




Thaw and Culture Details

Cell Line Name	WC-24-02-DS-M
WiCell Lot Number	WB18754
Provider	University of Wisconsin – Dr. Anita Bhattacharyya
Banked By	WiCell
Thaw and Culture Recommendations	WiCell recommends thawing 1 vial into 3 wells of a 6 well plate using mTeSR™1 and Matrigel®
Protocol	WiCell Feeder Independent Pluripotent Stem Cell Protocol
Culture Platform Prior to Freeze	Feeder Independent
	Medium: mTeSR™1
	Matrix: Matrigel®
Passage Number	p12 These cells were cultured for 11 passages prior to freeze. WiCell adds +1 to the passage number at freeze to best represent the overall passage number of the cells at thaw. Plated cells at thaw should be labeled passage 12.
Date Vialied	13-April-2015
Vial Label	WC-24-02-DS-M p12 WB18754
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	See Report
	Results: 47,XX,+21[20] Interpretation: This is an abnormal karyotype. Twenty of twenty cells examined have an extra chromosome 21 (trisomy 21). No other abnormalities were found.			
Post-Thaw Viable Cell Recovery	WiCell	SOP-CH-305	≥ 15 Undifferentiated Colonies prior to passage, ≤ 30% Differentiation prior to passage, and recoverable attachment after passage	Pass
Identity by STR	UW Translational Research Initiatives in Pathology Laboratory	PowerPlex 16 HS System by Promega	Defines STR profile of deposited cell line	Pass
Sterility	Steris	ST/07	Negative	Pass
Mycoplasma	WiCell	SOP-QU-004	Negative	Pass

Approval Date	Quality Assurance Approval
30-July-2015	<div style="text-align: right;">8/27/2020</div>  <small>X JKG J.K.G. Quality Assurance Signed by: Gay, Jenna</small>

Date Reported: Monday, May 11, 2015
Cell Line: WC-24-02-DS-M-WB18754 11248
Passage#: 12
Date of Sample: 4/30/2015
Specimen: iPSC
Results: 47,XX,+21[20]

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



Cell: 10
Slide: 3
Slide Type: Karyotype
Total Counted: 20
Total Analyzed: 8
Total Karyotyped: 4
Band Resolution: 450 - 500

Interpretation:

This is an abnormal karyotype. Twenty of twenty cells examined have an extra chromosome 21 (trisomy 21). No other abnormalities were found.

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 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.

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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:

11248-STR
Sample Name on Tube: 11248-STR
145.7 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: 05/18/15
Assay Date: 05/19/15
File Name: 150520 STR JAM
Report Date: 06/01/15
revised 09/14/15

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 11248-STR cells submitted by WiCell QA dated and received on 05/18/15, this sample (Label on Tube: 11248-STR) defines the STR profile of the human stem cell line WC-24-02-DS-M comprising 28 allelic polymorphisms across the 15 STR loci analyzed.

Interpretation: No STR polymorphisms other than those corresponding to the human WC-24-02-DS-M stem cell line were detected however, allelic imbalance (denoted by ** in table above) was observed at the Penta_D loci and could be the result of chromosomal gains and/or losses in this cell line. While per definition allelic imbalance is not cited on the table above, the signal strength of allele 31 at the D21S11 loci is less evident than allele 30. This line is a clinical model for Trisomy 21, consequently imbalance makes sense with regards to Penta_D and D21S11 loci. 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 11248-STR sample submitted corresponds to the WC-24-02-DS-M 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 09/14/15

TRIP Laboratory, Molecular

X_{WMR} Digitally Signed on 09/14/15

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>
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Sterility Report

Biotest Laboratories, Inc.

Making life-saving products possible

WiCell Research Institute, Inc.
WiCell Quality Assurance
505 South Rosa Road, Suite 120
Madison, WI 53719

BIOTEST SAMPLE # 15071050
VALIDATION # NG
TEST PURPOSE NG

PRODUCT Zeng02i-iPSH14-WB19497 11328
WIC01i-02-1c-WB18031 11329
WIP06i-iPSCas9Het-WB18995 11330
WA01-WB16377 11331
MIN07i-33113.2D-WB19574 11332
MIN22i-33113.2I-WB19575 11333
MIN08i-33114.B-WB19546 11334
MIN09i-33114.C-WB19768 11335
MIN12i-33362.C-WB19545 11336
WC-24-02-DS-M-WB18754 1337

PRODUCT LOT	NA	BI LOT	NA
STERILE LOT	NA	BI EXPIRATION DATE	NA
STERILIZATION LOT	NA	DATE RECEIVED	2015-07-14
STERILIZATION DATE	NA	TEST INITIATED	2015-07-15
STERILIZATION METHOD	NA	TEST COMPLETED	2015-07-29
SAMPLING BLDG / ROOM	NA		

REFERENCE Processed according to LAB-003: Sterility Test Procedure

Ten (10) 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	10	NA	2 Negatives

COMMENTS NA

REVIEWED BY  DATE 29 JUL 15

Specific test results may not be indicative of the characteristics of any other samples from the same lot or similar lots. Liability is limited to the costs of the tests.

Biotest Laboratories ■ 9303 West Broadway Ave. ■ Brooklyn Park, MN 55445 ■ USA ■ (763) 315-1200

A subsidiary of STERIS Corporation





Mycoplasma Detection Assay Report

Testing Performed by WiCell

Lot Release Testing

04-27-2015

FORM SOP-QU-004.01

Version D Edition 01

Reported by: SS

Reviewed by: JB

Berthold Flash n' Glo 539

#	Sample Name	Reading A			Reading B			Ratio B/A	Result	Comments/Suggestions
		RLU1	RLU2	Ave	RLU1	RLU2	Ave			
1	WC-24-02-DS-M-WB18754-11248	169	177	173	63	57	60	0.35	Negative	
2	Positive (+) Control	261	260	260.5	6542	6533	6538	25.10	Positive	
3	Negative (-) Control	441	438	439.5	36	37	36.5	0.08	Negative	

