



Certificate of Analysis

Thaw and Culture Details

Cell Line Name	PENN074i-415-3	
WiCell Lot Number	DB35036	
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 thawing using ROCK Inhibitor for best results.	
Protocol	WiCell Feeder Based (MEF) Pluripotent Stem Cell Protocol	
Culture Platform Prior to Freeze	Medium: Stem Cell 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 Vial	11-February-2015	
Vial Label	iPS-415 SeV3 p13 02/11/15 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

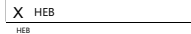
Results

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 (MEGAEX)

Approval Date	WiCell Quality Assurance Approval
15-February-2023	<div style="text-align: right; font-size: small;">2/15/2023</div>  <div style="font-size: x-small;"> X HEB HEB WiCell Quality Assurance Signed by: Bruner, Haley </div>

Date Reported: Wednesday, February 8, 2023

Cell Line Sex: Female

Cell Line: PENN074i-415-3-DB35036

Reason for Testing: LOT_RELEASE

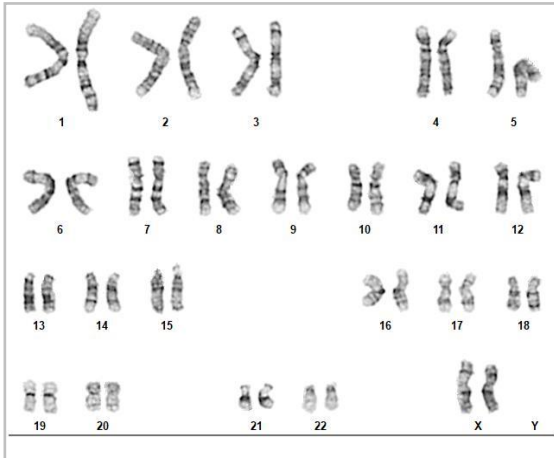
Submitted Passage #: 16

Date of Sample: 1/27/2023

Investigator: WiCell Stem Cell Bank, WiCell

Specimen: Human iPSC

Results: 46,XX



Cell: 126

Slide: G03

Slide Type: Karyotype

Total Counted: 20

Total Analyzed: 9

Total Karyogrammed: 5

Band Resolution: 375 - 425

Interpretation:

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

Completed by: Dawn Davis, CG(ASCP)

Reviewed and Interpreted by: Vanessa Horner, 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. 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: 27Jan23, 30Jan23

STR Amplification Date: 08Feb23

Form SOP-89.01

Version 9.0

Sample Name	PENN061i-821-2-DB36440 p15	PENN074i-415-3-DB35036 p16
WiCell CTR No.¹	95681	95678
FGA	Identifying information has been redacted to protect donor confidentiality. If more information is required, please contact info@wicell.org	
TPOX		
D8S1179		
vWA		
Amelogenin		
Penta_D		
CSF1PO		
D16S539		
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.*

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



Short Tandem Repeat

Requestor: WiCell Stem Cell Bank, WiCell

Samples Received: 27Jan23, 30Jan23

STR Amplification Date: 08Feb23

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 27-30 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%.

2/10/2023	2/13/2023	2/10/2023
<p>X Amber Kuhn</p> <hr/> <p>Tech #1 Characterization Signed by: Kuhn, Amber</p>	<p>X Justin Hobson</p> <hr/> <p>Tech #2 Characterization Signed by: Hobson, Justin</p>	<p>X 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
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 <hr/> Tech #1 Characterization Signed by: Mussar, Michael	X Amber Kuhn <hr/> Tech #2 Characterization Signed by: Kuhn, Amber	X Hunter Hefti <hr/> QA Review Quality Assurance Signed by: Hefti, Hunter

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A gel image is available upon request.

Sterility Report

Biotest Laboratories, Inc.

Making life-saving products possible

WiCell Research Institute, Inc.
WiCell Quality Assurance
504 South Rosa Road, Room 101
Madison, WI 53719

BIOTEST SAMPLE # 16080730
VALIDATION # NG
TEST PURPOSE NG

PRODUCT WA09-RB40917 11779, WA09-RB40918 11780, UCSD223i-NDC1-1-DB26652 11781, STAN002i-161-1-DB31139 11782, PENN001i-87-2-DB36483 11783, PENN002i-442-1-DB35052 11784, PENN066i-427-6-DB35047 11785, PENN074i-415-3-DB35036 11788, PENN134i-61-26-DB35028 11786, WA25-WB40296 11787

PRODUCT LOT NA

STERILE LOT NA

BI LOT NA

STERILIZATION LOT NA

BI EXPIRATION DATE NA

STERILIZATION DATE NA

DATE RECEIVED 2016-08-11

STERILIZATION METHOD EO

TEST INITIATED 2016-08-11

SAMPLING BLDG / ROOM NA

TEST COMPLETED 2016-08-25

REFERENCE Processed according to LAB-003: Sterility Test Procedure

Ten (10) products were divided between 40 mL TSB and 40 mL FTG. The sample was then cultured at 20-25 C and 30-35 C respectively and was monitored for a minimum of 14 days.

- USP
- BI Manufacturers Specifications
- Other

RESULTS	# POSITIVES	# TESTED	POSITIVE CONTROL	NEGATIVE CONTROL
Sterile	0	10	NA	2 Negatives

COMMENTS NA

REVIEWED BY



DATE

20 AUG 16

Specific test results may not be indicative of the characteristics of any other samples from the same lot or similar lots. Liability is limited to the costs of the tests. The uncertainty of measurement associated with the measurement result reported in this certificate is available from the organization upon request.

Biotest Laboratories ■ 9303 West Broadway Ave. ■ Brooklyn Park, MN 55445 ■ USA ■ (763) 315-1200

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