




## Product Information and Testing - Amended

### Product Information

Product Name	IISH1i-BM1
Lot Number	WB0179
Depositor	University of Wisconsin – Laboratory of Dr. Igor Slukvin
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	p10  These cells were cultured for 9 passages prior to freeze, at least 3 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 Viald	16-July-2012
Vial Label	WB0179 IISH1i-BM1 p10 DF 16JUL12
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	Consistent with known profile	Pass <sup>1</sup>
	<sup>1</sup> This test was the first STR performed for this cell line and therefore it establishes the STR identity for this cell line.			
Sterility - Direct transfer method	Apptec	30744	Negative	Pass
Mycoplasma	Bionique	M250	No contamination detected	Pass
Karyotype by G-banding	WiCell	SOP-CH-003	Normal karyotype	Pass

Date of Lot Release	Quality Assurance Approval
06-November-2012	<div style="text-align: right;">10/11/2016</div>  AMK Quality Assurance Signed by: Klade, Anjelica

# 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:**

11627-STR  
**Sample Name on Tube:** 11627-STR  
45.8 ng/μL, (A260/280=1.84)  
**Sample Type:** Cells  
**Cell Count:** ~2 million cells

**Requestor:**

WiCell Research Institute  
Quality Department

**Sample Date:** N/A

**Receive Date:** 05/19/16  
**Assay Date:** 05/24/16  
**File Name:** STR 160525 wmr  
**Report Date:** 06/02/16

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 <a href="#">WiCell's Technical Support</a> .
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 11627-STR cells submitted by WiCell QA dated and received on 05/19/16, this sample (Label on Tube: 11627-STR) exactly matches the STR profile of the human stem cell line IISH1i-BM1 comprising 25 allelic polymorphisms across the 15 STR loci analyzed.

**Interpretation:** No STR polymorphisms other than those corresponding to the human IISH1i-BM1 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 11627-STR sample submitted corresponds to the IISH1i-BM1 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<sub>RMB</sub>

Digitally Signed on 06/02/16

TRIP Laboratory, Molecular

X<sub>WMR</sub>

Digitally Signed on 06/02/16

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>

TRIP agrees to maintain the confidentiality of any information provided to it in connection with its performance of this STR analysis on the same conditions as set forth in paragraph 2 of WiCell's Terms and Conditions of Service (<http://www.wicell.org/media.acux/1a429b84-2b54-44a4-8ad8-5c05db93dd8a>).

## CORRECTED REPORT

WiCell Research Institute, Inc.  
WiCell Quality Assurance

BIOTEST SAMPLE # 16051350

VALIDATION # NG

TEST PURPOSE NG

PRODUCT WA43-WB32660 11659, WA38-WB32549 11656, WA47-WB32596 11658, WA46-WB32595 11657, WA35-WB32392 11654, WA40-WB32393 11660, WA32-WB32295 11652, WA37-WB32294 11655, WA41-WB33024 11661, WA30-WB32033 11651, WA33-WB32032 11653, RUES2-WB33127 11630, WA44-WB33154 11662, WC-52-01U-TG-1-WB33842 11675, WC-52-01U-TG-2-WB33843 11676, WC-52-01U-TG-3-WB33844 11677, iPS(IMR90)-4-WB33712 11663, MIN04i-33109.2B-WB33713 11664, WA14-WB33693 11665, MIN14i-33363.C-WB33622 11666, H9 hNanog-pGZ-WB33582 11667, H9 Cre-LoxP-WB33296 11668, NSC-H14iPSZeng-WB33374 11669, IISH2i-BM9-WB33257 11670, IISHi-BM1-WB33256 11671, WC-52-01A-TG-1-WB33850 11678, WC-52-01A-TG-2-WB33852 11679, WC-52-01A-TG-3-WB33853 11680, MIN03i-32642.B-WB33911 11672

PRODUCT LOT NA

STERILE LOT NA

BI LOT NA

STERILIZATION LOT NA

BI EXPIRATION DATE NA

STERILIZATION DATE NA

DATE RECEIVED 2016-05-19

STERILIZATION METHOD NA

TEST INITIATED 2016-05-20

SAMPLING BLDG / ROOM NA

TEST COMPLETED 2016-06-03

REFERENCE Processed according to LAB-003: Sterility Test Procedure

Twenty-nine (29) products were divided between 40 mL TSB and 40 mL FTG. The sample was then cultured at 20-25 C and 30-35 C respectively and was monitored for a minimum of 14 days.

- USP
- BI Manufacturers Specifications
- Other

RESULTS	# POSITIVES	# TESTED	POSITIVE CONTROL	NEGATIVE CONTROL
No Growth	0	29	NA	2 Negatives

COMMENTS Report revised due to updated product name.

REVIEWED BY \_\_\_\_\_ DATE 10/20/16

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

April 28th, 2016

FORM SOP-QU-004.01

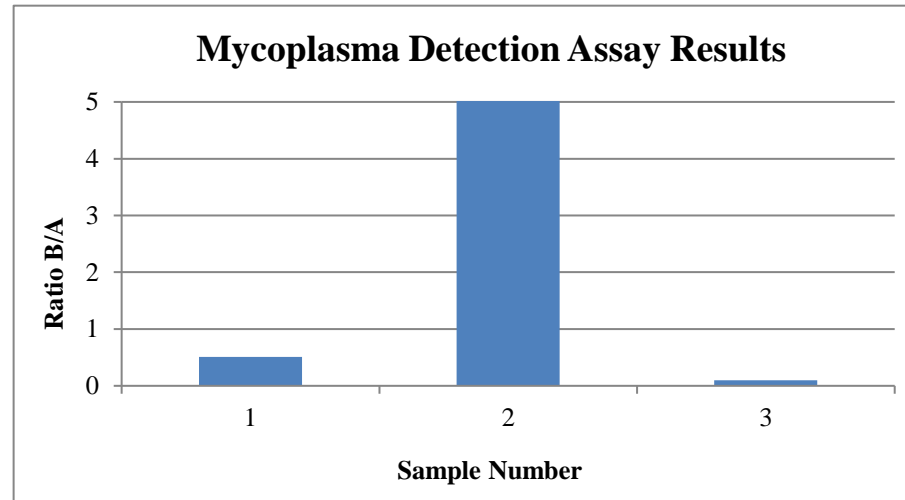
Version E Edition 01

Reported by: SS

Reviewed by: JB

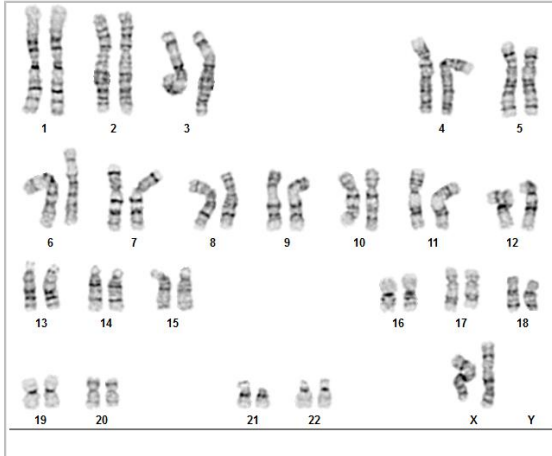
Berthold Flash n' Glo 539

#	Sample Name	Reading A			Reading B			Ratio B/A	Result	Comments/Suggestions
		RLU1	RLU2	Ave	RLU1	RLU2	Ave			
1	IISH1i-BM1-WB33256 11627	192	192	192	101	95	98	0.51	Negative	
2	Positive (+) Control	267	262	264.5	16713	16786	16750	63.33	Positive	
3	Negative (-) Control	424	421	422.5	39	43	41	0.10	Negative	



**Date Reported:** Friday, May 06, 2016  
**Cell Line:** IISH1i-BM1-WB33256 11627  
**Passage#:** 14  
**Date of Sample:** 5/4/2016  
**Specimen:** iPSC  
**Results:** 46,XX

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



**Cell:** 13  
**Slide:** 1  
**Slide Type:** Karyotype

**Total Counted:** 20  
**Total Analyzed:** 8  
**Total Karyogrammed:** 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 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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