Formats for AOAC Collaborative Study Manuscripts and Protocols

FORMAT FOR COLLABORATIVE STUDY MANUSCRIPTS

TITLE: Title of manuscript includes method title which includes the analyte(s), matrix(es), and analytical technique, if applicable. It may also include a *common* method name and ends with "Collaborative Study."

AUTHOR(S): Provides authors' full (e.g. no initials) names and contact information.

ABSTRACT:
- ✓ Specific information on the method and study.

INTRODUCTION:
- ✓ Information on why collaborative study was conducted, how many collaborators participated in the study, previous work done, and information on compound or process that was studied.

COLLABORATIVE STUDY:
- ✓ Information on matrices and number of test samples tested, test sample preparations, instructions for collaborators, etc.

METHOD:
- ✓ Written in AOAC style.

COLLABORATORS' COMMENTS:
- ✓ Any comments and suggestions received from collaborators and information on how they were addressed, e.g., incorporating instructions into the method, etc.

RESULTS AND DISCUSSION:
- ✓ Information on type of statistical analyses performed on raw data, reasons for rejecting some of the data, discussion of results with references to tables and figures, discussion of the method performance, etc.

RECOMMENDATION:
- ✓ Recommendation to adopt method First Action.

ACKNOWLEDGMENTS:
- ✓ Full names and addresses of all collaborators that participated in the study.

REFERENCES:
- ✓ Included all references cited in the text.

APPENDICES or **FIGURES AND TABLES**:
- ✓ Include any figures and tables that may make the manuscript and the performance of the method easier to understand and interpret.

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Online Technical Resources

Method Development, Optimization & Validation
- ❖ OMA - Appendix F - Guidelines for Standard Method Performance Requirements
- ❖ Homogeneity
- ❖ Guide for Writing Methods in AOAC Format
- ❖ Statistics Protocol Review Form
- ❖ OMA - Appendix D: Guidelines for Collaborative Study Procedures to Validate Characteristics of a Method of Analysis
- ❖ OMA - Appendix G: Procedures and Guidelines for the Use of AOAC Voluntary Consensus Standards to Evaluate Characteristics of a Method of Analysis
- ❖ OMA - Appendix I: AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Biological Threat Agent
- ❖ Methods and/or Procedures
- ❖ OMA - Appendix J: AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Microbiological Methods for Food and Environmental Surfaces
- ❖ OMA - Appendix K: Guidelines for Dietary Supplements and Botanicals
- ❖ OMA - Appendix L: AOAC Recommended Guidelines for Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) Single-Laboratory Validation
- ❖ OMA - Appendix M - Validation Procedures for Quantitative Food Allergen ELISA Methods: Community Guidance and Best Practices

Method Review
- ❖ Examples of Statistical Analysis
- ❖ Statistics Manuscript Review Form
- ❖ OMA - Appendix A: Standard Solutions and Reference Materials
- ❖ OMA - Appendix D: Guidelines for Collaborative Study Procedures to Validate Characteristics of a Method of Analysis
- ❖ OMA - Appendix H: Probability of Detection (POD) as a Statistical Model for the Validation of Qualitative Methods

Miscellaneous
- ❖ Definition of Terms and Explanatory Notes
- ❖ OMA - Appendix B: Laboratory Safety
- ❖ OMA - Appendix E: Laboratory Quality Assurance
- ❖ OMA - Appendix C: Reference Tables

All resources are accessible at
http://www.aoac.org/vmeth/guidelines.htm

For questions, please contact:
P 301-924-7077 x157 E dmckenzie@aoac.org

FORMAT FOR COLLABORATIVE STUDY PROTOCOLS

TITLE: Method title should include the analyte(s), matrix(es), and analytical technique, if applicable. It may also include a *common* method name (e.g., "Kjeldahl" method)

AUTHOR(S): Include your name, affiliation, mailing address, phone number, fax number and email address.

INTRODUCTION: Include the following:

- ✓ Background of the method and the analytical challenge is proposes to meet;
- ✓ Goals of the Study;
- ✓ Purpose and needs of the study;
- ✓ Description of your approach to the problem;
- ✓ Intended Use and scope/applicability of method; and
- ✓ Scientific principle(s) of the method.

COLLABORATORS: Qualify the collaborators:

- ✓ State whether study is planned in cooperation with any other organization.
- ✓ State number of planned collaborators.
- ✓ Tell how collaborators/laboratories will be selected.
- ✓ List the collaborators who have already agreed to participate with their full contact information (name, title, affiliation, mailing address, phone number, fax number and email addresses) when available

STUDY DESIGN: Outline the design of the study:

- ✓ Include the number of materials, number of blind duplicates or Youden pairs, number of blanks, number of positive and negative controls, where applicable, and number of analyte concentration levels.

TEST SAMPLE PREPARATION: Describe preparation of test samples:

- ✓ What will be the individual materials? What is the matrix, what is the analyte, and at what concentration?
- ✓ How will analyte/matrix combinations be prepared? By spiking or as naturally occurring materials?
- ✓ How will actual content be determined? If using a reference method to determine actual content, how will the reference method be determined to be in control? How will the reference method be selected?
- ✓ What other analytes or contents of interest to this test (interferences, etc.) will be included in materials?
- ✓ Comment on Homogeneity of the samples
- ✓ What will be the blanks, if appropriate?
- ✓ What quality control measures will be followed to assure content of samples?
- ✓ What stability data are available and how is that information used?
- ✓ How will test samples be packaged and how will collaborators handle them upon receipt?

METHOD: Write the method in AOAC style.

- ✓ Applicability statement (matrices, analyte concentrations)
- ✓ Write the method as a series of commands. For example, "add 10 mL," "stir the solution."

FORMAT FOR A COLLABORATIVE STUDY PROTOCOL *(con't)*

- ✓ List Apparatus and Reagents as separate sections at the beginning of the method in a list format.
  - Stock items found in every laboratory that don't need special preparation are listed.
  - Concentrations of reagents and any directions for purification, preparation, and storage and specifications of apparatus are essential elements of the method.
  - Describe apparatus and reagents generically in terms of performance and suitability tests.
- ✓ Present sampling, test sample preparation, or preparation of a standard curve (if crucial or involved).
- ✓ Describe procedural steps under the heading "Determination." Be as explicit as possible in listing details. (e.g., volume and number of extractions; order of elution; critical times and temperatures; special spectrophotometric conditions; size of containers, if important; vigorous or gentle shaking or stirring; criteria for judging an end point; suitable stopping places for a lengthy method; etc.)
- ✓ Provide calculations with SI units if applicable.
- ✓ Include any necessary alerts to critical steps, precautions, or warnings.

REPORTING RAW DATA:

- ✓ Provide instructions on how to report the data from the analysis. Provide a draft data reporting sheet.

ANALYZING RAW DATA:

- ✓ Indicate what method performance statistics will be determined from study design (recovery, RSD_r, RSD_R, s_r, s_R, HORRAT, etc.). See Appendix D of the OMA for additional information.

APPENDICES or **FIGURES AND TABLES**:

- ✓ Include any figures and tables that may make the manuscript and the performance of the method easier to understand and interpret.
- ✓ Provide examples of the the draft letter to collaborators that would include the information on the study, (e.g., type of analysis, equipment and reagents requirements, the intended date of beginning of the study, length of the study, time frame for reporting results of analyses, etc.)

REFERENCES CITED:

Include references for all cited work in the protocol.

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