



Certificate of Analysis

Thaw and Culture Details

Cell Line Name	CREM056i-BR39-1	
WiCell Lot Number	WB67703	
Parent Material	CREM056i-BR39-1-DB66775	
Provider/Client	Boston University – Laboratory of Dr. Martin Steinberg	
Banked By	WiCell	
Thaw and Culture Recommendations	WiCell recommends thawing 1 vial into 4 wells of a 6 well plate using mTeSR™ Plus and Matrigel®.	
Protocol	WiCell Feeder Independent Pluripotent Stem Cell Protocol	
Culture Platform Prior to Freeze	Medium: mTeSR™ Plus	Matrix: Matrigel®
Passage Number	p14 Cells were cultured for 13 passages prior to freeze and post colony selection. Plated cells at thaw should be labeled passage 14.	
Date Vialied	01-August-2021	
Vial Label	CREM056i-BR39-1 p14 WB67703	
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.	



Certificate of Analysis

Results

Test Description	Test Provider	Test Method	Test Specification	Result
Karyotype	WiCell	G-T-L Banding performed on 20 metaphase cells	Expected karyotype	See Report
	<p>Results: 46,XY Nonclonal findings: 47,XY,+8</p> <p>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 8) 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.</p>			
Post-Thaw Viable Cell Recovery	WiCell	Thaw using specified Thaw & Culture Recommendations	≥ 15 Undifferentiated Colonies prior to passage, ≤ 30% Differentiation prior to passage, and recoverable attachment after passage	Pass
Identity by STR	WiCell	PowerPlex 16 HS System by Promega™	Defines STR profile of deposited cell line	See Report
Mycoplasma	WiCell	PCR	Amplification of mycoplasma specific DNA detected with negative result	Pass
Sterility	Steris	Native Product Direct Transfer using FTM and TSB (ST/07)	Negative for growth following 14 days of culture	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 (MEGA^{EX})

Approval Date	WiCell Quality Assurance Approval
06-October-2021	<p style="text-align: right;">10/6/2021</p> <p>X JKG</p> <p><small>JKG WiCell Quality Assurance Signed by Gay, Jenna</small></p>

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The material provided under this certificate has been subjected to the tests specified and the results and data described herein are accurate based on WiCell's reasonable knowledge and belief. Appropriate Biosafety Level practices and universal precautions should always be used with this material. For clarity, the foregoing is governed solely by WiCell's Terms and Conditions of Service, which can be found at <http://www.wicell.org/privacyandterms>.

Date Reported: Thursday, September 16, 2021

Cell Line Sex: Male

Cell Line: CREM056i-BR39-1-WB67703

Reason for Testing: LOT_RELEASE

Submitted Passage #: 14

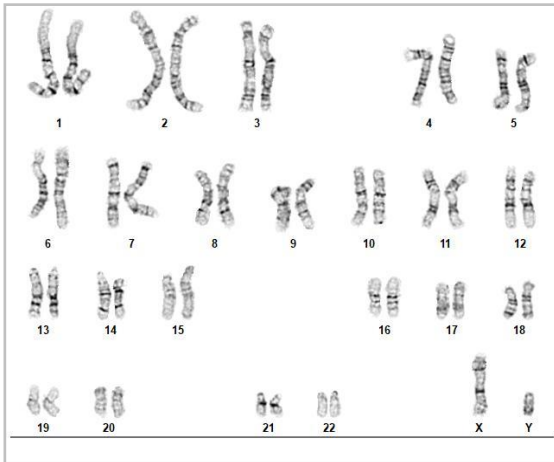
Date of Sample: 9/13/2021

Investigator: WiCell Stem Cell Bank, WiCell

Specimen: Human iPSC

Results: 46,XY

Nonclonal findings: 47,XY,+8



Cell: 35

Slide: G02

Slide Type: Karyotype

Total Counted: 40

Total Analyzed: 8

Total Karyogrammed: 5

Band Resolution: 375 - 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 8) 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: Jennifer Pecos, CG(ASCP)

Reviewed and Interpreted by: Kaitlin C. Lenhart, Ph.D.

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

Form SOP-89.01

Version 7.0

Requestor: WiCell Stem Cell Bank, WiCell
 Samples Received: 13Sep21, 14Sep21, 15Sep21, 16Sep21
 STR Amplification Date: 20Sep21

Sample Name	CREM055i- BR37-1- WB67683 p13	CREM056i- BR39-1- WB67703 p14					
Label on tube	88439	88440					
FGA	Identifying information has been redacted to protect donor confidentiality. If more information is required, please contact info@wicell.org						
TPOX							
D8S1179							
vWA							
Amelogenin							
Penta_D							
CSF1PO							
D16S539							
D7S820							
D13S317							
D5S818							
Penta_E							
D18S51							
D21S11							
TH01							
D3S1358							
Allelic Polymorphisms	28	26	27	27	27	27	27
Matches*			See Matches Comment	See Matches Comment	See Matches Comment	See Matches Comment	See Matches Comment
Comments							

**Note: The STR profile of the following sample is an exact match for the given sample/samples.*



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Sample Name	<p>Identifying information has been redacted to protect donor confidentiality. If more information is required, please contact info@wicell.org</p>	
Label on tube		
FGA		
TPOX		
D8S1179		
vWA		
Amelogenin		
Penta_D		
CSF1PO		
D16S539		
D7S820		
D13S317		
D5S818		
Penta_E		
D18S51		
D21S11		
TH01		
D3S1358		
Allelic Polymorphisms	27	27
Matches*	See Matches Comment	See Matches Comment
Comments		

**Note: The STR profile of the following sample is an exact match for the given sample/samples.*



Short Tandem Repeat

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STR Amplification Date: 20Sep21

Assay Description: STR analysis is performed using the PowerPlex 16 HS System by Promega™. Results are reported as 13 CODIS STR markers, Amelogenin for gender determination and two low-stutter, highly discriminating pentanucleotide STR markers.

Results: The genotypic profiles comprise a range of 26-28 allelic polymorphisms across the 15 STR loci analyzed.

Interpretation: 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. These results suggests that the cells submitted correspond to the cell lines as named and were 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%.

Matches: Samples 88628, 88629, 88630, 88657, 88659, 88664, and 88665 are exact matches to each other and to 88265, 88270, 88281, 88282, 88283, 88310, 88311, 88312, 88313, 88433, and additional profiles. Additional matches can be provided upon request.

9/21/2021	9/21/2021	9/24/2021
<p>X Amber Kuhn</p> <hr/> <p>Tech #1 Characterization Signed by: Kuhn, Amber</p>	<p>X Molly Miles</p> <hr/> <p>Tech #2 Characterization Signed by: Miles, Molly</p>	<p>X Dawn Graham</p> <hr/> <p>QA Review Quality Assurance Signed by: Graham Dawn</p>

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Raw data is available upon request.



Mycoplasma Assay Report

PCR-based assay performed by WiCell

WiCell
14Sep21

FORM SOP-83.01

Version 3.0

Sample Name	Result	Interpretation
CREM055i-BR37-1-WB67683 p13 (88439)	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
CREM056i-BR39-1-WB67703 p14 (88440)	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
Positive (+) Control	Positive	
Negative (-) Control	Negative	

9/17/2021

9/17/2021

9/17/2021

X Molly Miles

Tech #1
Characterization
Signed by: Miles, Molly

X Katie Remondini

Tech #2
Characterization
Signed by: Remondini, Katie

X Dawn Graham

QA Review
Quality Assurance
Signed by: Graham Dawn

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A gel image is available upon request.

Native Product Sterility Report



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

SAMPLE #: 21080662
DATE RECEIVED: 12-Aug-21
TEST INITIATED: 12-Aug-21
TEST COMPLETED: 26-Aug-21

SAMPLE NAME / DESCRIPTION: CREM056i-BR39-1-WB67703
STAN017i-171-1-DB31059
STAN019i-177-1-DB31114
STAN028i-42-1-DB30917
STAN010i-041-2-DB31056
PENN071i-216-13-DB34946
STAN018i-171-2-DB31075
STAN020i-177-2-DB31121
STAN029i-42-2-DB30926
STAN023i-41-1-DB31169

UNIQUE IDENTIFIER: N/A

TEST RESULTS:

# Tested	# Positives (Growth)	- Control
10	0	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

PD #: 000053

TEST METHODOLOGY: USP - Direct Transfer

COMMENTS: NA

REVIEWED BY

DATE 26 Aug 2021

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.