




# Certificate of Analysis

## Thaw and Culture Details

Cell Line Name	<b>hiPSC-Tri21-c2-4</b>	
WiCell Lot Number	<b>WB68517</b>	
Parent Material	hiPSC-Tri21-c2-4-WB67229	
Provider/Client	University of Washington - Dr. David Russell	
Banked By	WiCell	
Thaw and Culture Recommendations	WiCell recommends thawing 1 vial into 3 wells of a 6 well plate using mTeSR™ 1 and Matrigel®.	
Protocol	WiCell Feeder Independent Pluripotent Stem Cell Protocol	
Culture Platform Prior to Freeze	Medium: mTeSR™ 1	Matrix: Matrigel®
Passage Number	p31 Cells were cultured for 30 passages prior to freeze and post colony selection. Plated cells at thaw should be labeled passage 31.	
Date Viald	22-June-2024	
Vial Label	hiPSC-Tri21-c2-4  p31 WB68517  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

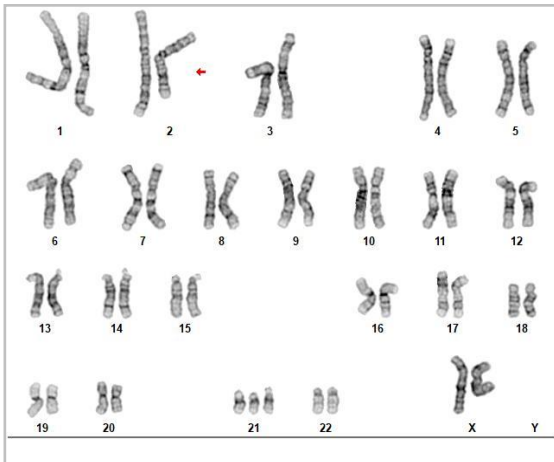
## Results

Test Description	Test Provider	Test Method	Test Specification	Result
Karyotype	WiCell	G-T-L Banding performed on 20 metaphase cells	Expected karyotype	See Report
	<p><b>Results:</b> 47,XX,del(2)(q21q31),+21[20]</p> <p><b>Interpretation:</b> This is an abnormal karyotype. An interstitial deletion in the long (q) arm of chromosome 2 and a gain 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.</p> <p>Comparison of this karyotype with the karyotype of the source (parental) specimen may be informative regarding the significance and origin of the chromosomal abnormality.</p>			
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
12-September-2024	<div>9/12/2024</div> <div>X HEB</div> <div>HEB</div> <div>WiCell Quality Assurance</div> <div>Signed by: Bruner, Haley</div>

**Date Reported:** July 09, 2024  
**Cell Line:** hIPSC-Tri21-c2-4-WB68517  
**Submitted Passage #:** 31  
**Date of Sample:** 7/1/2024  
**Specimen:** Human iPSC  
**Results:** 47,XX,del(2)(q21q31),+21[20]

**Cell Line Sex:** Female  
**Reason for Testing:** LOT\_RELEASE  
**Investigator:** WiCell Stem Cell Bank, WiCell



**Cell:** 15  
**Slide:** G02  
**Slide Type:** Karyotype  
**Total Counted:** 20  
**Total Analyzed:** 8  
**Total Karyogrammed:** 4  
**Band Resolution:** 475 - 550

## Interpretation:

**This is an abnormal karyotype. An interstitial deletion in the long (q) arm of chromosome 2 and a gain 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.**

**Comparison of this karyotype with the karyotype of the source (parental) specimen may be informative regarding the significance and origin of the chromosomal abnormality.**

**Completed by:** Kate Bird, CG(ASCP)  
**Reviewed and Interpreted by:** Justin Schleede, 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".

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

Requestor: WiCell Stem Cell Bank, WiCell

Sample Receipt Date: 01Jul24, 05Jul24

STR Amplification Date: 08Jul24

Form SOP-89.01

Version 13.0

Sample Name	hiPSC-Tri21-c2-4-WB68517 p31	UCSD087i-6-4-WB68518 p21	UCSD231i-SAD1-3- WB68512 p33
WiCell CTR No. <sup>1</sup>	102801	102800	102870
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	29	29	26
Matches <sup>2</sup>	See Results	100974, 72176, 100088, 99355	See Results
Comments			

<sup>1</sup> CTR No.: Characterization Test Request Number; also known as a laboratory accessioning number.

<sup>2</sup> The STR profile of the sample(s) listed are a 100% match for the given sample unless otherwise specified.



## Short Tandem Repeat

Requestor: WiCell Stem Cell Bank, WiCell

Sample Receipt Date: 01Jul24, 05Jul24

STR Amplification Date: 08Jul24

Form SOP-89.01

Version 13.0

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

**Results:** The genotypic profiles comprise a range of 26-29 allelic polymorphisms across the 15 STR loci analyzed. Sample 102801 is a 100% match to 77506, 77346, and a 93.75% match to 77505, 77901, and 101669. Sample 102870 is a 100% match to 57678, 73332, 101091, 102133, 52284, and a 96.67% match to 90755.

**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 suggest 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. A tri-allelic pattern was detected at the Penta\_D and D21S11 loci of sample 102801. This observation could be the result of chromosomal gains and/or amplifications in this cell line.

**Sensitivity:** Sensitivity limits for detection of STR polymorphisms unique to either this or other human cell lines is ~2-4%.

7/16/2024	7/16/2024	7/16/2024
<b>X</b> Julia Graham	<b>X</b> Amber Kuhn	<b>X</b> Hunter Hefti
Tech #1 Characterization Signed by: Graham, Julia	Tech #2 Characterization Signed by: Kuhn, Amber	QA Review Quality Assurance Signed by: Hefti, Hunter

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# Mycoplasma Assay Report

PCR-based assay performed by WiCell  
WiCell Stem Cell Bank, WiCell  
03Jul24

Form SOP-83.01  
Version 6.0

Sample Name	Result	Interpretation
hIPSC-Tri21-c2-4-WB68517 p31 (102801)	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
UCSD087i-6-4-WB68518 p21 (102800)	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).

7/3/2024	7/3/2024	7/9/2024
<b>X</b> Michael Mussar	<b>X</b> John Raff	<b>X</b> Dawn Graham
Tech #1 Characterization Signed by: Mussar, Michael	Tech #2 Characterization Signed by: Raff, John	QA Review Quality Assurance Signed by: Graham, Dawn

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A gel image is available upon request.

# Native Product Sterility Report



Accounting@wicell.org  
504 S Rosa Road, Rm 101  
Madison, WI 53719

SAMPLE #: 24080476  
DATE RECEIVED: 15-Aug-24  
TEST INITIATED: 16-Aug-24  
TEST COMPLETED: 30-Aug-24

SAMPLE NAME / DESCRIPTION: WC030i-5907-2-WB68495  
hiPSC-Tri21-c2-4-WB68517  
WC-24-02-DS-A-WB68530  
WC-24-02-DS-C-WB68529  
hiPSC-Di21-c2-4-4-WB68528  
STAN381i-652C1-DB44674  
STAN380i-092C2-DB44671  
STAN379i-783C6-DB44668  
STAN377i-572C5-DB44662  
STAN375i-961C1-DB44656  
STAN374i-565C4-DB44653  
STAN373i-412C4-DB44650  
STAN372i-411C8-DB44647  
STAN370i-190C3-DB44524

UNIQUE IDENTIFIER: N/A

## TEST RESULTS:

# Tested	# Positives (Growth)	- Control
14	3	2 Negatives

## TEST SUMMARY:

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

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

PD #: 000053

TEST METHODOLOGY: USP - Direct Transfer

# Native Product Sterility Report



COMMENTS: Sample labeled as ISMMS 565i C4 P11 PEC 042016 positive in both media and samples labeled as ISMMS 411i C8 P15 PEC 060316 and ISMMS 961i C1 P10 PEC 060316 positive in TSB

Sample 24080476

AUTHORIZED BY

A handwritten signature in blue ink, appearing to be "AR", written over a horizontal line.

DATE

03 SEP 2024

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.