Certificate of Analysis - Amended Distribution Lot

Product Description	H9 (WA09) WiCell Distribution Lot
Cell Line Provider	WiCell Research Institute (Madison, WI, USA)
Distribution Lot Number	H9-WCDL-12 (lot 12)
Date Vialed	17 May 2006
Passage Number	28
Culture Method	SOP-CC-030B, SOP-CC-020B
Cryopreservation Method	SOP-CC-034A

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

Test Description	Test Method	Test Specification	Result
Post-Thaw Viable Cell Recovery	SOP-CH-305A	Viable cells recovered	Pass
Identity by STR	SOP-CH-302B	Positive identity	Pass
Mycoplasma	SOP-SS-002A	No contamination detected	Pass
Karyotype by G-banding	SOP-CH-003B	Normal karyotype	Pass

Cells distributed by the National Stem Cell Bank are intended for research purposes only and are not intended for use in humans. These cells have undergone testing and are not known to harbor any pathogens or adventious agents. However, 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 or the NSCB is not responsible for damages or injuries that may result from the use of these cells.
Electronic versions of this certificate of analysis (CoA) complete with electronic copies of individual reports, results, and procedures are available on our website, www.wicell.org. There are also archived CoAs for past cell lots.
Please visit the technical service portion of the website for assistance with your human ES Cells. The knowledgeable technical support staff can assist with embryonic stem cell culture concerns, training, and any other customer service concerns you may encounter.

Amendment(s):

Reason for Amendment	Date
CoA updated to include copyright information and electronic signature, and update to WiCell logo. Links updated.	See signature
Original CoA	02-November-2007

Date of Lot Release	Quality Assurance Approval
02-November-2007	1/3/2014 X AMC AMC Quality Assurance Signed by: [redacted]

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: H9p32 Lot12 UW HLA#: 54393 Sample Date: 07/11/06
Lab Received 07/11/06

Requestor: WiCell Research Institute
Test Date: 07/14/06 File Name: 060714 Report Date: 07/25/06

Sample Name: (label on tube) H9ip32Lot12
1:3 DNA profile

Description:
Frozen pellet hESC for DNA profile

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 H9p32 Lot12 sample dated and received 07/11/06 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.

Please note the updated HLA ID# on this report, to correct "54398" reported on 7/17/06.

7-25-06
Date
HLA/Molecular Diagnostics Laboratory

07/25/06
Director Date
HLA/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

Mycoplasma Testing Services
Safe Cells

MYCOPLASMA
TESTING SERVICES

BIONIQUE TESTING LABORATORIES, INC
156 Fay Brook Drive
Saranac Lake, NY 12983
Phone: 518-891-2356 FAX: 518-891-5753

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 # **45247** **M-250** Date Rec'd: **07/11/2006** P.O. # **RP0905**

Indicator Cells Inoculated: Date/Initials: 7/13/06 /

Fixation: Date/Initials: 7/17/06 /

Staining: Date/Initials: 7/17/06 /

TEST/CONTROL ARTICLE:

H9 p 32

LOT# **12**

WiCell Research Institute

Phone:

Fax #:

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: 7/17/06 Results Read by: _____ Date of Review: 7/17/06 Reviewed by: _____

Mycoplasma Testing Services
Safe Cells

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

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 Research Institute

PHONE#: FAX#:

BTL SAMPLE ID#: **45247** P.O.#: **RP0905** DATE REC'D: **07/11/2006**

TEST/CONTROL ARTICLE:

H9 p 32

LOT#: **12**

DIRECT CULTURE SET-UP (DAY 0) DATE: **07/12/2006**

INDICATOR CELL LINE (VERO) SEE DNA FLUOROCHROME RECORD SHEET

			DATE
THIOGLYCOLLATE BROTH	DAY 7	+ (−)	07/19/2006
	DAY 28	+ (−)	08/09/2006
BROTH-FORTIFIED COMMERCIAL			
0.5 mL SAMPLE	DAY 7	+ (−)	07/19/2006
6.0 mL BROTH	DAY 28	+ (−)	08/09/2006
BROTH-MODIFIED HAYFLICK			
0.5 mL SAMPLE	DAY 7	+ (−)	07/19/2006
6.0 mL BROTH	DAY 28	+ (−)	08/09/2006
BROTH-HEART INFUSION			
0.5 mL SAMPLE	DAY 7	+ (−)	07/19/2006
6.0 mL BROTH	DAY 28	+ (−)	08/09/2006

(See Reverse)

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

SAMPLE ID#: 45247		AEROBIC	MICROAEROPHILIC	DATE
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ (−)	+ (−)	07/19/2006
	DAY 14	+ (−)	+ (−)	07/26/2006
	DAY 21	+ (−)	+ (−)	08/02/2006
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ (−)	+ (−)	07/19/2006
	DAY 14	+ (−)	+ (−)	07/26/2006
	DAY 21	+ (−)	+ (−)	08/02/2006
AGAR PLATES-HEART INFUSION	DAY 7	+ (−)	+ (−)	07/19/2006
	DAY 14	+ (−)	+ (−)	07/26/2006
	DAY 21	+ (−)	+ (−)	08/02/2006
BROTH SUBCULTURES (DAY 7)		DATE: 07/19/2006		
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ (−)	+ (−)	07/26/2006
	DAY 14	+ (−)	+ (−)	08/02/2006
	DAY 21	+ (−)	+ (−)	08/09/2006
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ (−)	+ (−)	07/26/2006
	DAY 14	+ (−)	+ (−)	08/02/2006
	DAY 21	+ (−)	+ (−)	08/09/2006
AGAR PLATES-HEART INFUSION	DAY 7	+ (−)	+ (−)	07/26/2006
	DAY 14	+ (−)	+ (−)	08/02/2006
	DAY 21	+ (−)	+ (−)	08/09/2006

RESULTS: No detectable mycoplasmal contamination

8/9/06
Date

Director, Technical Services

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 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.

Wisconsin State Laboratory of Hygiene
465 Henry Mall
Madison, WI 53706-1578
(608) 262-1293

JUL 27 2006

Laboratory Report

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

Cytogenetics (608) 262-0402

Patient Name: H9 Lot 12, p32
Patient Address:

SLH Lab #: 70715
Date of Birth:
Clinic or Hospital#:

Phone#:
Billing Code: 0835
Account #: 8208
MA #:

WICell Research Institute
P.O. Box 7365
Madison, WI 53707
and to:

Reason for Referral: Cell line chromosome analysis

Report Date: 7/27/2006
Date Collected: 7/10/2006
Date Received: 7/10/2006

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

CYTOGENETIC RESULTS:

No. Cells Counted: 20 No. Analyzed: 7 No. of Colonies: No. of Karyotypes: 3 Band Level: 550

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

UW Cytogenetic Services
465 Henry Mall
Madison, WI. 53706

Case name: 70715-CLID

Patient name: H9 Lot 12 p32

Result: 46,XX