Product Information and Testing
Cell Line: BG03
Lot: 11-Jul-04

Table of Contents

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

Thank you,

WiCell

UW Health
University of Wisconsin
Hospital and Clinics

Histocompatibility/Molecular Diagnostics Laboratory
D4/231; (608) 263-8815
600 Highland Avenue
Madison, WI 53792-2472

Short Tandem Repeat Analysis*

Sample Report: WiCell 8228-STR BG03 (lot# 11Jul04)

UW HLA#: 57551

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 8228-STR

Description: DNA Extracted by WiCell

99 ug/mL; 260/280 = 1.7

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

Comments: Based on the 8228-STR DNA submitted by WI Cell dated 11/21/07 and received on 11/21/07, this sample (UW HLA# 57551) matches exactly the STR profile of the human stem cell line BG03 comprising 11 allelic polymorphisms across the 8 STR loci analyzed. No STR polymorphisms other than those corresponding to the human BG03 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 BG03 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.

Test Facility:
1265 Kennestone Circle
Marietta, GA 30066

WiCell Research Institute
[redacted]
December 06, 2007
P.O. #: RP1540

STERILITY TEST REPORT

Sample Information: Human embryonic stem cell line on mouse feeder layer 3: BG03 (lot # 11 Jul 04)

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	0.48 mL	0.48 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.

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

BTL SAMPLE ID#: **50627** P.O.#: **RP1549** DATE REC'D: **11/13/2007**

TEST/CONTROL ARTICLE:

BG03 p31 lot 11-Jul-04

LOT#: **NA**

DIRECT CULTURE SET-UP (DAY 0) DATE: **11/14/2007**

INDICATOR CELL LINE (VERO) SEE DNA FLUOROCHROME RECORD SHEET

			DATE
THIOGLYCOLLATE BROTH	DAY 7	+ ⊖	11/21/2007
	DAY 28	+ ⊖	12/12/2007
BROTH-FORTIFIED COMMERCIAL			
0.5 mL SAMPLE	DAY 7	+ ⊖	11/21/2007
6.0 mL BROTH	DAY 28	+ ⊖	12/12/2007
BROTH-MODIFIED HAYFLICK			
0.5 mL SAMPLE	DAY 7	+ ⊖	11/21/2007
6.0 mL BROTH	DAY 28	+ ⊖	12/12/2007
BROTH-HEART INFUSION			
0.5 mL SAMPLE	DAY 7	+ ⊖	11/21/2007
6.0 mL BROTH	DAY 28	+ ⊖	12/12/2007

(See Reverse)

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

SAMPLE ID#: 50627		AEROBIC	MICROAEROPHILIC	DATE
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ ⊖	+ ⊖	11/21/2007
	DAY 14	+ ⊖	+ ⊖	11/28/2007
	DAY 21	+ ⊖	+ ⊖	12/05/2007
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ ⊖	+ ⊖	11/21/2007
	DAY 14	+ ⊖	+ ⊖	11/28/2007
	DAY 21	+ ⊖	+ ⊖	12/05/2007
AGAR PLATES-HEART INFUSION	DAY 7	+ ⊖	+ ⊖	11/21/2007
	DAY 14	+ ⊖	+ ⊖	11/28/2007
	DAY 21	+ ⊖	+ ⊖	12/05/2007
BROTH SUBCULTURES (DAY 7)		DATE: 11/21/2007		
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ ⊖	+ ⊖	11/28/2007
	DAY 14	+ ⊖	+ ⊖	12/05/2007
	DAY 21	+ ⊖	+ ⊖	12/12/2007
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ ⊖	+ ⊖	11/28/2007
	DAY 14	+ ⊖	+ ⊖	12/05/2007
	DAY 21	+ ⊖	+ ⊖	12/12/2007
AGAR PLATES-HEART INFUSION	DAY 7	+ ⊖	+ ⊖	11/28/2007
	DAY 14	+ ⊖	+ ⊖	12/05/2007
	DAY 21	+ ⊖	+ ⊖	12/12/2007

RESULTS: No detectable mycoplasmal contamination

12/12/07
Date

vices
h.D.

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
Safe Cells®

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 # **50627** **M-250** Date Rec'd: **11/13/2007** P.O. # **RP1549**

Indicator Cells Inoculated: Date/Initials: (B) 11/15/07 JA 11/15/07 / JA
~~11/14/07~~

Fixation: Date/Initials: 11/19/07 / KG

Staining: Date/Initials: 11/19/07 / KG

TEST/CONTROL ARTICLE:

BG03 p31

LOT# **NA**

Distribution Lab

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: 11/19/07 Results Read by: KG Date of Review: 11/19/07 Reviewed by: CW