Product Information and Testing - Amended

Product Information

Product Name	WA15.07.03[1]
	[1]The originally deposited material was subcloned to obtain optimal distribution material. The numbers at the end of the cell line name indicates the subclone.
Lot Number	WB0063
Depositor	University of Wisconsin – Laboratory of Dr. James Thomson
Banked by	WiCell
Thaw Recommendation	Thaw 1 vial into 4 wells of a 6 well plate.
Culture Platform	Feeder Independent
	Medium: mTeSR1
	Matrix: Matrigel
Protocol	WiCell Feeder Independent Protocol
Passage Number	p29 These cells were cultured for 28 passages prior to freeze. WiCelladds +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	26-October-2010
Vial Label	WB0063 WA15.07.03 P29 MW 26OCT10
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 Reported by Depositor

Test Description	Result	Report
Karyotype	Normal	See Publication
Oct 4	Present	See Publication
SSEA4	Present	See Publication
Tra 1-60	Present	See Publication
Tra 1-81	Present	See Publication
Terataoma	3 Germ Layers Present	See Publication

Product Information and Testing - Amended

Lot Specific Testing Performed by WiCell

The following tests were performed on this specific lot.

Test Description	Test Provider	Test Method	Test Specification	Result
Post-Thaw Viable Cell Recovery	WiCell	SOP-CH-305	≥ 15 Undifferentiated Colonies, ≤ 30% Differentiation	Pass
Identity by STR	UW Molecular Diagnostics Laboratory	PowerPlex 1.2 System by Promega	Consistent with known profile	Pass[2]
	[2]This test was the first STR performed for this cell line and therefore it establishes the STR identity for this cell line.			
Sterility - Direct transfer method	Apptec	30744	Negative	Pass
Mycoplasma	Bionique	M250	No contamination detected	Pass
Karyotype by G-banding	WiCell	SOP-CH-003	Normal karyotype	Pass

General Cell Line Testing Performed by WiCell

The following tests were performed on the cell line. The tests do not apply to any particular lot.

Test Description	Test Provider	Test Method
HLA	UW Molecular Diagnostics Laboratory	PowerPlex 1.2 System by Promega
ABO	American Red Cross	For ABO: Olsson ML, Chester MA. A rapid and simple ABO genotype screening method using a novel B/O2 versus A/O2 discriminating nucleotide substitution at the ABO locus. Vox Sang 1995; 69(3):242-7. For RHD: Singleton BK, Green CA, Avent ND, Martin PG, Smart E, Daka A, Narter-Olaga EG, Hawthorne LM, Daniels G. The presence of an RHD pseudogene containing a 37 base pair duplication and a nonsense mutation in Africans with the Rh D-negative blood group phenotype. Blood 2000; 95(1): 12-8.
Comprehensive Human Virus Panel	Charles River	ID 91/0

Date of Lot Release	Quality Assurance Approval
08-April-2011	8/6/2015 X AMK AMK Quality Assurance Signed by: [redacted]

UW Health

University of Wisconsin
Hospital and Clinics

Histocompatibility/Molecular Diagnostics Laboratory

[redacted]

Short Tandem Repeat Analysis*

Sample Report: 10056-STR | UW HLA#: 64814 | Sample Date: 03/11/11
Received Date: 03/11/11

Requestor: WiCell Research Institute
Test Date: 03/15/11 | File Name: 110316blb | Report Date: 03/17/11

Sample Name: (label on tube) **10056-STR**

Description: WiCell Research Institute provided genomic DNA
274.78 ug/mL; 260/280 = 1.90

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

Comments: Based on the 10056-STR DNA dated and received on 03/11/11 from WiCell Research Institute, this sample (UW HLA# 64814) defines the STR profile of the human stem cell line WA15 comprising 15 allelic polymorphisms across the 8 STR loci analyzed. No STR polymorphisms other than those corresponding to the human WA15 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 10056-STR DNA sample submitted corresponds to the WA15 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%.

[redacted] 3/17/11
Date
Molecular Diagnostics Laboratory

[redacted] 03/17/11
Date
Molecular Diagnostics Laboratory

* 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.

File: Final STR Report

Test Facility: [redacted]

WuXi AppTec

Report Number
852056.A01
Page 1 of 1

WiCell Research Institute
[redacted]

December 1, 2010
P.O. #: [redacted]
AMENDED REPORT
Original Issue Date:
11-27-10

❖ Amendment Summary

STERILITY TEST REPORT

Sample Information: hES Cells
1: WA15.07.07-WB0062 #1661
2: WA22-WB0046 #1491
3: WA13.C-WB0054 #7289
4: WA22-WB0053 #3855
5: iPS(IMR90)-3-WB0057 #3060
6: WA23-WB0067 #4696
7: WA15.07.03-WB0063 #8295

Date Received: November 09, 2010
Date in Test: November 11, 2010
Date Completed: November 25, 2010

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

TEST PARAMETERS	PRODUCT	
Approximate Volume Tested	0.5 mL	0.5 mL
Number Tested	14	14
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	14 NEGATIVE	14 NEGATIVE

❖ A01 – Dated 12-01-10: Corrected sample information for sample # 1.

[redacted] 12-01-10 Date

[redacted] 12-01-10 Date

Testing conducted in accordance with current Good Manufacturing Practices.

[redacted]

bionique Testing Laboratories

MYCOPLASMA TESTING SERVICES

APPENDIX

BIONIQUE® TESTING LABORATORIES, INC.

[redacted]

Document ID #:	DCF9002F
Title:	QUALITY ASSURANCE REPORT - GMP
Effective Date:	03/12/10
Edition #:	01

QUALITY ASSURANCE REPORT – GMP

TEST PERFORMED	PROCEDURAL REFERENCE	TEST PERFORMED	PROCEDURAL REFERENCE
☒ M-250	SOP's 3008, 3011, 3013	☐ M-700	SOP's 3008, 3009, 3010
☐ M-300	SOP's 3008, 3014	☐ M-800	SOP's 3008, 3011, 3016
☐ M-350	SOP's 3008, 3014, 3015		

Bionique Sample ID #(s) 64572 64573

This testing procedure was performed in compliance with the FDA's Current Good Manufacturing Practice (cGMP) standards (to the extent that the regulations pertain to the procedures performed) as specified in the Code of Federal Regulations, Title 21 Parts 210 and 211 [21 CFR 210 & 211]. All related records derived from the test procedures have been reviewed by the Quality Assurance Department. The individual's signature below verifies that the methods and procedures referenced above have been followed and that the Final Report accurately reflects the raw data generated during the course of the procedures. All records, including raw data and final reports are archived on site for a minimum of seven years.

The specified test's procedures determine the intervals at which samples are inspected. The medium used for testing must pass quality control mycoplasmal growth promotion testing and sterility testing. Traceability of all of the components used is assured and supporting documentation can be supplied upon request.

Quality Assurance Review Date: 4/6/11

Reviewed By [redacted] QA Assistant: [redacted]

NOTE:

1. Prior to receipt at Bionique® Testing Laboratories, Inc., the stability of the test article is the responsibility of the company submitting the sample. Bionique Testing Laboratories Inc. will assume responsibility for sample stability following receipt and prior to being placed on test.
2. This test is for the detection of microbiological growth and does not require statistical validation.

REFERENCES

Regulatory:

1. Department of Health and Human Services, Food and Drug Administration (USA) [FDA]. Code of Federal Regulations [CFR], Title 21 CFR Part 210, Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General. FDA. Office of the Federal Register, National Archives and Records Department.
2. Department of Health and Human Services, Food and Drug Administration (USA) [FDA]. Code of Federal Regulations [CFR], Title 21 CFR Part 211, Current Good Manufacturing Practice for Finished Pharmaceuticals. FDA. Office of the Federal Register, National Archives and Records Department.
3. Department of Health and Human Services, Food and Drug Administration (USA) [FDA]. Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals, Director, Center for Biologics Evaluation and Research, FDA. May, 1993. Docket No. 84N-0154.
4. Department of Health and Human Services, Food and Drug Administration (USA) [FDA]. Code of Federal Regulations [CFR], Title 21 CFR Part 610.30, General Biological Products Standards; Subpart D, Test for Mycoplasma. FDA. Office of the Federal Register, National Archives and Records Department.

General:

1. Barile MF, Kern J. Isolation of Mycoplasma arginini from commercial bovine sera and its implication in contaminated cell cultures. Proceedings of the Society for Experimental Biology and Medicine, Volume 138, Number 2, November 1971.
2. Chen, T.R. In situ detection of mycoplasma contamination in cell cultures by fluorescent Hoechst 33258 stain. Experimental Cell Research, 104: 255-262, 1977.
3. Carolyn K. Lincoln and Daniel J. Lundin. Mycoplasma Detection and Control. U. S. Fed. for Culture Collections Newsletter, Vol. 20, Number 4, 1990.
4. Fetal Bovine Serum; Proposed Guideline. National Committee For Clinical Laboratory Standards (NCCLS), Vol. 10, Number 6, 1990. (NCCLS publication M25-P).
5. McGarrity GJ, Sarama J, Vanaman V. Cell Culture Techniques. ASM News, Vol. 51, No. 4, 1985.
6. Tully JG, Razin S. Methods in Mycoplasmology, Volumes I and II. Academic Press, N.Y., 1983.
7. Barile MF, Razin S, Tully JG, Whitcomb RF. The Mycoplasmas, Volumes 1-4. Academic Press, N.Y., 1979.
8. http://www.bionique.com/ - Safe Cells Insights

bionique Testing Laboratories

MYCOPLASMA TESTING SERVICES

BIONIQUE TESTING LABORATORIES, INC

[redacted]

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: **WiCell QA**
WiCell Research Institute

[redacted]

BTL SAMPLE ID#: **64573** P.O.#: [redacted] DATE REC'D: **03/08/2011**

TEST/CONTROL ARTICLE:

WA15.07.03-WB0063 #10056

LOT#: **NA**

DIRECT CULTURE SET-UP (DAY 0) DATE: **03/09/2011**

INDICATOR CELL LINE (VERO) SEE DNA FLUOROCHROME RECORD SHEET

				DATE
THIOGLYCOLLATE BROTH	DAY 7	+	⊖	03/16/2011
	DAY 28	+	⊖	04/06/2011
BROTH-FORTIFIED COMMERCIAL				
0.5 mL SAMPLE	DAY 7	+	⊖	03/16/2011
6.0 mL BROTH	DAY 28	+	⊖	04/06/2011
BROTH-MODIFIED HAYFLICK				
0.5 mL SAMPLE	DAY 7	+	⊖	03/16/2011
6.0 mL BROTH	DAY 28	+	⊖	04/06/2011
BROTH-HEART INFUSION				
0.5 mL SAMPLE	DAY 7	+	⊖	03/16/2011
6.0 mL BROTH	DAY 28	+	⊖	04/06/2011

(See Reverse)

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

SAMPLE ID#: **64573**		AEROBIC	MICROAEROPHILIC	DATE
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ ⊖	+ ⊖	03/16/2011
	DAY 14	+ ⊖	+ ⊖	03/23/2011
	DAY 21	+ ⊖	+ ⊖	03/30/2011
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ ⊖	+ ⊖	03/16/2011
	DAY 14	+ ⊖	+ ⊖	03/23/2011
	DAY 21	+ ⊖	+ ⊖	03/30/2011
AGAR PLATES-HEART INFUSION	DAY 7	+ ⊖	+ ⊖	03/16/2011
	DAY 14	+ ⊖	+ ⊖	03/23/2011
	DAY 21	+ ⊖	+ ⊖	03/30/2011
BROTH SUBCULTURES (DAY 7)		DATE: **03/16/2011**		
AGAR PLATES-FORTIFIED COMMERCIAL	DAY 7	+ ⊖	+ ⊖	03/23/2011
	DAY 14	+ ⊖	+ ⊖	03/30/2011
	DAY 21	+ ⊖	+ ⊖	04/06/2011
AGAR PLATES-MODIFIED HAYFLICK	DAY 7	+ ⊖	+ ⊖	03/23/2011
	DAY 14	+ ⊖	+ ⊖	03/30/2011
	DAY 21	+ ⊖	+ ⊖	04/06/2011
AGAR PLATES-HEART INFUSION	DAY 7	+ ⊖	+ ⊖	03/23/2011
	DAY 14	+ ⊖	+ ⊖	03/30/2011
	DAY 21	+ ⊖	+ ⊖	04/06/2011

RESULTS: No detectable mycoplasmal contamination

4/6/11
Date

[redacted]

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 Laboratory 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.

bionique Testing Laboratories

MYCOPLASMA TESTING SERVICES

BIONIQUE® TESTING LABORATORIES, INC.

[redacted]

Document ID #:	DCF3008A
Title:	**DNA FLUOROCHROME ASSAY RESULTS**
Effective Date:	3/24/10
Edition #:	07

DNA-FLUOROCHROME ASSAY RESULTS

Procedures 3008, 3009, 3011

Sample ID # **64573** **M-250** Date Rec'd: **03/08/2011** P.O. # [redacted]

Indicator Cells Inoculated: Date/Initials: 3/10/11 / HS

Fixation: Date/Initials: 3/14/11 / HS

Staining: Date/Initials: 3/14/11 / HS

TEST/CONTROL ARTICLE:

WA15.07.03-WB0063 #10056

LOT# **NA**

WiCell QA
WiCell Research Institute

[redacted]

Phone: [redacted]

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: 3/14/11 Results Read by: HS Date of Review: 3/14/11 Reviewed by: SA

WiCell Cytogenetics Report: 003964

WISC 10020

Report Date: January 24, 2011

Case Details:

Cell Line: *WA15.07.03-WB0063 10020*

Passage #: *39*

Date Completed: *1/24/2011*

Cell Line Gender: *Male*

Investigator: [redacted]

Specimen: *hESC on Matrigel*

Date of Sample: *1/19/2011*

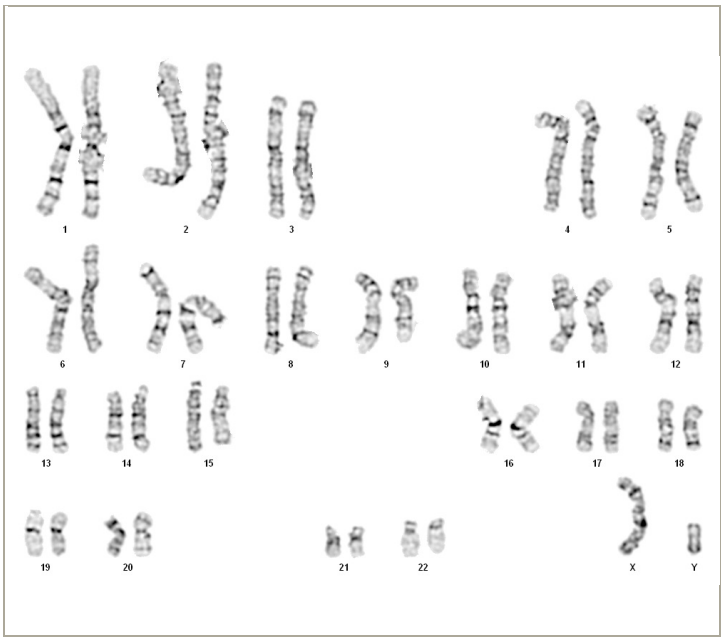
Tests,Reason for: *Karyotype repeat at p10+ from previous submission 0763 (normal)*

Results: *46,XY*

Completed by [redacted]*, CG(ASCP), on 1/21/2011*

Reviewed and interpreted by [redacted]*y, PhD, FACMG, on 1/24/2011*

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



Cell: *S01-16*

Slide: *2(8)KARYOTYPE*

Slide Type: *Karyotyping*

# of Cells Counted: *22*

# of Cells Karyotyped: *4*

# of Cells Analyzed: *8*

Band Level: *425-475*

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

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

QC Review By: _____ **Results Recorded:** _____

UW Health
University of Wisconsin
Hospital and Clinics

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

Date: 03/18/2011 08:57:45

To: WiCell Research Institute
Cytogenetics Lab
[redacted]

Re: High-resolution HLA results

Patient

Name / HLA / MR# received	Dates		HLA DNA-based typing* Method: PCR-SSP A*	B*	C*	Direct Sequencing DRB1*	DRB3*	DRB4*	DRB5*	PCR-SSP DQB1*
WICELL, 10056-HLA	DQB SSP		03:01	07:02g	07:02g	15:01				
64814 /	A,B,C SSP	03/17/2011	25:01	18:01g	12:03					
03/17/2011	DRB Seq	03/17/2011	Class I comment: B*07:02g includes B*07:02/61 B*18:01g includes B*18:01/17N C*07:02g includes C*07:02/50 Class II comment: HLA Allele database: IMGT/A 3.3.0 2011-01-14							

[redacted] anager
HLA/Molecular Diagnostics Laboratory
3-18-11 USW
Date

[redacted] PhD, Director
HLA/Molecular Diagnostics Laboratory
3/22/11
Date

This test was developed and its performance characteristics determined by the UWHC Clinical Laboratory. It has not been cleared or approved by the U.S. Food and Drug Administration. However, the FDA does not require licensure of analyte specific reagents since the laboratory is approved, under CLIA, for high complexity testing.

[I:\db\tx\ttmaster\vttmreport.frx]

New York Blood Center
Laboratory of Immunohematology and Genomics
45-01 Vernon Blvd., Long Island City, N.Y. 11101
718-752-4771 • Fax 718-752-4747

March 28, 2011

WiCell Research Institute
Attn: Quality Assurance
[redacted]

SAMPLE: DNA 10056-ABO (MA#110-11)

Date Received: 03/15/11
Sample Date: not provided

HISTORY: DNA from cell line.

TEST REQUESTED: Genotype for *ABO* and common *RH*

TESTING PERFORMED: *ABO:* Polymerase chain reaction-restriction fragment length polymorphism (PCR-RFLP) testing for nucleotide (nt) positions 261 (O^1), 467 (A^2), 703 (B), and 1096 (B and O^2). *RH:* Multiplex PCR-RFLP for *RHD* and *RHCE*C/c*. PCR-RFLP for *RHCE* Exon 5 (676C>G for E/e).

DNA RESULTS: PCR-RFLP indicated homozygous for nt 261G characteristic of O^1 alleles.

Result	Test Method
ABO* A/O^1	PCR-RFLP
RHD positive for exons 4, 7 and no inactivating pseudogene	Multiplex PCR
RHCE*C/c	Multiplex PCR
RHCE*e/e	PCR-RFLP

Predicted phenotype: Group A, RhD+C+E–c+e+

[redacted]MS
Manager, Genomics

[redacted]P)SBB, CQA(ASQ)
Director of Operations, Immunohematology

These *in vitro* diagnostic tests were developed and their performance characteristics established in the Molecular Analysis Laboratory. The tests have not been submitted to the Food and Drug Administration (FDA) for clearance or approval and; therefore, are not FDA-licensed tests. The Molecular Analysis Laboratory is certified under the Clinical Laboratory Improvement Amendment (CLIA) of 1988 as qualified to perform high complexity clinical testing. The New York Blood Center has been approved, by the New York State Department of Health to perform these tests under its current Clinical Laboratory Permit. These results are intended to predict a blood group antigen profile in a patient or donor, and are not intended for clinical diagnosis or as the sole means for patient management decisions. There are situations where testing DNA of a person may not reflect the red cell phenotype and not all performance characteristics have been determined. Nucleotide changes that inactivate gene expression or rare new variant alleles may not be identified in these assays.

New York BloodCenter

Immunohematology
Telephone: 718-752-4771
Genomics
Telephone: 718-752-4637

Sample: MA110-11; 10056-ABO

Test: RH/ABO - GF

CPT CODE	Description/Molecular Testing	RH/ABO
83890	Isolation /extraction	X1
83892	Enzymatic digestion	X3
83894	Separation by electrophoresis	X1
83912	Interpretation and report	X1

Charles River Research Animal Diagnostic Services
251 Ballardvale Street, Wilmington, MA 01887 USA
Tel: 781-222-6357 Fax: 978-658-7698

Sponsor: WiCell Research Institute **Accession #: 2011-017695**

Diagnostic Summary Report

[redacted]

Received: 22 Mar 2011
Approved: 23 Mar 2011, 16:33

Bill Method: [redacted]
Test Specimen: Human

Sample Set	Service (# Tested)	Profile	Assay	Tested	+	+/-	?
#1	Infectious Disease PCR (1)	All Results Negative					

+ = Positive, +/- = Equivocal, ? = Indeterminate

Service Approvals

Service	Approved By*	Date
Infectious Disease PCR	[redacted]	23 Mar 2011, 16:33

To assure the SPF status of your research animal colonies, it is essential that you understand the sources, pathobiology, diagnosis and control of pathogens and other adventitious infectious agents that may cause research interference. We have summarized this important information in infectious agent **Technical Sheets**, which you can view by visiting http://www.criver.com/info/disease_sheets.

**This report has been electronically signed by laboratory personnel. The name of the individual who approved these results appears in the header of this service report. All services are performed in accordance with and subject to General Terms and Conditions of Sale found in the Charles River Laboratories-Research Models and Services catalogue and on the back of invoices.*

Charles River Research Animal Diagnostic Services
251 Ballardvale Street, Wilmington, MA 01887 USA
Tel: 781-222-6357 Fax: 978-658-7698

Sponsor: WiCell Research Institute **Accession #: 2011-017695**

Product: Not Indicated **Test Specimen:** Human **Received:** 22 Mar 2011

Molecular Diagnostics Infectious Disease PCR Results Report

Department Review: Approved by [redacted], 23 Mar 2011, 16:33*

Human Comprehensive Virus Panel

Sample #: / **Code :**	**1** 15.07.03-WB0010
John Cunningham virus	-
BK virus	-
Herpesvirus type 6	-
Herpesvirus type 7	-
Herpesvirus type 8	-
Parvovirus B19	-
Epstein-Barr Virus	-
Hepatitis A virus	-
Hepatitis B virus	-
Hepatitis C virus	-
HPV-16	-
HPV-18	-
Human T-lymphotropic virus	-
Human cytomegalovirus	-
HIV-1	-
HIV-2	-
Adeno-associated virus	-
Human Foamy Virus	-
LCMV PCR	-
Hantavirus Hantaan PCR	-
Hantavirus Seoul PCR	-
Mycoplasma Genus PCR	-
DNA Spike	**PASS**
RNA Spike	**PASS**
NRC	**PASS**

Remarks: - = Negative; I = Inhibition, +/- = Equivocal; + = Positive.

Sample Suitability/Detection of PCR Inhibition:
Sample DNA or RNA is spiked with a low-copy number of a exogenous DNA or RNA template respectively. A spike template-specific PCR assay is used to test for the spike template for the purpose of determining the presence of PCR inhibitors. The RNA spike control is also used to evaluate the reverse-transcription of RNA. Amplification of spike template indicates that there is no detectable inhibition and the assay is valid.

NRC:
The nucleic acid recovery control (NRC) is used to evaluate the recovery of DNA/RNA from the nucleic acid isolation process. The test article is spiked with a low-copy number of DNA/RNA template prior to nucleic acid isolation. A template-specific PCR assay is used to detect the DNA/RNA spike.

**This report has been electronically signed by laboratory personnel. The name of the individual who approved these results appears in the header of this service report.*

Charles River Research Animal Diagnostic Services
251 Ballardvale Street, Wilmington, MA 01887 USA
Tel: 781-222-6357 Fax: 978-658-7698

Sponsor: WiCell Research Institute **Accession #: 2011-017695**

Product: Not Indicated **Test Specimen:** Human **Received:** 22 Mar 2011

Sample Descriptions

Total sample count = **1**

Sample #	Sample Code	Strain	Age	Sex
Sample Set # 1				**Type: Not Indicated**
1	WA15.07.03-WB0063 10075			