



# Certificate of Analysis

## Thaw and Culture Details

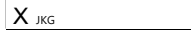
Cell Line Name	<b>WC-52-TSC2Null</b>	
WiCell Lot Number	<b>WB67719</b>	
Provider/Client	University of Wisconsin – Dr. Timothy Gomez	
Banked By	WiCell	
Thaw and Culture Recommendations	WiCell recommends thawing 1 vial into 3 wells of a 6 well plate using mTeSR™ Plus and Matrigel®.	
Protocol	WiCell Feeder Independent Pluripotent Stem Cell Protocol	
Culture Platform Prior to Freeze	Medium: mTeSR™ Plus	Matrix: Matrigel®
Passage Number	p20 Cells were cultured for 19 passages prior to freeze and post colony selection. Plated cells at thaw should be labeled passage 20.	
Date Vialied	22-August-2021	
Vial Label	WC-52-TSC2Null p20 WB67719	
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
	<b>Results:</b> 46,XY <b>Interpretation:</b> 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	<div style="text-align: right; font-size: small;">10/21/2021</div> <div style="text-align: center;"> JKG WiCell Quality Assurance Signed by Gay Jenna</div>

**Date Reported:** Thursday, September 2, 2021

**Cell Line Sex:** Male

**Cell Line:** WC-52-TSC2Null-WB67719

**Reason for Testing:** LOT\_RELEASE

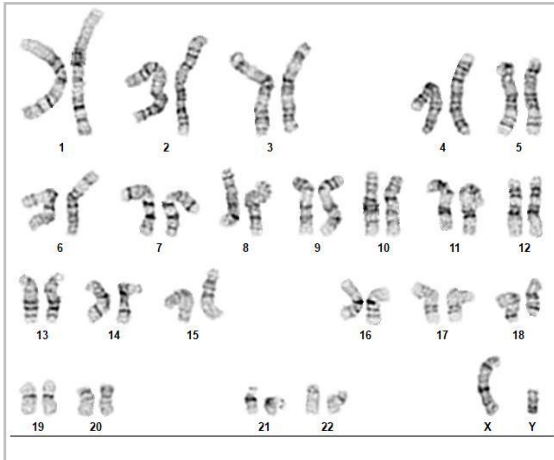
**Submitted Passage #:** 20

**Date of Sample:** 8/30/2021

**Investigator:** WiCell Stem Cell Bank, WiCell

**Specimen:** Human Modified iPSC

**Results:** 46,XY



**Cell:** 22

**Slide:** G03

**Slide Type:** Karyotype

**Total Counted:** 20

**Total Analyzed:** 8

**Total Karyogrammed:** 4

**Band Resolution:** 425 - 500

**Interpretation:**

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

**Completed by:** Erica Schutter, CG(ASCP)

**Reviewed and Interpreted by:** KaitlinC. 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".*

*This assay was conducted solely for listed investigator/institution. The results of this assay are for research use only. Unless otherwise mutually agreed in writing, the services provided to you hereunder by WiCell Research Institute, Inc. ("WiCell") are governed solely by WiCell's Terms and Conditions of Service, found at [www.wicell.org/privacyandterms](http://www.wicell.org/privacyandterms). Any terms you may attach to a purchase order or other document that are inconsistent, add to, or conflict with WiCell's Terms and Conditions of Service are null and void and of no legal force or effect.*



# Short Tandem Repeat

Form SOP-89.01

Version 7.0

Requestor: WiCell Stem Cell Bank, WiCell  
 Samples Received: 26Aug21, 27Aug21, 30Aug21  
 STR Amplification Date: 01Sep21

Sample Name	IMR90-TSC2Null-WB67713 p43	WC-52-TSC2Corr-WB67715 p24			WC-52-TSC2Null-WB67719 p20	PENN071i-216-13-DB34946 p18	
Label on tube	87887	87888			87921	87922	
FGA	Identifying information has been redacted to protect donor confidentiality. If more information is required, please contact <a href="mailto:info@wicell.org">info@wicell.org</a>						
TPOX							
D8S1179							
vWA							
Amelogenin							
Penta_D							
CSF1PO							
D16S539							
D7S820							
D13S317							
D5S818							
Penta_E							
D18S51							
D21S11							
TH01							
D3S1358							
Allelic Polymorphisms	28	30	27	27	30	27	27
Matches*	See Matches Comments	See Matches Comments	See Matches Comments	See Matches Comments	See Matches Comments		See Matches Comments
Comments							

*\*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: 26Aug21, 27Aug21, 30Aug21  
 STR Amplification Date: 01Sep21

Form SOP-89.01  
 Version 7.0

<b>Sample Name</b>			
<b>Label on tube</b>			
<b>FGA</b>	Identifying information has been redacted to protect donor confidentiality. If more information is required, please contact <a href="mailto:info@wicell.org">info@wicell.org</a>		
<b>TPOX</b>			
<b>D8S1179</b>			
<b>vWA</b>			
<b>Amelogenin</b>			
<b>Penta_D</b>			
<b>CSF1PO</b>			
<b>D16S539</b>			
<b>D7S820</b>			
<b>D13S317</b>			
<b>D5S818</b>			
<b>Penta_E</b>			
<b>D18S51</b>			
<b>D21S11</b>			
<b>TH01</b>			
<b>D3S1358</b>			
<b>Allelic Polymorphisms</b>	27	27	26
<b>Matches*</b>	See Matches Comments	See Matches Comments	
<b>Comments</b>			

*\*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: 26Aug21, 27Aug21, 30Aug21  
STR Amplification Date: 01Sep21

**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 26-30 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:** Sample 87887 is an exact match to 58649, 63441, 63444, 65704, 67351, 70422, 84550 and a 96.67% match to 58502 and 63442.

Samples 87888 and 87921 are exact matches to each other and to 34319, 34320, 34321, 34434, 34435, and 34436.

Samples 87893, 87894, 87923, 87924, and 87925 are exact matches to each other and to 87727.

9/2/2021	9/2/2021	9/3/2021
<b>X</b> Amber Kuhn	<b>X</b> Molly Miles	<b>X</b> Dawn Graham
<hr/> Tech #1 Characterization Signed by: Kuhn, Amber	<hr/> Tech #2 Characterization Signed by: Miles, Molly	<hr/> QA Review Quality Assurance Signed by: Graham, Dawn

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# Mycoplasma Assay Report

PCR-based assay performed by WiCell

WiCell  
01Sep21

FORM SOP-83.01

Version 3.0

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

9/8/2021

9/8/2021

**X** Hannah Rueth

Tech #1  
Characterization  
Signed by: Rueth, Hannah

**X** Callum Walker

Tech #2  
Characterization  
Signed by: Walker, Callum

**X** Dawn Graham

QA Review  
Quality Assurance  
Signed by: Graham Dawn

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*A gel image is available upon request.*

# Native Product Sterility Report

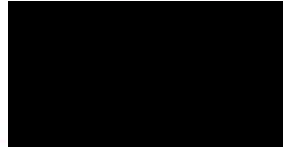


WiCell  
504 S Rosa Road, Rm 101  
Madison, WI 53719

## CORRECTED REPORT

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



SCR9001i-DB43138  
SCR9301i-DB43141  
SCR9501i-DB43147  
SCR9805i-DB43172  
SCR9904i-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



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

A handwritten signature in blue ink, appearing to read "S. L. ...", written over a horizontal line.

DATE 15 OCT 2021

Specific test results may not be indicative of the characteristics of any other samples from the same lot or similar lots. This test report shall not be reproduced, except in full, without prior written approval. Liability is limited to the costs of the tests. Results applied to samples as received.