




Product Information and Testing

Product Information

Product Name	WA09
Alias	H9
Lot Number	WB0299
Parent Material	WA09-MCB-01
Depositor	University of Wisconsin – Laboratory of Dr. James Thomson
Banked by	WiCell
Thaw Recommendation	Thaw 1 vial into 1 well of a 6 well plate.
Culture Platform	Feeder Dependent
	Medium: cKOSR Medium
	Matrix: MEF
Protocol	WiCell Feeder Dependent Protocol
Passage Number	p24 These cells were cultured for 23 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 Viald	02-June-2014
Vial Label	WA09 WB0299 p24 02JUN2014
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
10-March-2015	<div style="text-align: right;">3/16/2015</div> <div style="text-align: center;">  AMK AMK Quality Assurance Signed by: XXXXXXXXXX </div>

Short Tandem Repeat Analysis*

Molecular Diagnostics Laboratory
 600 Highland Avenue
 Clinical Sciences Center (D4/211)
 Madison, WI 53792-2472

Samples Report:
 (1) 10987-STR 210.0 ng/uL (260/280=1.93)

Requestor:
 WiCell Research Institute (Quality Assurance)
 Phone: 608-577-6625

Sample Date(s): 08/07/14
 Receive Date(s): 08/07/14
 Assay Date(s): 08/13/14
 File Name(s): 140813 CLN
 Report Date(s): 08/19/14

DNA Extracted by WiCell Research Institute

STR Locus	STR Genotype Repeat #	(1)
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

Comments: Based on the 10987-STR DNA dated and received on 08/07/14 from WI Cell, this sample (Label on Tube: 10987-STR) exactly matches and further defines the STR profile of the human stem cell line WA-09 (H9) comprising 24 allelic polymorphisms across the 15 STR loci analyzed. No STR polymorphisms other than those corresponding to the human WA-09 (H9) 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. These results suggest that the 10987-STR DNA sample submitted corresponds to the WA-09 (H9) 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%.


 Date: 8/19/14
 Molecular Diagnostics Laboratory


 08/19/14
 Molecular Diagnostics 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.

Sterility Report

Biotest Laboratories, Inc.

Making life-saving products possible

CORRECTED REPORT

WiCell Research Institute, Inc.
WiCell Quality Assurance

BIOTEST SAMPLE # 14071020

VALIDATION # NG

TEST PURPOSE NG

PRODUCT 10996, 10997, 10999, 11000, WA07-WB0292 11004, WA09-WB0299 11005,
NSC-H9-WB0305 11007, WISe-OGFP-H2CH-DB0035 11008

PRODUCT LOT NA

STERILE LOT NA

BI LOT NA

STERILIZATION LOT NA

BI EXPIRATION DATE NA

STERILIZATION DATE NA

DATE RECEIVED 2014-07-18

STERILIZATION METHOD NA

TEST INITIATED 2014-07-18

SAMPLING BLDG / ROOM NA

TEST COMPLETED 2014-08-01

REFERENCE Processed according to LAB-003: Sterility Test Procedure

Eight (8) 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	8	NA	2 Negatives

COMMENTS Report revised due to typo in Product Name.

REVIEWED BY

DATE

04 AUG 14

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

CDM LRT

11-21-2014

FORM SOP-QU-004.01

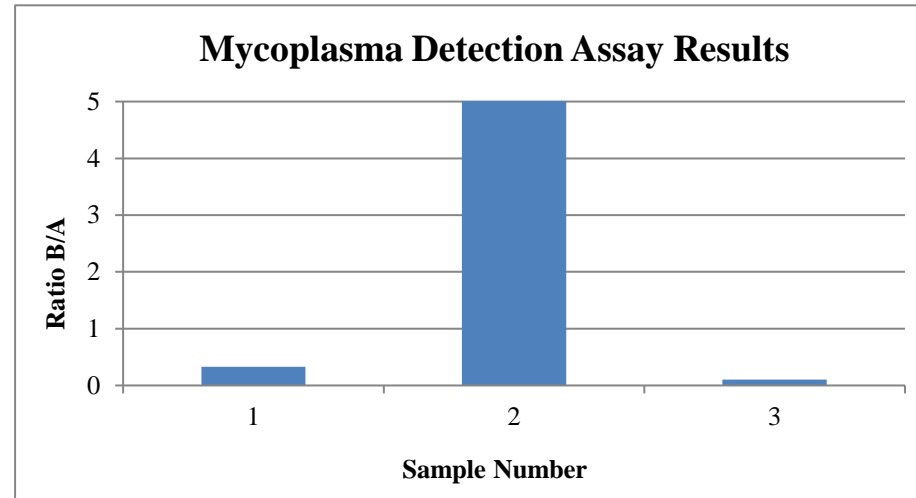
Version C Edition 01

Reported by: DF

Reviewed by: JB

BD Flash n' Glo 180

#	Sample Name	Reading A		A	Reading B		B Ave	Ratio B/A	Result	Comments/Suggestions
		RLU1	RLU2	Ave	RLU1	RLU2				
1	WA09-WB0299 11072	144	136	140	45	47	46	0.33	Negative	
2	Positive (+) Control	244	240	242	11523	11502	11512.5	47.57	Positive	
3	Negative (-) Control	421	433	427	44	42	43	0.10	Negative	



Date Reported: Friday, July 11, 2014

Cell Line: WA09-WB0299 10987

Passage#: 27

Date of Sample: 7/7/2014

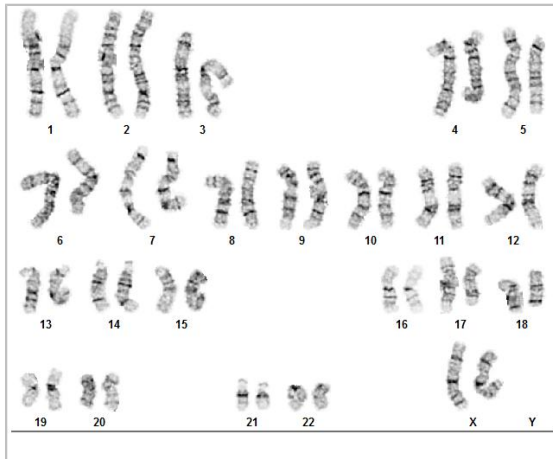
Specimen: hESC

Results: 46,XX

Cell Line Gender: Female

Reason for Testing: lot release testing

Investigator: [REDACTED], WiCell CDM



Cell: 70

Slide: 2

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]tgomery, 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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