Certificate of Analysis

Thaw and Culture Details

Cell Line Name	**PENN071i-216-13**	
WiCell Lot Number	**DB34946**	
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 1 well of a 6 well plate using Stem Cell Culture Medium and MEF. WiCell recommends passaging with 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	p16 Cells were cultured for 16 passages prior to freeze and post colony selection. Plated cells at thaw should be labeled passage 17.	
Date Vialed	21-July-2015	
Vial Label	iPS-216 Sev13 P16 07-21-15 JS	
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	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.

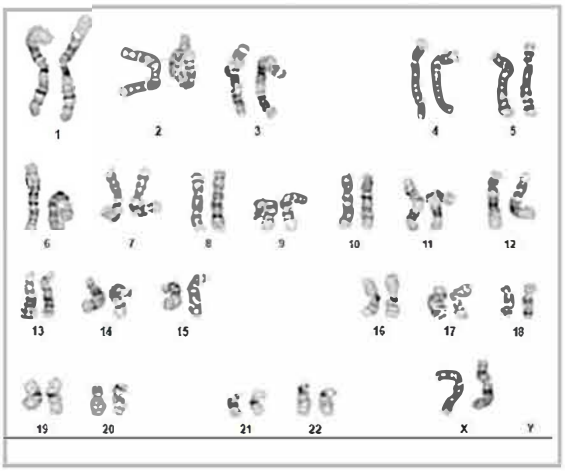
- SNP microarray
- Flow Cytometry (Tra1-60 and SSEA-4)
- Differentiation into hepatocytes
- Infinium® Expanded Multi-Ethnic Genotyping Array (MEGA^{EX})

Approval Date	WiCell Quality Assurance Approval
23-June-2016	9/8/2021 X JKG JKG WiCell Quality Assurance Signed by: Gay, Jenna

Chromosome Analysis Report: 087922

Date Reported: Thursday, September 2, 2021
Cell Line: PENN071i-216-13-DB34946
Submitted Passage #: 18
Date of Sample: 8/30/2021
Specimen: Human IPSC
Results: 46,XX

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



Cell: 34
Slide: G01
Slide Type: Karyotype

Total Counted: 20
Total Analyzed: 8
Total Karyogrammed: 4
Band Resolution: 350 - 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: 26Aug21, 27Aug21, 30Aug21
STR Amplification Date: 01Sep21

Form SOP-89.01
Version 7.0

Sample Name	IMR90-TSC2Null-WB67713 p43	WC-52-TSC2Corr-WB67715 p24	NDO.SS.004-DB67686 p10	NDO.SS.003-DB67685 p9	WC-52-TSC2Null-WB67719 p20	PENN071i-216-13-DB34946 p18	NDO.SS.001-DB67677 p9
Label on tube	87887	87888	87893	87894	87921	87922	87923
FGA	[redacted]						
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							

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

Sample Name	NDO.SS.002-DB67684 p9	NDO.SS.008-DB67691 p15	STAN014i-121-2-DB31149 p12
Label on tube	87924	87925	87926
FGA	[redacted]		
TPOX			
D8S1179			
vWA			
Amelogenin			
Penta_D			
CSF1PO			
D16S539			
D7S820			
D13S317			
D5S818			
Penta_E			
D18S51			
D21S11			
TH01			
D3S1358			
Allelic Polymorphisms	27	27	26
Matches*	See Matches Comments	See Matches Comments	
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: 26Aug21, 27Aug21, 30Aug21
STR Amplification Date: 01Sep21

Form SOP-89.01
Version 7.0

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

Mycoplasma Assay Report

PCR-based assay performed by WiCell

WiCell

10Aug21

FORM SOP-83.01
Version 3.0

Sample Name	Result	Interpretation
NDO.SS.015-DB67698 p20 (87404)	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
IMR90-TSC2Het-DB67679 p41 (87499)	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
STAN010i-041-2-DB31056 p11 (87500)	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
STAN028i-42-1-DB30917 p11 (87501)	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
PENN071i-216-13-DB34946 p16 (87562)	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
STAN017i-171-1-DB31059 p11 (87563)	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
STAN019i-177-1-DB31114 p11 (87564)	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
Positive (+) Control	Positive	
Negative (-) Control	Negative	

8/11/2021

X Hannah Rueth

Tech #1
Characterization
Signed by: Rueth, Hannah

8/11/2021

X Callum Walker

Tech #2
Characterization
Signed by: Walker, Callum

8/11/2021

X Dawn Graham

QA Review
Quality Assurance
Signed by: Graham, Dawn

A gel image is available upon request.

Native Product Sterility Report

STERIS

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

SAMPLE #: 21080662
DATE RECEIVED: 12-Aug-21
TEST INITIATED: 12-Aug-21
TEST COMPLETED: 26-Aug-21

SAMPLE NAME / DESCRIPTION:
CREM056i-BR39-1-WB67703
STAN017i-171-1-DB31059
STAN019i-177-1-DB31114
STAN028i-42-1-DB30917
STAN010i-041-2-DB31056
PENN071i-216-13-DB34946
STAN018i-171-2-DB31075
STAN020i-177-2-DB31121
STAN029i-42-2-DB30926
STAN023i-41-1-DB31169

UNIQUE IDENTIFIER: N/A

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 26 Aug 2021