# Product Information and Testing - Amended

## Product Information

| | |
|---|---|
| Product Name | WA25 |
| Lot Number | WB0176 |
| Depositor | WiCell |
| Banked by | WiCell |
| Thaw Recommendation | Thaw 1 vial into 1 well of a 6 well plate. WiCell recommends thawing using ROCK Inhibitor for best results. |
| Culture Platform | Feeder Independent |
| | Medium: E8 – WiCell recommends to passage using ROCK Inhibitor for best results. |
| | Matrix: Recombinant Human Vitronectin |
| Protocol | WiCell Feeder Independent E8 Medium Protocol modified to include ROCK Inhibitor at passage. |
| Passage Number | p12<br><br>These cells were cultured for 11 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 | 07-July-2012 |
| Vial Label | WB0176<br>WA25<br>p12 MW<br>07JUL2012 |
| 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.<br>Cells distributed by WiCell are intended for research purposes only and are not intended for use in humans. |

## 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 16 HS System by Promega | Consistent with known profile | Pass |
| Sterility | Biotest Laboratories | ST/07 | Negative | Pass |
| Mycoplasma | Bionique | M250 | Negative | Pass |
| Karyotype by G-banding | WiCell | SOP-CH-003 | Expected karyotype | Pass |

# Product Information and Testing - Amended

## 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 |
|---|---|---|
| Differentiation Potential by Teratoma | WiCell | SOP-CH-213<br>SOP-CH-214 |
| HLA | UW Histocompatibility Laboratory | High resolution sequencing method with Celera reagents on the ABI 3100 instrument |
| ABO | New York Blood Center | 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.<br>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. |
| Growth Curve (Doubling Time) | WiCell | Varies by culture platform |
| Flow Cytometry for ESC Marker Expression | WiCell | SOP-CH-024 |
| Comprehensive Human Virus Panel | Charles River | ID 91/0 |

Amendment(s):

| Reason for Amendment | Date |
|---|---|
| CoA updated to include copyright information. | See Signature |
| CoA updated for format changes. | 15-July-2013 |
| Amended CoA to update lot number and include cell line testing table. | 28-May-2013 |
| CoA amended to update sterility testing. | 11-March-2013 |
| Original CoA | 28-January-2013 |

| Date of Lot Release | Quality Assurance Approval |
|---|---|
| 28-January-2013 | 1/3/2014<br>X AMC<br>AMC<br>Quality Assurance<br>Signed by: [redacted] |

UW Health

University of Wisconsin
Hospital and Clinics

**Histocompatibility/Molecular Diagnostics Laboratory**

[redacted]

# Short Tandem Repeat Analysis*

**Sample Report: 10666-STR** Label on Tube: 10666-STR Sample Date: 12/14/12
Lab Received: 12/14/12

Requestor: WiCell Research Institute

Test Date: 12/19/12 File Name: STR 121219 SLE Report Date: 12/30/12

Sample Name: (label on tube) 10666-STR

**Description:** WI Cell Research Institute provided genomic DNA
236 ug/mL 260/280=1.93

| Locus | Repeat # | STR Genotype |
|---|---|---|
| D16S539 | 5, 8-15 | 8,14 |
| D7S820 | 6-14 | 10,11 |
| D13S317 | 7-15 | 11,12 |
| D5S818 | 7-15 | 11,12 |
| CSF1PO | 6-15 | 11,13 |
| TPOX | 6-13 | 8,9 |
| Amelogenin | NA | X,X |
| TH01 | 5-11 | 6,6 |
| vWA | 11, 13-21 | 16,17 |

**Comments: Based on the 10666-STR DNA submitted by WI Cell dated and received on 12/14/12, this sample (Label on Tube: 10666-STR) exactly matches the STR profile of the human stem cell line WA25 comprising 15 allelic polymorphisms across the 8 STR loci analyzed. No STR polymorphisms other than those corresponding to the human WA25 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 suggests that the 10666-STR DNA sample submitted corresponds to the WA25 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%.**

[redacted]

Molecular Diagnostics Laboratory

[redacted]

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

[redacted]
**Biotest Laboratories, Inc.**
FDA Registered GMP | ISO 13485:2003 www.biotestlabs.com | ISO/IEC 17025:2005 EN/ISO 17665
[redacted]

# STERILITY REPORT

WiCell Research Institute, Inc.
WiCell Quality Assurance
[redacted]

BIOTEST SAMPLE # 13020990
VALIDATION # NG
TEST PURPOSE NG

| | | | |
|---|---|---|---|
| PRODUCT NAME | WA25-WB0176 #10716 | | |
| PRODUCT LOT | NA | | |
| STERILE LOT | NA | BI LOT | NA |
| STERILIZATION LOT | NA | BI EXPIRATION DATE | NA |
| STERILIZATION DATE | NA | DATE RECEIVED | 2013-02-21 |
| STERILIZATION METHOD | NA | TEST INITIATED | 2013-02-22 |
| SAMPLING BLDG / ROOM | NA | TEST COMPLETED | 2013-03-08 |

REFERENCE: Processed according to SOP LAB-003: Sterility Test Procedure.

1 product was divided between 40 mL TSB and 40 mL FTG. The sample was then cultured at 20-25 C and 30-35 C respectively and was monitored for a minimum of 14 days.

☒ USP
☐ BI Manufacturers Specifications
☐ Other

| RESULTS | # POSITIVES | # TESTED | POSITIVE CONTROL | NEGATIVE CONTROL |
|---|---|---|---|---|
| ☒ Sterile<br>☐ Non-Sterile<br>☐ NA | 0 | 1 | NA | 2 Negatives |

COMMENTS NA

REVIEWED BY [redacted] DATE 08MAR13

bionique Testing Laboratories

MYCOPLASMA TESTING SERVICES

BIONIQUE® TESTING LABORATORIES, INC.

[redacted]

APPENDIX

| | |
|---|---|
| Document ID #: | DCF9002F |
| Title: | QUALITY ASSURANCE REPORT - GMP |
| Effective Date: | 11/2/11 |
| Edition #: | 03 |

# 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) 72788

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: 1/9/13

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

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156 FAY BROOK DRIVE
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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#: **72788** P.O.#: [redacted] DATE REC'D: **12/12/2012**

TEST/CONTROL ARTICLE:

**WA25-WB0176 #10666**

LOT#: **NA**

DIRECT CULTURE SET-UP (DAY 0) DATE: **12/12/2012**

INDICATOR CELL LINE (VERO) SEE DNA FLUOROCHROME RECORD SHEET

| | | | | DATE |
|---|---|---|---|---|
| THIOGLYCOLLATE BROTH | DAY 7 | + | ⊖ | 12/19/2012 |
| | DAY 28 | + | ⊖ | 01/09/2013 |
| BROTH-FORTIFIED COMMERCIAL | | | | |
| 0.5 mL SAMPLE | DAY 7 | + | ⊖ | 12/19/2012 |
| 6.0 mL BROTH | DAY 28 | + | ⊖ | 01/09/2013 |
| BROTH-MODIFIED HAYFLICK | | | | |
| 0.5 mL SAMPLE | DAY 7 | + | ⊖ | 12/19/2012 |
| 6.0 mL BROTH | DAY 28 | + | ⊖ | 01/09/2013 |
| BROTH-HEART INFUSION | | | | |
| 0.5 mL SAMPLE | DAY 7 | + | ⊖ | 12/19/2012 |
| 6.0 mL BROTH | DAY 28 | + | ⊖ | 01/09/2013 |

(See Reverse)

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

| SAMPLE ID#: **72788** | | AEROBIC | MICROAEROPHILIC | DATE |
|---|---|---|---|---|
| AGAR PLATES-FORTIFIED COMMERCIAL | DAY 7 | + ⊖ | + ⊖ | 12/19/2012 |
| | DAY 14 | + ⊖ | + ⊖ | 12/26/2012 |
| | DAY 21 | + ⊖ | + ⊖ | 01/02/2013 |
| AGAR PLATES-MODIFIED HAYFLICK | DAY 7 | + ⊖ | + ⊖ | 12/19/2012 |
| | DAY 14 | + ⊖ | + ⊖ | 12/26/2012 |
| | DAY 21 | + ⊖ | + ⊖ | 01/02/2013 |
| AGAR PLATES-HEART INFUSION | DAY 7 | + ⊖ | + ⊖ | 12/19/2012 |
| | DAY 14 | + ⊖ | + ⊖ | 12/26/2012 |
| | DAY 21 | + ⊖ | + ⊖ | 01/02/2013 |
| **BROTH SUBCULTURES (DAY 7)** | | DATE: 12/19/2012 | | |
| AGAR PLATES-FORTIFIED COMMERCIAL | DAY 7 | + ⊖ | + ⊖ | 12/26/2012 |
| | DAY 14 | + ⊖ | + ⊖ | 01/02/2013 |
| | DAY 21 | + ⊖ | + ⊖ | 01/09/2013 |
| AGAR PLATES-MODIFIED HAYFLICK | DAY 7 | + ⊖ | + ⊖ | 12/26/2012 |
| | DAY 14 | + ⊖ | + ⊖ | 01/02/2013 |
| | DAY 21 | + ⊖ | + ⊖ | 01/09/2013 |
| AGAR PLATES-HEART INFUSION | DAY 7 | + ⊖ | + ⊖ | 12/26/2012 |
| | DAY 14 | + ⊖ | + ⊖ | 01/02/2013 |
| | DAY 21 | + ⊖ | + ⊖ | 01/09/2013 |

RESULTS: No detectable mycoplasmal contamination

Date 1/9/13

[redacted]

ADDITIONAL COMMENTS:

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 # **72788** **M-250** Date Rec'd: **12/12/2012** P.O. # [redacted]

Indicator Cells Inoculated: Date/Initials: 12/13/12 / AM

Fixation: Date/Initials: 12/17/12 / MK

Staining: Date/Initials: 12/17/12 / MK

TEST/CONTROL ARTICLE:

**WA25-WB0176 #10666**

LOT# **NA**

**WiCell QA**
**WiCell Research Institute**

[redacted]

[redacted]

### 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.

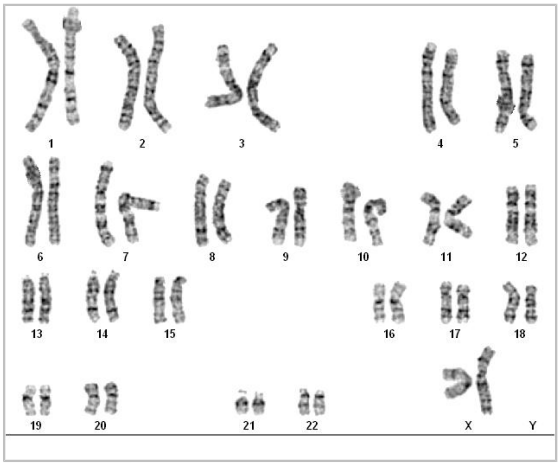
COMMENTS:

Date: 12/17/12 Results Read by: MK Date of Review: 12/17/12 Reviewed by: KC

# Chromosome Analysis Report: 009402

**Date Reported:** Monday, December 03, 2012
**Cell Line:** WA25-WB0176 10666
**Passage#:** 13
**Date of Sample:** 11/19/2012
**Specimen:** hESC
**Results:** 46,XX

**Cell Line Gender:** Female
**Reason for Testing:** Lot release testing
**Investigator:** [redacted], WiCell CDM




**Cell:** 24
**Slide:** 1
**Slide Type:** Karyotype

**Total Counted:** 20
**Total Analyzed:** 8
**Total Karyotyped:** 4
**Band Resolution:** 425 - 450

**Interpretation:**

**This is a normal karyotype. No clonal abnormalities were detected at the stated band level of resolution.**

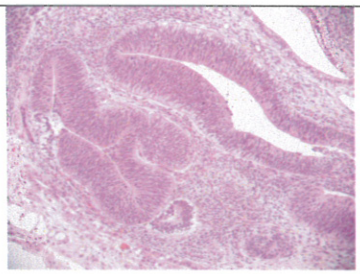
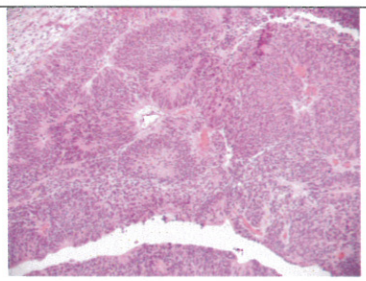
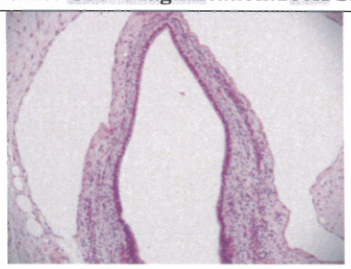
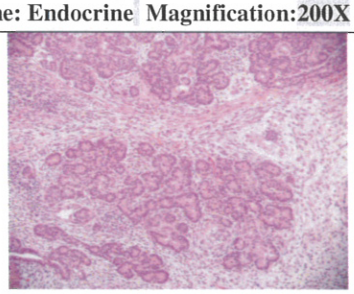
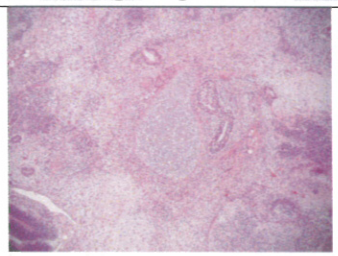
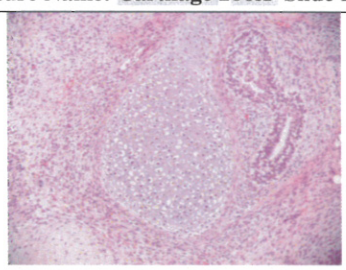
**Completed by:** [redacted] CG(ASCP)
**Reviewed and Interpreted by:** [redacted], PhD, FACMG

**A signed copy of this report is available upon request.**

**Date:**_____ **Sent By:**____ **Sent To:**_____ **QC Review By:** ____

*Limitations: This assay allows for microscopic visualization of numerical and structural chromosome abnormalities. The size of structural abnormality that can be detected is >3-10Mb, dependent upon the G-band resolution obtained from this specimen. For the purposes of this report, band level is defined as the number of G-bands per haploid genome. It is documented here as "band level", i.e., the range of bands determined from the four karyograms in this assay. Detection of heterogeneity of clonal cell populations in this specimen (i.e.,mosaicism) is limited by the number of metaphase cells examined, documented here as "# of cells counted".*

**Cell Line: WA25** **Cell Lot Number: NA** **Sample Number: 10404-A,B,C**

| ECTODERM | |
|---|---|
| **Structure Name: Neural tubules Magnification:200X Slide ID: A** | **Structure Name: Brain-like tissue Magnification: 200X Slide ID: B** |
|  |  |
| **ENDODERM** | |
| **Structure Name: Gut Magnification:200X Slide ID: C** | **Structure Name: Endocrine Magnification:200X Slide ID: A** |
|  |  |
| **MESODERM** | |
| **Structure Name: Cartilage Magnification:100X Slide ID: B** | **Structure Name: Cartilage 200X Slide ID: B** |
|  |  |

Comments: Structures identified include Ectoderm (2), Mesoderm (1) and Endoderm (2)

Sample(s) were assessed for the presence of differentiation into cell types characteristic of the three embryonic germ layers, which, if present in the sample(s) examined, are represented in the photographs above. The individual's signature below verifies that this report accurately reflects the pathology observed.

Pathologist (By/Date): 6/27/2012

[redacted]

QA Review (By/Date): [redacted] 03JUL12

① SOP ID SOP-CH-214. Error. 03JUL12 JCT

UW Health

University of Wisconsin
Hospital and Clinics

Name: WICELL, 10404-HLA
MRN: OS000181
DOB:
HLA#: WICELL

Hospital:
Physician: ,
Category:

## Bone Marrow Case Histocompatibility Summary
301417-DT

## HLA Typing Results

| Patient | Relation | Hap | A* | B* | C* | DRB1* | DRB3* | DRB4* | DRB5* | DQB1* | DPB1* | Tested Date / Collect Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| WICELL, 10404-HLA | | | 03:01 | 07:02:01G | 07:02:01G | 09:01 | | | | | | 03/12/12 |
| OS000181 / WICELL | Patient | | 11:01 | 51:07:01 | 14:02 | 11:01 | | | | | | 03/02/12 |

HLA typings performed by sequencing, SSO, SSP or a combination. For low-resolution testing, results are reported by Serologic Equivalents. A "+" in the HLA allele designation indicates that the typing was performed by low/mid-resolution molecular method and that additional alleles are possible. Only the most frequent allele is listed.

## HLA DNA-Based Typing

| Name / HLA / MR# / Received | Method / Test Date | A* | B* | C* | DRB1* | DRB3* | DRB4* | DRB5* | DQB1* |
|---|---|---|---|---|---|---|---|---|---|
| WICELL, 10404-HLA | | 03:01 | | | | | | | |
| OS000181 / WICELL | SEQ | 11:01 | | | | | | | |
| 03/02/2012 | 03/20/2012 | | | | | | | | |
| | | HLA Allele database: IMGT 3.7.0 2012-01-12 | | | | | | | |
| | | | 07:02:01G | | | | | | |
| | SEQ | | 51:07 | | | | | | |
| 03/02/2012 | 03/20/2012 | | | | | | | | |
| | | The reported allele group B*07:02:01G includes the following alleles, which share identical sequences in the antigen recognition site of exons 2 and 3: B*07:02 B*07:61<br>HLA Allele database: IMGT 3.7.0 2012-01-12 | | | | | | | |
| | | | | 07:02:01G | | | | | |
| | SEQ | | | 14:02 | | | | | |
| 03/02/2012 | 03/20/2012 | | | | | | | | |
| ) | | HLA Allele database: IMGT 3.7.0 2012-01-12<br>The reported allele group C*07:02:01G includes the following alleles, which share identical sequences in the antigen recognition site of exons 2 and 3: C*07:02 C*07:50<br>The following allele combination(s), in which both alleles are listed by the ASHI CWD review committee as rare or not well defined, cannot be excluded:C*07:37,14:06; C*07:51,14:13; C*07:172,14:18. | | | | | | | |
| | | | | | 09:01 | | | | |
| | SEQ | | | | 11:01 | | | | |
| 03/02/2012 | 03/20/2012 | | | | | | | | |
| | | HLA Allele database: IMGT 3.7.0 2012-01-12<br>Cannot rule out the rare allele DRB1*11:100, first identified in October 2010<br>The reported allele group DRB1*11:01:01G includes the following alleles, which share identical sequences in the antigen recognition site of exon 2 DRB1*11:01 DRB1*11:97 | | | | | | | |

## Comments

UW Health

University of Wisconsin
Hospital and Clinics

| | | | |
|---|---|---|---|
| Name: | WICELL, 10404-HLA | Hospital: | |
| MRN: | OS000181 | Physician: | , |
| DOB: | | Category: | |
| HLA#: | WICELL | | |

## Bone Marrow Case Histocompatibility Summary

301417-DT

This test was developed and its performance characteristics determined by this laboratory. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity clinical laboratory testing.

Electronically signed by [redacted]

03/25/2012 12:08
Date/Time

Histocompatibility Laboratory, Room D4/231, 600 Highland Ave., Madison, WI 53792-2472
Teresa Darcy, MD, Medical Director :: Thomas M. Ellis, PhD, D(ABHI) Laboratory Director
Lab: 608.263.8815 (option 3); Fax: 608.263.9610
ASHI: 01-4-WI-03-2, CLIA: 52DO661997

New York Blood Center
Laboratory of Immunohematology and Genomics
[redacted]

March 20, 2012

WiCell Research Institute
[redacted]

**SAMPLE: DNA WA25 #10404** (MA#166-12)

Date Received: 03/08/12
Sample Date: 03/02/12

**HISTORY:** DNA from cell line.

**TESTING 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 MOLECULAR RESULTS:** *ABO:* PCR-RFLP testing indicates the presence of a nt261 deleted G, characteristic of $O^1$ alleles, and an A background allele. *RH: RHD* exons 4 and 7 are present. Negative for the inactivating *RHD* pseudogene. *RH*Ee* and *RH*Cc*

| | Genotype | Predicted Phenotype |
|---|---|---|
| **WA25 #10404:** | *ABO*AO$^1$; RH*D, RH*Cc, RH*Ee* | **Group A; RhD**+, C+E+c+e+ |

[redacted]
Manager, Genomics

[redacted]
Director of Immunohematology and Genomics

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. In addition, test results obtained from DNA isolated from leucocytes and other hematopoietic cells may differ from DNA isolated from other tissues in persons with a history of transplantation.

NewYork BloodCenter

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

**Sample:** MA166-12; WA25 #10404

**Test:** ABO and RH - GF

| CPT CODE | Description/Molecular Testing | ABO/RH |
|---|---|---|
| 83892 | Enzymatic digestion | X2 |
| 83894 | Separation by electrophoresis | x3 |
| 83898 | Amplification each nucleic acid seq | x3 |
| 83912 | Interpretation and report | X1 |
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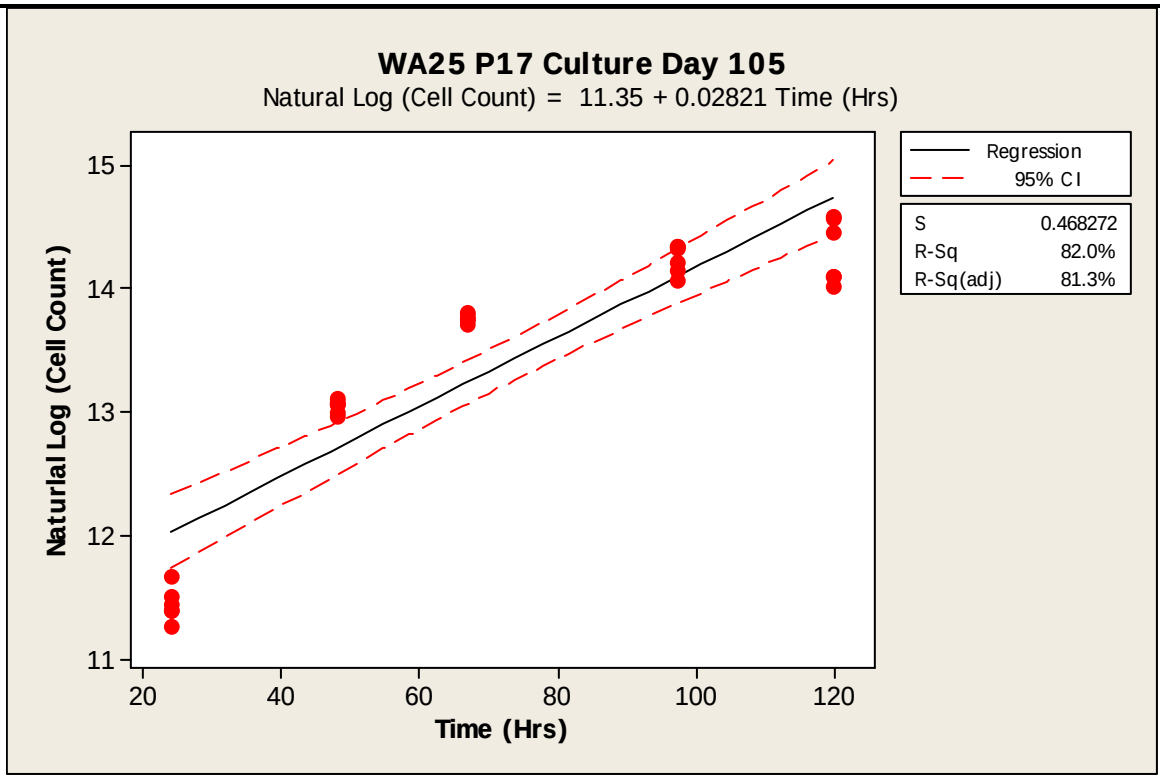
**Characterization Report- Growth Characteristics**

| Sample ID | Cell Line | Cell lot # | Passage | Culture Day | Medium | Matrix | Passaging Additive |
|---|---|---|---|---|---|---|---|
| 10448 | WA25 | N/A | 17 | 105 | E8 + PVA | rh-Vitronectin | Rho-kinase Inhibitor Y-27632 |

| Documentation of Growth Curve Data | Notebook # | Page(s) | Date Growth Curve Initiated |
|---|---|---|---|
| | 149 | 58-64 | 18APR12 |

| Growth Curved performed by | Report Prepared by | Date | QA Reviewed by | Date |
|---|---|---|---|---|
| Derivation Laboratory | LAN | 14AUG12 | JKT | 15Aug12 |




**Regression Analysis:**
**Natural Log (Cell Count) versus Time (Hrs)**

The regression equation is Natural Log (Cell Count) = 11.4 + 0.0282 Time (Hrs)

| *Predictor* | *Coef* | *SE Coef* | *T* | *P* |
|---|---|---|---|---|
| **Constant** | 11.3513 | 0.1976 | 57.45 | 0.000 |
| **Time (Hrs)** | 0.028206 | 0.002500 | 11.28 | 0.000 |

**S** = 0.468272 **R-Sq** = 82.0% **R-Sq(adj)** = 81.3%

***Analysis of Variance***

| *Source* | *DF* | *SS* | *MS* | *F* | *P* |
|---|---|---|---|---|---|
| **Regression** | 1 | 27.906 | 27.906 | 127.26 | 0.000 |
| **Residual Error** | 28 | 6.140 | 0.219 | | |
| **Total** | 29 | 34.046 | | | |

**Slope ± 95% C.I**

0.0282 ± 0.0051

**Apparent Doubling Time (hours) ± 95% C.I.**

24.57 ± 2.05

**Apparent Doubling Time (95% C.I.)**

20.80 hours – 30.03 hours

WiCell Research Institute

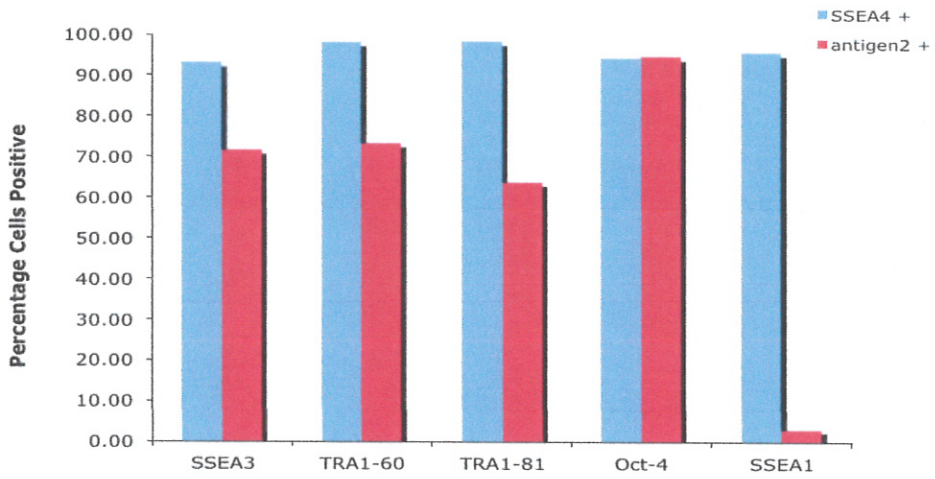
**Procedure performed:** **Cell line: WA25**
**Passage 8**
**Sample ID: 10412**

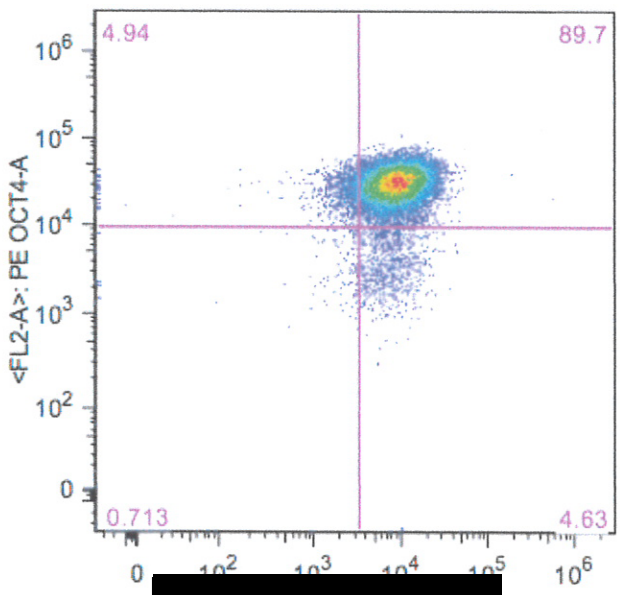
Date of: *(03/06/12)*
acquisition:
file creation:
file submission:

PERCENTS

| antigen2: | SSEA4 - antigen2 + | SSEA4 + antigen2 + | SSEA4 + antigen2 - | SSEA4 - antigen2 - | ALL SSEA4 + | ALL antigen2 + |
|---|---|---|---|---|---|---|
| SSEA3 | 0.88 | 70.70 | 22.30 | 6.08 | 93.00 | 71.58 |
| TRA1-60 | 1.55 | 71.80 | 26.30 | 0.31 | 98.10 | 73.35 |
| TRA1-81 | 1.25 | 62.50 | 35.80 | 0.45 | 98.30 | 63.75 |
| Oct-4 | 4.94 | 89.70 | 4.63 | 0.71 | 94.33 | 94.64 |
| SSEA1 | 0.19 | 2.93 | 92.80 | 4.05 | 95.73 | 3.12 |

Percent analyzable events: 27
#wells submitted: 6
Total # cells analyzed: 12.8 X $10^6$




prepared by [redacted]
10412 *(signature)*

***Charles River Research Animal Diagnostic Services***
[redacted]

**Sponsor: WiCell Research Institute** **Accession #: 2012-015912**

## *Diagnostic Summary Report*

[redacted]

**Received:** 20 Mar 2012
**Approved:** 27 Mar 2012, 13:11

**Bill Method:** [redacted]
**Test Specimen:** Human

| Sample Set | Service (# Tested) | Profile | Assay | Tested | + | +/- | ? | PDG |
|---|---|---|---|---|---|---|---|---|
| #1 | Infectious Disease PCR (3) | All Results Negative | | | | | | |

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

### Service Approvals

| Service | Approved By* | Date |
|---|---|---|
| Infectious Disease PCR | [redacted] | 27 Mar 2012, 13:11 |

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***
[redacted]

**Sponsor: WiCell Research Institute** **Accession #: 2012-015912**

**Product:** Not Indicated **Test Specimen:** Human **Received:** 20 Mar 2012

# *Molecular Diagnostics Infectious Disease PCR Results Report*

**Department Review:** Approved by [redacted] 27 Mar 2012, 13:11*

## *Human Comprehensive Virus Panel*

| Sample #: / Code : | 1<br>WA25-WB0132<br>10429 | 2<br>WA26-WB0131<br>10430 | 3<br>WA27-WB0130<br>10431 |
|---|---|---|---|
| *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** | **PASS** | **PASS** |
| *RNA Spike* | **PASS** | **PASS** | **PASS** |
| *NRC* | **PASS** | **PASS** | **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.*