Thaw and Culture Details

Cell Line Name	**LUEL8679i-4**
WiCell Lot Number	**WB67230**
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	p23 These cells were cultured for 22 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 23.
Date Vialed	23-June-2019
Vial Label	LUEL8679i-4 p23 WB67230
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,+14 ***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, which contains a chromosomal aberration (gain of chromosome 14) recurrently acquired in pluripotent stem cell cultures. An additional twenty cells were examined for this chromosomal aberration; it was not observed. 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	Consistent with known 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

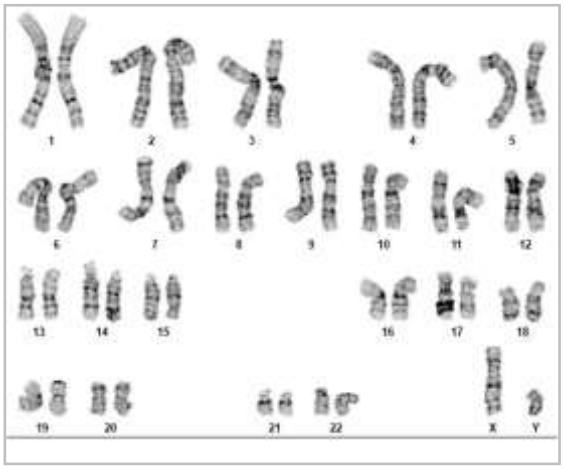
Approval Date	Quality Assurance Approval
01-Agusut-2019	8/1/2019 X JKG JKG Quality Assurance Signed by: Gay, Jenna

Chromosome Analysis Report: 077468

Date Reported: Friday, July 12, 2019
Cell Line: LUEL8679i-4-WB67230 14860
Passage#: 23
Date of Sample: 7/1/2019
Specimen: Human IPS
Results: 46,XY

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

Nonclonal findings: 47,XY,+14



Cell: 8
Slide: G02
Slide Type: Karyotype

Total Counted: 40
Total Analyzed: 8
Total Karyogrammed: 4
Band Resolution: 425 - 475

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, which contains a chromosomal aberration (gain of chromosome 14) recurrently acquired in pluripotent stem cell cultures. An additional twenty cells were examined for this chromosomal aberration; it was not observed. 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".

Short Tandem Repeat Analysis

TRIPath
HISTOLOGY - IHC - MOLECULAR - IMAGING

Department of Pathology and Laboratory Medicine
TRIP Laboratory (Molecular)
https://research.pathology.wisc.edu/trip-home/
(608) 265-9168

WiCell
Your Lab Partner

characterization@wicell.org
(608) 316-4145

Sample Report:
14860-STR
Sample Name on Tube: 14860-STR
75.9 ng/µL, (A260/280=2.11)
Sample Type: Cells
Cell Count: ~2 million cells

Requestor:
WiCell Research Institute
Quality Assurance Department

Receive Date: 07/08/19
Report Sent: 07/12/19
Assay Date: 07/10/19
File Name: STR 190711 wmr
Report Date: 07/15/19

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 14860-STR cells submitted by WiCell QA dated and received on 07/08/19, this sample (Label on Tube: 14860-STR) exactly matches the STR profile of the human cell line LUEL8679i-4 comprising 25 allelic polymorphisms across the 15 STR loci analyzed.

Interpretation: No STR polymorphisms other than those corresponding to the human LUEL8679i-4 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 14860-STR sample submitted corresponds to the LUEL8679i-4 cell line and was 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 ~2-5%.

X *RMB* **Digitally Signed on 07/15/19**

[redacted], *BA*
TRIP Laboratory, Molecular

X *WMR* **Digitally Signed on 07/15/19**

[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.

Native Product Sterility Report

STERIS

SAMPLE #:	19070830
DATE RECEIVED:	11-Jul-19
TEST INITIATED:	17-Jul-19
TEST COMPLETED:	31-Jul-19

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

SAMPLE NAME / DESCRIPTION:

SCRP2503i DB42072 14868
SCRP2506i DB42076 14869
SCRP2409i DB42066 14870
SCRP2411i DB42069 14871
JHU229i DB37022 14872
JHU232i DB37035 14873
JHU242i DB37058 14874
JHU246i DB37106 14875
JHU251i DB37118 14876
JHU253i DB37125 14877
WC047i-17097-01-36 WB67236 14878
LUEL8679i-4 WB67230 14879
MCW107i-40000886 WB67227 14880
hIPSC-Tri21-c2-4 WB67228 14881
hIPSC-Tri21-c2-4 WB67229 14882
SCRP2106i DB42037 14883
SCRP2211i DB42051 14884
MCW104i-U2175 WB67231 14885
MCW113i-U7145 WB67243 14886
STAN217i-496C2 DB35538 14887

UNIQUE IDENTIFIER: NA

TEST RESULTS:

# Tested	# Positives (Growth)	- Control
20	0	2 Negatives

TEST SUMMARY:

# Samples	Media Type	Volume (mL)	Incubation Temperature (° C)	Incubation Duration (Days)
20	TSB	40	20-25	14
20	FTG	40	30-35	14

REFERENCE: Processed according to LAB-003: Sterility Test Procedure
PD #: 000053
TEST METHODOLOGY: USP - Direct Transfer

Native Product Sterility Report

STERIS

COMMENTS: Sample # 19070830

REVIEWED BY _____ DATE 31 Jul 19

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.Results applied to samples as received.

Mycoplasma Assay Report

PCR-based assay performed by WiCell

Lot Release Testing

01Jul19

#	Sample Name	Result	Comments/Suggestions
1	LUEL8679i-4-WB67230 14860	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma
2	Positive (+) Control	Positive	
3	Negative (-) Control	Negative	

Reported by: Katie Remondini, Cell Culture Specialist
Reviewed by: Brenna Anderson, Research Specialist - Cytogenetics
Date:_____ Sent By:____ Sent To_____

A gel image is available upon request.