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 commonly requested analysis. MA does not offer the service of routine QC release testing to a specification.
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 pharmaceuticals, medical devices, food and beverage, personal care products, plastics and polymers, metals and alloys, paints, pigments and coatings, glass vials and containers, ceramics and composites….*
The Approach	• Most projects MA receives are truly mini research projects, with regard to investigating exactly what the materials, particles or defects of interest are. MA project costs are based on consulting time and instrument time. • Generally, samples are first characterized using optical microscopy methods using a stereomicroscope and/or a polarized light microscope to establish the general characteristics of the sample. The samples, or portions, are then mounted for appropriate microanalytical methods; microscopic transmission mode FTIR, SEM-EDS, PLM, Raman, micro-XRD, as determined by the optical examination and successively acquired information. MA strives for corroborating results to establish the identity of the samples, though only to the degree required by you the client. Our project scientists work directly with clients, directing analysis and communicating the progress of a project to our clients in order to ensure the correct level of information, quality and cost balance are appropriate for the client and the analysis requested.
Industries Served	Government, Pharmaceutical, Medical Device, Food & Beverage, Veterinary, Health & Beauty, Consumer Products, 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	Privately owned U.S. Corporation

Frequently Asked Questions	
Federal Tax ID # (EIN)	36-2486719
Dun & Bradstreet # (DUNS)	02-522-4023
CAGE	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	39 Full Time / 1 Part-Time
Administrative / Management	6 / 3
Facility Maintenance	1
IT	2
Quality Assurance	1 Full time / 3 Internal Auditors (Scientists) / 14 Peer Reviewers (Scientists)
Sales / Marketing	1
Scientists / Lab	26 (10 B.S. / 4 M.S. / 12 Ph.D.)
Facility Type	3-story, brick exterior
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

Regulations and Accreditations		**Yes**	**No**	**Comments**
1	Are you registered with the FDA?	X		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?	x		FDA, OSHA, DEA, FAA, AFTAC, DCMA McCrone Associates, Inc. (MA) is subject to OSHA and DEA but has not yet been inspected by these agencies. The FDA inspection report(s) can be provided upon

Regulations and Accreditations		Yes	No	Comments
				request. The AFTAC and DCMA reports are confidential.
3	Do you notify clients of regulatory inspections?	x	x	We do not notify clients of general regulatory inspections. We will notify clients within 24 hours if one of their projects has been requested and/or reviewed during a general inspection. We will also notify clients immediately if an inspector arrives specifically for an inspection related to their company, product or projects.
4	Are you accredited or certified to any international standards?	x		MA is accredited to ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*. MA completed the most recent renewal in Aug 2020. Through A2LA, the GMP and GLP checklists are completed to include GMP/GLP accreditation on the ISO 17025 certificate. MA maintains a cleanroom environment for particle control during sample preparation activities. It is certified to ISO 14644 annually by an approved supplier.
5	Are your services GMP/GLP compliant?	x		The McCrone 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 is currently not maintaining compliance to non-US regulations. Upon request and review of a non-US regulation McCrone may accommodate such requests.

General		Yes	No	Comments
1	Is this company a division/subsidiary of another corporation?	x		McCrone Associates, Inc. is a division of The McCrone Group which also includes McCrone Microscopes and Accessories and The Hooke College of Applied Sciences. All three entities are located at the one location in Westmont, Il. www.mccrone.com
2	Do you have an Organizational Chart?	x		Available upon request
3	Number of employees			See above
4	Number of work days per week			5
5	Number of shifts per day			McCrone operates a single shift from 7:30 to 5:00 pm Monday through Friday
6	Does your firm have a separate Quality Assurance unit?	x		The Quality Assurance Unit reports directly to the President/COO.
7	Does the QA Director have defined responsibility and authority for ensuring that the management system is implemented and followed at all times?	x		
8	Does the QA Director have direct access to the highest level of management at which decisions are	x		

General		Yes	No	Comments
	made on laboratory policy or resources?			
9	Who is the contact for quality related concerns?			Cheryl A. Murley, Director of Quality Assurance and Regulatory Affairs 630-887-7100 cmurley@mccrone.com
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.*
11	Does your company conduct internal audits of its processes?	x		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	Do you accommodate requests for client audits?	x		Yes, MA accommodates requests. MA will work with clients to accommodate one, single day, on site audit no more than once every two years or 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 submissions for a client are <5 samples or projects per year.
14	Do you require a confidentiality, non-disclosure or quality agreement to be in place for clients?		x	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 Quality 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.
15	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 the Annex LST-QMS-0015 *Client Notification Matrix*.
16	Do you have a business continuity or business disruption plan in place?	x		POL-QMS-0002 *Business Disruption Plan* In the event of a business disruption management will employ the plan and determine how best to address samples 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.

General		Yes	No	Comments
17	Do you have a cyber-incident response plan?	x		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.
18	Do you have a Management Review process?	x		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.
19	Has Top Management provided evidence of commitment to the development and implementation of the management system and to continually improve its effectiveness?	x		MA Top management is fully committed to the quality management system and its requirements. Annual company goals include a quality component.
20	Do you use subcontracted laboratories?		x	MA does not subcontract analysis and does not maintain a list of approved subcontractors.
21	Does MA have a risk management system that meets applicable GMP requirements?	x		GMP risk management is a systematic process for the assessment, control, communication and review of risks to the quality of the drug product across the product lifecycle. MA does not manufacture drugs. MA does incorporate risk management principles into critical processes such as change control, internal audits, supplier management and management reviews.
22	KPI Programs		x	MA does not participate in client KPI programs. MA management does monitor internal KPI's.
23	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?	x		MA has a business ethics policy that includes an impartiality section consistent with ISO/IEC 17025:2017 requirements.
24	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?	x		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.
25.	Does the laboratory have a Health and Safety program in place for all employees?	x		MA has an OSHA compliant health and safety plan in place. MA also has a designated Chemical Hygiene & Safety Officer. Annually, staff receive EH&S training.

Training		Yes	No	Comments
1	Are there written job descriptions defining each individual's responsibilities?	x		Yes, there are written, approved Job Descriptions for all employee job functions and secondary roles such as Chemical Hygiene & Safety Officer and the Inventory Control Clerk with a periodic review process.
2	Is there a documented training program for job skills?	x		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

Training		Yes	No	Comments
				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.
3	How are training and qualifications documented for each employee?			Technical training is documented via paper 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?	x		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?	x		Yes, all MA staff are required to receive annual quality training which includes ISO 17025 and GMP/GLP refresher training. Learning targets may be confirmed with the completion of a quiz after training.
6	Do you provide EH&S training for staff?	x		Yes, all MA staff are required to receive EH&S training, initially. Annual refresher training is also provided. Learning targets may be 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 and security for all staff members.
8	Does MA participate in proficiency testing programs?	x		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
3	Are there separate or defined areas for receipt and storage of samples, analysis, and data archives?	x		Reference McCrone Associates, Inc. building diagram which outlines areas for sample receipt and storage, cleanroom spaces, instruments labs and the IT Server Room. MA Project Folder records (paper 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

Building and Facilities		Yes	No	Comments
				protection and files are secured in waterproof storage containers.
4	Does the facility have a water system in place for analysis use?	x		MA performs forensic material analysis, which requires minimal use of particle free water. MA has several 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?	x		MA monitors temperature, relative humidity, differential pressure and particulates 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?	x		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?	x		MA has written cleaning procedures for the cleanroom environment with documentation. This cleaning is performed by cleanroom scientific staff per SOP-CLM-0019 *Cleanroom 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?	x		Access to and within MA 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. Visitor passes are provided to clearly identify visitors and will not activate key card readers. Reference SOP-IT-0004 *Physical Security.*
9	Do you have a backup generator?	x		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.*

Sample Receipt and Handling		**Yes**	**No**	**Comments**
1	Does your company have written procedures for sample receipt?	X		MA has a written procedure for 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 samples?	X		SOP-GEN-0013 *Sample Handling, Tracking, Storage, and Disposition* provides detailed steps for sample handling in the laboratory.
3	Do you have the capability of storing refrigerated or frozen samples?	X		MA has a sample freezer and a sample refrigerator. Freezers and refrigerators 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?		X	
5	Do you have stability chambers?		X	MA does not offer this service and has no stability test chambers.
6	Are written procedures in place for sample labelling and identification?	X		
7	Are all incoming samples identified with a distinctive code at receipt?	X		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.
8	How are special sample handling requirements conveyed?			Special sample handling should be addressed with the Project Leader handling the project during preliminary discussions. Clients can 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. For clients that intend to send samples routinely, MA can generate a client specific SOP. The *Sample Submission Form* is available on the website: www.mccrone.com.
9	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.
10	Are samples retained?		X	MA prefers to return samples to clients upon the completion of analysis and the issuance of the final report. 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?	x		MA has a change control management process for: □ Controlled documents outlined in SOP-QMS-0007

Change Control Management and Non Conformances		Yes	No	Comments
				☐ 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 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?		x	No, since MA does not perform routine chemistry or microbiology testing or other routine QC release type testing there is 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?	x		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. Each project is peer reviewed prior to release. We do not perform routine QC release type testing to a specification. We can generate client specific procedures for longer term projects with multiple sample sets or routine testing upon client request.
2	How are results reported?			A final written report is generated for each project by the Project Leader detailing the request, the analysis performed and conclusion drawn. The data generated (images and spectra) are included as part of the report. A preliminary draft of the report may be provided, upon request. A final report with the Project Leader signature is provided electronically (as a secured pdf) and a hard copy mailed, where requested. The report is provided to the client(s) of record on the *Sample Submission Form*.
3	Do you provide the raw data?	x		Each client report includes pdfs of the images and spectra generated during the project analysis.
4	Are records reviewed prior to release by the Quality Assurance Unit?	x		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.
5	Will you provide reports as an unsecured pdf or word document?	x	x	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?	x		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. We have also work with clients on method transfer protocols, where applicable.
2	Are USP methods verified at your facility prior to use?	x		Since MA performs forensic materials analysis, USP methods are not commonly used, but, if requested, MA can perform some USP methods and complete verifications as requested by the client.

Equipment		Yes	No	Comments
1	Are written procedures in place for equipment/glassware use and cleaning?	x		
2	Are glassware cleaning procedures validated?		x	MA is a materials testing lab not an analytical lab. We use very little glassware. We have procedures for cleaning glassware but we have not validated the cleaning procedures. 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 preventative maintenance?	x		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?	x		Yes, SOP-GEN-0008 *Analytical Instrument Qualification* and Annex C *Calibration Maintenance Service Matrix* provides general requirements. Each instrument SOP provides detailed procedures for preventive maintenance, performance verifications and calibrations were needed. The vendor typically performs any required calibration during the preventive maintenance.
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	x		All instrumentation covered under our ISO/IEC 17025 scope of accreditation have been qualified. McCrone typically hires the vendor to qualify new

Equipment		Yes	No	Comments
	performed on all laboratory equipment?			instrumentation. MA utilizes the guidance provided in USP <1058> Analytical Instrument Qualification (outlined in SOP-GEN-0008).
8	Are microscopes qualified?	x		Light microscopes containing an ocular reticle and used for measurements are 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?	x		There is an instrument usage log for each instrument used for client analysis.
10	Are logbooks maintained?	x		Each instrument has a preventive 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?	x		MA has standard operation 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.*
2	Do you have Electronic Notebooks or a LIMS?		x	MA does not utilize Electronic Notebooks and does not have a LIMS.
3	Do you utilize electronic signatures?	x		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 governed by SOP-IT-0006 *Electronic Signature Management* and must be approved by management.
4	How is laboratory data recorded, reviewed, and retained?			Investigational analysis ensures that all projects are unique. 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

Documentation and Record Keeping		Yes	No	Comments
				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.*
5	Do you have a written procedure for good documentation practices? Do you follow ALCOA principles?	x		SOP-QMS-0004 *Documentation Practices, Records and Retention*
6	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.
7	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.
8	How long are records retained?			MA project folders 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.*
9	Do you notify clients prior to destruction of records?	x		After a minimum of 10 years has passed, MA will attempt to notify the client of record listed on the *Sample Submission Form* and/or contacts listed in a quality agreement (or other type of agreement) prior to destruction of records, where required per client agreement.
10	Do you use indelible ink to record information?	x		

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.

Data Integrity & Security		**Yes**	**No**	**Comments**
2	Does project documentation meet the requirements of the MHRA GMP Data Integrity Definitions and Guidance?	x	x	Although we have done considerable work on ensuring data integrity and security and can meet most of these requirements, we cannot yet meet all of the MHRA definition expectations listed as “musts”. MA can ensure that data are complete, consistent, accurate and safe from manipulation or loss throughout the data lifecycle.
3	Do you have access security levels for computerized systems?	x		
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?	x		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?	x		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.
7	Does the audit trail get reviewed for each instrument analysis during the peer review process?		x	MA provides investigational materials analysis for a wide variety of industries. This activity would be considered a client specific request. If clients require this for investigational analysis, MA can provide an estimate for completion of this activity and work with the client to develop a client specific procedure.
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 a secure server to post confidential documents to. Clients are sent an email/link to retrieve the documents.
10	Does the laboratory have policies and procedures in place to ensure customer's information is kept confidential?	x		

Supplies / Reference Materials		**Yes**	**No**	**Comments**
1	Does MA have a process for approving suppliers?	x		MA has a formal process for approving service and supply providers consistent with ISO 17025

Supplies / Reference Materials		Yes	No	Comments
				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?	x		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. 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. Most of our references are materials: copper, stainless steel, silicon, polystyrene, etc.
4	Are secondary standards used?	x		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 Director of Quality Assurance and Regulatory Affairs	Cheryl A. Murley	Digitally signed by Cheryl A Murley Reason: I am the author of this document Date: 2021-02-23 11:02:26

- Available documentation:
  - ☐ McCrone Associates, Inc. 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