

biochimica clinica

Biochimica Clinica publishes papers on all aspects of Clinical Chemistry and Molecular Diagnostics. Both Italian and English languages are accepted.

At the Author request or in the judgement of the Editor, papers are published in the following sections of the Journal:

- Reviews
- Scientific Papers
- Opinions
- Documents
- SIBioC Documents
- Case Reports
- Letters to the Editor

The following rules must be strictly observed, otherwise manuscripts cannot be submitted to the editorial process.

Papers to be published in sections other than Scientific Papers do not need division into the parts listed below. Papers submitted as Letters to the Editor do not require an Abstract.

PREPARATION OF MANUSCRIPTS

Experimental papers should include the following sections, in this order:

Title: should be concise but informative and it should not include abbreviations.

Author(s): name and surname (in full), correct affiliation.

Abstract (in English, not exceeding 250 words): should be preceded by the title in English if the paper is in Italian.

An abstract in Italian is not required.

Introduction: short description of the area under research with references to the relevant literature. It should also include the aim of the paper.

Materials and Methods: describe exhaustively population or clinical cases, reagents, diagnostics kits, calibrators, control materials, analytical instruments and systems, analytical methods, statistical methods. If commercially available analytical reagents and systems are used, just indicate the principle of the method and the commercial analytical system. When using statistical methods, please follow the indications reported at the end of these Instructions.

In case of studies with human subjects it is compulsory for the Author(s) to declare (to be included in the text) that the study has been carried out according to the Helsinki Declaration of 1975 as revised in 1996 (http://www.wma.net/e/humanrights/policy_meetings.htm). If biological samples have been specifically collected for the study, an Informed Consent from all subjects (patients) is needed and has to be documented in the paper.

Results: must be reported concisely, in a logical sequence reflecting the aim of the study, with precise reference to the included tables and figures. Measurements must always be accompanied by the proper units. The results can be reported in tables (if the focus is on the number's detail, or if they are observations/descriptions) or in figures/graphs (when a quick global evaluation is important, or when there is no other possibility). For the same group of data use either one or the other procedure, **not both**.

Tables: must be arranged in rows and columns; each column should have a clear heading including units of the measurement. Each table should be prepared on a page separated from the text: the related legend, preceded by the table number, must be reported at the top of the page. The legend should be concise but informative as in the following example: "*Table 1. Data of the different groups studied*". Tables must be numbered consecutively using Arabic numerals, starting from 1, according to the order in which they are mentioned in the text.

Figures: must be black and white, of such a graphic quality as to allow a direct reproduction, taking into account the inevitable reduction. Photos, even if sent in colour, will be reproduced in black and white; for this reason they should be of a very high resolution. In case of graphs of various kinds, a correct representation and a correct expansion of axes are necessary. A computerized composition is strongly recommended, using a suitable software. Figures must

be numbered consecutively using Arabic numerals, starting from 1, according to the order in which they are mentioned in the text. Each figure should be accompanied by a legend. All legends, preceded by the number of the related figure, must be reported on a different page, separated from the figures, and included at the end of the manuscript with the title "Legends of figures".

Discussion: the meaning of the results obtained should be discussed with regard to the aim of the paper, to the hypotheses reported in the literature, to the hypotheses issued in the paper, and to possible concordances or discordances to already published observations. Report hints of clinical and/or analytical interpretation of results. End with a short conclusion, mentioning if the aim of the paper has been achieved or not, and the possible practical significance of obtained results.

The paper should be written in a concise but not telegraphic style, language should be appropriate and clear (cf. Ceriotti G, Ceriotti F, Franzini C. How to write a scientific paper. *Biochim Clin* 2008;38:196-203). Avoid jargons. Non-native English speakers should have their manuscript proofread by a native speaker before submitting it.

Abbreviations must be reported in brackets, after the expression in full, when they first appear in the text (except those in standard usage and non-ambiguous, listed below in these Instructions).

Units must be correct and rational. Use the litre ("L") as the denominator uniformly, both in the text and in the iconography, for concentration units (mass, substance, activity, number). Figures should be reported with a consistent number of relevant digits, according to the variability of the measurements; the decimal digits should be separated by a comma (in text, tables and figures!) if the paper is in Italian and by a point if it is in English.

References: should be numbered consecutively in the order in which they appear in the text, starting from 1. The sequence number must appear in the text (in parentheses) where appropriate. References must be reported according to the following format, paying attention to the correct punctuation marks.

1. Soper CPR, Bending MR, Barron JL. An automated enzymatic insulin assay, capable of full sinistrin hydrolysis. *Eur J Clin Chem Clin Biochem* 1995;33:497-501.
2. Barrati J, Ettalbi M. Thermostable insulinases from *A. ficcum*. In: Fusch A, ed. *Insulin and insulin-containing crops*. London: Elsevier Science Publisher, 1993:211-6.
3. Constantin E, Schnell A, eds. *Mass spectrometry*. Chichester: Ellis Horwood Limited, 1991.

For each reference indicate the names of all the Author(s) in full. If Authors are more than three, report the first three followed by "et al."

ELECTRONIC SUBMISSION OF MANUSCRIPTS

Only manuscripts submitted electronically are considered. The submitted papers should be sent as e-mail attachments to the Editorial Office (see below).

For the text, use preferably MS Word or other compatible softwares. Use "Times New Roman" type, size 12. Number all pages consecutively from the title page (page 1); use A4 format sheets, line space should be 1.5 and the four side margins 2.5. Do not justify, avoiding headings (titles, subtitles) in formats different from the text.

Important: Keep a copy of all files sent.

LAYOUT

Text and Tables

Page 1. Report: a) Title; b) Author(s) in the chosen order, name followed by surname, each of them with first name in full; c) Affiliation(s), with a progressive number in apex as a reference to the Author(s) if they are present in more than one affiliation; d) name and complete address (including telephone, fax, e-mail) of the Author to whom the correspondence should be sent.

Page 2. Abstract in English.

Page 3 and following (all numbered consecutively). Report in this order: a) Introduction; b) Materials and Methods; c) Results; d) Discussion; e) Acknowledgements; f) References; g) Tables (one table per page, each with its own legend); h) Legends of the figures (all on one page), headed by the number of the figure in the format: "Figure 1. ..."

Figures

Set up diagrams (e.g. by MS Power Point) writing numbers, letters and symbols of experimental points (in Arial type) of a size to be readable after reduction. Send each figure in a single file, named by the figure number (figure 1, figure 2, etc.), without legend or title. In case of more than one graph being grouped in one figure, send more files as well, naming them figure 1a, figure 1b, etc. Send more complex figures (i.e. photos, chromatograms, etc.) in single files format, named with the figure number, suitable for electronic transmission (e.g. jpeg).

ACCOMPANYING LETTER

This must be submitted in electronic format; it should report the manuscript title, Author(s) and their affiliation. It must be signed by the corresponding Author, whose address must be clearly indicated, including telephone and fax numbers, and e-mail address. All the Authors and the Director of the Institution to which the Authors belong should declare that they agree with the submission of the paper and approve its content. The Author can also indicate in which section of the Journal they wish his/her manuscript to appear. Finally, a declaration for the Conflict of Interest should be submitted. The corresponding form is available on the journal website (www.bc.sibioc.it).

REVISION AND ACCEPTANCE

The Editor has the right to accept or not the submitted papers after consulting highly qualified external reviewers. Changes in style or in language both in text and in iconography may be made directly by the Editorial Office and approved by the Author(s) when proof-reading.

OFFPRINTS

The corresponding Author will receive a pdf file of his article, once it has been published. He/she will make copies for co-author(s). Usually, offprints are not sent; however they can be ordered at a price by the corresponding Author.

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e-mail: biochimica.clinica@sibioc.it

Redazione di Biochimica Clinica

Telephone 02 45498282 ext. 221; fax 02 45498199

ABBREVIATIONS

The abbreviations in this list should be used in this text without definition in full:

ADP	AIDS	AMP	ANOVA	ATP	cAMP	cGMP	CoA
CV	DEAE	DNA	DNase	EDTA	ELISA	EQA	F(ab') ₂
Fab	FAD	FADH ₂	Fc	HDL	HEPES	HIV	HLA
HPLC	IQC	IFCC	IgA	IgE	IgG	IgM	IRMA
LDL	MHC	MW	NADH	NADPH	NADP ⁺	NAD ⁺	oligo(dT)
pH	pI	poly(A)	pK	RIA	RNA	ROC	rpm
SIBioC	SE	SD	t $\frac{1}{2}$	Tris	U	UK	US
UV	VLDL	WHO					

STATISTICAL GUIDELINES

These guidelines are designed to help Authors to prepare statistical data for publication and are not a substitute for the detailed guidance required to design a study or perform a statistical analysis. Each section of a scientific paper is addressed separately.

Abstract: the number and source of data must be stated and conclusions which have a statistical basis must be substantiated by inclusion of pertinent descriptive statistics [mean or median, standard deviation (SD) or interquartile range, percentage coefficient of variation (%CV), 95% confidence limits, regression equations, etc.].

Methods: experimental design, subject selection and randomization procedures should be described and analytical accuracy quoted when appropriate. The hypothesis to be tested by a statistical procedure must be stated and where appropriate power calculations for the sample size used should be given (it is recommended that the power is >80%).

In case-control studies, clearly define how cases and controls were selected and what matching has taken place. Statistical tests should be described, but need not be referenced unless they are unusual or are applied in a non-standard way. Computer software used should be referenced.

If the paper is reporting the results of a diagnostic trial read the STARD statement (1) and for a clinical trial read the CONSORT statement (2) to improve the quality of the report.

Results: Rounded figures are easier to compare and extra decimal places are rarely important. Descriptive statistics require an additional digit to those used for the raw data. Percentages should not be expressed to more than one decimal place and not be used at all for small samples.

Normally distributed data should be described using a mean, SD and/or %CV and expressed as »mean (SD)« not »mean \pm SD«. When data are not normally distributed, following demonstration by tests such as the Shapiro-Wilk test (3), then medians and interquartile ranges should be used in place of mean and SD. Skewed data can often be normalized by logarithmic transformation or a power transformation. The statistical analysis and calculation of summary statistics should be carried out on the transformed data and the summary statistics transformed back to the original scale for presentation. If a logarithmic scale is used, then graphs should display non-transformed data on a logarithmic scale.

Graphs showing data of comparable magnitude should be of similar size and design. All individual points should be displayed where possible by displacing overlapping points. Error bars showing the standard error of the mean (SE) or interquartile range, as appropriate, can be used to aid the interpretation of data.

The results of significance tests, such as Student's and chi-squared, should be presented with descriptive statistics, degrees of freedom (if appropriate) and probability P. The validity of any assumptions should be checked (e.g. conventional t-tests assume a normal distribution and equal variance for each set of data). For 2×2 contingency table analysis by the chi-squared test the continuity correction must be applied, and for small expected frequencies Fisher's exact test used.

P values should be reported in full with 1 or 2 significant figures. Describing P values as >0.05 or NS (not significant) should be avoided. If the results are highly significant and the calculated P value from the computer is e.g. 0.000, then the use of $P < 0.0005$ is acceptable. Confidence intervals should be stated, particularly for non-significant results.

The conventional use of statistical significance is $P \leq 0.05$. If a different significance level needs to be used, then reasons for this must be clearly stated in the statistical method section.

Discussion: statistical significance should not be equated to clinical importance and P values should not be compared between different statistical tests. Association should not be interpreted as causation without additional evidence.

Problem areas: multiple comparisons can produce spurious and misleading significance values. The primary hypothesis should always be clearly stated and associations detected by retrospective analysis should be interpreted with caution. Whenever possible a single overall statistical test should be applied, e.g. ANOVA. If this is not significant, then multiple comparisons must not be applied. If it is significant then some form of multiple range test can be applied. If a single overall test is not possible, then multiple comparisons must use a Bonferroni type significance level.

With paired data differences between individual pairs of data and the variability of the differences are more important than the individual values. Graphical presentation should also show the difference between individual pairs, e.g. by plotted lines joining the paired data points.

Standard regression analysis requires data points to be independent (repeated measurements are not independent). The independent variable should be measured without significant error, e.g. age or time, and the points should be evenly distributed over the range and have no outliers (this can be easily examined with a scatter plot). These requirements are rarely satisfied with biological data.

Method comparison using regression and correlation coefficients is not enough and should be associated to Altman and Bland difference plots (4).

References

1. Bossuyt PM, Reitsma JB, Bruns DE, et al., for the STARD Group. Towards complete and accurate reporting of studies of diagnostic accuracy: the STARD initiative. *Ann Clin Biochem* 2003;40:357-63.
2. Moher D, Schultz KF, Altman DG, for the CONSORT Group. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. *Lancet* 2001;357:1191-4.
3. Altman DG. *Practical statistics for medical research*. London: Chapman & Hall, 1991.
4. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet* 1986;8476:307-10.