



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

ELEMENT MATERIALS TECHNOLOGY DALEVILLE, LLC
DBA ELEMENT WARSAW
909 Executive Drive
Warsaw, IN 48674
Tim Esau Phone: 513 808 9172

BIOLOGICAL

Valid To: October 31, 2022

Certificate Number: 6462.01

In recognition of the successful completion of the A2LA evaluation process (including an assessment of the laboratory's compliance with the A2LA Food Testing Program Requirements, containing the 2018 "AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals"), accreditation is granted to this laboratory to perform the following tests on pharmaceuticals, food products, swabs, water, drinking water, wastewater, aqueous materials, medical devices, ingredients, and meat:

<u>Test(s)/Technology(ies)</u>	<u>Test Method(s)</u>
Bioburden	ISO 11737-1
<i>Candida albicans</i> <i>Clostridia</i> <i>Escherichia coli</i> <i>Pseudomonas aeruginosa</i> <i>Salmonella</i> <i>Staphylococcus aureus</i>	USP <62>
Cytotoxicity	ISO 10993-5; USP<87>
Enterobacteriaceae	AOAC 2003.01
<i>E. coli</i> (Food products, Ingredients, Swabs)	AOAC 990.11E; AOAC 991.14; AOAC 998.08;
<i>E. coli</i> (Wastewater)	SM 9223B
<i>E. coli</i> O157:H7	AOAC RI 021501
Heterotrophic Plate Count; Total Microbial Count	SM 9215B; USP <1231>
Limulus Amebocyte Lysate (LAL)	ANSI/AAMI ST72; USP <161>; USP <85>
<i>Listeria monocytogenes</i> (PCR)	AOAC RI 061302
<i>Listeria</i> spp. (PCR)	AOAC RI 071304

<u>Test(s)/Technology(ies)</u>	<u>Test Method(s)</u>
<i>Salmonella enteritidis</i> (PCR)	SOP No. 7011
<i>Salmonella enteritidis</i> (Reveal)	AOAC RI111001
<i>Salmonella</i> spp. (PCR)	AOAC RI 051303
<i>S. aureus</i>	AOAC 2003.07; AOAC 2003.08; AOAC 2003.11
Total Aerobic Microbial Count (TAMC); Total Yeast & Mold Count (TYMC) – Microbial Limits Test	USP <61>
Total Bacterial Count	AOAC 986.32; AOAC 990.12
Total Coliform (Food Products, Ingredients, Swabs)	AOAC 990.11; AOAC 991.14
Total Coliform (Drinking Water)	SM 9223B
Yeast and Mold; 3M Rapid Yeast & Mold	AOAC 2014.05; AOAC 995.21; AOAC 997.02; AOAC RI 121301

CHEMICAL

<u>Test(s)/Technology(ies)</u>	<u>Test Method(s)</u>
Calcium by EDTA	AOAC 983.19 (Modified)
Conductivity	USP <645>
Fat	AOCS Am 5-04
Moisture (Loss on Drying)	AOAC 925.10; AOAC 926.08; AOAC 930.15; AOAC 950.46
pH	AOAC 981.12; SM 4500 HB; USP <791>
TOC	SM 5310C; USP <643>
Water Activity	AOAC 978.18





Accredited Laboratory

A2LA has accredited

ELEMENT MATERIALS TECHNOLOGY DALEVILLE, LLC DBA ELEMENT WARSAW

Warsaw, IN

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 laboratory also meets the requirements of A2LA R204 – *Specific Requirements – Food and Pharmaceutical Testing Laboratory Accreditation Program*. 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 30th day of August 2021.

A blue ink signature of the Vice President of Accreditation Services.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 6462.01
Valid to October 31, 2022

For the tests to which this accreditation applies, please refer to the laboratory's Biological Scope of Accreditation.