850 Pasquinelli Drive

Westmont, Il 60559 USA

Services Provided	MA is an ISO/IEC 17025:2017 accredited, GMP/GLP compliant, service provider specializing in **forensic material analysis**. McCrone provides **non-routine and investigative microscopy** and **microanalysis** including, but not limited to, material defect and contaminant identification and imaging. **Particle isolation and identification** is the most requested analysis. MA does not offer the service of routine QC release testing or stability of a product or ingredient to a specification for the purposes of release.
ISO 17025 Scope of Accreditation 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.*
The Approach	• Most projects MA receives are truly mini research projects where the client is requesting an investigation into materials that are defective or contaminants in a process, raw material, or product. MA project costs are based on consulting time and instrument time. • The MA Project Leader will provide a Project Proposal outlining the project plan with an estimate of cost and timing. • Generally, project samples are characterized using optical microscopy (stereomicroscope and/or a polarized light microscope) to establish the general characteristics of the sample or material of interest. The materials of interest are then mounted to a suitable substrate for the appropriate microanalytical method to further characterize and identify the material. The primary tools are micro FTIR and scanning electron microscopy with energy dispersive X-ray spectrometry. Raman microscopy and X-Ray diffraction are also used where appropriate. MA strives for corroborating results to establish the identity of the material of interest, though only to the degree required by the client. Our project scientists work directly with clients, directing analysis and communicating the progress of a project to ensure the client request is met.
Industries Served	Government, Pharmaceutical, Medical Device, Food & Beverage, Veterinary, Health & Beauty, Dietary Supplements, Consumer Products, Construction, Automotive, Electronics, Forensics & Crime Labs, Legal Industry, Museums

Frequently Asked Questions	
Corporation Name	McCrone Associates, Inc. (MA) a subsidiary of The McCrone Group www.mccrone.com
Established	1956
SIC Code	8734 (Testing Laboratory)
NAICS Code	541380 (Testing Laboratory)
Business Size / Type	Large / For Profit
Supplier Diversity Classification	Large Business - EEO
Ownership	Woman owned U.S. Corporation
Federal Tax ID # (EIN)	36-2486719
Dun & Bradstreet # (DUNS) / CAGE	02-522-4023 / 5D342
Liability Insurance Provider	Willis
EMR rating	0.84
FDA Registration No. (EIR)	1421090 (Registered as an “Analytical Laboratory”) Registration is updated annually in December
GDUFA Self Identification	Registration is updated annually in May
FDA Inspections (most recent)	Jan 2019 (no 483’s issued) Oct 2016 (no 483’s issued) Sep 2014 (no 483’s issued) Dec 2012 (no 483’s issued)
cGMP Compliance	US Code of Federal Regulations: Portions of sections 210, 211, 820 and 58 as applicable to forensic material analysis
DEA Registration	RM0182787 (Schedule I-V)
ISO/IEC 17025 Accreditation	A2LA Certificate # 3631.01 www.a2la.org
Number of Employees	47
Administrative / HR	8 / 1
Facility Maintenance	1
IT	3
Quality Assurance	2 Full time / 3 Quality Auditors (Scientists) / 15 Peer Reviewers (Scientists)
Scientists / Lab	28 (12 B.S. / 5 M.S. / 11 Ph.D.)
Facility Type	Laboratory / office
Facility Size	1987 - 25,000 sq. ft. designed/built for McCrone Associates, Inc. 2007 - 40,000 sq. ft. addition for MMA and HCAS
Anderson Pest Control License#	051010734

General		Yes	No	Comments
1	Is this company a division/subsidiary of another corporation?	Yes		McCrone Associates, Inc. (laboratory) is a division of The McCrone Group which also includes McCrone Microscopes and Accessories (MMA, sales) and The Hooke College of Applied Sciences (HCAS, continuing education). All three entities are located at the one location in Westmont, Il. www.mccrone.com
2	Do you have an Organizational Chart?	Yes		Available upon request.
3	Number of employees			See above
4	Number of workdays per week			5 - Monday through Friday
5	Number of shifts per day			McCrone operates a single shift Normal business hours: 7:30 to 5:00 pm
6	Does your firm have a separate Quality Assurance unit?	Yes		Quality Assurance reports directly to the President & COO.
7	Do QA personnel have defined responsibility and authority for ensuring that the management system is implemented and followed at all times?	Yes		
8	Do QA personnel have direct access to the highest level of management at which decisions are made on laboratory policy or resources?	Yes		
9	Who are the primary contacts for quality related concerns?	Cheryl A. Murley - Vice President & Director of Quality Assurance Karen A. Petraitis – Quality Assurance Manager		
10	Please describe the procedure for handling **complaints**.			The laboratory has a policy and procedure for the investigation and resolution of complaints, received from clients, employees or other parties that is consistent with ISO 17025 requirements. Reference SOP-QMS-0016 *Complaint Management. MA averages <1 complaint/year.*
11	Does your company conduct **internal audits** of its processes?	Yes		The laboratory conducts an internal audit of all activities once annually, as required per ISO/IEC 17025. SOP-QMS-0017 *Internal Audit Program* outlines the details. MA has a team of ASQ or A2LA trained internal auditors. Findings are risk assessed, reported to management, evaluated and corrective/preventive actions are identified that are appropriate to the magnitude and risk of the finding.
12	How are internal audits documented?			After completing the physical audit, the audit team risk assesses the findings and prepares an official report to management detailing the findings. Management reviews the findings and provides a written response outlining the plan for corrective or preventive actions.
13	What credentials are required to perform audits?			An ASQ, A2LA or equivalent training course on ISO 19011 auditing practices
14	Do you accommodate requests for **client audits**?	Yes		Requests are handled on a first come first serve basis. MA will work with clients to accommodate one, single day, on site audit no more than once every two years or

General		Yes	No	Comments
				the virtual equivalent. Client audits typically last about 5-6 hours. Audits for just cause are addressed as needed. MA reserves the right to institute a risk-based audit frequency when client project loads are low and client audit requests are high.
15	Do you require a confidentiality, non-disclosure, or quality agreement to be in place for clients?		No	MA does not require a confidentiality, master service agreement, statement of work, or quality agreement for client project work. MA will work with clients, within reason, to negotiate an agreement if they require it. For agreements, we offer a template that reflects our unique services and will save time for both parties. Agreements will be edited to reflect the forensic type services that we offer. Client quality audits conducted as a virtual or desk audit may require a CDA/NDA to be in place depending on what is requested.
16	What job position is responsible for notifying clients of significant company changes?			Client notification responsibilities are outlined in SOP-QMS-0015 *Service to Clients* and LST-QMS-0015 *Client Notification Matrix*.
17	Do you have a **business continuity** or business disruption plan in place?	Yes		POL-QMS-0002 *Business Disruption Plan* In the event of a business disruption, management will employ the plan and determine how best to address projects in process given the unique circumstances involved, notifying those clients promptly. The McCrone website will be updated regularly in the event of a business disruption until normal operations resume.
18	Do you have a **cyber-incident response** plan?	Yes		As a DOD prime contractor, MA is required to comply with NIST 800-171 *Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations*. The Cyber-incident response plan is codified in POL-IT-0002.
19	Do you have a **Management Review** process?	Yes		Our management review process is completed annually per ISO/IEC 17025 requirements and is outlined in SOP-QMS-0006 *Management Review.* Our management review process has been praised by auditors and assessors for its thoroughness.
20	Has Top Management provided evidence of commitment to the development and implementation of the management system and to continually improve its effectiveness?	Yes		MA Top management is fully committed to the quality management system and its requirements. Annual company goals include a quality component.
21	Do you use **subcontracted laboratories**?		No	MA does not subcontract analysis and does not maintain a list of approved subcontractors.

General		Yes	No	Comments
22	Does MA have a **risk management** system that meets applicable GMP requirements?	Yes		MA does incorporate risk management principles into critical processes such as change control, internal audits, supplier management and management reviews.
23	Does McCrone participate in client KPI Programs?		No	MA does not participate in client KPI programs. MA management does monitor internal KPI's.
24	Does the laboratory ensure that its management and personnel are free from any internal or external commercial, financial and other pressures that may adversely affect the quality of their work?	Yes		MA has a business ethics policy that includes an impartiality section consistent with ISO/IEC 17025:2017 requirements.
25	Does the laboratory provide adequate supervision of analytical staff, including trainees, by persons familiar with methods and procedures, the purpose of each test and or calibration and the assessment of its results?	Yes		MA department managers are working managers and scientists. Managers overseeing the analytical staff are well versed with the scientific methodology and instrumentation utilized for MA client work. Trainees are mentored by an assigned staff member to ensure adequate training and oversight.
26	Does the laboratory have a Health and Safety program in place for all employees?	Yes		MA has an OSHA compliant health and safety plan in place. MA also has a designated Chemical Hygiene & Safety Officer who has responsibility and oversight for safety programs and training. MA has a Radiation Safety Officer to ensure compliance with IEMA requirements.

Regulations and Accreditations		Yes	No	Comments
1	Are you registered with the FDA?	Yes		MA registers with the FDA annually as an analytical laboratory. MA also registers annually under the GDUFA Self Identification requirement.
2	Are you subject to inspection by any authority/agency?	Yes		FDA, OSHA, IEMA, DEA, FAA, AFTAC The FDA conducts general inspections periodically and inspection report(s) can be provided upon request. We have never been part of a client pre-approval inspection or been inspected by a foreign regulatory agency. MA is subject to OSHA and DEA but has not yet been inspected by these agencies. The AFTAC reports are confidential. IEMA inspects periodically as well.
3	Do you notify clients of regulatory inspections?	Yes		MA does not notify clients of general regulatory inspections. We will notify clients within 1 business day if one of their projects has been requested and/or reviewed during a general FDA inspection.

Regulations and Accreditations		Yes	No	Comments
				We will notify clients immediately if the FDA sends notice of or an inspector arrives specifically for an inspection related to their company, product, or projects.
4	Are you accredited or certified to any international standards?	Yes		MA is accredited to ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*. Through A2LA, the GMP and GLP checklists are also completed to include GMP/GLP accreditation on the ISO 17025 certificate. The most current ISO certificate is available at www.mccrone.com or www.a2la.org. MA maintains a cleanroom environment for particle control where needed for sample preparation activities. It is certified to ISO 14644 annually by an approved supplier.
5	Are your services **GMP/GLP compliant?**	Yes		The MA quality management system is written to include the ISO/IEC 17025 requirements and applicable requirements from 21 CFR Parts 210, 211, 820 and 58. McCrone does not maintain compliance to non-US regulations. Upon request and review of a non-US regulation McCrone may accommodate requests for foreign regulations.

Training		Yes	No	Comments
1	Are there written **job descriptions** defining responsibilities?	Yes		There are written, approved job descriptions for all employee job functions and secondary roles such as Chemical Hygiene & Safety Officer and the Radiation Safety Officer with a periodic review process.
2	Is there a documented **training** program for job skills?	Yes		MA has a training program outlined in SOP-GEN-0001 *Training, Education and Mentorship* that details general staff training requirements. Department managers have created department specific training SOPs, as well. Personnel are trained and qualified on the basis of appropriate education, training, experience and demonstration of skills. Project Leader hiring requirements are strict and require sufficient, education, technical skill and experience to perform forensic material analysis with a minimum six months mentoring process. Controlled document training and other self-directed training activities are managed and documented through a validated electronic document management system.

Training		Yes	No	Comments
3	How are training and qualifications documented for each employee?			Technical training is documented via technical training records (training forms and certificates). McCrone has validated and implemented an electronic document management system with a training management component for controlled document training. The training management component is used for autonomous training on document revisions and other self-directed training activities.
4	Are backgrounds of internal/external trainers sufficient? Is there a train-the-trainer program?	Yes		MA is fortunate to have highly educated and highly skilled scientists available for training of new hires. Where MA does not have the expertise in house to perform training, outside vendors are used such as instrument vendors.
5	Do you provide **annual quality training**, including GMP training for staff?	Yes		All MA staff associated with client project work are required to receive annual quality training which includes ISO 17025 and GMP/GLP refresher training. Learning targets are confirmed with the completion of a quiz after training.
6	Do you provide EH&S training for staff?	Yes		All MA staff are required to receive EH&S training. Learning targets are confirmed with the completion of a quiz after training.
7	What other training requirements are there?			MA performs annual refresher training for business ethics, drug free workforce, security, and sexual harassment for all staff members.
8	Does MA participate in proficiency testing programs?	Yes		MA has a proficiency testing program consistent with A2LA requirements. Proficiency test samples are received from several accredited services specializing in forensic material analysis.

Building and Facilities		Yes	No	Comments
1	What is the total square footage of the facility that analyzes materials?			~25,000 sq. ft. of laboratory space >2200 sq. ft. of cleanroom space
2	What is the date the facility was built?			1986 – single story lab building 2006 – 3 story addition for MMA and HCAS
3	Are there separate or defined areas for receipt and storage of samples, analysis, and data archives?	Yes		Reference McCrone Associates, Inc. building diagram which outlines areas for sample receipt and storage, cleanroom spaces, and instruments labs. MA Project records are stored on site in the general office in locked cabinets or archived in the record retention room. The record retention room requires key card access, has fire protection and files are secured in waterproof storage containers.

Building and Facilities		Yes	No	Comments
4	Does the facility have a **water system** in place for analysis use?	Yes		MA performs forensic material analysis, which requires minimal use of particle free water. MA has several small systems (0.2 micron filtered, deionized water) for use as needed. These systems are maintained by the vendor. The water systems were qualified and are monitored for conductivity daily. Semi-annually, samples are sent out for chemical and microbiological analysis per a written procedure.
5	Is **temperature** and humidity controlled and/or monitored in the laboratory?	Yes		MA monitors temperature, relative humidity, differential pressure, and particulate in the cleanroom environment continuously via a validated environmental monitoring system with alarming and reporting capability. Temperature and relative humidity are also monitored continuously in instrumentation labs and sample storage spaces throughout the building via the same system. Environmental monitoring is governed by written procedures.
6	Is there a documented **pest control** program for the facility?	Yes		A licensed, pest control company is contracted to provide service semiannually for exterior treatments. MA has a process for approving internal treatments, as needed. Reference SOP-GEN-0003 *Facility – General Maintenance, Safety, and Security.*
7	Is there a documented **housekeeping** program for the testing laboratories?	Yes		MA has written cleaning procedures for the cleanroom environment with documentation. This cleaning is performed by cleanroom scientific staff per SOP-CLM-0019 *Cleanroom and Clean Lab Cleaning*. The instrument labs are cleaned as needed by scientific staff. Twice a year a cleaning day is scheduled by management. A cleaning service takes care of housekeeping in non-laboratory areas (offices, halls, bathrooms, conference rooms). Reference SOP-GEN-0003 *Facility – General Maintenance, Safety, and Security.*
8	Is access to the facility controlled or restricted?	Yes		Access into and within the facility is controlled through key cards. There are readers to enter the laboratory from the reception area and, within the laboratory, certain areas and laboratories require key card access. Personnel must have a business reason for access to key card areas. Key card access is controlled by the President & COO and is reviewed annually. Visitors must be escorted. Reference SOP-IT-0004 *Physical Security.*

Building and Facilities		Yes	No	Comments
9	Do you have a **backup generator**?	Yes		MA has a generator that automatically starts when external power is lost to the McCrone facility. The generator is serviced semi-annually by an outside service provider. The generator can support the facility for two days on one tank of diesel fuel. Reference SOP-GEN-0003 *Facility – General Maintenance, Safety, and Security.*
10	Do you have dedicated staff for facility maintenance?	Yes		
11	Do you have facility management software?		No	
12	Do you have **change control** processes for facilities changes?	Yes		SOP-QMS-0003 *Change Control Management* covers facility changes that could directly impact analysis spaces.

Sample Receipt and Handling		Yes	No	Comments
1	Does your company have written procedures for project sample receipt?	Yes		MA has a written procedure for project sample receipt and handling, SOP-GEN-0011 *Sample Receipt and Log In,* as well as a procedure for DEA controlled substances outlined in SOP-GEN-0012 *DEA Controlled Substances Management.*
2	Are written procedures in place for handling, storage, testing and disposition of incoming project samples?	Yes		SOP-GEN-0013 *Sample Handling, Tracking, Storage, and Disposition* provides detailed steps for project sample handling in the laboratory.
3	Do you have the capability of storing refrigerated or frozen samples?	Yes		MA has a sample storage freezer and two (2) sample storage refrigerators. These units are monitored for temperature via the environmental monitoring system with alarming and reporting. Sample refrigerator: 2 to 8°C. Sample freezer: -25 to -10°C.
4	Do you have -70°C storage?		No	
5	Can you store samples at a controlled humidity?		No	
6	Do you have stability chambers?		No	MA does not offer this service and has no stability test chambers.
7	Are written procedures in place for sample labelling and identification?	Yes		
8	Are all incoming samples identified with a distinctive code at receipt?	Yes		MA assigns a unique MA Project Number for each set of samples, which is recorded on all samples/ packaging, included in a project. We maintain the client sample identifiers for individual containers.

Sample Receipt and Handling		Yes	No	Comments
9	How are special sample handling requirements conveyed?			Special sample handling should be addressed with the Project Leader handling the project during preliminary discussions. Clients must also outline special requirements on the *Sample Submission Form* which is maintained in the Project Folder for those working on the sample. A Project Leader (scientist) oversees each project and directs analysis. The *Sample Submission Form* is available on the website: www.mccrone.com
10	How is **cross contamination** of samples prevented?			MA maintains cleanrooms that are certified to ISO 14644 annually, to minimize contamination during sample preparation activities. There are also ventilated enclosures and hoods in the instrument labs to minimize contamination for sample handling activities. Only one project is worked on at a time and workspaces are wiped down between samples.
11	Are project samples retained?		No	MA disposes or returns project samples to clients upon the completion of analysis and the issuance of the final report as directed by the client on the *Sample Submission Form*. Where the client requests disposal, the samples are disposed per local, state, and federal regulations. MA does not offer services related to routine stability analysis or long-term storage.

Change Control Management and Non-Conformances		Yes	No	Comments
1	Do you have a **Change Control** procedure in place?	Yes		MA has a change control management process for: - Controlled documents outlined in SOP-QMS-0007 - Equipment / Facilities outlined in SOP-QMS-0003 - IT Change Control outlined in SOP-IT-0003
2	How does your company handle **deviations** and non-conformances?			MA has an investigation procedure that is compliant with ISO 17025 requirements and outlined in SOP-QMS-0002 *QMS Investigations and CAPAs* that includes root cause investigation and corrective or preventive actions as needed.
3	Does MA have an **OOS** procedure?		No	MA does not offer the service of routine QC release testing of a product or ingredient to a specification. We, therefore, have no need for an OOS procedure. If a project were to require that, MA would follow the client requirements or generate a Client Specific SOP.

Specification Control		Yes	No	Comments
1	Are written procedures in use to control meeting customer specifications / requirements?	Yes		MA conducts projects per client request (client proposal and/or project request outlined in the *Sample Submission Form*). Each project is unique and all relevant information goes into the project folder. Projects are completed per MA procedures. Each project is peer reviewed prior to release of the final report. We do not perform routine QC release type testing of raw materials or products to a specification. We can generate client specific procedures for longer term projects with multiple sample sets upon client request.
2	How are results reported?			A final report is generated for each project by the Project Leader detailing the request, the analysis performed, and conclusions drawn. The data generated (images and spectra) are included as part of the report. A final report with the Project Leader signature is provided electronically (as a secured pdf). The report is provided to the client(s) of record listed on the *Sample Submission Form*.
3	Do you allow clients to approve or provide input into the final report?		No	If the client finds errors in sample identifiers or typographical errors, we will correct those. To meet the ISO 17025 requirements for impartiality, however, we do not allow clients to materially change any of the conclusions that the scientists make based on their analysis. Clients do not have a signature or approval on McCrone final project reports.
4	Do you provide the raw data?	Yes		Each client report includes pdfs of the images and spectra generated during the project analysis.
5	Are records reviewed prior to release by Quality Assurance?	Yes		Each project receives a thorough peer review per SOP-GEN-0015 *Client Project and Report Review – Technical, Quality, and Administrative* prior to release of the final report. The peer review scientists are working as extended members of the quality assurance unit while conducting the peer review.
6	Will you provide reports as an unsecured pdf or word document?		No	Project leaders are required, per written procedure, to provide reports as secured pdfs. Requests for unsecured reports must be made through Quality Assurance.

Methods and Method Development		Yes	No	Comments
1	Does the laboratory have the capability to perform analytical method development?	Yes		All work at McCrone is investigational and project oriented. We do take on projects for method development and can validate per SOP-GEN-0010 *Methods and Method Validation* or client specific procedures for materials-based projects. We have also worked with clients on method transfer protocols, where applicable.
2	Are USP methods verified at your facility prior to use?	Yes		Since MA performs forensic materials analysis, USP methods are not commonly used. If required for a materials project, MA can perform some USP methods and complete verifications, as requested by the client, and captured in a Project Proposal.

Equipment		Yes	No	Comments
1	Are written procedures in place for equipment/glassware use and cleaning?	Yes		
2	Are glassware cleaning procedures validated?		No	MA is a material testing lab and uses minimal glassware for the services provided. There are written approved procedures for cleaning glassware, but the cleaning procedures are not validated. Our procedures do include an evaluation for water insoluble residues and a list of approved cleaning agents.
3	Is there a written program for equipment preventive maintenance?	Yes		MA maintains vendor service contracts on instrumentation for preventive maintenance and service.
4	How is equipment identified?			Most equipment and instrumentation at MA is government acquired property and is managed under the FAR 52.245-1 and DFARS 252.242-7004 requirements. Government acquired property is identified by a unique GP#; non-GP property is identified by the serial number. MA maintains a *Master Instrument List*.
5	Is there an established **equipment calibration** program?	Yes		SOP-GEN-0008 *Analytical Instrument Qualification* and LST-GEN-0004 *Calibration Maintenance Service Matrix* provide general requirements. Instrument procedures outline the requirements for preventive maintenance, performance verifications and calibrations where needed. The vendor typically performs any required calibration during the preventive maintenance.

Equipment		Yes	No	Comments
6	What is/are the frequencies for equipment calibration?			Most instrumentation is used in a qualitative or semi-quantitative manner (optical characterization, imaging, and spectral analysis) and is maintained by the vendor. Preventive maintenance activities are typically performed annually. Performance verifications are conducted for confirmation of performance in between vendor visits, typically monthly.
7	Has Installation Qualification / Operation Qualification been performed on all laboratory equipment?	Yes		All instrumentation covered under our ISO/IEC 17025 scope of accreditation have been qualified. McCrone typically hires the vendor to qualify new instrumentation. MA utilizes the guidance provided in USP <1058> Analytical Instrument Qualification (outlined in SOP-GEN-0008).
8	Are microscopes qualified?	Yes		Where present, the light microscope ocular reticle used for measurements is calibrated or verified against a certified stage micrometer. Microscopes used to view samples for characterization and imaging purposes do not require this calibration. Scanning electron microscopes have qualifications completed by the vendor as stated above.
9	Is there a written program for documenting equipment use and the performance of service activities?	Yes		There is an instrument usage log for each instrument used for industrial client analysis. Maintenance activities are documented. Vendor service reports are maintained on file.
10	Are logbooks maintained?	Yes		Each instrument has a maintenance logbook that is officially issued and numbered.

Documentation and Record Keeping		Yes	No	Comments
1	Are standard operating procedures (**SOPs**) controlled and in place that address all of the laboratory quality and testing operations?	Yes		MA has standard operating procedures for quality management system requirements, general technical requirements, and all departmental requirements. These SOPs are created, revised, and maintained in an electronic document management system (EDMS) which has been validated to GAMP 5 and 21 Part 11 requirements. There is a periodic review requirement established for each document. SOPs are reviewed and approved by an author, a member of QA and top management. The process is covered in SOP-QMS-0007 *Controlled Document Management.* MA has received many positive comments by client auditors regarding the thoroughness of the written procedures.
2	Do you have Electronic Notebooks?		No	MA does not currently utilize Electronic Notebooks.
3	Do you utilize electronic signatures?	Yes		Electronic signatures are validated for use. Wet ink signatures, using indelible ink, are used for sample preparation and data analysis activities. Implementation and use of electronic signatures is

Documentation and Record Keeping		Yes	No	Comments
				governed by SOP-IT-0006 *Electronic Signature Management* and must be approved by management.
4	Do you have a LIMS?			MA has purchased and configured a LIMS for industrial project management. 2025 will see the completion of validation activities per GAMP 5 requirements and a pilot launch followed by cutover to paperless project management and data collection. QA will provide more information about project status and timing upon request.
5	How is laboratory data recorded, reviewed, and retained?			Investigational analysis ensures that all projects are unique. Until the launch of LIMS, MA maintains a pre-numbered MA Project Folder that holds all sample related information including the *Sample Submission Form*, safety information, client correspondence, original observations, instrument printouts, preliminary and final reports. Controlled Forms (analytical data sheets) used to document sample receipt, sample preparation, and analysis results are completed and maintained in the Project Folder. Images and instrumentation results are printed at the time generated, paginated, signed, dated, and stored in the Project Folder. A formal peer review process and a separate administrative review process is completed per written procedure, with defined checklists, to ensure all raw data and records are present and accounted for. Electronic information is secured through the requirements outlined in SOP-IT-0001 *Data Storage Backup and Recovery* and SOP-IT-0008 *Data Integrity & Security.*
6	Do you have a written procedure for good documentation practices? Do you follow **ALCOA** principles?	Yes		SOP-QMS-0004 *Documentation Practices, Records and Retention* includes ALCOA principles.
7	Why does MA not implement **ALCOA Plus**?			MA cannot meet '**CONSISTENT**' due to the investigational project-based nature of forensic materials analysis. Project work is unique and does not have an expected sequence or order, it is driven by the nature of the client request. One client might send 5 liquids and request that all blue fibers be isolated and identified. A week later they might change that and request only one blue fiber per vial. Another client might send 100 tape lifts from a piece of equipment and ask for images and a metal profile of the particulates. **ENDURING** – Until the launch of LIMS, we have rules for recording data on the proper paper record format. Instrument data is saved to a network drive which is backed up with a copy maintained on site. The dynamic proprietary instrument file can only be read with the proprietary instrument software. Once an instrument is retired, we may not have a means of reading the proprietary instrument file. The client receives all human readable data (images/ spectra) in the final report.

Documentation and Record Keeping		Yes	No	Comments
8	Describe how documents are controlled to assure only current ones are used?			MA uses a validated electronic controlled document management system (EDMS) for document lifecycle management. MA personnel access the most current version of controlled documents from this system. The system manages change control, periodic reviews and obsoletion, creating records of these activities. There are computers available at all workstations with multiples screens so that staff can view procedures as they work. Obsolete documents are archived within EDMS.
9	How are approved/current versions of test methods updated when required?			Documents are revised through automated workflows in the EDMS. Revised documents are approved by QA and/or Management prior to becoming effective.
10	How long are records retained?			MA project records are retained for a minimum of 10 years. Record retention requirements are covered in LST-QMS-0006 *Record Retention List.* MA has a written procedure for record disposal activities: SOP-QMS-0018 *MA Record Disposal.*
11	Do you notify clients prior to destruction of records?		No	McCrone does not have the resources to notify clients prior to destruction of records. MA holds records for at least 10 years giving clients ample opportunity to contact us if records are pertinent to litigation, government inquiry, or legal proceedings.
12	Do you use indelible ink to record information?	Yes		For handwritten records, indelible ink is required.

Data Integrity & Security		Yes	No	Comments
1	How is the data integrity and security of computer controlled instrumentation maintained?			MA has written procedures for logical security and physical security. IT utilizes a least privileged model for administration rights. Because every industrial client project is investigational and unique, MA scientists must have the flexibility to utilize different instrument methods and parameters to address the client sample analysis that is requested by the client. MA labs require key card access and instrument computers require a unique log in and password for the user to access, acquire analysis and save raw data files. Network drives are structured and monitored with auditing software that records all activity and is identifiable to a person. SOP-IT-0008 *Data Integrity & Security* outlines these requirements.
2	Does project documentation meet the requirements of the MHRA GMP Data Integrity Definitions and Guidance?		No	MA maintains awareness and compliance to US regulatory requirements. If a client has specific non-US requirements, we request that they be discussed during the Project Proposal phase so that we can determine if we can meet the requirements.

Data Integrity & Security		Yes	No	Comments
3	Do you have access security levels for computerized systems?	Yes		
4	Who is responsible for system administration of laboratory instruments/software?			IT utilizes a least privileged model for administration rights for instrument computers while ensuring that the instrument owner can operating the instrument as needed to conduct analysis to meet the client requests. Software updates are handled via change control.
5	Do you have procedures in place for disaster recovery and restoring of raw data and records?	Yes		Raw data and records are saved to secured network drives, which are backed up by IT per SOP-IT-0001 *Data Storage Backup and Recovery.* Weekly, a set of tapes is taken offsite for storage. Annually, IT performs a backup and recovery test from the tapes stored offsite. POL-QMS-0002 *Business Disruption Plan* provides a road map for responding to business disruptions. POL-IT-0002 *Cyber Incident Response* provides detailed instructions for responding to a cyber-incident.
6	Is all data stored in a secure manner so it is protected from deletion, overwriting, alteration, accidents, and natural disasters?	Yes		Through the procedural and electronic controls identified above, MA has developed sufficient processes and procedures to mitigate risk to data integrity and ensure that data are complete, consistent, accurate and safe from manipulation or loss throughout the data lifecycle. Implementation of LIMS in 2025 is expected to enhance these capabilities considerably.
7	Does the **audit trail** get reviewed for each instrument analysis during the peer review process?		No	MA provides microscopy based investigational materials analysis for a wide variety of industries. Audit trail review is not typically required for the scope of services that MA provides and would be considered a client specific request. If clients require this for investigational analysis, MA can provide a cost estimate for completion of this activity and work with the client to develop a client specific procedure for their requirements.
8	How is the date and time controlled on all instruments throughout the laboratory?			All network devices are synchronized to the Domain Controller for time and date.
9	How are confidential documents delivered to ensure security?			MA uses Microsoft native encryption functionality.
10	Does the laboratory have policies and procedures in place to ensure customer's information is kept confidential?	Yes		Because of the nature of our business, client confidentiality is a high priority for us.

Supplies / Reference Materials		**Yes**	**No**	**Comments**
1	Does MA have a process for **approving suppliers**?	Yes		MA has a formal process for approving service and supply providers consistent with ISO 17025 requirements and maintains an approved supplier list. Reference SOP-QMS-0011. MA uses a risk-based approach for supplier management.
2	Does MA have a periodic re-evaluation of approved suppliers?	Yes		The periodic re-evaluation of suppliers at McCrone is an annual review of all suppliers during the Management Review process.
3	How are primary **reference standards** acquired and stored? How long are they retained?			McCrone uses NIST traceable reference materials where they are available. Most of our references are materials: copper, stainless steel, silicon, polystyrene, etc. Reference materials are governed by SOP-GEN-0014 *Reference Materials and Traceability*. Reference Materials are logged into an inventory system and labeled with an expiration date. We use the vendor expiration date or 10 years if no expiration date is provided by the vendor.
4	Are secondary standards used?	Yes		MA has a written procedure governing reference materials and qualification of secondary standards. Commonly, clients provide reference materials for investigational analysis. Client provided reference materials are considered project samples and restricted to use for that particular project.
5	How are **reagents** maintained and identified?			Chemicals, reagents, and reference materials are logged into an inventory system which generates a label with an expiration date, reference SOP-QMS-0014 *Chemical Inventory Management*. MA uses the vendor expiration date. A report of expiring chemicals is issued to a designated staff member monthly so that chemicals are disposed upon expiry.

Updated by Cheryl A. Murley Vice President & Director of Quality Assurance	Cheryl A. Murley Digitally signed by Cheryl A Murley Reason: I am approving this document Date: 2024-12-23 13:27:58

- Available documentation:
  - ☐ Building Diagram
  - ☐ Master Document List
  - ☐ Quality Manual
  - ☐ Organizational Chart
  - ☐ ISO/IEC 17025 Accreditation Certificate (3631.01 www.a2la.org)
  - ☐ EIR for most recent FDA inspection
  - ☐ DEA Licenses