




Product Information and Testing

Product Information

Product Name	WA07
Alias	H7
Lot Number	WB0289
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: hES Medium – WiCell recommends to passage using collagenase for 12 minutes for best results.
	Matrix: MEF
Protocol	WiCell Feeder Dependent Protocol
Passage Number	p25 These cells were cultured for 24 passages prior to freeze, 3 of them on MEF. 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	28-January-2014
Vial Label	WA07 WB0289 p25 28JAN14
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
20-May-2014	<div style="text-align: right;">10/19/2015</div> <div style="text-align: center;">  X AMK AMK Quality Assurance Signed by: XXXXXXXXXX </div>

Short Tandem Repeat Analysis*

Sample Report: 10945-STR

Tube Label: 10945-STR

Sample Date: 03/28/14

Requestor: WiCell Research Institute

Lab Received 03/28/14

Test Date: 04/02/14

File Name: 140402 STR CLN

Report Date: 04/05/14

Sample Name (label on tube): 10945-STR

Description: WI Cell Research Institute provided
genomic DNA
192.6 ug/mL 260/280=1.91

Locus	Repeat #	STR Genotype
D16S539	5, 8-15	12,13
D7S820	6-14	10,11
D13S317	7-15	11,12
D5S818	7-15	11,13
CSF1PO	6-15	12,12
TPOX	6-13	8,11
Amelogenin	NA	X,X
TH01	5-11	6,6
vWA	11, 13-21	14,15

Comments: Based on the 10945-STR DNA submitted by WI Cell dated and received on 03/28/14, this sample (Tube Label: 10945-STR) exactly matches the STR profile of the human stem cell line WA07 (H7) comprising 14 allelic polymorphisms across the 8 STR loci analyzed. No STR polymorphisms other than those corresponding to the human WA07 (H7) 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 suggest that the 10945-STR DNA samples submitted corresponds to the WA07 (H7) 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

Molecular Diagnostics Laboratory



Date

Molecular Diagnostics Laboratory

* Testing to assess engraftment following bone marrow transplantation 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

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

BIOTEST SAMPLE # 14041244
VALIDATION # NG
TEST PURPOSE NG

PRODUCT **WA07-WB0289 #10959**, WA07-WB0284 #10960, WA07-WB0291 #10961,
iPS-GM01715-DB0030 #10962, iPS-GM07125-DB0031 #10963,
iPS-GM12365-DB0032 #10964, iPS-GM20920-DB0033 #10965,
iPSH14-DB0013 #10966, H9iPSclone2-DB0014 #10967

PRODUCT LOT	NA	BI LOT	NA
STERILE LOT	NA	BI EXPIRATION DATE	NA
STERILIZATION LOT	NA	DATE RECEIVED	2014-04-22
STERILIZATION DATE	NA	TEST INITIATED	2014-04-23
STERILIZATION METHOD	NA	TEST COMPLETED	2014-05-08
SAMPLING BLDG / ROOM	NA		

REFERENCE Processed according to LAB-003: Sterility Test Procedure

Nine (9) 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
Non-Sterile	2	9	NA	2 Negatives

COMMENTS Nine (9) samples were received at Biotest Laboratories, Inc. Sample WA07-WB0284 was positive in both TSB and FTG. Sample iPS-GM07125 was positive in FTG.

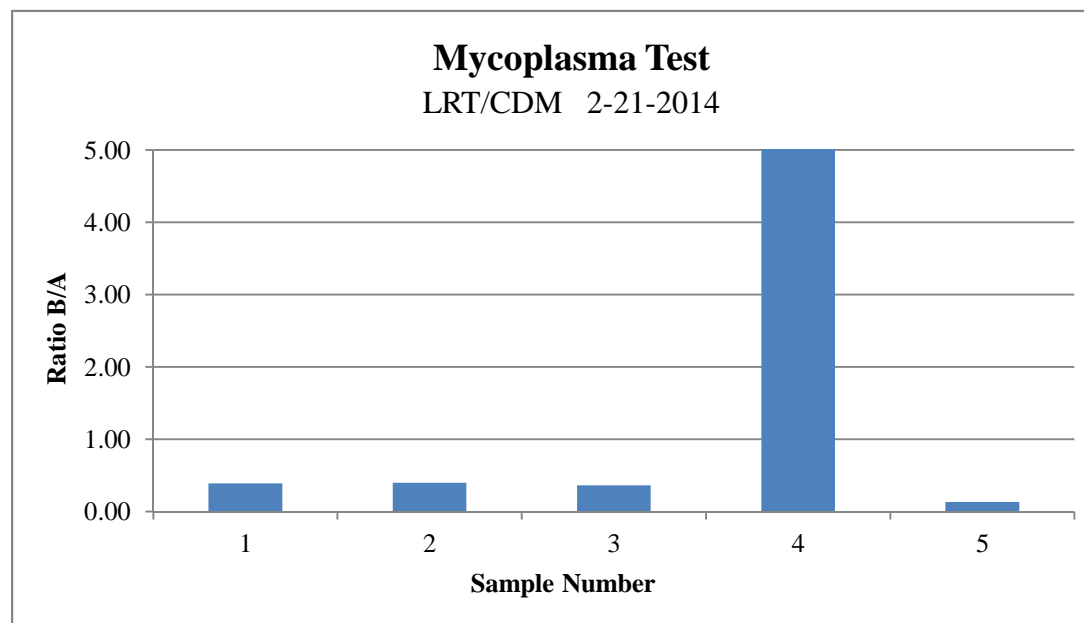
REVIEWED BY _____ DATE 15 MAY 14

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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Sample Number and ID	Reading A		A Average	Reading B		B Average	Ratio B/A	Mycoplasma Results	Comments/Suggestions
	A1	A2		B1	B2				
1 LRT 10942 WA07-WB0289	198	191	194.5	74	77	75.5	0.39	Negative	
2 LRT 10943 WA07-WB0284	196	198	197	76	81	78.5	0.40	Negative	
3 LRT 10936 WA07-WB0252	192	197	194.5	70	71	70.5	0.36	Negative	
4 Positive (+) Control	179	175	177	12968	12939	12953.5	73.18	Positive	
5 Negative (-) Control	386	403	394.5	49	55	52	0.13	Negative	



Date Reported: Tuesday, February 25, 2014

Cell Line: WA07-WB0289 10942

Passage#: 27

Date of Sample: 2/21/2014

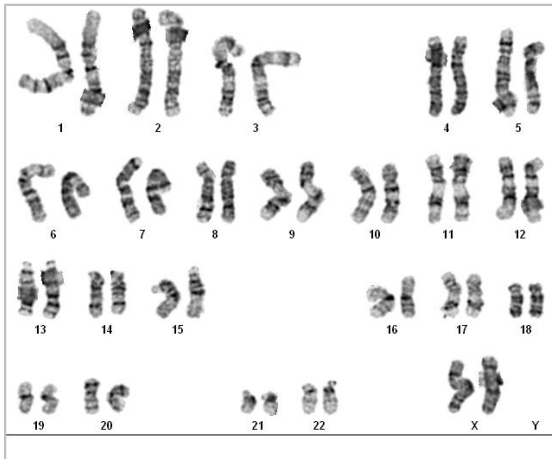
Specimen: hESC

Results: 46,XX

Cell Line Gender: Female

Reason for Testing: lot release testing

Investigator: [REDACTED], WiCell CDM



Cell: 40

Slide: 1

Slide Type: Karyotype

Total Counted: 20

Total Analyzed: 8

Total Karyotyped: 4

Band Resolution: 350 - 450

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.