



Thaw and Culture Details

Cell Line Name	WC016i-CMT2A-3.1
WiCell Lot Number	WB58636
Provider	University of Wisconsin – Dr. John Svaren
Banked By	WiCell
Thaw and Culture Recommendations	WiCell recommends thawing 1 vial into 3 wells of a 6 well plate.
Culture Platform	Feeder Independent
	Medium: TeSR™-E8™
	Matrix: Matrigel®
Protocol	WiCell Feeder Independent E8 Medium Protocol
Passage Number	p13 These cells were cultured for 12 passages prior to freeze and post reprogramming. WiCell adds +1 to the passage number to best represent the overall passage number of the cells at thaw.
Date Vialied	29-January-2017
Vial Label	WC016i-CMT2A-3.1 p13 WB58636
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 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
Karyotype by G-banding	WiCell	SOP-CH-003	Expected karyotype	Pass

Approval Date	Quality Assurance Approval
18-August-2017	X AMK Quality Assurance

Short Tandem Repeat Analysis

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

Sample Report:

12201-STR
Sample Name on Tube: 12201-STR
69.1 ng/μL, (A260/280=1.91)
Sample Type: Cells
Cell Count: ~2 million cells

Requestor:

WiCell Research Institute
Quality Department

Sample Date: N/A

Receive Date: 02/20/17
Assay Date: 02/21/17
File Name: STR 170222 wmr
Report Date: 02/23/17

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 12201-STR cells submitted by WiCell QA dated and received on 02/20/17, this sample (Label on Tube: 12201-STR) defines the STR profile of the human stem cell line WC016i-CMT2A-3.1 comprising 24 allelic polymorphisms across the 15 STR loci analyzed.

Interpretation: No STR polymorphisms other than those corresponding to the human WC016i-CMT2A-3.1 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 12201-STR sample submitted corresponds to the WC016i-CMT2A-3.1 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 02/24/17

TRIP Laboratory, Molecular

X *WMR*

Digitally Signed on 02/24/17

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

Sterility Report



Laboratories

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

SAMPLE # 17020763

VALIDATION # NG

TEST PURPOSE NG

PRODUCT WC013i-CMT2A-2.1-WB58590 12219, WC014i-CMT2A-2.2-WB58591 12220, WC015i-CMT2A-2.3-WB58600 12221, WC016i-CMT2A-3.1-WB58636 12222, WC017i-CMT2A-3.2-WB58712 12223, WC018i-CMT2A-3.3-WB58715 12224, HVRDi001-A-DB46570 12225, HVRDi001-A-1-DB46573 12226, HVRDi002-A-DB46576 12227, JHU001i-DB36193 12260

PRODUCT LOT NA

STERILE LOT NA

BI LOT NA

STERILIZATION LOT NA

BI EXPIRATION DATE NA

STERILIZATION DATE NA

DATE RECEIVED 2017-02-09

STERILIZATION METHOD NA

TEST INITIATED 2017-02-10

SAMPLING BLDG / ROOM NA

TEST COMPLETED 2017-02-24

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
Sterile

POSITIVES
0

TESTED
10

POSITIVE CONTROL
NA

NEGATIVE CONTROL
2 Negatives

COMMENTS NA

REVIEWED BY

DATE 01MAR17

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.
The uncertainty of measurement associated with the measurement result reported in this certificate is available from the organization upon request.



Mycoplasma Detection Assay Report

Testing Performed by WiCell

Lot Release Testing

February 06, 2017

FORM SOP-QU-004.01

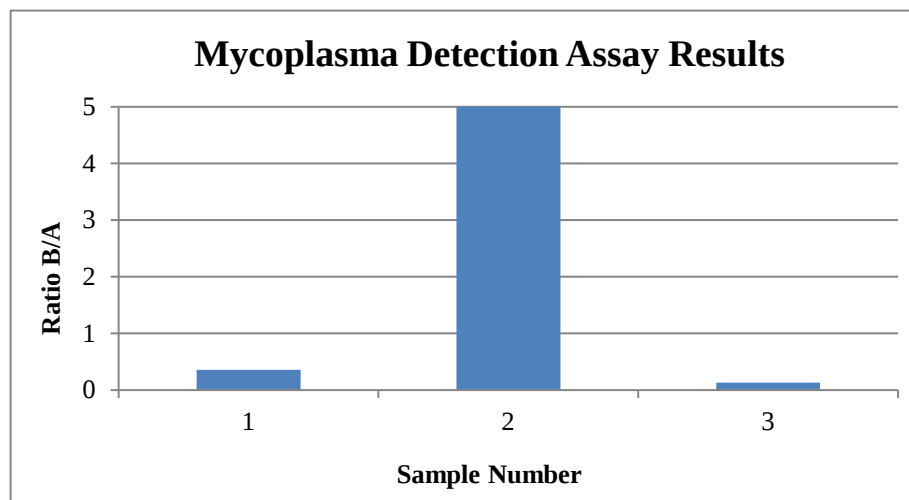
Version F Edition 02

Reported by:OG

Reviewed by: JB

BD Monolight 180

#	Sample Name	Reading A		A Ave	Reading B		B Ave	Ratio B/A	Result	Comments/Suggestions
		RLU1	RLU2		RLU1	RLU2				
1	WC016i-CMT2A-3.1-WB58636 12201	275	284	279.5	99	101	100	0.36	Negative	
2	Positive (+) Control	343	334	338.5	34723	35179	34951	103.25	Positive	
3	Negative (-) Control	591	600	595.5	77	78	77.5	0.13	Negative	





Chromosome Analysis Report: 059344

Date Reported: Monday, February 13, 2017

Cell Line: WC016i-CMT2A-3.1-WB58636
12201

Passage#: 13

Date of Sample: 2/7/2017

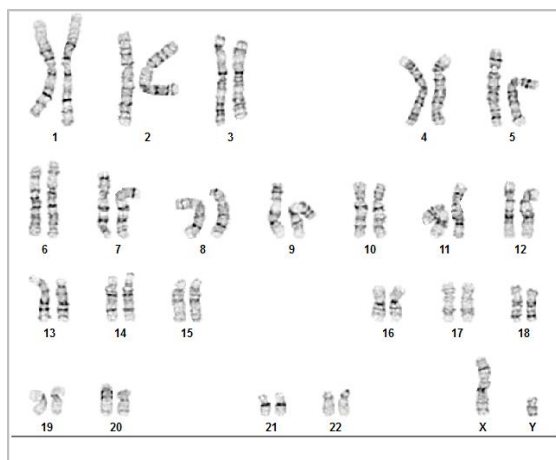
Specimen: iPSC

Results: 46,XY

Cell Line Gender: Male

Reason for Testing: lot release testing

Investigator: [REDACTED], WiCell CDM



Cell: 46

Slide: 1

Slide Type: Karyotype

Total Counted: 20

Total Analyzed: 8

Total Karyogrammed: 4

Band Resolution: 450 - 550

Interpretation:

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

Completed by: [REDACTED] re, 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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