



Product Information and Testing

Product Information

Product Name	WC005i-FX11-7
Alias	FX11-7
Lot Number	WB20449
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 mTeSR1 Protocol
Passage Number	p6 These cells were cultured for 5 passages prior to freeze, 3 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	22-June-2015
Vial Label	WC005i-FX11-7 p6 WB20449
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
21-September-2015	9/21/2015 X AMK AMK Quality Assurance Signed by: [REDACTED]

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:

11339-STR
Sample Name on Tube: 11339-STR
220.3 ng/μL, (A260/280=1.97)
Sample Type: Cells
Cell Count: ~2 million cells

Requestor:

WiCell Research Institute
Quality Department

Sample Date: N/A

Receive Date: 08/04/15
Assay Date: 08/12/15
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 11339-STR cells submitted by WiCell QA dated and received on 08/04/15, this sample (Label on Tube: 11339-STR) defines the STR profile of the human stem cell line WC005i-FX11-7 comprising 22 allelic polymorphisms across the 15 STR loci analyzed.

Interpretation: No STR polymorphisms other than those corresponding to the human WC005i-FX11-7 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 11339-STR sample submitted corresponds to the WC005i-FX11-7 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>
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 # 15081899
VALIDATION # NG
TEST PURPOSE NG

PRODUCT WA09(LOXGFP)-WB20971 11368
UWWC1-2DS3-WB20846 11369
WC005i-FX11-7-WB20449 11370
UWWC1-DS1-WB21343 11371
WC-3801-2-WB21395 11372
WA07-WB21842 11373
LT2e-H9CAGGFP-WB0207 11374
MIN01i-32517.A-WB20571 11375
MIN03i-32642.B-WB20013 11376
MIN04i-33109.2B-WB20383 11377

PRODUCT LOT	NA	BI LOT	NA
STERILE LOT	NA	BI EXPIRATION DATE	NA
STERILIZATION LOT	NA	DATE RECEIVED	2015-08-27
STERILIZATION DATE	NA	TEST INITIATED	2015-08-28
STERILIZATION METHOD	NA	TEST COMPLETED	2015-09-11
SAMPLING BLDG / ROOM	NA		


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  DATE 11/5/15

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

A subsidiary of STERIS Corporation





Mycoplasma Detection Assay Report

Testing Performed by WiCell

Lot Release Test

07-16-2015

FORM SOP-QU-004.01

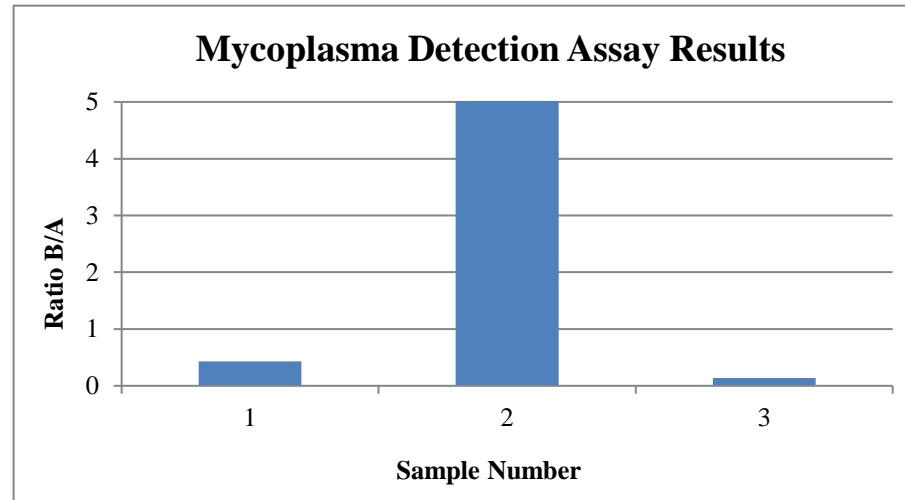
Version E Edition 01

Reported by: SS

Reviewed by: JB

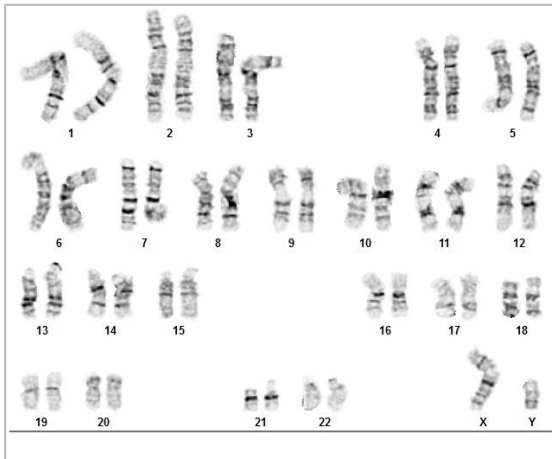
Berthold Flash n' Glo 539

#	Sample Name	Reading A			Reading B			Ratio B/A	Result	Comments/Suggestions
		RLU1	RLU2	Ave	RLU1	RLU2	Ave			
1	WC005i-FX11-7-WB20449 11339	140	135	137.5	57	61	59	0.43	Negative	
2	Positive (+) Control	224	220	222	18175	18184	18180	81.89	Positive	
3	Negative (-) Control	352	359	355.5	49	47	48	0.14	Negative	



Date Reported: Wednesday, July 29, 2015
Cell Line: WC005i-FX11-7-WB20449 11339
Passage#: 7
Date of Sample: 7/21/2015
Specimen: iPSC
Results: 46,XY

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



Cell: 55
Slide: 2
Slide Type: Karyotype
Total Counted: 20
Total Analyzed: 8
Total Karyotyped: 4
Band Resolution: 425 - 500

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.

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.