TEST SAMPLE SUBMISSION GUIDELINES

* Generally, 15 grams (solids) or milliliters (liquids) of test substance is sufficient for most assays. If the quantity of your test substance is limited, please consult with your Study Director to determine the minimum required amount for the testing you have requested.
* Please send no more than 100 grams or milliliters of test substance in the smallest vessel possible for the quantity sent.
* Please ensure all necessary or relevant paperwork is included with your shipment (completed copy of the IIVS sample submission form, SDS, Certificate of Analyses, etc.)
* Please send test samples to:

**Institute for In Vitro Sciences, Inc.**

**Attn.: IIVS Lab Orders**

**30 W. Watkins Mill Road, Suite 100**

**Gaithersburg, MD 20878**

**Phone: (301)-947-6523**

**Email:** [**LabOrders@iivs.org**](mailto:LabOrders@iivs.org)

* Test substances must be received at IIVS no later than COB Thursday the week prior to the scheduled assay initiation date. Test substances received later than this may be subject to administrative rush fees and/or rescheduling testing to a later date.
* PLEASE NOTE: Unless otherwise specified on the form:
  + All non-hazardous test sample(s) will be discarded 6 months after issuance of Final Report.
  + Dosing dilutions will be discarded after administration to the test system.

*Please complete the following pages, email them to* [LabOrders@iivs.org](mailto:LabOrders@iivs.org) *and then include a SIGNED COPY with your test articles.*

*PLEASE NOTE: The form is meant to be completed in Word, rather than printed and hand-written.*

**STUDY PLACEMENT**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Date:** | Click to enter date. | **Sponsor’s Study Number(s):** | | Click to enter text. | **Number of Test Samples: (max. 12 per form.)** | Click to enter text. |
| **Type of study/studies to be performed:** | | | Click to enter text. | | | |
| Would you like an **OPTIONAL unsigned Draft Report** for review prior to the Final Report? | | | | | Choose item. | |
| Would you like an **OPTIONAL IUCLID Report** in addition to the Final Report? **(IUCLID Report fee: $500 per Assay)** | | | | | Choose item. | |
| If BCOP, would you like us to save corneas for **OPTIONAL** histology? ($50 holding/storage fee per test article) | | | | | Choose item. | |
| If corneas are to be saved, would you like us to **perform histopathology?** (histopathology pricing based upon protocol): | | | | | Choose item. | |

**SPONSOR / AUTHORIZED REPRESENTATIVE INFORMATION**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Authorized Representative’s Name:** | | Click to enter text. | | | **Signature:** |  | |
| **Sponsor Company:** | | Click to enter text. | | | | | |
| **Address:** | Click to enter text. | | | | **Country:** | | Click to enter text. |
| **City:** | Click to enter text. | | **State:** | Click to enter text. | **Postal/Zip Code:** | | Click to enter text. |
| **Telephone:** | Click to enter text. | | | | **Email:** | | Click to enter text. |

**BILLING INFORMATION *(if different than Sponsor Representative Information)***

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Unless otherwise specified by Contract or Agreement, invoices will be submitted upon issuance of the draft report  and are due for payment in full within thirty (30) days. If no draft report is requested, then the invoice will be submitted  upon issuance of the final report and are due for payment in full within thirty (30) days. | | | | | | | | |
| **Billing Representative:** | Click to enter text. | | | **PO# Needed?** | Choose item. | | **PO#:** | Click to enter text. |
| **Address:** | Click to enter text. | | | **Country:** | | Click to enter text. | | |
| **City:** | Click to enter text. | **State:** | Click to enter text. | **Postal/Zip Code** | | Click to enter text. | | |
| **Telephone:** | Click to enter text. | | | **Email:** | | Click to enter text. | | |

**GOOD LABORATORY PRACTICES (GLP) STUDIES**

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| --- | --- | --- | --- | --- | --- | --- |
| Unless otherwise indicated, studies will **NOT** be conducted under full compliance with GLPs. GLP compliant study with quality assurance audits available at additional charge. | | | **Do you require a GLP study?** | | Choose item. | |
| **If YES, which regulatory guidelines would you like followed?**  *(In the absence of guidance, IIVS will default to OECD GLPs)* | OECD | EPA (FIFRA) | | FDA | | EPA (TSCA) |
| Other (please specify): Click to enter text. | | | | | |
| GLP-compliant studies require documentation of the identity, strength, purity, and composition or other characteristics which define each lot/batch of test sample, and the stability of the test sample, to be included in the Final report. *If a test article is to be prepared in a solvent/vehicle and then applied to the test system, analysis of the dosing dilution is required for compliance. IIVS does NOT perform analyses, but can return dosing dilutions to you (or laboratory of your choosing) – See page 2 “Disposal or Return”.* | | | | | | |
| **Will you provide test sample characterization (*i.e., Certif. of Analyses*) and stability documentation?** | | | | | Choose item. | |

**SAFETY INFORMATION**

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| --- | --- | --- | --- | --- | --- |
| * To comply with OSHA regulations, RCRA, Department of Transportation and Maryland State Regulations for the proper handling and management of hazardous materials, please provide an SDS for your test samples. * *ALL Hazardous test samples shipped to IIVS are to be packaged according to Dept. of Transportation regulations.* * If you wish to maintain secrecy of the test sample identity during testing, the SDS / Hazard Communication documentation can be provided to our Quality Assurance Unit, which will not disclose the identity to laboratory personnel. | | | | | |
| **DOT Hazardous?** | Choose item. | **If YES, please indicate Class, Packing Group, etc.** | | Click to enter text. | |
| **Precautions for Handling:** | Click to enter text. | | **Primary Constituent (Hazard):** | | Click to enter text. |
| **Instructions for Waste Disposal:** | Click to enter text. | | **Percent of Constituent:** | | Click to enter text. |

TEST SAMPLE IDENTITY AND CHARACTERIZATION

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Test Sample Designation** (designation will be presented in protocol and the final report) | **Lot / Batch#**  (if applicable) | **Quantity** | **Physical Description** (color, clarity, physical state, etc.) | **Expiration Date** | **Storage Requirement** |
| Click to enter text. | Click to enter text. | Click to enter text. | Click to enter text. | Click to enter date. | Choose an item. |
| Click to enter text. | Click to enter text. | Click to enter text. | Click to enter text. | Click to enter date. | Choose an item. |
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| Click to enter text. | Click to enter text. | Click to enter text. | Click to enter text. | Click to enter date. | Choose an item. |

**INSTRUCTIONS FOR RETURN OR DISPOSAL OF TEST ARTICLE(S) OR DOSING DILUTION(S)**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **TEST SAMPLE RETURN / DISPOSAL**  Unless indicated below, all non-hazardous test sample(s) will be discarded 6 months after issuance of Final Report. | | | | | | | **RETURN OF DOSING DILUTION(S) *(if applicable)***  Unless indicated below, dosing dilutions will be discarded after administration to the test system. | | | | | | |
| **Do you want your test sample(s) returned to you?** | | | Choose item. | | | | | **Do you want dosing dilutions returned?**  *For GLP studies, analysis of the dosing dilution is required for compliance. IIVS does NOT perform analyses, but can return dosing dilutions to you (or laboratory of your choosing).* | | | | Choose item. | |
| **Please select the appropriate shipping conditions NOTE: Hazardous shipment charges may be additional** | | | | | | Choose item. | | | | | | | |
| **If returning to an address OTHER than that of the Authorized Representative, please provide below:** | | | | | | | | | | | | | |
| **Name:** | | Click to enter text. | | | | | **Sponsor Company:** | | | Click to enter text. | | |
| **Address:** | Click to enter text. | | | | | | | | **Country:** | | Click to enter text. | |
| **City:** | Click to enter text. | | | **State:** | Click to enter text. | | | | **Postal/Zip Code:** | | Click to enter text. | |
| **Telephone:** | Click to enter text. | | | | | | | | **Email:** | | Click to enter text. | |