Product Information and Testing

Product Information

Product Name	WA01
Alias	H1
Lot Number	WB16217
Depositor	University of Wisconsin – Laboratory of Dr. James Thomson
Banked by	WiCell
Thaw Recommendation	Thaw 1 vial into 3 wells of a 6 well plate
Culture Platform	Feeder Independent Medium: mTeSR1 Matrix: Matrigel
Protocol	WiCell Feeder Independent Protocol
Passage Number	p23 These cells were cultured for 22 passages prior to freeze, 7 of them in mTeSR1/Matrigel. 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	12-December-2014
Vial Label	WA01 p23 WB16217
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 Translational Research Initiatives in Pathology Laboratory	PowerPlex 16 HS System by Promega	Consistent with known profile	Pass
Sterility	Biotest Laboratories	ST/07	Negative	Pass
Mycoplasma	WiCell	SOP-QU-004	Negative	Pass
Karyotype by G-banding	WiCell	SOP-CH-003	Expected karyotype	Pass

Date of Lot Release	Quality Assurance Approval
07-April-2015	4/7/2015 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:
11129-STR 34.1 ng/µL
(A260/280=1.78) ~2 million cells
Sample Name on Tube:
11129-STR
DNA Extracted by:
TRIP Lab

Requestor:
WiCell Research Institute
[redacted]

Sample Date: 02/27/15
Receive Date: 02/27/15
Assay Date: 03/03/15
File Name: 150318 test
Report Date: 03/19/15

STR Locus	STR Genotype Repeat #	11129-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	20,24
TPOX	6-13	8,11
D8S1179	7-18	12,13
vWA	10-22	15,17
Amelogenin	X,Y	X,Y
Penta_D	2.2, 3.2, 5, 7-17	10,13
CSF1PO	6-15	12,13
D16S539	5, 8-15	9,13
D7S820	6-14	8,12
D13S317	7-15	8,11
D5S818	7-16	9,11
Penta_E	5-24	10,12
D18S51	8-10, 10.2, 11-13, 13.2, 14-27	17,18
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	28,32.2
TH01	4-9,9.3,10-11,13.3	9.3,9.3
D3S1358	12-20	15,15

Comments: Based on the 11129-STR cells submitted by WiCell QA dated and received on 02/27/15, this sample (Label on Tube: 11129-STR) exactly matches the STR profile of the human stem cell line WA01 comprising 28 allelic polymorphisms across the 15 STR loci analyzed. No STR polymorphisms other than those corresponding to the human WA01 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 11129-STR sample submitted corresponds to the WA01 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] 3-19-15
TRIP Laboratory, Molecular — Date

[redacted] 03/19/15
Molecular Diagnostics Laboratory — Date

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

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

BIOTEST SAMPLE #	15011040
VALIDATION #	NG
TEST PURPOSE	NG

PRODUCT	WC007i-FX13-2-WB16523 11109 WC006i-FX11-9U-WB16522 11110 WC008i-C603-4-WB16524 11111 WC005i-FX11-7-WB16506 11112 WC-3801-2-WB16438 11113 UWWC1-DS2U-WB16352 11114 WA01-WB16217 11115 WIC03i-02-11E-WB15892 11116 IISH8i-GM07125-WB15718 11117 WC009i-FX08-01-WB16840 11118
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	2015-01-22
TEST INITIATED	2015-01-23
TEST COMPLETED	2015-02-06

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: [redacted] DATE: 06FEB15

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.
[redacted]

Mycoplasma Detection Assay Report

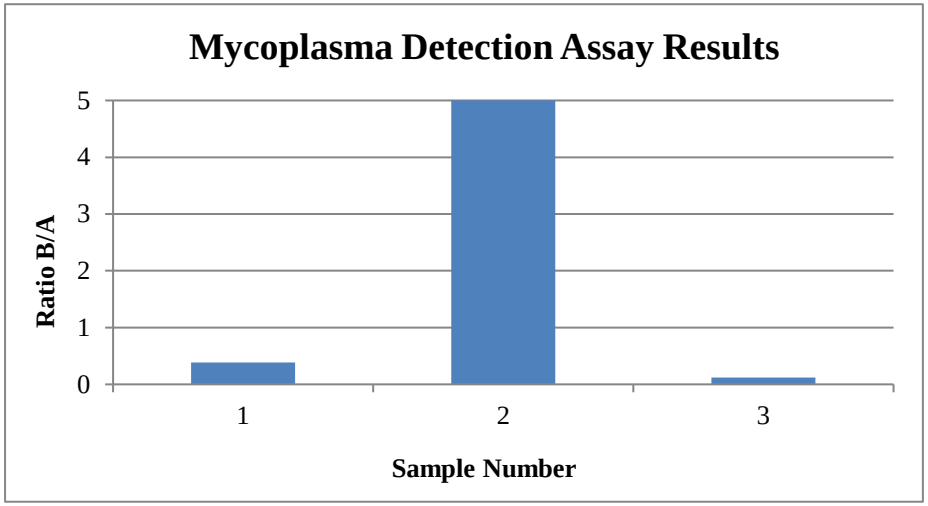
Testing Performed by WiCell

Lot Release Testing

02-13-2015

FORM SOP-QU-004.01
Version C Edition 01
Reported by: SS
Reviewed by: JB
Berthold Flash n' Glo 539

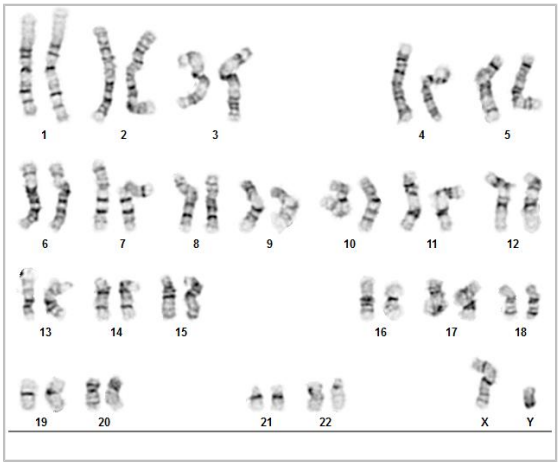
#	Sample Name	Reading A		A Ave	Reading B		B Ave	Ratio B/A	Result	Comments/Suggestions
		RLU1	RLU2		RLU1	RLU2				
1	WA01-WB16217, 11129	149	148	148.5	60	55	57.5	0.39	Negative	
2	Positive (+) Control	257	271	264	17153	17141	17147	64.95	Positive	
3	Negative (-) Control	488	499	493.5	59	59	59	0.12	Negative	



Chromosome Analysis Report: 017107

Date Reported: Monday, February 09, 2015
Cell Line: WA01-WB16217 11129
Passage#: 24
Date of Sample: 2/2/2015
Specimen: hESC
Results: 46,XY

Cell Line Gender: Male
Reason for Testing: Lot release testing
Investigator: [redacted], CDM



Cell: 30
Slide: 1
Slide Type: Karyotype

Total Counted: 20
Total Analyzed: 8
Total Karyotyped: 4
Band Resolution: 425 - 475

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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