



Thaw and Culture Details

Cell Line Name	JFMD2
WiCell Lot Number	DB29701
Provider	Jain Foundation
Banked By	Cellular Dynamics International
Thaw and Culture Recommendations	WiCell recommends thawing 1 vial into 1 well of a 6 well plate.
Culture Platform	Feeder Independent
	Medium: E8
	Matrix: Matrigel®
Protocol	WiCell Feeder Independent E8 Medium Protocol
Passage Number	p11 These cells were cultured for 11 passages prior to freeze and post reprogramming. Add +1 to the passage number to best represent the overall passage number of the cells at thaw.
Date Vialied	21-August-2014
Vial Label	MyCell® Products Cat #: iPSC Lot #: 01458.102.11 Passage #: 11 Storage Temp Liquid Nitrogen
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
Karyotype by G-banding	WiCell	SOP-CH-003	Expected karyotype	See Report
	Result: This is an abnormal karyotype. There is an extra copy of chromosome 12 in six of twenty cells examined. Trisomy 12 is a recurrent acquired abnormality in human pluripotent stem cell cultures. No other clonal abnormalities were found.			
Post-Thaw Viable Cell Recovery	WiCell	SOP-CH-305	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



Testing Reported by Provider

This testing was performed prior to banking unless otherwise specified.

Test Description	Method	Result
Genetic Analysis	Karyotype by G-Banding	Normal Karyotype
Pluripotency	Multiplex RT-PCR to quantify endogenous expression of 7 genes. Scores generated from the analysis predict probability samples are iPSC-like.	Passing sample score ≥ 0.9
Mycoplasma	Commercially available mycoplasma detection kit.	Negative
Human Virus Testing	HIV I/II CPT Code 87389; detects both antigen and antibodies for HIV I and HIV II. HBV CPT Code 87340; detects Hepatitis B surface antigen. HCV CPT Code 86803; Immunoassay detects Hepatitis C antibody.	Donor samples tested negative for the following human viruses. HIV I HIV II HBV HCV
Identity	Multiplex STR analysis of 9 commonly used alleles.	Match of iPS cell line to incoming donor material.

Approval Date	Quality Assurance Approval
21-December-2015	<div>2/2/2018</div> <div>X JKG</div> <div>JKG Quality Assurance Signed by Gay, Jenna</div>



Chromosome Analysis Report: 033500

Date Reported: Friday, April 29, 2016

Cell Line: JFMD2-DB29701 11632

Passage#: 15

Date of Sample: 4/27/2016

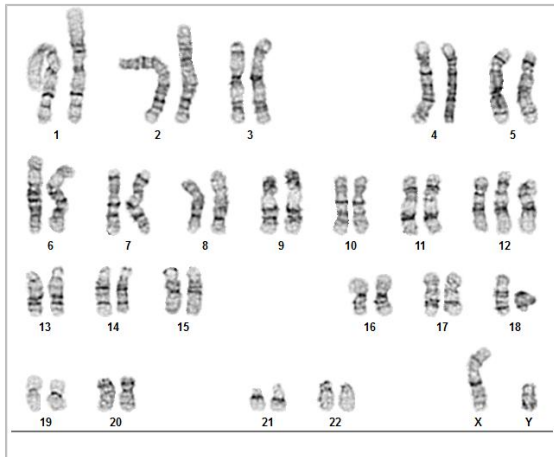
Specimen: iPSC

Results: 47,XY,+12[6]/46,XY[14]

Cell Line Gender: Male

Reason for Testing: Lot release testing

Investigator: [REDACTED], WiCell CDM



Cell: 57

Slide: 1

Slide Type: Karyotype

Total Counted: 20

Total Analyzed: 8

Total Karyogrammed: 4

Band Resolution: 450 - 550

Interpretation:

This is an abnormal karyotype. There is an extra copy of chromosome 12 in six of twenty cells examined. Trisomy 12 is a recurrent acquired abnormality in human pluripotent stem cell cultures. No other clonal abnormalities were found.

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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Short Tandem Repeat Analysis

Department of Pathology and Laboratory Medicine
TRIP Laboratory (Molecular)
<http://www.pathology.wisc.edu/research/trip>

Sample Report:

11632-STR
Sample Name on Tube: 11632-STR
10.4 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: 03/20/17
Assay Date: 03/21/17
File Name: STR 170322 wmr
Report Date: 03/23/17

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 11632-STR cells submitted by WiCell QA dated and received on 03/20/17, this sample (Label on Tube: 11632-STR) defines the STR profile of the human stem cell line JFMD2 comprising 26 allelic polymorphisms across the 15 STR loci analyzed.

Interpretation: No STR polymorphisms other than those corresponding to the human JFMD2 stem cell line were detected however, allelic imbalance (denoted by ** in table above) was observed at the D18S51 and Penta_E loci and could be the result of chromosomal gains and/or losses in this cell line. 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 11632-STR sample submitted corresponds to the JFMD2 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 03/24/17

TRIP Laboratory, Molecular

X *WMR*

Digitally Signed on 03/24/17

, PhD, Director / Co-Director
UWHC Molecular Diagnostics Laboratory / UWSMPH TRIP Laboratory

Sterility Report

Biotest Laboratories, Inc.

Making life-saving products possible

WiCell Research Institute, Inc.
WiCell Quality Assurance
504 South Rosa Road, Room 101
Madison, WI 53719

BIOTEST SAMPLE # 16041630

VALIDATION # NG

TEST PURPOSE NG

PRODUCT JFMD2-DB29701 11613

PRODUCT LOT NA

STERILE LOT NA

BI LOT NA

STERILIZATION LOT NA

BI EXPIRATION DATE NA

STERILIZATION DATE NA

DATE RECEIVED 2016-04-21

STERILIZATION METHOD NA

TEST INITIATED 2016-04-28

SAMPLING BLDG / ROOM NA

TEST COMPLETED 2016-05-12

REFERENCE Processed according to LAB-003: Sterility Test Procedure

One (1) product was 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	1	NA	2 Negatives

COMMENTS NA

REVIEWED BY  DATE 12 MAY 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 Testing

April 21st, 2016

FORM SOP-QU-004.01

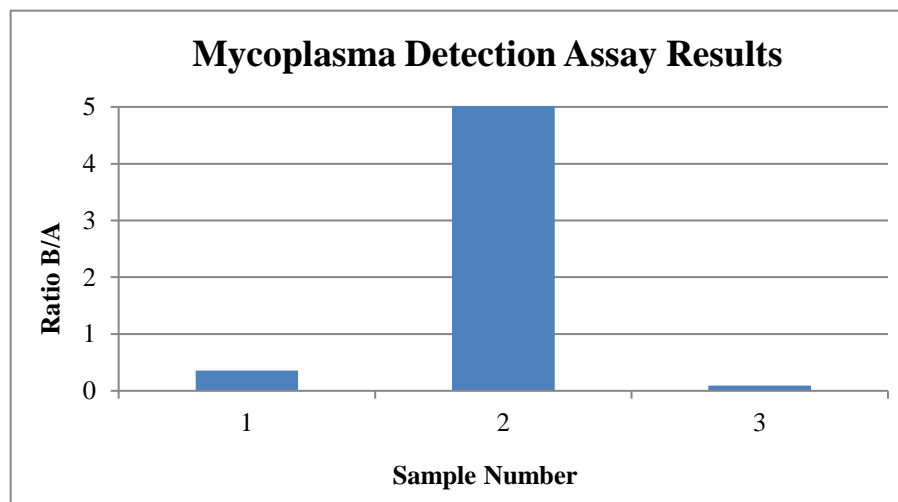
Version E Edition 01

Reported by: SS

Reviewed by: JB

Berthold Flash n' Glo 539

#	Sample Name	Reading A		A Ave	Reading B		B Ave	Ratio B/A	Result	Comments/Suggestions
		RLU1	RLU2		RLU1	RLU2				
1	JFMD2-DB29701 11624	86	88	87	32	30	31	0.36	Negative	
2	Positive (+) Control	137	127	132	8898	8747	8823	66.84	Positive	
3	Negative (-) Control	244	228	236	21	22	21.5	0.09	Negative	





Testing Reported by Provider

The testing reports following this placeholder are described on the certificate of analysis found in the beginning of this packet.



Chromosome Analysis Report: 014921

Date Reported: Wednesday, August 13, 2014

Cell Line: VIH0035

Passage#: 8

Date of Sample: 8/6/2014

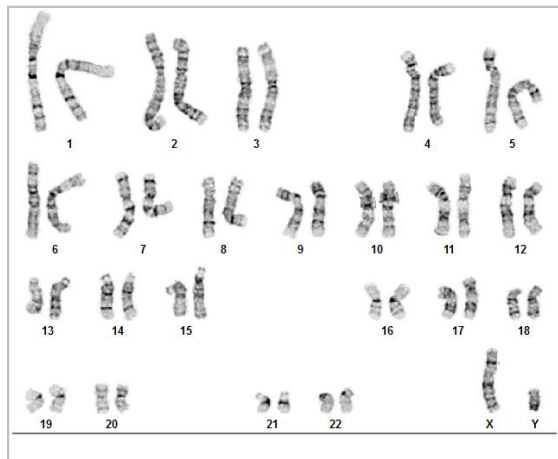
Specimen: iPSC

Results: 46,XY

Cell Line Gender: Male

Reason for Testing: Routine testing

Investigator: [REDACTED], CDI



Cell: 40

Slide: 2

Slide Type: Karyotype

Total Counted: 20

Total Analyzed: 8

Total Karyotyped: 4

Band Resolution: 425 - 450

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".

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