

AOAC Research Institute
CONSULTING AGREEMENT

This Agreement is made on _____, 2004 by and between the AOAC Research Institute, 481 N. Frederick Ave, Suite 500, Gaithersburg, MD., USA 20877-2417 (“AOAC RI”) and _____, (“COMPANY”).

1. Services. The AOAC RI agrees to perform the following Services:

1.1 The AOAC Research Institute will develop and submit a Validation Outline to be used by COMPANY to validate its analytical test kit.

1.1.1 The Validation Outline will comply with the AOAC standards and guidelines. Data produced following the Validation Guideline shall satisfy the requirements for Performance Tested Methods; and/or the “pre-collaborative” study portion of the Official Methods program.

1.1.2 The Validation Outline will be individualized for each specific analytical test kit based on the information Company provides AOAC RI and will take into consideration the performance claims and technology of the kit.

1.1.3 The Validation Outline is composed of the following components:

1.1.3.1 Overview of validation requirements for each analytical test kit.

1.1.3.2 Specific validation protocols.

1.1.3.3 Discussion of testing procedures and acceptance criteria for all validation parameters.

1.1.3.4 Discussion of areas of potential difficulties.

1.1.3.5 Validation flowchart, PERT and GANTT Charts.

1.1.3.6 List of strains/species for testing (if microbiological test).

1.1.3.7 Reference documentation such as reference methods and MPN procedure.

1.1.3.8 Recommended factors for ruggedness testing.

1.1.3.9 Proposed independent testing by AOAC Research Institute.

1.2 Develop and deliver the Validation Outline within 20 working days (US calendar) after receiving an application, COMPANY information and package insert or user’s manual.

2. Payment. As compensation for the performance of the Services, COMPANY agrees to pay the AOAC RI US \$3,000 as a Non-AOAC RI Contributing Member; or US \$2,000 as an AOAC RI Contributing Member. An AOAC RI Contributing Member is a Member which supports AOAC RI's efforts including an annual donation of \$5,000.

2.2 US \$500 will be applied to the application fee if the method is submitted for Performance Tested Methods review.

2.3 All payments will be made in U.S. dollars.

- 2.4 Payment Schedule: An invoice will be presented when the Validation Guideline is ordered. Fees will be paid within 20 working days of submission of invoice
3. Relationship of Parties. It is understood and agreed that the AOAC RI is an independent organization. The AOAC Research Institute shall perform the Services at the request of COMPANY, but the AOAC RI shall determine, in it's sole discretion, the manner, sequence, and means by which the Services are accomplished.
 4. Caveats. The AOAC Research Institute cannot guarantee that additional validation studies will not be required by independent expert reviewers, nor that the test kit can be approved or certified based on data collected using the Validation Outline. Data collected using the Validation Outline will be subjected to the same level of scrutiny as all other methods under review in either the Performance Tested Methods or the Official Methods program. AOAC RI's liability is limited to a refund of the payment made, which is COMPANY's exclusive remedy. AOAC RI will not be liable for any special, incidental or consequential damages, either in tort or contract.
 5. Confidential Information. AOAC RI may acquire knowledge, information, and materials about the COMPANY, its business, its products and services, and its customers and that all such knowledge, information and materials acquired are and shall be the trade secrets and confidential and proprietary information of COMPANY. The AOAC RI agrees to hold such confidential information in strict confidence and not to disclose it to others or use it in any way without prior written consent of the Sponsor.

IN WITNESS WHEREOF, the parties hereto have signed this Agreement as of the date first above written.

For the AOAC Research Institute:

_____, "COMPANY":

Scott Coates

Signature:

Signature:

Scott G. Coates
Name

Name

Managing Director
Title

Title

Date

Date