



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

EXPONENT, INC.¹
25 N 38th Street Suite 700
Philadelphia, PA 19104
Ryan Siskey Phone: 215 594 8896
Email: rsiskey@exponent.com



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

Biomaterials Testing (continued):

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

Hydroxyapatite Testing:

Dissolution Testing	SOP.348 ^{3,6} ; ASTM F1926
Solubility	SOP.348 ^{3,6}

Textiles:

Ball Burst Testing	ASTM D6797
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Syringes, Needles and Related Equipment- Conical Fittings/Lock Fittings⁹:

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

Passive Device MRI Testing:

Artifacts	ASTM F2119
Induced Force and Displacement	ASTM F2052
Induced RF Heating ⁷	ASTM F2182
Induced Torque	ASTM F2213

Active Device MRI Testing:

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 ⁷⁷	

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 Mater Res B Appl Biomater, vol. 79, pp 79-85, 2006.

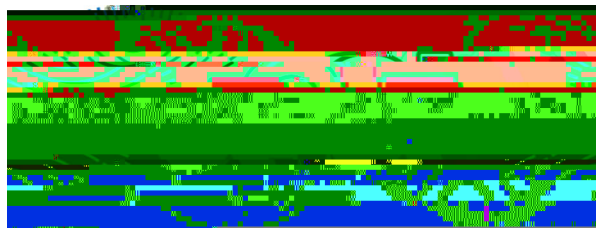
⁵S. M. Kurtz, J. Peloza, R. Siskey, and M. L. Villarraga, "Analysis of a retrieved polyethylene total disc replacement component," Spine J, vol. 5, pp 344-50, 2005

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

Philadelphia, PA

General requirements for the competence of testing and calibration laboratories

refer to joint ISO-ILAC-IAF Communiqué dated April 2017



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.
149 Commonwealth Drive
Menlo Park, CA 94025
Kevin Reichelderfer Phone: 650 688 6996
E-mail: Kreichelderfer@exponent.com

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:

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

FTIR	ASTM E334, ASTM E573, ASTM E1252
GCMS	SF_SOP 020 / Modified EPA Method 8270D
LC-UV-MS	SF_SOP 035

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

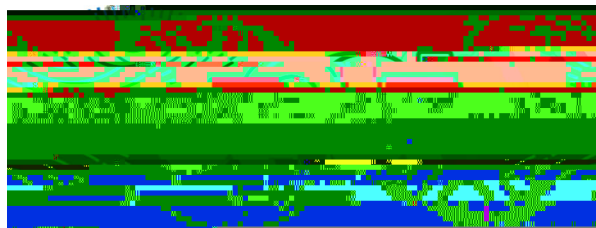


Card Warpage / Overall Card Warpage	ISO/IEC 10373-1 (section 5.1), ISO/IEC 7810 (section 8.10)
Dimensions of Cards	ISO/IEC 10373-1 (section 5.2) ISO/IEC 7810 (section 5.1)
Peel Strength	ISO/IEC 10373-1 (section 5.3) ISO/IEC 7810 (section 8.7)
Resistance to Chemicals	ISO/IEC 10373-1 (section 5.5) <i>(except 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

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



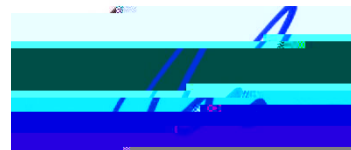


Accredited Laboratory

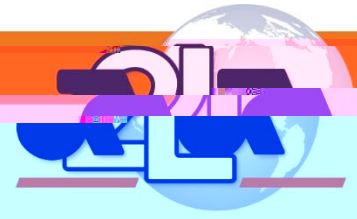
Menlo Park, CA

General requirements for the competence of testing and calibration laboratories

refer to joint ISO-ILAC-IAF Communiqué dated April 2017



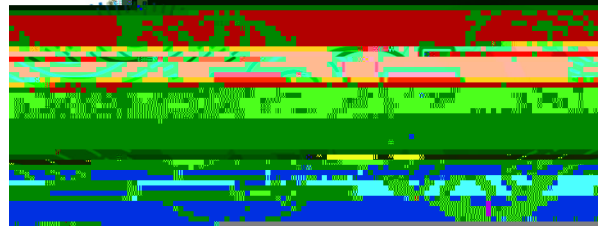
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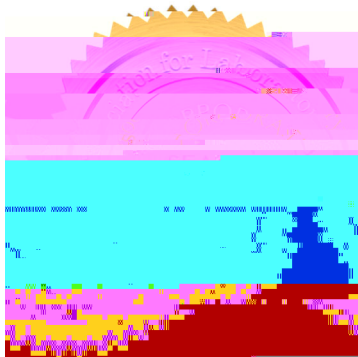


Accredited Laboratory

Natick, MA

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