Product Information and Testing for Depositor Material - Amended

Product Information

Product Name	NSC-H14
WiCell Lot Number	DB0003
Depositor	Buck Institute for Research on Aging
Banked by	Buck Institute for Research on Aging
Thaw Recommendation	Thaw 1 vial into 4 wells of a 6 well plate.
Culture Platform	Feeder Independent
	Medium: NSC Medium
	Matrix: Geltrex
Protocol	WiCell recommends using the depositor protocol included in the CoA and testing results packet.
Passage Number	p18 These cells were cultured for 17 passages prior to freeze. 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 Vialed	08-February-2012
Vial Label	Vials are provided as received from the Depositor. Vial labels are not firmly attached and therefore the vial has been placed in a secondary bag to ensure identity of the vial. H14 NSC p18 02/08/12
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
Mycoplasma Detection	Negative	Not available
Sterility Assessment	Negative	Not available
Karyotype	Normal Karyotype	Attached

Testing Performed by WiCell

Test Description	Test Provider	Test Method	Test Specification	Result
Post-Thaw Viable Cell Recovery	WiCell	SOP-CH-305	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	Report karyotype	Pass

Date of Lot Release	Quality Assurance Approval
25-January-2013	1/30/2014 X AMC AMC Quality Assurance Signed by: [redacted]

Cell Line GENETICS

Cell Line Characterization

Cell Line ID: H14 p18
Passage #: 18
Specimen Type: Human Neural Stem Cell Culture
Indication for Study: Routine Culture QC

[redacted]

Address:
Buck Institute for Research on Aging
[redacted]

Test Code: 100
Account #: NA
[redacted]

Date Received: 2/16/2012
Date Reported: 3/2/2012
Time in Culture: 1 Day

Additional copies sent to:

Banding Technique: GTL **Band Resolution:** Good
Metaphases Counted: 20 Analyzed: 5 Karyotyped: 2

RESULTS: 46,XY[20] Apparently NORMAL Male Human Karyotype

Non-clonal Aberrations: None

INTERPRETATION:

Cytogenetic analysis was performed on twenty G-banded metaphase cells from human cell line H14 p18 and all twenty cells demonstrated an apparently normal male karyotype. No abnormal cells were detected.

[redacted]

[redacted]

UW Health

University of Wisconsin
Hospital and Clinics

Histocompatibility/Molecular Diagnostics Laboratory

[redacted]

Short Tandem Repeat Analysis*

Sample Report: 10634-STR Label on Tube: 10634-STR Sample Date: 11/16/12
Received Date: 11/30/12

Requestor: WiCell Research Institute
Test Date: 12/05/12 File Name: 121205 BLB Report Date: 12/08/12

Sample Name: (label on tube)
10634-STR

Description: DNA Extracted by WiCell

252 ug/mL; 260/280 = 1.91

Locus	Repeat #	STR Genotype
D16S539	5, 8-15	11,13
D7S820	6-14	10,11
D13S317	7-15	11,11
D5S818	7-15	11,13
CSF1PO	6-15	11,12
TPOX	6-13	8,8
Amelogenin	NA	X,Y
TH01	5-11	6,7
vWA	11, 13-21	15,16

Comments: Based on the 10634-STR DNA dated and received on 11/30/12 from WiCell, this sample (UW HLA# Label on Tube: 10634-STR 11/16/12) exactly matches the STR profile of the human stem cell line WA14 (H14) comprising 14 allelic polymorphisms across the 8 STR loci analyzed. No STR polymorphisms other than those corresponding to the human WA14 (H14) 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 10634-STR DNA sample submitted corresponds to the WA14 (H14) stem cell line and it 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%.

[redacted]
Molecular Diagnostics Laboratory

[redacted]
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.

File: Final STR Report

STERILITY REPORT

WiCell Research Institute, Inc.
WiCell Quality Assurance
[redacted]

BIOTEST SAMPLE # 13030760

VALIDATION # NG

TEST PURPOSE NG

PRODUCT NAME	Please see packing slip under product name.		
PRODUCT LOT	NA		
STERILE LOT	NA	BI LOT	NA
STERILIZATION LOT	NA	BI EXPIRATION DATE	NA
STERILIZATION DATE	NA	DATE RECEIVED	2013-03-15
STERILIZATION METHOD	NA	TEST INITIATED	2013-03-15
SAMPLING BLDG / ROOM	NA	TEST COMPLETED	2013-03-29

REFERENCE: Processed according to SOP LAB-003: Sterility Test Procedure.

11 products were 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 ☐ Non-Sterile ☐ NA	0	11	NA	2 Negatives

COMMENTS NA

REVIEWED BY [redacted] DATE 29MAR13

WiCell Research Institute

Packing Slip

[redacted]

Sent to:
Sterility Testing Services
BiotestLabs, Sterility Testing Services
[redacted]

Date:
12Mar13

Product Name	Condition
[redacted] NSC-H14 #10725 [redacted]	-80

13030760 SLK
MAR 15 2013

Mycoplasma Report

Testing Performed by WiCell

H14 NSC #10634 Quarantine JB 9-26-2012

FORM SOP-QU-004.01

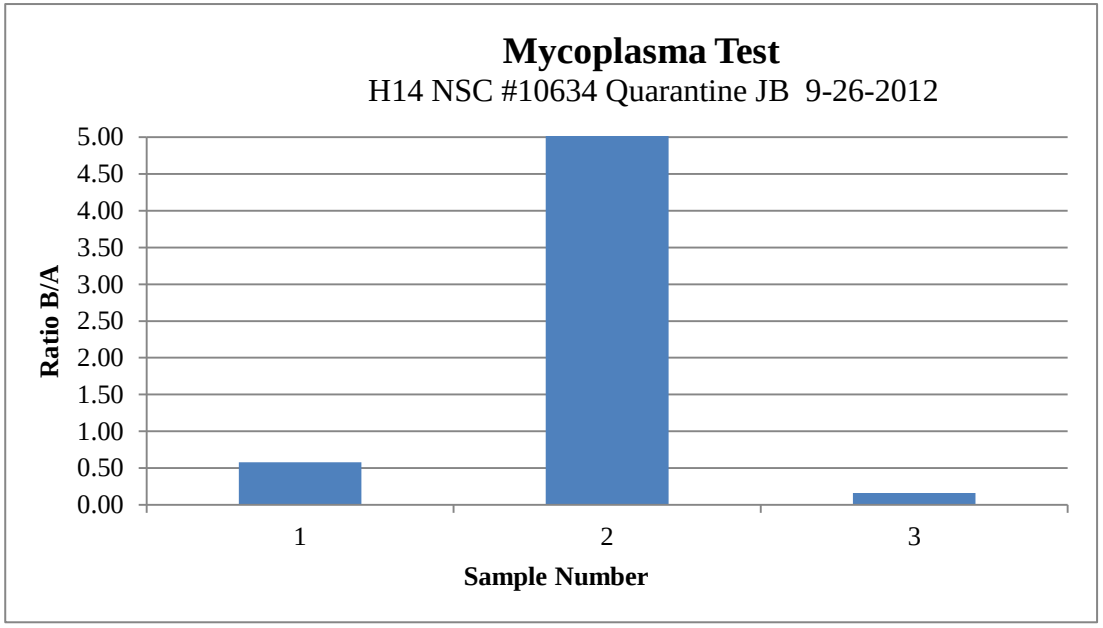
Version B

Edition 01

Assay performed and reported by: MW

Reviewed by: JB

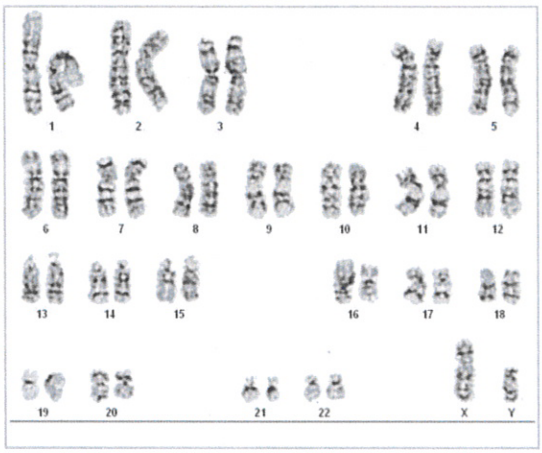
Sample Number and ID		Reading A		A	Reading B		B	Ratio		
		A1	A2	Average	B1	B2	Average	B/A	Mycoplasma Results	Comments/Suggestions
1	H14 NSC #10634 JB	580	567	573.5	312	355	333.5	0.58	Negative	
2	Positive (+) Control	542	543	542.5	36286	36449	36367.5	67.04	Positive	
3	Negative (-) Control	620	644	632	102	100	101	0.16	Negative	



Chromosome Analysis Report: 009208

Date Reported: Friday, November 02, 2012
Cell Line: H14NSC 10651
Passage#: 24
Date of Sample: 10/29/2012
Specimen: Neural Stem Cell
Results: 46,XY

Cell Line Gender: Male
Reason for Testing: lot release testing
Investigator: [redacted] WiCell CDM



Cell: 11
Slide: 1
Slide Type: Karyotype

Total Counted: 20
Total Analyzed: 8
Total Karyotyped: 4
Band Resolution: 350 - 400

Interpretation:
This is a normal karyotype. No clonal abnormalities were detected at the stated band level of resolution.
(1) NOTE: The karyotype of this specimen is XY; the test requisition form accompanying this specimen indicates a female cell line.

Completed by: [redacted]
Reviewed and Interpreted by:

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.

(1) The cyto testing request form had the wrong gender listed for the cell line. H14 is male (XY). 06Dec12JK6

WiCell Research Institute - WiCell Cytogenetics Lab - PO Box 7365 Madison - Wisconsin - 53707-7365