McCRONE ASSOCIATES, INC.
ANALYTICAL SERVICES LABORATORY

MEDICAL DEVICES SERVICES

McCrone Associates offers you expertise in the analysis of medical devices, contaminants and packaging. Our team of scientists has unmatched experience in solving a wide variety of particle identification and materials problems in an ISO 17025 accredited cGMP compliant laboratory.

The root cause of many contamination and material defects can often be identified through isolation, characterization, and identification of particles. Our staff scientists use specialized techniques, over 60 years of experience and an unparalleled collection of microscopy, spectroscopy and micro-analytical instrumentation to provide you with accurate, confidential and defensible results. All of our services begin with consultation and evaluation of your problem and samples. The issue is resolved through comprehensive analysis and reporting.

Sample evaluation begins with isolation and characterization in our certified ISO Class 5 cleanrooms. Materials are analyzed and identified using multiple microscopy methods. The results are compiled into a confidential report that is checked by peer review before secure transmission to you.

Analytical Services:

- Materials Characterization
- Contaminant Identification
- Product Comparisons
- Failure Analysis
- Surface Analysis
- Residue Analysis
- Assist with New Product Development
- Raw Material Testing
- Microstructure Examination

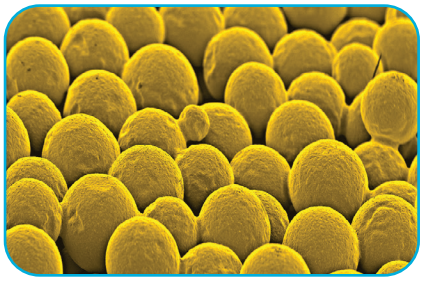
Common Samples:

- Plastics and Polymers
- Metals and Alloys
- Implants
- Stents
- Surface Coatings
- Glass Vials and Containers
- Ceramic and Composites
- Device Packaging

On-site Services:

- Consultation
- Sample Collection
- Report Review
- Expert Testimony

McCrone Associates is ISO/IEC 17025:2017 A2LA accredited (certificate #3631.01), registered with the FDA (analytical laboratory), DEA (Schedules I, II, III, IV and V), and GDUFA, operating in compliance with applicable Good Manufacturing Practices (cGMP) as outlined in the Code of Federal Regulations.



Surface structure of an knee implant.

Our capabilities include:

ISO Class 5 Cleanroom

- *Particle isolation and sample preparation from a wide variety of matrices*
- *Risk of outside contamination is minimized*

Light Microscopy

- Particle identification by optical, morphological, and physical properties
- Imaging and photomicrography
- Particle size measurements
- Analysis and identification of fibers, dust, food, minerals, pigments, glasses and combustion products and more

Scanning Electron Microscope and X-ray Micro Analysis (SEM, EPMA)

- Secondary electron imaging for high resolution imaging
- Backscattered electron imaging for compositional variation and topographic imaging
- EDS and WDS attachments for elemental analysis
- Electron backscatter diffraction (EBSD)
  - Elemental and crystal structure analysis of materials; as small as 20 nm resolution imaging
  - Phase identification, grain distribution and orientation
  - Analysis of material deformation fabrics

Transmission Electron Microscopy (TEM)

- High resolution imaging and analysis of materials
- Morphological, elemental, crystallographic and electronic state
- Analysis of pure and mixed phases, multiple components, nanocomposites
- Analysis of samples including polymers, minerals, pharmaceuticals, metals and ceramics

Infrared and Raman Micro-Spectroscopy

- Identification of organic and many inorganic materials
- Phase identification, polymorphism, crystallinity
- Analysis of samples including contaminants, pharmaceuticals, food, consumer products, polymers, coatings, fibers, forensic evidence and art and archaeology

X-ray Diffraction (XRD)

- Phase determination for inorganic and many organic materials
- Revealing mixed compounds in a single sample
- Analysis including compound identification, polymorphism, corrosion identification, asbestos, pigment identification and relative degree of crystallinity

X-ray Photoelectron Spectroscopy (XPS or ESCA)

- Surface analysis of solids, powders and fibers for elemental and chemical information
- Effective for very thin (<5nm) surface films; thicker films can be analyzed with depth profiling
- Analysis of samples including thin surface films, powders and fibers, and contamination on metals, ceramics, glasses, plastics, paper and other materials

LC-MS/MS

- Produces a molecular ion and molecular ion fragments
- Small organic molecule identification/confirmation; quantitation of small organic molecule analytes
- Identification confirmation/quantitative results of multiple sample components

Direct Analysis in Real Time – Mass Spectrometry (DART–MS)

- Time-of-flight molecular ion mass spectrometry
- Analysis of samples at atmospheric conditions without sample preparation
- Successfully analyzes materials in liquids, extracts, and solids; and on surfaces
- Identification of organic compounds based on their mass spectra

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