



# CERTIFICATE OF ACCREDITATION

## ANSI National Accreditation Board

11617 Coldwater Road, Fort Wayne, IN 46845 USA

This is to certify that

**Element Materials Technology Daleville, LLC**  
**dba Element Warsaw**  
**909 Executive Drive**  
**Warsaw, IN 46580**

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

**ISO/IEC 17025:2017**

and the

**AOAC International Guidelines for Laboratories Performing Microbiological and  
Chemical Analysis of Food, Dietary Supplements and Pharmaceuticals (2015)**

while demonstrating technical competence in the field of

**TESTING**

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

L2228

Certificate Number

  
ANAB Approval

Certificate Valid Through: 02/20/2022  
Version No. 003 Issued: 02/07/2020



This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017.  
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).

**SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017  
and  
AOAC INTERNATIONAL GUIDELINES FOR LABORATORIES  
PERFORMING MICROBIOLOGICAL AND CHEMICAL ANALYSIS OF  
FOOD, DIETARY SUPPLEMENTS AND PHARMACEUTICALS (2015)**

**Element Materials Technology Daleville, LLC  
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**TESTING**

Valid to: **February 20, 2022**

Certificate Number: **L2228**

**Microbiology**

<b>Specific Tests and/or Properties Measured</b>	<b>Specification, Standard, Method, or Test Technique</b>	<b>Items, Materials or Product Tested</b>	<b>Key Equipment or Technology</b>
E. Coli	AOAC 990.11E; AOAC 998.08; AOAC 991.14	Food Products, Ingredients, Swabs	Incubator, Petrifilm, Agar Plates
E. Coli	SM 9223B	Wastewater	Incubator, Colilert
Total Bacterial Count	AOAC 986.32; AOAC 990.12	Food Products, Ingredients, Swabs	Incubator, Petrifilm, Agar Plates
Total Coliform	AOAC 990.11; AOAC 991.14	Food Products, Ingredients, Swabs	Incubator, Petrifilm, Agar Plates
Total Coliform	SM 9223B	Drinking Water	Incubator, Colilert
Yeast and Mold 3M Rapid Yeast & Mold	AOAC 995.21; AOAC 997.02; AOAC 121301; AOAC 2014.05	Food Products, Ingredients, Swabs	Incubator, Petrifilm, Agar Plates
Heterotrophic Plate Count Total Microbial count	SM 9215B; USP <1231>	Drinking Water	Incubator, Agar Plates



**Microbiology**

<b>Specific Tests and/or Properties Measured</b>	<b>Specification, Standard, Method, or Test Technique</b>	<b>Items, Materials or Product Tested</b>	<b>Key Equipment or Technology</b>
Staphylococcus Aureus	AOAC 2003.07; AOAC 2003.08; AOAC 2003.11	Food Products, Ingredients, Swabs	Incubator, Petrifilm, Agar Plates
Limulus Amebocyte Lysate (LAL)	USP <85>; USP <161>; ANSI/AAMI ST72	Aqueous, Medical Devices	Plate Reader, Clean Room
E. Coli 0157:H7	AOAC RI 021501	Food Products, Ingredients, Swabs	Incubator, ELISA, RT-PCR
Salmonella Enteritidis (PCR)	SOP No. 7011	Environmental Swabs and Shell Eggs	Incubator, RT-PCR
Salmonella Enteritidis (Reveal)	AOAC RI111001	Environmental Swabs and Shell Eggs	Incubator, ELISA
Salmonella Species (PCR)	AOAC RI 051303	Food Products, Ingredients, Swabs	Incubator, RT-PCR
Listeria Monocytogenes (PCR)	AOAC RI 061302	Food Products, Ingredients, Swabs	Incubator, RT-PCR
Listeria Species (PCR)	AOAC RI 071304	Food Products, Ingredients, Swabs	Incubator, RT-PCR
Enterobacteriaceae	AOAC 2003.01	Food Products, Ingredients, Swabs	Incubator, Petrifilm, Agar Plates
Bioburden	ISO 11737-1	Medical Device	Incubator, Agar Plates
Total Aerobic Microbial Count (TAMC); Total Yeast & Mold Count (TYMC) - Microbial Limits Test	USP <61>	Pharmaceuticals, Ingredients	Incubator, Agar Plates
Escherichia coli Salmonella Staphylococcus aureus Pseudomonas aeruginosa Clostridia Candida albicans	USP <62>	Pharmaceuticals, Ingredients, Water	Incubator, Agar Plates
Cytotoxicity	ISO 10993-5; USP<87>	Aqueous, Ingredients, Materials, Medical Devices	CO <sup>2</sup> Incubator, Microscope



Chemistry

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Calcium by EDTA	AOAC 983.19	Meat	Titration
pH	SM 4500 HB; AOAC 981.12; USP <791>	Water, Aqueous, Food Samples	Ion Meter
Water Activity	AOAC 978.18	Food Products, Ingredients	Water Activity Meter
Moisture (Loss on Drying)	AOAC 925.10; AOAC 926.08; AOAC 950.46; AOAC 930.15	Food Products, Ingredients	Air Oven, Balance
Ash	AOAC 923.03	Food Products, Ingredients	LECO
Protein	AOAC 992.15; AOAC 990.03	Food Products, Ingredients	LECO
Fat	AOCS Am 5-04	Food Products, Ingredients	Ankom
TOC	USP <643>; SM 5310C	Water, Swabs, Medical Devices	GE
Conductivity	USP <645>	Water	GE

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. L2228.



Vice President