Certificate of Analysis

Thaw and Culture Details

Cell Line Name	**WAi001-B-1-iETV2**	
WiCell Lot Number	**WB67568**	
Provider/Client	University of Wisconsin – Dr. Igor Slukvin	
Banked By	WiCell	
Thaw and Culture Recommendations	WiCell recommends thawing 1 vial into 3 wells of a 6 well plate using TeSR™-E8™ and Matrigel®.	
Protocol	WiCell Feeder Independent Pluripotent Stem Cell Protocol	
Culture Platform Prior to Freeze	Medium: TeSR™-E8™	Matrix: Matrigel®
Passage Number	p7 Cells were cultured for 6 passages prior to freeze and post colony selection. Plated cells at thaw should be labeled passage 7.	
Date Vialed	18-September-2020	
Vial Label	WAi001-B-1-iETV2 p7 WB67568	
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

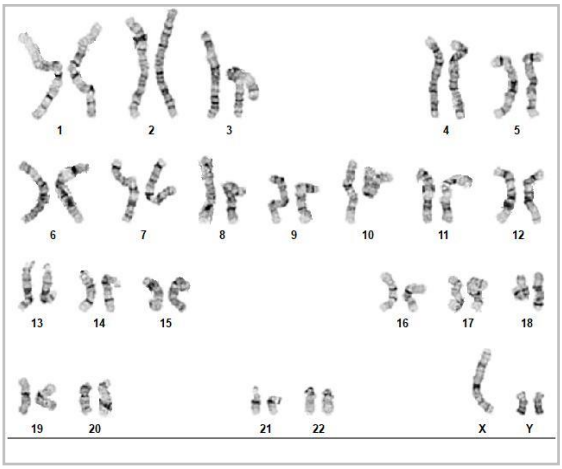
Test Description	Test Provider	Test Method	Test Specification	Result
Karyotype	WiCell	G-T-L Banding performed on 20 metaphase cells	Expected karyotype	See Report
	Results: 47,XY,+Y[3]/46,XY[17] ***Interpretation:*** This is an abnormal karyotype. An additional copy of chromosome Y is present in three of twenty cells examined. Gain of chromosome Y is recurrently acquired in pluripotent stem cell cultures. No other clonal abnormalities were detected at the stated band level of resolution.			
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™	Consistent with 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

Approval Date	WiCell Quality Assurance Approval
29-July-2021	7/29/2021 X JKG JKG WiCell Quality Assurance Signed by: Gay, Jenna

Chromosome Analysis Report: 083014

Date Reported: Friday, October 2, 2020
Cell Line: WAi001-B-1-iETV2-WB67568
Submitted Passage #: 7
Date of Sample: 9/25/2020
Specimen: Human Modified iPSC
Results: 47,XY,+Y[3]/46,XY[17]

Cell Line Sex: Male
Reason for Testing: LOT_RELEASE
Investigator: WiCell Stem Cell Bank, WiCell



Cell: 5
Slide: G01
Slide Type: Karyotype

Total Counted: 20
Total Analyzed: 9
Total Karyogrammed: 5
Band Resolution: 400 - 525

Interpretation:

This is an abnormal karyotype. An additional copy of chromosome Y is present in three of twenty cells examined. Gain of chromosome Y is recurrently acquired in pluripotent stem cell cultures. No other clonal abnormalities were detected at the stated band level of resolution.

Completed by: Pam Mill
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".

Short Tandem Repeat

Requestor: WiCell Stem Cell Bank, WiCell
Samples Received: 25Sep20
STR Amplification Date: 30Sep20

Sample Name	WAi001-B-1-iETV2-WB67568
Label on tube	83014
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	27
Matches*	82887
Comments	

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

Short Tandem Repeat

Requestor: WiCell Stem Cell Bank, WiCell
Samples Received: 25Sep20
STR Amplification Date: 30Sep20

ResultsThe genotypic profiles comprise a range of ___27__ 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%.

10/2/2020

X Molly Miles

Tech #1
Characterization
Signed by: Miles, Molly

10/5/2020

X Anna Lisa Larson

Tech #2
Characterization
Signed by: Larson, Anna Lisa

10/2/2020

X Haley Bruner

QA Review
Quality Assurance
Signed by: Bruner, Haley

Raw data is available upon request.

Native Product Sterility Report

STERIS

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

SAMPLE #: 21041910
DATE RECEIVED: 29-Apr-21
TEST INITIATED: 03-May-21
TEST COMPLETED: 17-May-21

SAMPLE NAME / DESCRIPTION: WAi001-B-1-iETV2-WB67568 [redacted]
SCRP4301i-DB42912
SCRP4406i-DB42915
SCRP4502i-DB42918
SCRP4603i-DB42921
SCRP4703i-DB42924
SCRP4803i-DB42953
SCRP4903i-DB42958

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 Lorie Buckland DATE 17May2021

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

WiCell

30Sep20

FORM SOP-83.01
Version 01

Sample Name	Result	Comments/Suggestions
WAi001-B-1-iETV2-WB67568 (83014)	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
CRFi001-A-DB67540 (83023)	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
H13-FMR1-KO-DB67483 (83024)	Negative	Band was not seen at 270bp, indicating the absence of mycoplasma.
Positive (+) Control	Positive	
Negative (-) Control	Negative	

Reported by: Callum Walker, Assistant Research Specialist
Reviewed by: Alex Paguirigan, Assistant Cell Culture Specialist

A gel image is available upon request.