



# Certificate of Analysis

## Thaw and Culture Details

Cell Line Name	<b>PENN016i-821-1</b>	
WiCell Lot Number	<b>DB35119</b>	
Provider/Client	University of Pennsylvania – Dr. Daniel Rader	
Banked By	Penn Institute for Regenerative Medicine iPS Core Facility	
Thaw and Culture Recommendations	WiCell recommends thawing 1 vial into 2 well of a 6 well plate using Stem Cell Culture Medium and MEF. WiCell recommends thawing using ROCK Inhibitor.	
Protocol	WiCell Feeder Based (MEF) Pluripotent Stem Cell Protocol	
Culture Platform Prior to Freeze	Medium: Stem Cell Culture Medium	Matrix: MEF
Passage Number	p14 Cells were cultured for 14 passages prior to freeze and post colony selection. Plated cells at thaw should be labeled passage 15.	
Date Vial	23-February-2015	
Vial Label	iPS-821 SeV1 p14 02/23/15 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.	



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## 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> 46,XX,del(21)(q22)[2]/46,XX[17] Nonclonal Findings: 48,XX,+X,+3</p> <p><b>Interpretation:</b> This is an abnormal karyotype. A terminal deletion of the long (q) arm of chromosome 21 is present in two of twenty cells examined. No other clonal abnormalities were detected at the stated band level of resolution. There is a nonclonal finding, listed above, which contains a chromosomal aberration (gain of chromosome X) recurrently acquired in pluripotent stem cell cultures. Nonclonal findings may result from technical artifact, but may be due to a developing clonal abnormality or to low-level mosaicism.</p>			
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™	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	<p>6/15/2023</p> 

**Date Reported:** Friday, February 3, 2023

**Cell Line Sex:** Female

**Cell Line:** PENN016i-821-1-DB35119

**Reason for Testing:** LOT\_RELEASE

**Submitted Passage #:** 16

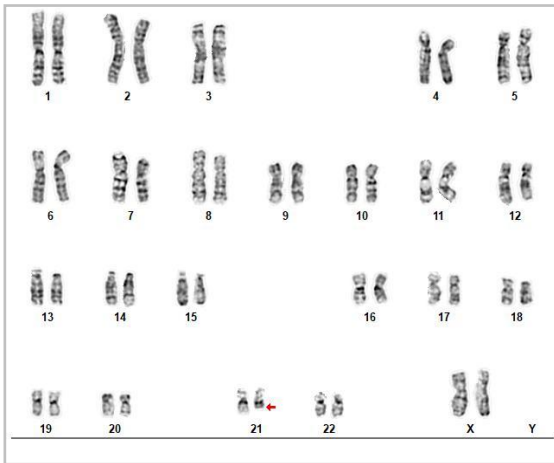
**Date of Sample:** 1/20/2023

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

**Specimen:** Human iPSC

**Results:** 46,XX,del(21)(q22)[2]/46,XX[17]

**Nonclonal Findings:** 48,XX,+X,+3



**Cell:** 51

**Slide:** G02

**Slide Type:** Karyotype

**Total Counted:** 20

**Total Analyzed:** 8

**Total Karyogrammed:** 4

**Band Resolution:** 350 - 400

**Interpretation:**

**This is an abnormal karyotype. A terminal deletion of the long (q) arm of chromosome 21 is present in two of twenty cells examined. No other clonal abnormalities were detected at the stated band level of resolution.**

**There is a nonclonal finding, listed above, which contains a chromosomal aberration (gain of chromosome X) recurrently acquired in pluripotent stem cell cultures. Nonclonal findings may result from technical artifact, but may be due to a developing clonal abnormality or to low-level mosaicism.**

**Completed by:** Pam Mill

**Reviewed and Interpreted by:** Xiangqiang Shao, PhD

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

Samples Received: 20Jan23

STR Amplification Date: 25Jan23

Form SOP-89.01

Version 9.0

<b>Sample Name</b>	<b>PENN016i-821-1-DB35119 p16</b>
<b>WiCell CTR No.<sup>1</sup></b>	95525
<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>	30
<b>Matches*</b>	
<b>Comments</b>	

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

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



# Short Tandem Repeat

Requestor: WiCell Stem Cell Bank, WiCell

Samples Received: 20Jan23

STR Amplification Date: 25Jan23

Form SOP-89.01

Version 9.0

**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 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 ~2-4%.

1/27/2023	1/31/2023	1/30/2023
<p><b>X</b> Justin Hobson</p> <hr/> <p>Tech #1 Characterization Signed by: Hobson, Justin</p>	<p><b>X</b> Anna Lisa Larson</p> <hr/> <p>Tech #2 Characterization Signed by: Larson, Anna Lisa</p>	<p><b>X</b> Hunter Hefti</p> <hr/> <p>QA Review Quality Assurance Signed by: Hefti, Hunter</p>

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# Mycoplasma Assay Report

PCR-based assay performed by WiCell  
WiCell Stem Cell Bank, WiCell  
24Jan23

Form SOP-83.01  
Version 5.0

Sample Name	Result	Interpretation
PENN016i-821-1-DB35119 p16 (95525)	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).

1/24/2023	1/25/2023	1/25/2023
<p><b>X</b> Kaylie Petersen</p> <hr/> <p>Tech #1 Characterization Signed by: Petersen, Kaylie</p>	<p><b>X</b> Justin Hobson</p> <hr/> <p>Tech #2 Characterization Signed by: Hobson, Justin</p>	<p><b>X</b> Hunter Hefti</p> <hr/> <p>QA Review Quality Assurance Signed by: Hefti, Hunter</p>

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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

SAMPLE #: 19111615  
DATE RECEIVED: 21-Nov-19  
TEST INITIATED: 26-Nov-19  
TEST COMPLETED: 10-Dec-19

SAMPLE NAME / DESCRIPTION: WC051i-FX08-23 WB67327 15143  
STAN140i-243C1 WB67329 15144  
MIN13i-33362.D WB67326 15145  
JHU050i WB67328 15146  
WC060i-226-1-2-22 WB67334 15147  
WTB DB66964 15148  
PENN014i-37-3 DB36309 15149  
PENN016i-821-1 DB35119 15150  
PENN149i-M1-6 DB36089 15162  
PENN151i-M1-5 DB36083 15163

UNIQUE IDENTIFIER: NA

## 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

REVIEWED BY \_\_\_\_\_

DATE 11 Dec 19

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.