



Product Information and Testing – Amended

Product Information

Product Name	DF6-9-9T.B
Lot Number	WB0199
Depositor	University of Wisconsin – Laboratory of Dr. James Thomson
Banked by	WiCell
Thaw Recommendation	Thaw 1 vial into 2 wells of a 6 well plate.
Culture Platform	Feeder Independent
	Medium: mTeSR1
	Matrix: Matrigel
Protocol	WiCell Feeder Independent Protocol
Passage Number	p26 These cells were cultured for 25 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 Vial	16-December-2012
Vial Label	WB0199 DF6-9-9T.B p26 DF 16DEC2012
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 Molecular Diagnostics 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

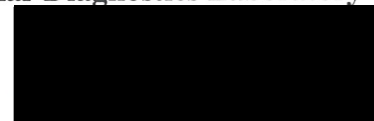
Amendment(s):

Reason for Amendment	Date
CoA updated to include copyright information.	See Signature
Original CoA.	04-Apr-2013



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Date of Lot Release	Quality Assurance Approval
04-April-2013	<div>12/31/2013</div> <div>X AMC</div> <div>AMC</div> <div>Quality Assurance</div> <div>Signed by [REDACTED]</div>



Short Tandem Repeat Analysis*

Sample Report: 10693-STR

Label on Tube: 10693-STR

Sample Date: 01/25/13

Received Date: 01/25/13

Requestor: WiCell Research Institute

Test Date: 01/28/13

File Name: 130128

Report Date: 01/31/13

Sample Name: (label on tube) 10693-STR

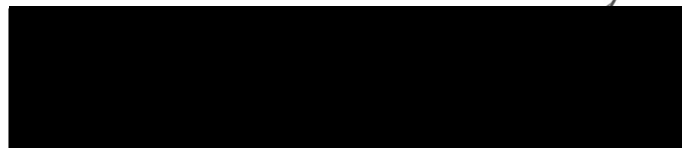
Description: WiCell Research Institute
provided genomic DNA
262.2 ug/mL; 260/280 = 1.96

Locus	Repeat #	STR Genotype
D16S539	5, 8-15	Identifying information has been redacted to protect donor confidentiality. If more information is required, please, contact WiCell's Technical Support .
D7S820	6-14	
D13S317	7-15	
D5S818	7-15	
CSF1PO	6-15	
TPOX	6-13	
Amelogenin	NA	
TH01	5-11	
vWA	11, 13-21	

Comments: Based on the DNA 10693-STR dated and received on 01/25/13 from WI Cell, this sample (Label on Tube: 10693-STR) exactly matches the STR profile of the human stem cell line iPS (foreskin) comprising 15 allelic polymorphisms across the 8 STR loci analyzed. No STR polymorphisms other than those corresponding to the human iPS (foreskin) 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. These results suggest that the 10693-STR DNA sample submitted corresponds to the iPS (foreskin) stem cell line and it was not contaminated with any other human stem cells or a significant amount of mouse feeder layer cells. Sensitivity limits for detection of STR polymorphisms unique to either this or other human stem cell lines is ~5%.



Molecular Diagnostics Laboratory



Molecular Diagnostics Laboratory

* Testing to assess engraftment following bone marrow transplantation 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.

Biotest Laboratories, Inc.

FDA Registered
GMP

ISO 13485:2003
www.biotestlabs.com

ISO/IEC 17025:2005
EN/ISO 17665

Phone: 763-315-1200
Fax: 763-315-1201

STERILITY REPORT

WiCell Research Institute, Inc.
WiCell Quality Assurance

BIOTEST SAMPLE # 13030760

VALIDATION # NG

TEST PURPOSE NG

PRODUCT NAME Please see packing slip under product name.

PRODUCT LOT NA

STERILE LOT NA

BI LOT NA

STERILIZATION LOT NA

BI EXPIRATION DATE NA

STERILIZATION DATE NA

DATE RECEIVED 2013-03-15

STERILIZATION METHOD NA

TEST INITIATED 2013-03-15

SAMPLING BLDG / ROOM NA

TEST COMPLETED 2013-03-29

REFERENCE Processed according to SOP LAB-003: Sterility Test Procedure.

11 products were 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
<input checked="" type="checkbox"/> Sterile				
<input type="checkbox"/> Non-Sterile	0	11	NA	2 Negatives
<input type="checkbox"/> NA				

COMMENTS NA

REVIEWED BY

DATE

29 MAR 13

Form: M-002 rev. 10

Effective: 21SEP12

Biotest Laboratories, Inc.

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.

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WiCell Research Institute

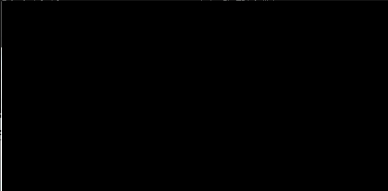
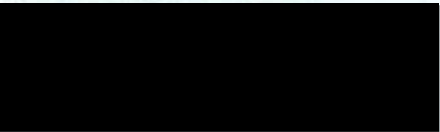
Packing Slip



Sent to:
Sterility Testing Services
BiotestLabs, Sterility Testing Services



Date:
12Mar13

Product Name	Condition
 DF6-9-T.B-WB0199 #10730 	-80

13030760 suc
MAR 15 2013

Mycoplasma Report

Testing Performed by WiCell

RP WiCell /LRT 10693 1-17-13

FORM SOP-QU-004.01

Version B

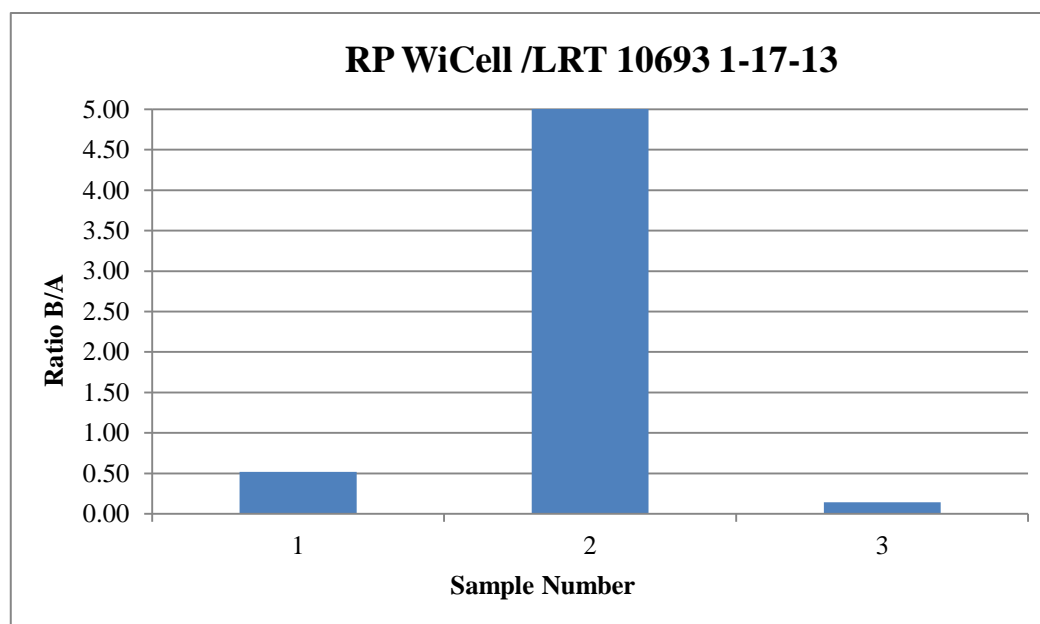
Edition 01

Assay performed and reported by: MW

Reviewed by: JB

Equipment: 539 Berthold

Sample Number and ID	Reading A		A Average	Reading B		B Average	Ratio B/A	Mycoplasma Results	Comments/Suggestions
	A1	A2		B1	B2				
1 DF6-9-9T.B-WB0199 LK	160	151	155.5	82	79	80.5	0.52	Negative	
2 Positive (+) Control	153	153	153	13001	12986	12993.5	84.92	Positive	
3 Negative (-) Control	347	354	350.5	51	49	50	0.14	Negative	



Date Reported: Friday, January 18, 2013

Cell Line: DF6-9-9T.B-WB0199 10693

Passage#: 26

Date of Sample: 1/15/2013

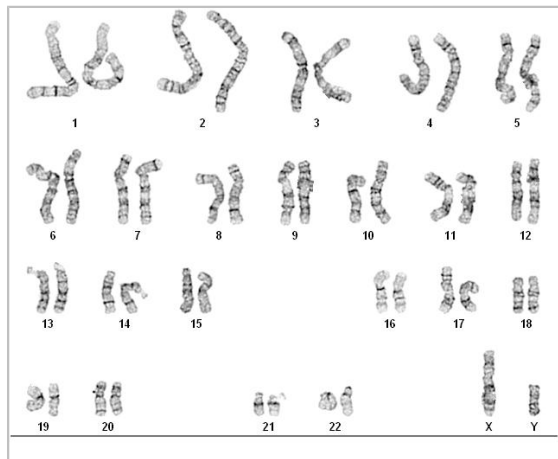
Specimen: iPSC

Results: 46,XY

Cell Line Gender: Male

Reason for Testing: Lot release testing

Investigator: [REDACTED] WiCell CDM



Cell: 24

Slide: 2

Slide Type: Karyotype

Total Counted: 20

Total Analyzed: 8

Total Karyotyped: 4

Band Resolution: 450 - 525

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.