



Certificate of Analysis - Amended Distribution Lot

Product Description	WA13 (H13.B)
Cell Line Provider	WiCell Research Institute (Madison, WI, USA)
Distribution Lot Number	H13.B-WCDL-1
Date Viald	1 January 2004
Passage Number	10+15
Culture Method	Protocol III-Thawing; Protocol IV-Splitting
Cryopreservation Method	Protocol VI-Freezing

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
Virus testing		Negative HIV, HTLV, and HBV	Negative/Pass

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.

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 pathogens. 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. The NSCB is not responsible for damages or injuries that may result from the use of these cells.

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	Not available

Date of Lot Release	Quality Assurance Approval
Not available	<div style="text-align: right;">1/3/2014</div> <div style="text-align: center;">  X AMC </div> <div style="text-align: center;"> AMC Quality Assurance Signed by: [REDACTED] </div>

DNA FINGERPRINT

Lab Number 61806

Cell Line ID Identifier H13.B p(10+18)

Species Human ES

RESULTS and INTERPRETATION

	Loci							
	D3S1358	TH01	D21S11	D18S51	PENTA E	D5S818	D13S317	D7S820
Alleles	15,16	6,6	29,31.2	12,14	7,11	11,13	11,12	10,11

	Loci							
	D16S539	CSF1PO	PENTA D	AMEL	V _{wa}	D8S1179	TPOX	FGA
Alleles	9,11	12,12	12,13	X,Y	14,15	11,13	8,11	18,22

Gender assignment XY

Fingerprint matches as of 1/27/04 H13 profile

The population frequency for the genotype observed in this cell line ranges from 1 in 1.83 x10¹⁷ 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.

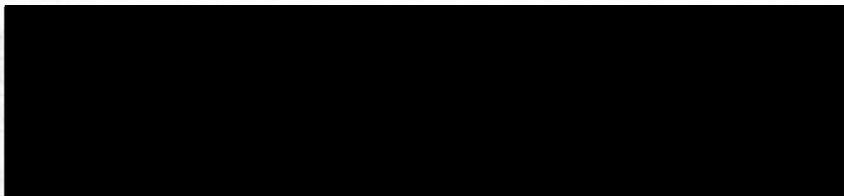


Document#: DCF3013D
Edition#: 10
Effective Date: 07/15/2003
Title: **M-250 FINAL REPORT SHEET**

M-250 FINAL REPORT

Direct Specimen Culture
Procedure 3008, 3011, 3013

TO:



BIONIQUE SAMPLE ID#: **36873** P.O.#: [REDACTED] DATE REC'D: **02/04/2004**

TEST/CONTROL ARTICLE:

H13.B p10+19

LOT#: **NA**

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

DATE: **02/04/2004**

SEE DNA FLUOROCHROME RECORD SHEET

DATE

Media	Volume	Day	Result	Date
THIOGLYCOLLATE BROTH		DAY 7	+ ⊖	<u>02/11/2004</u>
		DAY 28	+ ⊖	<u>03/03/2004</u>
BROTH-FORTIFIED COMMERCIAL	0.5 mL SAMPLE	DAY 7	+ ⊖	<u>02/11/2004</u>
	6.0 mL BROTH	DAY 28	+ ⊖	<u>03/03/2004</u>
BROTH-MODIFIED HAYFLICK	0.5 mL SAMPLE	DAY 7	+ ⊖	<u>02/11/2004</u>
	6.0 mL BROTH	DAY 28	+ ⊖	<u>03/03/2004</u>
BROTH-HEART INFUSION	0.5 mL SAMPLE	DAY 7	+ ⊖	<u>02/11/2004</u>
	6.0 mL BROTH	DAY 28	+ ⊖	<u>03/03/2004</u>

(See Reverse)



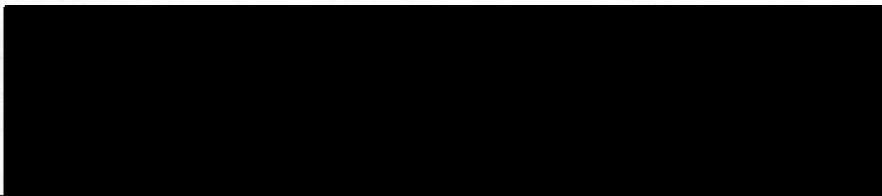
APPENDIX IV

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#: **36873** P.O.#: [REDACTED] DATE REC'D: **02/04/2004**

TEST/CONTROL ARTICLE:

H13.B p10+19

LOT#: **NA**

DIRECT CULTURE SET-UP (DAY 0) DATE: **02/04/2004**
 INDICATOR CELL LINE (VERO) SEE DNA FLUOROCROME RECORD SHEET

			DATE
THIOGLYCOLLATE BROTH	DAY 7	+ ⊖	<u>02/11/2004</u>
	DAY 28	+ ⊖	<u>03/03/2004</u>
BROTH-FORTIFIED COMMERCIAL			
<u>0.5</u> mL SAMPLE	DAY 7	+ ⊖	<u>02/11/2004</u>
<u>6.0</u> mL BROTH	DAY 28	+ ⊖	<u>03/03/2004</u>
BROTH-MODIFIED HAYFLICK			
<u>0.5</u> mL SAMPLE	DAY 7	+ ⊖	<u>02/11/2004</u>
<u>6.0</u> mL BROTH	DAY 28	+ ⊖	<u>03/03/2004</u>
BROTH-HEART INFUSION			
<u>0.5</u> mL SAMPLE	DAY 7	+ ⊖	<u>02/11/2004</u>
<u>6.0</u> mL BROTH	DAY 28	+ ⊖	<u>03/03/2004</u>

(See Reverse)

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

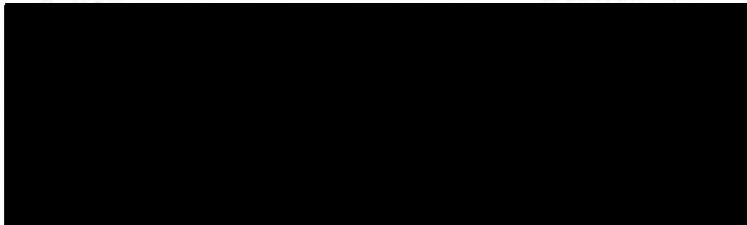
SAMPLE ID#:	36873	AEROBIC	ANAEROBIC	DATE
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ ⊖	+ ⊖	<u>02/11/2004</u>
	DAY 14	+ ⊖	+ ⊖	<u>02/18/2004</u>
	DAY 21	+ ⊖	+ ⊖	<u>02/25/2004</u>
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ ⊖	+ ⊖	<u>02/11/2004</u>
	DAY 14	+ ⊖	+ ⊖	<u>02/18/2004</u>
	DAY 21	+ ⊖	+ ⊖	<u>02/25/2004</u>
AGAR PLATES-HEART INFUSION	DAY 7	+ ⊖	+ ⊖	<u>02/11/2004</u>
	DAY 14	+ ⊖	+ ⊖	<u>02/18/2004</u>
	DAY 21	+ ⊖	+ ⊖	<u>02/25/2004</u>

BROTH SUBCULTURES (DAY 7) DATE: 02/11/2004

AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ ⊖	+ ⊖	<u>02/18/2004</u>
	DAY 14	+ ⊖	+ ⊖	<u>02/25/2004</u>
	DAY 21	+ ⊖	+ ⊖	<u>03/03/2004</u>
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ ⊖	+ ⊖	<u>02/18/2004</u>
	DAY 14	+ ⊖	+ ⊖	<u>02/25/2004</u>
	DAY 21	+ ⊖	+ ⊖	<u>03/03/2004</u>
AGAR PLATES-HEART INFUSION	DAY 7	+ ⊖	+ ⊖	<u>02/18/2004</u>
	DAY 14	+ ⊖	+ ⊖	<u>02/25/2004</u>
	DAY 21	+ ⊖	+ ⊖	<u>03/03/2004</u>

RESULTS: No detectable mycoplasmal contamination

3/3/04
 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 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.



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 # 36873 M-250 Date Rec'd: 02/04/2004 P.O. # RP0304

Indicator Cells Inoculated: Date/Initials: 2/5/04 | u

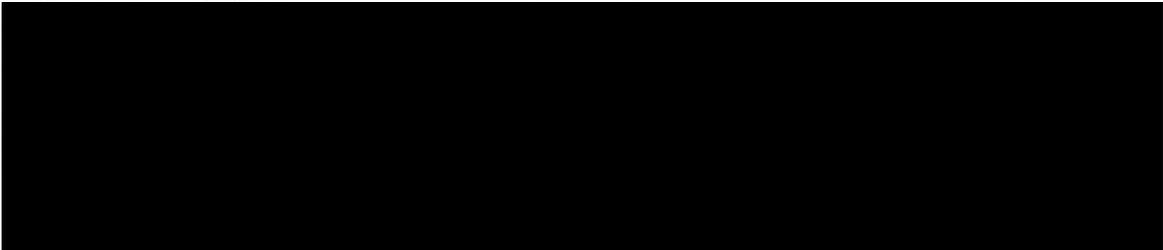
Fixation: Date/Initials: 2/9/04 | SA

Staining: Date/Initials: 2/9/04 | SA

TEST/CONTROL ARTICLE:

H13.B p10+19

LOT# NA



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: 2/9/04 Results Read by: SA Date of Review: 2/9/04 Reviewed by: cu

FEB 03 2004



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

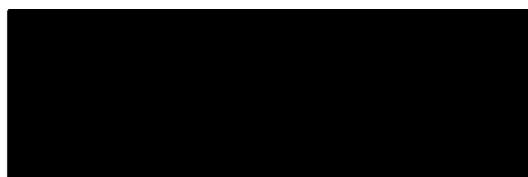
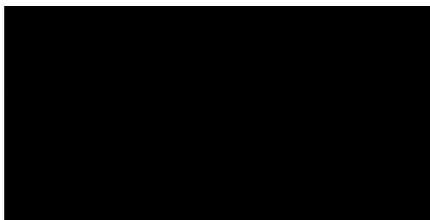
Laboratory Report

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

Cytogenetics
(608) 262-0402

Patient Name: H13.B (10+18),
Patient Address:

SLH Lab #: 61806
Date of Birth:
Clinic or Hospital#:



Reason for Referral: Confirm, identify cell lines

Report Date: 2/2/04
Date Collected: 1/21/04
Date Received: 1/22/04

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:** 650

Results: 46,XY

Interpretation: DNA was isolated from cultured cells 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 1/27/04: H13

Cytogenetic analysis was performed on twenty G-banded metaphase spreads from human embryonic stem cells. All twenty cells demonstrated an apparently normal male karyotype with no extra copies of chromosomes 12 and 17.

Results called to

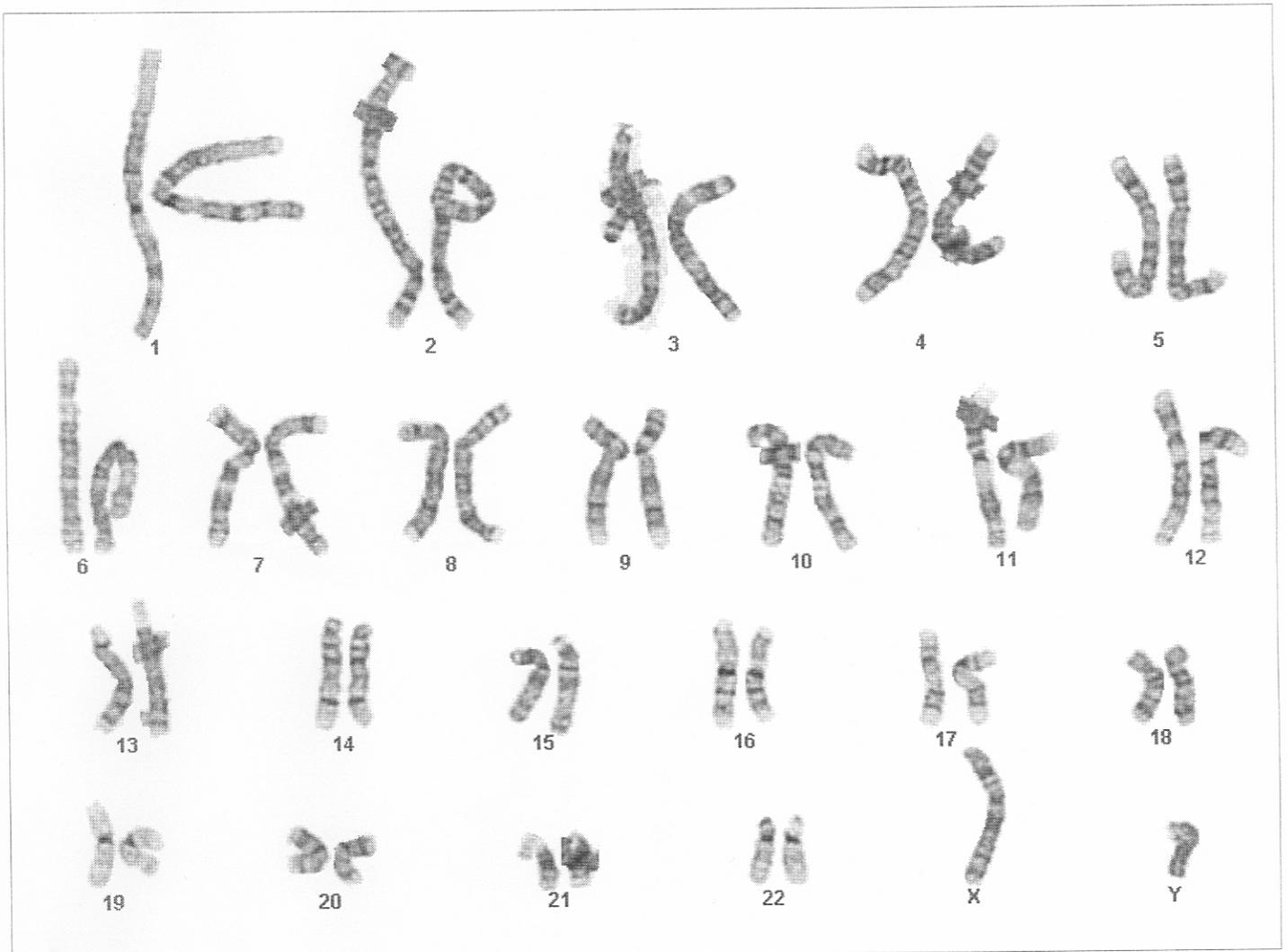
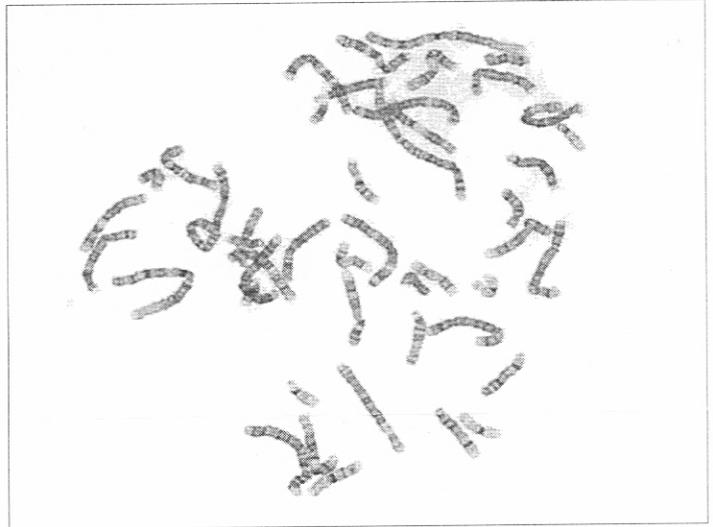


UW Cytogenetic Services
465 Henry Mall
Madison, WI 53706-1578

Case name: 61806-CLID

Patient name: H13.B (10+18)

Result: 46,XY





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

JAN 29 2004

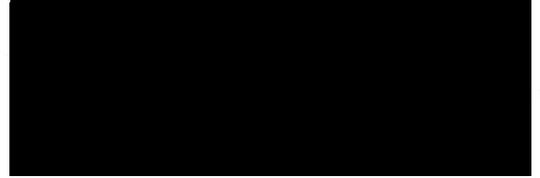
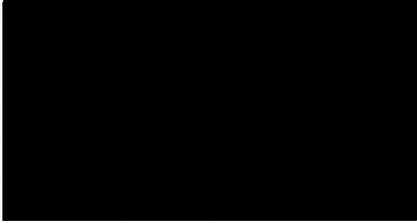
Laboratory Report

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

Cytogenetics
 (608) 262-0402

Patient Name: H13.B (10+18),
 Patient Address:

SLH Lab #: 61806
 Date of Birth:
 Clinic or Hospital#:



Reason for Referral: Confirm, identify cell lines

Report Date: 1/29/04
 Date Collected: 1/21/04
 Date Received: 1/22/04

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:

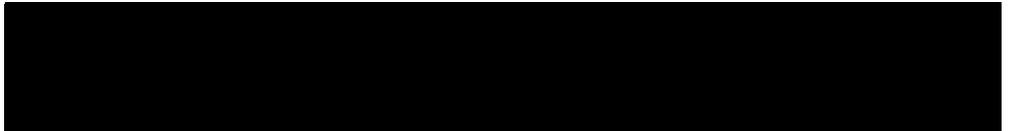
Results:

Interpretation: Method

DNA was isolated from cultured cells 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 1/27/04: H13

Results called to

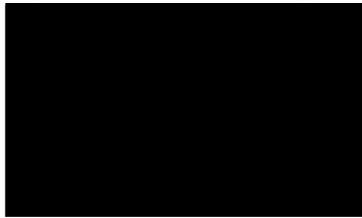


RESEARCH & DEVELOPMENT FINAL REPORT

PROTOCOL 30725.01

TITLE: Detection of Viral HIV-1 DNA by Polymerase Chain Reaction (PCR): (Research Grade 1).

SPONSOR:

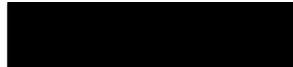


CONTACT:

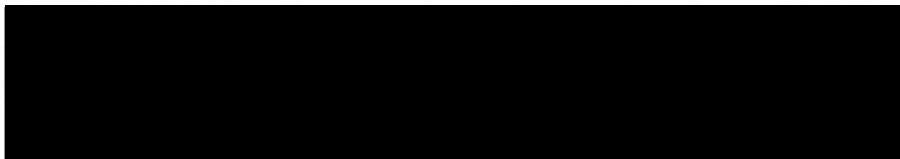
SPONSOR TEST ARTICLE DESIGNATION:	ACCESSION NUMBER:
H13p24	03-000001
H9p24	03-000002
H7p27	03-000003

REPORT GENERATION DATE: January 30, 2003

STUDY DIRECTOR:



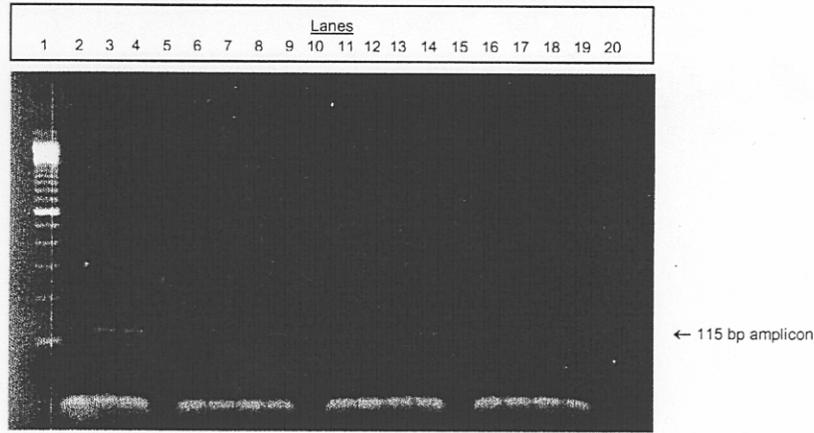
ACCESSION NUMBER:	TEST RESULTS:
03-000001	Negative. HIV-1 DNA sequences were not detected in the Sponsor's sample.
03-000002	Negative. HIV-1 DNA sequences were not detected in the Sponsor's sample.
03-000003	Negative. HIV-1 DNA sequences were not detected in the Sponsor's sample.



Research Test: Not appropriate for use in support of regulatory submissions.



Scanned Photograph of Ethidium Bromide Stained Gel



Scanned photograph of ethidium bromide stained 1.8% agarose gel. Size of PCR products was determined from an ethidium bromide stained DNA 100 bp ladder marker. Order of lanes from left to right is as follows:

Lanes:

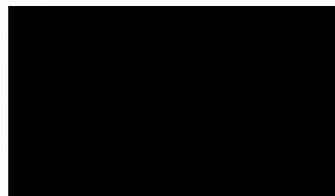
- Lane 1 100 bp ladder marker
- Lane 2 Reagent Control, unspiked
- Lane 3 Reagent Control, spiked with 50 copies of HIV-1 DNA
- Lane 4 Reagent Control, spiked with 500 copies of HIV-1 DNA
- Lane 5 Blank
- Lane 6 Test article 03-000001 DNA, unspiked
- Lane 7 Test article 03-000001 DNA, unspiked
- Lane 8 Test article 03-000001 DNA, unspiked
- Lane 9 Test article 03-000001 DNA, spiked with 500 copies of HIV-1 DNA
- Lane 10 Blank
- Lane 11 Test article 03-000002 DNA, unspiked
- Lane 12 Test article 03-000002 DNA, unspiked
- Lane 13 Test article 03-000002 DNA, unspiked
- Lane 14 Test article 03-000002 DNA, spiked with 500 copies of HIV-1 DNA
- Lane 15 Blank
- Lane 16 Test article 03-000002 DNA, unspiked
- Lane 17 Test article 03-000002 DNA, unspiked
- Lane 18 Test article 03-000002 DNA, unspiked
- Lane 19 Test article 03-000002 DNA, spiked with 500 copies of HIV-1 DNA
- Lane 20 Blank

RESEARCH & DEVELOPMENT FINAL REPORT

PROTOCOL 30725.01

TITLE: Detection of Viral HTLV DNA by Polymerase Chain Reaction (PCR): (Research Grade 1).

SPONSOR:



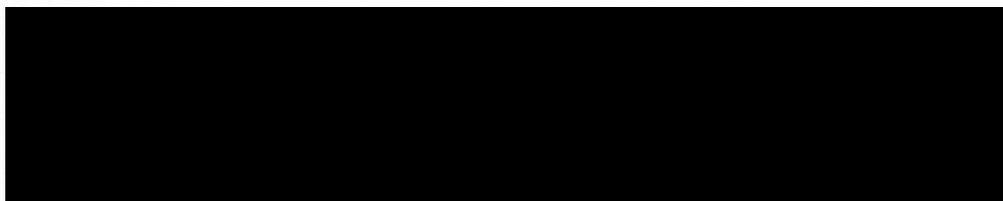
CONTACT:

SPONSOR TEST ARTICLE DESIGNATION:	ACCESSION NUMBER:
H13p24	03-000001
H9p24	03-000002
H7p27	03-000003

REPORT GENERATION DATE: January 30, 2003



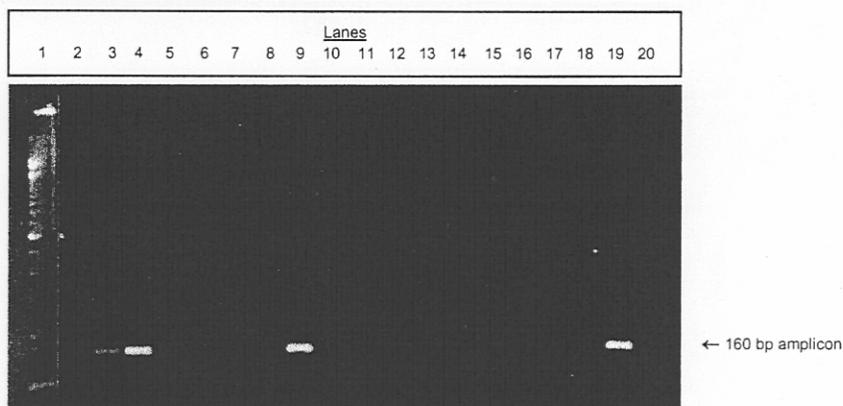
ACCESSION NUMBER:	TEST RESULTS:
03-000001	Negative. HTLV DNA sequences were not detected in the Sponsor's sample.
03-000002	Negative. HTLV DNA sequences were not detected in the Sponsor's sample.
03-000003	Negative. HTLV DNA sequences were not detected in the Sponsor's sample.



Research Test: Not appropriate for use in support of regulatory submissions.



Scanned Photograph of Ethidium Bromide Stained Gel



Scanned photograph of ethidium bromide stained 1.8% agarose gel. Size of PCR products was determined from an ethidium bromide stained DNA 100 bp ladder marker. Order of lanes from left to right is as follows:

Lanes:

- Lane 1 100 bp ladder marker
- Lane 2 Reagent Control, unspiked
- Lane 3 Reagent Control, spiked with 100 copies of HTLV DNA
- Lane 4 Reagent Control, spiked with 1,000 copies of HTLV DNA
- Lane 5 Blank
- Lane 6 Test article 03-000001 DNA, unspiked
- Lane 7 Test article 03-000001 DNA, unspiked
- Lane 8 Test article 03-000001 DNA, unspiked
- Lane 9 Test article 03-000001 DNA, spiked with 1,000 copies of HTLV DNA
- Lane 10 Blank
- Lane 11 Test article 03-000002 DNA, unspiked
- Lane 12 Test article 03-000002 DNA, unspiked
- Lane 13 Test article 03-000002 DNA, unspiked
- Lane 14 Test article 03-000002 DNA, spiked with 1,000 copies of HTLV DNA
- Lane 15 Blank
- Lane 16 Test article 03-000002 DNA, unspiked
- Lane 17 Test article 03-000002 DNA, unspiked
- Lane 18 Test article 03-000002 DNA, unspiked
- Lane 19 Test article 03-000002 DNA, spiked with 1,000 copies of HTLV DNA
- Lane 20 Blank

Research Test: Not appropriate for use in support of regulatory submissions.

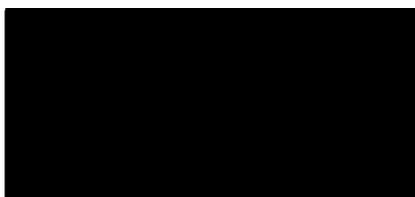


RESEARCH & DEVELOPMENT FINAL REPORT

PROTOCOL 30725.01

TITLE: Detection of Viral HBV DNA by Polymerase Chain Reaction (PCR): (Research Grade 1).

SPONSOR:



CONTACT:

SPONSOR TEST ARTICLE DESIGNATION:	ACCESSION NUMBER:
H13p24	03-000001
H9p24	03-000002
H7p27	03-000003

REPORT GENERATION DATE: January 30, 2003

STUDY DIRECTOR:

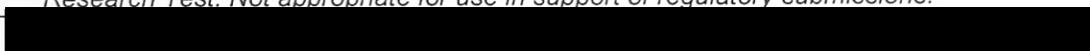


ACCESSION NUMBER:	TEST RESULTS:
03-000001	Negative. HBV DNA sequences were not detected in the Sponsor's sample.
03-000002	Negative. HBV DNA sequences were not detected in the Sponsor's sample.
03-000003	Negative. HBV DNA sequences were not detected in the Sponsor's sample.

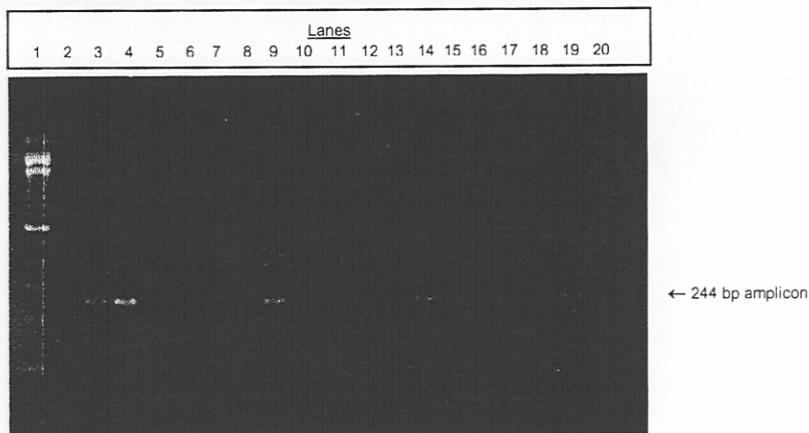


31 Jan 03
Date

Research Test: Not appropriate for use in support of regulatory submissions.



Scanned Photograph of Ethidium Bromide Stained Gel



Scanned photograph of ethidium bromide stained 1.8% agarose gel. Size of PCR products was determined from an ethidium bromide stained DNA 100 bp ladder marker. Order of lanes from left to right is as follows:

Lanes:

- Lane 1 100 bp ladder marker
- Lane 2 Reagent Control, unspiked
- Lane 3 Reagent Control, spiked with 100 copies of HBV DNA
- Lane 4 Reagent Control, spiked with 1,000 copies of HBV DNA
- Lane 5 Blank
- Lane 6 Test article 03-000001 DNA, unspiked
- Lane 7 Test article 03-000001 DNA, unspiked
- Lane 8 Test article 03-000001 DNA, unspiked
- Lane 9 Test article 03-000001 DNA, spiked with 1,000 copies of HBV DNA
- Lane 10 Blank
- Lane 11 Test article 03-000002 DNA, unspiked
- Lane 12 Test article 03-000002 DNA, unspiked
- Lane 13 Test article 03-000002 DNA, unspiked
- Lane 14 Test article 03-000002 DNA, spiked with 1,000 copies of HBV DNA
- Lane 15 Blank
- Lane 16 Test article 03-000002 DNA, unspiked
- Lane 17 Test article 03-000002 DNA, unspiked
- Lane 18 Test article 03-000002 DNA, unspiked
- Lane 19 Test article 03-000002 DNA, spiked with 1,000 copies of HBV DNA
- Lane 20 Blank

1.0 COMMENTS

DNA bands larger than the expected amplicon size (244 bp) were visible in Lanes 6 to 9 and 11 to 14, however, they were of the incorrect size to have come from HBV.

Research Test: Not appropriate for use in support of regulatory submissions.