




Thaw and Culture Details

Product Name	WC007i-FX13-2
Lot Number	WB16523
Depositor	University of Wisconsin – Laboratory of Dr. Anita Bhattacharyya
Banked by	WiCell
Thaw Recommendation	Thaw 1 vial into 1 well of a 6 well plate.
Culture Platform	Feeder Dependent
	Medium: hESC Medium (KOSR)
	Matrix: MEF
Protocol	WiCell Feeder Dependent Protocol
Passage Number	p16 These cells were cultured for 15 passages prior to freeze on MEF. 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 Viald	02-January-2015
Vial Label	WC007i-FX13-2 p16 WB16523
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

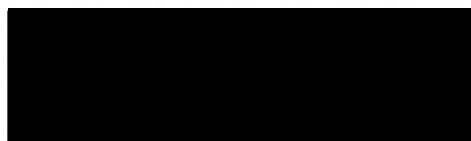
Test Description	Test Provider	Test Method	Test Specification	Result
Karyotype by G-banding	WiCell	SOP-CH-003	Expected karyotype	See Report
Post-Thaw Viable Cell Recovery	WiCell	SOP-CH-305	≥ 15 Undifferentiated Colonies, ≤ 30% Differentiation and recoverable attachment after passage	Pass
Identity by STR	UW Translational Research Initiatives in Pathology Laboratory	PowerPlex 16 HS System by Promega	Consistent with STR profile of donor material	Pass
Sterility	Steris	ST/07	Negative	Pass
Mycoplasma	WiCell	SOP-QU-004	Negative	Pass

Date of Lot Release	Quality Assurance Approval
07-April-2015	<div style="text-align: right;">11/15/2019</div> <div style="text-align: center;">  X JKG <small>JKG Quality Assurance Signed by: Gay, Jenna</small> </div>

Short Tandem Repeat Analysis*



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

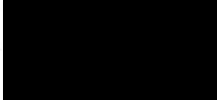


Samples Report:
 11104-STR 27.2 ng/μL
 (A260/280=1.89) ~2 million cells

Requestor:
 WiCell Research Institute

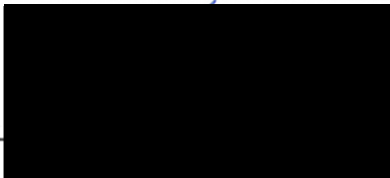
Sample Date: 02/27/15
Receive Date: 02/27/15
Assay Date: 03/03/15
File Name: 150318 test
Report Date: 03/19/15

Sample Name on Tube:
 11104-STR
DNA Extracted by:
 TRIP Lab



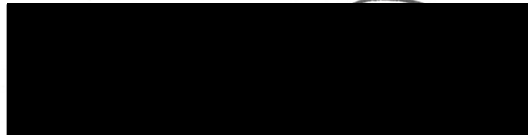
STR Locus	STR Genotype Repeat #	11104-STR
FGA	16-18,18.2,19,19.2,20,20.2,21,21.2,22, 22.2, 23, 23.2, 24, 24.2, 25, 25.2, 26-30, 31.2, 43.2, 44.2,45.2, 46.2	Identifying information has been redacted to protect donor confidentiality. If more information is required, please, contact WiCell's Technical Support .
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 11104-STR cells submitted by WiCell QA dated and received on 02/27/15, this sample (Label on Tube: 11104-STR) defines the STR profile of the human stem cell line WC007i-FX13-2 comprising 25 allelic polymorphisms across the 15 STR loci analyzed. No STR polymorphisms other than those corresponding to the human WC007i-FX13-2 stem cell line were detected however, allelic imbalance (denoted by ** in table above) was observed at the TH01 loci and could be the result of chromosomal gains and/or losses in this cell line. 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 11104-STR sample submitted corresponds to the WC007i-FX13-2 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%.



3-19-15
 Date

TRIP Laboratory, Molecular



03/19/15
 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

WiCell Research Institute, Inc.
WiCell Quality Assurance

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 _____ DATE 06 FEB 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.

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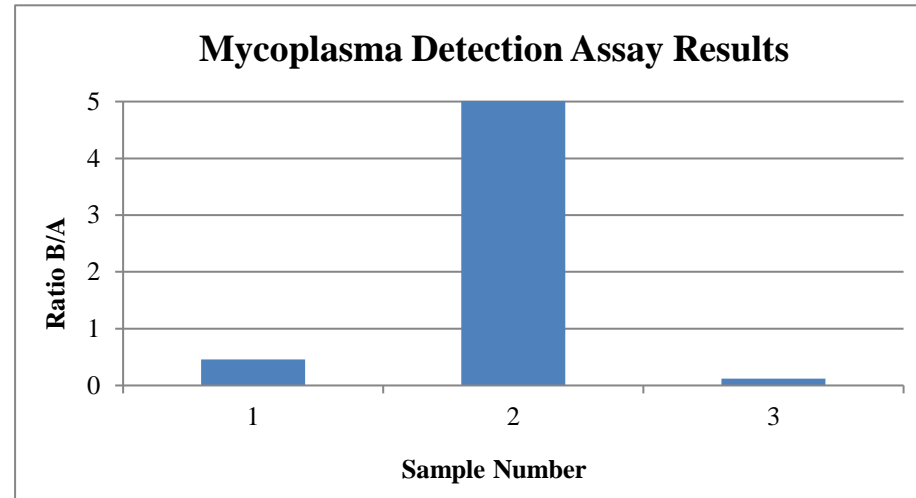


Mycoplasma Detection Assay Report

Testing Performed by WiCell
Lot Release Testing
01-16-2015

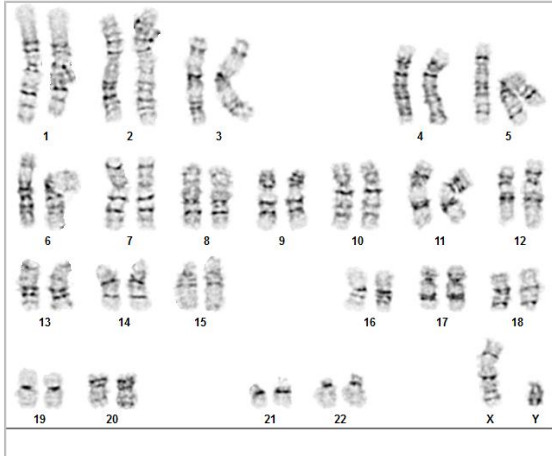
FORM SOP-QU-004.01
Version C Edition 01
Reported by: SS
Reviewed by: JB
Berthold Monolight 539

#	Sample Name	Reading A		A	Reading B		B Ave	Ratio B/A	Result	Comments/Suggestions
		RLU1	RLU2	Ave	RLU1	RLU2				
1	WC007i-FX13-2-WB16523 11104	155	156	155.5	72	71	71.5	0.46	Negative	
2	Positive (+) Control	192	193	192.5	12981	12930	12955.5	67.30	Positive	
3	Negative (-) Control	342	352	347	44	39	41.5	0.12	Negative	



Date Reported: Tuesday, April 07, 2015
Cell Line: WC007i-FX13-2-WB16523 11104
Passage#: 18
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: 26
Slide: 2
Slide Type: Karyotype

Total Counted: 20
Total Analyzed: 8
Total Karyotyped: 4
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], 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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