



CERTIFICATE OF ACCREDITATION

ANSI National Accreditation Board

11617 Coldwater Road, Fort Wayne, IN 46845 USA

This is to certify that

JTL America

3205 Clairmont Ct., Ste. B

Fort Wayne, IN 46808

(and satellite location as listed on the scope)

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

ISO/IEC 17025:2017

while demonstrating technical competence in the field of

TESTING and DIMENSIONAL MEASUREMENT

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

L2167

Certificate Number



ANAB Approval

Certificate Valid Through: 01/19/2020
Version No. 004 Issued: 03/14/2019



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

JTL America
3205 Clairmont Ct., Ste. B
Fort Wayne, IN 46808
Kevin Knight
260 489 1444

TESTING

Valid to: January 9, 2020

Certificate Number: L2167

Mechanical

Table with 4 columns: Specific Tests and/or Properties Measured, Specification, Standard, Method, or Test Technique, Items, Materials or Product Tested, and Key Equipment or Technology. It lists four types of mechanical tests: Tension & Compression Monotonic Testing, Force Controlled Cyclic Testing, Displacement Controlled Cyclic Testing, and Torsional Monotonic Testing.



Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Torque Controlled Cyclic Testing (-225 to 225) Nm (0 to 270) degrees (0 to 5) Hz	Customer supplied specifications Laboratory developed specifications approved by the client	Mechanical components: medical, automotive, aerospace, heavy vehicle, agricultural, defense, and consumer products	Load Frames Controllers LVDTs ADTs Load Cells
Fracture Toughness Testing (-250 000 to 250 000) N (Up to 5) in	ASTM E399 ASTM B645 ASTM E1820	All Metal Alloys	Load Frames Controllers LVDTs COD Gage Load Cells
Axial Fatigue Testing (Strain and Stress) (-250 000 to 250 000) N	ASTM E466 ASTM E606	All Metal Alloys	Load Frames Controllers LVDTs Load Cells Extensometer

JTL America has demonstrated technical competency to perform ISO/IEC 17025:2005 accredited testing activities per the test technologies identified in the table above and the test methods identified below per the attached annex 1.

Annex 1 – ISO/IEC 17025 Accredited Test Methods

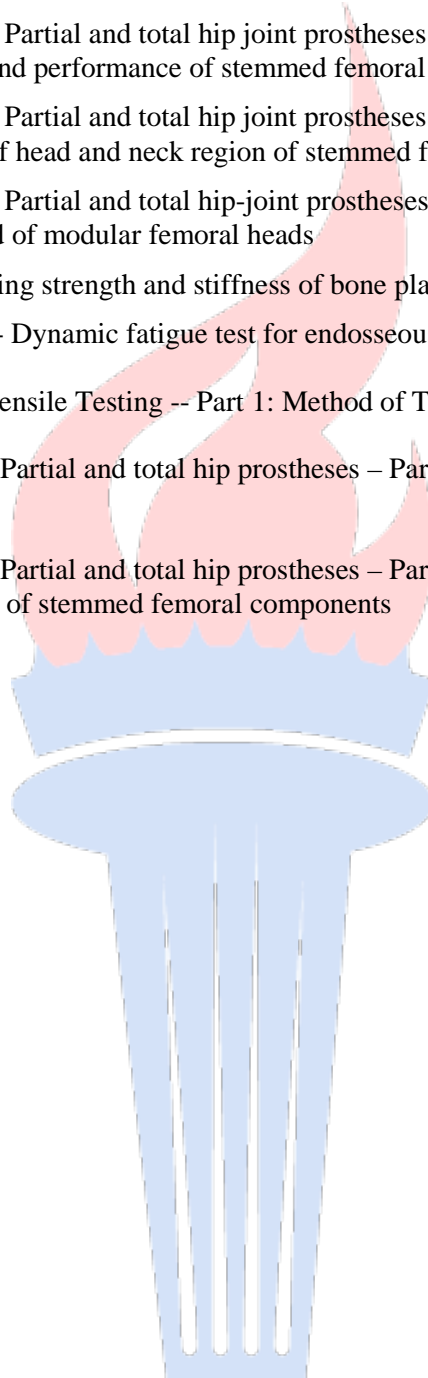
ASTM Test Methods:

- F382 Standard Specification and Test Method for Metallic Bone Plates
- F543 Standard Specification and Test Methods for Metallic Medical Bone Screws
- F564 Standard Specification and Test Methods for Metallic Bone Staples
- F1044 Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings
- F1147 Standard Test Method for Tension Testing of Calcium Phosphate and Metal Coatings
- F1160 Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings
- F1440 Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components without Torsion

- F1223 Standard Test Method for Determination of Total Knee Replacement Constraint
- F1264 Standard Specification and Test Methods for Intramedullary Fixation Devices
- F1612 Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components with Torsion
- F1717 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
- F1798 Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants
- F1800 Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements
- F1820 Standard Test Method for Determining the Axial Disassembly Force of a Modular Acetabular Device
- F2009 Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses
- F2028 Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation
- F2077 Test Methods for Intervertebral Body Fusion Devices
- F2193 Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System
- F2267 Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device under Static Axial Compression
- F2345 Standard Test Methods for Determination of Static and Cyclic Fatigue Strength of Ceramic Modular Femoral Heads
- F2502 Standard Specification and Test Methods for Bioabsorbable Plates and Screws for Internal Fixation Implants
- F2706 Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model
- F2777 Standard Test Method for Evaluating Knee Bearing (Tibial Insert) Endurance and Deformation Under High Flexion
- E8 Standard Test Methods for Tension Testing of Metallic Materials
- E9 Standard Test Methods of Compression Testing of Metallic Materials at Room Temperature
- E466 Standard Practice for Conducting Force Controlled Constant Amplitude Axial Fatigue Tests of Metallic Materials
- E606 Standard Test Method for Strain-Controlled Fatigue Testing
- E1820 Standard Test Method for Measurement of Fracture Toughness J_{Ic}
- E399 Standard Test Method for Linear-Elastic Plane-Strain Fracture Toughness K_{Ic} of Metallic Materials
- B645 Standard Test Method for Linear-Elastic Plane-Strain Fracture Toughness of Aluminum Alloys

ISO Test Methods:

- 7206-4 Implants for surgery -- Partial and total hip joint prostheses -- Part 4: Determination of endurance properties and performance of stemmed femoral components
- 7206-6 Implants for surgery -- Partial and total hip joint prostheses -- Part 6: Determination of endurance properties of head and neck region of stemmed femoral components
- 7206-10 Implants for surgery -- Partial and total hip-joint prostheses -- Part 10: Determination of resistance to static load of modular femoral heads
- 9585 Determination of bending strength and stiffness of bone plates
- 14801 Dentistry -- Implants -- Dynamic fatigue test for endosseous dental implants
- 6892-1 Metallic Materials -- Tensile Testing -- Part 1: Method of Test at Room Temperature
- 7206-12 Implants for surgery – Partial and total hip prostheses – Part 12: Deformation test method for acetabular shells
- 7206-13 Implants for surgery – Partial and total hip prostheses – Part 13: Determination of resistance torque of head fixation of stemmed femoral components





Satellite Location

JTL America

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Livonia, MI 48150

Peter Sinn peter.sinn@jtlamerica.com

260 489 1444

TESTING AND DIMENSIONAL MEASUREMENT

Testing

Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Vibration (Sine, Random, Shock, and Sine on Random)	Per Customer Specifications	Mechanical components: medical, automotive, aerospace, heavy vehicle, agricultural, defense, and consumer products	Vibration Test System and Environmental Chambers 5 to 3000 Hz Up to 8000lb/F Sine and Random. Up to 60 g Shock

Environmental Simulation

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Temperature	Per Customer Specifications	Mechanical components: medical, automotive, aerospace, heavy vehicle, agricultural, defense, and consumer products	Temperature Chambers -50°C to +180°C (-58°F to +350°F)
Humidity	Per Customer Specifications	Mechanical components: medical, automotive, aerospace, heavy vehicle, agricultural, defense, and consumer products	Temperature/Humidity Chambers 10% to 98%



Dimensional Measurement

Dimensional 3D

Parameter/Equipment	Range	Expanded Uncertainty of Measurement (+/-)	Reference Standard, Method, and/or Equipment
3D Inspection/Measurement	MV 100 - 100 x 75 x 70 mm MV 320 - 320 x 240 x 240 mm MV 700 - 700 x 530 x 520 mm (Single Scan Range)	MV100 - $\pm 20 \mu\text{m}$ MV320 - $\pm 54 \mu\text{m}$ MV700 - $\pm 94 \mu\text{m}$	Blue Light 3D Scanner. Scans performed according to Customer Specifications
Real Time X-Ray	1900 by 1500 pixels (Pixel Size changes depending on magnification, vertical scans can be matched together)	$\pm 4\%$ of Measured Value	X-Ray / CT Machine, VG Studio Software, Scans performed to Customer Specifications

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. L2167.
2. This laboratory offers commercial testing service.

Vice President

