



**Product Information and Testing  
- Amended  
Product Information**

Product Name	DF19-9-11T.H
Alias	iPS-DF19-9-11T
Lot Number	WB0219
Depositor	WiCell
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	p27  These cells were cultured for 26 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 Viald	19-March-2013
Vial Label	WB0219 DF19-9-11T.H p27 LK 19MAR13
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	01-July-2013



## Product Information and Testing - Amended

Date of Lot Release	Quality Assurance Approval
01-July-2013	<p style="text-align: right;">12/31/2013</p> <p>X AMC _____ AMC Quality Assurance Signed by [REDACTED]</p>

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## Short Tandem Repeat Analysis\*

Sample Report: 10767-STR

Label on Tube: 10767-STR

Sample Date: 05/10/13

Received Date: 05/10/13

Requestor: WiCell Research Institute

Test Date: 05/15/13

File Name: 130515 TCS

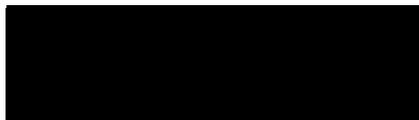
Report Date: 05/19/13

Sample Name: 10767-STR

Description: DNA Extracted by WiCell  
251.8 ug/mL; 260/280 = 1.92

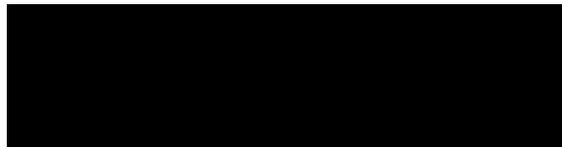
Locus	Repeat #	STR Genotype
D16S539	5, 8-15	Identifying information has been redacted to protect donor confidentiality. If more information is required, please, contact <a href="#">WiCell's Technical Support</a> .
D7S820	6-14	
D13S317	7-15	
D5S818	7-15	
CSF1PO	6-15	
TPOX	6-13	
Amelogenin	NA	
TH01	5-11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

Comments: Based on the DNA 10767-STR dated and received on 05/10/13, this sample (Label on Tube: 10767-STR) matches exactly the STR profile of the human stem cell line DF19-9 comprising 15 allelic polymorphisms across the 8 STR loci analyzed. 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. These results suggest that the 10767-STR DNA sample submitted corresponds to the DF19-9 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%.



5/21/13  
Date

Molecular Diagnostics Laboratory



05/19/13  
Date

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.

# Sterility Report

**Biotest Laboratories, Inc.**

*Making life-saving products possible*

WiCell Research Institute, Inc.  
WiCell Quality Assurance

BIOTEST SAMPLE # 13060494

VALIDATION # NG

TEST PURPOSE NG

PRODUCT Please see packing list under product name.

PRODUCT LOT NA

STERILE LOT NA

BI LOT NA

STERILIZATION LOT NA

BI EXPIRATION DATE NA

STERILIZATION DATE NA

DATE RECEIVED 2013-06-11

STERILIZATION METHOD NA

TEST INITIATED 2013-06-12

SAMPLING BLDG / ROOM NA

TEST COMPLETED 2013-06-26

REFERENCE Processed according to LAB-003: Sterility Test Procedure

5 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	5	NA	2 Negatives

COMMENTS NA

REVIEWED BY

DATE

26 JUN 13

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.

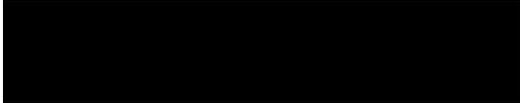
A subsidiary of STERIS Corporation



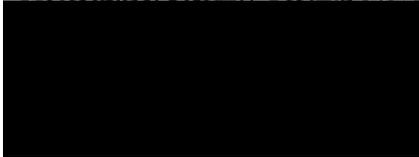


# WiCell Research Institute

*Packing Slip*



**Sent to:**  
Sterility Testing Services  
Biotest Labs, Sterility Testing Services



**Date:**  
05Jun13

Product Name	Condition
DF19-9-11T.H-WB0219 #10786 	-80

13060494 *SK*  
JUN 12 2013





# Mycoplasma Report

Testing Performed by WiCell

DF19-9-11T.H-WB0219-Ep29 MWS/10767 17MAY2013

FORM SOP-QU-004.01

Version B

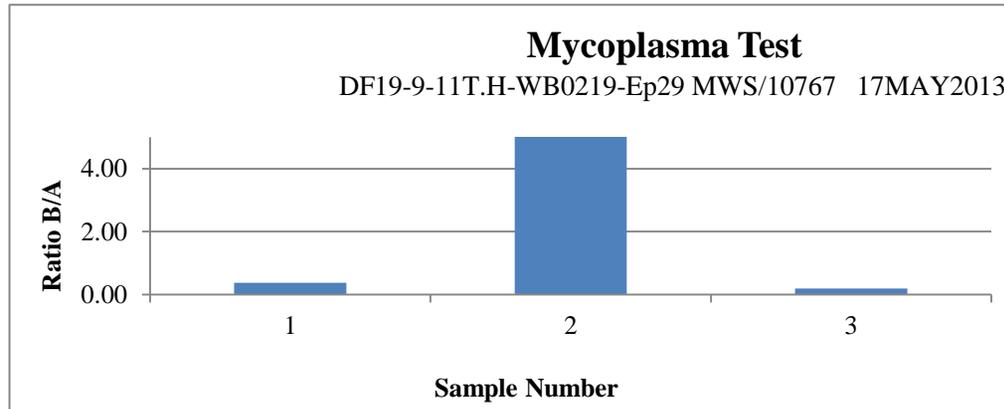
Edition 01

Assay performed and reported by: MWS

Equipment: Monolight 3010

Reviewed by: TL

Sample Number and ID	Reading A		A Average	Reading B		B Average	Ratio B/A	Mycoplasma Results	Comments/Suggestions
	A1	A2		B1	B2				
1 10767	302	324	313	119	119	119	0.38	Negative	
2 Positive (+) Control	484	486	485	50581	50808	50694.5	104.52	Positive	
3 Negative (-) Control	949	911	930	166	186	176	0.19	Negative	



**Date Reported:** Thursday, May 09, 2013

**Cell Line:** DF19-9-11T.H-WB0219 10767

**Passage#:** 28

**Date of Sample:** 5/8/2013

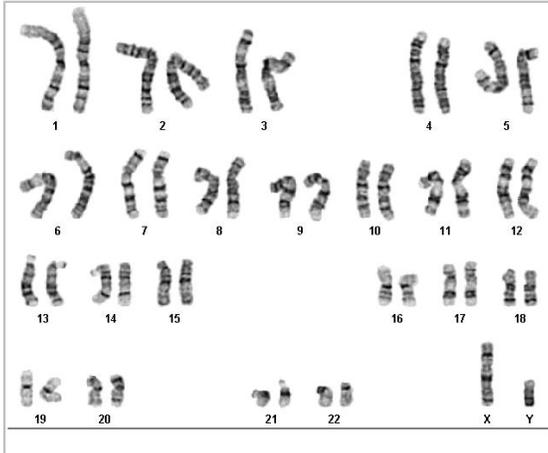
**Specimen:** iPSC

**Results:** 46,XY

**Cell Line Gender:** Male

**Reason for Testing:** Lot release testing

**Investigator:** [REDACTED], WiCell CDM



**Cell:** 8

**Slide:** 2

**Slide Type:** Karyotype

**Total Counted:** 20

**Total Analyzed:** 8

**Total Karyotyped:** 4

**Band Resolution:** 425 - 475

### 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.*