



Product Information and Testing - Amended

Product Information

| | |
|-------------------------------|--|
| Product Name | WA09 Research Bank |
| Alias | H9 |
| Lot Number | WIC-WA09-RB-001 |
| Parent Material | WIC-WA09-MB-001 |
| Depositor | WiCell |
| Banked by | WiCell |
| Thaw Recommendation | Thaw 1 vial into 3 wells of a 6 well plate. |
| Culture Platform | Feeder Independent |
| | Medium: mTeSR1 |
| | Matrix: Matrigel |
| Protocol | WiCell Feeder Independent Protocol |
| Passage Number | p30 These cells were cultured for 29 passages prior to freeze, 7 of them in mTeSR1/Matrigel. 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 Vialled | 08-May-2009 |
| Vial Label | WiCell WA09 Research Cell Bank WIC WA09 RB 001 08-May-09 |
| 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 | ≥ 15 Undifferentiated Colonies, ≤ 30% Differentiation | Pass |
| Identity by STR | UW Molecular Diagnostics Laboratory | PowerPlex 1.2 System by Promega | Positive identity | Pass |
| Sterility - Direct transfer method | Apptec | 30744 | No contamination detected | Pass |
| Mycoplasma | Bionique | M250 | No contamination detected | Pass |
| Karyotype by G-banding | WiCell | SOP-CH-003 | Normal karyotype | Pass |
| Flow Cytometry for ESC Marker Expression | UW Flow Cytometry Laboratory | SOP-CH-101 SOP-CH-102 SOP-CH-103 SOP-CH-105 | Report - no specification | See report |



Product Information and Testing - Amended

Amendment(s):

| Reason for Amendment | Date |
|---|-------------------|
| CoA updated to include copyright information. | See Signature |
| CoA updated for format changes, addition of product information, and removal of footnotes. | 13-Mary-2013 |
| CoA updated to include text regarding research purposes only, include passage information, removed text regarding technical services, and update product description. | 19-January-2011 |
| CoA updated to reflect correct product description. | 07-September-2010 |
| CoA updated for format changes, clarification of test specifications, test method, addition of test provider, culture platform, and electronic signature. | 10-JUN-2010 |
| Original CoA | 06-AUG-2009 |

| Date of Lot Release | Quality Assurance Approval |
|---------------------|---|
| 06-August-2009 | 1/21/2014 X AMC AMC Quality Assurance Signed by: [REDACTED] |

Short Tandem Repeat Analysis*

Sample Report: 2693-STR

UW HLA#: 61145

Sample Date: 06/18/09

Received Date: 06/18/09

Requestor: WiCell Research Institute

Test Date: 06/23/09

File Name: 090624

Report Date: 06/25/09

Sample Name: (label on tube) 2693-STR

Description: DNA Extracted by WiCell
267.58 ug/mL; 260/280 = 1.85

| Locus | Repeat # | STR Genotype |
|------------|-----------|--------------|
| D16S539 | 5, 8-15 | 12,13 |
| D7S820 | 6-14 | 9,11 |
| D13S317 | 7-15 | 9,9 |
| D5S818 | 7-15 | 11,12 |
| CSF1PO | 6-15 | 11,11 |
| TPOX | 6-13 | 10,11 |
| Amelogenin | NA | X,X |
| TH01 | 5-11 | 9.3,9.3 |
| vWA | 11, 13-21 | 17,17 |

Comments: Based on the DNA 2693-STR dated 06/18/09 and received on 06/18/09 from WI Cell, this sample (UW HLA# 61145) matches exactly the STR profile of the human stem cell line H9 comprising 12 allelic polymorphisms across the 8 STR loci analyzed. No STR polymorphisms other than those corresponding to the human H9 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 2693-STR DNA sample submitted corresponds to the H9 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%.

1

6/23/09

Manager Date

HLA/Molecular Diagnostics Laboratory

06/29/09

PhD, Director Date

HLA/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.

Test Facility:

This report is confidential. No part may be used for advertising or public announcement without written permission. Results apply only to the sample(s) tested.



WiCell Research Institute

Report Number
809718
Page 1 of 1

June 04, 2009
P.O. #:

STERILITY TEST REPORT

Sample Information: hES Cells, WIC-WA09-RB001 #4208

Date Received: May 19, 2009
Date in Test: May 20, 2009
Date Completed: June 03, 2009

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 | 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 |

QA Reviewer

Date

06-05-09

Technical Reviewer

Date

06-05-09

Testing conducted in accordance with current Good Manufacturing Practices.





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

BTL SAMPLE ID#: **57619** P.O.#: DATE REC'D: **06/03/2009**

TEST/CONTROL ARTICLE:

WIC-WA09.RB-001-B

LOT#: **#2693**

DIRECT CULTURE SET-UP (DAY 0)

DATE: **06/03/2009**

INDICATOR CELL LINE (VERO)

SEE DNA FLUOROCHROME RECORD SHEET

| | | | DATE |
|-----------------------------|--------|-----|--------------------------|
| THIOGLYCOLLATE BROTH | DAY 7 | + ⊖ | <u>06/10/2009</u> |
| | DAY 28 | + ⊖ | <u>07/01/2009</u> |
| BROTH-FORTIFIED COMMERCIAL | | | |
| <u>0.5</u> mL SAMPLE | DAY 7 | + ⊖ | <u>06/10/2009</u> |
| <u>6.0</u> mL BROTH | DAY 28 | + ⊖ | <u>07/01/2009</u> |
| BROTH-MODIFIED HAYFLICK | | | |
| <u>0.5</u> mL SAMPLE | DAY 7 | + ⊖ | <u>06/10/2009</u> |
| <u>6.0</u> mL BROTH | DAY 28 | + ⊖ | <u>07/01/2009</u> |
| BROTH-HEART INFUSION | | | |
| <u>0.5</u> mL SAMPLE | DAY 7 | + ⊖ | <u>06/10/2009</u> |
| <u>6.0</u> mL BROTH | DAY 28 | + ⊖ | <u>07/01/2009</u> |

(See Reverse)

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

| SAMPLE ID#: | 57619 | AEROBIC | MICROAEROPHILIC | DATE |
|-------------------------------------|--------|---------|-----------------|-------------------|
| AGAR PLATES-FORTIFIED COMMERCIAL | DAY 7 | + ⊖ | + ⊖ | <u>06/10/2009</u> |
| | DAY 14 | + ⊖ | + ⊖ | <u>06/17/2009</u> |
| | DAY 21 | + ⊖ | + ⊖ | <u>06/24/2009</u> |
| AGAR PLATES-MODIFIED HAYFLICK | DAY 7 | + ⊖ | + ⊖ | <u>06/10/2009</u> |
| | DAY 14 | + ⊖ | + ⊖ | <u>06/17/2009</u> |
| | DAY 21 | + ⊖ | + ⊖ | <u>06/24/2009</u> |
| AGAR PLATES-HEART INFUSION | DAY 7 | + ⊖ | + ⊖ | <u>06/10/2009</u> |
| | DAY 14 | + ⊖ | + ⊖ | <u>06/17/2009</u> |
| | DAY 21 | + ⊖ | + ⊖ | <u>06/24/2009</u> |

BROTH SUBCULTURES (DAY 7)DATE: 06/10/2009

| | | | | |
|-------------------------------------|--------|-----|-----|-------------------|
| AGAR PLATES-FORTIFIED COMMERCIAL | DAY 7 | + ⊖ | + ⊖ | <u>06/17/2009</u> |
| | DAY 14 | + ⊖ | + ⊖ | <u>06/24/2009</u> |
| | DAY 21 | + ⊖ | + ⊖ | <u>07/01/2009</u> |
| AGAR PLATES-MODIFIED HAYFLICK | DAY 7 | + ⊖ | + ⊖ | <u>06/17/2009</u> |
| | DAY 14 | + ⊖ | + ⊖ | <u>06/24/2009</u> |
| | DAY 21 | + ⊖ | + ⊖ | <u>07/01/2009</u> |
| AGAR PLATES-HEART INFUSION | DAY 7 | + ⊖ | + ⊖ | <u>06/17/2009</u> |
| | DAY 14 | + ⊖ | + ⊖ | <u>06/24/2009</u> |
| | DAY 21 | + ⊖ | + ⊖ | <u>07/01/2009</u> |

RESULTS: No detectable mycoplasmal contamination.

7-1-09
Date

Laboratory Director

Ph.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 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 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.



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 # 57619 M-250 Date Rec'd: 06/03/2009 P.O. #

Indicator Cells Inoculated: Date/Initials: 6/4/09 / KG

Fixation: Date/Initials: 6/8/09 / KG

Staining: Date/Initials: 6/8/09 / KG

TEST/CONTROL ARTICLE:

WIC-WA09.RB-001-B

LOT# #2693

Wicell OA

DNA FLUOROCHROME ASSAY RESULTS:

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: 6/8/09 Results Read by: KG Date of Review: 6/8/09 Reviewed by: ce

Report Date: May 29, 2009

Case Details:

Cell Line: WIC-WA09-RB-001 (2693)

Passage #: 31

Date Completed: 5/29/2009

Cell Line Gender: Female

Investigator:

Specimen: hESC on Matrigel

Date of Sample: 5/20/2009

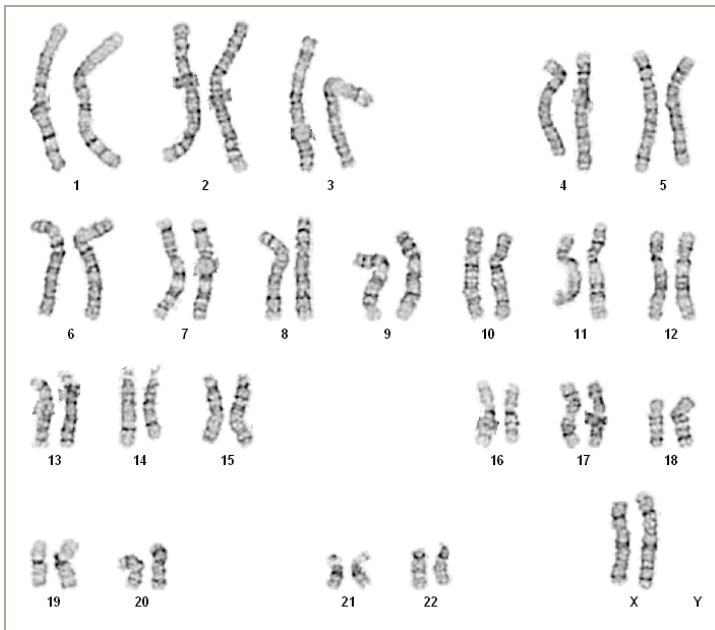
Tests, Reason for: GMP Research Bank Testing

Results: 46,XX

Completed by _____, CLSp(CG), on 5/29/2009

Reviewed and interpreted by _____, PhD, FACMG, on 5/29/2009

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



Cell: S01-01

Slide: A

Slide Type: Karyotyping

Cell Results: Karyotype: 46,XX

of Cells Counted: 20

of Cells Karyotyped: 4

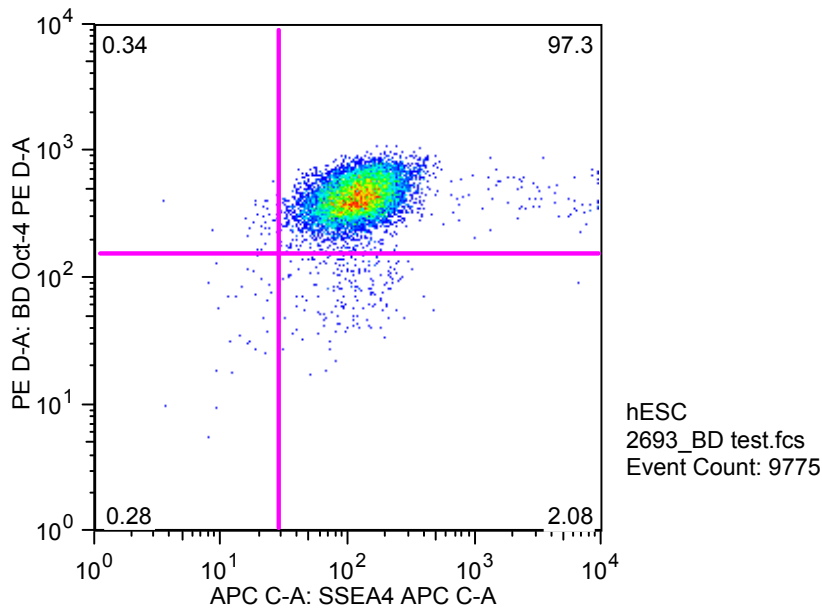
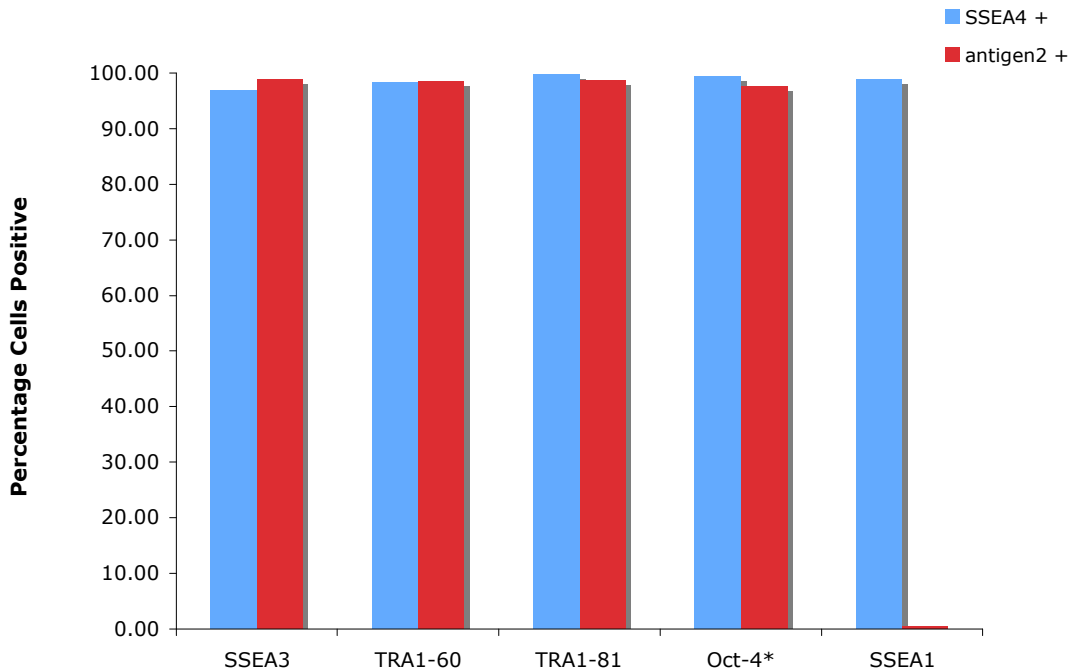
of Cells Analyzed: 8

Band Level: 450-550

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

Date: _____
Sent To: _____

| <u>antigen2:</u> | SSEA4 - <u>antigen2 +</u> | SSEA4 + <u>antigen2 +</u> | SSEA4 + <u>antigen2 -</u> | SSEA4 - <u>antigen2 -</u> | ALL <u>SSEA4 +</u> | ALL <u>antigen2 +</u> |
|------------------|------------------------------|------------------------------|------------------------------|------------------------------|-----------------------|--------------------------|
| SSEA3 | 2.63 | 96.30 | 0.60 | 0.46 | 96.90 | 98.93 |
| TRA1-60 | 1.46 | 97.00 | 1.32 | 0.25 | 98.32 | 98.46 |
| TRA1-81 | 0.20 | 98.50 | 1.24 | 0.05 | 99.74 | 98.70 |
| Oct-4* | 0.34 | 97.30 | 2.08 | 0.28 | 99.38 | 97.64 |
| SSEA1 | 0.01 | 0.43 | 98.50 | 1.09 | 98.93 | 0.44 |



*PE-conjugated Oct-3/4 from BD Biosciences was used (cat #560186).