



Thaw and Culture Details

Cell Line Name	CREM023i-SS35-1
WiCell Lot Number	WB66438
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	p21 These cells were cultured for 20 passages after colony picking prior to freeze. WiCell adds +1 to the passage number to best represent the overall passage number of the cells at thaw.
Date Vialied	07-July-2017
Vial Label	CREM023i-SS35-1 p21 WB66438
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	Fail
	Result from report: This is an abnormal karyotype. There is an interstitial duplication in the long arm of chromosome 20 in twelve of twenty cells examined. This abnormality appears to be the recurrent acquired duplication of 20q seen in human pluripotent stem cell cultures. Confirmation of this abnormality by higher resolution (fluorescence in situ hybridization—FISH) testing is recommended. No other clonal defined abnormalities were found.			
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	Biotest Laboratories	ST/07	Negative	Pass
Mycoplasma	WiCell	SOP-QU-004	Negative	Pass



Testing Reported by Provider

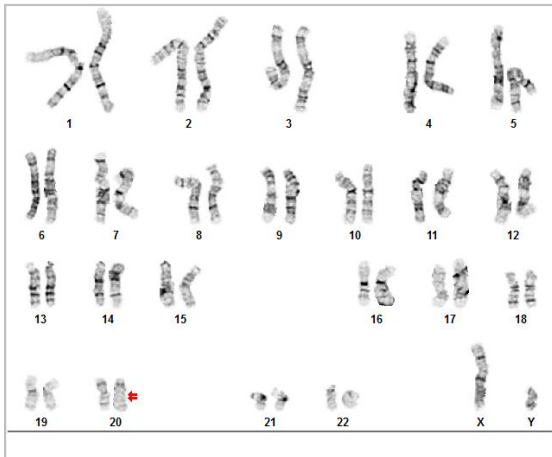
The Provider stated that some or all of the additional analyses listed below may have been performed for this cell line. For more information, publication and dbGaP links, where available, are provided on the cell line specific web page on the WiCell website.

- Digital Genome Sequencing
- Infinium® Expanded Multi-Ethnic Genotyping Array (MEGA^{EX})

Approval Date	Quality Assurance Approval
11-August-2017	<p style="text-align: right;">8/16/2017</p> <p>X AMK</p> <p><small>AMK Quality Assurance Signed by Klade, Anjelica</small></p>

Date Reported: Tuesday, July 25, 2017
Cell Line: CREM023i-SS35-1-WB66438 12620
Passage#: 21
Date of Sample: 7/13/2017
Specimen: Human IPS
Results: 46,XY,dup(20)(q11.2q11.2)[12]/46,XY[8]

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



Cell: 22
Slide: G01
Slide Type: Karyotype

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

Interpretation:

This is an abnormal karyotype. There is an interstitial duplication in the long arm of chromosome 20 in twelve of twenty cells examined. This abnormality appears to be the recurrent acquired duplication of 20q seen in human pluripotent stem cell cultures. Confirmation of this abnormality by higher resolution (fluorescence in situ hybridization—FISH) testing is recommended. No other clonal defined abnormalities were found.

Completed by: [REDACTED] MS, 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 may not be relied upon by any other party without the prior written consent of the Director of the WiCell Cytogenetics Laboratory. The results of this assay are for research use only. If the results of this assay are to be used for any other purpose, contact the Director of the WiCell Cytogenetics Laboratory.

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

Department of Pathology and Laboratory Medicine
TRIP Laboratory (Molecular)
<http://www.pathology.wisc.edu/research/trip>

WiCell®
info@wicell.org
(888) 204-1782

Sample Report:

12620-STR
Sample Name on Tube: 12620-STR
83.0 ng/μL, (A260/280=1.98)
Sample Type: Cells
Cell Count: ~2 million cells

Requestor:

WiCell Research Institute
Quality Department

Sample Date: N/A

Receive Date: 07/24/17
Assay Date: 07/25/17
File Name: STR 170727 wmr
Report Date: 07/31/17

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 12620-STR cells submitted by WiCell QA dated and received on 07/24/17, this sample (Label on Tube: 12620-STR) defines the STR profile of the human stem cell line CREM023i-SS35-1 comprising 28 allelic polymorphisms across the 15 STR loci analyzed.

Interpretation: No STR polymorphisms other than those corresponding to the human CREM023i-SS35-1 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 12620-STR sample submitted corresponds to the CREM023i-SS35-1 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%.

X *RMB* Digitally Signed on 07/31/17

X *WMR* Digitally Signed on 07/31/17

TRIP Laboratory, Molecular

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 #: 17071248
DATE RECEIVED: 20-Jul-17
TEST INITIATED: 24-Jul-17
TEST COMPLETED: 07-Aug-17

SAMPLE NAME / DESCRIPTION: HVRDi002-A-1-WB66253 12586
WA01-WB66269 12611
UCSD238i-APP1-3-DB26825 12612
UCSD223i-NDC1-1-WB66285 12613
WC025i-FXS-Nluc2-WB66292 12614
WC024i-FXS-Nluc1-WB66443 12615
WIC09i-02-11E-WB66435 12616
CREM023i-SS35-1-WB66438 12617
WIC08i-02-11E-WB66437 12618
UCSD239i-APP2-1-WB66436 12619

UNIQUE IDENTIFIER: NA
PRODUCT REGISTRATION: Human iPS cells

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
METHOD VALIDATION / PD #: 000053
TEST METHODOLOGY: USP - Direct Transfer

COMMENTS: NA

REVIEWED BY *D. S. S. S.*

DATE 08AUG17

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

July 12, 2017

FORM SOP-QU-004.01

Version F Edition 02

Reported by: KR

Reviewed by: DF 12Jul17

BD Monolight 180

#	Sample Name	Reading A		A Ave	Reading B		B Ave	Ratio B/A	Result	Comments/Suggestions
		RLU1	RLU2		RLU1	RLU2				
1	CREM023i-SS35-1-WB66438 12620	177	196	186.5	66	66	66	0.35	Negative	
2	Positive (+) Control	349	363	356	31431	31358	31395	88.19	Positive	
3	Negative (-) Control	543	529	536	53	54	53.5	0.10	Negative	

