Certificate of Analysis

Thaw and Culture Details

Cell Line Name	**IMR90-TSC2Het**	
WiCell Lot Number	**WB67712**	
Provider/Client	University of Wisconsin – Dr. Timothy Gomez	
Banked By	WiCell	
Thaw and Culture Recommendations	WiCell recommends thawing 1 vial into 3 wells of a 6 well plate using mTeSR™Plus and Matrigel®.	
Protocol	WiCell Feeder Independent Pluripotent Stem Cell Protocol	
Culture Platform Prior to Freeze	Medium: mTeSR™Plus	Matrix: Matrigel®
Passage Number	p44 Cells were cultured for 43 passages prior to freeze and post colony selection. Plated cells at thaw should be labeled passage 44.	
Date Vialed	14-August-2021	
Vial Label	IMR90-TSC2Het p44 WB67712	
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

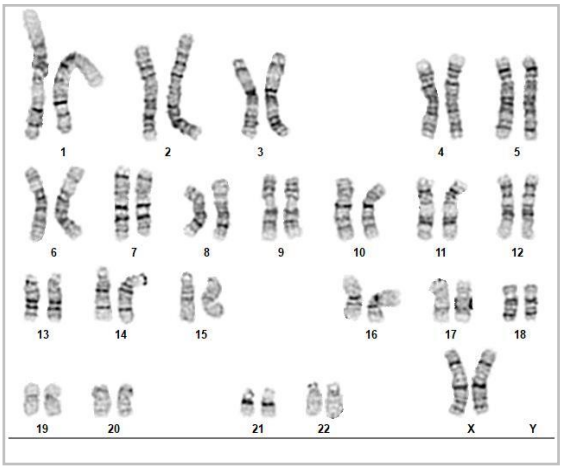
Test Description	Test Provider	Test Method	Test Specification	Result
Karyotype	WiCell	G-T-L Banding performed on 20 metaphase cells	Expected karyotype	See Report
	Results: 46,XX ***Interpretation:*** This is a normal karyotype; no clonal abnormalities were detected at the stated band level of resolution.			
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™	Defines 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
21-October-2021	10/21/2021 X JKG JKG WiCell Quality Assurance Signed by: Gay, Jenna

Chromosome Analysis Report: 087793

Date Reported: Tuesday, August 31, 2021
Cell Line: IMR90-TSC2Het-WB67712
Submitted Passage #: 44
Date of Sample: 8/24/2021
Specimen: Human Modified iPSC
Results: 46,XX

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



Cell: 23
Slide: G01
Slide Type: Karyotype

Total Counted: 20
Total Analyzed: 8
Total Karyogrammed: 4
Band Resolution: 400 - 525

Interpretation:
This is a normal karyotype; no clonal abnormalities were detected at the stated band level of resolution.

Completed by: Pam Mill
Reviewed and Interpreted by: Kaitlin C. Lenhart, Ph.D.

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: 23Aug21, 24Aug21, 25Aug21
STR Amplification Date: 21Aug21

Sample Name	STAN023i-41-1-DB31169 p12	[redacted]	IMR90-TSC2Het-WB67712 p44	[redacted]	
Label on tube	87772		87793		
FGA	[redacted]				
TPOX					
D8S1179					
vWA					
Amelogenin					
Penta_D					
CSF1PO					
D16S539					
D7S820					
D13S317					
D5S818					
Penta_E					
D18S51					
D21S11					
TH01					
D3S1358					
Allelic Polymorphisms	27	27	28	27	27
Matches*		See Matches Comment	See Matches Comment	See Matches Comment	See Matches Comment
Comments					

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 an exact match for the given sample/samples.*

Short Tandem Repeat

Requestor: WiCell Stem Cell Bank, WiCell
Samples Received: 23Aug21, 24Aug21, 25Aug21
STR Amplification Date: 21Aug21

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 27-28 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 ~2-5%.

Matches: Samples 87792, 87794, and 87805 are exact matches to each other and to 87925, 87924, 87923, 87894, 87893, and 87727. Sample 87793 is an exact match to 87887, 84550, 70422, 67351, 65704, 63444, 63441, 58649 and a 96.67% match to 63442 and 58502.

9/3/2021 X Callum Walker Tech #1 Characterization Signed by: Walker, Callum	9/3/2021 X Molly Miles Tech #2 Characterization Signed by: Miles, Molly	9/3/2021 X Dawn Graham QA Review Quality Assurance Signed by: Graham, Dawn

Raw data is available upon request.

Mycoplasma Assay Report

FORM SOP-83.01
Version 3.0

PCR-based assay performed by WiCell
WiCell
01Sep21

Sample Name	Result	Interpretation
IMR90-TSC2Het-WB67712 p44 (87793)	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
IMR90-TSC2Null-WB67713 p43 (87887)	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
WC-52-TSC2Corr-WB67715 p24 (87888)	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
[redacted]	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
[redacted]	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
[redacted]	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
[redacted]	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
[redacted]	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
[redacted]	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
[redacted]	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
[redacted]	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
WC-52-TSC2Null-WB67719 p20 (87921)	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
[redacted]	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
[redacted]	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
[redacted]	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
STAN014i-121-2-DB31149 p12 (87926)	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
STAN017i-171-1-DB31059 p11 (87928)	Uninformative	Internal control band was not seen after a retest, WiCell recommends resubmitting this sample.
Positive (+) Control	Positive	
Negative (-) Control	Negative	

9/8/2021

X Hannah Rueth

Tech #1
Characterization
Signed by: Rueth, Hannah

9/8/2021

X Callum Walker

Tech #2
Characterization
Signed by: Walker, Callum

9/8/2021

X Dawn Graham

QA Review
Quality Assurance
Signed by: Graham, Dawn

A gel image is available upon request.

Native Product Sterility Report

STERIS

CORRECTED REPORT

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

SAMPLE #: 21090138
DATE RECEIVED: 02-Sep-21
TEST INITIATED: 09-Sep-21
TEST COMPLETED: 23-Sep-21

SAMPLE NAME / DESCRIPTION:

STAN061i-164-1-WB67675
CREM055i-BR37-1-WB67683
IMR90-TSC2Het-WB67712
IMR90-TSC2Null-WB67713
WC-52-TSC2Corr-WB67715
WC-52-TSC2Null-WB67719
STAN014i-121-2-DB31149
STAN073i-180-1-DB31159
STAN074i-180-2-DB31166
[redacted]
SCRP9001i-DB43138
SCRP9301i-DB43141
SCRP9501i-DB43147
SCRP9805i-DB43172
SCRP9904i-DB43177
CREM031i-SS47-1-DB48067

UNIQUE IDENTIFIER: N/A

TEST RESULTS:

# Tested	# Positives (Growth)	- Control
19	1	2 Negatives

TEST SUMMARY:

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

Native Product Sterility Report

STERIS

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

PD #: 000053

TEST METHODOLOGY: USP - Direct Transfer

COMMENTS: Sample # 21090138

Report revised due to updated comment.

Sample labeled STAN014i-121-2-DB31149 is positive.

REVIEWED BY _____ DATE 15OCT2021