



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

ELEMENT MATERIALS TECHNOLOGY BOSTON – ACTON INC.

33 Nagog Park
Acton, MA 01720

Mr. Mark W Przybyla Phone: 978 393-4095
Mark.Przybyla@element.com

BIOLOGICAL

Valid To: January 31, 2027

Certificate Number: 3383.02

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests on injectable, topical, and oral pharmaceuticals, raw materials, personal care products, cosmetics, medical devices, water, biological indicators, and controlled environments:

<u>Test:</u>	<u>Test Method(s):</u>	<u>Internal Method(s):</u>
Antimicrobial Effectiveness Testing	USP <51>; CTFA M-3, M-4	P-0002, P-0014, P-0015
Biological Indicators BI Population Verification	USP <55>	QC-0005
Endotoxin Testing	USP <85>	P-0010, P-0013, P-0017, P-0025
Environmental Evaluation of Clean Rooms ¹	USP <1116>, <797>	P-0007, P-0029
Microbial Examination of Nonsterile Products: Microbial Enumeration Tests and Tests for Specified Microorganism	USP <61>, <62>	P-0018
Microbiological Examination of Non-Sterile Products: Tests for <i>Burkholderia cepacia</i> Complex	USP<60>	P-0040
Sterility Testing	USP <71>; ASNI/AAMI ISO 11137, ISO 11737-2, EN ISO 11737-2	P-0004, P-0006, P-0009
Water Microbial Testing Total Heterotrophic Plate Count, Coliform Test	USP <1231> Water for Pharmaceutical Methods	P-0003

¹ This laboratory performs field testing activities for these tests.



Accredited Laboratory

A2LA has accredited

ELEMENT MATERIALS TECHNOLOGY BOSTON – ACTON INC.

Acton, MA

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 22nd day of November 2024.

A blue ink signature of Mr. Trace McInturff, written in a cursive style.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3383.02
Valid to January 31, 2027

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