Thaw and Culture Details

Cell Line Name	LUEL8312i-1
WiCell Lot Number	WB66907
Provider	Luebeck University, Dr. Christine Klein
Banked By	WiCell
Thaw and Culture Recommendations	WiCell recommends thawing 1 vial into 3 wells of a 6 well plate.
Culture Platform	Feeder Independent
	Medium: mTeSR™1
	Matrix: Matrigel®
Protocol	WiCell Feeder Independent mTeSR™1 Protocol
Passage Number	p18 These cells were cultured for 17 passages prior to freeze and post colony picking. WiCell adds +1 to the passage number at freeze to best represent what the overall passage number of the cells at thaw. Plated cells at thaw should be labeled passage 18.
Date Vialed	01-September-2018
Vial Label	LUEL8312i-1 p18 WB66907
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.

Testing Performed by WiCell

Test Description	Test Provider	Test Method	Test Specification	Result
Karyotype by G-banding	WiCell	SOP-CH-003	Expected karyotype	See Report
Post-Thaw Viable Cell Recovery	WiCell	SOP-CH-305	≥ 15 Undifferentiated Colonies, ≤ 30% Differentiation and 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 has provided the following testing and results for this cell line. If available, a link to the relevant publication is provided on the cell line specific web page on the WiCell website.

Test Description	Result	Report
HIV, HBV, and HCV Screening	Negative	Report not available

Approval Date	Quality Assurance Approval
08-November-2018	11/8/2018 X JKG JKG Quality Assurance Signed by: Gay, Jenna

Chromosome Analysis Report: 073632

Date Reported: Thursday, October 25, 2018

Cell Line Sex: Male

Cell Line: LUEL8312i-1-WB66907 14023

Reason for Testing: lot release testing

Passage#: 18

Date of Sample: 10/17/2018

Investigator: [redacted], WiCell

Specimen: Human IPS

Results: 46,XY

Cell: 9

Slide: G04

Slide Type: Karyotype

Total Counted: 20

Total Analyzed: 8

Total Karyogrammed: 4

Band Resolution: 375 - 475

Interpretation:

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

Completed by: [redacted], CG(ASCP)

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

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".

TRIPath
HISTOLOGY - IHC - MOLECULAR - IMAGING
Department of Pathology and Laboratory Medicine
TRIP Laboratory (Molecular)
(608) 265-9168

Short Tandem Repeat Analysis

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

Sample Report:
14023-STR
Sample Name on Tube: 14023-STR
63.5 ng/µL, (A260/280=2.02)
Sample Type: Cells
Cell Count: ~2 million cells

Requestor:
WiCell Research Institute
Quality Department

Sample Date: N/A
Receive Date: 10/22/18
Assay Date: 10/23/18
File Name: STR 181024 wmr
Report Date: 10/26/18

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	

<u>Results:</u> Based on the 14023-STR cells submitted by WiCell QA dated and received on 10/22/18, this sample (Label on Tube: 14023-STR) defines the STR profile of the human stem cell line LUEL8312i-1 comprising 26 allelic polymorphisms across the 15 STR loci analyzed.

<u>Interpretation:</u> No STR polymorphisms other than those corresponding to the human LUEL8312i-1 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 14023-STR sample submitted corresponds to the LUEL8312i-1 stem cell line and was not contaminated with any other human stem 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 stem cell lines is ~2-5%.

X *RMB* **Digitally Signed on 10/26/18**

[redacted], *BA*
TRIP Laboratory, Molecular

X *WMR* **Digitally Signed on 10/26/18**

[redacted], *PhD, Director / Co-Director*
UWHC Molecular Diagnostics Laboratory / UWSMPH TRIP Laboratory

Native Product Sterility Report

STERIS

SAMPLE #:	18091843
DATE RECEIVED:	27-Sep-18
TEST INITIATED:	03-Oct-18
TEST COMPLETED:	17-Oct-18

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

SAMPLE NAME / DESCRIPTION: JHU018i, WB66902 14027
UCSD182i-3-2, WB66903 14028
LUEL8361i-1, WB66906 14029
LUEL8312i-1, WB66907 14030
LUEL8363i-2, WB66912 14031
LUEL7159i-7,WB66914 14032
UCSD231i-SAD1-3, WB66915 14033
LUEL7994i-1, WB66916 14034
LUEL8357i-2, WB66917 14035
LUEL7153i-2, WB66918 14036

UNIQUE IDENTIFIER: NA

PRODUCT REGISTRATION: Other: Human iPS cells

TEST RESULTS:

# Tested	# Positives (Growth)	- Control
10	1	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

COMMENTS: Sample labeled as LUEL7159i-7 was positive in both TSB and FTG.

REVIEWED BY _____ DATE 22OCT18

Mycoplasma Detection Assay Report

Testing Performed by WiCell

Lot Release Testing

October 18, 2018

FORM SOP-QU-004.01
Version G Edition 02
Reported by: AP
Reviewed by: JB
BD Monolight 180

#	Sample Name	Reading A		A Ave	Reading B		B Ave	Ratio B/A	Result	Comments/Suggestions
		RLU1	RLU2		RLU1	75				
1	LUEL8312i-1-WB66907 14023	265	251	258	100	94	97	0.38	Negative	
2	Positive (+) Control	193	190	191.5	5519	5687	5603	29.26	Positive	
3	Negative (-) Control	641	642	641.5	79	73	76	0.12	Negative