

#### **Thaw and Culture Details**

Cell Line Name	LUEL8361i-1						
WiCell Lot Number	WB66906						
Provider	ovider Luebeck University, Dr. Christine Klein						
Banked By							
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	p24 These cells were cultured for 23 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 24.						
Date Vialed	26-August-2018						
Vial Label	LUEL8361i-1 p24 WB66906						
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	X JKG Quality Assurance			



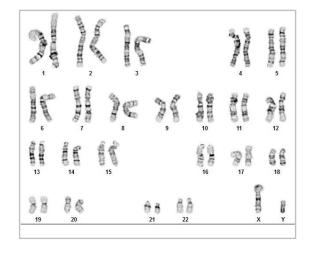
#### Chromosome Analysis Report: 073623

Date Reported: Monday, October 22, 2018 Cell Line: LUEL8361i-1-WB66906 14024

Passage#: 24

Date of Sample: 10/16/2018 Specimen: Human IPS

Results: 46,XY



Cell Line Sex: Male

Reason for Testing: lot release testing

Investigator: WiCell

Cell: 7

Slide: G02

Slide Type: Karyotype

Total Counted: 20
Total Analyzed: 8

Total Karyogrammed: 4
Band Resolution: 450 - 525

#### Interpretation:

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

Completed by:	, CG(ASCP)
Reviewed and Interpreted by:	, 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.



# Short Tandem Repeat Analysis

HISTOLOGY - IHC - MOLECULAR - IMAGING

Department of Pathology and Laboratory Medicine TRIP Laboratory (Molecular) (608) 265-9168 WiCell® info@wicell.org (888) 204-1782

Sample Report:

14024-STR

Sample Name on Tube: 14024-STR

 $85.7 \text{ ng/}\mu\text{L}$ , (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						
TPOX	6-13							
D8S1179	7-18	protect donor						
vWA	10-22	confidentiality. If						
Amelogenin	X,Y	more information is required,						
Penta_D	<b>D</b> 2.2, 3.2, 5, 7-17							
CSF1PO								
D16S539	5, 8-15							
D7S820								
D13S317	7-15							
D5S818	D5S818       7-16         Penta_E       5-24         D18S51       8-10, 10.2, 11-13, 13.2, 14-27							
Penta_E								
D18S51								
D21S11	<b>D21S11</b> 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 <b>TH01</b> 4-9,9.3,10-11,13.3							
TH01								
D3S1358	<b>D3S1358</b> 12-20							

<u>Results:</u> Based on the 14024-STR cells submitted by WiCell QA dated and received on 10/22/18, this sample (Label on Tube: 14024-STR) defines the STR profile of the human stem cell line LUEL8361i-1 comprising 27 allelic polymorphisms across the 15 STR loci analyzed.

<u>Interpretation:</u> No STR polymorphisms other than those corresponding to the human LUEL8361i-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 14024-STR sample submitted corresponds to the LUEL8361i-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

BA
TRIP Laboratory, Molecular

BA
UWHC Molecular Diagnostics Laboratory / UWSMPH TRIP Laboratory

### Native Product Sterility Report



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:** 

WiCell

504 S Rosa Rd, Rm 101

Madison, WI 53719

# 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 220ct 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

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

		Reading A A		Read	ing B	В	Ratio			
#	Sample Name	RLU1	RLU2	Ave	RLU1	75	Ave	B/A	Result	Comments/Suggestions
1	LUEL8361i-1-WB66906 14024	278	289	283.5	133	119	126	0.44	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	

