

Product Information and Testing for Depositor Material - Amended

Product Information


Product Name	NSC-H14iPSZeng
WiCell Lot Number	DB0010
Depositor	Buck Institute for Research on Aging
Banked by	Buck Institute for Research on Aging
Thaw Recommendation	Thaw 1 vial 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	p9 To create this cell line, neural stem cells were derived from WA14 at passage 44. These ES cell derived neural cells were then reprogrammed to iPS cells at passage 13 post-differentiation. The resulting iPS cells were again differentiated to neural stem cells at passage 30 post reprogramming. 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 Vial	07-February-2013
Vial Label	NSC XZ-14 p9 02/07/2013 2xE6
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
Karyotype	Normal Karyotype	Attached
Mycoplasma	Negative	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 Translational Research Initiatives in Pathology 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
24-September-2013	<div style="text-align: right;">5/16/2016</div>  <p>AMK Quality Assurance Signed by: Klade, Anjelica</p>

Short Tandem Repeat Analysis

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

WiCell®
info@wicell.org
(888) 204-1782

Sample Report:

11609-STR
Sample Name on Tube: 11609-STR
71.8 ng/μL, (A260/280=1.81)
Sample Type: Cells
Cell Count: ~2 million cells

Requestor:

WiCell Research Institute
Quality Department

Sample Date: N/A

Receive Date: 04/22/16
Assay Date: 04/26/16
File Name: STR 160428 wmr
Report Date: 05/04/16

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	21,21
TPOX	6-13	8,8
D8S1179	7-18	13,14
vWA	10-22	15,16
Amelogenin	X,Y	X,Y
Penta_D	2.2, 3.2, 5, 7-17	12,13
CSF1PO	6-15	11,12
D16S539	5, 8-15	11,13
D7S820	6-14	10,11
D13S317	7-15	11,11
D5S818	7-16	11,13
Penta_E	5-24	13,20
D18S51	8-10, 10.2, 11-13, 13.2, 14-27	12,14
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	30,31
TH01	4-9,9.3,10-11,13.3	6,7
D3S1358	12-20	15,16

Results: Based on the 11609-STR cells submitted by WiCell QA dated and received on 04/22/16, this sample (Label on Tube: 11609-STR) exactly matches the STR profile of the human stem cell line WA14 comprising 27 allelic polymorphisms across the 15 STR loci analyzed.

Interpretation: No STR polymorphisms other than those corresponding to the human WA14 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 11609-STR sample submitted corresponds to the WA14 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 05/04/16

TRIP Laboratory, Molecular

X_{WMR}

Digitally Signed on 05/04/16

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>

TRIP agrees to maintain the confidentiality of any information provided to it in connection with its performance of this STR analysis on the same conditions as set forth in paragraph 2 of WiCell's Terms and Conditions of Service (<http://www.wicell.org/media.acux/1a429b84-2b54-44a4-8ad8-5c05db93dd8a>).

Sterility Report

Biotest Laboratories, Inc.

Making life-saving products possible

WiCell Research Institute, Inc.
WiCell Quality Assurance

BIOTEST SAMPLE # 16032814

VALIDATION # NG

TEST PURPOSE NG

PRODUCT UCSD001i-5-1-DB25307 11584, UCSD002i-16-1-DB25351 11585, UCSD003i-16-2-DB25354 11586, UCSD004i-42-1-DB25357 11587, UCSD005i-43-1-DB25344 11588, JFRBi3-DB29686 11589, JFRBi2-DB29695 11590, JFRBi1-DB29683 11591, JFNY1-DB29680 11592, NSC-H14iPSZeng-DB0010 11593

PRODUCT LOT NA

STERILE LOT NA

BI LOT NA

STERILIZATION LOT NA

BI EXPIRATION DATE NA

STERILIZATION DATE NA

DATE RECEIVED 2016-03-30

STERILIZATION METHOD NA

TEST INITIATED 2016-04-18

SAMPLING BLDG / ROOM NA

TEST COMPLETED 2016-05-02

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
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COMMENTS NA

REVIEWED BY

DATE

02 MAY 16

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

A subsidiary of STERIS Corporation





Mycoplasma Detection Assay Report

Testing Performed by WiCell

Lot Release Testing

April 7th, 2016

FORM SOP-QU-004.01

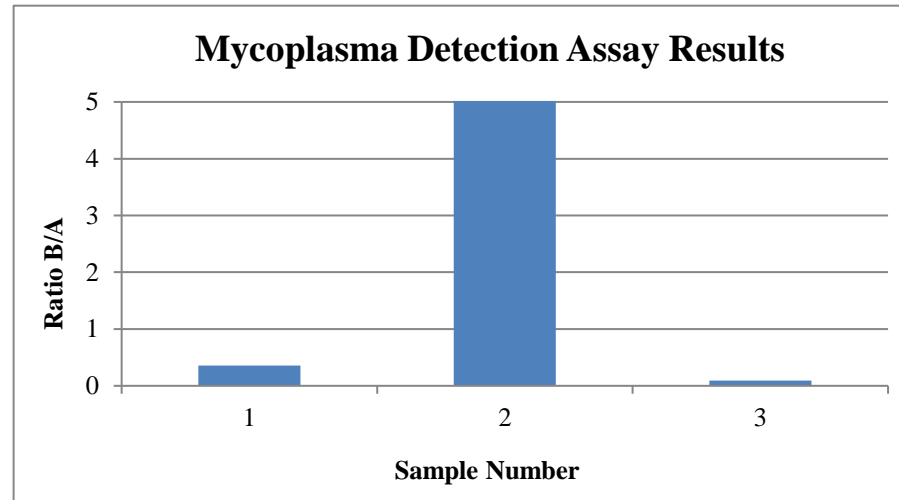
Version E Edition 01

Reported by: SS

Reviewed by: JB

Berthold Flash n' Glo 539

#	Sample Name	Reading A			Reading B			Ratio B/A	Result	Comments/Suggestions
		RLU1	RLU2	Ave	RLU1	RLU2	Ave			
1	NSC-H14iPSZeng-DB0010 11609	127	130	128.5	47	45	46	0.36	Negative	
2	Positive (+) Control	118	120	119	10234	10238	10236	86.02	Positive	
3	Negative (-) Control	203	198	200.5	20	18	19	0.09	Negative	



Date Reported: Wednesday, April 20, 2016

Cell Line: NSC-H14iPSZeng -DB0010 11609

Passage#: 10

Date of Sample: 4/13/2016

Specimen: Neural Stem Cell

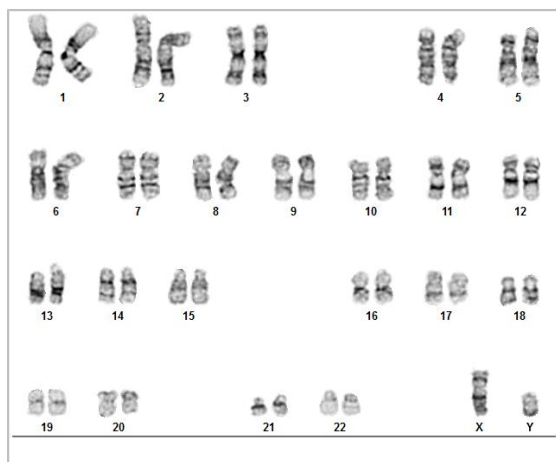
Results: 46,XY

Cell Line Gender: Male

Reason for Testing: lot release testing

Investigator: [REDACTED], WiCell CDM

Nonclonal Findings: 47,XY,+del(1)(p10) 46,XY,add(17)(p13) 47,XY,+mar



Cell: 33

Slide: 2

Slide Type: Karyotype

Total Counted: 40

Total Analyzed: 9

Total Karyogrammed: 7

Band Resolution: 350 - 400

Interpretation:

This is a normal karyotype. No clonal abnormalities were detected at the stated band level of resolution.

There are three nonclonal findings, listed above. Standard analysis requires that chromosomes are counted in twenty cells. Twenty additional cells were examined with no further evidence of this nonclonal aberration. 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.

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Date Reported: Tuesday, January 29, 2013

Cell Line: N2-14

Passage#: 4

Date of Sample: 1/17/2013

Specimen: NSC

Results: 46,XY

Cell Line Gender: Male

Reason for Testing: derived from iPS line

Investigator: ██████████ Buck Institute



Cell: 7

Slide: 4

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.

Completed by: ██████████ CG(ASCP)

Reviewed and Interpreted by: ██████████ 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.

NSC XZ-14p9

- Passage number of fresh NSC is 9

Lonza MycoAlert™ Mycoplasma Detection Kit

Procedure

- Collect 100-500ul media from cells 24-48h after passage in eppendorf tube
- Spin down for 5min at 200g
- Transfer 25ul of supernatant to 96 well white wall plate
- Add 25ul MycoAlert™ Reagent to sample. Wait 5min
- Measure luminescence (Read A)
- Add 25ul MycoAlert™ Substrate to sample and wait for 10min
- Measure luminescence (Read B)

Results

- Divide Read B by Read A to produce ratio (Read B/Read A)

Ratio	Interpretation
< 0.9	Negative for mycoplasma
0.9-1.2	Quarantine cells & retest in 24h
>1.2	Mycoplasma contamination

Mycoplasma test on H14 NSC p18 had a ratio of 0.39
NSC XZ-14 culture was negative for mycoplasma presence.