

Thaw and Culture Details

Cell Line Name	UWWC1-DS4							
WiCell Lot Number	WB18225							
Provider	University of Wisconsin – Dr. Anita Bhattacharyya							
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: mTeSR™1							
	Matrix: Matrigel®							
Protocol WiCell Feeder Independent mTeSR™1 Protocol								
Passage Number	p38 These cells were cultured for 37 passages prior to freeze, at least 13 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 Vialed	25-March-2015							
Vial Label	UWWC1-DS4 p38 WB18225							
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	Pass
	karyotype. Twenty of twenty c 21).	ells examined		
Post-Thaw Viable Cell Recovery	WiCell	SOP-CH-305	≥ 15 Undifferentiated Colonies, ≤ 30% Differentiation and recoverable attachment after passage	Pass
Identity by STR	y STR UW Translational PowerPlex 16 HS Research Initiatives in Pathology Laboratory Promega		Defines profile	Pass
Sterility	Biotest Laboratories	ST/07	Negative	Pass
Mycoplasma	WiCell	SOP-QU-004	Negative	Pass

Approval Date	Quality Assurance Approval		
28-May-2015	8/9/2017 X AMK AMK Quality Assurance Signed by Klade, Anjelica		



Chromosome Analysis Report: 018409

Date Reported: Thursday, April 09, 2015 Cell Line Gender: Male

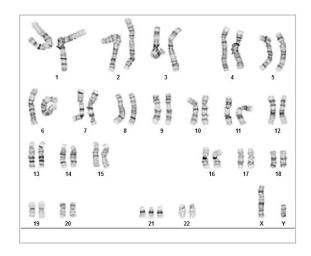
Cell Line: UWWC1-DS4-WB18225 11218 Reason for Testing: lot release testing

Passage#: 38

Date of Sample: 3/31/2015 Investigator: Steve Schreiber, CDM

Specimen: iPSC Results: 47,XY,+21[19]

Nonclonal findings: 47,XY,del(2)(q13),+21



Cell: 35 Slide: 2

Slide Type: Karyotype

Total Counted: 20
Total Analyzed: 8
Total Karyotyped: 4

Band Resolution: 450 - 475

Interpretation:

This is an abnormal karyotype. Twenty of twenty cells examined have an extra chromosome 21 (trisomy 21).

There is one nonclonal finding, listed above. Nonclonal findings likely result from technical artifact, but may be due to a developing clonal abnormality or to low-level mosaicism. Standard analysis requires that chromosomes are counted in twenty cells; an additional twenty cells were examined with no further evidence of the nonclonal abnormalities.

Completed by: Kim Leonhard, CG(ASCP)

Reviewed and Interpreted by: Karen Dyer Montgomery, 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

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(888) 204-1782

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

Sample Report: 11218-STR

Sample Name on Tube: 11218-STR 157.3 ng/μL, (A260/280=1.92)

Sample Type: Cells

Cell Count: ~2 million cells

Requestor:WiCell Research Institute
Quality Department

Sample Date: N/A Receive Date: 04/20/15 Assay Date: 04/21/15

File Name: STR_150422_wmr

Report Date: 04/27/15

STR Locus	R Locus STR Genotype Repeat #							
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	19,23						
TPOX								
D8S1179	7-18	13,15						
vWA	10-22	15,17						
Amelogenin	X,Y	X,Y						
Penta_D	2.2, 3.2, 5, 7-17	11,13**						
CSF1PO	6-15	10,11						
D16S539	5, 8-15	11,13						
D7S820	6-14	10,12						
D13S317	7-15	11,11						
D5S818	7-16	10,12						
Penta_E	5-24	10,15						
D18S51	8-10, 10.2, 11-13, 13.2, 14-27	13,16						
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	29,30,31.2						
TH01	4-9,9.3,10-11,13.3	6,9						
D3S1358	12-20	15,16						

<u>Results:</u> Based on the 11218-STR cells submitted by WiCell QA dated and received on 04/20/15, this sample (Label on Tube: 11218-STR) defines the STR profile of the human stem cell line UWWC1-DS4 comprising 30 allelic polymorphisms across the 15 STR loci analyzed.

Interpretation: No STR polymorphisms other than those corresponding to the human UWWC1-DS4 stem cell line were detected, including a triploid genotype at the D21S11 locus. Additionally, allelic imbalance (denoted by ** in the table above) was observed at the Penta_D locus. These observations could be the result of chromosomal gains, losses and/or amplifications 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 11218-STR sample submitted corresponds to the UWWC1-DS4 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 04/27/15 X WMR Digitally Signed on

William M. Rehrauer, PhD, Director / Co-Director

UWHC Molecular Diagnostics Laboratory / UWSMPH TRIP Laboratory

04/27/15

Rebecca M. Baus TRIP Laboratory, Molecular

Sterility Report

Biotest Laboratories, Inc.

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WiCell Research Institute, Inc.

WiCell Quality Assurance

505 South Rosa Road, Suite 120

Madison, WI 53719

BIOTEST SAMPLE # 15050336

VALIDATION #

NG

TEST PURPOSE

NG

PRODUCT WIPO5i-iPSCas9KO-WB17902 11253

RUES3-DB18144 11255

WC005i-FX11-7-WB18030 11256 WIC02i-02-05-WB18279 11257 PACT-ESC-WA01-RB18519 11258 PACT-ESC-WA01-RB18522 11259 WIP07e-H9Cas9Het-WB18521 11260 WIPO6i-iPSCas9Het-WB18520 11261 UWWC1-DS4-WB18225 11262 UWWC1-2DS3-WB18532 11263 WC-24-02-DS-C-WB18862 11264 WC-24-02-DS-B-WB18712 11265 WC-24-02-DS-M-WB18754 11266 UWWC1-DS2U-WB19012 11267 WIC07i-07982-4-WB18972 11268 WC-24-02-DS-P-WB18907 11269 WC-24-02-DS-A-WB18711 11270 WC-24-02-DS-O-WB19180 11271

PRODUCT LOT NA

STERILE LOT NA

BI LOT NA

STERILIZATION LOT NA

BI EXPIRATION DATE NA

STERILIZATION DATE NA

DATE RECEIVED

TEST INITIATED 2015-05-07

STERILIZATION METHOD NA

2015-05-06

SAMPLING BLDG / ROOM NA

TEST COMPLETED

2015-05-21

REFERENCE Processed according to LAB-003: Sterility Test Procedure

WC-3801-5-WB16647 11272

Nineteen (19) 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

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

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BIOTEST SAMPLE # 15050336

RESULTS

POSITIVES

TESTED 19

POSITIVE CONTROL

NEGATIVE CONTROL

NA

2 Negatives

Non-Sterile

One (1) sample labeled as WC-24-02-DS-M-WB18754 11266 had growth in FTG.

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



Mycoplasma Detection Assay Report Testing Performed by WiCell

Testing Performed by WiCell Lot Release Test 04-03-2015

FORM SOP-QU-004.01 Version D Edition 01 Reported by: SS Reviewed by: JB Berthold Flash n' Glo 539

		Read	ing A	A	Read	ing B	В	Ratio		
#	Sample Name	RLU1	RLU2	Ave	RLU1	RLU2	Ave	B/A	Result	Comments/Suggestions
1	UWWC1-DS4-WB18225 11218	141	138	139.5	51	49	50	0.36	Negative	
2	Positive (+) Control	303	303	303	12342	12317	12330	40.69	Positive	
3	Negative (-) Control	478	462	470	47	47	47	0.10	Negative	

