Product Information and Testing

Product Information

Product Name	WIC06i-07982-2
Alias	iPS-V247X-WT
WiCell Lot Number	WB0313
Depositor	University of Wisconsin – Laboratory of Dr. Qiang Chang
Banked by	WiCell
Thaw Recommendation	Thaw 1 vial into 2 wells of a 6 well plate.
Culture Platform	Feeder Dependent
	Medium: hES Medium
	Matrix: MEFs
Protocol	WiCell Feeder Dependent Protocol
Passage Number	p26 These cells were cultured for 25 passages after iPSC generation prior to freeze. WiCell adds +1 to the passage number at freeze so that the number on the vial best represents the overall passage number of the cells at thaw.
Date Vialed	21-August-2014
Vial Label	WIC06i-07982 WB0313 p26 21Aug14
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
Post-Thaw Viable Cell Recovery	WiCell	SOP-CH-305	≥ 15 Undifferentiated Colonies, ≤ 30% Differentiation	Pass
Identity by STR	UW Molecular Diagnostics Laboratory	PowerPlex 16 HS System by Promega	Defines profile	Pass
Sterility	WiCell	SOP-QU-026	Negative	Pass
Mycoplasma	WiCell	SOP-QU-004	Negative	Pass
Karyotype by G-banding	WiCell	SOP-CH-003	Report karyotype	Pass

Date of Lot Release	Quality Assurance Approval
13-February-2015	2/13/2015 X AMK AMK Quality Assurance Signed by: [redacted]

UW Health

University of Wisconsin Hospital and Clinics

Short Tandem Repeat Analysis*

Molecular Diagnostics Laboratory

[redacted]

Samples Report:
(1) 11044-STR 243.58 ng/uL (260/280=1.97)

DNA Extracted by WiCell Research Institute

Requestor:
WiCell Research Institute (Quality Assurance)

[redacted]

Sample Date(s): 10/27/14
Receive Date(s): 10/27/14
Assay Date(s): 10/29/14
File Name(s): 141029 BLB
Report Date(s): 11/03/14

STR Locus	STR Genotype Repeat #	(1)
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	

Comments: Based on the 11044-STR DNA dated and received on 10/27/14 from WI Cell, this sample (Label on Tube: 11044-STR) defines the STR profile of the human stem cell line WIC06i-07982-2 comprising 25 allelic polymorphisms across the 15 STR loci analyzed. No STR polymorphisms other than those corresponding to the human WIC06i-07982-2 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. These results suggest that the 11044-STR DNA sample submitted corresponds to the WIC06i-07982-2 stem cell line and was not contaminated with any other human stem cells or a significant amount of mouse feeder layer cells. Sensitivity limits for detection of STR polymorphisms unique to either this or other human stem cell lines is ~2-5%.

[redacted] 11/05/14
Date
Molecular Diagnostics Laboratory

[redacted] 11/5/14
Molecular Diagnostics 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.

Sterility Report

Biotest Laboratories, Inc.
Making life-saving products possible

CORRECTED REPORT

WiCell Research Institute, Inc.
WiCell Quality Assurance
[redacted]

BIOTEST SAMPLE #	14110465
VALIDATION #	NG
TEST PURPOSE	NG

PRODUCT	NSC-H9-WB0309 11053, WIC06i-07982-2-WB0313 11054, WIC05i-127-325-WB0312 11055, IISH10i-GM20920-WB0308 11056, WIC02i-02-05-WB15064 11057, WIC04i-127-33-WB15053 11058, WIC07i-07982-4-WB15086 11059, WIC03i-02-11E-WB15127 11060
PRODUCT LOT	NA
STERILE LOT	NA
STERILIZATION LOT	NA
STERILIZATION DATE	NA
STERILIZATION METHOD	NA
SAMPLING BLDG / ROOM	NA

BI LOT	NA
BI EXPIRATION DATE	NA
DATE RECEIVED	2014-11-07
TEST INITIATED	2014-11-10
TEST COMPLETED	2014-11-24

REFERENCE: Processed according to LAB-003: Sterility Test Procedure

Eight (8) products were each divided between 40 mL TSB and 40 mL FTG. The samples were then cultured at 20-25 C and 30-35 C respectively and were monitored for a minimum of 14 days.

- ☒ USP
- ☐ BI Manufacturers Specifications
- ☐ Other

RESULTS	# POSITIVES	# TESTED	POSITIVE CONTROL	NEGATIVE CONTROL
Sterile	0	8	NA	2 Negatives

COMMENTS: Report revised due to Customer request to correct one number in Product Name.

REVIEWED BY [redacted] DATE 12DEC14

Mycoplasma Detection Assay Report

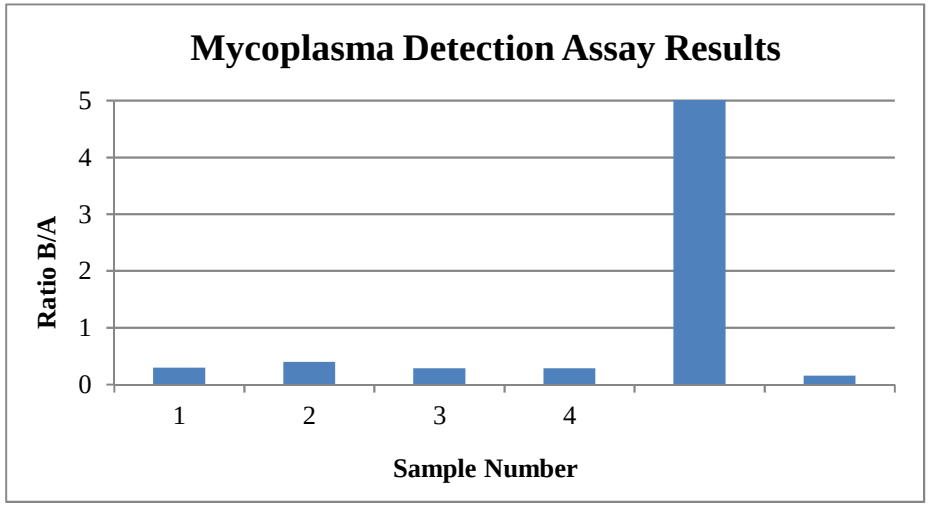
Testing Performed by WiCell

CDM Lot Release Testing

03-10-2014

FORM SOP-QU-004.01
Version C Edition 01
Reported by: DF
Reviewed by:
BD Flash n' Glo 180

#	Sample Name	Reading A		A Ave	Reading B		B Ave	Ratio B/A	Result	Comments/Suggestions
		RLU1	RLU2		RLU1	RLU2				
1	IISH10i-WB0308 #11045	140	141	140.5	42	41	41.5	0.30	Negative	
2	WIC02i-WB15064 #11047	254	249	251.5	99	100	99.5	0.40	Negative	
3	WIC05i-WB0312 #11042	250	253	251.5	70	74	72	0.29	Negative	
4	WIC06i-WB0313 #11044	241	255	248	70	70	70	0.28	Negative	
	Positive (+) Control	431	414	422.5	20114	20074	20094	47.56	Positive	
	Negative (-) Control	752	748	750	114	120	117	0.16	Negative	



Chromosome Analysis Report: 015388

Date Reported: Wednesday, October 15, 2014

Cell Line Gender: Female

Cell Line: WIC06i-07982-2-WB0313 11044

Reason for Testing: lot release testing

Passage#: 27

Date of Sample: 10/6/2014

Investigator: [redacted], WiCell CDM

Specimen: iPSC

Results: 46,XX

Cell: 12

Slide: 1

Slide Type: Karyotype

Total Counted: 20

Total Analyzed: 9

Total Karyotyped: 5

Band Resolution: 425 - 450

Interpretation:

This is a normal karyotype. No clonal abnormalities were detected at the stated band level of resolution.

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 resu lts 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.