Certificate of Analysis

Thaw and Culture Details

Cell Line Name	**UWWC1-DS1**	
WiCell Lot Number	**WB68233**	
Parent Material	UWWC1-DS1- WB21343	
Provider/Client	University of Wisconsin – Dr. Anita Bhattacharyya	
Banked By	WiCell	
Thaw and Culture Recommendations	WiCell recommends thawing 1 vial into 1 well of a 3 wells plate using mTeSR™1 and Cultrex®.	
Protocol	WiCell Feeder Independent Pluripotent Stem Cell Protocol	
Culture Platform Prior to Freeze	Medium: mTeSR™1	Matrix: Cultrex®
Passage Number	p30 Cells were cultured for 29 passages prior to freeze. Plated cells at thaw should be labeled passage 30.	
Date Vialed	20-JANUARY-2024	
Vial Label	UWWC1-DS1 p30 WB68233 Store at -135C or colder Made in United States Research Use Only	
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.	

Certificate of Analysis

Results

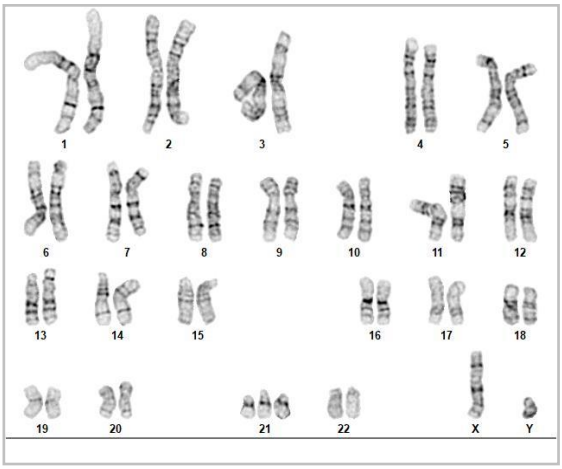
Test Description	Test Provider	Test Method	Test Specification	Result
Karyotype	WiCell	G-T-L Banding performed on 20 metaphase cells	Expected karyotype	See Report
	Results: 47,XY,+21[20] ***Interpretation:*** This is an abnormal karyotype. An extra copy of chromosome 21 (trisomy 21) is present in twenty of twenty cells examined. No other clonal abnormalities were detected at the stated band level of resolution. This report has been updated to remove a reference to testing the parental line on 23Feb24.			
Post-Thaw Viable Cell Recovery	WiCell	Thaw using specified Thaw & Culture Recommendations	≥ 15 Undifferentiated Colonies prior to passage, ≤ 30% Differentiation prior to passage, and recoverable attachment after passage	Pass
Identity by STR	WiCell	PowerPlex 16 HS System by Promega™	Consistent with STR profile of deposited cell line	See Report
Mycoplasma	WiCell	PCR	Amplification of mycoplasma specific DNA detected with negative result	Pass
Sterility	Steris	Native Product Direct Transfer using FTM and TSB (ST/07)	Negative for growth following 14 days of culture	Pass

Approval Date	WiCell Quality Assurance Approval
17-September-2024	9/17/2024 X DLG DLG WiCell Quality Assurance Signed by: Graham, Dawn

Updated Chromosome Analysis Report: 100470

Date Reported: February 23, 2024
Cell Line: UWWC1-DS1-WB68233
Submitted Passage #: 30
Date of Sample: 1/31/2024
Specimen: Human IPSC
Results: 47,XY,+21[20]

Cell Line Sex: Male
Reason for Testing: LOT_RELEASE
Investigator: WiCell Stem Cell Bank, WiCell



Cell: 54
Slide: G03
Slide Type: Karyotype

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

Updated Interpretation:

This is an abnormal karyotype. An extra copy of chromosome 21 (trisomy 21) is present in twenty of twenty cells examined. No other clonal abnormalities were detected at the stated band level of resolution.

This report has been updated to remove a reference to testing the parental line on 23Feb24.

Completed by: Pam Mill
Reviewed and Interpreted by: Vanessa Horner, PhD, FACMG

For internal use only

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

Requestor: WiCell Stem Cell Bank, WiCell
Samples Received: 31Jan24
STR Amplification Date: 06Feb24

Sample Name	UWWC1-DS1-WB68233 p30
WiCell CTR No.[1]	100470
FGA	[redacted]
TPOX	
D8S1179	
vWA	
Amelogenin	
Penta_D	
CSF1PO	
D16S539	
D7S820	
D13S317	
D5S818	
Penta_E	
D18S51	
D21S11	
TH01	
D3S1358	
Allelic Polymorphisms	31
Matches*	71618 (96.88%), 92696 (93.75%), 17989 (93.75%), 21511
Comments	[2]Tri Allelic Pattern

Identifying information has been redacted to protect donor confidentiality. If more information is required, please contact info@wicell.org

**Note: The STR profile of the following sample is a 100% match for the given sample/samples unless otherwise specified.*

[1] CTR No.: Characterization Test Request Number; also known as a laboratory accessioning number.

Short Tandem Repeat

Requestor: WiCell Stem Cell Bank, WiCell
Samples Received: 31Jan24
STR Amplification Date: 06Feb24

Assay Description: STR analysis is performed using the PowerPlex 16 HS System by Promega™. Results are reported as 13 CODIS STR markers, Amelogenin for gender determination and two low-stutter, highly discriminating pentanucleotide STR markers.

Results: The genotypic profiles comprise a range of 31 allelic polymorphisms across the 15 STR loci analyzed.

Interpretation: 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 suggests that the cells submitted correspond to the cell lines as named and were not contaminated with any other human 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 cell lines is ~2-4%.

[2]Tri-allelic Pattern: A tri-allelic pattern was detected at the FGA and D21S11 loci of sample 100470. This observation could be the result of chromosomal gains and/or amplifications in this cell line.

2/7/2024 X Amber Kuhn Tech #1 Characterization Signed by: Kuhn, Amber	2/8/2024 X Anna Lisa Larson Tech #2 Characterization Signed by: Larson, Anna Lisa	2/13/2024 X Ryen Smith QA Review Quality Assurance Signed by: Smith, Ryen

Mycoplasma Assay Report

PCR-based assay performed by WiCell

WiCell Stem Cell Bank, WiCell

05Feb24

Form SOP-83.01
Version 5.0

Sample Name	Result	Interpretation
UWWC1-DS1-WB68233 p30 (100470)	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
Positive (+) Control	Positive	
Negative (-) Control	Negative	

Assay Description
Sample is tested for presence of mycoplasma using EZ-PCR™ Mycoplasma Detection Kit (Sartorius).

2/5/2024	2/5/2024	2/5/2024
X Julia Graham	X Amber Kuhn	X Andy Arntz
Tech #1 Characterization Signed by: Graham, Julia	Tech #2 Characterization Signed by: Kuhn, Amber	QA Review Quality Assurance Signed by: Arntz, Andy

A gel image is available upon request.

Native Product Sterility Report

STERIS

SAMPLE #:	24020041
DATE RECEIVED:	01-Feb-24
TEST INITIATED:	02-Feb-24
TEST COMPLETED:	16-Feb-24

WiCell
504 S Rosa Road, Rm 101
Madison, WI 53719

SAMPLE NAME / DESCRIPTION:
WA-AICS-0075-085-WB68226
WA-AICS-0011-WB68228
WA-AICS-0012-WB68229
WA-AICS-0052-003-WB68230
WA-AICS-0013-WB68231
WA-AICS-0016-WB68232
UWWC1-DS1-WB68233
STAN146i-286C2-DB44174
STAN152i-307C2-DB38135
STAN145i-286C1-DB44171

UNIQUE IDENTIFIER: N/A

TEST RESULTS:

# Tested	# Positives (Growth)	- Control
10	0	2 Negatives

TEST SUMMARY:

# Samples	Media Type	Volume (mL)	Incubation Temperature (° C)	Incubation Duration (Days)
10	TSB	40	20-25	14
10	FTG	40	30-35	14

REFERENCE: Processed according to LAB-003: Sterility Test Procedure

PD #: 000053

TEST METHODOLOGY: USP - Direct Transfer

COMMENTS: NA

AUTHORIZED BY _____ DATE 20FEB2024