

Product Information and Testing

Product Information

| Product Name | IISH2i-BM9 | | | | | |
|-------------------------------|--|--|--|--|--|--|
| Alias | ВМ9 | | | | | |
| Lot Number | WB0266 | | | | | |
| Parent Material | IISH2i-BM9-DB0006 | | | | | |
| 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 | p23 | | | | | |
| | These cells were cultured for 22 passages prior to freeze. 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 | 16-September-2013 | | | | | |
| Vial Label | IISH2i-BM9 WB0266 p23 16SEP13 LK | | | | | |
| 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

| <u> </u> | | | | | | | |
|--------------------------------|--|--------------------------------------|---|--------|--|--|--|
| 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 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 | | |
|---------------------|--|--|--|
| 19-November-2013 | AMC AMC Quality Assurance Signed by: | | |



Short Tandem Repeat Analysis*

Sample Report: 10886-STR

Label on Tube: 10886-STR

Sample Date: 10/16/13

Received Date: 10/16/13

Requestor: WiCell Research Institute

Test Date: 10/23/13

File Name: 131024 STR BLB

Report Date: 10/25/13

Sample Name: (label on tube) 10886-STR

Description: DNA Extracted by WiCell

 $217.2 \text{ ng/}\mu\text{L}$; 260/280 = 1.93

| 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 10886-STR DNA dated and received on 10/16/13 from WI Cell, this sample (Label on Tube: 10886-STR) matches exactly the STR profile of the human stem cell line IISH2i-BM9 comprising 14 allelic polymorphisms across the 8 STR loci analyzed. No STR polymorphisms other than those corresponding to the human IISH2i-BM9 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. These results suggest that the 10886-STR DNA sample submitted corresponds to the IISH2i-BM9 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%.

10/28/13 Date

Molecular Diagnostics Laboratory

10/25/13 Date

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, | Inc. | BIOTEST SAMPLE # | 13100572 | | |
|----------------------------|--|--------------------------|-------------------------------------|--|--|
| WiCell Quality Assurance | | VALIDATION # | NG | | |
| | | TEST PURPOSE | NG | | |
| PRODUCT | Please see packing list under prod | luct name. | | | |
| PRODUCT LOT | NA | | | | |
| STERILE LOT | NA | BI LOT | NA | | |
| STERILIZATION LOT | NA | BI EXPIRATION DATE | NA | | |
| STERILIZATION DATE | NA | DATE RECEIVED | 2013-10-10 | | |
| STERILIZATION METHOD | NA | TEST INITIATED | 2013-10-10 | | |
| SAMPLING BLDG / ROOM | NA | TEST COMPLETED | 2013-10-24 | | |
| 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 Sterile | # POSITIVES # TESTED 0 10 | POSITIVE CONTF NA | ROL NEGATIVE CONTROL 2 Negatives | | |
| COMMENTS NA | | | | | |
| REVIEWED BY | | DATE | 240CTI3 | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

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: 09Oct13

| Contents - Number of Vials | Condition | | |
|----------------------------|-----------|--|--|
| | -80 | | |
| IISH2i-BM9-WB0266 #10889 | | | |
| | A | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |



Mycoplasma Report

Testing Performed by WiCell LRT #10886 / LK 10-04-2013

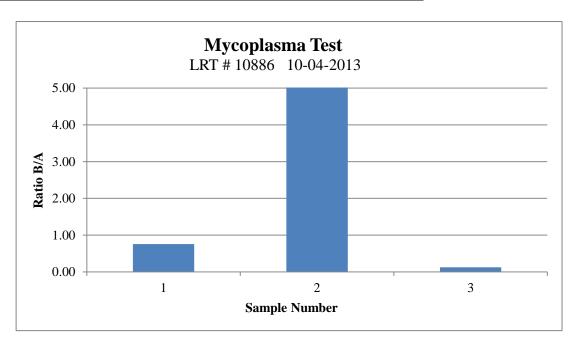
Version B Edition 01

Assay performed and reported by: MWS

Reviewed by: TL

Equipment used: Berthold #539

| | Reading A | | Α | Read | ing B | В | Ratio | | |
|------------------------|-----------|-----|---------|-------|-------|---------|-------|--------------------|----------------------|
| Sample Number and ID | A1 | A2 | Average | B1 | B2 | Average | B/A | Mycoplasma Results | Comments/Suggestions |
| 1 LK LRT#10886 | 135 | 128 | 131.5 | 110 | 89 | 99.5 | 0.76 | Negative | |
| 2 Positive (+) Control | 244 | 245 | 244.5 | 20694 | 20811 | 20752.5 | 84.88 | Positive | |
| 3 Negative (-) Control | 428 | 424 | 426 | 57 | 50 | 53.5 | 0.13 | Negative | |





Chromosome Analysis Report: 012176

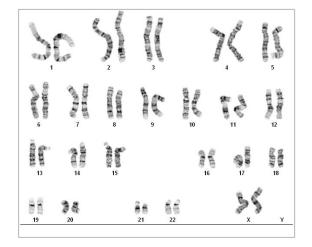
Date Reported: Monday, October 14, 2013

Cell Line: IISH2i-BM9-WB0266 10886

Passage#: 24

Date of Sample: 9/30/2013

Specimen: iPSC Results: 46,XX



Cell Line Gender: Female

Reason for Testing: lot release testing

Investigator:

CDM

Cell: 43

Slide: 4

Slide Type: Karyotype

Total Counted: 20
Total Analyzed: 9
Total Karyotyped: 4

Band Resolution: 450 - 550

Interpretation:

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

Completed by: rd, CG(ASCP)

Interpreted by: PhD, FACMG

Reviewed and Interpreted by:

A signed copy of this report is available upon request.

Date:_____ Sent By:____ Sent To:_____ QC Review By: _____ imitations: This assay allows for microscopic visualization of numerical and structural chromosome abnormalities. The size of structural abnormality that can be dis

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.