August 06, 2013

QUOTATION NUMBER:
13-08-06-0003

QUOTATION PREPARED FOR

Steve Nixon
Viamed Ltd.
15 Station Road
Cross Hills
Keighley, West Yorkshire BD20 7DT

Catalog/Test Description	Investment per GLP Test
ISO-CYTO-NRU-1 concentration	$440.00
ISO-SENSITIZATION-KLIGMAN-2 EXT	$7,850.00
ISO-IRRITATION-INTRACUTANEOUS INJ-2 EXT	$995.00
ISO-IRRITATION-OCULAR-2 EXT	$1,205.00

DEVICE TERMS & CONDITIONS:

STANDARD PAYMENT TERMS:
Studies are invoiced and sent with the final report (or at draft when applicable). Payment is NET 30 days from date of invoicing. All prices are listed in U. S. dollars. This quote is valid for 90 days from the date of quotation. Terms are subject to credit approval, and Toxikon reserves the right to make reasonable changes to client terms at any time without prior notification. All balances which are due and owed by client to Toxikon which are not paid within terms will accrue interest at the rate of 8% per annum until payment is received in full.

PREPAYMENT POLICY:
Any individual study with a price of $25,000.00 or more will be invoiced 50% in advance, which is payable upon receipt of invoice of the study. The remaining 50% will be invoiced upon study completion as listed in the Payment Terms, above. Additional charges incurred during study will be billed under the same terms.

SPONSOR ACCEPTANCE:
Upon signing this study quotation, the Sponsor agrees to all of the terms and conditions set forth in this document. Study protocols will be issued only upon acceptance and receipt of the signed quotation. Studies are not scheduled until receipt of the signed study contract documents and test material. Study contract documents include 1) signed quotation, 2) completed test request forms, 3) purchase order number, 4) protocol acceptance. Study scheduling is subject to animal availability, special supplies, and test article availability.

Sponsor Representative_____**Date**_____

ADDITIONAL COSTS:

Toxikon will perform the above named study (-ies) in accordance with all relevant guidelines and applicable study protocol/outline. Additional fees will be incurred for all work or requests beyond the scope of the study, as stated in the quotation and/or protocol. Modifications to standard study designs (replicates, animal numbers, etc.), protocol amendments, reporting, special handling, shipping of study materials, retests and other requests, including consulting and custom protocol development will be additionally charged. Study support post-reporting for regulatory submission will be quoted and charged separately. Test article disposal, Hazardous Waste disposal which include but not limited to (Radioactive materials, animals, and bedding) will be quoted and charged separately**.** Technical and regulatory support are quoted on a time and materials basis. Please inquire. Study support post close for submissions will be charged separately. Please inquire based on scope of work.

Standard Fees:

Additional dilutions	$100.00 per dilution
Minimum report/study fees	$100.00
STAT requests	Inquire
Sample return fee	$200.00 minimum
On-site work	Inquire
Consulting	Inquire
Off-site archive requests	Inquire

Amendments, second original requests	*Non-GLP*	*GLP/GMP*
2006-current	$150.00	$250.00
2005-prior	$250.00	$350.00

Extraction Fees:

EtO Residual-each additional extract	$125.00 per extract
EtO Dilutions-each additional dilution	$100.00 per dilution
Weekend extractions	Inquire

Microbiology Fees:

Note: fees will be added to study price and are based on product size and media volume requirements.

Bioburden; pooled samples	$125.00 per test
Sample item portion (SIP)	$125.00 per test
Sterility; additional media	See below

Media volume	*Additional fee per sample*
Up to 100 mL	Standard price
101-400 mL	$2.50
401-700 mL	$5.00
701-1,000 mL	$7.50
Other	Inquire

***In vitro* Fees:**

Additional charges will apply when test article size and/or design require additional media.

Media type	*Volume limit*
MEM	Applicable if volume > 50 mL
Plasma/blood	Applicable if volume > 3 mL/replicate
Additional dilutions; Genotoxicity	Inquire

Implantation Fees:

Note: fees will be added to the base price of requested implant testing as applicable.

Absorbable materials	$650.00	
Surgical implantation	$350.00	
Device with multiple components	2 materials	$230.00
	3+ materials	Inquire
Additional control material	$230.00	
Special histology orientation	Inquire	
Additional slides/strains	Inquire	

CUSTOM PROTOCOL DEVELOPMENT:
Upon request Toxikon may customize study protocols to meet Sponsor-specifications. An invoice will be issued upon issuance of the protocol and payment due within 30 days. If work is placed utilizing the protocol, a portion of the paid protocol charge will be applied to reduce the total charge of the study invoice.

STUDY DELAY OR CANCELLATION:
Due to the high costs involved with a study delay, including protocol development, technical scheduling, animal costs and rescheduling activities, Sponsor will be charged 10% of the study cost plus expenses when a study delay is attributable to the Sponsor. Study cancellation will result in the following charges: Up to 2 weeks before study initiation, per diem costs, expenses plus 10% of the study quotation; Less than 2 weeks before study initiation, Sponsor will be charged a minimum of 25% of study quotation, plus per diems and all associated expenses (i.e. animal purchase).

REPORTING:
After completion of the study, a final report will be issued to the Sponsor. Sponsor-specific formats or changes to Toxikon-standard format may incur additional charges. Format requirements must be disclosed during protocol development and prior to start of the study. One draft report will be issued only upon request and acceptance of additional charge. Multiple draft revisions may incur additional charges. When a draft report is issued, the Sponsor has up to 30 days in which to make comments. Toxikon will work closely with Sponsor to ensure the report is acceptable to both parties. After 30 days, if no comments or other remarks regarding the draft report have been made, Toxikon will issue a final report. A final report will only be modified upon written request by the Sponsor, at which point a study amendment will be issued at an additional cost.

EXPEDITED STUDY REQUESTS (STAT):
Sponsor requests for a test and/or report to be completed in less time than standard turn around time, must be communicated to a Toxikon Service Representative. Toxikon will make every effort to accommodate all Sponsor requests, however scheduling will be dependent on current lab resources. Sponsor must provide a purchase order for STAT processing fees.

METHOD SUITABILITY:
Method validation may be required prior to sample analysis. Toxikon maintains validated analytical methods for a variety of compounds in an aqueous matrix, as well as in vitro assays with validated standards. The performance of analysis in non-validated matrices or of non-validated compounds may be conducted in a semi-quantitative manner, however the effects of the matrix on results will not have been documented. Sponsor is encouraged to evaluate the intended use of the data and the appropriateness of conducting a method validation study in advance of definitive testing.

SHIPPING:
International shipments are required to pass through U.S. Customs. To minimize delays in Customs, Sponsor should clearly label test articles as "Not For Human Use" on all shipping documents. All handling and costs associated with U.S. or International Customs are the responsibility of the Sponsor. Controlled Substances and Hazardous Materials require notification of planned shipment date and submission of appropriate documentation (i.e. MSDS) to Toxikon prior to shipment. Hazardous materials to be disposed of by Toxikon will incur additional charges. Shipment of Study-related materials is the responsibility of the Sponsor. Study materials may be returned to Sponsor when indicated on the Test Requisition Form. Sponsor account numbers for shipment may be provided to Toxikon for third-party billing; otherwise, Sponsor will be invoiced for study-related shipping expenses.

CONFIDENTIALITY:
Strict confidentiality will be maintained between Toxikon and its clients. Toxikon has a standard confidentiality agreement available for Sponsor review and acceptance. During governmental audits and visits, Toxikon will not disclose Sponsor's identity and project testing unless permission is received from Sponsor.

DISPUTE RESOLUTION:
Any dispute arising out of, concerning, or related to either parties' performance under this agreement, the test protocols, or any other agreement between these parties, shall be settled in the courts of Commonwealth of Massachusetts, or in a federal court sitting in Massachusetts, provided federal jurisdiction applies.

ATTORNEYS FEES & COSTS:
In the event that the Sponsor fails to pay for laboratory and/or the testing services contracted for, and said past due account is referred for legal counsel for collection, Sponsor agrees to pay reasonable attorneys' fees and costs incurred in collection of any past due invoices.

ON-SITE WORK/REGULATORY INSPECTIONS:
Sponsor representatives may visit Toxikon at reasonable times during normal business hours to discuss or observe the progress of a project. Toxikon will assist Sponsor in scheduling such visits in advance and will notify Sponsor of any additional charges. Sponsor audits shall be at mutually agreed upon times and dates and may incur additional cost-please inquire with Regulatory Affairs.

RECORD RETENTION:
All Non-GLP and GMP data (i.e. reports, raw data, slides, blocks) will be maintained for up to five years and all GLP data for up to seven years, or as required by law. Wet tissues will be stored for up to one year post- study completion, at which time the Sponsor will be contacted for choice of return (at Sponsor's cost) or disposal. Sponsor will incur charges for requests requiring archived data to be retrieved from off-site storage. Sponsor is responsible for retaining test article samples per GLP requirement, 21 CFR Part 58.105, (d).

TEST MATERIAL:
Toxikon does not warranty or guarantee the condition of any test material and/or supply that has been utilized in the performance of studies conducted at our facility when properly handled per Sponsor's specifications. Study materials may be returned to Sponsor as per instructions in the protocol or Test Requisition Form and in compliance with Toxikon shipping policies, and permitting requirements.

STUDY GUARANTEE:
Toxikon conducts all studies with utmost professional care and competence but makes no qualifications or guarantees regarding study outcome. Sponsors are advised to verify the intended testing plan with their own regulatory personnel. Toxikon cannot and will not guarantee that a specific test material will be accepted or rejected by any regulatory body. Toxikon can only ensure the integrity of the study performed as specified by the Sponsor and to the study protocol or specification and the data generated. Toxikon has no knowledge if test materials or finished products have been previously qualified and relies upon information provided by the Sponsor. Toxikon does not assume any liability for any actual or perceived failure of the study.