



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

EXPONENT, INC.¹
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Philadelphia, PA 19104
Ryan Siskey Phone: 215 594 8896
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MECHANICAL

Valid To: June 30, 2025

Certificate Number: 2561.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory at the location listed above, *as well as the two satellite laboratory locations listed below*, to perform the following types of tests on the following materials: medical grade plastics, metals and biomaterials, medical consumables, tissue and medical devices in conformance with the U.S. FDA Good Laboratory Practice (GLP) Regulations per 21 CFR 58²:

Testing is completed for the following parameters within the ranges specified below:

<u>Parameter</u>	<u>Range [Units]</u>
Load:	0 to ± 30 [kN]
Displacement:	0 to ±100 [mm]
Torque:	0 to ±100 [Nm]
Angle:	0 to 360 [°]
Pressure:	0 to 500 [psi]
Flow:	0 to 22 [L/min]

<u>Test</u>	<u>Test Method(s)</u>
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Electrochemical Tests:

Corrosion Susceptibility	ASTM F2129
Evaluation of Galvanic Corrosion	ASTM F3044
Potentiostatic and Potentiodynamic Anodic Polarization Measurements	ASTM G5 ⁸
Fretting Corrosion of Modular Orthopedic Components	ASTM F1875

Biotribology:

Spinal Implant Wear Rate	ASTM F2423, F3295; ISO 18192-1
Knee Implant Wear Rate	ISO 14243-1, -2, -3
Material Wear Rate	ASTM F732

Test**Test Method(s)*****Biotribology (continued):***

Particle Analysis ASTM F1877

Tissue Characterization:

Mechanical Characterization of Cadaveric and Animal Tissue SOP.160³, 053³, 116³

MicroCT Imaging and Analysis SOP.286³

Tissue Ball Burst Testing SOP.287³

Device Specific Tests:

Bone Screw Testing ASTM F543

Static and Dynamic Characterization of Spinal Constructs ASTM F1717

Mechanical Methods for Intervertebral Body Fusion Devices ASTM F2077

Subsidence Testing ASTM F2267

Mechanical Characterization of Total Disc Replacements ASTM F2346

Push-out Testing ASTM Draft Guide Dated Aug 29, 2000; SOP.357³

Hip Rim Impingement ASTM F2582

Total Hip Disassembly ASTM F1820

Axial Disassembly Force of Taper Connections and Modular Prostheses ASTM F2009

Breast Implant Fatigue ISO 14607 Annex C

Sample Preparation and Conditioning:

Accelerated Shelf Aging ASTM F1980

Accelerated Aging ASTM F2003

Implant Characterization:

Characterization of Retrieved Implants SOP.200³; ASTM F561; ISO 12891

SEM and EDS ASTM E1508, E766; SOP.213³

Surface Characterization Using a Zygo White Light Interferometer SOP.011^{3,5}

Test**Test Method(s)*****Implant Characterization (continued):***

Photomicrographs	ASTM E883; SOP.264 ³
Taper Measurement Using a Talyrond	ASTM F3129; SOP.309 ³
MicroCT Imaging and Analysis	SOP.286 ³

Cardiovascular Device Characterization:

Peripheral Stent Testing (MAPS)	ASTM F2942, F2477; SOP.342 ³
Heart Valve Pulse Duplication	ISO 5840-1, -2, -3
Heart Valve Durability	ISO 5840-1, -2, -3

Spectroscopy/Chemical Tests:

FTIR	ASTM E1252, E334; SOP.081 ³
Hydroperoxide Index	SOP.064 ^{3,4} , SOP.347 ³
Oxidation Index	ASTM F2102; SOP.347 ³
Trans-Vinylene Index	ASTM F2381; SOP.347 ³
UHMWPE Crystallinity Index	ASTM F2102; SOP.347 ³
PEEK Crystallinity Index	ASTM F2778; SOP.256 ³

Biomaterials Testing:

Tensile	ASTM D638, E8
Compression Modulus	ASTM D695, F451
IZOD Impact	ASTM F648 (Annex A1), D256
Poisson's Ratio Testing	SOP.006 ³
Small Punch	ASTM F2183, F2977
Fatigue Crack Propagation	ASTM E647
Nitinol Tensile Testing	ASTM F2516
Bending of Bone Cement	ISO 5833
Fatigue Life of Bone Cement	ASTM F2118
Coefficient of Friction	ASTM D1894

<u>Test</u>	<u>Test Method(s)</u>
<i>Biomaterials Testing (continued):</i>	
Density using Helium Pycnometer	SOP.244
Preparation of Metallographic Specimens	ASTM E3
Standard Practice for Microetching Metals and Alloys	ASTM E407
Standard Test Method for Tension Testing of Calcium Phosphate and Metallic	ASTM F1147
Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings	ASTM F1044
Standard Test Method for Shear and Bending Fatigue of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings	ASTM F1160
<i>Hydroxyapatite Testing:</i>	
Dissolution Testing	SOP.348 ^{3,6} ; ASTM F1926
Solubility	SOP.348 ^{3,6}
<i>Textiles:</i>	
Ball Burst Testing	ASTM D6797
<i>Syringes, Needles and Related Equipment-Conical Fittings/Lock Fittings⁹:</i>	
Gauging	ISO 594/1, 4.1, 5.1
Liquid Leakage	ISO 80369-7; ISO 594/1, 4.2, 5.2; ISO 594/2, 4.2, 5.2, 5.3
Air Leakage	ISO 80369-7; ISO 594/1, 4.3, 5.3
Separation Force	ISO 80369-7; ISO 594/1, 4.4, 5.4; ISO 594/2, 4.3, 5.4
Stress Cracking	ISO 80369-7; ISO 594/1, 4.5, 5.5; ISO 594/2, 4.7, 5.8
Unscrewing Torque	ISO 80369-7; ISO 594/2, 4.4, 5.5
Ease of Assembly	ISO 594/2, 4.5, 5.6
Resistance to Overriding	ISO 80369-7; ISO 594/2, 4.6, 5.7

Test

Test Method(s)

Catheters:

Tensile Testing	ISO 10555-1 Annex B
Leak Testing	ISO 10555-1 Annex C
Gravity Flow	ISO 10555-1 Annex E
Burst Testing	ISO 10555-1 Annex F

Consumer Product Testing:

Football Glove Testing	SFIA Specification FBG - V.001 - 2015
Condom Testing	ASTM D3492

EXPONENT¹
MRI
University of Pennsylvania
3600 Civic Center Blvd Philadelphia, PA 19104

<u>Test</u>	<u>Test Method(s)</u>
<i>Passive Device MRI Testing:</i>	
Artifacts	ASTM F2119
Induced Force and Displacement	ASTM F2052
Induced RF Heating ⁷	ASTM F2182
Induced Torque	ASTM F2213
<i>Active Device MRI Testing:</i>	
RF Heating ⁷	ISO 10974: Clause 8
Gradient Heating ⁷	ISO 10974: Clause 9
Vibration	ISO 10974: Clause 10
Induced Force	ISO 10974: Clause 11
Induced Torque	ISO 10974: Clause 12
RF Unintended Stimulation ⁷	ISO 10974: Clause 15
Gradient Unintended Stimulation ⁷	ISO 10974: Clause 13
Static Field Malfunction	ISO 10974: Clause 14
RF Malfunction ⁷	ISO 10974: Clause 15
Gradient Malfunction ⁷	ISO 10974: Clause 16
Combined Fields Malfunction	ISO 10974: Clause 17
<i>General MRI:</i>	
MRI Safety Labeling	ASTM F2503
MRI Modeling	SOP.398

EXPONENT¹
Liz Smith
Thomas Jefferson Department of Radiology
111 S. 11th St. Suite 300, Philadelphia, PA 19107

Test

Test Method(s)

Device Imaging

Radiopacity

ASTM F640

¹This accreditation covers testing performed at all laboratories listed above.

²The materials testing standards listed on this scope of accreditation may be used for both medical and non-medical plastics and metals.

³In-House method

Literature References:

⁴D. C. Mazzucco, J. Dumbleton, and S. M. Kurtz, "Can accelerate aqueous aging simulate in vivo oxidation of gamma-sterilized UHMWPE?," J. Biomed Water Res B Appl Biomater, vol. 79, pp 79-85, 2006.

⁵S. M. Kurtz, J. Peloza, R. Siskey, and M. L. Villarraga, "Analysis of a retrieved polyethylene total disc replacement component," Spine J, vol. 5, pp 344-50, 2005

⁶FDA Guidance: 510(K) Information Needed for Hydroxyapatite Coated Orthopedic Implants (February 27, 1997)

⁷Method utilizes RF and/or gradient coils found in the main laboratory.

⁸This method is used as a quality control method for the CAB, not used for reporting.

⁹ISO 591-1 and ISO 594-2 are withdrawn and still used in CAB operating procedures



Accredited Laboratory

A2LA has accredited

EXPONENT, INC.

Philadelphia, PA

for technical competence in the field of

Mechanical 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 September 2023.

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 2561.01
Valid to June 30, 2025

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



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

EXPONENT, INC.
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Menlo Park, CA 94025
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MECHANICAL

Valid to: June 30, 2025

Certificate Number: 2561.03

In recognition of the successful completion of the A2LA Accreditation Program, accreditation is granted to this laboratory to perform the following tests: medical grade plastics, metals and biomaterials, medical consumables, tissue and medical devices in conformance with the U.S. FDA Good Laboratory Practice (GLP) Regulations per 21 CFR 58¹:

Biomedical Engineering Group

<u>Test Type/Technology:</u>	<u>Test Method:</u>
Retrieval Analysis	SF_SOP 002; ASTM F561 (<i>except section 16</i>); ISO 12891
Advanced (Water) Contact Angle	ASTM D7334

Materials and Corrosion Engineering

<u>Test Type/Technology:</u>	<u>Test Method:</u>
Corrosion – Cyclic Polarization	ASTM F2129
Corrosion – Anodic Polarization	ASTM G5 ²
Corrosion – Galvanic Corrosion	ASTM F3044
Corrosion – Metal Ion Release	ASTM F3306
Computer Tomography (CT) Examination	SF_SOP 032

Polymer Science and Materials Chemistry

<u>Test Type/Technology:</u>	<u>Test Method:</u>
FTIR	ASTM E334, ASTM E573, ASTM E1252
GCMS	SF_SOP 020 / Modified EPA Method 8270D
LC-UV-MS	SF_SOP 035

Electrical Engineering and Computer Science

<u>Test Type/Technology:</u>	<u>Test Method:</u>
Determination of Alpha and Accessible Exposure for Sources with a Single Centroid Wavelength Between 400 nm and 1100 nm and Continuous Wave Operation	IEC 60825-1 section 5.4.3 for Condition 3

Card Warpage / Overall Card Warpage	ISO/IEC 10373-1 (section 5.1), ISO/IEC 7810 (section 8.10)
Dimensions of Cards	ISO/IEC 10373-1 (section 5.2) ISO/IEC 7810 (section 5.1)
Peel Strength	ISO/IEC 10373-1 (section 5.3) ISO/IEC 7810 (section 8.7)
Resistance to Chemicals	ISO/IEC 10373-1 (section 5.5) <i>(except Salt Mist)</i> ISO/IEC 7810 (section 8.3)
Card Dimensional Stability and Warpage with Temperature and Humidity	ISO/IEC 10373-1 (section 5.6) ISO/IEC 7810 (section 8.4)
Adhesion and Blocking	ISO/IEC 10373-1 (section 5.7) ISO/IEC 7810 (section 8.8)
Bending Stiffness	ISO/IEC 10373-1 (section 5.8) ISO/IEC 7810 (section 8.1)
Dynamic Bending Stress	ISO/IEC 10373-1 (section 5.9)
Dynamic Torsional Stress	ISO/IEC 10373-1 (section 5.10)
Opacity	ISO/IEC 10373-1 (section 5.11) ISO/IEC 7810 (section 8.9)
Resistance to Heat	ISO/IEC 10373-1 (section 5.14) ISO/IEC 7810 (section 8.11)
Flex Testing with In-situ RFID Field Monitoring	ANSI 322

¹ The materials testing standards listed on this scope of accreditation may be used for both medical and non-medical plastics and metals.

² This method is used as a quality control method for the CAB, not used for reporting.





Accredited Laboratory

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EXPONENT, INC.

Menlo Park, CA

for technical competence in the field of

Mechanical 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 16th day of June 2023.

A blue ink signature of Mr. Trace McInturff, written over a horizontal line.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 2561.03
Valid to June 30, 2025

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



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

EXPONENT, INC.
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MECHANICAL

Valid to: June 30, 2025

Certificate Number: 2561.04

In recognition of the successful completion of the A2LA Accreditation Program, accreditation is granted to this laboratory to perform the following tests on the following materials: metals, biomaterials, medical consumables, and medical devices:

Test Type/Technology:

Test Method:

Corrosion:

Cyclic Polarization – Small Implant
Devices
Anodic Polarization
Galvanic

ASTM F2129
ASTM G5¹
ASTM G71; ASTM F3044

Cyclic Polarization Measurements for
Localized Corrosion, Susceptibility of
Iron, Nickel, and Cobalt Alloys

ASTM G61

Electrical Engineering and Computer Science:

Determination of Alpha and Accessible
Exposure for Sources with a Single
Centroid Wavelength Between 400 nm
and 1100 nm and Continuous Wave
Operation

IEC 60825-1 section 5.4.3 for Condition 3

¹ This method is used as a quality control method for the CAB, not used for reporting.



Accredited Laboratory

A2LA has accredited

EXPONENT, INC

Natick, MA

for technical competence in the field of

Mechanical 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 15th day of June 2023.

A blue ink signature of Mr. Trace McInturff, written over a horizontal line.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 2561.04
Valid to June 30, 2025

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