



## Product Information and Testing

### Product Information

Product Name	WA01
Alias	H1
Lot Number	RB18522
Depositor	WiCell
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	p32  These cells were cultured for 31 passages prior to freeze, at least 3 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 Vialied	07-April-2015
Vial Label	PACT-ESC-WA01 p32 RB18522
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 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 of Lot Release	Quality Assurance Approval
28-May-2015	<div>9/14/2015</div> <div>X AMK</div> <div>AMK Quality Assurance Signed by [REDACTED]</div>

# Short Tandem Repeat Analysis

Department of Pathology and Laboratory Medicine  
TRIP Laboratory (Molecular)  
<http://www.pathology.wisc.edu/research/trip>

**Sample Report:**

11229-STR

**Sample Name on Tube:** 11229-STR

95.4 ng/μL, (A260/280=1.96)

**Sample Type:** Cells

**Cell Count:** ~2 million cells

**Requestor:**

WiCell Research Institute

Quality Department

**Sample Date:** N/A

**Receive Date:** 05/04/15

**Assay Date:** 05/05/15

**File Name:** 150507 str jam

**Report Date:** 05/12/15

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	20,24
TPOX	6-13	8,11
D8S1179	7-18	12,13
vWA	10-22	15,17
Amelogenin	X,Y	X,Y
Penta_D	2.2, 3.2, 5, 7-17	10,13
CSF1PO	6-15	12,13
D16S539	5, 8-15	9,13
D7S820	6-14	8,12
D13S317	7-15	8,11
D5S818	7-16	9,11
Penta_E	5-24	10,12
D18S51	8-10, 10.2, 11-13, 13.2, 14-27	17,18
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	28,32.2
TH01	4-9,9.3,10-11,13.3	9.3,9.3
D3S1358	12-20	15,15

**Results:** Based on the 11229-STR cells submitted by WiCell QA dated and received on 05/04/15, this sample (Label on Tube: 11229-STR) exactly matches the STR profile of the human stem cell line WA01 comprising 28 allelic polymorphisms across the 15 STR loci analyzed.

**Interpretation:** No STR polymorphisms other than those corresponding to the human WA01 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 11229-STR sample submitted corresponds to the WA01 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<sub>RMB</sub>

Digitally Signed on 05/12/15

TRIP Laboratory, Molecular

X<sub>WMR</sub>

Digitally Signed on 05/12/15

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

BIOTEST SAMPLE # 15050336

VALIDATION # NG

TEST PURPOSE NG

PRODUCT  
WIP05i-iPSCas9KO-WB17902 11253  
RUES3-DB18144 11255  
WC005i-FX11-7-WB18030 11256  
WIC02i-02-05-WB18279 11257  
PACT-ESC-WA01-RB18519 11258  
PACT-ESC-WA01-RB18522 11259  
WIP07e-H9Cas9Het-WB18521 11260  
WIP06i-iPSCas9Het-WB18520 11261  
UWWC1-DS4-WB18225 11262  
UWWC1-2DS3-WB18532 11263  
WC-24-02-DS-C-WB18862 11264  
WC-24-02-DS-B-WB18712 11265  
WC-24-02-DS-M-WB18754 11266  
UWWC1-DS2U-WB19012 11267  
WIC07i-07982-4-WB18972 11268  
WC-24-02-DS-P-WB18907 11269  
WC-24-02-DS-A-WB18711 11270  
WC-24-02-DS-O-WB19180 11271  
WC-3801-5-WB16647 11272

PRODUCT LOT NA

STERILE LOT NA

STERILIZATION LOT NA

STERILIZATION DATE NA

STERILIZATION METHOD NA

SAMPLING BLDG / ROOM NA

BI LOT NA

BI EXPIRATION DATE NA

DATE RECEIVED 2015-05-06

TEST INITIATED 2015-05-07

TEST COMPLETED 2015-05-21

REFERENCE Processed according to LAB-003: Sterility Test Procedure

Nineteen (19) 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

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

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BIOTEST SAMPLE # 15050336

RESULTS	# POSITIVES	# TESTED	POSITIVE CONTROL	NEGATIVE CONTROL
Non-Sterile	1	19	NA	2 Negatives

COMMENTS One (1) sample labeled as WC-24-02-DS-M-WB18754 11266 had growth in FTG.

REVIEWED BY



DATE

26 MAR 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.

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Form: M-002 rev. 11  
Effective:

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# Mycoplasma Detection Assay Report

Testing Performed by WiCell

Lot Release Testing

04-17-2015

FORM SOP-QU-004.01

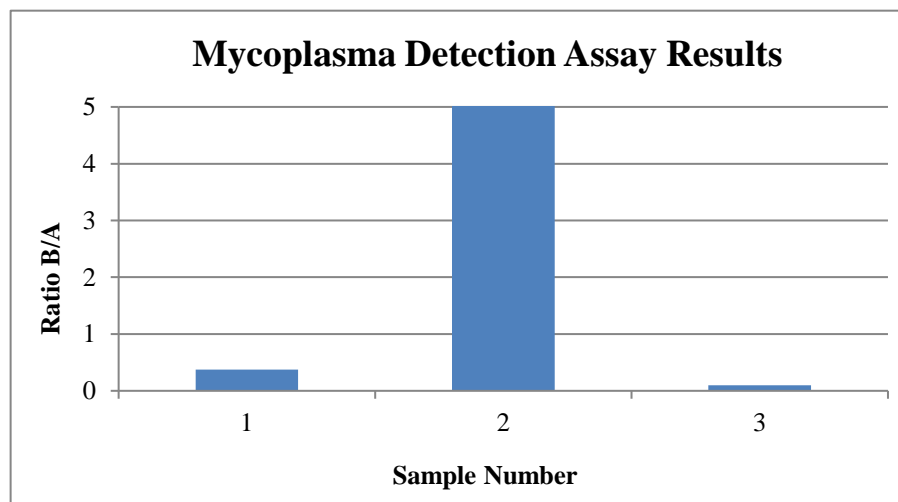
Version D Edition 01

Reported by: SS

Reviewed by: JB

Berthold Flash n' Glo 539

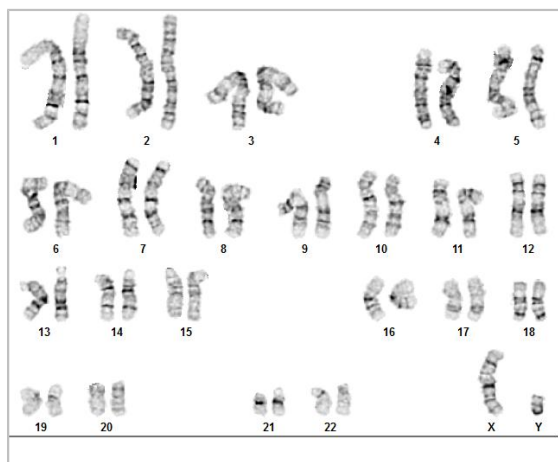
#	Sample Name	Reading A		A Ave	Reading B		B Ave	Ratio B/A	Result	Comments/Suggestions
		RLU1	RLU2		RLU1	RLU2				
1	PACT-ESC-WA01 RB18522 11229	166	162	164	58	64	61	0.37	Negative	
2	Positive (+) Control	262	270	266	9695	9762	9729	36.57	Positive	
3	Negative (-) Control	452	442	447	45	42	43.5	0.10	Negative	



**Date Reported:** Monday, April 27, 2015  
**Cell Line:** PACT-ESC-WA01-RB18522 11229  
**Passage#:** 33  
**Date of Sample:** 4/17/2015  
**Specimen:** hESC  
**Results:** 46,XY

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

**Nonclonal finding: 47,XY,+6**



**Cell:** 16  
**Slide:** 1  
**Slide Type:** Karyotype

**Total Counted:** 20  
**Total Analyzed:** 8  
**Total Karyotyped:** 4  
**Band Resolution:** 425 - 450

## Interpretation:

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

**There is one nonclonal finding, listed above. Nonclonal findings likely result from technical artifact, but may be due to a developing clonal abnormality or to low-level mosaicism.**

**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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# Short Tandem Repeat Analysis

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TRIP Laboratory (Molecular)  
<http://www.pathology.wisc.edu/research/trip>

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11229-STR  
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95.4 ng/μL, (A260/280=1.96)  
**Sample Type:** Cells  
**Cell Count:** ~2 million cells

**Requestor:**

WiCell Research Institute  
Quality Department

**Sample Date:** N/A

**Receive Date:** 05/04/15  
**Assay Date:** 05/05/15  
**File Name:** 150507 str jam  
**Report Date:** 05/12/15

STR Locus	STR Genotype Repeat #	STR Genotype
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TPOX	6-13	8,11
D8S1179	7-18	12,13
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**Sensitivity:** Sensitivity limits for detection of STR polymorphisms unique to either this or other human stem cell lines is ~2-5%.

X<sub>RMB</sub>

Digitally Signed on 05/12/15

Rebecca M. Baus  
TRIP Laboratory, Molecular

X<sub>WMR</sub>

Digitally Signed on 05/12/15

William M. Rehrauer, 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.

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# Sterility Report

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*Making life-saving products possible*

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

BIOTEST SAMPLE # 15050336

VALIDATION # NG

TEST PURPOSE NG

PRODUCT WIP05i-iPSCas9KO-WB17902 11253  
RUES3-DB18144 11255  
WC005i-FX11-7-WB18030 11256  
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WC-24-02-DS-A-WB18711 11270  
WC-24-02-DS-O-WB19180 11271  
WC-3801-5-WB16647 11272

PRODUCT LOT NA

STERILE LOT NA

STERILIZATION LOT NA

STERILIZATION DATE NA

STERILIZATION METHOD NA

SAMPLING BLDG / ROOM NA

BI LOT NA

BI EXPIRATION DATE NA

DATE RECEIVED 2015-05-06

TEST INITIATED 2015-05-07

TEST COMPLETED 2015-05-21

REFERENCE Processed according to LAB-003: Sterility Test Procedure

Nineteen (19) 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

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BIOTEST SAMPLE # 15050336

RESULTS	# POSITIVES	# TESTED	POSITIVE CONTROL	NEGATIVE CONTROL
Non-Sterile	1	19	NA	2 Negatives

COMMENTS One (1) sample labeled as WC-24-02-DS-M-WB18754 11266 had growth in FTG.

REVIEWED BY



DATE

26 MAR 15

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Effective:

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# Mycoplasma Detection Assay Report

Testing Performed by WiCell

Lot Release Testing

04-17-2015

FORM SOP-QU-004.01

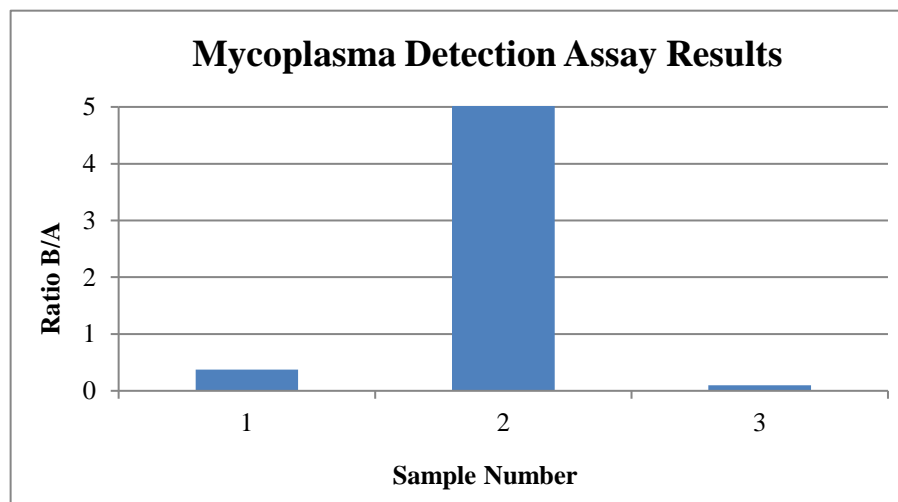
Version D Edition 01

Reported by: SS

Reviewed by: JB

Berthold Flash n' Glo 539

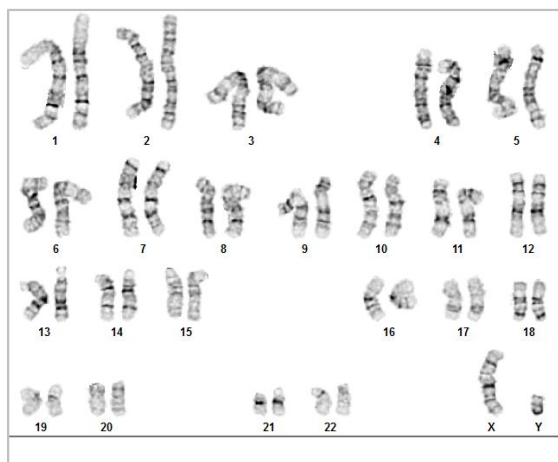
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2	Positive (+) Control	262	270	266	9695	9762	9729	36.57	Positive	
3	Negative (-) Control	452	442	447	45	42	43.5	0.10	Negative	



**Date Reported:** Monday, April 27, 2015  
**Cell Line:** PACT-ESC-WA01-RB18522 11229  
**Passage#:** 33  
**Date of Sample:** 4/17/2015  
**Specimen:** hESC  
**Results:** 46,XY

**Cell Line Gender:** Male  
**Reason for Testing:** Lot release testing  
**Investigator:** Steve Schreiber, WiCell CDM

**Nonclonal finding: 47,XY,+6**



**Cell:** 16  
**Slide:** 1  
**Slide Type:** Karyotype

**Total Counted:** 20  
**Total Analyzed:** 8  
**Total Karyotyped:** 4  
**Band Resolution:** 425 - 450

## Interpretation:

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

**There is one nonclonal finding, listed above. Nonclonal findings likely result from technical artifact, but may be due to a developing clonal abnormality or to low-level mosaicism.**

**Completed by:** Kim Leonhard, CG(ASCP)  
**Reviewed and Interpreted by:** Karen Dyer Montgomery, 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".

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