



Cell Line: WA14
Lot: 4

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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



Laboratory Report

Cytogenetics
(608) 262-0402

Patient Name: H14p22 Lot4,
Patient Address:

SLH Lab #: 61099
Date of Birth:
Clinic or Hospital#:



Reason for Referral: DNA Fingerprinting

Report Date: 12/5/2003
Date Collected: 11/11/2003
Date Received: 11/11/2003

Specimen: CLID	Test(s) Performed: Culture, Karyotype	Amount:
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CYTOGENETIC RESULTS:

No. of Cells Examined: No. of Colonies: No. of Karyotypes: Band Level:

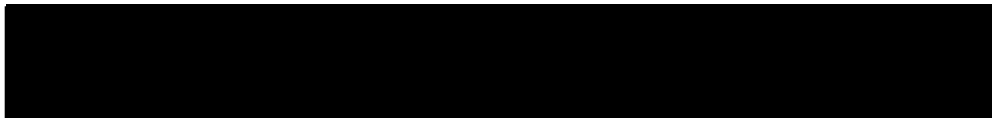
Results: see page 2

Interpretation: Method

DNA was isolated from a frozen cell pellet using the Promega-IQ DNA isolation kit. The isolated DNA was amplified by PCR using the Promega Powerplex16 amplification kit with primers for 15 STR(short tandem repeat) loci consisting of short repetitive sequence elements 3-7 base pairs in length. The post PCR product was analyzed on the ABI 3100 DNA sequencer and the data was used to make allele assignments for each locus.

Fingerprint matches as of 12/10/03: H14.5 p25 (61094 CLID), H14 Lot2 (61096 CLID)

Results called to



DNA FINGERPRINT

Lab Number 61099 CLID

Cell Line ID Identifier H14 p22 Lot 4

Species Human ES

RESULTS and INTERPRETATION

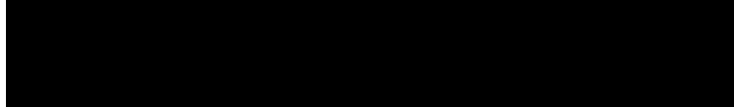
Loci								
	D3S1358	TH01	D21S11	D18S51	PENTA E	D5S818	D13S317	D7S820
Alleles	15,16	6,7	30,31	12,14	13,20	11,13	11,11	10,11

Loci								
	D16S539	CSF1PO	PENTA D	AMEL	Vwa	D8S1179	TPOX	FGA
Alleles	11,13	11,12	12,13	X,Y	15,16	13,14	8,8	21,21

Gender assignment XY
Fingerprint matches as of 12/10/03: H14.5 p25 (61094 CLID) H14 Lot 2 (61096 CLID)

The population frequency for the genotype observed in this cell line ranges from 1 in 1.83 x 10¹⁷ for Caucasian-Americans to 1 in 1.41 x 10¹⁸ for African Americans.

This test was validated in our laboratory using NIST DNA standards. These results are not for clinical use and are intended for research use on cell lines.



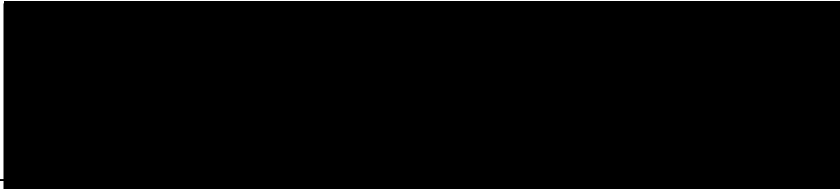
APPENDIX IV

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:



BIONIQUE SAMPLE ID#: 36120 P.O.# [REDACTED] DATE REC'D: 11/11/2003

TEST/CONTROL ARTICLE:

H14 p22 5/22/03 KV (Cryovial resuspended in 5 mL HMEM + 5% FBS and sedimented @2600 rpm X 10Min. Pellet is resuspended in 5 mL HMEM + 5% FBS.)

LOT#: 4

DIRECT CULTURE SET-UP (DAY 0)
INDICATOR CELL LINE (VERO)

DATE: 11/12/2003
SEE DNA FLUOROCHROME RECORD SHEET

			DATE
THIOGLYCOLLATE BROTH	DAY 7	+ ⊖	<u>11/19/2003</u>
	DAY 28	+ ⊖	<u>12/10/2003</u>
BROTH-FORTIFIED COMMERCIAL <u>0.5</u> mL SAMPLE	DAY 7	+ ⊖	<u>11/19/2003</u>
	DAY 28	+ ⊖	<u>12/10/2003</u>
BROTH-MODIFIED HAYFLICK <u>0.5</u> mL SAMPLE	DAY 7	+ ⊖	<u>11/19/2003</u>
	DAY 28	+ ⊖	<u>12/10/2003</u>
BROTH-FORTIFIED COMMERCIAL <u>6.0</u> mL BROTH	DAY 7	+ ⊖	<u>11/19/2003</u>
	DAY 28	+ ⊖	<u>12/10/2003</u>
BROTH-MODIFIED HAYFLICK <u>6.0</u> mL BROTH	DAY 7	+ ⊖	<u>11/19/2003</u>
	DAY 28	+ ⊖	<u>12/10/2003</u>
BROTH-FORTIFIED COMMERCIAL <u>0.5</u> mL SAMPLE	DAY 7	+ ⊖	<u>11/19/2003</u>
	DAY 28	+ ⊖	<u>12/10/2003</u>
BROTH-FORTIFIED COMMERCIAL <u>6.0</u> mL BROTH	DAY 7	+ ⊖	<u>11/19/2003</u>
	DAY 28	+ ⊖	<u>12/10/2003</u>

(See Reverse)

APPENDIX IV

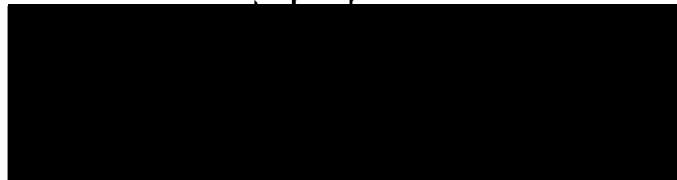
Page 2 of 2

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

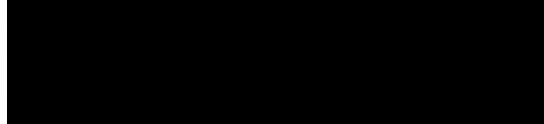
SAMPLE ID#:	36120	AEROBIC	ANAEROBIC	DATE
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ ⊖	+ ⊖	<u>11/19/2003</u>
	DAY 14	+ ⊖	+ ⊖	<u>11/26/2003</u>
	DAY 21	+ ⊖	+ ⊖	<u>12/03/2003</u>
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ ⊖	+ ⊖	<u>11/19/2003</u>
	DAY 14	+ ⊖	+ ⊖	<u>11/26/2003</u>
	DAY 21	+ ⊖	+ ⊖	<u>12/03/2003</u>
AGAR PLATES-HEART INFUSION	DAY 7	+ ⊖	+ ⊖	<u>11/19/2003</u>
	DAY 14	+ ⊖	+ ⊖	<u>11/26/2003</u>
	DAY 21	+ ⊖	+ ⊖	<u>12/03/2003</u>
BROTH SUBCULTURES (DAY 7)		DATE: <u>11/19/2003</u>		
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ ⊖	+ ⊖	<u>11/26/2003</u>
	DAY 14	+ ⊖	+ ⊖	<u>12/03/2003</u>
	DAY 21	+ ⊖	+ ⊖	<u>12/10/2003</u>
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ ⊖	+ ⊖	<u>11/26/2003</u>
	DAY 14	+ ⊖	+ ⊖	<u>12/03/2003</u>
	DAY 21	+ ⊖	+ ⊖	<u>12/10/2003</u>
AGAR PLATES-HEART INFUSION	DAY 7	+ ⊖	+ ⊖	<u>11/26/2003</u>
	DAY 14	+ ⊖	+ ⊖	<u>12/03/2003</u>
	DAY 21	+ ⊖	+ ⊖	<u>12/10/2003</u>

RESULTS: No detectable mycoplasmal contamination

12/10/03
Date



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 combined an indirect DNA staining approach to detect non-cultivable mycoplasmas with a direct culture methodology utilizing three different mycoplasma 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 mycoplasma 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 mycoplasma 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.



APPENDIX I

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

DNA-FLUROCHROME ASSAY RESULTS
Procedures 3008, 3009, 3011

Sample ID # 36120 M-250 Date Rec'd: 11/11/2003 P.O. # [Redacted]

Indicator Cells Inoculated: Date/Initials: 11/13/03 / JA

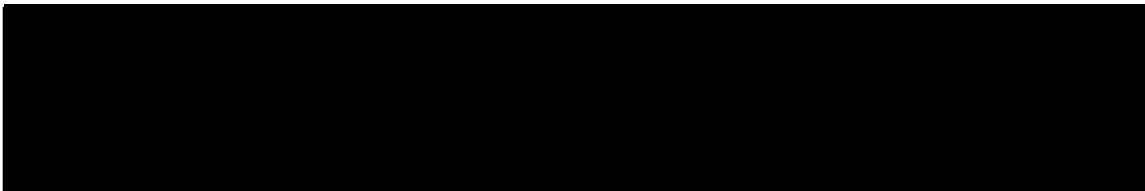
Fixation: Date/Initials: 11/17/03 / KG

Staining: Date/Initials: 11/17/03 / KG

TEST/CONTROL ARTICLE:

H14 p22 5/22/03 KV (Cryovial resuspended in 5 mL HMEM + 5% FBS and sedimented @2600 rpm X 10Min. Pellet is resuspended in 5 mL HMEM + 5% FBS, Lot# 128-1)

LOT# 4



DNA FLUROCHROME 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: 11/17/03 Results Read by: KG Date of Review: 11/17/03 Reviewed by: AU



Laboratory Report

Cytogenetics

Patient Name: H14p25 Lot 4,
Patient Address:

SLH Lab #: 59553
Date of Birth:
Clinic or Hospital#:

Reason for Referral: Confirm, identify cell lines

Report Date: 7/15/03
Date Collected: 6/24/03
Date Received: 6/24/03

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

No. of Cells Examined: 20 No. of Colonies: No. of Karyotypes: 2 Band Level: 500

Results: 46,XY[20]
FISH: no trisomy 12 or 17 cells

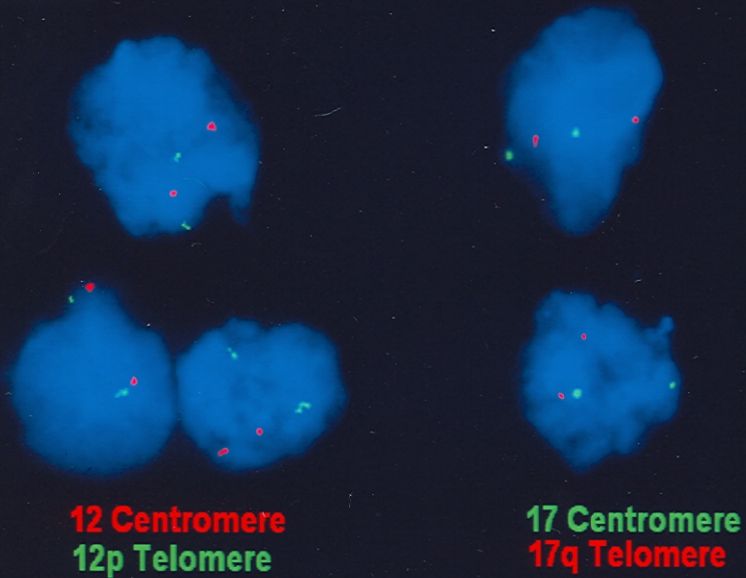
Interpretation: The H14p25 Lot4 cells demonstrated an apparently normal male karyotype. Fluorescent in-situ hybridization (FISH) was performed to evaluate the possibility of cells with an extra chromosome 12 or 17, as well as with copies of i(12p) or i(17q). Evaluation of 200 cells using probes specific for 12p and 12q demonstrated a single cell with an extra copy of both the short and the long arm telomeres, while 200 cells probed with the chromosome 17 centromere yielded a single cell with two long arm signals. Such a low frequency (0.5%) is most likely due to background and does not reflect extra copies of 12 or 17.

12/18/03 Amended report: The original cell line name was incorrect on the request form. The lot number was changed from lot 1 to lot 4 per Leanne Crandall.

Results called to

Vysis 12 alpha satellite with 12p Telomere Probe
Vysis 17 alpha satellite with 17q Telomere Probe

59553CLID



Patient name: H14p25

Case name: 59553-CLID



Case name: 59553-CLID

Patient name: H14p25

Result: 46,XY

