

Product Information and Testing

Product Information

Product Name	iPS-DF-19-9-11T
Lot Number	WB0239
Parent Material	iPS-DF-19-9-11T-MCB-01
Depositor	University of Wisconsin – Laboratory of Dr. James Thomson
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	p27
	These cells were cultured for 26 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 Vialed	16-May-2013
Vial Label	WB0239 DF19-9-11T.H p27 LK 16MAY13
Biosafety and Use Information	This cell line is of human origin. 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

<u> </u>							
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	
14-November-2016	11/14/2016 X AMK AMK Quality Assurance Signed by: Klade, Anjelica	



Short Tandem Repeat Analysis

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

Department of Pathology and Laboratory Medicine TRIP Laboratory (Molecular)

http://www.pathology.wisc.edu/research/trip

Sample Report: 11500-STR

Sample Name on Tube: 11500-STR 154.1 ng/μL, (A260/280=1.85)

Sample Type: Cells

Cell Count: ~2 million cells

Requestor: WiCell Research Institute

Quality Department

Sample Date: N/A Receive Date: 02/09/16 Assay Date: 02/23/16

File Name: STR 160229 wmr

Report Date: 03/02/16

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
TPOX	6-13	been redacted to
D8S1179	7-18	protect donor
vWA	10-22	confidentiality. If
Amelogenin	X,Y	more information
Penta_D	2.2, 3.2, 5, 7-17	is required, please, contact
CSF1PO	6-15	WiCell's Technical
D16S539	5, 8-15	Support.
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	

<u>Results:</u> Based on the 11500-STR cells submitted by WiCell QA dated and received on 02/09/16, this sample (Label on Tube: 11500-STR) is an exact match to the STR profile of the human stem cell line DF19-9 (10767-STR submitted 05/10/13, 8 loci reported/15 loci analyzed) comprising 27 allelic polymorphisms across the 15 STR loci analyzed.

<u>Interpretation:</u> No STR polymorphisms other than those corresponding to the human DF19-9 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 11500-STR sample submitted corresponds to the DF19-9 stem cell line, matches DF19-9 (10767-STR), and was not contaminated with any other human stem cells or a significant amount of mouse feeder layer cells.

<u>Sensitivity:</u> 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 03/02/16	X WMR Digitally Signed on 03/02/16
TRIP Laboratory, Molecular	r, PhD, Director / Co-Director UWHC Molecular Diagnostics Laboratory / UWSMPH TRIP Laborator

Sterility Report

Biotest Laboratories, Inc.

Making life-saving products possible

BIOTEST SAMPLE # 13100572 WiCell Research Institute, Inc. WiCell Quality Assurance **VALIDATION #** NG **TEST PURPOSE** NG **PRODUCT** Please see packing list under product name. PRODUCT LOT NA STERILE LOT **BILOT** NA NA BI EXPIRATION DATE NA STERILIZATION LOT NA DATE RECEIVED STERILIZATION DATE 2013-10-10 NA **TEST INITIATED** STERILIZATION METHOD NA 2013-10-10 SAMPLING BLDG / ROOM NA TEST COMPLETED 2013-10-24 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 10 NA 2 Negatives COMMENTS 240CTI3 DATE **REVIEWED BY**

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



WiCell Research Institute

Packing Slip

P.O. Box 7365 Madison, WI 53707-7365

Sent to:

Sterility Testing Services
Biotest Labs, Sterility Testing Services

Date: 09Oct13

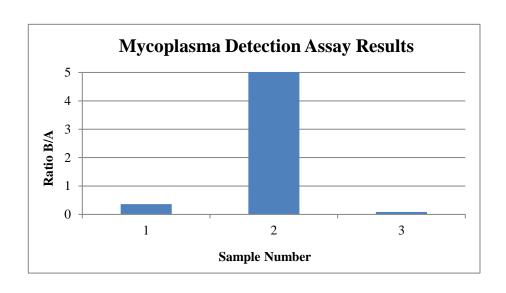
Contents - Number of Vials	Condition
DF19-9-11T.H-WB0239 #10888	-80
IISH2i-BM9-WB0266 #10889	
IISH3i-CB6-WB0267 #10890	
WA26-WB0268 #10891	
MEF 6D37 IRR002 #10894	
MEF 6D37 IRR003 #10895	
MEF 6D33 IRR004 #10896	
MEF 6D33 IRR005 #10897	
MEF 6D33 IRR006 #10898	
MEF 6D33 IRR007 #10899	



Mycoplasma Detection Assay Report

Testing Performed by WiCell Lot Release Test January 13th, 2016 FORM SOP-QU-004.01 Version E Edition 01 Reported by: SS Reviewed by: JB Berthold Flash n' Glo 539

		Read	ing A	A	Read	ing B	В	Ratio		
#	Sample Name	RLU1	RLU2	Ave	RLU1	RLU2	Ave	B/A	Result	Comments/Suggestions
1	DF19-9-11T.H-WB0239 11500	108	112	110	41	39	40	0.36	Negative	
2	Positive (+) Control	166	170	168	11607	11641	11624	69.19	Positive	
3	Negative (-) Control	306	307	306.5	27	26	26.5	0.09	Negative	





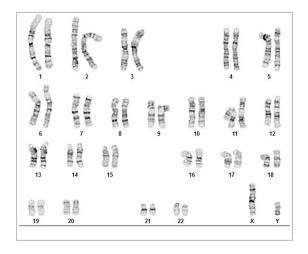
Chromosome Analysis Report: 030165

Date Reported: Tuesday, January 19, 2016 Cell Line: DF19-9-11T.H-WB0239 11500

Passage#: 28

Date of Sample: 1/14/2016

Specimen: iPSC Results: 46,XY



Cell Line Gender: Male

Reason for Testing: Lot release testing

Investigator: , WiCell CDM

Cell: 48 Slide: 1

Slide Type: Karyotype

Total Counted: 20
Total Analyzed: 8

Total Karyogrammed: 4
Band Resolution: 450 - 550

QC Review By:

Interpretation:

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

Completed by:	CG(ASCP)
Reviewed and Interpreted by:	, PhD, FACMG

Sent By:____

A signed copy of this report is available upon request.

Director of the WiCell Cytogenetics Laboratory.

Limitations:	This assay allows for microscopic visualization of numerical and structural chromosome abnormalities	s. The size of structural abnormality that can be detected
	dependent upon the G hand resolution obtained from this specimen. For the purposes of this report	

Sent To:

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

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