

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

MCCRONE ASSOCIATES, INC. 850 Pasquinelli Drive Westmont, IL 60559

Kent L. Rhodes Phone: 630-887-7100

CHEMICAL

Valid To: September 30, 2024 Certificate Number: 3631.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests in conformance with applicable *U.S. FDA Good Manufacturing Practice Standard (GMP)* and *Good Laboratory Practice (GLP) Regulations* per 21 CFR 58, 210, 211, and 820 on suitable samples and materials, including, but not limited to, metals and alloys; plastics and polymers; glass; paper and wood; ceramics; composites; and rocks and minerals. Applications include, but are not limited to, pharmaceuticals; medical devices; food and beverage; personal care products; paints, inks, and pigments; thin-films and coatings; packaging and containers; semiconductors and electronics; and surface chemistry and treatments.

Test:	Test Technology:	Test Method(s):
Material Isolation, Manipulation, Characterization, and Imaging in a Cleanroom Environment	Filtration and Micromanipulation	SOP-CLM-0001, -0002; ISO 14644
	Optical Microscopy	SOP-ALM-0003, -0004, -0006
	Polarized Light Microscopy (PLM)	SOP-ALM-0002, -0004, -0006
Characterization, Identification, and Imaging of Materials	Scanning Electron Microscope (SEM)	SOP-EOG-0004, -0005, -0007, -0008, -0012, -0018
	Electron Backscatter Diffraction Analysis (EBSD)	SOP-EOG-0019
	Energy Dispersive X-Ray Spectrometry (EDS)	SOP-EOG-0003, -0009, -0013
	Direct Analysis Real Time – Time of Flight Mass Spectrometry (DART- TOF-MS)	SOP-CHM-0018
	Fourier Transform Infrared Spectroscopy (FTIR)	SOP-CHM-0008, -0009

Au_

Test:	Test Technology:	Test Method(s):
Characterization, Identification, and Imaging of Materials (cont.)	Gas Chromatography Mass Spectrometry (GCMS)	SOP-CHM-0016, -0017
	Liquid Chromatography Tandem Mass Spectrometry (LCMSMS)	SOP-CHM-0013, -0014
	Optical Microscopy	SOP-ALM-0003, -0004, -0006
	Polarized Light Microscopy (PLM)	SOP-ALM-0002, -0004, -0006
	Raman Spectroscopy	SOP-CHM-0004
	X-ray Photoelectron Spectrometry (XPS)	SOP-EOG-0022
	X-Ray Diffraction Spectrometry (XRD)	SOP-CHM-0010
Characterization, Identification, and Isotope Analysis of Complex Minerals and Particles ¹	Secondary Ion Mass Spectrometry (SIMS)	SOP-EOG-0020
	Thermal Ionization Mass Spectrometry (TIMS)	SOP-TPA-0025
Determination of Particulate Matter in Injectable and Ophthalmic Solutions	Microscopic Particle Count Test	SOP-CLM-0006; USP: <788>, <789> Method 2
Characterization of Crystalline and Partially Crystalline Solids by X-Ray Powder Diffraction (XRPD)	X-Ray Diffraction Spectrometry (XRD)	SOP-CHM-0010, -0011; USP: <941>
Detection of High Explosive Compounds	Liquid Chromatography Tandem Mass Spectrometry (LCMSMS)	SOP-CHM-0013, -0014, -0015
Measurement of Isotope Composition ¹	Secondary Ion Mass Spectrometry (SIMS)	SOP-TPA-0030
	Thermal Ionization Mass Spectrometry (TIMS)	SOP-TPA-0025

¹ Not commercially available

hu



Accredited Laboratory

A2LA has accredited

MCCRONE ASSOCIATES, INC.

Westmont, IL

for technical competence in the field of

Chemical 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 September 2022.

Mr. Trace McInturff, Vice President, Accreditation Services

For the Accreditation Council Certificate Number 3631.01

Valid to September 30, 2024