CERTIFICATE OF ACCREDITATION

ANSI-ASQ National Accreditation Board

500 Montgomery Street, Suite 625, Alexandria, VA 22314, 877-344-3044

This is to certify that

Nelson Laboratories, LLC
1500 West Thorndale Avenue
Itasca IL 60143

has been assessed by ANAB
and meets the requirements of international standard

ISO/IEC 17025:2005

while demonstrating technical competence in the field of

TESTING

Refer to the accompanying Scope of Accreditation for information regarding the types of tests to which this accreditation applies.

AT-2490
Certificate Number

ANAB Approval

Certificate Valid: 02/01/2018-08/15/2019
Version No. 004 Issued: 02/01/2018

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communiqué dated April 2017).

ANSI-ASQ National Accreditation Board

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

Nelson Laboratories, LLC

1500 West Thorndale Avenue
Itasca, IL 60143
Michael Rahn
630-285-9121

TESTING

Valid to: **August 15, 2019** Certificate Number: **AT-2490**

Microbiological

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Bacterial Endotoxins	STP0046 USP 85 USP 161 ANSI/AAMI ST72	Medical Devices, Pharmaceuticals	Microplate Reader
Bioburden	STP0036 ISO 11737-1:2006	Medical Devices, Pharmaceuticals	Biosafety Cabinet Incubators
Biological Indicator Sterility	STP0079 ISO 11138-1 and 2 ISO 14161 USP 71	BIs, PCDs	BI Sterility Suite ISO Class 5 Hoods Incubator
Product Sterility Bacteriostasis / Fungistasis	STP0077 STP0078 ISO 11737-2:2009 USP 71	Medical Devices, Pharmaceuticals	Product Sterility Suite ISO Class 5 Hoods Incubators
Biological Indicator Population Verification (Enumeration and Specified Organisms, USP 61/62)	STP0045 ISO 11138	Medical Devices, Pharmaceuticals	Incubators

Chemical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Ethylene Oxide (EO) Residual Analysis	G-WI-LB-CHM-008 ISO 10993-7:2008 USP 1225 USP 621	Medical Devices	Gas Chromatograph (GC)

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-2490.

Vice President

Nelson Labs™
A Sotera Health company

04 Jun 2018

Statement of Compliance to GDUFA Self-Identification Requirement

Nelson Laboratories, LLC (NL), a Sotera Health Company, is a provider of full, life-cycle microbiology testing services for pharmaceutical, medical device, natural products, and processed tissue industries. NL's main facility is in Salt Lake City, UT with Sotera Health located in Broadview Heights, OH.

Under the Generic Drug User Fee Amendments of 2012 (GDUFA), all facilities involved in the manufacture and testing of human generic drugs are now required to electronically self-identify with the FDA.

With this letter, NL confirms that all drug facilities, sites and organizations listed below have been registered under the new GDUFA requirements effective 31 May 2018.

Address	Business Operations	FEI # & DUNS #	Fiscal Year
Nelson Laboratories, LLC 1500 W Thorndale Ave, Itasca, IL 60123 USA	API / FDF Analytical Testing	FEI #**3000717698** DUNS #**032350261**	**FY2019**
Nelson Laboratories, LLC 6280 South Redwood Road Salt Lake City, UT 84123 USA	API / FDF Analytical Testing	FEI #**3000233845** DUNS #**151663234**	**FY2019**

Sincerely,

Matt Cushing

Matthew D. Cushing
Senior Director, Quality – North America
Nelson Laboratories, LLC
6280 S. Redwood Road
Salt Lake City, UT 84123
mcushing@nelsonlabs.com
O: 801-290-7692
F: 801-290-7998

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)

(See reverse side for instructions)

1. REGISTRATION NUMBER
(FDA Establishment Identifier)

FEI: 3007950533

2. REASON FOR SUBMISSION

a. ☐ INITIAL REGISTRATION / LISTING
b. ☒ ANNUAL REGISTRATION / LISTING
c. ☐ CHANGE IN INFORMATION
d. ☐ INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:08-DEC-2017
DISTRICT: Chicago
PRINTED BY FDA:27-JAN-2018

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS

a. BLOOD FDA 2830 NO. _____

b. DEVICES FDA 2891 NO. _____

c. DRUG FDA 2656 NO. FEI: 3000717698

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)

Sterigenics US LLC

1500 W. Thorndale Ave
Itasca, Illinois 60143

a. PHONE 630-285-9121 EXT

b. ☐ SATELLITE RECOVERY ESTABLISHMENT
(MANUFACTURING ESTABLISHMENT FEI NO._____

c. ☒ TESTING FOR MICRO-ORGANISMS ONLY

5. ENTER CORRECTIONS TO ITEM 4

6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)

Sotera Health LLC
Attn: Aaron DeMent
2015 Spring Road
Suite 650
Oak Brook, Illinois 60523

a. PHONE 630-928-1700 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Aaron DeMent
b. E-MAIL adement@sterigenics.com
c. TITLE VP of Global Quality Assurance d. DATE 08-DEC-2017

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions: Recover	Screen	Test	Package	Process	Store	Label	Distribute	11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
a. Bone			X						X			
b. Cartilage			X						X			
c. Cornea			X						X			
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia			X						X			
g. Heart Valve			X						X			
h. Ligament			X						X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium												
k. Peripheral Blood Stem ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera			X						X			
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin			X						X			
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon			X						X			
q. Umbilical Cord Blood ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft			X						X			
s.												
t.												
u.												
v.												