



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

ELEMENT MATERIALS TECHNOLOGY OAKLAND – CONCORD INC.

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BIOLOGICAL

Valid To: December 31, 2024

Certificate Number: 3383.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests on pharmaceuticals, biotech products, drug products, food products, controlled environments, water, environmental samples, and medical devices:

<u>Test</u>	<u>Reference Method(s)</u>	<u>SOP(s)</u>
Antimicrobial Effectiveness Test	USP <51>	MB-0024
Bacterial Endotoxin Test	USP <85>	MB-0041 MB-0042 MB-0043 MB-0044
Biological Indicators	USP <55>	MB-0022
*Compressed Gas Sampling and Testing	USP <797> USP <1116> ISO 8573	EM-0006 EM-0010 EM-0012 EM-0014
Cytotoxicity and Biological Reactivity	ISO 10993-5 USP <87>	CC-0002 CC-0006
Detection of Mycoplasma and Virus by PCR	EU 2.6.7	PC-0001 PC-0003 PC-0005 PC-0006 PC-0007 PC-0011 MY-0008
Detection of Virus in Test Articles	USP <1050> USP <1237>	VI-0002
*Environmental Monitoring Testing	USP <797> USP <1116> ISO 14644-1 ISO 14644-2	EM-0002 EM-0003 EM-0009 EM-0011 EM-0013 EM-0015
Incubation of Media	USP <797> USP <1116> ISO 14644 ISO 13408	MB-0020 MB-0027

<u>Test(s)</u>	<u>Reference Method(s)</u>	<u>SOP(s)</u>
Growth Promotion and Sterility Testing of Microbiological Media	USP <61> USP <62> USP <71> USP <2021>	MB-0001
Microbial Identification	USP <1113>	MB-0004
Microbiological Examination of Non-Sterile Products: Pour Plate, Spread Plate, Membrane Filtration Methods and Microbial Enumeration Method Suitability	USP <61> USP <2021> ISO 11737	MB-0006 MB-0007 MB-0025 MB-0032
Microbiological Examination of Non-Sterile Products: Test for Specified Microorganisms for: <i>Escherichia coli</i> , <i>Salmonella</i> , <i>Pseudomonas aeruginosa</i> , <i>Staphylococcus aureus</i> , <i>Clostridia</i> , <i>Candida Albicans</i> , <i>Burkholderia cepacia</i>	USP <60> USP <62>	MB-0012 MB-0013 MB-0045 MB-0046
Mycoplasma Detection by Direct and Indirect Methods	USP <63> EP 2.6.7	MY-0001 MY-0003 MY-0004 MY-0005 MY-0006 MY-0007
*Sampling of Water Systems	USP <1116>	EM-0004
Sterility Test	USP <71>	MB-0016 MB-0017 MB-0028 MB-0029 MB-0037 MB-0038
Water Microbial Testing Total Heterotrophic Plate Count, Coliform Test	USP <1231> EPA 1604	MB-0003 MB-0015

CHEMICAL

<u>Test</u>	<u>Reference Method(s)</u>	<u>SOP</u>
Conductivity Test	USP <645>	CH-0002
Nitrogen Purity Assay	USP-NF Nitrogen EP 1247	CH-0010
Total Organic Carbon	USP <643>	CH-0001

*This laboratory meets A2LA R104 – General Requirements: Accreditation of Field Testing and Field Calibration Laboratories for these tests.





Accredited Laboratory

A2LA has accredited

ELEMENT MATERIALS TECHNOLOGY OAKLAND – CONCORD INC.

Concord, CA

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 28th day of December, 2022.

A blue ink signature of Mr. Trace McInturff.

Mr. Trace McInturff, Vice President, Accreditation Services
for the Accreditation Council
Certificate Number 3383.01
Valid to December 31, 2024

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