



Product Information and Testing

Product Information

Product Name	WC006i-FX11-9U
Alias	FX11-9U
Lot Number	WB18069
Parent Material	WC006i-FX11-9U-WB16522
Depositor	University of Wisconsin – Laboratory of Anita Bhattacharyya
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	p39 These cells were cultured for 38 passages prior to freeze, 8 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 Viald	17-March-2015
Vial Label	WC006i-FX11-9U p39 WB18069
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	Consistent with known 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
27-July-2015	<div style="text-align: right;">7/27/2015</div> <div style="text-align: center;"> <p>X AMK</p> <p>AMK Quality Assurance Signed by: XXXXXXXXXX</p> </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:

11200-STR
Sample Name on Tube: 11200-STR
128.0 ng/μL, (A260/280=1.88)
Sample Type: Cells
Cell Count: ~2 million cells

Requestor:

WiCell Research Institute
Quality Department

Sample Date: N/A

Receive Date: 04/20/15
Assay Date: 04/21/15
File Name: STR_150422_wmr
Report Date: 04/27/15

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 11200-STR cells submitted by WiCell QA dated and received on 04/20/15, this sample (Label on Tube: 11200-STR) exactly matches the STR profile of the human stem cell line WC006i-FX11-9U comprising 22 allelic polymorphisms across the 15 STR loci analyzed.

Interpretation: No STR polymorphisms other than those corresponding to the human WC006i-FX11-9U stem cell line were detected however, allelic imbalance (denoted by ** in table above) was observed at the D7S820 loci and could be the result of chromosomal gains and/or losses in this cell line. This imbalance was not seen previously in WC006i-FX11-9U. 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 11200-STR sample submitted corresponds to the WC006i-FX11-9U 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 04/27/15

TRIP Laboratory, Molecular

X *WMR*

Digitally Signed on 04/27/15

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>

Unless otherwise mutually agreed in writing, the services provided to you hereunder by WiCell Research Institute, Inc. ("WiCell") are governed solely by WiCell's Terms and Conditions of Service, found at www.wicell.org/privacyandterms. Any terms you may attach to a purchase order or other document that are inconsistent, add to, or conflict with WiCell's Terms and Conditions of Service are null and void and of no legal force or effect.

Sterility Report

Biotest Laboratories, Inc.

Making life-saving products possible

WiCell Research Institute, Inc.
WiCell Quality Assurance

BIOTEST SAMPLE # 15040038

VALIDATION # NG

TEST PURPOSE NG

PRODUCT UWWC1-2DS3-WB17713 11202
WIC01i-02-1c-WB17715 11203
UWWC1-DS1-WB17810 11204
UWWC1-DS2U-WB17714 11205
WC-3801-2-WB17984 11206
WC006i-FX11-9U-WB18069 11207
WC-3902-10-RS-WB16861 11208
WC-3902-08-RS-WB17010 11209
RUES2-DB17752 11210
RUES1-DB17210 11211

RUES2-DB17752 is labeled as R2 p23 11.30.14
RUES1-DB17210 is labeled as R1 p25.

PRODUCT LOT NA

STERILE LOT NA

BI LOT NA

STERILIZATION LOT NA

BI EXPIRATION DATE NA

STERILIZATION DATE NA

DATE RECEIVED 2015-04-01

STERILIZATION METHOD NA

TEST INITIATED 2015-04-02

SAMPLING BLDG / ROOM NA

TEST COMPLETED 2015-04-16

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

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

A subsidiary of STERIS Corporation

BIOTEST SAMPLE # 15040038

COMMENTS NA

REVIEWED BY

[Redacted Signature]

DATE

16 APR 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

Form: M-002 rev. 11
Effective:

A subsidiary of STERIS Corporation





Mycoplasma Detection Assay Report

Testing Performed by WiCell

Lot Release Test

03-27-2015

FORM SOP-QU-004.01

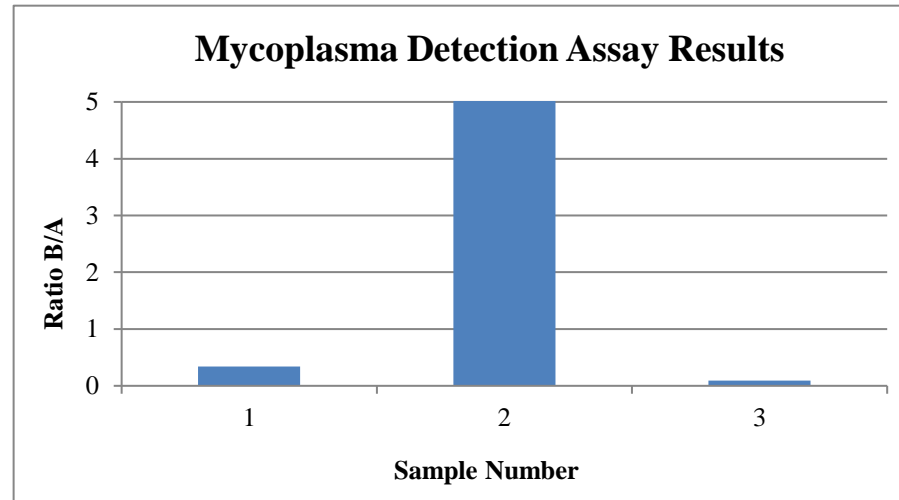
Version D Edition 01

Reported by: SS

Reviewed by: JB

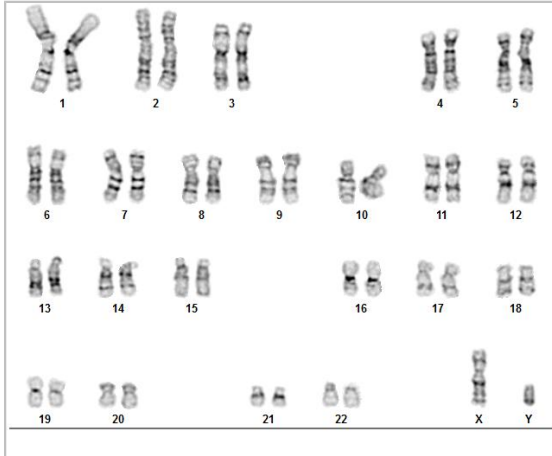
Berthold Flash n' Glo 539

#	Sample Name	Reading A			Reading B			Ratio B/A	Result	Comments/Suggestions
		RLU1	RLU2	Ave	RLU1	RLU2	Ave			
1	WC006i-FX11-9U WB18069 11200	151	153	152	52	52	52	0.34	Negative	
2	Positive (+) Control	243	228	235.5	17549	17565	17557	74.55	Positive	
3	Negative (-) Control	503	494	498.5	44	50	47	0.09	Negative	



Date Reported: Tuesday, April 07, 2015
Cell Line: WC006i-FX11-9U-WB18069 11200
Passage#: 40
Date of Sample: 3/27/2015
Specimen: iPSC
Results: 46,XY

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



Cell: 6
Slide: 1
Slide Type: Karyotype

Total Counted: 20
Total Analyzed: 8
Total Karyotyped: 4
Band Resolution: 425 - 525

Interpretation:

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

Completed by: [REDACTED] MS, 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.

Unless otherwise mutually agreed in writing, the services provided to you hereunder by WiCell Research Institute, Inc. ("WiCell") are governed solely by WiCell's Terms and Conditions of Service, found at www.wicell.org/privacyandterms. Any terms you may attach to a purchase order or other document that are inconsistent, add to, or conflict with WiCell's Terms and Conditions of Service are null and void and of no legal force or effect.