

### SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

### EUROFINS SF ANALYTICAL – GMP MICROBIOLOGY 215 Witmer Road Horsham, PA 19044 Maureen Dougherty Phone: (267) 282-2100

#### BIOLOGICAL

Valid To: March 31, 2025

Certificate Number: 6174.01

In recognition of the successful completion of the A2LA evaluation process, including an assessment of the laboratory's conformance with applicable U.S. FDA Current Good Manufacturing Practice (cGMP) regulations per 21 CFR 210 and 211, accreditation is granted to this laboratory to perform the following tests on <u>nonsterile products</u>, <u>purified water</u>, and <u>infant</u> formula:

Test	Method
Antimicrobial Effectiveness Testing	USP <51>
Total Organic Carbon	USP <643>
Infant Formula Testing/Technology	
APC Count (3M <sup>TM</sup> Petrifilm <sup>TM</sup> )	AFNOR 3M 01/0-09/89
Coliforms Count (3M <sup>TM</sup> Petrifilm <sup>TM</sup> )	AOAC 991.14 (modified)
<i>Cronobacter</i> spp. (Cultural Detection and Confirmation using API <sup>®</sup> 20 E)	ISO 22964
Detection of <i>Cronobacter</i> (3M <sup>TM</sup> MDA2)	AFNOR 3M 01/20-03/18
Detection of <i>Listeria monocytogenes</i> (3M <sup>TM</sup> MDA2)	AFNOR 3M 01/15-09/16
Detection of <i>Listeria</i> spp. (3M <sup>TM</sup> MDA2)	AFNOR 3M 01/14-05/16
Detection of <i>Salmonella</i> spp. (3M <sup>TM</sup> MDA2)	AFNOR 3M 01/16-11/16
Enterobacteriaceae Count (3M <sup>TM</sup> Petrifilm <sup>TM</sup> )	AFNOR 3M 01/06-09/97
Enumeration of Presumptive Bacillus cereus	ISO 7932
<i>Escherichia coli</i> Count (3M <sup>TM</sup> Petrifilm <sup>TM</sup> )	AOAC 991.14 (modified)

(A2LA Cert. No. 6174.01) 04/17/2023

An

Page 1 of 2

Test	Method
<i>Listeria</i> spp. (Cultural Detection and Confirmation using API <sup>®</sup> Listeria)	ISO 11290-1
Mesophilic Plate Count	SMEDP 8.090 (modified)
Rapid Yeast & Mold Count (3M <sup>TM</sup> Petrifilm <sup>TM</sup> )	AFNOR 3M 01/13-07/14
Salmonella spp. (Cultural Detection and Confirmation using API <sup>®</sup> 20 E)	ISO 6579-1
Staphylococcus aureus (Direct Plate Count)	FDA BAM Chpt 12
Microbial Enumeration of Nonsterile Products	
Total Aerobic Microbial Count	USP <61>
Total Yeast and Mold Count	USP <61>
Microbial Enumeration of Purified Water	1
Total Aerobic Microbial Count	USP <1231>
Tests for Specified Microorganisms in Nonsterile Produ	icts
Bile-Tolerant Gram-Negative Bacteria / Enterobacteriaceae	USP <62>
Burkholderia cepacia complex (BCC)	USP <60>
Candida albicans	USP <62>
E. coli	USP <62>
Pseudomonas aeruginosa	USP <62>
Salmonella	USP <62>
S. aureus	USP <62>

hu



# **Accredited Laboratory**

A2LA has accredited

## **EUROFINS SF ANALYTICAL – GMP MICROBIOLOGY**

Horsham, PA

for technical competence in the field of

### **Biological Testing**

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories. 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).



Presented this 17<sup>th</sup> day of April 2023.

Mr. Trace McInturff, Vice President, Accreditation Services For the Accreditation Council Certificate Number 6174.01 Valid to March 31, 2025