

# ell Product Information and Testing

### **Product Information**

Product Name	IISH3i-CB6					
Lot Number	WB0269					
Parent Material	IISH3i-CB6-DB0005					
Depositor	University of Wisconsin – Laboratory of Dr. Igor Slukvin					
Banked by	WiCell					
Thaw Recommendation	Thaw 1 vial into 4 wells of a 6 well plate.					
Culture Platform	Feeder Independent					
	Medium: mTeSR1					
	Matrix: Matrigel					
Protocol	WiCell Feeder Independent Protocol					
Passage Number	p15					
	These cells were cultured for 14 passages prior to freeze, 2 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	29-October-2013					
Vial Label	IISH3i-CB6 WB0269 p15 29OCT2013					
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	Consistent with STR profile of deposited cell line	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		
	7/14/2020		
11-February-2014	X AA		
111 0514417 2011	AA Quality Assurance		
	Signed by: Arntz, Andy		





# Short Tandem Repeat Analysis\*

Sample Report: 10905-STR

Label on Tube: 10905-STR

Sample Date: 11/20/13

Lab Received 11/20/13

Requestor: WiCell Research Institute

Test Date: 11/27/13

File Name: 131127 BLB

Report Date: 11/29/13

Sample Name: (label on tube) 10905-STR

Description: WI Cell Research Institute provided

genomic DNA

245.2 ug/mL 260/280=1.88

Locus	Repeat #	STR Genotype
D16S539	5, 8-15	Identifying information
D7S820	6-14	has been redacted to
D13S317	7-15	protect donor
D5S818	7-15	confidentiality. If more information is
CSF1PO	6-15	required, please,
TPOX	6-13	contact WiCell's
Amelogenin	NA	Technical Support.
TH01	5-11	
vWA	11, 13-21	

Comments: Based on the 10905-STR DNA submitted by WI Cell dated 11/20/13 and received on 11/20/13, this sample (Label on Tube: 10905-STR) exactly matches the STR profile of the human stem cell line IISH3i-CB6 comprising 13 allelic polymorphisms across the 8 STR loci analyzed. No STR polymorphisms other than those corresponding to the human IISH3i-CB6 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 10905-STR DNA sample submitted corresponds to the IISH3i-CB6 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 ~5%.

12/2/13 Date

Molecular Diagnostics Laboratory

Molecular Diagnostics Laboratory

\* Testing to assess engraftment following bone marrow transplantation 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.

File: Final STR Report

## Sterility Report

# Biotest Laboratories, Inc.

Making life-saving products possible

WiCell Research Institute, WiCell Quality Assurance	Inc.		BIOTEST SAMPLE #	14011118
Wicell Addilly Assurance			VALIDATION #	NG
			TEST PURPOSE	NG
PRODUCT	Please see packing lis	t under prodi	uct name.	
PRODUCT LOT	NA			
STERILE LOT	NA		BI LOT	NA
STERILIZATION LOT	NA		BI EXPIRATION DATE	NA
STERILIZATION DATE	NA		DATE RECEIVED	2014-01-24
STERILIZATION METHOD	NA		TEST INITIATED	2014-01-27
SAMPLING BLDG / ROOM	NA		TEST COMPLETED	2014-02-10
REFERENCE	Processed according	to LAB-003: \$	Sterility Test Procedure	
	Ten (10) products wer were then cultured at minimum of 14 days.	e each divid 20-25 C and	ed between 40 mL TSB 30-35 C respectively o	and 40 mL FTG. The samples and were monitored for a
	□ USP     □ BI Manufacturers Sp     □ Other	ecifications		
RESULTS Sterile	# POSITIVES 0	# TESTED 10	POSITIVE CONTR NA	ROL NEGATIVE CONTROL 2 Negatives
COMMENTS NA				
REVIEWED BY			DATE	10FB14

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.





### WiCell Research Institute

Packing Slip



Sent to: Sterility Testing Services Biotest Labs, Sterility Testing Services Date: 22Jan14

Condition			
-80	(4)		
	-80		



### Mycoplasma Report

Testing Performed by WiCell LRT# 10905 11-22-2013

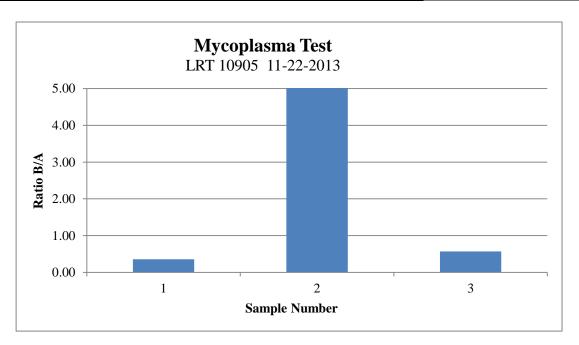
Version B Edition 01

Assay performed and reported by: MWS

Reviewed by: JB

Equipment: Berthold 1150

	Readi	ing A	Α	Read	ing B	В	Ratio		
Sample Number and ID	A1	A2	Average	B1	B2	Average	B/A	Mycoplasma Results	Comments/Suggestions
1 WB0269 #10905	231	232	231.5	88	78	83	0.36	Negative	
2 Positive (+) Control	246	247	246.5	21852	21876	21864	88.70	Positive	
3 Negative (-) Control	517	514	515.5	294	295	294.5	0.57	Negative	





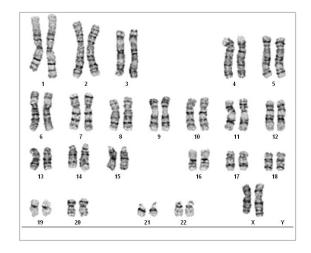
#### Chromosome Analysis Report: 012524

Date Reported: Tuesday, November 12, 2013 Cell Line Gender: Female
Cell Line: IISH3i-CB6-WB0269 10905 Reason for Testing: Lot release testing

Passage#: 15

Date of Sample: 11/4/2013

Specimen: iPSC Results: 46,XX



Reason for resulig. Lot release testing

Investigator: WiCell CDM

QC Review By:

Cell: 21 Slide: 2

Slide Type: Karyotype

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

Band Resolution: 400 - 500

#### Interpretation:

This is a normal karyotype. No clonal abnormalities were detected at the stated band level of resolution.

Completed by:	, CG(ASCP)
Reviewed and Interpreted by:	, PhD, FACMG

Sent By:

A signed copy of this report is available upon request.

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".

Sent To:

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.