. 20, Number 4, 1990.

9. Fetal Bovine Serum; Proposed Guideline. National Committee For Clinical Laboratory Standards (NCCLS), Vol. 10, Number 6, 1990. (NCCLS publication M25-P).

10. Gerard J. McGarrity, Judi Sarama, and Veronica Vanaman. Cell Culture Techniques. *ASM News*, Vol. 51, No. 4, 1985.

11. J. G. Tully, S. Razin (eds.), *Methods in Mycoplasmology*, Volumes I and II. Academic Press, N.Y., 1983.

12. M. F. Barile, S. Razin, J. G. Tully and R. F. Whitcomb (eds.), *The Mycoplasmas*, Volumes 1-4. Academic Press, N.Y., 1979.

Mycoplasma Testing Services

Safe Cells

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: [redacted]

BIONIQUE SAMPLE ID#: **42072** P.O.#: [redacted] DATE REC'D: **07/27/2005**

TEST/CONTROL ARTICLE:

H9p29

LOT#: **9**

DIRECT CULTURE SET-UP (DAY 0) DATE: **07/27/2005**

INDICATOR CELL LINE (VERO) SEE DNA FLUOROCHROME RECORD SHEET

				DATE
THIOGLYCOLLATE BROTH	DAY 7	+	⊖	08/03/2005
	DAY 28	+	⊖	08/24/2005
BROTH-FORTIFIED COMMERCIAL				
0.5 mL SAMPLE	DAY 7	+	⊖	08/03/2005
6.0 mL BROTH	DAY 28	+	⊖	08/24/2005
BROTH-MODIFIED HAYFLICK				
0.5 mL SAMPLE	DAY 7	+	⊖	08/03/2005
6.0 mL BROTH	DAY 28	+	⊖	08/24/2005
BROTH-HEART INFUSION				
0.5 mL SAMPLE	DAY 7	+	⊖	08/03/2005
6.0 mL BROTH	DAY 28	+	⊖	08/24/2005

(See Reverse)

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

SAMPLE ID#: **42072**		AEROBIC	ANAEROBIC	DATE
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ (−)	+ (−)	08/03/2005
	DAY 14	+ (−)	+ (−)	08/10/2005
	DAY 21	+ (−)	+ (−)	08/17/2005
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ (−)	+ (−)	08/03/2005
	DAY 14	+ (−)	+ (−)	08/10/2005
	DAY 21	+ (−)	+ (−)	08/17/2005
AGAR PLATES-HEART INFUSION	DAY 7	+ (−)	+ (−)	08/03/2005
	DAY 14	+ (−)	+ (−)	08/10/2005
	DAY 21	+ (−)	+ (−)	08/17/2005

BROTH SUBCULTURES (DAY 7) DATE: 08/03/2005

AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ (−)	+ (−)	08/10/2005
	DAY 14	+ (−)	+ (−)	08/17/2005
	DAY 21	+ (−)	+ (−)	08/24/2005
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ (−)	+ (−)	08/10/2005
	DAY 14	+ (−)	+ (−)	08/17/2005
	DAY 21	+ (−)	+ (−)	08/24/2005
AGAR PLATES-HEART INFUSION	DAY 7	+ (−)	+ (−)	08/10/2005
	DAY 14	+ (−)	+ (−)	08/17/2005
	DAY 21	+ (−)	+ (−)	08/24/2005

RESULTS: No detectable mycoplasmal contamination

8/24/05
Date

[redacted]

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 anaerobically in order to detect any colony forming units morphologically indicative of mycoplasmal contamination. Issuance of the final report with signature of the Scientific Director/Study 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.

Mycoplasma Testing Services

Safe Cells

MYCOPLASMA
TESTING SERVICES

BIONIQUE TESTING LABORATORIES, INC

[redacted]

APPENDIX I

Document #:	DCF3008A
Edition #:	06
Effective date:	9/17/2003
Title:	DNA FLUOROCHROME ASSAY RESULTS

DNA-FLUOROCHROME ASSAY RESULTS

Procedures 3008, 3009, 3011

Sample ID # **42072** **M-250** Date Rec'd: **07/27/2005** P.O. # [redacted]

Indicator Cells Inoculated: Date/Initials: 7/28/05 / BMS

Fixation: Date/Initials: 8/1/05 / KG

Staining: Date/Initials: 8/1/05 / KG

TEST/CONTROL ARTICLE:

H9p29

LOT# **9**

[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: 8/1/05 Results Read by: KG Date of Review: 8/1/05 Reviewed by: CW

Wisconsin State Laboratory of Hygiene
[redacted]

SEP 2 3 2005

Laboratory Report

Daniel F. I. Kurtycz, M.D., Medical Director • Ronald H. Laessig, Ph.D., Director

Cytogenetics (608) 262-0402

Patient Name: H9 Lot 9, pass 31
Patient Address:

[redacted]

SLH Lab #: 67559
Date of Birth:
Clinic or Hospital#:

[redacted]

Reason for Referral: Cell line chromosome analysis

Report Date: 9/20/05
Date Collected: 8/8/05
Date Received: 8/10/05

Specimen: CLID	Test(s) Performed: Culture, Karyotype G-Banding	Amount:

CYTOGENETIC RESULTS:

No. Analyzed: 7 No. Cells Counted: 20 No. of Colonies: No. of Karyotypes: 2 Band Level: 500

Results: 46,XX

Interpretation: Cytogenetic analysis of cultured embryonic stem cells showed an apparently normal female karyotype. No clonal abnormalities were detected.

Results called to [redacted]

UW Cytogenetic Services

[redacted]

Case name: 67559-CLID

Patient name: H9 Lot 9 pass 31

Result: 46,XX