



AOAC Research Institute
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Application Instructions

Please read the entire application package material and the *Performance Tested Methods^K* Program POLICIES AND PROCEDURES document before completing the application form.

- o An "Application Check List" is included to serve as a reminder to the applicant of the material and information to be submitted.
- o Complete the application form to include the requested information on the firm and test kit for which application is being made. **Complete a separate application form for each test kit model for which application is being made.**
- o Be sure to provide the requested information concerning compliance with any regulatory requirements on the first page of the application. If the primary use of the test kit is to determine compliance with regulatory requirements, those regulatory agencies may be required to participate in the performance testing and review process.
- o The test kit manufacturer is required to submit manufacturer-generated data for the parameters listed on the "Data Submission Requirements", where applicable.
- o The test kit manufacturer is required to submit copies of test kit labels, manuals and test kit information insert containing the information listed in the "Descriptive Insert Requirements" sheet.
- o The manufacturer is required to submit the manufacturing quality assurance and quality control practices as outlined in the *Performance Tested Methods^K* Program POLICIES AND PROGRAM document.
- o The manufacturer is required to include the appropriate application fee as stated on the Fee Schedule. Do not include a laboratory fee at the time of making the application. The manufacturer will be invoiced for the laboratory fee after all parties have agreed on the study protocol.
- o Please review the **Certification Mark License Agreement**. This Agreement doesn't need to be signed now, but it will be required before the *Performance Tested Method^K* certification mark is issued after a successful validation.
- o Submit the application package to:
 - Managing Director
 - AOAC Research Institute
 - 481 N. Frederick Ave, Suite 500
 - Gaithersburg, MD 20877-2417 USA
- o The test kit manufacturer is required to submit at least three test kits after the data submission is accepted and expert reviewers have been assigned. The AOAC Research Institute will provide further instructions and addresses when appropriate. Additional test kits will be requested after the evaluation protocol has been designed, and an independent laboratory has been selected.