



CERTIFICATE OF ANALYSIS
Recombinant Human β -NGF Animal-Free
Nerve growth factor beta AF
Powder
(Catalog Number 300-819P)

Lot Number: G116070

Date Received: _____

Storage Temperature: $\leq -10^{\circ}\text{C}$

Product Expiry*: _____

For Cell culture, Further Manufacturing or Research use Only. Not for Direct Therapeutic Use.

*Expiration Date is one year from the date of receipt when stored at -20 to -80°C

Test	Methodology	Analysis
Biological Testing Endotoxin	Kinetic LAL	<0.05 EUs/ μg
Biological Testing Purity	Reducing and Non-reducing SDS- PAGE	$>95\%$
Biological Activity ED ₅₀	TF-1 cell proliferation	7.6×10^5 units/mg

The testing that has been performed as part of this lot release has been reviewed by Quality Assurance personnel and has confirmed that the testing meets the specifications presented on this Certificate of Analysis.

Korrina Nicewonger

Name

QC Associate I

Title

11 AUG 2022

Date



Certificate of Analysis

Recombinant Animal-Free Human β -NGF

Catalog Number: 100-38AF

Lot Number: 1116-100-38AF

Product Description

Alternate Names: NGF- β **Accession/Uniprot Number:** P01138

Description: Nerve growth factor beta (β -NGF) is a neurotrophic factor that is important for the development and maintenance of sensory and sympathetic neurons. β -NGF signals through the low affinity nerve growth factor receptor (LNGFR) and the tropomyosin receptor kinase A (TrkA) to activate PI3K, Ras, and PLC signaling pathways. β -NGF is also involved in the growth, differentiation, and survival of B lymphocytes. Human, mouse, and rat β -NGF proteins are cross-reactive.

Source: Genetically modified *E.coli*. **This product is produced with no animal-derived raw products. All processing and handling employs animal-free equipment and animal-free protocols.**

Predicted MW: Noncovalent Homodimer, 13.6 kDa (121 amino acids)

AA Sequence: MSSSHPIFHR GEFSVCDVS VWVGDKTTAT DIKGKEVMVL GEVNINNSVF KQYFFETKCR DPNPVDSGCR GIDSKHWNSY CTTHTFVKA LTMDGKQAAW RFIRIDTACV CVLSRKAARR A

Formulation: Lyophilized from a sterile (0.2 micron) filtered aqueous solution containing 0.1% Trifluoroacetic Acid (TFA)

Product Specifications

Specification	Method of Determination	Acceptance Criteria	Result
Purity	Reducing and Non-reducing SDS-PAGE	$\geq 95\%$	$> 95\%$
Endotoxin	Kinetic LAL (50% confidence)	≤ 1 EUs/ug	< 0.05 EUs/ug
Biological Activity	TF-1 cell proliferation	ED50 ≤ 5 ng/mL ($\geq 2.0 \times 10^5$ units/mg)	ED50 = 1.31 ng/mL (7.6×10^5 units/mg)

Product Preparation and Storage

Country of Origin: USA **Shipping:** Room temperature **Storage Prior to Reconstitution:** -20°C

Reconstitution: Sterile water at 0.1 mg/mL **Date of Recon.:** _____ **Initials:** _____

Centrifuge vial before opening. Suspend the product by gently pipetting the above recommended solution down the sides of the vial. DO NOT VORTEX. Allow several minutes for complete reconstitution. For prolonged storage, dilute to working aliquots in a 0.1% BSA solution, store at -80°C and avoid repeat freeze thaws.

Expiration Date: _____ **Date Received:** _____

12 months from date of receipt when stored at -20°C to -80°C as supplied.

1 month when stored at 4°C after reconstituting as directed.

3 months when stored at -20°C to -80°C after reconstituting as directed.

THIS PRODUCT IS FOR RESEARCH USE ONLY AND IS NOT FOR USE IN HUMANS!

XOlivia Schneider, PhD 3-6-17

Quality Assurance


Shenandoah Biotechnology

Warwick, PA 18974 USA



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	Document #: QC.SOP.006.F1	Effective: 28APR2021
	Revision: 002	Page 1 of 3

Title: OEM Product Receiving Form

Raw Material # <input checked="" type="checkbox"/> N/A		Lot # <input type="checkbox"/> N/A	6116070
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Manufacturer Name	Shenandoah	Manufacturer Lot #	1116-100-38AF
Qty Received	1 x 20mg	Date Received	11AUG2022
Recorded By /Date	KN 11AUG2022		


Step	Procedure	Performed By/Date
1.0	Visual Inspection of Shipment	
1.1	Shipping Boxes:	KN 11AUG2022
	<input checked="" type="checkbox"/> Good Condition <input type="checkbox"/> N/A <input type="checkbox"/> Damaged <input checked="" type="checkbox"/> N/A	
1.2	Traceability	KN 11AUG2022
	<input checked="" type="checkbox"/> Certificate of Analysis <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Packing Slip PO # <u>63744</u> <input checked="" type="checkbox"/> Packing list matches with PO	
2.0	Visual Inspection of Product Container	
2.1	Cracked or Open <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A	KN 11AUG2022
2.2	Product Container Label	
	<input checked="" type="checkbox"/> Product Name <input checked="" type="checkbox"/> Lot Number <input type="checkbox"/> Manufacture Date <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Expiration Date <input checked="" type="checkbox"/> N/A	
2.3	CoA matches with Product Lot Number <input type="checkbox"/> N/A	KN 11AUG2022

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Title: OEM Product Receiving Form

Raw Material # <input checked="" type="checkbox"/> N/A		Lot # <input type="checkbox"/> N/A	G116070
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Step	Procedure	Performed By/Date
3.0	Acceptance Status	
3.1	<input checked="" type="checkbox"/> Purchased finished product is accepted for general sale; it meets Gemini Bio-Products' critical control limits.	<input type="checkbox"/> N/A KN 11 AUG 2022
3.2	<input type="checkbox"/> The purchased finished product is conditionally accepted ; however, further testing is required to verify that this product meets Gemini Bio-Products' critical control limits	<input checked="" type="checkbox"/> N/A
3.3	List of additional tests needs to be performed _____	<input checked="" type="checkbox"/> N/A
3.4	<input type="checkbox"/> Product is in QC hold, and waiting for test results.	<input checked="" type="checkbox"/> N/A
3.5	<input type="checkbox"/> Purchased finished product has passed all the test requirement and ready for general sale	<input checked="" type="checkbox"/> N/A
3.6	<input type="checkbox"/> Purchased finished product has not passed all the test requirement	<input checked="" type="checkbox"/> N/A
4.0	European Union Export Status (For accepted animal origin material only) <input checked="" type="checkbox"/> N/A	
4.1	<input type="checkbox"/> BSA <input type="checkbox"/> FBS <input type="checkbox"/> Bovine Serum <input type="checkbox"/> Sheep Serum <input type="checkbox"/> Goat Serum <input type="checkbox"/> Equine	
4.2	Name of Supplier _____	
4.3	<input type="checkbox"/> N/A <input type="checkbox"/> Documentation received from Supplier and Finished product is eligible for export to E.U. <input type="checkbox"/> Technical Blood Equidae <input type="checkbox"/> Technical Blood Other than Equidae <input type="checkbox"/> Technical Blood Other than Equidae - Treated	

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Title: OEM Product Receiving Form

Raw Material # <input checked="" type="checkbox"/> N/A		Lot # <input type="checkbox"/> N/A	6116070
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Step	Procedure	Performed By/Date
4.4	<input type="checkbox"/> N/A <input type="checkbox"/> This finished product is ineligible for export to the E. U	


Comments:

N/A

Reviewed By/Date	<i>Am</i> 11 AUG 2022
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Document Revision History

Document #	Rev. #	Reason for New Revision	DCR#
QC.SOP.006.F1	002	Correct document number in revision history for Revision 001	DCR-21-0139
QC.SOP.006.F1	001	Update Template	DCR-21-0137

	Document #: MFG.SOP.016.F1	Effective: 10MAY2021
	Revision: 002	Page 1 of 2
Title: Repackaging Procedure Form		

Material Description: Human Beta Nerve Growth Factor (AF)

Gemini Cat. #: ~~G11670~~ 300-814P Gemini Lot #: G11670

Expiration Assay Draw Date: 11/2016

Supplier: Shenandoah Supplier Cat. #: 100-38AF Supplier Lot #: 1116-100-38AF

Type of Repackage: Relabel Only Repackage and Relabel

Total Quantity Processed 1

Enter quantities by fill size below:


Quantity	Fill Size
1	20ug
	N/A

Quantity Scrapped, or N/A: _____

Completed by/Date: KC 11 AUG 2022


Verified by/Date: MC 11 AUG 2022

Quality Reviewed by/Date: MK 11 AUG 2022

	Document #: MFG.SOP.016.F1	Effective: 10MAY2021
	Revision: 002	Page 2 of 2
Title: Repackaging Procedure Form		

Document Revision History

Document #	Rev. #	Reason for New Revision	DCR#
MFG.SOP.016.F1	002	Update Template	DCR-21-0143

	Document #: QA.SOP. 011.F1	Effective: 13SEP2021
	Revision: 004	Page 1 of 2
Title: Label Request Form		

LABEL INFORMATION

Product Name: Human Beta Nerve Growth Factor (AF) Catalog No.: 300-819P
 Lot No.: G116070 MFG Lot No.: 1116-100-38AF N/A Origin: N/A
 Expiration Assay Draw Date: 11/1/2016 Storage Requirement: ≤ -10°C
 Quantity of Labels Requested: 1 Product Unit Size: 20 ug
 Label(s) Requested By/Date: GC / 11AUG2022
 No. Crate Tag(s) N/A Equine Serum Production Facility Labels Required Yes or N/A

EU Eligibility and Production Facility Labels for Equine Serum

EU Eligible If EU Eligible box is checked, Affix EU Eligible Sticker to crate tags.
 Production Facility Label Sample or N/A:

Production Facility Label Reconciliation or N/A:

# Printed	# Voided	# Delivered	Initial/Date:



Label Generation and Approval (Quality)

Sample Label(s) Verified By/Date: ST 11AUG2022
 Labels Printed By/Date: KN 11AUG2022
 Reconciliation:

# Printed	# Voided	# Delivered
2	1	1

Reconciliation and Label Verification By/Date: ST 11AUG2022

LABEL USE

# Received*	*If different than # Delivered above, contact Quality.
1	

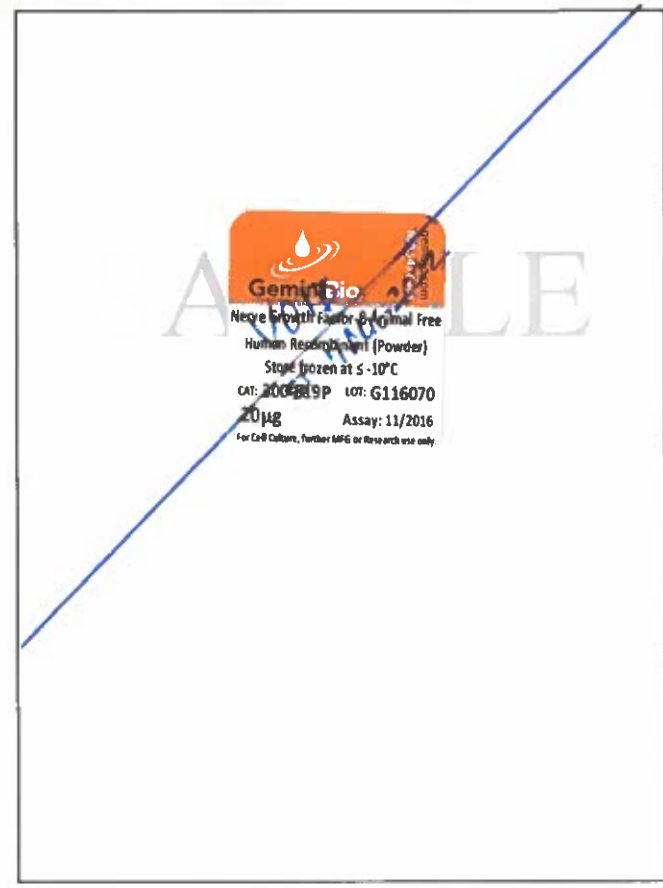
Label(s) Received By/Date: KA 11AUG2022


# Used	# Returned
1	0

Reported By/Date: KA 11AUG2022

Comments: DIA

(Quality) Labels Destroyed and Form Reviewed By/Date: MK 11AUG 2022



	Document #: QA.SOP. 011.F1	Effective: 13SEP2021
	Revision: 004	Page 2 of 2
Title: Label Request Form		

Document Revision History

Document #	Rev. #	Reason for New Revision	DCR#
QA.SOP.011.F1	004	Update template format; changed "collection" to "production."	DCR-21-0232