

Clinical Chemistry

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Information for Authors

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Clinical Chemistry, issued monthly, is published in print and electronically (<http://www.clinchem.org>) by the American Association for Clinical Chemistry. The journal welcomes contributions, either experimental or theoretical, in the field of laboratory medicine. Papers may address basic materials or principles, analytical techniques, molecular diagnostics, test utilization or testing-related health or financial outcomes, instrumentation, data processing, statistical analyses of data, clinical investigations in which laboratory testing has played a major role, or laboratory animal studies of chemically oriented problems of human disease. Contributions should meet the following criteria:

1. Subject matter that is original and significantly advances the state of knowledge of clinical chemistry.
2. Conclusions that are justified from the design of the experiments and the data presented.
3. Information that is sufficiently detailed to permit replication of the work by a competent clinical chemist.
4. Writing that is clear, concise, and grammatically correct.

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- Laboratory Management
- Lipids, Lipoproteins, and Cardiovascular Risk Factors
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- Proteomics and Protein Markers

Editorials and Reviews are usually invited, although unsolicited manuscripts in these categories are welcome.

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Submit and track status of manuscripts at <http://submit.clinchem.org>. See below for detailed manuscript preparation guidelines.

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Use wide (2 cm) margins and double spacing throughout the abstract, text, references, tables, figure legends, and footnotes. Place references, table, and figure legends on separate pages, in that order. Do not use headers or footers, but include page numbering. For guidance on manuscript preparation and style, consult the *CBE Style Manual (3)* or, as

needed, *The ACS Style Guide: A Manual for Authors and Editors* (4). Use the International System of Units (SI) (5) consistently throughout. Values expressed in conventional units may be added in parentheses after the value in SI units. Space in the journal is limited, and authors are expected to present their work concisely. Special limits apply to Technical Briefs and Letters to the Editor (see *Journal categories*). Additional data, images, or method details may be submitted for archival electronic posting with the published paper. (See "Data Supplements" below.)

Title page. Prepare the title page on a separate page with the authors' first and last names, in that order, and in full, using footnotes to indicate their complete mailing addresses (if different from where the work was done) with names of Departments, Divisions, or Centers, as appropriate, as well as postal codes, and the corresponding author. Include a fax number and e-mail address for the corresponding author. If submitting a full Article, include a subject heading (from the list under *Journal categories*) on the top left corner of the page and provide an abbreviated title of no more than 50 characters to be used as a running title.

Abstract. On a separate page, provide a structured abstract of 250 words or fewer. (Editorials, Technical Briefs, and Letters to the Editor do not require an abstract.) For abstracts of regular articles, include the following four headings: Background, Methods, Results, and Conclusions. The Background should state the context and rationale for the studies, usually in one sentence. The Results should contain numerical data and appropriate statistical information. The Conclusions should follow from the presented results and be objectively verifiable; avoid qualitative words such as "good", and use "acceptable" only in reference to explicit criteria for acceptance.

Abbreviations. Define all nonstandard abbreviations the first time they are used in the text and (if more than two) in a single footnote after the abstract. Avoid unnecessary new abbreviations. For terms used fewer than four times in a report, do not introduce an abbreviation. A list of abbreviations that may be used without definitions is available with the *Information for Authors* at <http://www.aacc.org/ccj/authors.stm>.

Materials and Methods. Identify the apparatus used and provide the name of the manufacturer and the model number if multiple versions exist. For modified or newly created equipment, provide enough detail for the reader to duplicate the construction. Describe the roles, if any, of funding organizations in (a) the design of the study, (b) the data collection, analysis and interpretation, and (c) the preparation of the manuscript, and their rights to approve, delay, or disapprove of publication of the work.

Acknowledgments. In a paragraph preceding the references, acknowledge financial support, gifts, technical help, or other assistance, including that rendered by a company in evaluation of a product. (See the *Conflict of interest* section above.)

Figures. Acceptable image file formats for print publication are TIFF and EPS, at resolutions dictated by our print publication vendor at <http://cpc.cadmus.com/da/guidelines.asp>, and must be submitted as independent files, not embedded within a word processing document Microsoft PowerPoint (.PPT) files are also acceptable, but the graphics contained within them must also meet the vendor's resolution requirements. GIF, JPEG, PDF, and embedded figures may be used for initial submission and review; however, authors are advised to create and keep print-quality files on hand, as they will be required upon first revision of the manuscript. In the case that publication quality electronic figure files cannot be provided, acceptable publication prints are: for halftones, glossy prints; for line drawings, glossy prints or laser prints on coated (nonabsorbent) laser-printer paper or drawings in black India ink on tracing paper. Figures printed with dot-matrix printers are not acceptable. Figures, electronic or otherwise, should be redesigned or recreated if they do not appear sharp and clear on paper. Authors are advised to test print electronic files before submitting them for publication. Verify that symbols and lettering will be legible when the figure is reduced to one column (85 mm) or two columns (176 mm) wide. Letters should be 8\10 points when reduced, subscripts at least 6 points. Use a medium (not bold) sans serif (Swiss, Helvetica, Arial) font. Lowercase lettering with an initial capital is preferred. Use abbreviations appropriate for journal style (e.g., mL and mmol/L, not ml and mM). Use a period (full stop), not a comma, to indicate decimal position.

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Journals

1. Fiechtner M, Ramp J, England B, Knudson MA, Little RR, England JD, et al. Affinity binding assay of glycohemoglobin by two-dimensional centrifugation referenced to hemoglobin A_{1c}. *Clin Chem* 1992;38:2372–9.
2. Demers LM. New biochemical marker for bone disease: is it a breakthrough? [Editorial]. *Clin Chem* 1992;38:2169–70.
3. Davey L, Naidoo L. Urinary screen for acetaminophen (paracetamol) in the presence of *N*-acetylcysteine [Letter]. *Clin Chem* 1993;39:2348–9.

Books and monographs (except serial volumes, which are treated as journals)

4. Siminovitch KA. Molecular characterization of human anti-DNA antibodies. In: Farid NR, Bona CA, eds. *The molecular aspects of autoimmunity*. San Diego: Academic Press, 1991:59–72.
5. Bailar JC III, Mosteller F, eds. *Medical uses of statistics*, 2nd ed. Boston: NEJM Books, 1992:449pp.
6. Harley JB, Gaither KK. Autoantibodies. In: Klippel JH, ed. *Systemic lupus erythematosus*. *Rheumatic disease clinics of North America*, Vol. 14. Philadelphia: WB Saunders, 1988:43–56.
7. Houghton MA. Immunonephelometric measurement of vitamin D binding protein [MAppSci thesis]. Sydney, Australia: University of Technology, 1989:87pp.

Internet sources should include the author (if any), the title of the site, the URL (address), and the date accessed.

8. American Association for Clinical Chemistry. AACC continuing education. <http://www.aacc.org/services/default.stm> (Accessed November 1998).

Reference to unpublished work. Authors citing manuscripts in press, personal communications, or other unpublished work related to the manuscript must submit with their manuscript a letter from the individuals concerned, confirming the work and giving permission for the citation. If any of the authors' unpublished manuscripts submitted to other journals are cited in the manuscript submitted to *Clinical Chemistry* or may be critical to its evaluation, a copy of each unpublished manuscript must be included with the original submission. Personal communications, unpublished work, and manuscripts that have not been accepted must be cited parenthetically in the text and not as numbered references.

Data supplements. Supplemental data too large for print publication or exceeding the bounds of the manuscript type may be submitted with a manuscript for inclusion in the on-line version of *Clinical Chemistry*. Files intended for online publication only should be uploaded to the submission system at <http://submit.clinchem.org> as type "Supplemental Files", and referred to as online supplements in the text. Such supplemental information will be reviewed as part of the manuscript and will be evaluated for its importance and relevance. If accepted, the supplemental data will be referenced in the text of the article, directing readers to the URL of the Web site.

Description of Analytical Methods and Results

Manuscripts describing the development and evaluation of the performance of methods and instruments should discuss linearity, imprecision, analytical specificity, recovery, lower limit of detection, comparability with other analytical methods, lower limit of quantification and reference interval(s); some clinical data are usually needed. Document the analytical advantages of the new or modified method over existing methods.

Calibration curves and linearity. Data for these studies should be subjected to linear regression analysis (if a linear response is obtained) and should include the slope, intercept, standard error of estimate (standard deviation about the regression line), and the standard deviations of the slope and intercept. Standard deviations of repeated points may be included. In preparing radioimmunoassay calibration curves, authors may use any objective, statistically valid method but must specify the method used [see, e.g., Ref. (6)].

Imprecision. Studies must include estimates of “within-run” and “total” standard deviations. Each should be determined at low, normal, and above-normal concentrations with use of specimens that are in an appropriate biological matrix. One method of estimating both within-run and total standard deviations is the analysis of variance experiment described in NCCLS EP5-T (7), which calls for two replicates per specimen per run and two runs per day for 20 days. This permits separate estimation of between-day and between-run, within-day standard deviations, as well as within-run and total standard deviations. For acceptable alternatives that include only one run per day, see the cited document.

Indicators of Accuracy (“Trueness”). (a) *Analytical recovery studies* involve analyses after known amounts of analyte are added to the biological fluid on which the determination will be performed. Recovery of *added* analyte should be calculated. (b) *Interference studies* should be performed to assess the effects of common interferents, e.g., lipids, hemoglobin, bilirubin, and components of uremic plasma. Exogenous materials, such as commonly used or commonly coadministered drugs that might interfere with the determination, should also be tested for interferences. (c) *Comparison-of-methods studies* should compare results by the new or proposed method with those by a reference-quality method or other generally accepted analytical method for which assay performance is documented (8, 9). It is desirable to test 100 to 200 different samples from patients who have been selected to include a wide variety of pathologic conditions and to present a range of values for the analyte that includes those likely to be encountered in routine application. For a table of the required number of samples, see Linnet (10). If regression analysis is used for statistical evaluation of the data, authors must supply slopes and intercepts (and their standard deviations) and standard deviations of residuals ($S_{y|x}$, often called standard errors of estimates). Unbiased (e.g., Deming) regression is typically required (11). A program to perform Deming regression is available on-line as a supplement from this journal (12). The correlation coefficient has limited utility. Residuals plots [e.g., Bland–Altman (13)] are often useful. (d) Analyses of reference materials are (along with comparisons with a Reference Method) indicators of accuracy (trueness).

Analytical sensitivity and detection limit. These terms are commonly confused. The International Union of Pure and Applied Chemistry defines *analytical sensitivity* as the ability of an analytical procedure to produce a change in signal for a defined change of the quantity (e.g., the slope of the calibration curve). *Detection limit* (or limit of detection) is defined as the lowest concentration or quantity of an analyte that can be detected with a stated reasonable uncertainty for a given analytical procedure. The operational definition of this limit must be supplied by the author: e.g., the concentration at a signal-to-noise ratio of 10 or the concentration corresponding to a signal 3 SD above the mean for a calibrator that is free of analyte.

Analytical quality. Results obtained for the performance characteristics should be compared objectively with well-documented quality specifications, e.g., published data on the state of the art, performance required by regulatory bodies such as CLIA '88, or recommendations documented by expert professional groups (14).

Reference interval (normal range). Depending on the conclusions of the accuracy studies, modification of an accepted reference interval may be indicated. Description of the reference interval study should include details about sampling; selection of subjects, including their number, age, and sex distribution; the statistical method for summarizing the results (15); and other factors that would influence the values obtained.

Chromatograms. Chromatograms from gas–liquid and liquid chromatography should usually be presented so that readers can see the efficiency of the separation and observe the resolution from interferents in the matrix. Similar images are often needed for electrophoretic separations.

Enzyme activities. Enzyme activities may be expressed in international units (U) or katal. Temperature and other key assay features must be described in the text or by reference to a published method. When first mentioned in the text, enzymes (whether measured by activity or mass assays) must be numbered (EC no.) in accordance with the recommendations of the Nomenclature Committee of the International Union of Biochemistry and Molecular Biology on the Nomenclature and Classification of Enzymes (16).

Studies of Diagnostic Accuracy

For studies of diagnostic accuracy of tests, complete and return the STARD Checklist for Evaluations of Diagnostic Accuracy (17). The STARD statement (17) and explanatory document (18) provide guidance. Provide literature reference(s) describing the evaluated test(s) and criterion (“gold”) standard test(s) or include detailed descriptions of them. Follow accepted methodologic standards including the following: (a) Specify spectrum of evaluated patients (age and sex distributions, eligibility criteria, and summary of symptoms or disease stage). (b) Analyze pertinent subgroups of subjects (e.g., symptomatic and asymptomatic patients). (c) Avoid verification bias (usually by application of a “gold-standard” test to all subjects rather than to a clinically selected subset). (d) Categorize test results and patients independently to avoid reviewer bias (usually by performance of tests with blinding to patient information and vice versa). (e) Provide confidence intervals (or SE) for indices of diagnostic accuracy such as sensitivity/specificity, likelihood ratios, and areas under receiver-operating characteristic (ROC) curves (19). (f) Indicate the number of indeterminate test results and their use (if any) in further data analysis. (g) Provide laboratory data on analytical imprecision of the test (usually day-to-day CV at two or more concentrations) or reproducibility of observer interpretation [e.g., for a visually read, dichotomous (e.g., positive/negative) test]. See below for statistical treatment of data. A flow diagram is strongly recommended (17,18).

Statistics

Describe statistical methods with enough detail to enable a knowledgeable reader with access to the original data to verify the reported results. When possible, quantify findings and present them with appropriate indicators of measurement error or uncertainty. Avoid sole reliance on statistical hypothesis testing, such as the use of *P* values, which fails to convey important quantitative information. When appropriate, confidence intervals should be presented; see, e.g., Harris (20), Henderson (21), and references therein.

Evaluation of diagnostic accuracy. (See also “Studies of Diagnostic Accuracy” above). In clinical studies, simple testing of the significance of differences between mean values of patient groups (e.g., by Student’s *t*-test) provides insufficient information to assess diagnostic accuracy. Scatter plots of data, calculations of diagnostic sensitivities and specificities and their confidence intervals (19), and use of approaches such as ROC curves (22), cumulative distribution analyses (23), likelihood ratios (24), and discriminant analysis (25) provide information that is appropriate to specific situations. Confidence intervals should be provided (17). Discussions of predictive values in illustrative settings may be useful additions to assess the potential clinical utility of tests. Analysis of serial measurements requires special attention (26).

Outcomes Studies. The design and reporting of outcomes studies can be complex. The CONSORT statement (27), although designed for randomized controlled trials and used for therapeutic rather than diagnostic interventions, is recommended as an often-useful guide. For other guidance, contact the Editor.

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