



Thaw and Culture Details

Cell Line Name	LUEL8357i-2
WiCell Lot Number	WB66917
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	p22 These cells were cultured for 21 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 22.
Date Vialied	15-September-2018
Vial Label	LUEL8357i-2 p22 WB66917
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
	Results: 46,XY Nonclonal Findings: 47,XY,+15 Interpretation: This is a normal karyotype; no clonal abnormalities were detected at the stated band level of resolution. There is a 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.			
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.

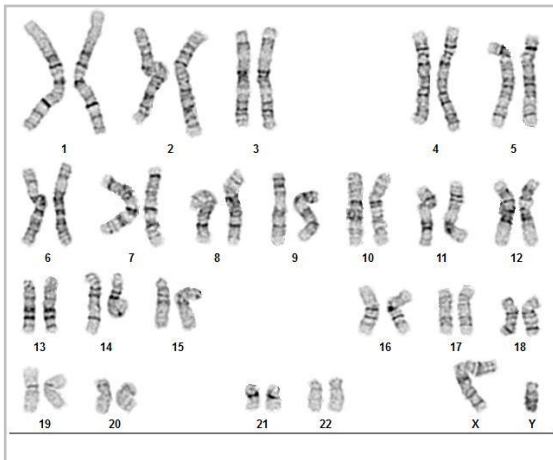
Test Description	Result	Report
HIV, HBV, and HCV Screening	Negative	Report not available

Approval Date	Quality Assurance Approval
25-October-2018	 Quality Assurance

Date Reported: Friday, September 28, 2018
Cell Line: LUEL8357i-2-WB66917 14026
Passage#: 22
Date of Sample: 9/24/2018
Specimen: Human IPS
Results: 46,XY

Cell Line Sex: Male
Reason for Testing: lot release testing
Investigator: [REDACTED], WiCell

Nonclonal Findings: 47,XY,+15



Cell: 92
Slide: G02
Slide Type: Karyotype

Total Counted: 20
Total Analyzed: 8
Total Karyogrammed: 4
Band Resolution: 450 - 550

Interpretation:

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

There is a 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

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.

Sample Report:

14026-STR

Sample Name on Tube: 14026-STR

119.2 ng/μL, (A260/280=1.89)

Sample Type: Cells**Cell Count:** ~2 million cells**Requestor:**

WiCell Research Institute

Quality Department

Sample Date: N/A**Receive Date:** 10/01/18**Assay Date:** 10/02/18**File Name:** STR 181005 wmr**Report Date:** 10/11/18

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	

Results: Based on the 14026-STR cells submitted by WiCell QA dated and received on 10/01/18, this sample (Label on Tube: 14026-STR) defines the STR profile of the human stem cell line LUEL8357i-2 comprising 30 allelic polymorphisms across the 15 STR loci analyzed.

Interpretation: No STR polymorphisms other than those corresponding to the human LUEL8357i-2 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 14026-STR sample submitted corresponds to the LUEL8357i-2 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%.



Digitally Signed on 10/11/18

[Redacted], BA
TRIP Laboratory, Molecular

Digitally Signed on 10/11/18

[Redacted] 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 #: 18091843
DATE RECEIVED: 27-Sep-18
TEST INITIATED: 03-Oct-18
TEST COMPLETED: 17-Oct-18

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 22 OCT 18

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
September 27, 2018

FORM SOP-QU-004.01
Version G Edition 02
Reported by: AP
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	LUEL8357i-2-WB66917 14026	213	217	215	95	93	94	0.44	Negative	
2	Positive (+) Control	332	345	338.5	37525	37868	37697	111.36	Positive	
3	Negative (-) Control	620	628	624	66	70	68	0.11	Negative	

