



Thaw and Culture Details

Cell Line Name	CREM003i-BU3C2
WiCell Lot Number	WB66874
Parent Material	CREM003i-BU3C2- DB47974
Provider	Boston University – Laboratory of Dr. Martin Steinberg
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	p42 These cells were cultured for 41 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 42.
Date Viald	02-August-2018
Vial Label	CREM003i-BU3C2 p42 WB66874
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
	<p>Results: 46,XY,i(20)(q10)[17]/46,XY[3] Interpretation: This is an abnormal karyotype. There is an isochromosome of the long (q) arm of chromosome 20 in seventeen of twenty cells examined. This imbalance results in trisomy for 20q and monosomy for 20p. Gain of chromosome 20q is a recurrent acquired abnormality in cultures of this cell type. No other clonal abnormalities were detected at the stated band level of resolution.</p>			
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 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.

- Digital Genome Sequencing
- Infinium® Expanded Multi-Ethnic Genotyping Array (MEGAEX)

Approval Date	Quality Assurance Approval
27-September-2018	<p style="text-align: right;">9/27/2018</p> <p>X JKG</p> <p>JKG Quality Assurance Signed by Gay, Jenna</p>

Date Reported: Wednesday, August 22, 2018

Cell Line: CREM003i-BU3C2-WB66874 13947

Passage#: 42

Date of Sample: 8/16/2018

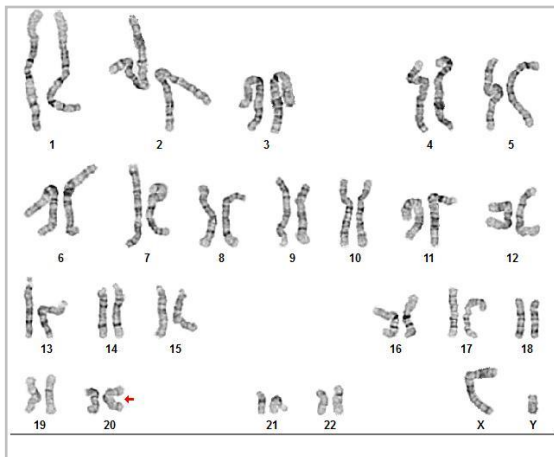
Specimen: Human IPS

Results: 46,XY,i(20)(q10)[17]/46,XY[3]

Cell Line Sex: Male

Reason for Testing: lot release testing

Investigator: [REDACTED], WiCell



Cell: 32

Slide: G03

Slide Type: Karyotype

Total Counted: 20

Total Analyzed: 8

Total Karyogrammed: 4

Band Resolution: 500 - 525

Interpretation:

This is an abnormal karyotype. There is an isochromosome of the long (q) arm of chromosome 20 in seventeen of twenty cells examined. This imbalance results in trisomy for 20q and monosomy for 20p. Gain of chromosome 20q is a recurrent acquired abnormality in cultures of this cell type. No other clonal abnormalities were detected at the stated band level of resolution.

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 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:

13947-STR

Sample Name on Tube: 13947-STR

89.3 ng/μL, (A260/280=1.87)

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

WiCell Research Institute

Quality Department

Sample Date: N/A**Receive Date:** 08/27/18**Assay Date:** 08/29/18**File Name:** STR 180830 wmr**Report Date:** 09/05/18

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 13947-STR cells submitted by WiCell QA dated and received on 08/27/18, this sample (Label on Tube: 13947-STR) defines the STR profile of the human stem cell line CREM003i-BU3C2 comprising 26 allelic polymorphisms across the 15 STR loci analyzed.

Interpretation: No STR polymorphisms other than those corresponding to the human CREM003i-BU3C2 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 13947-STR sample submitted corresponds to the CREM003i-BU3C2 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 09/06/18

BA
TRIP Laboratory, Molecular

Digitally Signed on 09/06/18

, 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 #: 18081822
DATE RECEIVED: 23-Aug-18
TEST INITIATED: 29-Aug-18
TEST COMPLETED: 12-Sep-18

SAMPLE NAME / DESCRIPTION: UCSD027i-9-2 WB57332 13953
WA07 CY66889 13954
LUEL7159i-16 WB66875 13955
UCSD028i-9-3 WB66873 13956
CREM003i-BU3C2 WB66874 13957
CREM018i-SS24-1 WB66883 13958
LUEL5748i-2 WB66878 13959
WC036i-0498-1 WB66882 13960
WC036i-0498-1 WB66884 13961
CREM024i-SS36-1 WB66886 13962
LUEL8360i-2 WB66888 13963
LUEL7991i-1 WB66891 13964
LUEL5748i-3 WB66894 13965
LUEL7153i-1 WB66895 13966
LUEL7673i-2 WB66898 13967
LUEL7149i-1 WB66899 13968
CREM029i-SS44-1 DB48061 13969
CREM030i-SS45-1 DB48064 13970
JHU012i-2 DB36196 13971
JHU017i DB36203 13972

UNIQUE IDENTIFIER: NA
PRODUCT REGISTRATION: Other: Human iPS cells

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

METHOD VALIDATION / PD #: 000053

Native Product Sterility Report



TEST METHODOLOGY: USP - Direct Transfer

COMMENTS: NA

REVIEWED BY

A handwritten signature in blue ink, written over a horizontal line. The signature is cursive and appears to read "G. Malin".

DATE

17 SEP 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

August 16, 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	RLU2				
1	CREM003i-BU3C2-WB66874 13947	261	258	259.5	102	98	100	0.39	Negative	
2	Positive (+) Control	486	434	460	19592	19817	19705	42.84	Positive	
3	Negative (-) Control	896	897	896.5	94	87	90.5	0.10	Negative	

