Thaw and Culture Details

Cell Line Name	UWWC1-DS1
WiCell Lot Number	WB21343
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	p27 These cells were cultured for 26 passages prior to freeze, 3 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-July-2015
Vial Label	UWWC1-DS1 p27 WB21343
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

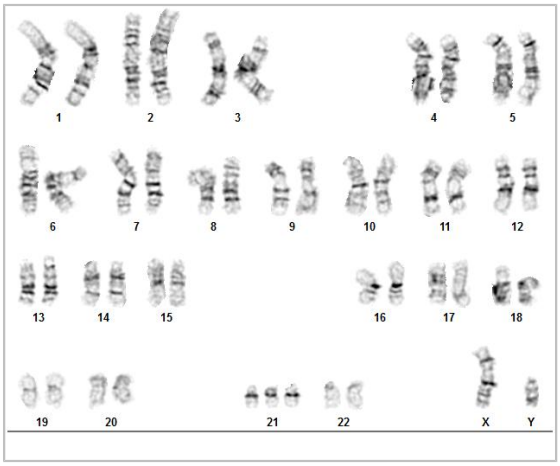
Test Description	Test Provider	Test Method	Test Specification	Result
Karyotype by G-banding	WiCell	SOP-CH-003	Expected karyotype	Pass
	Result from report: This is an abnormal karyotype. Three copies of chromosome 21 (trisomy 21) were found in twenty of twenty cells examined. No other clonal abnormalities were found.			
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

Approval Date	Quality Assurance Approval
21-September-2015	8/9/2017 X AMK AMK Quality Assurance Signed by: Klade, Anjelica

Chromosome Analysis Report: 021511

Date Reported: Monday, August 10, 2015
Cell Line: UWWC1-DS1-WB21343 11342
Passage#: 27
Date of Sample: 7/31/2015
Specimen: iPSC
Results: 47,XY,+21[20]

Cell Line Gender: Male
Reason for Testing: lot release testing
Investigator: [redacted], WiCell CDM



Cell: 26
Slide: 1
Slide Type: Karyotype

Total Counted: 20
Total Analyzed: 8
Total Karyotyped: 4
Band Resolution: 425 - 450

Interpretation:

This is an abnormal karyotype. Three copies of chromosome 21 (trisomy 21) were found in twenty of twenty cells examined. 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".

Short Tandem Repeat Analysis

School of Medicine and Public Health
UNIVERSITY OF WISCONSIN-MADISON
Department of Pathology and Laboratory Medicine
TRIP Laboratory (Molecular)
http://www.pathology.wisc.edu/research/trip

WiCell®
info@wicell.org
(888) 204-1782

Sample Report:
11342-STR
Sample Name on Tube: 11342-STR
162.6 ng/µL, (A260/280=1.87)
Sample Type: Cells
Cell Count: ~2 million cells

Requestor:
WiCell Research Institute
Quality Department

Sample Date: N/A
Receive Date: 08/11/15
Assay Date: 08/18/15
File Name: 1508202str jam
Report Date: 08/21/15
revised 09/14/15

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 11342-STR cells submitted by WiCell QA dated and received on 08/11/15, this sample (Label on Tube: 11342-STR) defines the STR profile of the human stem cell line UWWC1-DS1 comprising 31 allelic polymorphisms across the 15 STR loci analyzed.**

Interpretation: **No STR polymorphisms other than those corresponding to the human 11342-STR stem cell line were detected, including triploid genotypes at the FGA and D21S11 loci. Additionally, allelic imbalance (denoted by ** in the table above) was observed at the FGA and Penta_D loci. These observations could be the result of chromosomal gains, losses and/or amplifications in this cell line. This line is a clinical model for Trisomy 21, consequently imbalance and triploidy make sense with regards to Penta_D and D21S11 loci. 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 11342-STR sample submitted corresponds to the UWWC1-DS1 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 09/14/15**

[redacted]
TRIP Laboratory, Molecular

X *WMR* **Digitally Signed on 09/14/15**

[redacted], *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
[redacted]

BIOTEST SAMPLE # 15081899

VALIDATION # NG

TEST PURPOSE NG

PRODUCT	WA09(LOXGFP)-WB20971 11368 UWWC1-2DS3-WB20846 11369 WC005i-FX11-7-WB20449 11370 UWWC1-DS1-WB21343 11371 WC-3801-2-WB21395 11372 WA07-WB21842 11373 LT2e-H9CAGGFP-WB0207 11374 MIN01i-32517.A-WB20571 11375 MIN03i-32642.B-WB20013 11376 MIN04i-33109.2B-WB20383 11377
PRODUCT LOT	NA
STERILE LOT	NA
STERILIZATION LOT	NA
STERILIZATION DATE	NA
STERILIZATION METHOD	NA
SAMPLING BLDG / ROOM	NA

BI LOT	NA
BI EXPIRATION DATE	NA
DATE RECEIVED	2015-08-27
TEST INITIATED	2015-08-28
TEST COMPLETED	2015-09-11

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	# POSITIVES	# TESTED	POSITIVE CONTROL	NEGATIVE CONTROL
Sterile	0	10	NA	2 Negatives

COMMENTS NA

REVIEWED BY [redacted] DATE 11Sep15

Mycoplasma Detection Assay Report

Testing Performed by WiCell

Lot Release Test

08-06-2015

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	UWWC1-DS1-WB21343 11342	153	165	159	62	61	61.5	0.39	Negative	
2	Positive (+) Control	221	231	226	14243	14281	14262	63.11	Positive	
3	Negative (-) Control	496	493	494.5	52	51	51.5	0.10	Negative