



Cell Line Information and Testing – Material Produced by Provider

Cell Line Characteristics

This table contains general information regarding the cell line.

Cell Line Name	MIN13i-33362.D
Cell Line Alias	MIN33362 D
Cell Type	Induced Pluripotent Stem Cell
Phenotype	Control
Sex	Male
Age at Collection	18 years
Reprogramming Method	Sendai Virus
Tissue Origin	Skin Fibroblast
Provider	Massachusetts General Hospital

Lot Specific Information

The following culture information is for the specified lot.

WiCell Lot Number	WB19561
Banked By	WiCell
Thaw Recommendation	WiCell recommends thawing 1 vial into 3 wells of a 6 well plate.
Culture Platform	Feeder Independent Medium: mTeSR1 Matrix: Matrigel
Protocol	WiCell Feeder Independent mTeSR1 Protocol
Passage Number	p17 These cells were cultured for 16 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 Vialled	15-May-2015
Vial Label	MIN13i-33362.D p17 WB19561
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.



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Testing Reported by Provider

Test Description & Method	Result
Genetic Analysis by Karyotype	Normal
Embryoid Body Formation	RT(q)PCR (Brachyury, GATA2 - Meso; AFP, Sox17 - Endo; Pax6, MAP2 - Ectoderm)
Teratoma	No Teratoma Formed
Pluripotency Markers; AP, Oct4, Nanog, SSEA-3, SSEA-4, TRA1-60	All Markers Expressed

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 Translational Research Initiatives in Pathology 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 Available	Quality Assurance Approval
09-October-2015	5/2/2016 X AMK AMK Quality Assurance Signed by: [REDACTED]

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:

11582-STR
Sample Name on Tube: 11582-STR
88.0 ng/μL, (A260/280=1.83)
Sample Type: Cells
Cell Count: ~2 million cells

Requestor:

WiCell Research Institute
Quality Department

Sample Date: N/A

Receive Date: 03/30/16
Assay Date: 04/05/16
File Name: 160407 STR JAM
Report Date: 04/1/16

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 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	

Results: Based on the 11582-STR cells submitted by WiCell QA dated and received on 03/30/16, this sample (Label on Tube: 11582-STR) defines the STR profile of the human stem cell line MIN13i-33362.D comprising 26 allelic polymorphisms across the 15 STR loci analyzed.

Interpretation: No STR polymorphisms other than those corresponding to the human MIN13i-33362.D 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 11582-STR sample submitted corresponds to the MIN13i-33362.D 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 *RMB*
Digitally Signed on 04/11/16

TRIP Laboratory, Molecular

X *WMR*
Digitally Signed on 04/11/16

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>).

Sterility Report

Biotest Laboratories, Inc.

Making life-saving products possible

WiCell Research Institute, Inc.
WiCell Quality Assurance

BIOTEST SAMPLE # 15111558

VALIDATION # NG

TEST PURPOSE NG

PRODUCT WA28-WB25835 11480, WA31-WB25836 11481, WA36-WB25808 11482
WA39-WB26020 11483, WA42-WB25838 11484, WA45-WB25712 11485
MIN10i-33360.A-WB20014 11486, MIN11i-33360.B-WB20012 11487
MIN13i-33362.D-WB19561 11488, MIN18i-33811.A-WB20022 11489

PRODUCT LOT NA

STERILE LOT NA

BI LOT NA

STERILIZATION LOT NA

BI EXPIRATION DATE NA

STERILIZATION DATE NA

DATE RECEIVED 2015-11-18

STERILIZATION METHOD NA

TEST INITIATED 2015-11-25

SAMPLING BLDG / ROOM NA

TEST COMPLETED 2015-12-09

REFERENCE Processed according to LAB-003: Sterility Test Procedure

Ten (10) products were each cultured in 40 mL TSB at 20-25 C and 10 products were each cultured in 40 mL FTG at 30-35 C and 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

09 DEC 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.

Biotest Laboratories ■ 9303 West Broadway Ave. ■ Brooklyn Park, MN 55445 ■ USA ■ (763) 315-1200

A subsidiary of STERIS Corporation

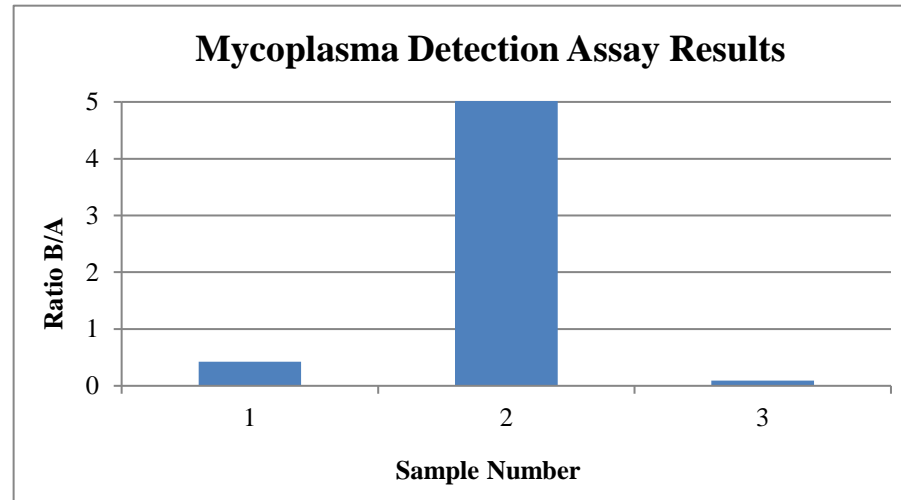


Mycoplasma Detection Assay Report

Testing Performed by WiCell
Lot Release Testing
March 17th, 2016

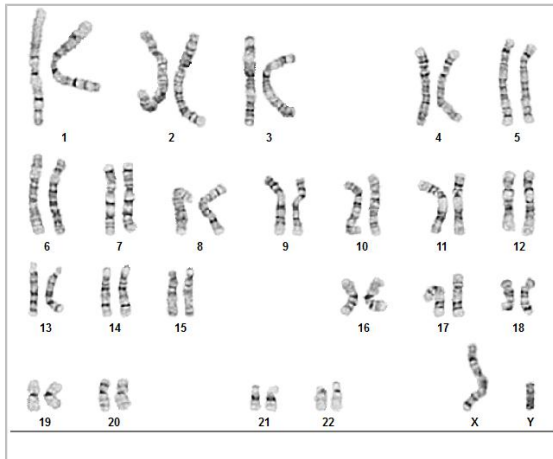
FORM SOP-QU-004.01
Version E Edition 01
Reported by: SS
Reviewed by: JB
Berthold Flash n' Glo 539

#	Sample Name	Reading A			Reading B			Ratio B/A	Result	Comments/Suggestions
		RLU1	RLU2	Ave	RLU1	RLU2	Ave			
1	MIN13i-33362.D-WB19561 11582	72	63	67.5	28	29	28.5	0.42	Negative	
2	Positive (+) Control	96	97	96.5	9977	9990	9984	103.46	Positive	
3	Negative (-) Control	214	216	215	20	20	20	0.09	Negative	



Date Reported: Wednesday, March 23, 2016
Cell Line: MIN13i-33362.D-WB19561 11582
Passage#: 17
Date of Sample: 3/18/2016
Specimen: iPSC
Results: 46,XY

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



Cell: 29
Slide: 1
Slide Type: Karyotype
Total Counted: 20
Total Analyzed: 8
Total Karyogrammed: 4
Band Resolution: 450 - 525

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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