




Product Information and Testing

Product Information

Product Name	iPS DF-19-9-7T
Lot Number	WB0136
Parent Material	iPS DF-19-9-7T-MCB-01
Depositor	University of Wisconsin – Laboratory of Dr. James Thomson
Banked by	WiCell
Thaw Recommendation	Thaw 1 vial into 4 wells of a 6 well plate.
Culture Platform	Feeder Independent
	Medium: mTeSR1
	Matrix: Matrigel
Protocol	WiCell Feeder Independent mTeSR1 Protocol
Passage Number	p31 These cells were cultured for 30 passages prior to freeze, 10 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	02-March-2012
Vial Label	WB0136 DF19-9-7T P31 MW 02MAR12
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

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	<div style="text-align: right;">11/14/2016</div> <div style="text-align: center;">  X AMK AMK Quality Assurance Signed by: Klade, Anjelica </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:

11499-STR
Sample Name on Tube: 11499-STR
157.4 ng/μL, (A260/280=1.87)
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 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 11499-STR cells submitted by WiCell QA dated and received on 02/09/16, this sample (Label on Tube: 11499-STR) is an exact match to the STR profile of the human stem cell line DF19-9-7T (10456-STR submitted 05/04/12, 8 loci reported/15 loci analyzed) comprising 27 allelic polymorphisms across the 15 STR loci analyzed.

Interpretation: No STR polymorphisms other than those corresponding to the human DF19-9-7T 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 11499-STR sample submitted corresponds to the DF19-9-7T stem cell line, matches DF19-9-7T (10456-STR), 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 03/02/16

TRIP Laboratory, Molecular

X *WMR*

Digitally Signed on 03/02/16

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>

TRIP agrees to maintain the confidentiality of any information provided to it in connection with its performance of this STR analysis on the same conditions as set forth in paragraph 2 of WiCell's Terms and Conditions of Service (<http://www.wicell.org/media.acux/1a429b84-2b54-44a4-8ad8-5c05db93dd8a>).

Sterility Report

Biotest Laboratories, Inc.

Making life-saving products possible

WiCell Research Institute, Inc.
WiCell Quality Assurance

BIOTEST SAMPLE # 16020409

VALIDATION # NG

TEST PURPOSE NG

PRODUCT MIN19i-33811.D-WB20032 11514
MIN20i-34363.A-WB20384 11515
MIN21i-34363.B-WB20385 11516
MIN15i-33363.D-WB20945 11517
MIN14i-33363.C-WB20811 11518
MIN17i-33808.B-WB20714 11519
MIN16i-33808.A-WB20715 11520
DF19-9-7T-WB0136 11521
JFHZ3-DB29774 11522
JFHZ2-DB29769 11523

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 2016-02-02

TEST INITIATED 2016-02-05

TEST COMPLETED 2016-02-19

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 22 FEB 16

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

January 13th, 2016

FORM SOP-QU-004.01

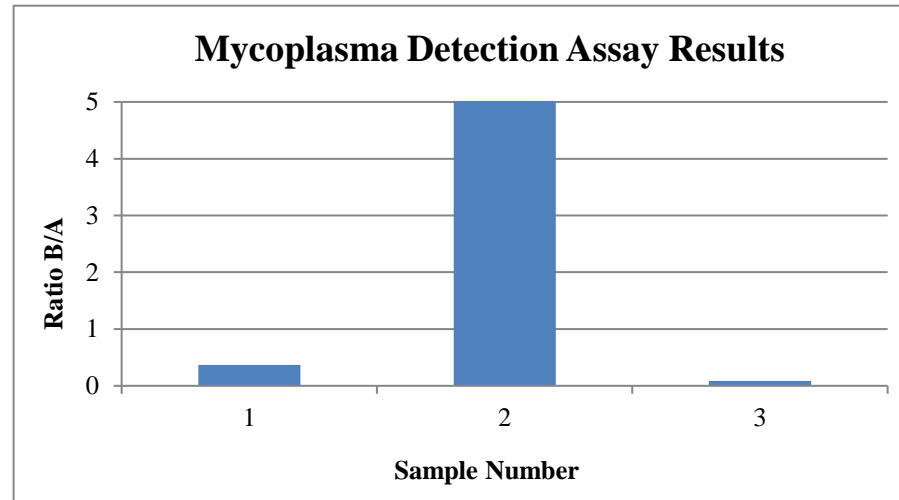
Version E Edition 01

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	DF19-9-7T-WB0136 11499	103	100	101.5	39	36	37.5	0.37	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	



Date Reported: Tuesday, January 19, 2016

Cell Line: DF19-9-7T-WB0136 11499

Passage#: 32

Date of Sample: 1/13/2016

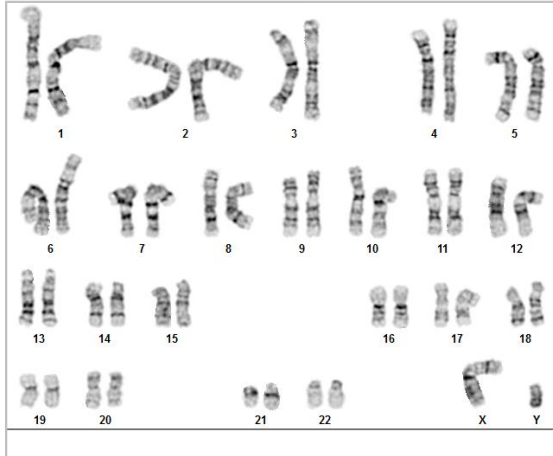
Specimen: iPSC

Results: 46,XY

Cell Line Gender: Male

Reason for Testing: Lot release testing

Investigator: [REDACTED], WiCell CDM



Cell: 49

Slide: 1

Slide Type: Karyotype

Total Counted: 20

Total Analyzed: 8

Total Karyogrammed: 4

Band Resolution: 450 - 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.

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