




Product Information and Testing

Product Information

| | |
|-------------------------------|--|
| Product Name | WC009i-FX08-01 |
| Alias | FX08-1 |
| Lot Number | WB16840 |
| Depositor | University of Wisconsin – Laboratory of Dr. Anita Bhattacharyya |
| Banked by | WiCell |
| Thaw Recommendation | Thaw 1 vial into 1 well of a 6 well plate. |
| Culture Platform | Feeder Dependent |
| | Medium: hES Medium |
| | Matrix: MEF |
| Protocol | WiCell Feeder Dependent Protocol |
| Passage Number | p25 These cells were cultured for 24 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 Vialied | 20-January-2015 |
| Vial Label | WC009i-FX08-01 p25 WB16840 |
| 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 and recoverable attachment after passage | Pass |
| Identity by STR | UW Translational Research Initiatives in Pathology Laboratory | PowerPlex 16 HS System by Promega | Defines profile | Pass |
| Sterility | Biotest Laboratories | ST/07 | Negative | Pass |
| Mycoplasma | WiCell | SOP-QU-004 | Negative | Pass |
| Karyotype by G-banding | WiCell | SOP-CH-003 | Expected karyotype | Pass |

| Date of Lot Release | Quality Assurance Approval |
|---------------------|--|
| 09-September-2015 | <div style="text-align: right;">9/9/2015</div> <div style="text-align: center;">  AMK Quality Assurance Signed by: XXXXXXXXXX </div> |

Short Tandem Repeat Analysis

Department of Pathology and Laboratory Medicine
TRIP Laboratory (Molecular)
<http://www.pathology.wisc.edu/research/trip>

WiCell®
info@wicell.org
(888) 204-1782

Sample Report:

11145-STR
Sample Name on Tube: 11145-STR
166.5 ng/μL, (A260/280=1.91)
Sample Type: Cells
Cell Count: ~2 million cells

Requestor:

WiCell Research Institute
Quality Department

Sample Date: N/A

Receive Date: 08/10/15
Assay Date: 08/11/15
File Name: 150813 STR CLN
Report Date: 08/17/15

| STR Locus | STR Genotype Repeat # | STR Genotype |
|------------|---|---|
| FGA | 16-18,18.2,19,19.2,20,20.2,21,21.2,22, 22.2, 23, 23.2, 24, 24.2, 25, 25.2, 26-30, 31.2, 43.2, 44.2,45.2, 46.2 | Identifying information has been redacted to protect donor confidentiality. If more information is required, please, contact WiCell's Technical Support . |
| TPOX | 6-13 | |
| D8S1179 | 7-18 | |
| vWA | 10-22 | |
| Amelogenin | X,Y | |
| Penta_D | 2.2, 3.2, 5, 7-17 | |
| CSF1PO | 6-15 | |
| D16S539 | 5, 8-15 | |
| D7S820 | 6-14 | |
| D13S317 | 7-15 | |
| D5S818 | 7-16 | |
| Penta_E | 5-24 | |
| D18S51 | 8-10, 10.2, 11-13, 13.2, 14-27 | |
| D21S11 | 24,24.2,25,25.2,26-28,28.2,29,29.2, 30, 30.2,31, 31.2,32,32.2,33,33.2, 34,34.2,35,35.2,36-38 | |
| TH01 | 4-9,9.3,10-11,13.3 | |
| D3S1358 | 12-20 | |

Results: Based on the 11145-STR cells submitted by WiCell QA dated and received on 08/10/15, this sample (Label on Tube: 11145-STR) defines the STR profile of the human stem cell line WC009i-FX08-01 comprising 25 allelic polymorphisms across the 15 STR loci analyzed.

Interpretation: No STR polymorphisms other than those corresponding to the human WC009i-FX08-01 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 11145-STR sample submitted corresponds to the WC009i-FX08-01 stem cell line and was not contaminated with any other human stem cells or a significant amount of mouse feeder layer cells.

Sensitivity: Sensitivity limits for detection of STR polymorphisms unique to either this or other human stem cell lines is ~2-5%.

X_{RMB} Digitally Signed on 08/17/15

TRIP Laboratory, Molecular

X_{WMR} Digitally Signed on 08/17/15

PhD, Director / Co-Director
UWHC Molecular Diagnostics Laboratory / UWSMPH TRIP Laboratory

Testing 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.

Acknowledge TRIP in your publications, posters & presentations. For details, see: <http://www.pathology.wisc.edu/research/trip/acknowledging>
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Sterility Report

Biotest Laboratories, Inc.

Making life-saving products possible

WiCell Research Institute, Inc.
WiCell Quality Assurance

BIOTEST SAMPLE # 15011040

VALIDATION # NG

TEST PURPOSE NG

PRODUCT WC007i-FX13-2-WB16523 11109
WC006i-FX11-9U-WB16522 11110
WC008i-C603-4-WB16524 11111
WC005i-FX11-7-WB16506 11112
WC-3801-2-WB16438 11113
UWWC1-DS2U-WB16352 11114
WA01-WB16217 11115
WIC03i-02-11E-WB15892 11116
IISH8i-GM07125-WB15718 11117
WC009i-FX08-01-WB16840 11118

PRODUCT LOT NA

STERILE LOT NA

STERILIZATION LOT NA

STERILIZATION DATE NA

STERILIZATION METHOD NA

SAMPLING BLDG / ROOM NA

BI LOT NA

BI EXPIRATION DATE NA

DATE RECEIVED 2015-01-22

TEST INITIATED 2015-01-23

TEST COMPLETED 2015-02-06

REFERENCE Processed according to LAB-003: Sterility Test Procedure

Ten (10) products were each divided between 40 mL TSB and 40 mL FTG. The samples were then cultured at 20-25 C and 30-35 C respectively and were monitored for a minimum of 14 days.

- USP
- BI Manufacturers Specifications
- Other

| RESULTS | # POSITIVES | # TESTED | POSITIVE CONTROL | NEGATIVE CONTROL |
|---------|-------------|----------|------------------|------------------|
| Sterile | 0 | 10 | NA | 2 Negatives |

COMMENTS NA

REVIEWED BY [Redacted] DATE 06 FEB 15

Specific test results may not be indicative of the characteristics of any other samples from the same lot or similar lots. Liability is limited to the costs of the tests.

Biotest Laboratories • 9303 West Broadway Ave. • Brooklyn Park, MN 55445 • USA • (763) 315-1200

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Mycoplasma Detection Assay Report

Testing Performed by WiCell

Lot Release Testing

02-20-2015

FORM SOP-QU-004.01

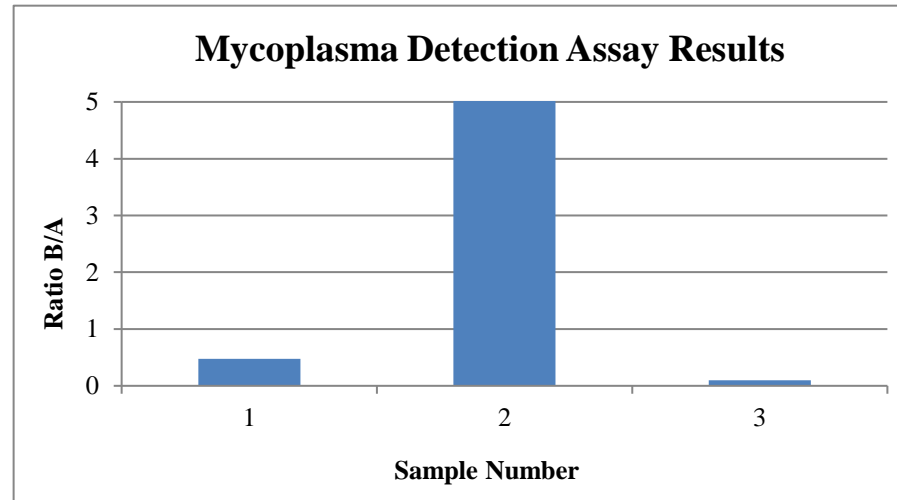
Version C Edition 01

Reported by: SS

Reviewed by: JB

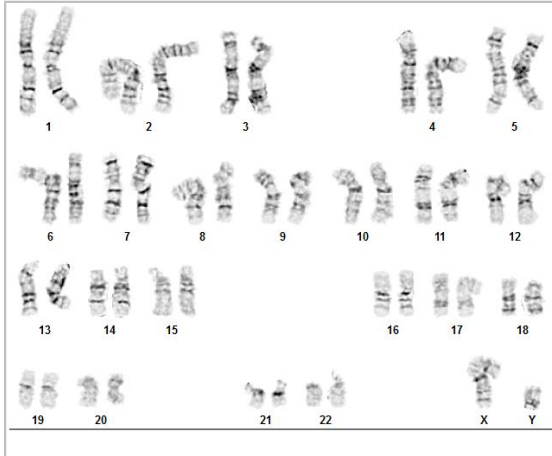
Berthold Flash n' Glo 539

| # | Sample Name | Reading A | | | Reading B | | | Ratio B/A | Result | Comments/Suggestions |
|---|------------------------------|-----------|------|-------|-----------|-------|-------|-----------|----------|----------------------|
| | | RLU1 | RLU2 | Ave | RLU1 | RLU2 | Ave | | | |
| 1 | WC009i-FX08-01 WB16840 11145 | 175 | 190 | 182.5 | 88 | 86 | 87 | 0.48 | Negative | |
| 2 | Positive (+) Control | 248 | 238 | 243 | 19340 | 19347 | 19344 | 79.60 | Positive | |
| 3 | Negative (-) Control | 435 | 440 | 437.5 | 43 | 43 | 43 | 0.10 | Negative | |



Date Reported: Tuesday, March 10, 2015
Cell Line: WC009i-FX08-01-WB16840 11145
Passage#: 27
Date of Sample: 3/3/2015
Specimen: iPSC
Results: 46,XY

Cell Line Gender: Male
Reason for Testing: lot release testing
Investigator: [REDACTED], CDM



Cell: 5
Slide: 3
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".

This assay was conducted solely for listed investigator/institution. The results may not be relied upon by any other party without the prior written consent of the Director of the WiCell Cytogenetics Laboratory. The results of this assay are for research use only. If the results of this assay are to be used for any other purpose, contact the Director of the WiCell Cytogenetics Laboratory.

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