

Product Information and Testing
for
Material Produced by Depositor

Product Information

Product Name	RUES1	
WiCell Lot Number	DB17210	
Depositor	The Rockefeller University - Laboratory of Dr. Ali Brivanlou	
Banked by	The Rockefeller University - Laboratory of Dr. Ali Brivanlou	
Culture Platform	<u>Culture Platform Prior to Freeze</u> Medium: Conditioned Medium Matrix: Laminin-521	<u>Thaw Recommendation</u> Medium: mTeSR1 Matrix: Matrigel Thaw 1 vial into 2 wells of a 6 well plate.
Protocol	WiCell recommends using our WiCell Feeder Independent mTeSR1 Protocol when thawing these cells. The protocol provided by the depositor is available upon request.	
Passage Number	p25 These cells were cultured for 24 passages prior to freeze, 4 of them in Conditioned Medium/Laminin-521. The Depositor 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 Vialied	22-January-2015	
Vial Label	R1 p25	
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 Reported by Depositor

Test Description	Result	Report
Karyotype	No abnormalities	See publication
Teratoma	3 germ layers	See publication
Embryoid Bodies	3 germ layers	See publication
Oct 3/4	Present	See publication
SSEA4	Present	See publication
Tra-1-60	Present	See publication

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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	Defines 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
29-May-2015	7/27/2015 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:

11282-STR
Sample Name on Tube: 11282-STR
160.2 ng/μL, (A260/280=1.93)
Sample Type: Cells
Cell Count: ~2 million cells

Requestor:

WiCell Research Institute
Quality Department

Sample Date: N/A

Receive Date: 05/22/15
Assay Date: 05/26/15
File Name: 150528 STR JAM
Report Date: 06/02/15

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	20,20
TPOX	6-13	8,11
D8S1179	7-18	14,15
vWA	10-22	14,17
Amelogenin	X,Y	X,Y
Penta_D	2.2, 3.2, 5, 7-17	12,13
CSF1PO	6-15	12,12
D16S539	5, 8-15	11,12
D7S820	6-14	11,12
D13S317	7-15	9,12
D5S818	7-16	9,13
Penta_E	5-24	5,16
D18S51	8-10, 10.2, 11-13, 13.2, 14-27	14,15
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	29,33.2
TH01	4-9,9.3,10-11,13.3	6,9.3
D3S1358	12-20	16,17

Results: Based on the 11282-STR cells submitted by WiCell QA dated and received on 05/22/15, this sample (Label on Tube: 11282-STR) defines the STR profile of the human stem cell line RUES1 comprising 28 allelic polymorphisms across the 15 STR loci analyzed.

Interpretation: No STR polymorphisms other than those corresponding to the human RUES1 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 11282-STR sample submitted corresponds to the RUES1 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 06/02/15

TRIP Laboratory, Molecular

X *WMR*

Digitally Signed on 06/02/15

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>
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Sterility Report

Biotest Laboratories, Inc.

Making life-saving products possible

WiCell Research Institute, Inc.
WiCell Quality Assurance
505 South Rosa Road, Suite 120
Madison, WI 53719

BIOTEST SAMPLE # 15040038

VALIDATION # NG

TEST PURPOSE NG

PRODUCT UWWC1-2DS3-WB17713 11202
WIC01i-02-1c-WB17715 11203
UWWC1-DS1-WB17810 11204
UWWC1-DS2U-WB17714 11205
WC-3801-2-WB17984 11206
WC006i-FX11-9U-WB18069 11207
WC-3902-10-RS-WB16861 11208
WC-3902-08-RS-WB17010 11209
RUES2-DB17752 11210
RUES1-DB17210 11211

RUES2-DB17752 is labeled as R2 p23 11.30.14

RUES1-DB17210 is labeled as R1 p25.

PRODUCT LOT NA

STERILE LOT NA

BI LOT NA

STERILIZATION LOT NA

BI EXPIRATION DATE NA

STERILIZATION DATE NA

DATE RECEIVED 2015-04-01

STERILIZATION METHOD NA

TEST INITIATED 2015-04-02

SAMPLING BLDG / ROOM NA

TEST COMPLETED 2015-04-16

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
0

TESTED
10

POSITIVE CONTROL
NA

NEGATIVE CONTROL
2 Negatives

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.

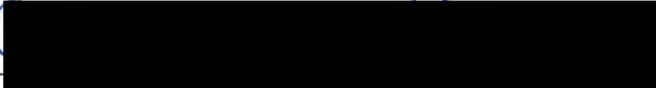
Biotest Laboratories ■ 9303 West Broadway Ave. ■ Brooklyn Park, MN 55445 ■ USA ■ (763) 315-1200

A subsidiary of STERIS Corporation

BIOTEST SAMPLE # 15040038

COMMENTS NA

REVIEWED BY



DATE

16 APR 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

Form: M-002 rev. 11
Effective:

A subsidiary of STERIS Corporation





Mycoplasma Detection Assay Report

Testing Performed by WiCell

Lot Release Test

05-22-2015

FORM SOP-QU-004.01

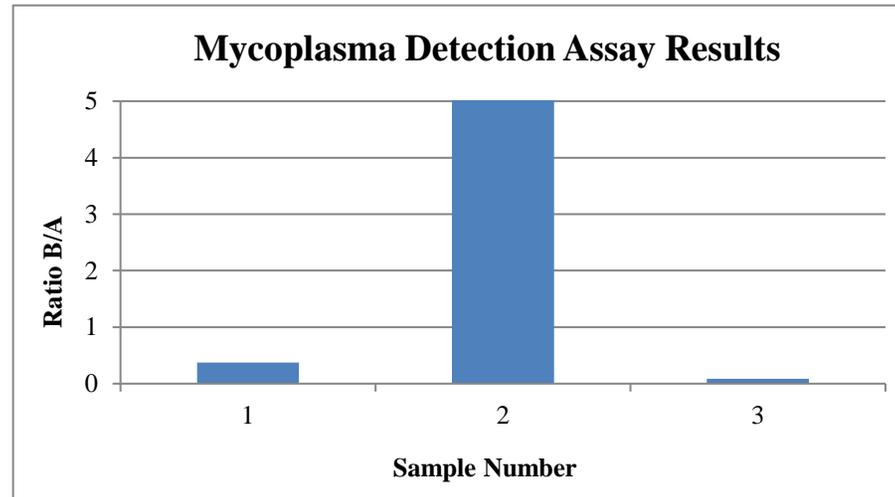
Version D Edition 01

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	RUES1-DB17210 11282	150	158	154	60	55	57.5	0.37	Negative	
2	Positive (+) Control	309	303	306	9453	9385	9419	30.78	Positive	
3	Negative (-) Control	544	541	542.5	48	46	47	0.09	Negative	



Date Reported: Friday, May 22, 2015

Cell Line: RUES1-DB17210 11282

Passage#: 26

Date of Sample: 5/20/2015

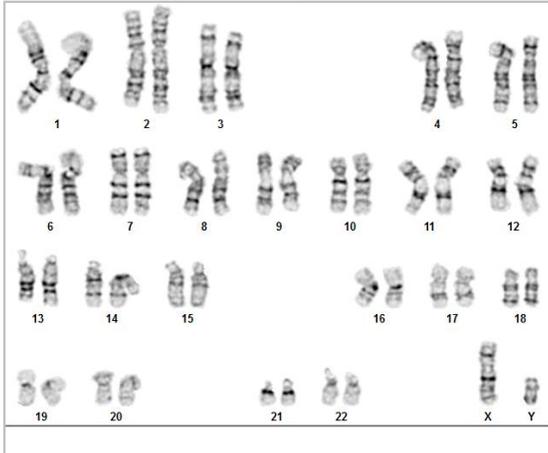
Specimen: hESC

Results: 46,XY

Cell Line Gender: Male

Reason for Testing: Lot release testing

Investigator: [REDACTED], WiCell CDM



Cell: 48

Slide: 1

Slide Type: Karyotype

Total Counted: 20

Total Analyzed: 8

Total Karyotyped: 4

Band Resolution: 450 - 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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