



Sample Submission Form

850 Pasquinelli Drive, Westmont, IL, 60559-5539
630.887.7100

For Office Use Only

MA#

PL

Fields Marked with * are Required Information

*Client Company Name		*Method of Payment (See General Provisions)	<input type="checkbox"/> PO #
			*PO copy Required
			<input type="checkbox"/> Check #
			<input type="checkbox"/> Credit Card (phone)
*Primary Contact Name <input type="checkbox"/> Mr. <input type="checkbox"/> Ms. <input type="checkbox"/> Mx. <input type="checkbox"/> Dr.	(First and Last Name)		<input type="checkbox"/> Electronic Funds Transfer
*Street Address		Accounts Payable Who should McCrone Submit the invoice to?	
*City/State/Province		*Accounts Payable Email	
* Zip/Postal Code Country		*Name	
*Phone		*Phone	
*Email		*Address	
*Authorization to share results with (Limit 2) (Include name and email)			
Project Information			
*McCrone Contact		Samples Pertain to	<input type="checkbox"/> a new project with McCrone <input type="checkbox"/> an open project with McCrone: MA #
Cost Estimate Required	<input type="checkbox"/> No <input type="checkbox"/> Yes	Litigation Support	<input type="checkbox"/> No <input type="checkbox"/> Yes
*Project Proposal #		*Requested TAT	<input type="checkbox"/> Standard Turnaround <input type="checkbox"/> RUSH (100% surcharge)
*Sample Return? (fees may apply; provide address if different)	<input type="checkbox"/> No <input type="checkbox"/> Yes		
*Project Analysis Request	<input type="checkbox"/> Refer to attached documentation		

***Project Samples** - Must be completed in full or attach a document with the same information

#	Name / Descriptor	Quantity and Unit Volume 5 x 10 ml vials	Lot or ID #	DEA / Schedule	For biologics: What biological safety level are the samples manufactured in?
				*Storage Requirements	
1				<input type="checkbox"/> No <input type="checkbox"/> Yes Schedule:	<input type="checkbox"/> BSL1 <input type="checkbox"/> BSL2 <input type="checkbox"/> n/a
				<input type="checkbox"/> Ambient <input type="checkbox"/> Refrigerator <input type="checkbox"/> Freezer <input type="checkbox"/> Light Sensitive <input type="checkbox"/> Hazardous <input type="checkbox"/> Other:	
2				<input type="checkbox"/> No <input type="checkbox"/> Yes Schedule:	<input type="checkbox"/> BSL1 <input type="checkbox"/> BSL2 <input type="checkbox"/> n/a
				<input type="checkbox"/> Ambient <input type="checkbox"/> Refrigerator <input type="checkbox"/> Freezer <input type="checkbox"/> Light Sensitive <input type="checkbox"/> Hazardous <input type="checkbox"/> Other:	
3				<input type="checkbox"/> No <input type="checkbox"/> Yes Schedule:	<input type="checkbox"/> BSL1 <input type="checkbox"/> BSL2 <input type="checkbox"/> n/a
				<input type="checkbox"/> Ambient <input type="checkbox"/> Refrigerator <input type="checkbox"/> Freezer <input type="checkbox"/> Light Sensitive <input type="checkbox"/> Hazardous <input type="checkbox"/> Other:	
4				<input type="checkbox"/> No <input type="checkbox"/> Yes Schedule:	<input type="checkbox"/> BSL1 <input type="checkbox"/> BSL2 <input type="checkbox"/> n/a
				<input type="checkbox"/> Ambient <input type="checkbox"/> Refrigerator <input type="checkbox"/> Freezer <input type="checkbox"/> Light Sensitive <input type="checkbox"/> Hazardous <input type="checkbox"/> Other:	
5				<input type="checkbox"/> No <input type="checkbox"/> Yes Schedule:	<input type="checkbox"/> BSL1 <input type="checkbox"/> BSL2 <input type="checkbox"/> n/a
				<input type="checkbox"/> Ambient <input type="checkbox"/> Refrigerator <input type="checkbox"/> Freezer <input type="checkbox"/> Light Sensitive <input type="checkbox"/> Hazardous <input type="checkbox"/> Other:	
6				<input type="checkbox"/> No <input type="checkbox"/> Yes Schedule:	<input type="checkbox"/> BSL1 <input type="checkbox"/> BSL2 <input type="checkbox"/> n/a
				<input type="checkbox"/> Ambient <input type="checkbox"/> Refrigerator <input type="checkbox"/> Freezer <input type="checkbox"/> Light Sensitive <input type="checkbox"/> Hazardous <input type="checkbox"/> Other:	
*Total Number of Samples Shipped			<input type="checkbox"/> Additional sample information attached *SDS or other safety information <u>must</u> be included for each project sample		

GENERAL TERMS AND CONDITIONS GOVERNING THIS AGREEMENT (THE “AGREEMENT”)

Payment Terms & Consent: New clients are required to prepay their first project. By submitting samples to McCrone Associates (“MA”) for analysis, you are acknowledging your responsibility to pay in full for all analyses agreed upon and completed. All undisputed payments will be made by the Client within twenty (20) days after its receipt of an invoice submitted via email to address Client provides on Page 1. All invoices are payable in U.S. Dollars (USD). An approved payment method is required prior to the initiation of any analyses. If selecting Purchase Order (PO), an official PO copy must be submitted to mapo@mccrone.com prior to the release of data. If selecting credit card, please provide the credit card information by phone. Accounts deemed to be past due must be made current before new samples will be accepted. At our discretion, we may require full or partial advance payment for certain services/projects. Wire transfer fees, bank fees, and non-U.S. taxes, tariffs, or import/export fees are the responsibility of the client. Clients are notified if special payment terms apply. Minimum charge per project is \$800.

International clients are required to prepay all projects submitted to McCrone Associates. Please note our policy and guidance statement (below) on shipping samples from outside the USA.

Liability: (I) The Client will defend, indemnify, and hold MA harmless from and against any and all losses resulting from third party claims arising from or in any way related to (a) the Client’s use of the deliverables, except to the extent such claims result from MA’s material breach of this Agreement, gross negligence or willful misconduct; (b) the Client’s gross negligence or willful misconduct in performing obligations under this Agreement; or (c) the Client’s breach of this Agreement. **(II)** MA will defend, indemnify, and hold the Client harmless from and against any and all losses resulting from third party claims arising from or in any way related to (a) MA’s performance of the services under this Agreement, except to the extent such claims result from the Client’s material breach of this Agreement, gross negligence or willful misconduct; (b) MA’s gross negligence or willful misconduct in performing obligations under this Agreement; or (c) MA’s breach of this Agreement. The Client understands that MA is not liable for any damages or financial loss resulting from samples or documents lost or damaged in transit to or from MA, or a third party, except to the extent any claim, demand, action or liability results from the negligence or misconduct of, or breach of any agreement by MA.

Proprietary Rights: For the purposes of this agreement, investigational analyses pertain only to characterization and identification of product contaminants or unexpected product particulate defects. The purposes of this agreement do not involve creation, research, or development of “inventions” as works for hire. The purposes of this agreement do not include developmental research or work on sample product materials. Client’s materials shall be used solely for the purposes of this Agreement. All information and data collected from product contaminants or defects during characterization and identification of the contaminants or defects, including any analyses of product materials that may be used for comparison against the contaminants or defects, shall be Client Confidential Information. McCrone Associates shall assign all right, title, and ownership of this Client Confidential Information to Client. Additionally, any modifications to the materials that may be made shall be considered Client Confidential Information. For the benefit of doubt, all McCrone Associates knowledge, processes, methods, procedures, know-how, and any improvements to such, are not included as works for hire under the purposes of this agreement, and are the Intellectual Property of McCrone Associates.

Quality: MA is accredited to ISO/IEC 17025:2017 and conforms to 21 CFR Parts 210, 211, 820 and 58 as applicable to the scope of services offered. Analysis utilizing test technology covered on the ISO 17025 scope of accreditation shall be performed per a quality management system that encompasses these requirements. Clients with additional quality or regulatory requirements for their projects shall discuss these with the MA Project Leader for incorporation into the Project Proposal.

Submitting a Sample: Please include all of the following in your shipment.

- Samples must be packaged and shipped in a manner to ensure their integrity is maintained and limit their degradation. Sharps/needles MUST be capped. Please avoid packing materials that may create extraneous cellulose fibers such as paper, or granular material such as vermiculite.
- Completed Sample Submission Form
- Safety Data Sheets (applicable to all samples) and/or Sample Hazard Information Client Request Form
- Proper Hazard Labeling & Packaging (if necessary)

FRM-GEN-0027 Rev 09	Effective Date: 01 Mar 2024	Reference: SOP-GEN-0011, SOP-GEN-0012
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Safety Information: All applicable safety data sheets (SDS) or a suitable equivalent for investigational drugs are required to be shipped with the sample(s) along with the completed Sample Submission Form. Samples containing known hazardous materials or substances must be clearly and properly marked, labeled, packaged, and transported in accordance with state, federal, and international regulations. Please contact MA before shipping hazardous samples to determine if MA has appropriate environmental and engineering controls for handling the samples properly. To do this adequately, MA requires OEL/PEL's of the API's if they exist, MA may be able to handle biological hazards rated as Biological Safety 1 and 2, only. MA will not accept materials that require a RAM license or contain actinides.

Shipping of Samples from outside the USA:

- Send your shipment to McCrone under **INCO terms – DDP (Delivered Duty Paid)**
- The sender delivers the goods to the named place of destination.
- The sender bears **all** the responsibility, costs, and risks involved in shipping their goods/samples to McCrone Associates, Inc.
- The sender must clear the products not only for export but also for import, pay any duty/taxes for both export and import, and carry out all customs formalities. **McCrone is not the Importer of Record**, only the receiver of the shipment.
- All of the necessary paperwork (Sample Submission Form, Safety Data Sheet(s), packing list, customs invoice, TSCA, etc.) are to be provided by the sender.
- The sender is responsible for any and all costs associated with delivering the sample materials to our laboratory for analysis. Please deliver the sample material to our laboratory using this address:
 - McCrone Associates, Inc.
 - Attn: (the Scientist who provides the quote)
 - 850 Pasquinelli Drive
 - Westmont, IL 60559
- International samples are only returned upon request. The sender is responsible for providing the same as above and any/all costs for any material they would like McCrone Associates to return to the sender.
- **The items shipped to McCrone Associates are for testing purposes only; they are not for sale/resale.**

We recommend you contact your local international courier or delivery service such as **World Courier or DHL International** to handle all of the necessary paperwork and any Broker details to ensure the shipment arrives in a timely manner. Please see our website for Frequently Asked Questions regarding INCOTerms.

Requested TAT: MA cannot guarantee specific turnaround durations or dates due to the investigational nature of the projects. The turnaround clock does not start until the project request is understood and samples and required safety and payment information are received. Standard and rush turnaround times may vary. Please speak directly with your MA Project Leader to obtain turnaround time information. Once a turnaround time is communicated, MA will make every effort to comply with the arranged timeframe.

Sample Disposition / Return (USA Domestic): All samples will be appropriately disposed approximately two to four weeks following final report issuance. When requested on page 1, samples or remnants will be returned by MA. A sample disposition fee of \$75 per project is included to cover disposal or USA domestic return shipping and handling. Additional fees may apply for disposition of especially hazardous material, or return of temperature-controlled shipments, or return of special client-owned shipping containers or devices.

DEA Controlled Substances: Per 21 CFR Chapter 13 Subpart A Subsection 1305.03, a FORM 222 is not required in addition to this form to send samples to MA. Once DEA substances are received, they are processed and/or disposed per DEA regulations. MA does not return controlled substances.

Confidentiality: Information included in, pertaining to and/or resulting from the samples and information included herein shall be regarded by MA as strictly confidential and shall not be used by, disseminated to, or disclosed to any individual, corporation, or organization other than that explicitly stated by and consented to by the client contact and/or company identified above. The samples and information resulting from the samples and the services provided by MA with respect to the samples will be held by MA in strict confidence and will only be used by MA for the provisions of the services hereunder and not for any other purpose not requested by the client.

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These confidentiality obligations survive the termination of the services for a period of 7 years. Client must provide names and email addresses of additional persons authorized to receive report(s) and or share information with.

Final Report Delivery: Final reports will be delivered electronically and shall be the property of the Client. An additional fee of \$50 will be charged for providing a hard copy of the final report(s).

Addendum: For MA to cross reference a document with client specific requirements _____

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