Accutek Facility

Accutek’s 50,000 sq. foot facility is located just outside Cincinnati, OH, and houses our high capacity mechanical and metallurgical testing labs. Our expansive mechanical test lab features state-of-the-art equipment for a multitude of test types and applications. Our metallurgical test lab provides accurate and timely results for material identification and verification.

Accutek recognizes how mission-critical your testing requirements are. We work with you to develop a customized and cost-effective testing plan and, if necessary, test equipment modified to your organization’s exact testing needs. Our attention to detail and dedication to quality through every stage of our projects produce quantifiable results in a timely manner. We work hard to understand your needs before embarking on a test.

Your test is done right – the first time.

Testing Capabilities Include:

• Static Tension/Compression, milligrams to 200,000 lbs
• Static Torsion, 20,000 in-lbs (2,300 N-m)
• 65+ Dynamic Tension/Compression Fatigue Frames, up to 200,000 lbs at 0–50 Hz
• 10+ Dynamic Torsion Fatigue Frames, up to 20,000 in-lbs (2,300 N-m) at 0-30 Hz
• Hip/Knee/Spine Prosthesis Wear Simulation
• Pin on Disc Wear
• Custom Multiple Degree of Freedom Wear and Fatigue Test Frames
• Charpy Impact Tester
• Custom Environmental Test Chambers
• Rotating Beam, Taber Abrasion, Friction
• Hardness - Brinell, Rockwell, Superficial, and Micro Knoop & Vickers, 10-1000gf
• Dimensional, Optical Comparator, Thread Gaging
• CNC Machine shop for specimen preparation and custom mechanical test setup
• Displacement measurement capability for all mechanical tests
• Metallographic capability for grain evaluation, failure analysis and other surface conditions up to 1000X

Testing Capabilities:

• Mechanical
• Metallurgical
• Failure Analysis
• Welding & Brazing
• Certification
• Fracture Mechanics

Accreditations:

• ISO/IEC 17025:2005(E)
• Nadcap Certified
• GSA Schedule 871-4
• CCR Registered
• Pratt & Whitney / GE Aircraft Engines
• PE Certificates
• CWI Services

Industries Served:

• Aerospace
• Automotive
• Composite
• Defense
• Manufacturing
• Medical
• Utilities
Below is a list of medical device test specifications Accutek routinely tests. However, our capabilities are not limited to these.

**ASTM**
- F382 Specification and Test Method for Metallic Bone Plates
- F564 Specification and Test Method for Metallic Bone Staples
- F543 Standard Specification and Test Methods for Metallic Medical Bone Screws
- F1044 Test Method for Shear Testing of Porous Metal Coatings
- F1147 Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings
- F1223 Standard Test Method for Total Knee Replacement Constraint
- F1264 Specification and Test Method for Intramedullary Fixation Devices
- F1440 Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components Without Torsion
- F1541 Standard Specification and Test Methods for External Skeletal Fixation Devices
- F1612 Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components With Torsion
- F1659 Test Method for Bending and Shear Fatigue Testing of Calcium Phosphate Coatings on Solid Metallic Substrates
- F1717 Standard Test Method for Spinal Implant Constructs in a Vertebrectomy Model
- F1798 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”
- F1814 Standard Guide for Modular Hip and Knee Joint Components
- F1854 Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants
- F2077 Test Methods for Intervertebral Body Fusion Devices
- F2083 Standard Specification for Total Knee Prosthesis (contact area)
- F2193 Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System
- F2267 Test Method for Measuring Load Induced Subsidence of Intervertebral Body Diffusion Device Under Static Axial Compression
- F2423 Standard Guide for Functional, Kinematic and Wear Assessment of Total Disc Prosthesis
- F2624 Standard Test Method for the Static, Dynamic, and Wear Assessment of Lumbar ExtraDiscal Spinal Motion-Preserving Implants

**ISO**
- 7206-4 Determination of Endurance Properties of Stemmed Femoral Components
- 7206-6 Determination of Endurance Properties of Head and Neck Region of Stemmed Femoral Component
- 7206-8 Endurance Performance of Stemmed Femoral Components with Application of Torsion

**FDA**
- Various Guidance Documents
Introducing ProAgility MC4

The Accutek ProAgility MC4 mechanical testing machines offers an unparalleled solution for testing orthopedic implants. The MC4 features:

- Electromechanical power supply; No air or hydraulic power required
- Prewritten programs for static and fatigue tests
- Easy setup for various specimen sizes and custom tests
- Streamlined user interface for minimal input requirements
- Minimal space requirements
- Quiet operation

Typical Tests include: ASTM F382, F543, F1717, F1798, F2706

Axial Specifications:
Static
 +/- 7kN Static Tension-Compression
 0-150mm Axial Stroke

Dynamic
 +/- 4.5kN Dynamic Tension-Compression
 0-30 Hz Dynamic Test Frequency

Torsion Specifications:
Static
 +/- 75 N-m Static Torsion
 Infinite Torsional Travel

Dynamic
 +/- 7.5 N-m Dynamic Torsion
 0-30 Hz Dynamic Test Run Frequency

Dimensions
 Width 30 in (76 cm)
 Depth 21 in (54 cm)
 Height 72 in (183 cm)

The ProAgility MC4 is a single test frame, plus data acquisition system. Requires Single Phase or 3 Phase 220VAC + 110VAC.

For more information visit: www.accutektesting.com/test-machines/

Patent Pending.
Accutek Testing Laboratory is an ISO 17025 (A2LA) Accredited Laboratory. Accutek routinely performs static and dynamic fatigue testing, wear testing, and failure analysis on medical devices and orthopedic implants.

Our Medical Device Testing experience includes:

- Hips
- Knees
- Spine constructs and VBR’s
- Screws
- Plates
- Shoulders
- Ankles

Accutek boasts over 65 axial fatigue frames and more than 10 torsional fatigue frames - we have the capacity to meet all your testing needs. Our attention to detail and dedication to quality throughout your project produces quantifiable results in a timely manner. We work hard to understand your needs before embarking on a test.

Our engineering professionals are experienced in every stage of testing for medical device design and development - from test protocol development to prototype/feasibility trials to testing for 510(k) and other regulatory submittals to failure analysis and material validation/identification.

We recognize that test methods in ASTM, ISO and other regulatory specifications may not always be suitable for your device, or that there may not be existing test standards for your device. Our test engineers will work with you to develop a customized and cost-effective medical device testing plan and, if necessary, customize test equipment to the exact testing needs of your organization. Accutek performs all testing on-site.

**Full Service Test Facility**

Accutek’s extensive inventory of medical device testing equipment includes:

- Static Tension/Compression, milligrams to 200,000 lbs
- Static Torsion, 20,000 in-lbs (2,300 N-m)
- 65+ Dynamic Tension/Compression Fatigue Frames, up to 200,000 lbs at 0–50 Hz
- 10+ Dynamic Torsion Fatigue Frames, up to 20,000 in-lbs (2,300 N-m) at 0-30 Hz
- Hip/Knee/Spine Prosthesis Wear Simulation
- Six Station Pin on Disc Wear
- Custom Multiple Degree of Freedom Test Frames
- Dimensional, Optical Comparator, Thread Gaging
- In-house CNC Machine shop
- Displacement measurement capability
- Metallographic capability for grain evaluation, failure analysis and other surface conditions
ASTM C297 Standard Test Method for Flatwise Tensile Strength of Sandwich Constructions
ASTM C364 Standard Test Method for Edgewise Compressive Strength of Sandwich Constructions
ASTM E1922 Standard Test Method for Translaminar Fracture Toughness of Laminated and Pultruded Polymer Matrix Composite Materials
ASTM D2344 Standard Test Method for Short Beam Strength of Polymer Matrix Composite Materials and Their Laminates
ASTM D3410 Standard Test Method for Compressive Properties of Polymer Matrix Composite Materials with Unsupported Gage Section by Shear Loading
ASTM D3479 Standard Test Method for Tension Tension Fatigue of Polymer Matrix Composite Materials
ASTM D3846 Standard Test Method for In-Plane Shear Strength of Reinforced Plastics
ASTM D4255 Standard Test Method for In-Plane Shear Properties of Polymer Matrix Composite Materials by the Rail Shear Method
ASTM D5528 Standard Test Method for Mode I Interlaminar Fracture Toughness of Unidirectional Fiber Reinforced Polymer Matrix Composites
ASTM D5766 Standard Test Method for Open Hole Tensile Strength of Polymer Matrix Composite Laminates
ASTM D6115 Standard Test Method for Mode I Fatigue Delamination Growth Onset of Unidirectional Fiber Reinforced Polymer Matrix Composites
ASTM D6272 Standard Test Method for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials by Four Point Bending
ASTM D6484 Standard Test Method for Open Hole Compressive Strength of Polymer Matrix Composite Laminates
ASTM D7078 Standard Test Method for Shear Properties of Composite Materials by V Notched Rail Shear Method
ASTM D7264 Standard Test Method for Flexural Properties of Polymer Matrix Composite Materials
Accutek Testing Laboratory offers Weld Testing and Certification Services to assist our clients with their performance qualifications and welding procedures. Our full-time Certified Welding Inspectors on staff combine for over 25 years experience and can help determine your welding qualification, testing, and inspection needs in an efficient and timely manner.

**Weld Testing**

Accutek’s weld testing team is supported by our in-house machine shop, full service mechanical testing laboratory, and metallurgical group. Accutek’s professionals are experienced in all phases and aspects of weld technology, evaluation, qualification and procedure, as well as failure analysis.

Upon receipt of your weld test coupon at our facility, Accutek prepares and tests the specimen in our mechanical testing laboratory. Accutek performs all common weld joint evaluation tests in-house: tensile, root bend, face bend and side bend.

If necessary, our NIST certified Charpy “V” Notch Impact Test Machine can fulfill any required impact strength testing and our metallurgical laboratory offers a full spectrum of hardness testing options.

**CWI Services**

Accutek’s Certified Welding Inspectors provide the knowledge and experience to ensure accurate and timely completion of welding qualification and inspection.

Accutek offers weld joint evaluation in accordance with AWS, ASME and MIL Specifications. Our metal joining experts are available to assist you in many welding processes including GTAW, GMAW, SMAW, TB, LBW, etc. We specialize in aluminum conductor, brazing & ASME/AWS procedures for various industries, including aerospace, military, medical, power generation & manufacturing.

**Weld Qualification and Testing Capabilities**

- ISO 17025 Accredited Laboratory
- Plate, Pipe, and Sheet Weldments
- Root, Face, and Side Bend Testing
- Metallurgical Evaluation
- CWI Witness Service
- Failure Analysis/Defect Detection
- Cross Sectional Analysis
- Braze Procedure/Process Analysis
- Resistance Weld Peel Testing
- Chemistry
- Microhardness
  - Weld
  - H.A.Z.
  - Base Metal
- Tensile
- Impact Tests at Various Temperatures
- Fatigue Testing
Composite Testing
Accutek has extensive experience testing various ASTM standards for composite testing, as well as many custom testing methods. Our engineering professionals have the crucial knowledge necessary to deliver precise results for your composite testing project. Combined with our extensive composite testing experience, our state-of-the-art testing facility and numerous test machines assure your project, whether large or small, will be completed on time. We also can develop customized testing plans and test equipment modified to your organization’s exact composite testing needs.

Mechanical Testing
Accutek’s mechanical testing qualifications include: Tensile, Fatigue (axial, flexural, torsion), Rotating Beam Fatigue, Abrasion, Welding, Adhesives and more. Depending on your requirements, testing can be performed to organization (ISO, MIL, ASTM, NAS, AWS, ASME, etc.) protocols or test procedures can be customized to client product requirements for use in gaining regulatory approval or meeting product performance goals. Advanced data acquisition systems, controllers and equipment allow for accurate and efficient documentation to support test results.

Fracture Mechanics Testing
Accutek offers fracture mechanics testing to provide the information necessary to improve the mechanical performance of materials and components for the aerospace industry. Our experienced staff and cutting edge technologies supply the data needed to predict or prevent fatigue crack growth. Accutek routinely performs: K_{lc} Testing, Charpy V-notch Testing (NIST Certified), CTOD Testing (Crack Tip Opening Displacement), FCP Testing (Fatigue Crack Propagation), J/R Analysis, and K_{isc} Testing (Stress Corrosion Cracking).

Metallurgical Testing
As a qualified Pratt & Whitney commercial laboratory for more than 15 years, we specialize in aerospace metallography. Accutek’s testing facility performs regular hardness tests (micro/Rockwell/Bri-nell/Shore A/D/M), chemical analyses and microstructure evaluations up to 2000X. Utilizing our color digital microphotography, Accutek’s Metallurgical Laboratory provides precise and cost-effective results for your organization’s immediate use.

Failure Analysis
Accutek performs failure evaluations involving metals, coatings, assemblies and weldments. Utilizing our diagnostic equipment, our experienced staff performs efficient and timely discovery in our lab. Our goal is to keep failure evaluations quick, direct and economical for our clients.
Quality of Test Plans to Maintain Your Test Budget

Before your testing is quoted for cost, lead-time, and delivery, Accutek Testing Laboratory will focus on your testing goals. Whether you are testing for product conformance (to an internal protocol or international specification) or comparison testing (good guy vs. bad guy), Accutek reviews the proposed test plan and outlines the critical criteria that applies to your needs. Simple, cost-effective and timely tests are developed from our 20+ years of experience and large database of internationally recognized testing specifications. Accutek often assists in defining failure definitions for intricate test systems.

Ensure Definitive Test Results

Useful, reliable and accurate test results are measured by:

- Repeatability of Results: Can the results be repeated at Accutek’s lab? What are the uncertainties associated with the results? Are the methods and equipment used in testing statistically capable?
- Reproducibility of Results: Will the results from Accutek Testing Laboratory compare to other results from other labs?

Accutek Testing Laboratory participates in a variety of round-robin and interlaboratory verification testing that ensures your results will fall within a circle of confidence among other national and international laboratories. Uncertainty budgets and calibration curves are maintained on all digital transducers.

Speed & Accuracy with eData Acquisition

Accutek Testing Laboratory collects, stores and produces test data electronically with robust data acquisition systems from single and multiple channel processors. With an in-house CNC machine shop and the ability to lay strain gages, Accutek is able to custom design static and dynamic test equipment for cost-effective, custom applications. All fatigue equipment utilize automated closed loop control to maintain test parameters. Data logs are automatically produced in real-time displays and stored electronically for verification of test performance and for any additional data reduction.

Accutek Testing Laboratory’s test reports are sent electronically (pdf file or CD); hard copies follow.
A2LA has accredited

ACCUTEK TESTING LABORATORY

Fairfield, OH

for technical competence in the field of

Mechanical Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005 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 8 January 2009).

Presented this 7th day of May 2012.

President & CEO
For the Accreditation Council
Certificate Number 2422.01
Valid to April 30, 2014

For the tests to which this accreditation applies, please refer to the laboratory’s Mechanical Scope of Accreditation.
In accordance with SAE Aerospace Standard AS7003, to the revision in effect at the time of the audit, this certificate is granted and awarded by the authority of the Nadcap Management Council to:

Accutek Testing Laboratory
3701 Port Union Road
Fairfield, OH 45014

This certificate demonstrates conformance and recognition of accreditation for specific services, as listed in www.eAuditNet.com on the Qualified Manufacturers List (QML), to the revision in effect at the time of the audit for:

Materials Testing

This certificate expiration is updated based on periodic audits. The current expiration date and scope of accreditation are listed at: www.eAuditNet.com - Online QML (Qualified Manufacturer Listing)

Certified since: 13 September 2007

Joseph G. Pinto, Vice President and Chief Operating Officer

Performance Review Institute (PRI) 161 Thorn Hill Road Warrendale, PA 15086-7527