

# **Certificate of Analysis**

### **Thaw and Culture Details**

Cell Line Name	PENN061i-821-2		
WiCell Lot Number	DB36440		
Provider/Client	University of Pennsylvania – Dr. Daniel Rader		
Banked By	Penn Institute for Regenerative Medicin	e iPS Core Facility	
Thaw and Culture Recommendations	WiCell recommends thawing 1 vial into 1 well of a 6 well plate using Stem Cell Culture Medium and MEF. WiCell recommends thawing using ROCK Inhibitor for best results.		
Protocol	WiCell Feeder Based (MEF) Pluripotent	Stem Cell Protocol	
Culture Platform Prior to Freeze	Medium: Culture Medium	Matrix: MEF	
Passage Number	p13 Cells were cultured for 13 passages prior to freeze and post colony selection. Plated cells at thaw should be labeled passage 14.		
Date Vialed	16-February-2015		
Vial Label	iPS-821 SeV2 p13 02/16/15 KS		
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

<b>Test Description</b>	Test Provider	Test Method	Test Specification	Result	
	WiCell	G-T-L Banding performed on 20 metaphase cells	Expected karyotype	See Report	
Karyotype	Interpretation: To chromosome 9 in of chromosome 9 17q. Gain of chromosome	retation: This is an abnormal karyotype. Four of twenty cells examined contain an unbalanced rearrangement of cosome 9 in which an extra copy of the long (q) arm of chromosome 17 was translocated to the long arm of chromosome 9. The derivative chromosome 9 results in loss of chromosome 9q and gain of chromosome ain of chromosome 17q is a recurrent acquired abnormality in pluripotent stem cell cultures. No other abnormalities were detected at the stated band level of resolution.			
Post-Thaw Viable Cell Recovery	WiCell	Thaw using specified Thaw & Culture Recommendations  Recoverable attachment after passage		Pass	
Identity by STR	WiCell	PowerPlex 16 HS System by Promega <sup>TM</sup>	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	

## **Testing Reported by Provider**

The Provider stated that some or all of the additional analyses listed below may have been performed for this cell line. For more information, publication and dbGaP links, where available, are provided on the cell line specific web page on the WiCell website.

- SNP microarray
- Flow Cytometry (Tra1-60 and SSEA-4)
- Differentiation into hepatocytes
- Infinium® Expanded Multi-Ethnic Genotyping Array (MEGAEX)

Approval Date	WiCell Quality Assurance Approval	
15-June-2023	6/15/2023  X_HEB  HEB  WiC-cill Quality Assurance Signed by Bruner, Halley	



### Chromosome Analysis Report: 095681

Date Reported: Saturday, February 4, 2023 Cell Line Sex: Female

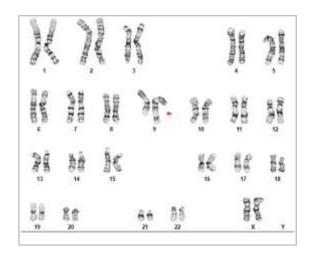
Cell Line: PENN061i-821-2-DB36440 Reason for Testing: LOT\_RELEASE

Submitted Passage #: 15

Date of Sample: 1/30/2023

Specimen: Human IPSC

Results: 46,XX,der(9)t(9;17)(q34;q21)[4]/46,XX[16]



Cell: 91 Slide: G03

Investigator:

Slide Type: Karyotype

WiCell Stem Cell Bank, WiCell

Total Counted: 20
Total Analyzed: 8

Total Karyogrammed: 5

Band Resolution: 425 - 475

#### Interpretation:

This is an abnormal karyotype. Four of twenty cells examined contain an unbalanced rearrangement of chromosome 9 in which an extra copy of the long (q) arm of chromosome 17 was translocated to the long arm of chromosome 9. The derivative chromosome 9 results in loss of chromosome 9q and gain of chromosome 17q. Gain of chromosome 17q is a recurrent acquired abnormality in pluripotent stem cell cultures. No other clonal abnormalities were detected at the stated band level of resolution.

Completed by: Jennifer Pecos, CG(ASCP)
Reviewed and Interpreted by: Xiangqiang Shao, PhD

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For internal use only			
Date:	Sent Bv:	_ Sent To:	QC Review By:
	risualization of numeric	al and structural chromosome abnorma	lities. The size of structural abnormality that can be detected out. band level is defined as the number of G-bands per

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. 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 9.0

Requestor: WiCell Stem Cell Bank, WiCell Samples Received: 27Jan23, 30Jan23 STR Amplification Date: 08Feb23

Sample Name	PENN061i-821- 2-DB36440 p15	PENN074i-415- 3-DB35036 p16	
WiCell CTR No.1	95681	95678	
FGA			
ТРОХ			
D8S1179		Identifying	
vWA		information has been redacted to	
Amelogenin		protect donor	
Penta_D		confidentiality. If more information	
CSF1PO		is required,	
D16S539	please contact info@wicell.org		
D7S820			
D13S317			
D5S818			
Penta_E			
D18S51			
D21S11			
TH01			
D3S1358			
Allelic Polymorphisms	30	27	
Matches*	95525		
Comments			

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

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



## **Short Tandem Repeat**

Form SOP-89.01 Version 9.0

Requestor: WiCell Stem Cell Bank, WiCell Samples Received: 27Jan23, 30Jan23 STR Amplification Date: 08Feb23

<u>Assay Description:</u> STR analysis is performed using the PowerPlex 16 HS System by Promega<sup>TM</sup>. 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 27-30 allelic polymorphisms across the 15 STR loci analyzed.

<u>Interpretation:</u> 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.

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

2/10/202	2/13/2023	2/10/2023
X Amber Kuhn	X Justin Hobson	X Hunter Hefti
Tech #1 Characterization Signed by: Kuhn, Amber	Tech #2 Characterization Signed by: Hobson, Justin	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 08Feb23

Form SOP-83.01 Version 5.0

Sample Name	Result	Interpretation
PENN074i-415-3-DB35036 p16 (95678)	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
PENN061i-821-2-DB36440 p15 (95681)	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
WA09-WB68071 p26 (95822)	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
WA09-WB68073 p27 (95823)	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).			

	2/8/2023	2/8/2023	2/10/2023
X Michael Mussar		X Amber Kuhn	X Hunter Hefti
Tech #1 Tech #2 Characterization Characterization Signed by: Mussar, Michael Signed by: Kuhn, Amber		Characterization	QA Review Quality Assurance Signed by: Hefti, Hunter

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A gel image is available upon request.

# Native Product Sterility Report



SAMPLE #:

22041128

DATE RECEIVED:

21-Apr-22

TEST INITIATED:

28-Apr-22

TEST COMPLETED:

12-May-22

SAMPLE NAME / DESCRIPTION:

504 S Rosa Road, Rm 101

Madison, WI 53719

PENN169i-M17-3-DB36515

PENN106i-75-39-DB36117

PENN107i-145-1-DB34930

PENN061i-821-2-DB36440

PENN109i-802-2-DB36444

PENN110i-389-6-DB36406

FEMM1101-363-0-DB30400

PENN059i-555-1-DB36432 PENN112i-304-6-DB34872

PENN113i-126-66-DB35039

UCSD241i-APP2-3-WB67856

UNIQUE IDENTIFIER:

N/A

**TEST RESULTS:** 

WiCell

# 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

REVIEWED BY Janua Buck

DATE DOMONDOD =

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.