

Guidelines for Laboratory Selection for Participation in a Collaborative Study

A laboratory must demonstrate technical competence suitable for participation in an AOAC collaborative study. A laboratory may qualify for selection based on meeting either Requirements I or all the sections of Requirements II. Each set of requirements specifies the documentation necessary to meet those requirements. Documents are to be submitted, if requested by an AOAC staff member. Special circumstances might permit a deviation from these requirements. Deviations require approval by one of the following:

OMB Chair (Official Methods Board Chair) or appointee

Requirements I

1. A laboratory is accredited to ISO/IEC 17025 or equivalent and the analytical technique required for the study is in the laboratory's scope of accreditation. A copy of the certificate of accreditation and the scope of accreditation are required
2. A laboratory performs the practice sample analysis satisfactorily.

Requirements II

1. The laboratory has experience with the analyte or a related compound and the matrix. Chromatograms must be provided upon request.
2. The laboratory may not subcontract the analysis for the study to another laboratory.
3. The laboratory has an independent Quality Assurance Unit. An organizational chart must be provided upon request.
4. The laboratory has a Quality Manual and Standard Operating Procedures. A copy of the Table of Contents from the Standard Operating Procedures must be provided upon request. The Standard Operating Procedures must include all requirements for analytical technique to be used in the study. The laboratory has evidence of an internal audit function.
5. The laboratory has the required equipment. This equipment will include the appropriate facilities to store samples properly as well as to analyze the samples.
6. The maintenance and calibration of equipment is performed and recorded on a regular prescribed basis. A copy of these records must be provided upon request.
7. The laboratory has training records demonstrating that personnel have been trained to perform appropriate analytical technique(s). A copy of these training records must be provided upon request.

8. The laboratory has both internal and external quality control measures. Records of these measures must be provided upon request. Examples of possible records include, but are not limited to:
 - a. Control Charts
 - b. Use of reference materials, when available
 - c. Proficiency Testing results when proficiency testing is available
 - d. Replicate tests using the same or different methods
 - e. Retesting of retained items
 - f. Correlation of results for different characteristics of an item
9. The laboratory has a satisfactory system in place for recording data and maintaining records.
10. The laboratory performs the practice sample analysis satisfactorily, if applicable.