Product Information and Testing - Amended

Product Information

Product Name	ES02
Lot Number	ES02-FTDL-01
Depositor	ES Cell International
Banked by	WiCell
Thaw Recommendation	Thaw 1 vial into 1 well of a 6 well plate.
Culture Platform	Feeder Dependent
	Medium: hES Medium
	Matrix: MEF
Protocol	WiCell Feeder Dependent Protocol
Passage Number	p63 These cells were cultured for 62 passages prior to freeze. WiCell adds +1 to the passage number at freeze so that the number on the vial best represents the overall passage number of the cells at thaw.
Date Vialed	13-June-2008
Vial Label	ES02-FTDL-1 p63 MW 13 JUNE 2008 SOPCC035D
Biosafety and Use Information	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 is not responsible for damages or injuries that may result from the use of these cells. Cells distributed by WiCell are intended for research purposes only and are not intended for use in humans.

Testing Performed by WiCell

Test Description	Test Provider	Test Method	Test Specification	Result
Post-Thaw Viable Cell Recovery	WiCell	SOP-CH-305	Viable Cells recovered	Pass
Identity by STR	UW Molecular Diagnostics Laboratory	SOP-CH-302	Positive identity	Pass
Sterility	Apptec	30744	No contamination detected	Pass
Mycoplasma	Apptec	30055F	No contamination detected	Pass
Karyotype by G-banding	WiCell	SOP-CH-003	Normal karyotype	Pass

Amendment(s):

Reason for Amendment	Date
CoA updated for format changes, including adding fields of thaw recommendation, vial label, protocol, and banked by, and removal of footnotes. Test methods were clarified when possible, test provider was added, culture platform, electronic signature, and reference to WiCell instead of NSCB. CoA now includes copyright information.	See Signature
Original CoA	21-August-2008

Date of Lot Release	Quality Assurance Approval
21-August-2008	12/30/2013 X AMC AMC Quality Assurance Signed by: [redacted]

UW Health
University of Wisconsin
Hospital and Clinics

Histocompatibility/Molecular Diagnostics Laboratory

Short Tandem Repeat Analysis*

Sample Report: NSCB 1798 ES02-FTDL-1

UW HLA#: 59278

Sample Date: 08/11/08
Received Date: 08/11/08

Requestor: WiCell Research Institute

Test Date: 08/11/08

File Name: 080812

Report Date: 08/13/08

Sample Name: **(label on tube)** **DNA 183 1798-STR**

Description: DNA Extracted by WiCell

248.7 ug/mL; 260/280 > 1.9

Locus	Repeat #	STR Genotype
D16S539	5, 8-15	9,12
D7S820	6-14	9,11
D13S317	7-15	8,11
D5S818	7-15	11,11
CSF1PO	6-15	11,11
TPOX	6-13	8,12
Amelogenin	NA	X,X
TH01	5-11	7,9
vWA	11, 13-21	18,20

Comments: Based on the DNA 183 1798-STR dated and received on 08/11/08 from WI Cell, the NSCB 1798 sample (UW HLA# 59278) matches exactly the STR profile of the human stem cell line ES02 comprising 14 allelic polymorphisms across the 8 STR loci analyzed. No STR polymorphisms other than those corresponding to the human ES02 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. These results suggest that the DNA 183 1798-STR sample submitted corresponds to the ES02 stem cell line and it 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 the Cytogenetics Laboratory of the WI Cell Research Institute on Wednesday, August 13, 2008.

* 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.

WuXi AppTec

WiCell Research Institute

July 08, 2008
P.O. #:

STERILITY TEST REPORT

Sample Information: hES Cells

1: TE03-FTDL-1

2: ES05-DL-1

3: WA07-DL-1

4: ES02-FTDL-1

Date Received: June 17, 2008
Date in Test: June 19, 2008
Date Completed: July 03, 2008

Test Information: Test Codes: 30744, 30744A
Immersion, USP / 21 CFR 610.12
Procedure #: BS210WCR.201

QA Reviewed:

Reviewed:

Testing conducted in accordance with current Good Manufacturing Practices.

WuXi AppTec

WiCell Research Institute

July 08, 2008
P.O. #:

STERILITY TEST REPORT

Sample Information: hES Cells
4: ES02-FTDL-1

Date Received: June 17, 2008
Date in Test: June 19, 2008
Date Completed: July 03, 2008

Test Information: Test Codes: 30744, 30744A
Immersion, USP / 21 CFR 610.12
Procedure #: BS210WCR.201

TEST PARAMETERS	PRODUCT	
Number Tested	2	2
Type of Media	SCD	FTM
Media Volume	400 mL	400 mL
Incubation Period	14 Days	14 Days
Incubation Temperature	20 °C to 25 °C	30 °C to 35 °C
RESULTS	2 NEGATIVE	2 NEGATIVE

PRODUCT	APPROXIMATE VOLUME TESTED (each media)
1	0.45 mL
2	0.5 mL

QA Reviewed: Page 1 Signed

Reviewed: Page 1 Signed

Testing conducted in accordance with current Good Manufacturing Practices

St. Paul

Report

WuXi AppTec

Copy of Original

FINAL STUDY REPORT

STUDY TITLE:	**MYCOPLASMA DETECTION: "Points to Consider"**
PROTOCOL NUMBER:	30055F
TEST ARTICLE IDENTIFICATION:	ES02-FTDL-1
SPONSOR:	WiCell Research Institute
PERFORMING LABORATORY:	WuXi AppTec, Inc.
STUDY NUMBER:	108626
RESULT SUMMARY:	Considered **negative** for mycoplasma contamination

Reference PO # !

QUALITY ASSURANCE UNIT SUMMARY

STUDY: Mycoplasma Detection: "Points to Consider"

The objective of the Quality Assurance Unit is to monitor the conduct and reporting of nonclinical laboratory studies. This study has been performed under Good Laboratory Practices regulations (FDA, 21 CFR, Part 58 - Good Laboratory Practice for Nonclinical Laboratory Studies) and in accordance to standard operating procedures and a standard protocol. The Quality Assurance Unit maintains copies of study protocols and standard operating procedures and has inspected this study on the dates listed below. Studies are inspected at time intervals to assure the quality and integrity of the study.

Critical Phase	Date	Study Director	Management
Staining of coverslips	07/14/08	07/15/08	08/20/08
Final Report	08/19/08	08/19/08	08/20/08

The findings of these inspections have been reported to management and the Study Director.

Quality Assurance Auditor: Date: 8/20/08

GOOD LABORATORY PRACTICES STATEMENT

The study referenced in this report was conducted in compliance with U.S. Food and Drug Administration Good Laboratory Practice (GLP) regulations set forth in 21 CFR part 58.

The studies not performed by or under the direction of WuXi AppTec, Inc., are exempt from this Good Laboratory Practice Statement and include characterization and stability of the test compound(s)/test article.

Study Director: Date: 8/20/08

Professional Personnel Involved:

1.0 PURPOSE

To demonstrate that a test article consisting of a cell bank, production or seed lots, or raw materials is free of mycoplasmal contamination, according to "Points to Consider" criteria.

2.0 SPONSOR: WiCell Research Institute

3.0 TEST FACILITY: WuXi AppTec, Inc.

4.0 SCHEDULING

DATE SAMPLE RECEIVED: 07/08/08
STUDY INITIATION DATE: 07/09/08
STUDY COMPLETION DATE: 08/20/08

5.0 TEST ARTICLE IDENTIFICATION: WiCell Research Institute ES02-FTDL-1

6.0 SAMPLE STORAGE

Upon receipt by the Sample Receiving Department, the test samples were placed in a designated, controlled access storage area ensuring proper temperature conditions. Test and control article storage areas are designed to preclude the possibility of mix-ups, contamination, deterioration or damage. The samples remained in the storage area until retrieved by the technician for sample preparation and/or testing. Unused test samples remained in the storage area until the study was completed. Once completed, the remaining samples were discarded or returned as requested by the Sponsor.

7.0 TEST ARTICLE CHARACTERIZATION

The Sponsor was responsible for all test article characterization data as specified in the GLP regulations. The identity, strength, stability, purity, and chemical composition of the test article were solely the responsibility of the Sponsor. The Sponsor was responsible for supplying to the testing laboratory results of these determinations and any others that may have directly impacted the testing performed by the testing laboratory, prior to initiation of testing. Furthermore, it was the responsibility of the Sponsor to ensure that the test article submitted for testing was representative of the final product that was subjected to materials characterization. Any special requirements for handling or storage were arranged in advance of receipt and the test article was received in good condition.

The Vero cells were maintained by WuXi AppTec's Cell Production Laboratory.

8.0 EXPERIMENTAL DESIGN

8.1 Overview

Whereas no single test is capable of detecting all mycoplasmal strains, freedom from mycoplasmal contamination may be demonstrated by the use of both an indirect and direct procedure.

8.2 Justification for Selection of the Test System

Contamination of cell cultures by mycoplasma is a common occurrence and is capable of altering normal cell structure and function. Among other things, mycoplasma may affect cell antigenicity, interfere with virus replication, and mimic viral actions. Testing for the presence of mycoplasma for cell lines used to produce biologicals is recommended by the FDA, Center for Biologics Evaluation and Research (CBER) under "Points to Consider."

9.0 EXPERIMENTAL SUMMARY

The indirect method of detection allows visualization of mycoplasma, particularly non-cultivable strains, by growing the mycoplasma on an indicator cell line and then staining using a DNA-binding fluorochrome stain. The indicator cell line should be easy to grow, have a large cytoplasmic to nuclear area ratio and support the growth of a broad spectrum of mycoplasma species. The African green monkey kidney cell line, Vero, fits this description and was used in this assay. The assay was performed with negative and positive controls. Both a strongly cyto-adsorbing (*M. hyorhinis*) and a poorly cyto-adsorbing (*M. orale*) mycoplasma species were used as positive controls. Poor cyto-adsorbing mycoplasma species may not give reliable positive results when inoculated in low numbers. A second dilution of *M. orale* was used to ensure cyto-adsorption. Staining the cultures with DNA binding fluorochrome allows for the detection of mycoplasma based on the staining pattern observed. Only the cell nuclei demonstrate fluorescence in the negative cultures but nuclear and extra-nuclear fluorescence is observed in positive cultures.

Direct cultivation is a sensitive and specific method for the detection of mycoplasma. The agar and broth media employed supply nutrients necessary for the growth of cultivable mycoplasmas. These media also supply a source of carbon and energy, and favorable growth conditions. The direct assay was performed with both negative and positive controls. A fermentative mycoplasma (*M. pneumoniae)* and a non-fermentative mycoplasma *(M. orale)* were used as positive controls. The procedure employed in this study is based on the protocol described in the 1993 Attachment # 2 to the "Points To Consider" document, as recommended by the FDA, Center for Biologics Evaluation and Research (CBER).

10.0 TEST MATERIAL PREPARATION

10.1 Test Article Identification:

Test Article Name:	ES02-FTDL-1
Lot/Batch #:	Not Given
General Description:	hES cells
Number of Aliquots used:	1 x 15 mL
Stability (Expiration):	Not Given
Storage Conditions:	Ultracold (< -60°C)
Safety Precautions:	BSL-1
Intended Use/Application:	Not Given

10.2 Test Sample Preparation

The test article was thawed in a water bath at 37 ± 2°C and 1:5 and 1:10 dilutions of the test article were prepared in sterile phosphate buffered saline (PBS). 1.0 mL of the undiluted sample, the 1:5 and 1:10 dilutions were then inoculated onto each of two (2) coverslips (per sample/dilution) containing Vero cells. The coverslips were incubated in incubator E770 for 1-2 hours at 37 ± 1°C / 5 ± 2% CO_2 and then 2.0 mL of EMEM, 8% Fetal Bovine Serum (FBS) was added to each coverslip. The coverslips were returned to incubator E770 at 37 ± 1°C / 5 ± 2% CO_2. After three days of incubation, the coverslips were fixed, stained, and then read using an epifluorescent microscope.

0.2 mL of the undiluted test article was then inoculated onto each of two SP-4 agar plates, and 10.0 mL was inoculated into a 75 cm^2 flask containing 50 mL of SP-4 broth. The plates were placed in an anaerobic GasPak system and incubated at 36 ± 1°C for a minimum of 14 days.

The broth flask was incubated aerobically at 36 ± 1°C, and subcultured onto each of two SP-4 agar plates (0.2 mL/plate) on Days 3, 7, and 14. These subculture plates were placed in an anaerobic GasPak system and incubated at 36 ± 1°C for a minimum of 14 days. The broth flask was read each working day for 14 days. The SP-4 agar plates (Day 0) were read after 14 days of incubation. The SP-4 broth subculture plates (Days 3, 7, and 14) were read after 14 days incubation.

10.3 Controls and Reference Materials

10.3.1 Sterile SP-4 broth served as the negative control for both the direct and indirect assays.

10.3.2 Positive Controls

a. Indirect Assay

a.1 Strongly cyto-adsorbing species - *M. hyorhinis* GDL (ATCC #23839) at 100 or fewer colony forming units (CFU) per inoculum.

a.2 Poorly cyto-adsorbing species - *M. orale* (ATCC #23714) at 100 or fewer CFU and at approximately 100 ID_{50} per inoculum

b. Direct Assay

b.1 Nonfermentative mycoplasma species - *M. orale* (ATCC #23714) at 100 or fewer CFU per inoculum.

b.2 Fermentative mycoplasma species - *M. pneumoniae* FH (ATCC #15531) at 100 or fewer CFU per inoculum.

10.3.3 Control Preparation

a. Negative Controls

a.1 1.0 mL of sterile SP-4 broth was inoculated onto each of two (2) coverslips containing Vero cells to serve as the negative control in the indirect assay.

a.2 0.2 mL of SP-4 broth was inoculated onto each of two (2) SP-4 agar plates to serve as the negative control in the direct assay. 10.0 mL of SP-4 broth was inoculated into a 75 cm^2 flask containing 50 mL of SP-4 broth to serve as the negative control in the direct assay.

b. Positive Controls

b.1 *M. hyorhinis, M. orale,* and *M. pneumoniae* were diluted to less than 100 CFU per inoculum in sterile SP-4 broth. 1.0 mL of *M. hyorhinis* and *M. ora*le at less than 100 CFU/mL was inoculated onto each of two (2) coverslips containing Vero cells. 1.0 mL of *M. orale* at 100 ID_{50} CFU per inoculum was also inoculated onto each of two (2) coverslips containing Vero cells. These coverslips served as the positive controls in the indirect assay.

b.2 The coverslips were incubated in incubator E770 for 1-2 hours at 37 ± 1°C / 5 ± 2% CO_2 and then 2.0 mL of EMEM, 8% Fetal Bovine Serum (FBS) was added to each coverslip. The coverslips were returned to incubator E770 at 37 ± 1°C / 5 ± 2% CO_2. After three days of incubation, the cell cultures were fixed, stained, and then read using an epifluorescent microscope.

b.3 0.2 mL of *M. orale* and *M. pneumoniae* at less than 100 CFU/plate was inoculated onto each of two (2) SP-4 agar plates. 10.0 mL of *M. orale* and *M. pneumoniae* at less than 10 CFU/mL (≤100 CFU/inoculum) were each inoculated into a 75 cm^2 flask containing 50 mL of sterile SP-4 broth.

b.4 The agar plates were placed in an anaerobic GasPak system and incubated at 36 ± 1°C for 14 days. The broth cultures were incubated aerobically at 36 ± 1°C for a minimum of 14 days and were read each working day for 14 days. On Days 3, 7, and 14, 0.2 mL from each broth culture flask was subcultured onto each of two (2) SP-4 agar plates. These subculture plates were placed in an anaerobic GasPak system and incubated at 36 ± 1°C. The subculture plates were observed microscopically for the presence of mycoplasma colonies after a minimum of 14 days incubation.

c. See Section 15.0, Results, for the results of these controls.

11.0 DATA ANALYSIS

The results of this study were based on visual observations, therefore, no data analysis was required.

12.0 STATISTICAL METHODS

The results of this study were qualitative, therefore, no statistical analysis was required.

13.0 EVALUATION CRITERIA

Final evaluation of the validity of the assay and test article results was based upon the criteria listed below and scientific judgment.

13.1 Indirect Assay

DETECTION OF MYCOPLASMA CONTAMINATION BY INDIRECT ASSAY

CONTROLS	MYCOPLASMA FLUORESCENCE OBSERVED (AT LEAST ONE COVERSLIP REQUIRED FOR THE EVALUATION)
Negative Control	-
M. hyorhinis	+
M. orale (≤100 CFU)	+/-*
M. orale (100 ID_{50})	+

*Mycoplasma must be observed for at least one dilution of the poorly cyto-adsorbing mycoplasma species *M. orale*.

13.2 Direct Assay

DETECTION OF MYCOPLASMA CONTAMINATION BY DIRECT ASSAY

	NEGATIVE CONTROL	*M. PNEUMONIAE*	*M. ORALE*
Broth (Color change or turbidity change)	-	+ / -	+ / -
Agar Day 0 (at least one plate)	-	+	+
Agar Day 3, 7, 14 (at least one plate on one day)	-	+	+
Results	-	+	+

14.0 TEST EVALUATION

14.1 Indirect Assay

Hoechst stain will bind to most DNA containing organisms and organelles present in the culture; this includes indicator cell nuclei, prokaryotes including mycoplasma and cell debris. The source of DNA is determined by the staining pattern. The indicator cell nuclei fluoresce brightly and are generally 10-20 μm in diameter. Mycoplasma fluorescence is less intense, is extra-nuclear and typically appears as small round bodies approximately 0.3 μm in diameter.

14.2 Direct Assay

Change in color or turbidity of broth culture can be an indicator of the presence of mycoplasma growth. Fermentative mycoplasma produce acid from the carbohydrates in the medium causing the pH of the medium to drop and the broth to turn yellow in color. Nonfermentative mycoplasma produce ammonia by arginine hydrolysis causing the pH to rise and the broth to turn red. In general, growth of mycoplasma can cause the broth to become turbid. These changes must be confirmed by agar plate subculture or DNA-staining since changes in the appearance of the broth culture can also be caused by the properties of the inoculum.

Mycoplasma colonies grow down into the agar causing the center of the colony to appear opaque and the peripheral surface growth to appear translucent. These "fried-egg" colonies vary in size, 10-500 μm, and can be readily observed unstained using a light microscope.

14.3 Indirect Assay and Direct Assay Results Interpretation

IF:	TEST ARTICLE				
Mycoplasmal fluorescence	-	+	+/-	+/-	-
Broth (Color change or turbidity change)	-	+/-	+/-	+/-	+*
Agar - Day 0 (at least one plate)	-	+/-	+/-	+	-
Agar - Day 3, 7, 14 (at least one plate on one day)	-	+/-	+	+/-	-
THEN: OVERALL FINAL RESULT	-	+	+	+	-

*A change in the appearance of a broth culture must be confirmed by positive subculture plate(s).

14.4 Positive Results

The test article is considered positive if the direct assay (agar or broth media procedure) or the indirect assay (indicator cell culture procedure) show evidence of mycoplasma contamination and resemble the positive controls for the procedure.

14.5 Negative Results

The test article is considered as negative if both the direct assay (agar and broth media procedure) and the indirect assay (indicator cell culture procedure) show no evidence of mycoplasma contamination and resemble the negative control for each procedure.

15.0 RESULTS

Indirect Assay and Direct Assay Results

	INDIRECT	DIRECT		OVERALL
		BROTH FLASKS	AGAR PLATES	
Test Article: ES02-FTDL-1	Negative	Negative	Negative	Negative
Negative Control	Negative	Negative	Negative	Negative
M. hyorhinis	Positive			Positive
M. orale	Positive	Positive	Positive	Positive
M. pneumoniae		Positive	Positive	Positive

For the indirect assay, the coverslips for the undiluted test article were read and determined negative.

16.0 ANALYSIS AND CONCLUSION

16.1 The results of the negative and positive controls indicated the validity of this test.

16.2 These findings indicated that the test article, ES02-FTDL-1, is considered negative for the presence of mycoplasma contamination.

17.0 DEVIATIONS: None.

18.0 AMENDMENTS: The Study Directorship was reassigned to Sheri J. Zielinski

19.0 RECORD RETENTION

An exact copy of the original final report and all raw data pertinent to this study will be stored at WuXi AppTec, Inc., 2540 Executive Drive, St. Paul, MN 55120. It is the responsibility of the Sponsor to retain a sample of the test article.

20.0 TECHNICAL REFERENCES

20.1 Barile, Michael F. and McGarrity, Gerard J. (1983). "Isolation of Mycoplasmas from Cell Culture by Agar and Broth Techniques." Methods in Mycoplasmology, Vol II, ed. J.G. Tully and S. Razin. (New York: Academic Press) pp. 159-165.

20.2 Del Giudice, Richard A. and Joseph G. Tully. 1996. "Isolation of Mycoplasma from Cell Cultures by Axenic Cultivation Techniques," ed. J.G. Tully and S. Razin, Molecular and Diagnostic Procedures in Mycoplasmology, Vol. II (New York: Academic Press).

20.3 McGarrity, Gerard J. and Barile, Michael F. 1983. "Use of Indicator Cell Lines for Recovery and Identification of Cell Culture Mycoplasmas," ed. J.G. Tully and S. Razin, Methods in Mycoplasmology, Vol. II (New York: Academic Press).

20.4 Masover, Gerald and Frances Becker. 1996. "Detection of Mycoplasma by DNA Staining and Fluorescent Antibody Methodology," ed. J.G. Tully and S. Razin, Molecular and Diagnostic Procedures in Mycoplasmology, Vol. II (New York: Academic Press).

20.5 Schmidt, Nathalie J. and Emmons, Richard W. 1989. "Cell Culture Procedures for Diagnostic Virology," ed. Nathalie J. Schmidt and Richard W. Emmons, 6th ed., Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections (Washington: American Public Health Association).

20.6 U.S. Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (CBER). 1993. "Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals."

WuXi AppTec

GLP COMPLIANT TEST PROTOCOL AMENDMENT

Copy of Original

1.0 Amendment Number: 1

2.0 Effective Date: August 11, 2008

3.0 Amendment Date: August 11, 2008

4.0 Sponsor: WiCell Research Institute

5.0 Test Facility: WuXi AppTec Inc.

6.0 WuXi AppTec Protocol Number: 30055F

7.0 WuXi AppTec Project Number: 108626

8.0 Modification to Protocol:
The Study Directorship of this assay was reassigned to

9.0 Reason for Change:
Study director change

10.0 Impact to Protocol Interpretation:
none

11.0 Review
Signatures below represent authorization of the amendment (e.g. authorize change to the SOP and protocol).

_____ _____ 8/11/08
Study Director Date

NA _____ NA
Sponsor (if applicable) Date

Check applicable box as task is completed:
NA
☐ ☑ Amendment attached to protocol
☑ ☐ Annotation made in protocol
☑ ☐ Special Instructions Worksheet/Study Worksheets Updated
☑ ☐ IACUC Protocol Amended/Updated

The following should be completed for amendments that alter the study schedule:
☑ ☐ Project Schedules updated
☑ ☐ Worksheets updated
☑ ☐ Project Folder Annotations/Stamps updated
☑ ☐ Critical Phase Audited Re-scheduled
☑ ☐ Cage Card Termination Date updated
☑ ☐ Special Instruction Worksheet updated

Updates Complete:

_____ 8/20/08
Study Director or Manager Date

WiCell Cytogenetics Report: 000640-071108
NSCB 1798

Report Date: July 13, 2010

Case Details:

Cell Line: *ES02-FTDL-1 (1798)*

Passage #: *66*

Date Completed: *7/18/2008*

Cell Line Gender: *Female*

Investigator: *National Stem Cell Bank*

Specimen: *hESC on MEF feeder*

Date of Sample: *7/11/2008*

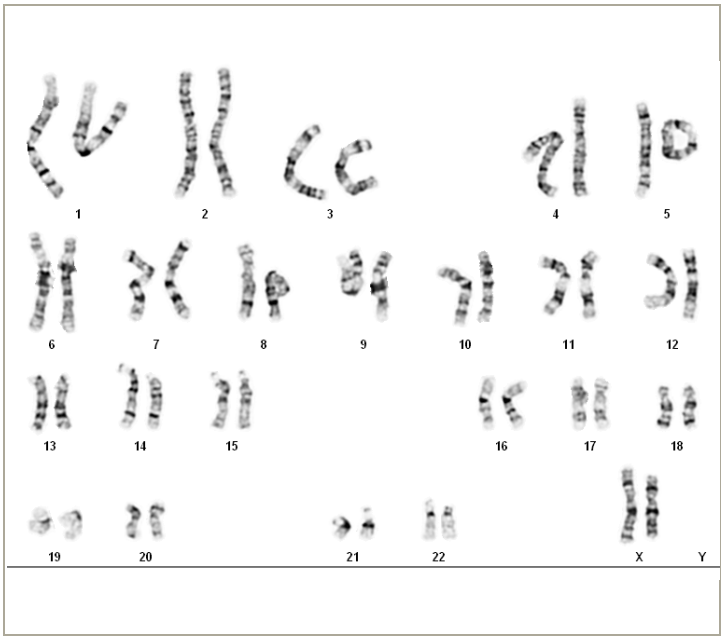
Tests,Reason for: *NSCB-FTDL testing*

Results: *46XX*

Completed by ST, CLSp(CG), on 7/18/2008

Reviewed and interpreted by KDM, PhD, FACMG, on 7/18/2008

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



Cell: *S01-03*

Slide: *B*

Slide Type: *Karyotyping*

Cell Results: *Karyotype: 46,XX*

# of Cells Counted: *20*

# of Cells Karyotyped: *3*

# of Cells Analyzed: *6*

Band Level: *450-550*

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

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