Product Information and Testing

Product Information

Product Name	WIC04i-127-33
Alias	iPS-R306C-WT
Lot Number	WB15053
Depositor	University of Wisconsin – Laboratory of Dr. Qiang Chang
Banked by	WiCell
Thaw Recommendation	Thaw 1 vial into 1 well of a 6 well plate.
Culture Platform	Feeder Dependent Medium: hES Medium Matrix: MEF
Protocol	WiCell Feeder Dependent Protocol
Passage Number	p25 These cells were cultured for 24 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	27-August-2014
Vial Label	WIC04i-127-33 WB15053 p25 27AUG14
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 and recoverable attachment after passage	Pass
Identity by STR	UW Molecular Diagnostics Laboratory	PowerPlex 16 HS System by Promega	Defines profile	Pass
Sterility	Biotest Laboratories	ST/07	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]

Short Tandem Repeat Analysis*

School of Medicine and Public Health
UNIVERSITY OF WISCONSIN-MADISON

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

[redacted]

Samples Report:
11051-STR 71.1 ng/µL
(A260/280=1.76)
Sample Name on Tube:
WIC04i-127-33-WB-15053 TI5436 p32
DNA Extracted by:
TRIP Lab

Requestor:
WiCell Research Institute
[redacted]

Sample Date: 11-24-14
Receive Date: 11-24-14
Assay Date: 12-5-14
File Name: STR 141205
Report Date: 12-8-14

STR Locus	STR Genotype Repeat #	11051-STR
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 11051-STR cells submitted by WiCell QA dated and received on 11-24-14, this sample (Label on Tube: WIC04i-127-33-WB-15053 TI5436 p32) defines the STR profile of the human stem cell line WIC04i-127-33 comprising 27 allelic polymorphisms across the 15 STR loci analyzed. No STR polymorphisms other than those corresponding to the human WIC04i-127-33 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 11051-STR sample submitted corresponds to the WIC04i-127-33 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] 12.8.14
Date
TRIP Laboratory, Molecular

[redacted] 12/8/14
Date
Molecular Diagnostics Laboratory

Remember to acknowledge TRIP in your publications, posters & presentations. For details, visit:
http://www.pathology.wisc.edu/research/trip/acknowledging

* 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

[redacted]

Mycoplasma Detection Assay Report

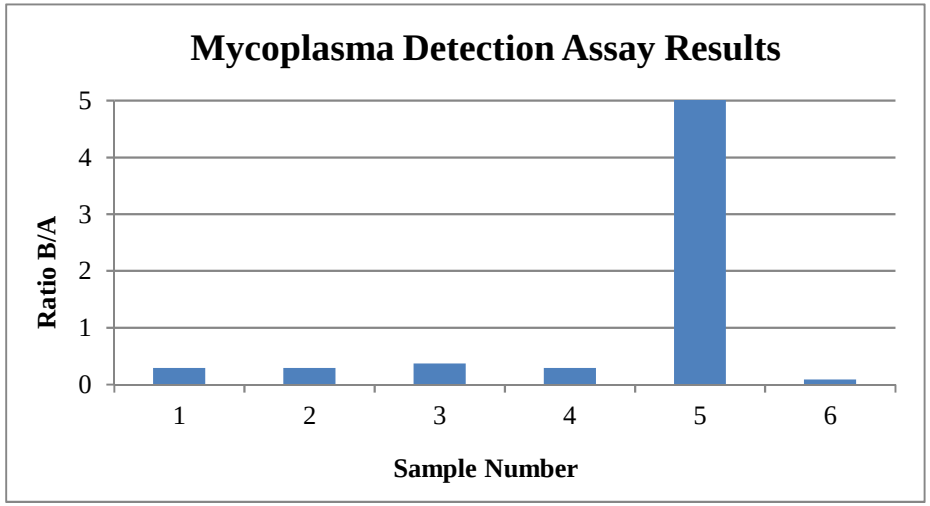
Testing Performed by WiCell

Lot Release Testing

11-07-2014

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

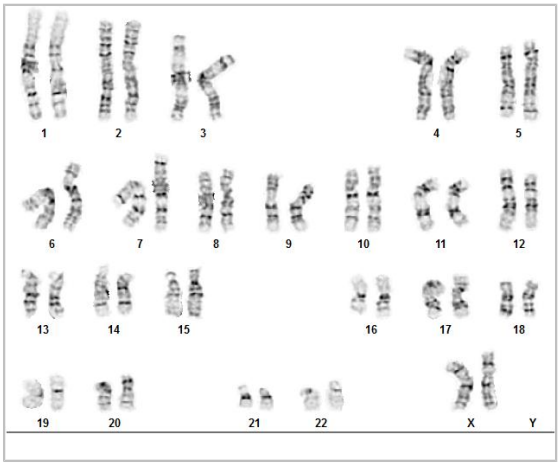
#	Sample Name	Reading A		A Ave	Reading B		B Ave	Ratio B/A	Result	Comments/Suggestions
		RLU1	RLU2		RLU1	RLU2				
1	11051 WIC04i-127-33-WB15053	221	224	222.5	67	62	64.5	0.29	Negative	
2	11065 UWWC1-DS4-DB15219	219	223	221	65	64	64.5	0.29	Negative	
3	11066 UWWC1-2DS3-DB15244	204	205	204.5	72	79	75.5	0.37	Negative	
4	11050 WIC07i-07982-4-WB15086	188	184	186	54	54	54	0.29	Negative	
5	Positive (+) Control	308	299	303.5	6912	6880	6896	22.72	Positive	
6	Negative (-) Control	505	498	501.5	42	42	42	0.08	Negative	



Chromosome Analysis Report: 015869

Date Reported: Tuesday, November 18, 2014
Cell Line: WIC04i-127-33-WB15053 11051
Passage#: 30
Date of Sample: 11/14/2014
Specimen: iPSC
Results: 46,XX

Cell Line Gender: Female
Reason for Testing: Lot release testing
Investigator: [redacted] WiCell CDM



Cell: 40
Slide: 1
Slide Type: Karyotype

Total Counted: 20
Total Analyzed: 8
Total Karyotyped: 4
Band Resolution: 450 - 500

Interpretation:

This is a normal karyotype. No 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 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.

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