

AGREEMENT BETWEEN
AOAC RESEARCH INSTITUTE
AND

AGREEMENT, made this _____, between AOAC Research Institute, 481 North Frederick Avenue, Suite 500, Gaithersburg, Maryland USA, (the "Sponsor"), and _____ (the "Contractor").

1. Conduct of Study. The contractor agrees to perform a study (the "Study") of the test kit (the "Test Kit") as described in the study protocol attached to this Agreement as Exhibit A (the "Protocol"), subject to the terms and conditions of this Agreement, including those attached to this Agreement as Exhibit B, and in a manner consistent with the most current Good Laboratory Practices Standards and requirements, or other governmental agencies which have jurisdiction over Contractor's laboratory facility or the Study. The Protocol may not be modified except by agreement between Contractor and Sponsor, which agreement must be in writing. Contractor shall, in any event, promptly notify Sponsor in writing of any such emergency change that has been agreed to by Contractor and Sponsor. If, during the Study, Sponsor and Contractor develop additional protocols or changes to the Protocol that are to govern the conduct of the Study, Sponsor and Contractor shall execute an addendum to Exhibit A stating the terms of the changes to the Protocol or such additional protocol.
2. Study Director. Contractor will appoint a "Study Director" to be responsible for the Study, and Sponsor will appoint a "Technical Representative" (AOAC RI Managing Director) to be responsible for the Study. Contractor's Study Director will coordinate performance of the Study with Sponsor's Technical Representative, who shall have the responsibility for all matters related to the performance of the Study on behalf of Sponsor. Contractor shall be entitled to rely upon representations and statements made to Contractor by Sponsor's Technical Representative.
3. Guidelines. Contractor agrees to conduct the Study under guidelines specified in the Protocol attached hereto as Exhibit A. Contractor shall use its best efforts to identify any changes in such guidelines that occur during the performance of the Study. If compliance with such new guidelines necessitates a change in the Protocol for the Study, Contractor will submit to Sponsor's Technical Representative a revised technical and cost proposal for review prior to making any changes in the Protocol or the Study. Within five (5) days following the receipt of such revised proposal by Sponsor's Technical Representative, Sponsor will notify Contractor whether Sponsor accepts such revised proposal. If Sponsor does not accept such proposal, Contractor will not be responsible for the rejection of such Study. Contractor will not be responsible for any changes in guidelines and regulations that Contractor is not aware of before the completion of the Study or for any changes in guidelines after completion of the Study that may have retroactive application to the Study.
4. Reports. A report including copies of the raw data and other pertinent laboratory notes will be sent to the Sponsor after the Study is completed. Within thirty (30) days the Sponsor will review

Appendix 9

the report and notify Contractor of the report's acceptability, as related to the protocol requirements, including any specific comments pertaining to the report. The Contractor will provide to the Sponsor a written response to any Sponsor comments.

5. Payment Terms.

(a) In consideration for the performance of the Study, Sponsor agrees to pay Contractor the fee set forth in Exhibit B in the manner and on or before the due dates set forth in Exhibit B.

(b) If Contractor breaches any of the terms and conditions of this Agreement and such breach adversely affects the scientific validity of the Study in a material manner, or the acceptability of the Study to Sponsor, Contractor will repeat the Study at Contractor's sole cost and expense.

(c) The Contractor shall be entitled to a \$250 bonus if the Study is completed and the Study Report is received one or more weeks before the due date specified in Exhibit B.

(d) A penalty will be assessed against the Contractor if the Study is not completed and the Study Report is not received on or before the due date specified in Exhibit B. Subject to the conditions described in section 5.(d)(iv), the Contractor shall be penalized US\$100 (one hundred dollars) if the study is delivered more than one week late. The Contractor shall be penalized at a rate of US\$10 per day for each day after the first week that a Study Report is late until a maximum penalty of US\$1000 is reached.

- (i) Penalties shall be assessed on a daily pro rata basis after the first week.
- (ii) A Study is not complete until the entire study protocol is completed and the Study Report is received by Sponsor.
- (iii) Penalties shall be deducted from the fee amount specified in Exhibit B and assessed when the Sponsors submits its payment for the Study.
- (iv) Section 15. Force Majeure of this Agreement applies. The Contractor must immediately notify the Sponsor of any conditions that are beyond their control. The Sponsor agrees to renegotiate the Study Report due date if Force Majeure applies. No waiver of the due date specified in Exhibit B shall be effective unless in writing and signed by the Study Director.

6. Indemnification and Limitation of Liability.

(a) Sponsor assumes all responsibility for and shall indemnify and hold harmless Contractor against any and all losses sustained by Contractor resulting from, arising out of or connected with:

- (i) Any inaccuracy in, breach of, or nonfulfillment of any representation, warranty, covenant or agreement made by, or other obligation of, Sponsor contained in this Agreement;
- (ii) Negligent or wrongful acts of Sponsor;
- (iii) Any violation of third party patents of proprietary information, or other proprietary rights, concerning the use or sale of the Test Kit by Sponsor, or concerning any of the activities performed by Contractor pursuant to the terms of this Agreement;
- (iv) Damages, personal injury, product liability, or property damages related to the study resulting from (a) the shipment, transportation, handling, use, possession, release, testing, or labeling of the Test Kit; and (b) any activities performed by Contractor to the extent such activities are performed in substantial conformance with the Protocol; and/or

Appendix 9

- (v) Illness, injury or other harm to a third party arising from the use, sale or handling of the Test Kit by or for Sponsor.

(b) Contractor shall indemnify and hold harmless Sponsor against any and all losses sustained by Sponsor resulting from, arising out of or in connection with:

- (i) Any inaccuracy in, breach of, or nonfulfillment of any representation, warranty, covenant or agreement made by, or other obligation of, Contractor in this Agreement; and
- (ii) Negligent or wrongful acts of Contractor in the performance of this Agreement.

7. Inspections. Sponsor shall have the right to inspect Contractor's laboratory facilities at reasonable times upon at least forty-eight (48) hours advance notice and with reasonable frequency during the term of this Agreement in accordance with the standard operating policies and procedures of the Contractor. Sponsor's representatives shall have controlled access only to those laboratory facilities which are being or will be used for Sponsor's Study, including, but not limited to storage facilities, Contractor's operation facilities, and analytical laboratory facilities. Sponsor may observe the progress of the Study and inspect all records and copy all records and data, including shipping documents pertaining to Sponsor's Study. Contractor shall not under any circumstances be required to provide Sponsor's representatives with access to those facilities or records of Contractor which are being used for projects of other clients. If the security requirements of Contractor's other clients conflict with the visits of Sponsor's representatives, a compatible visitation schedule will be negotiated between Sponsor and Contractor. Sponsor's representatives will abide by all of Contractor's rules and regulations while at Contractor's laboratory facilities.

8. Retention of Study Materials. Contractor agrees to use reasonable care in safeguarding, inventorying and handling any property of Sponsor entrusted to Contractor's care. The Study Materials, as hereafter defined, shall remain the property of the Sponsor. "Study Materials" means the Study report and any data, information, or documentation acquired by Contractor from Sponsor or generated or developed by Contractor on behalf of the Sponsor during the Study whether written or physical, including without limitation, notebooks, original data, tissues, slides, samples, photographs, test materials, and electronic data disks or tapes. At such time as specified in Sponsor's request, or upon completion of the Study, Contractor will transmit the Study Materials to Sponsor. All raw data will be forwarded to the Sponsor with the final report. Contractor will maintain copies of the Study Materials (excluding test materials) in its archives for a period of two (2) years. In the event Contractor desires to dispose of Study Materials or, after the ten year retention period, the retained copies of the Study Materials, Contractor shall send Sponsor a letter requesting authorization for such disposal, and describing the manner of disposal. Contractor's obligation to store the Study Materials and raw data shall end upon the issuance of the final report, with the exception of copies of the Study Materials retained for archive purposes. During Contractor's period of retention, Sponsor shall have the right to have complete and full access to the Study Materials and raw data consistent with Section 7 hereof, and the right to duplicate such items for its use. Neither Sponsor nor Contractor will unreasonably withhold access by the other Study Materials or copies of the Study Materials if such access is required for validation of laboratory results or procedures to comply with a government regulatory agency request or applicable law.

Appendix 9

9. Patents and Inventions. Upon request by Sponsor, Contractor will assign or cause to be assigned to Sponsor all right, title and interest in and to any invention made by Contractor or its agents or employees which relates to the Study or to the Test Kit. Contractor will cooperate with Sponsor in preparing patent applications with respect to such inventions, and will execute or cause to be executed any documents reasonably necessary to vest full right, title and interest in Sponsor to patents, patent applications and other intellectual property rights included hereunder. Sponsor will reimburse Contractor for its reasonable out-of-pocket costs and consultant fees and expenses incurred in such cooperation.

10. Confidentiality. Contractor shall maintain the Study Materials in confidence for a period of ten (10) years beginning on the date of this Agreement. Contractor shall not publish or disclose the Study Materials or use the Study Materials for any purpose other than performance of this Agreement. The obligations of confidentiality set forth in this paragraph shall not apply to data or information which: (a) is available to the public or is general industry knowledge at the time of disclosure to or generation by Contractor, or subsequently becomes so available to the public or such general industry knowledge, except as a result of breach of this Agreement; (b) is acquired by Contractor from a third party (other than Sponsor, its agents, employees or representatives) having a right to disclose such information; or (c) is known by Contractor prior to execution of the Agreement. Nothing in this Agreement shall prohibit Contractor from complying with a subpoena or other lawful process issued by a court or administrative agency acting within the scope of its jurisdiction, or from otherwise complying with applicable law; provided however, that Contractor shall immediately notify Sponsor of any such subpoena, process or request for disclosure and shall permit Sponsor to challenge at Sponsor's expense such disclosure in accordance with applicable law.

11. Request for Data.

(a) Contractor shall promptly notify the Sponsor of any private or governmental request for information of which it becomes aware on any matters relating to this Agreement. In the event that Contractor's facilities become the subject of a governmental inspection and confidential records or data pertaining to this Agreement are requested in the course of such inspection, Contractor shall immediately notify the Sponsor. Contractor shall inform the government of the confidential nature of the material. The Sponsor shall have the right to participate in Contractor's response to the inspection notice. Contractor shall provide the Sponsor copies of any data provided to the government relating to this Agreement.

(b) In the event Contractor receives any legal instrument requiring production of data, work papers, computer printouts or other materials relating to this Agreement, the following provisions shall apply:

- (i) Contractor shall give sponsor the opportunity to respond to such legal instrument.
- (ii) Contractor shall cooperate fully with any effort by the Sponsor, at Sponsor's expense, to narrow the scope of any such legal instrument, to obtain a protective order limiting the use or disclosure of the information sought therein, or in any other way to obtain continued protection of the confidentiality of the Sponsor's material. Sponsor shall pay Contractor's then current professional hourly rate for services, and other reasonable out-of-pocket expenses, travel and lodging associated with the aforementioned requests.

Appendix 9

12. Term. This Agreement shall take effect on the date hereof, and shall continue until issuance of the final Study report, except that the provisions of Paragraph 6, 8, 10, and 11 shall survive this term and continue for five years unless otherwise stated.

13. Termination. Either party shall have the right at any time to terminate the Study prior to completion by giving written notice to the other party. In the event of such notice from Sponsor, Contractor shall, upon receipt of such notice, endeavor to reduce loss and cost to Sponsor as a result of such termination. Sponsor shall pay Contractor a pro rate portion of the fees due under this Agreement for the portion of the Study completed plus out-of-pocket costs and expenses (including any costs of terminating the Study). Termination of this Agreement shall not affect any claim that one party may have in the event of a breach of this Agreement by the other party. If the study is terminated, any data which has been generated will be returned to Sponsor.

14. Assignment. This Agreement may be assigned by either party to a successor to substantially fulfill the entire business of such party to which this Agreement relates, provided the successor assumes the obligations hereunder of the assignor. Any other purported assignment by one party without the written consent of the other party shall be null and void.

15. Force Majeure. Notwithstanding any provision to the contrary contained herein, no liability shall result to either party from delay in performance or nonperformance caused by circumstances beyond the reasonable control of the party charged with performance, including, but not limited to Acts of God, fire, flood, explosion, war action or request of governmental authority, government regulations, permit requirements, accident, labor trouble or shortage, and inability to obtain material, equipment or transportation.

16. Notices. Any notice required or permitted to be given by the terms of this Agreement shall be deemed duly given when hand delivered or delivered by facsimile transmission or by certified or registered mail, or other registered delivery service, postage and fees prepaid, to the following address (or to such other address as shall be specified by notice):

If to Sponsor: AOAC Research Institute
481 N. Frederick Ave, Suite 500
Gaithersburg, MD 20877-2417
Attn: Deborah McKenzie

If to Contractor:
(Name & Address)

Appendix 9

17. Public Reference. Neither party shall, without the prior written approval of the other, use the name of the other party in connection with any advertising, promotional literature, or other public disclosures. In scientific articles published with the consent of the other party, the publishing party shall give credit to the other party and its personnel as appropriate.

18. Severability. If any provision of this Agreement is, becomes or is deemed invalid or unenforceable in any jurisdiction, such provision shall be deemed amended to conform to applicable law so as to be valid, legal and enforceable in such jurisdiction so deeming. The validity, legality and enforceability of such provision shall not in any way be affected or impaired thereby in any other jurisdiction. If such provision cannot be amended without materially altering the intention of the parties, it shall be stricken and the remainder of this Agreement shall remain in full force and effect.

19. Governing Law. This Agreement shall be governed by and construed and interpreted in accordance with the laws of the Commonwealth of Virginia which is stipulated to be the jurisdiction for any litigation to enforce this Agreement. Producer has executed this Agreement by its authorized officer expressly to induce reliance hereon.

20. Entire Agreement. This Agreement (together with the Exhibits attached hereto) supersedes any and all prior negotiations and oral and written agreements, if any, executed and delivered simultaneously with or subsequent to the date of this Agreement, constitutes the entire agreement of the parties relating to the subject matter hereof.

21. Independent Contractor. Contractor and Sponsor agree that no provision in this Agreement shall be construed to make Contractor an employee, agent or representative of Sponsor. Contractor and Sponsor agree that Contractor is an independent contractor.

22. Amendments. This Agreement may not be altered or amended except in writing signed by the duly authorized representatives of the parties hereto.

23. Waiver. No waiver of any terms of this Agreement shall be effective unless in writing and signed by the duly authorized representative of the party to be charged herewith. No waiver of any provision hereof shall extend to or affect any obligation not expressly waived, impair any rights consequent on such obligation, or imply a subsequent waiver of that or any other provision.

24. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

25. Binding Effect. Except as otherwise provided to the contrary, this Agreement shall be binding upon and insure to the benefit of the parties and their respective heirs, executors, administrators, successors and permitted assigns.

26. Headings. The description headings of the several sections of this Agreement are inserted for convenience only and do not qualify or affect the terms and conditions thereof.

27. Exhibits. The Exhibits hereof are incorporated herein by reference and made a part hereof.

Appendix 9

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Agreement as of the date set forth above.

AOAC Research Institute

Contractor

Signature: *Deborah McKenzie*

By: _____

Name: Deborah McKenzie

Name: _____

Title: Managing Director

Title: _____

Date: _____

Date: _____

EXHIBIT B: TERMS AND CONDITIONS