Product Information and Testing for Depositor Material - Amended

Product Information

Product Name	NSC-H9
WiCell Lot Number	DB0002
Depositor	Buck Institute for Research on Aging
Banked by	Buck Institute for Research on Aging
Thaw Recommendation	Thaw 1vial into 1 well 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	p15 These cells were cultured for 14 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	02-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. H9 NSC p15 2/2/12
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 Performed by Depositor

Test Description	Result	Report
Mycoplasma	Negative	Not available
Sterility	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	Variable; see attached reports

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

Cell Line GENETICS

Cell Line Characterization

Cell Line ID: H9 p15
Passage #: 15
Specimen Type: Human Neural Stem Cell Culture
Indication for Study: Routine Culture QC

[redacted]
PI: [redacted]
Contact Person: [redacted]
Email: [redacted]
Address:
Buck Institute for Research on Aging
[redacted]

Test Code: 100
Account #: NA
PO #: 10156

Date Received: 2/16/2012
Date Reported: 3/2/2012
Time in Culture: 4 Days

Additional copies sent to:

Banding Technique: GTL **Band Resolution:** Fair
Metaphases Counted: 20 Analyzed: 7 Karyotyped: 3

RESULTS: 46,XX[20] Apparently NORMAL Female Human Karyotype

Non-clonal Aberrations: None

INTERPRETATION:

Cytogenetic analysis was performed on twenty G-banded metaphase cells from human cell line H9 p15 and all twenty cells demonstrated an apparently normal female 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: 10604-STR Label on the tube: 10604-STR Sample Date: 08/27/12
Received Date: 11/09/12

Requestor: WiCell Research Institute

Test Date: 11/14/12 File Name: STR 121115 TCS Report Date: 11/16/12

Sample Name: (label on tube) 10604-STR

Description: DNA Extracted by WiCell
260.66 ug/mL; 260/280 = 1.86

Locus	Repeat #	STR Genotype
D16S539	5, 8-15	12,13
D7S820	6-14	9,11
D13S317	7-15	9,9
D5S818	7-15	11,12
CSF1PO	6-15	11,11
TPOX	6-13	10,11
Amelogenin	NA	X,X
TH01	5-11	9.3,9.3
vWA	11, 13-21	17,17

Comments: Based on the DNA 10604-STR dated 08/27/12 and received on 11/09/12 from WI Cell, this sample (Label on tube: 10604-STR) matches exactly the STR profile of the human stem cell line WA09 (H9) comprising 12 allelic polymorphisms across the 8 STR loci analyzed. No STR polymorphisms other than those corresponding to the human WA09 (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 10604-STR DNA sample submitted corresponds to the WA09 (H9) 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 estimated to be ~5%.

[redacted] 11/16/12
Date
Molecular Diagnostics Laboratory

[redacted] 11/16/12
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.

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
NSC-H9 #10724 [redacted]	-80

13030760 SLK
MAR 15 2013

Mycoplasma Report

Testing Performed by WiCell

H9NSC-A #10604 08-16-2012

FORM SOP-QU-004.01

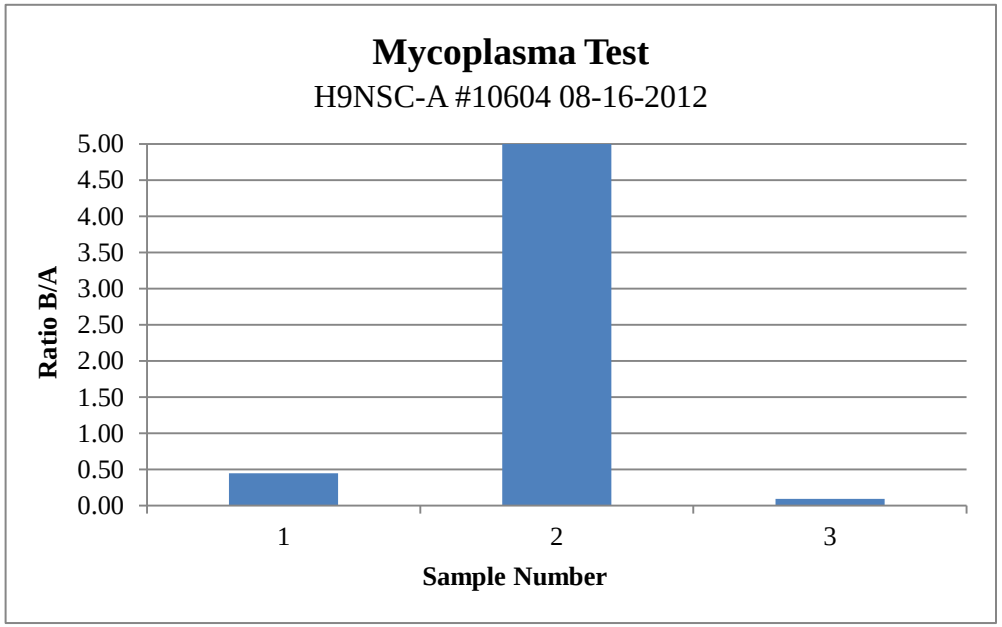
Version B

Edition 01

Assay performed and reported by: AJ

Reviewed by: JB

	Sample Number and ID	Reading A		A	Reading B		B	Ratio	Mycoplasma Results	Comments/Suggestions
		A1	A2	Average	B1	B2	Average	B/A		
1	H9 NSC p15 thaw JB inc#121 (10604)	473	470	471.5	211	210	210.5	0.45	Negative	
2	Positive (+) Control	541	549	545	29397	30203	29800	54.68	Positive	
3	Negative (-) Control	667	678	672.5	65	62	63.5	0.09	Negative	



Chromosome Analysis Report: 008941

Report Date: Thursday, September 20, 2012

Cell Line: H9NSC 10618

Passage #: 21

Date of Sample Receipt: 9/12/2012

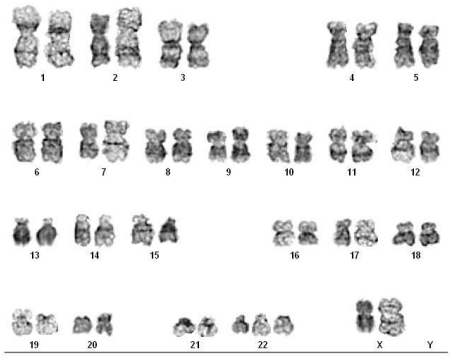
Specimen: Neural Stem Cell

Results: 47,XX,+22[2]/46,XX[18]

Cell Line Gender: Female

Reason for Testing: Lot release testing

Investigator: [redacted] WiCell Distribution



Cell: 1

Slide: 3

# of Cells Counted: 20

# of Cells Karyotyped: 5

# of Cells Analyzed: 9

Band Level: 350

Interpretation:

This is an abnormal karyotype, with trisomy 22 as the only clonal aberration detected. Trisomy 22 was found in two of twenty cells examined. This is not a recurrent acquired abnormality in human pluripotent stem cell cultures.

Completed by [redacted], CG(ASCP)
Reviewed and interpreted by [redacted] PhD, FACMG

A signed copy of this report is available upon request.

Date: _____ *Sent To:* _____

Sent By: _____ *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".

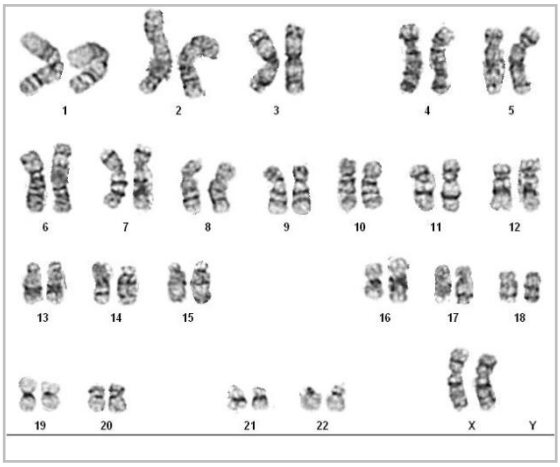
This assay was conducted solely for listed investigator/institution. The results may not be relied upon by any other party without the prior written consent of the Director of the WiCell Cytogenetics Laboratory. The results of this assay are for research use only. If the results of this assay are to be used for any other purpose, contact the Director of the WiCell Cytogenetics Laboratory.

Chromosome Analysis Report: 009067

Date Reported: Wednesday, October 10, 2012
Cell Line: H9NSC 10633
Passage#: 16
Date of Sample: 10/3/2012
Specimen: Neural Stem Cell
Results: 46,XX

Cell Line Gender: Female
Reason for Testing: Lot release testing
Investigator: [redacted] WiCell CDM

Nonclonal Finding(s): 47,XX,+19



Cell: 28
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.

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:** ____

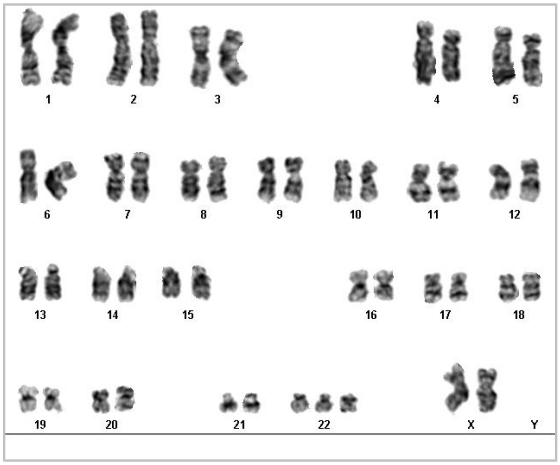
Limitations: This assay allows for microscopic visualization of numerical and structural chromosome abnormalities. The size of structural abnormality that can be detected is >3-10Mb, dependent upon the G-band resolution obtained from this specimen. For the purposes of this report, band level is defined 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.

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

Chromosome Analysis Report: 009243

Date Reported: Wednesday, November 14, 2012
Cell Line: H9NSC 10650
Passage#: 21
Date of Sample: 11/7/2012
Specimen: Neural Stem Cell
Results: 47,XX,+22[1]/46,XX[23]

Cell Line Gender: Female
Reason for Testing: Lot release testing
Investigator: [redacted] WiCell CDM



Cell: 9
Slide: 2
Slide Type: Karyotype

Total Counted: 24
Total Analyzed: 8
Total Karyotyped: 4
Band Resolution: 350 - 400

Interpretation:

This is an abnormal karyotype. Trisomy 22 was found in one of twenty-four cells examined. Although the does not meet requirements for clonality in individual specimens, this abnormality was found in a previous H9NSC (WiCell #8941; 9.12.12).

No other abnormalities were found.

Completed by: [redacted] CG(ASCP)
Reviewed and Interpreted by: [redacted], PhD, FACMG
A signed copy of this report is available upon request.

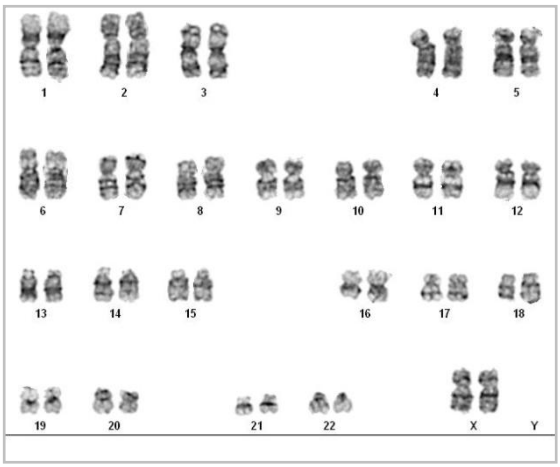
Date:_____ **Sent By:**____ **Sent To:**_____ **QC Review By:** ____

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".

Chromosome Analysis Report: 009490

Date Reported: Friday, December 28, 2012
Cell Line: H9NSC 10667
Passage#: 16
Date of Sample: 12/7/2012
Specimen: Neural Progenitor
Results: 46,XX[39]
Nonclonal finding: 46,XX,t(1;10)(q21;q22)

Cell Line Gender: Female
Reason for Testing: Informative
Investigator: [redacted] WiCell CDM



Cell: 8
Slide: 4
Slide Type: Karyotype

Total Counted: 40
Total Analyzed: 9
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.

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] MS, 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.