



Product Information and Testing

Cell Line: BG02

Lot: 19-Nov-04

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If you have any questions please contact WiCell's technical support staff via www.wicell.org and we will be happy to assist you.

Thank you,

WiCell

Short Tandem Repeat Analysis*

Sample Report: **WiCell 7004-STR**
BG02 (lot# 19Nov04)

UW HLA#: 57552

Sample Date: 11/21/07
 Received Date: 11/21/07

Requestor: WiCell Research Institute

Test Date: 11/21/07

File Name: 071126

Report Date: 12/01/07,
 reformatted 12/09/07

Sample Name: (label on tube)

WiCell 7004-STR

Description: DNA Extracted by WiCell

102 ug/mL; 260/280 = 1.8

Locus	Repeat #	STR Genotype
D16S539	5, 8-15	12,12
D7S820	6-14	12,14
D13S317	7-15	11,11
D5S818	7-15	11,12
CSF1PO	6-15	8,10
TPOX	6-13	11,11
Amelogenin	NA	X,Y
TH01	5-11	8,9
vWA	11, 13-21	18,19

Comments: Based on the 7004-STR DNA submitted by WI Cell dated 11/21/07 and received on 11/21/07, this sample (UW HLA# 57555) matches exactly the STR profile of the human stem cell line **BG02** comprising 13 allelic polymorphisms across the 8 STR loci analyzed. No STR polymorphisms other than those corresponding to the human BG02 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 sample submitted corresponds to the BG02 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 copy of this report was issued via electronic mail to both CS and JJ of WI Cell Research Institute on Monday, December 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.

Report Number
762719
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WiCell Research Institute

December 06, 2007
P.O. #: RP1540

STERILITY TEST REPORT

Sample Information: Human embryonic stem cell line on mouse feeder layer
1: BG01 (lot # 11Jun04)

Date Received: November 20, 2007
Date in Test: November 21, 2007
Date Completed: December 05, 2007

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

TEST PARAMETERS	PRODUCT	
Approximate Volume Tested	0.5 mL	0.5 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.



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

lte 20

9 FAX#:

BTL SAMPLE ID#: **50800** P.O.#: **RP1569** DATE REC'D: **11/27/2007**

TEST/CONTROL ARTICLE:

BG02-pDL-01-AP27

LOT#: **NA**

DIRECT CULTURE SET-UP (DAY 0)

DATE: **11/28/2007**

INDICATOR CELL LINE (VERO)

SEE DNA FLUOROCHROME RECORD SHEET

			DATE
THIOGLYCOLLATE BROTH	DAY 7	+ ⊖	<u>12/05/2007</u>
	DAY 28	+ ⊖	<u>12/26/2007</u>
BROTH-FORTIFIED COMMERCIAL <u>0.5</u> mL SAMPLE	DAY 7	+ ⊖	<u>12/05/2007</u>
	DAY 28	+ ⊖	<u>12/26/2007</u>
<u>6.0</u> mL BROTH	DAY 7	+ ⊖	<u>12/05/2007</u>
	DAY 28	+ ⊖	<u>12/26/2007</u>
BROTH-MODIFIED HAYFLICK <u>0.5</u> mL SAMPLE	DAY 7	+ ⊖	<u>12/05/2007</u>
	DAY 28	+ ⊖	<u>12/26/2007</u>
<u>6.0</u> mL BROTH	DAY 7	+ ⊖	<u>12/05/2007</u>
	DAY 28	+ ⊖	<u>12/26/2007</u>
BROTH-HEART INFUSION <u>0.5</u> mL SAMPLE	DAY 7	+ ⊖	<u>12/05/2007</u>
	DAY 28	+ ⊖	<u>12/26/2007</u>
<u>6.0</u> mL BROTH	DAY 7	+ ⊖	<u>12/05/2007</u>
	DAY 28	+ ⊖	<u>12/26/2007</u>

(See Reverse)

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

SAMPLE ID#:	50800	AEROBIC	MICROAEROPHILIC	DATE
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ ⊖	+ ⊖	<u>12/05/2007</u>
	DAY 14	+ ⊖	+ ⊖	<u>12/12/2007</u>
	DAY 21	+ ⊖	+ ⊖	<u>12/19/2007</u>
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ ⊖	+ ⊖	<u>12/05/2007</u>
	DAY 14	+ ⊖	+ ⊖	<u>12/12/2007</u>
	DAY 21	+ ⊖	+ ⊖	<u>12/19/2007</u>
AGAR PLATES-HEART INFUSION	DAY 7	+ ⊖	+ ⊖	<u>12/05/2007</u>
	DAY 14	+ ⊖	+ ⊖	<u>12/12/2007</u>
	DAY 21	+ ⊖	+ ⊖	<u>12/19/2007</u>
BROTH SUBCULTURES (DAY 7)		DATE: <u>12/05/2007</u>		
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ ⊖	+ ⊖	<u>12/12/2007</u>
	DAY 14	+ ⊖	+ ⊖	<u>12/19/2007</u>
	DAY 21	+ ⊖	+ ⊖	<u>12/26/2007</u>
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ ⊖	+ ⊖	<u>12/12/2007</u>
	DAY 14	+ ⊖	+ ⊖	<u>12/19/2007</u>
	DAY 21	+ ⊖	+ ⊖	<u>12/26/2007</u>
AGAR PLATES-HEART INFUSION	DAY 7	+ ⊖	+ ⊖	<u>12/12/2007</u>
	DAY 14	+ ⊖	+ ⊖	<u>12/19/2007</u>
	DAY 21	+ ⊖	+ ⊖	<u>12/26/2007</u>

RESULTS: No detectable mycoplasmal contamination

12/26/07
 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 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 microaerophilically 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-FLUOROCHROME ASSAY RESULTS

Procedures 3008, 3009, 3011

Sample ID # 50800 M-250 Date Rec'd: 11/27/2007 P.O. # RP1569

Indicator Cells Inoculated: Date/Initials: 11/29/07 JA

Fixation: Date/Initials: 12/3/07 JA

Staining: Date/Initials: 12/3/07 JA

TEST/CONTROL ARTICLE:

BG02-pDL-01-AP27

LOT# NA

Distribution Lab
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: 12/3/07 Results Read by: JA Date of Review: 12/3/07 Reviewed by: u

Report Date: November 28, 2007

Case Details:

Cell Line: NSCB# 7004 (BG02 lot# 19Nov04 (BG02-DDL-A))

Passage #: p26

Date Completed: 11/28/2007

Cell Line Gender: male

Investigator: National Stem Cell Bank

Specimen: hESC on MEF feeder

Date of Sample: 11/19/2007

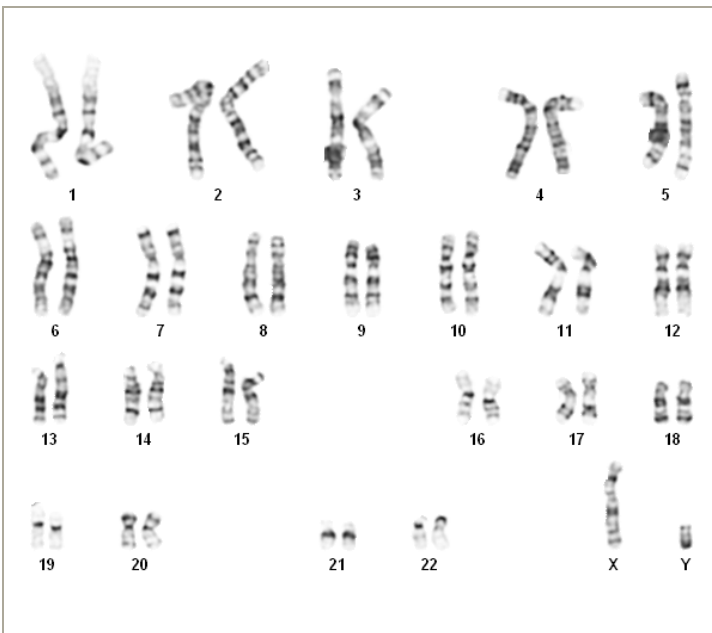
Tests, Reason for: Confirmation of normal karyotype prior to redistribution

Results: 46,XY

Completed by ST, CLSp(CG), on 11/27/2007

Reviewed and interpreted by KDM, PhD, FACMG, on 11/28/2007

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



Cell: S01-01

Slide: A

Slide Type: Karyotyping

Cell Results: Karyotype: 46,XY

of Cells Counted: 20

of Cells Karyotyped: 4

of Cells Analyzed: 8

Band Level: 450-575

Results Transmitted by Fax / Email / Post
Sent By: _____

Date: _____
Sent To: _____