




Product Information and Testing

Product Information

Product Name	MIRJT7i-mND2-0
Alias	mND2-0
Lot Number	WB0248
Parent Material	MIRJT7i-mND2-0-WB0119
Depositor	Morgridge Institute for Research – Laboratory of Dr. James Thomson
Banked by	WiCell
Thaw Recommendation	Thaw 1 vial into 1 well of a 6 well plate. WiCell recommends thawing using ROCK Inhibitor for best results.
Culture Platform	Feeder Independent
	Medium: E8 – WiCell recommends to passage using ROCK Inhibitor for best results.
	Matrix: Matrigel
Protocol	WiCell Feeder Independent E8 Medium Protocol
Passage Number	p28 These cells were cultured for 27 passages prior to freeze, at least 7 passages in E8/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	20-May-2013
Vial Label	WB0248 MIRJT7i-mND2-0 P28 LK 20MAY13
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 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
15-July-2013	<div style="text-align: right; font-size: small;">1/25/2019</div> <div style="text-align: center;">  X_{RK} <small>RK Quality Assurance Signed by: Kremers, Erik</small> </div>

Short Tandem Repeat Analysis*

Sample Report: 10798-STR

Label on Tube: 10798-STR

Sample Date: 06/24/13

Lab Received 06/24/13

Requestor: WiCell Research Institute

Test Date: 06/26/13

File Name: 130627 BLB

Report Date: 07/01/13

Sample Name: (label on tube) 10798-STR

Description: WI Cell Research Institute provided
genomic DNA
232.75 ug/mL 260/280=1.97

Locus	Repeat #	STR Genotype
D16S539	5, 8-15	
D7S820	6-14	
D13S317	7-15	
D5S818	7-15	
CSF1PO	6-15	
TPOX	6-13	
Amelogenin	NA	
TH01	5-11	
vWA	11, 13-21	

Comments: Based on the 10798-STR DNA submitted by WI Cell dated and received on 06/24/13, this sample (Label on Tube: 10798-STR) exactly matches the STR profile of the human stem cell line MIRJT7i-mND2-0 comprising 15 allelic polymorphisms across the 8 STR loci analyzed. No STR polymorphisms other than those corresponding to the human stem cell line MIRJT7i-mND2-0 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 10798-STR DNA sample submitted corresponds to the MIRJT7i-mND2-0 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%.

[Redacted Signature]

7/1/13

Date

Molecular Diagnostics Laboratory

[Redacted Signature]

07/01/13
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.

Sterility Report

Biotest Laboratories, Inc.

Making life-saving products possible

WiCell Research Institute, Inc.
WiCell Quality Assurance

BIOTEST SAMPLE # 13060494

VALIDATION # NG

TEST PURPOSE NG

PRODUCT Please see packing list under product name.

PRODUCT LOT NA

STERILE LOT NA

BI LOT NA

STERILIZATION LOT NA

BI EXPIRATION DATE NA

STERILIZATION DATE NA

DATE RECEIVED 2013-06-11

STERILIZATION METHOD NA

TEST INITIATED 2013-06-12

SAMPLING BLDG / ROOM NA

TEST COMPLETED 2013-06-26

REFERENCE Processed according to LAB-003: Sterility Test Procedure

5 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	5	NA	2 Negatives

COMMENTS NA

REVIEWED BY

DATE

26 JUN 13

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

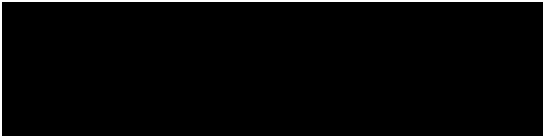
A subsidiary of STERIS Corporation





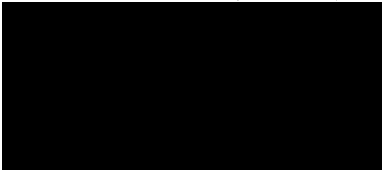
WiCell Research Institute


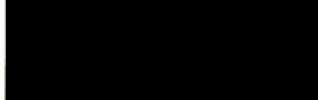
Packing Slip



Sent to:
Sterility Testing Services
BiotestLabs, Sterility Testing Services

Date:
05Jun13



Product Name	Condition
 MIRJT7i-mND2-0-WB0248 #10787 	-80

13060494 *SK*
JUN 12 2013





Mycoplasma Report

Testing Performed by WiCell

Mycoplasma LRT/CDM Lab 6-21-2013

FORM SOP-QU-004.01

Version B

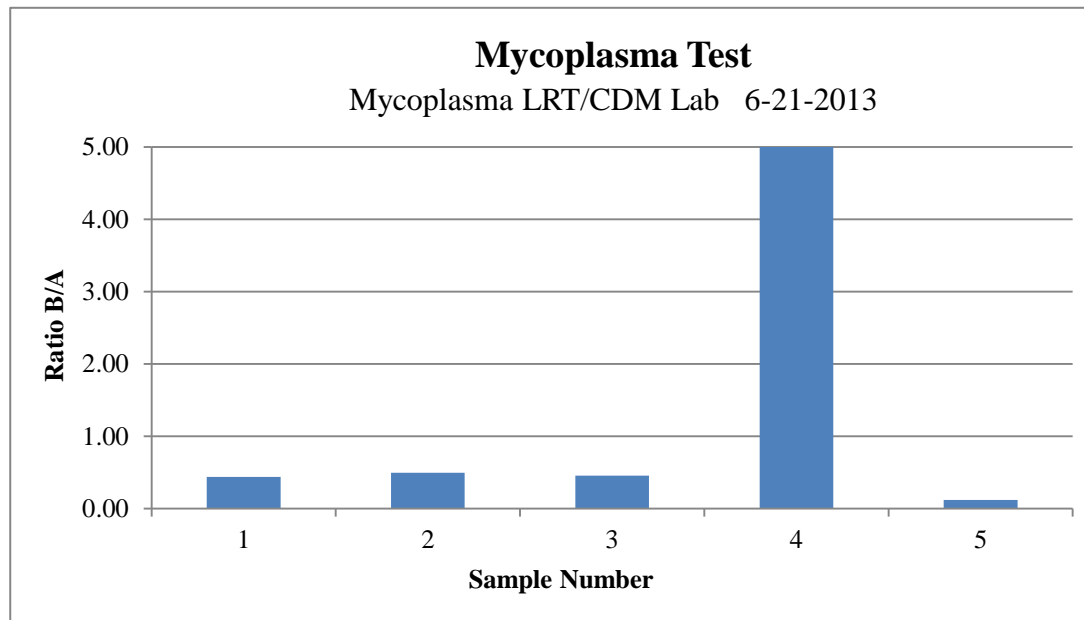
Edition 01

Assay performed and reported by: MWS

Reviewed by: JB

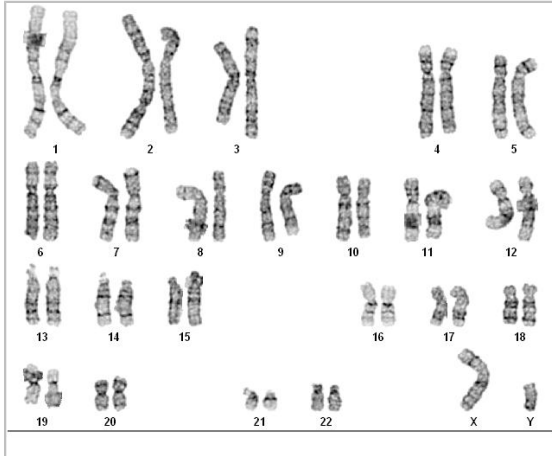
Equipment: Monolight 3010

Sample Number and ID	Reading A		A Average	Reading B		B Average	Ratio B/A	Mycoplasma Results	Comments/Suggestions
	A1	A2		B1	B2				
1 10798 LK	398	385	391.5	169	173	171	0.44	Negative	
2 10802 LK	454	457	455.5	228	223	225.5	0.50	Negative	
3 10800 MWS	561	561	561	253	259	256	0.46	Negative	
4 Positive (+) Control	504	508	506	40286	41560	40923	80.88	Positive	
5 Negative (-) Control	1133	1169	1151	145	134	139.5	0.12	Negative	



Date Reported: Friday, June 28, 2013
Cell Line: MIRJT7i-mND2-0-WB0248 10798
Passage#: 30
Date of Sample: 6/21/2013
Specimen: iPSC
Results: 46,XY

Cell Line Gender: Male
Reason for Testing: lot release testing
Investigator: [REDACTED] WiCell CDM



Cell: 32
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: [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.