



Product Information and Testing

Product Information

Product Name	H9 CreLoxP
Alias	WA09(LoxGFP)
Lot Number	WB20971
Parent Material	WA09(LoxGFP)-MCB-01
Depositor	University of Wisconsin – Laboratory of Dr. Su-Chun Zhang
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 mTeSR1 Protocol
Passage Number	p25 These cells were cultured for 24 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 Vialled	09-July-2015
Vial Label	WA09(LoxGFP) p25 WB20971
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 STR profile of deposited cell line	Pass
Sterility	Biotech Laboratories	ST/07	Negative	Pass
Mycoplasma	WiCell	SOP-QU-004	Negative	Pass
Karyotype by G-banding	WiCell	SOP-CH-003	Expected karyotype	Pass
Expression of Reporter Proteins	WiCell	SOP-CH-032	Expression of reporter proteins reported	Pass

Date of Lot Release	Quality Assurance Approval
01-October-2015	<div>7/14/2020</div> <div>X AA</div> <div>AA Quality Assurance Signed by: Arntz, Andy</div>

Short Tandem Repeat Analysis

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

Sample Report:

11361-STR
Sample Name on Tube: 11361-STR
155.0 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: 08/24/15
Assay Date: 08/25/15
File Name: 150826 STR TCS
Report Date: 08/31/15

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	26,28
TPOX	6-13	10,11
D8S1179	7-18	8,14
vWA	10-22	17,17
Amelogenin	X,Y	X,X
Penta_D	2.2, 3.2, 5, 7-17	9,13
CSF1PO	6-15	11,11
D16S539	5, 8-15	12,13
D7S820	6-14	9,11
D13S317	7-15	9,9
D5S818	7-16	11,12
Penta_E	5-24	11,14
D18S51	8-10, 10.2, 11-13, 13.2, 14-27	13,13
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	30,30
TH01	4-9,9.3,10-11,13.3	9.3,9.3
D3S1358	12-20	13,16

Results: Based on the 11361-STR cells submitted by WiCell QA dated and received on 08/24/15, this sample (Label on Tube: 11361-STR) exactly matches the STR profile of the human stem cell line WA09 comprising 24 allelic polymorphisms across the 15 STR loci analyzed.

Interpretation: No STR polymorphisms other than those corresponding to the human WA09 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 11361-STR sample submitted corresponds to the WA09 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 08/31/15

TRIP Laboratory, Molecular

X_{WMR}

Digitally Signed on 08/31/15

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 # 15081899

VALIDATION # NG

TEST PURPOSE NG

PRODUCT WA09(LOXGFP)-WB20971 11368
UWWC1-2DS3-WB20846 11369
WC005i-FX11-7-WB20449 11370
UWWC1-DS1-WB21343 11371
WC-3801-2-WB21395 11372
WA07-WB21842 11373
LT2e-H9CAGGFP-WB0207 11374
MIN01i-32517.A-WB20571 11375
MIN03i-32642.B-WB20013 11376
MIN04i-33109.2B-WB20383 11377

PRODUCT LOT NA

STERILE LOT NA

BI LOT NA

STERILIZATION LOT NA

BI EXPIRATION DATE NA

STERILIZATION DATE NA

DATE RECEIVED 2015-08-27

STERILIZATION METHOD NA

TEST INITIATED 2015-08-28

SAMPLING BLDG / ROOM NA

TEST COMPLETED 2015-09-11

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

COMMENTS NA

REVIEWED BY

DATE 11 Sep 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

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Mycoplasma Detection Assay Report

Testing Performed by WiCell

Lot Release Test

08-20-2015

FORM SOP-QU-004.01

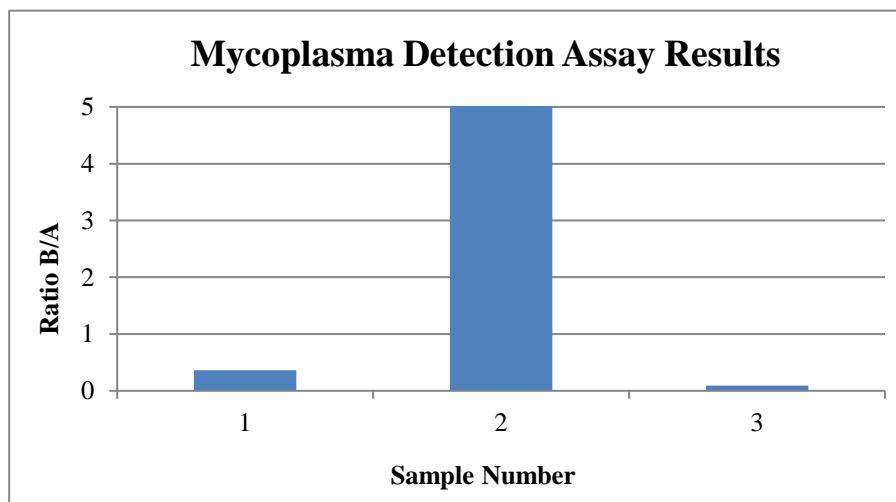
Version E Edition 01

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	WA09(LoxGFP)-WB20971 11361	148	144	146	52	54	53	0.36	Negative	
2	Positive (+) Control	279	273	276	18128	18087	18108	65.61	Positive	
3	Negative (-) Control	502	501	501.5	49	45	47	0.09	Negative	





Chromosome Analysis Report: 021778

Date Reported: Wednesday, August 19, 2015

Cell Line: WA09(LoxGFP)-WB20971 11361

Passage#: 25

Date of Sample: 8/11/2015

Specimen: hESC

Results: 46,XX

Cell Line Gender: Female

Reason for Testing: Lot release testing

Investigator: [REDACTED] WiCell CDM



Cell: 6

Slide: 2

Slide Type: Karyotype

Total Counted: 20

Total Analyzed: 8

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: [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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Cell Line-Lot Number	H9 Cre-LoxP-WB20971
Sample ID	11361
Passage Number	27
Reported By/Date	JB 11FEB15
QA Review By/Date	[REDACTED] 30Mar16
Percent Positive for Reporter Protein	99.7
Deviations from Procedure	<input checked="" type="checkbox"/> N/A
Notes	<input checked="" type="checkbox"/> N/A

Histogram Plot Indicating Positive Percentage of the Reporting Gene

Red peak is negative control population. Blue peak is test population.

