Distribution Lot

Certificate of Analysis – Amended

Product Description	H14 (WA14) WiCell Distribution Lot
Cell Line Provider	WiCell Research Institute (Madison, WI, USA)
Distribution Lot Number	H14-WCDL-5 (lot 5)
Date Vialed	12 June 2007
Passage Number	23
Culture Method	SOP-CC-030B, SOP-CC-020B
Cryopreservation Method	SOP-CC-034B

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
Sterility - Direct transfer method	SOP-CH-304A	No contamination detected	Pass
Mycoplasma	SOP-SS-002A	No contamination detected	Pass
Karyotype by G-banding	SOP-CH-003B	Normal karyotype	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.

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
Updated CoA to include copyright information.	See Signature
Original CoA	31-October-2007

Date of Lot Release	Quality Assurance Approval
31-October-2007	1/10/2014 X AMC AMC Quality Assurance Signed by: [redacted]

UW Health
University of Wisconsin
Hospital and Clinics

Histocompatibility/Molecular Diagnostics Laboratory
Madison, WI 53792-2472

Short Tandem Repeat Analysis*

Sample Report: H14p25 UW HLA#: 57100 Sample Date: 09/18/07
Lab Received 09/18/07

Requestor: WiCell Research Institute

Test Date: 09/21/07 File Name: 070921, 071009 Report Date: 10/10/07

Sample Name: (label on tube) DNA050
H14p25

Description: WI Cell Cytogenetics provided genomic DNA of H14p25 (DNA 050)

Locus	Repeat #	STR Genotype
D16S539	5, 8-15	11,13
D7S820	6-14	10,11
D13S317	7-15	11,11
D5S818	7-15	11,13
CSF1PO	6-15	11,12
TPOX	6-13	8,8
Amelogenin	NA	X,Y
TH01	5-11	6,7
vWA	11, 13-21	15,16

100ug/mL 260/280=2.0

Comments: Based on the H14p25 DNA submitted by WI Cell dated 09/18/07 and received on 09/18/07, this sample (UW HLA# 57100) matches exactly the STR profile of the human stem cell line H14A comprising 14 allelic polymorphisms across the 8 STR loci analyzed. No STR polymorphisms other than those corresponding to the human H14A 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. This result suggest that the DNA sample submitted corresponds to the H14A stem cell line and 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%. A preliminary copy of this report was issued via electronic mail to JJ and CS of WI Cell Research Institute on Wednesday, October 10, 2007.

* 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.

UW Health
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Histocompatibility/Molecular Diagnostics Laboratory
Madison, WI 53792-2472

***** 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.

Test Facility:
1265 Kennestone Circle
Marietta, GA 30066

WiCell Research Institute
[redacted]
Madison, WI 53719

August 13, 2007
P.O. #: RP1370

STERILITY TEST REPORT

Sample Information: Human embryonic stem cell line on mouse feeder layer
4: H14

Date Received: July 17, 2007
Date in Test: July 26, 2007
Date Completed: August 09, 2007

Test Information: Test Codes: 30744, 30744A
Immersion, USP / 21 CFR 610.12
Procedure #: BS210WCR.02

TEST PARAMETERS	PRODUCT	
Approximate Volume Tested	0.45 mL	0.45 mL
Number Tested	1	1
Type of Media	SCD	FTM
Media Volume	200 mL	200 mL
Incubation Period	14 Days	14 Days
Incubation Temperature	20 °C to 25 °C	30 °C to 35 °C
RESULTS	1 NEGATIVE	1 NEGATIVE

QA Reviewed: Page 1 Signed _____

Reviewed: Page 1 Signed _____

Testing conducted in accordance with current Good Manufacturing Practices.

WiCell Cytogenetics Report: 000221-091707

Report Date: October 09, 2007

Case Details:

Cell Line: *H14*

Passage #: *25*

Date Completed: *9/20/2007*

Cell Line Gender: *male*

Investigator: *RD*

Specimen: *hESC on MEF feeder*

Date of Sample: *9/17/2007*

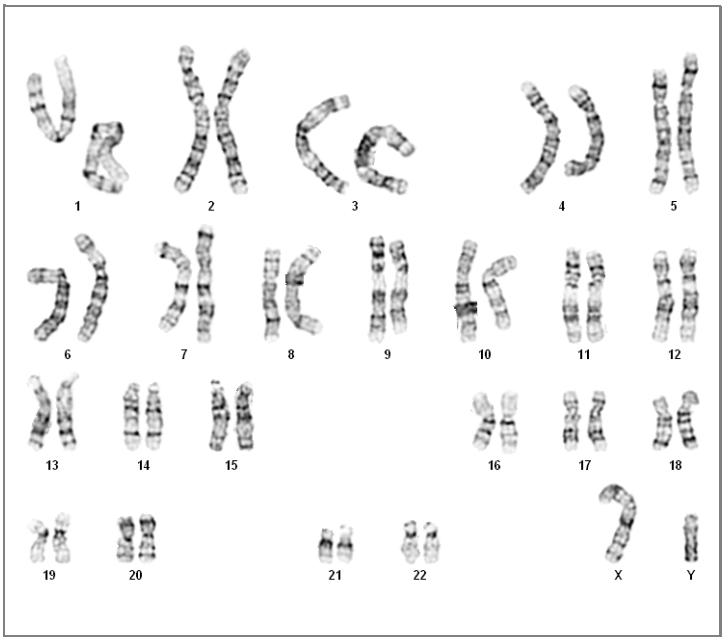
Tests,Reason for: *Confirmation of normal karyotype at lot release*

Results: *46,XY*

Completed by CS, CLSp(CG), on 9/18/2007

Reviewed and interpreted by KDM, PhD, FACMG, on 9/20/2007

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



Cell: *S01-05*

Slide: *B*

Slide Type: *Karyotyping*

Cell Results: *Karyotype: 46,XY*

# of Cells Counted: *20*

# of Cells Karyotyped: *4*

# of Cells Analyzed: *8*

Band Level: *450-550*

Results Transmitted by Fax / Email / Post **Date:**_____

Sent By:_____ **Sent To:**_____

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

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: **Distribution Lab**
WiCell Research Institute

Madison, WI 53719
PHONE#: FAX#:

BTL SAMPLE ID#: **49973** P.O.#: **RP1487** DATE REC'D: **09/25/2007**

TEST/CONTROL ARTICLE:

H14 p27 9-21-07

LOT#: **NA H14-WCDL-5**

DIRECT CULTURE SET-UP (DAY 0) DATE: **09/26/2007**

INDICATOR CELL LINE (VERO) SEE DNA FLUOROCHROME RECORD SHEET

				DATE
THIOGLYCOLLATE BROTH	DAY 7	+	⊖	10/03/2007
	DAY 28	+	⊖	10/24/2007
BROTH-FORTIFIED COMMERCIAL				
0.5 mL SAMPLE	DAY 7	+	⊖	10/03/2007
6.0 mL BROTH	DAY 28	+	⊖	10/24/2007
BROTH-MODIFIED HAYFLICK				
0.5 mL SAMPLE	DAY 7	+	⊖	10/03/2007
6.0 mL BROTH	DAY 28	+	⊖	10/24/2007
BROTH-HEART INFUSION				
0.5 mL SAMPLE	DAY 7	+	⊖	10/03/2007
6.0 mL BROTH	DAY 28	+	⊖	10/24/2007

(See Reverse)

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

SAMPLE ID#: **49973**

		AEROBIC	MICROAEROPHILIC	DATE
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ ⊖	+ ⊖	10/03/2007
	DAY 14	+ ⊖	+ ⊖	10/10/2007
	DAY 21	+ ⊖	+ ⊖	10/17/2007
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ ⊖	+ ⊖	10/03/2007
	DAY 14	+ ⊖	+ ⊖	10/10/2007
	DAY 21	+ ⊖	+ ⊖	10/17/2007
AGAR PLATES-HEART INFUSION	DAY 7	+ ⊖	+ ⊖	10/03/2007
	DAY 14	+ ⊖	+ ⊖	10/10/2007
	DAY 21	+ ⊖	+ ⊖	10/17/2007
BROTH SUBCULTURES (DAY 7)		DATE: 10/03/2007		
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ ⊖	+ ⊖	10/10/2007
	DAY 14	+ ⊖	+ ⊖	10/17/2007
	DAY 21	+ ⊖	+ ⊖	10/24/2007
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ ⊖	+ ⊖	10/10/2007
	DAY 14	+ ⊖	+ ⊖	10/17/2007
	DAY 21	+ ⊖	+ ⊖	10/24/2007
AGAR PLATES-HEART INFUSION	DAY 7	+ ⊖	+ ⊖	10/10/2007
	DAY 14	+ ⊖	+ ⊖	10/17/2007
	DAY 21	+ ⊖	+ ⊖	10/24/2007

RESULTS: No detectable mycoplasmal contamination

10/24/07
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.

Mycoplasma Testing Services
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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 # **49973** **M-250** Date Rec'd: **09/25/2007** P.O. # **RP1487**

Indicator Cells Inoculated: Date/Initials: 9/27/07 / JA

Fixation: Date/Initials: 10/1/07 / JA

Staining: Date/Initials: 10/1/07 / JA

TEST/CONTROL ARTICLE:

H14 p27 9-21-07

LOT# **NA**

Distribution Lab
WiCell Research Institute

Madison, WI 53719

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: 10/1/07 Results Read by: JA Date of Review: 10/1/07 Reviewed by: CM

UW Health
University of Wisconsin
Hospital and Clinics

Histocompatibility/Molecular Diagnostics Laboratory
Madison, WI 53792-2472

Short Tandem Repeat Analysis*

Sample Report: H14p25 UW HLA#: 57100 Sample Date: 09/18/07
Lab Received 09/18/07

Requestor: WiCell Research Institute

Test Date: 09/21/07 File Name: 070921, 071009 Report Date: 10/10/07

Sample Name: (label on tube) DNA050
H14p25

Description: WI Cell Cytogenetics provided genomic DNA of H14p25 (DNA 050)

Locus	Repeat #	STR Genotype
D16S539	5, 8-15	11,13
D7S820	6-14	10,11
D13S317	7-15	11,11
D5S818	7-15	11,13
CSF1PO	6-15	11,12
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Amelogenin	NA	X,Y
TH01	5-11	6,7
vWA	11, 13-21	15,16

100ug/mL 260/280=2.0

Comments: Based on the H14p25 DNA submitted by WI Cell dated 09/18/07 and received on 09/18/07, this sample (UW HLA# 57100) matches exactly the STR profile of the human stem cell line H14A comprising 14 allelic polymorphisms across the 8 STR loci analyzed. No STR polymorphisms other than those corresponding to the human H14A 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. This result suggest that the DNA sample submitted corresponds to the H14A stem cell line and 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%. A preliminary copy of this report was issued via electronic mail to JJ and CS of WI Cell Research Institute on Wednesday, October 10, 2007.

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Madison, WI 53792-2472

***** 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.

Test Facility:
1265 Kennestone Circle
Marietta, GA 30066

WiCell Research Institute
[redacted]
Madison, WI 53719

August 13, 2007
P.O. #: RP1370

STERILITY TEST REPORT

Sample Information: Human embryonic stem cell line on mouse feeder layer
4: H14

Date Received: July 17, 2007
Date in Test: July 26, 2007
Date Completed: August 09, 2007

Test Information: Test Codes: 30744, 30744A
Immersion, USP / 21 CFR 610.12
Procedure #: BS210WCR.02

TEST PARAMETERS	PRODUCT	
Approximate Volume Tested	0.45 mL	0.45 mL
Number Tested	1	1
Type of Media	SCD	FTM
Media Volume	200 mL	200 mL
Incubation Period	14 Days	14 Days
Incubation Temperature	20 °C to 25 °C	30 °C to 35 °C
RESULTS	1 NEGATIVE	1 NEGATIVE

QA Reviewed: Page 1 Signed _____

Reviewed: Page 1 Signed _____

Testing conducted in accordance with current Good Manufacturing Practices.

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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: **Distribution Lab**
WiCell Research Institute

Madison, WI 53719
PHONE#: FAX#:

BTL SAMPLE ID#: **49973** P.O.#: **RP1487** DATE REC'D: **09/25/2007**

TEST/CONTROL ARTICLE:

H14 p27 9-21-07

LOT#: **NA H14-WCDL-5**

DIRECT CULTURE SET-UP (DAY 0) DATE: **09/26/2007**

INDICATOR CELL LINE (VERO) SEE DNA FLUOROCHROME RECORD SHEET

				DATE
THIOGLYCOLLATE BROTH	DAY 7	+	⊖	10/03/2007
	DAY 28	+	⊖	10/24/2007
BROTH-FORTIFIED COMMERCIAL				
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BROTH-HEART INFUSION				
0.5 mL SAMPLE	DAY 7	+	⊖	10/03/2007
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(See Reverse)

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

SAMPLE ID#: **49973**

		AEROBIC	MICROAEROPHILIC	DATE
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ ⊖	+ ⊖	10/03/2007
	DAY 14	+ ⊖	+ ⊖	10/10/2007
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	DAY 21	+ ⊖	+ ⊖	10/17/2007
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AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ ⊖	+ ⊖	10/10/2007
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	DAY 21	+ ⊖	+ ⊖	10/24/2007
AGAR PLATES-HEART INFUSION	DAY 7	+ ⊖	+ ⊖	10/10/2007
	DAY 14	+ ⊖	+ ⊖	10/17/2007
	DAY 21	+ ⊖	+ ⊖	10/24/2007

RESULTS: No detectable mycoplasmal contamination

10/24/07
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.

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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 # **49973** **M-250** Date Rec'd: **09/25/2007** P.O. # **RP1487**

Indicator Cells Inoculated: Date/Initials: 9/27/07 / JA

Fixation: Date/Initials: 10/1/07 / JA

Staining: Date/Initials: 10/1/07 / JA

TEST/CONTROL ARTICLE:

H14 p27 9-21-07

LOT# **NA**

Distribution Lab
WiCell Research Institute

Madison, WI 53719

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: 10/1/07 Results Read by: JA Date of Review: 10/1/07 Reviewed by: CM

WiCell Cytogenetics Report: 000221-091707

Report Date: October 09, 2007

Case Details:

Cell Line: *H14*

Passage #: *25*

Date Completed: *9/20/2007*

Cell Line Gender: *male*

Investigator: *RD*

Specimen: *hESC on MEF feeder*

Date of Sample: *9/17/2007*

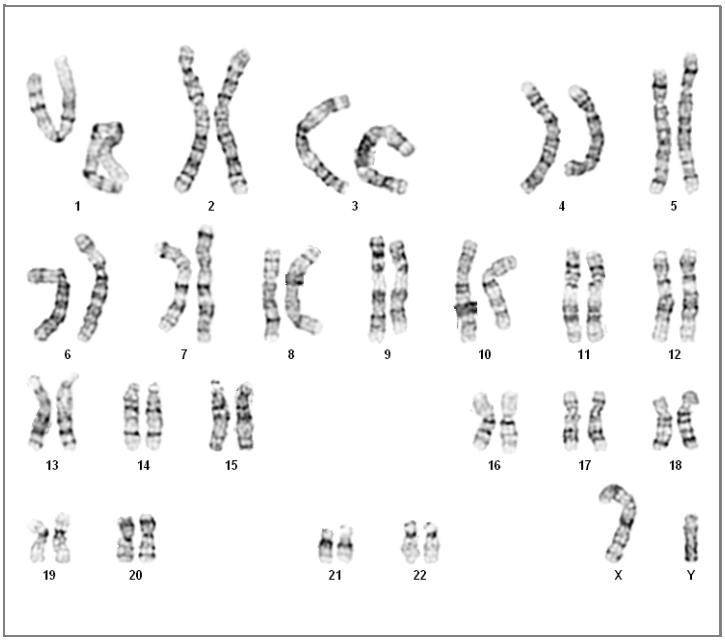
Tests,Reason for: *Confirmation of normal karyotype at lot release*

Results: *46,XY*

Completed by CS, CLSp(CG), on 9/18/2007

Reviewed and interpreted by KDM, PhD, FACMG, on 9/20/2007

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



Cell: *S01-05*

Slide: *B*

Slide Type: *Karyotyping*

Cell Results: *Karyotype: 46,XY*

# of Cells Counted: *20*

# of Cells Karyotyped: *4*

# of Cells Analyzed: *8*

Band Level: *450-550*

Results Transmitted by Fax / Email / Post **Date:**_____

Sent By:_____ **Sent To:**_____