

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

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

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CHEMICAL

Valid To: September 30, 2022 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 solid, vacuum-compatible 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; Olympus Operation Manuals; Wild Operation Manuals; Nikon Operation Manuals
	Polarized Light Microscopy	SOP-ALM-0002, -0004, -0006; Olympus Operation Manuals; Nikon Operation Manuals
Characterization, Identification, and Imaging of Materials	Scanning Electron Microscope (SEM)	SOP-EOG-0004, -0005, -0007, -0008, -0012, -0018; FEI Manuals; JEOL Manuals
	Electron Backscatter Diffraction Analysis (EBSD)	SOP-EOG-0019; Oxford Instruments Manuals
	Energy Dispersive X-Ray Spectrometry (EDS)	SOP-EOG-0003, -0009, -0013; Oxford Instruments Manuals

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Test:	Test Technology:	Test Method(s):
Characterization, Identification, and Imaging of Materials (cont.)	Direct Analysis Real Time – Time of Flight Mass Spectrometry (DART- TOF-MS)	SOP-EOG-0015; JEOL Instrument Manuals
	FTIR	SOP-CHM-0008, -0009; Thermo Fisher Scientific Manuals
	GCMS	SOP-CHM-0016, -0017; ThermoFisher Scientific Operation Manuals
	LCMSMS	SOP-CHM-0013, -0014; Shimadzu Operation Manuals
	Optical Microscopy	SOP-ALM-0003, -0004, -0006; Olympus Operation Manuals; Wild Operation Manuals; Nikon Operation Manuals
	Polarized Light Microscopy	SOP-ALM-0002, -0004, -0006; Olympus Operation Manuals; Nikon Operation Manuals
	Raman Spectroscopy	SOP-CHM-0004; Renishaw Operation Manuals
	X-ray Photoelectron Spectrometer (XPS)	SOP-EOG-0022; ThermoFisher Scientific Operation Manuals
	X-Ray Diffraction Spectrometry (XRD)	SOP-CHM-0010; Rigaku Operation Manuals
Characterization, Identification, and Isotope Analysis of Complex Minerals and Particles ¹	Secondary Ion Mass Spectrometry (SIMS)	SOP-EOG-0020; Cameca Operation Manuals
	Thermal Ionization Mass Spectrometry (TIMS)	SOP-TPA-0025; ThermoFisher Scientific Operation Manuals
Determination of Particulate Matter in Injectable and Ophthalmic Solutions	Microscopy and Light Obscuration	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>



Test:	Test Technology:	Test Method(s):
Detection of High Explosive Compounds	LCMSMS	SOP-CHM-0013, -0014, -0015; Shimadzu Operation Manuals
Measurement of Isotope Composition ¹	Secondary Ion Mass Spectrometry (SIMS)	SOP-TPA-0030; Cameca Operation Manuals
	Thermal Ionization Mass Spectrometry (TIMS)	SOP-TPA-0025; ThermoFisher Scientific Operation Manuals

¹ Not commercially available

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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).

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Presented this 10th day of September 2020.

Vice President, Accreditation Services For the Accreditation Council Certificate Number 3631.01

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