



Thaw and Culture Details

Cell Line Name	JHU045i
WiCell Lot Number	DB41060
Provider	Johns Hopkins University – Laboratory of Dr. Lewis Becker
Banked By	Johns Hopkins University – Laboratory of Dr. Lewis Becker
Thaw and Culture Recommendations	The Provider recommends thawing 1 vial into 6 wells of a 6 well plate, and using ROCK inhibitor as an additive at thaw.
	Feeder Independent
	Medium: E8
	Matrix: Vitronectin
Protocol	WiCell Feeder Independent E8 Medium Protocol
Passage Number	p4 These cells were cultured for 4 passages post reprogramming prior to freeze. Add +1 to the passage number to best represent the overall passage number of the cells at thaw.
Date Vialied	20-June-2016
Vial Label	P045 hips P4 1.4X10 ⁶ 6/20/16
Biosafety and Use Information	This cell line is of human origin. 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.

Testing Performed by WiCell

Test Description	Test Provider	Test Method	Test Specification	Result
Karyotype by G-banding	WiCell	SOP-CH-003	Unexpected karyotype	Fail
	<i>Interpretation: This is an abnormal karyotype. There is an extra X chromosome in 5 of 20 cells examined. Gain of an X chromosome is a recurrent acquired abnormality in human pluripotent stem cell cultures. No other clonal abnormalities were found.</i>			
Post-Thaw Viable Cell Recovery	WiCell	SOP-CH-305	Recoverable attachment after passage	Pass
Identity by STR	UW Translational Research Initiatives in Pathology Laboratory	PowerPlex 16 HS System by Promega	Defines profile	Pass
Sterility	Steris	ST/07	Negative	Pass
Mycoplasma	WiCell	SOP-QU-004	Negative	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.

- Embryoid bodies
- Infinium® Expanded Multi-Ethnic Genotyping Array (MEGA^{EX})

Approval Date	Quality Assurance Approval
26-August-2016	<p style="text-align: right;">9/13/2017</p> <p>X AMK _____ AMK Quality Assurance Signed by: Klade, Anjelica</p>

Date Reported: Friday, July 14, 2017

Cell Line Gender: Female

Cell Line: JHU045i-DB41060 12603

Reason for Testing: lot release testing

Passage#: 6

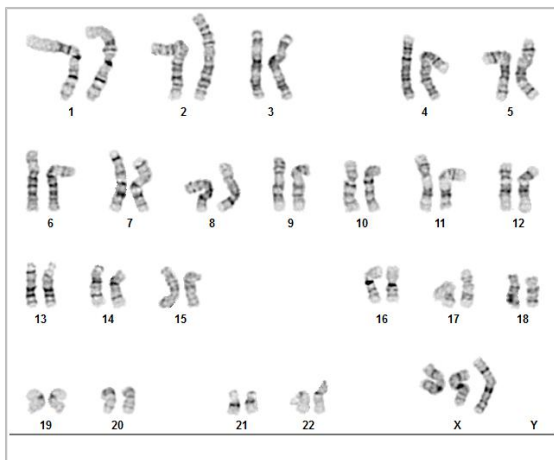
Date of Sample: 7/5/2017

Investigator: [REDACTED], WiCell CDM

Specimen: Human ESC

Results: 47,XX,+X[5]/46,XX[14]

Nonclonal findings: 46,XX,t(2;18)(q32.2;q21.1)



Cell: 71

Slide: G03

Slide Type: Karyotype

Total Counted: 20

Total Analyzed: 9

Total Karyogrammed: 5

Band Resolution: 425 - 550

Interpretation:

This is an abnormal karyotype. There is an extra X chromosome in 5 of 20 cells examined. Gain of an X chromosome is a recurrent acquired abnormality in human pluripotent stem cell cultures. No other clonal abnormalities were found.

There is one nonclonal finding, listed above. Nonclonal findings may result from technical artifact, but may be due to a developing clonal abnormality or to low-level mosaicism.

Completed by: [REDACTED] CG(ASCP)

Reviewed and Interpreted by: [REDACTED], PhD, FACMG

A signed copy of this report is available upon request.

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 may not be relied upon by any other party without the prior written consent of the Director of the WiCell Cytogenetics Laboratory. The results of this assay are for research use only. If the results of this assay are to be used for any other purpose, contact the Director of the WiCell Cytogenetics Laboratory.

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 Analysis

Department of Pathology and Laboratory Medicine
TRIP Laboratory (Molecular)
<http://www.pathology.wisc.edu/research/trip>

WiCell®
info@wicell.org
(888) 204-1782

Sample Report:

12603-STR
Sample Name on Tube: 12603-STR
43.4 ng/μL, (A260/280=2.18)
Sample Type: Cells
Cell Count: ~2 million cells

Requestor:

WiCell Research Institute
Quality Department

Sample Date: N/A

Receive Date: 07/10/17
Assay Date: 07/18/17
File Name: 170720 STR TCS
Report Date: 07/21/17

STR Locus	STR Genotype Repeat #	STR Genotype
FGA	16-18,18.2,19,19.2,20,20.2,21,21.2,22, 22.2, 23, 23.2, 24, 24.2, 25, 25.2, 26-30, 31.2, 43.2, 44.2,45.2, 46.2	Identifying information has been redacted to protect donor confidentiality. If more information is required, please, contact WiCell's Technical Support .
TPOX	6-13	
D8S1179	7-18	
vWA	10-22	
Amelogenin	X,Y	
Penta_D	2.2, 3.2, 5, 7-17	
CSF1PO	6-15	
D16S539	5, 8-15	
D7S820	6-14	
D13S317	7-15	
D5S818	7-16	
Penta_E	5-24	
D18S51	8-10, 10.2, 11-13, 13.2, 14-27	
D21S11	24,24.2,25,25.2,26-28,28.2,29,29.2, 30, 30.2,31, 31.2,32,32.2,33,33.2, 34,34.2,35,35.2,36-38	
TH01	4-9,9.3,10-11,13.3	
D3S1358	12-20	

Results: Based on the 12603-STR cells submitted by WiCell QA dated and received on 07/10/17, this sample (Label on Tube: 12603-STR) defines the STR profile of the human stem cell line JHU045i comprising 29 allelic polymorphisms across the 15 STR loci analyzed.

Interpretation: No STR polymorphisms other than those corresponding to the human JHU045i stem cell line were detected and 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. This result suggests that the 12603-STR sample submitted corresponds to the JHU045i stem cell line and was not contaminated with any other human stem 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 stem cell lines is ~2-5%.

X *RMB* Digitally Signed on 07/21/17

TRIP Laboratory, Molecular

X *WMR* Digitally Signed on 07/21/17

PhD, Director / Co-Director
UWHC Molecular Diagnostics Laboratory / UWSMPH TRIP Laboratory

Testing was accomplished by analysis of human genetic polymorphisms at STR loci. This methodology has not yet been approved by the FDA and is for investigational use only. Acknowledge TRIP in your publications, posters & presentations. For details, see: <http://www.pathology.wisc.edu/research/trip/acknowledging> TRIP agrees to maintain the confidentiality of any information provided to it in connection with its performance of this STR analysis on the same conditions as set forth in paragraph 2 of WiCell's Terms and Conditions of Service (<http://www.wicell.org/media.acux/1a429b84-2b54-44a4-8ad8-5c05db93dd8a>).

Native Product Sterility Report



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

SAMPLE #: 17062122
DATE RECEIVED: 29-Jun-17
TEST INITIATED: 30-Jun-17
TEST COMPLETED: 14-Jul-17

SAMPLE NAME / DESCRIPTION: JHU024i-DB40969 12578
JHU044i-DB41057 12579
JHU045i-DB41060 12580
JHU204i-DB36815 12581
JHU222i-DB36892 12582
JHU236i-DB37047 12583
HVRDi001-A-1-WB66254 12584
HVRDi002-A-WB65326 12585
UCSD236i-APP1-1-WB66255 12587
UCSD237i-APP1-2-DB26822 12589

UNIQUE IDENTIFIER: NA
PRODUCT REGISTRATION: Human iPS cells

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
METHOD VALIDATION / PD #: 000053
TEST METHODOLOGY: USP - Direct Transfer

Native Product Sterility Report



COMMENTS: Sample # 17062122

REVIEWED BY Dusad

DATE 17 JUL 17

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.



Mycoplasma Detection Assay Report

Testing Performed by WiCell

Lot Release Testing

June 23, 2017

FORM SOP-QU-004.01

Version F Edition 02

Reported by: KR

Reviewed by: JB

BD Monolight 180

#	Sample Name	Reading A			Reading B			Ratio B/A	Result	Comments/Suggestions
		RLU1	RLU2	Ave	RLU1	RLU2	Ave			
1	JHU045i-DB41060 12573	302	314	308	109	113	111	0.36	Negative	
2	Positive (+) Control	416	429	422.5	37466	37744	37605	89.01	Positive	
3	Negative (-) Control	672	698	685	60	62	61	0.09	Negative	

