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
- Research Articles
- Opinions
- Documents
- SIBioC Documents
- Case Reports
- Letters to the Editor

General format and length of the different types of articles

	Abstract/words	Word count	Tables & Figures	N. of references
Reviews	YES/250	6000	8	150
Scientific papers	YES/250	3500	8	50
Opinions	YES/250	3500	5	50
Documents	YES/250	NA	NA	NA
SIBioC Documents	YES/250	NA	NA	NA
Lettes to the Editor	NO	1200	2	12
Case reports	YES/250	1500	2	10

The figures in the table should be considered as maximum values; NA, not applicable.

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

PREPARATION OF MANUSCRIPTS

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

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

Abstract: not exceeding 250 words.

Key words: indicate three key words, using preferably MeSH terms.

Research Articles should be structured into:

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

Methods: describe exhaustively population or clinical cases, reagents, diagnostics kits, calibrators, control materials, analytical instruments and systems, analytical methods, statistical methods. If analytical reagents and systems commercially available are used, just indicate the principle of the method and the 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 1964 as revised 2013 (https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects). 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 figure'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 measurement units. 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 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, 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 they are mentioned in the text. Each figure should be accompanied by a caption. All captions, 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 the obtained results.

Text: the paper should be written in a concise but not telegraphic style, language should be appropriate and clear (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 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. Geraud G, Spierings EL, Keywood C. Tolerability and safety of frovatriptan with short- and long-term use for treatment of migraine and in comparison with sumatriptan. Headache 2002;42 Suppl 2:S93-9.
3. 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.
4. 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."

ISO Documents: ISO14971.2012 Medical devices: applicationof risk management to medical devices. International Organization for Standardization: Geneva 2012.
CLSI Documents: Clinical Laboratory Standards Institute (CLSI). Procedures for collection of diagnostic blood specimens by venipuncture; approved guideline, 6th ed. CLSI document H3-A6. CLSI Wayne, PA, 2007.

Web site citations should include the date (month/year) of the last visit: http://www.nhlbi.nih.gov/guidelines/cholesterol /index.htm (accessed: December 2012)

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 software. 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 more than one affiliation is present; d) name and complete address (including telephone, 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. …"*
Only Research Articles requireto be organized in Introduction, Methods, Results, Discussion.

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 indicate in which section of the Journal they wish his/her manuscript to appear. The Author can also indicate one or more possible reviewers. 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 subsequently approved by the Author(s).

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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ABBREVIATIONS

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

ADP	AIDS	AMP	ANOVA	ATP	cAMP	cDNA	cGMP
CoA	CV	DEAE	DNA	DNase	EDTA	EFLM	ELISA
EQA	F(ab')2	Fab	FAD	FADH2	Fc	HDL	HEPES
HIV	HLA	HPLC	IQC	IFCC	IgA	IgE	IgG
IgM	IRMA	LDL	MHC	miRNA	mRNA	MW	NADH
NADPH	NADP+	NAD+	oligo(dT)	pH	pI	poly(A)	pK
RIA	RNA	ROC	rpm	SIBioC	SE	SD	t½
Tris	U	UK	US	UV	VLDL	WHO	

STATISTICAL GUIDELINES

These guidelines are designed to help Authors to prepare statistical data for publication in Biochimica Clinica and are not a substitute for the detailed guidance required to design a study or perform a statistical analysis. Please refer to specific guidelines for describing results of specific study designs (e.g. observational studies, randomized clinical trials), available at the EQUATOR Network website (1).
Each section of a scientific paper is addressed separately.

Abstract: sample size and main results of the study (estimated parameters, group comparisons, associations) must be reported by relevant descriptive statistics, mean or median, standard deviation (SD) or interquartile range, confidence interval (CI95%) and p value. Moreover, it is also advisable to report the raw (unstandardized) or standardized effect size (2).

Methods: the main guiding principle for statistical reporting should be to describe statistical methods with enough detail to enable a knowledgeable reader with access to the original data to verify the reported results. Authors should describe the experimental design, primary and secondary (surrogate and/or intermediate) endpoints, subject selection (inclusion and exclusion criteria), randomization and blinding procedures (1). Sample size should be reported with data needed for its calculation (alpha, power, effect). Methods used for dealing with missing, censored (e.g. results lower than limit of sensitivity) or aberrant data should be described with the total amount (or percentage) of the results affected. Statistical tests and methods used to verify assumptions (e.g. homoscedasticity, or homogeneity of variance, and normality) should be reported. If data were transformed to normalize the distribution, describe the mathematical transformation (log, power) applied with graphical and statistical methods used to verify the Gaussian model before and after transformation. References for statistical methods, unless unusual, are not required. However, it is mandatory to report the statistical software used (name, version, Company's data).

Results: if not described in previous sections, report total sample and group sizes and the number of subjects for each phase of the study design (subjects assessed for eligibility, excluded, randomized, allocated to treatments, lost to follow-up) (1). Relative frequencies, percentages or any other calculated ratio should be reported together with numerators and denominators. Relative frequencies should be reported with two significant figures (e.g. 0.37; 0.026); percentages should not be expressed with more than one decimal place and should be avoided when dealing with small samples (N<10). If observations have been organized into classes, lower and upper class limits should be unambiguously stated. Descriptive statistics require an additional digit than those used for the raw data. Normally distributed data should be described by mean, SD and/or %CV and expressed as "mean (SD)" and not as "mean±SD". When data are not normally distributed, or show a skewed distribution, median and interquartile range (25° - 75° percentiles) should be used instead of mean and SD. If a mathematical transformation has been applied, summary statistics should be carried out on the transformed data and then transformed back to the original scale for presentation (mean and interval limits, but not standard deviation, can be back transformed). Bar graphs can be used

only to describe counts, relative frequencies or percentages but not means or other summary statistics. With continuous variables, best choices are histograms, Box and Whisker plot or dotplot (the latter with small sample size, N<20). Do not use 3D graphs.
When comparing two groups with the Student's t-test, authors should report mean and SD for each group, difference between means with the 95% confidence interval, degrees of freedom, the t-value and the p value. A measure of effect size, such as Cohen's d, may be further specified (2).
When dealing with more than two groups authors should use the ANOVA test, reporting mean and SD for each group, degrees of freedom, the F-value and the overall p value. If this is not statistically significant, then multiple comparisons must not be applied. If it is significant, multiple-comparison post-hoc correction should be applied (e.g. Bonferroni's correction or Tukey).
When reporting association between variables (e.g. by chi-squared test, Fisher's exact test), authors should clearly indicate variables, a correct summary statistic, degrees of freedom, the test value and the p value. When the chi-square assumptions are violated, the Fisher's exact test should be preferred. Reporting an additional measure of size effect (e.g. phi or Cramer's V) is advisable (2).
For correlation analysis, specify the type of correlation used (Pearson or Spearman), the correlation coefficient with its 95% confidence interval and the t-test (degrees of freedom, t-value and p value). Do not use correlation analysis for analytical method comparison. In these cases, regression analysis (Deming or non-parametric Passing-Bablok) and the Bland-Altman plot should be preferred (3-4).
For linear regression, authors should report ANOVA table results (degrees of freedom, F-value and p value), the equation parameters (slope and intercept) with their 95% confidence intervals and the coefficient of determination R^2.
With more complex statistical models (multiple regression, ANOVA models) it is necessary to report the verification of assumptions, the overall p value of the model and model parameters arranged in tabular form (including parameter estimates, confidence intervals, p values). Reporting an additional measure of size effect (e.g. omega-squared) may be useful (2).
Paired data should be analyzed with specific tests. When using non-parametric tests, authors should evaluate variable distribution by graphical methods or formal statistical tests.
P values must be reported with 1 or 2 significant figures. Describing p values as p<0.05 or p>0.05 or NS (not significant) should be avoided. If the results are highly significant and the calculated p value is reported by the software as 0.000, then the use of p<0.0005 or p<0.001 is acceptable. Confidence intervals should be stated also for non-significant results. If one of the limits of the confidence interval is negative, report it as "X to Y". The conventional use of statistical significance is p<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; similarly, non-statistical significance should not be interpreted as no difference or no effect. Indeed, the lack of statistical significance may be due to small sample size and hence to a low statistical power. Moreover, p values should not be compared among different statistical tests. Association between variables should not be interpreted as causation without additional evidence.

Further readings: the SAMPL Guidelines (5).

References

1. EQUATOR Network: https://www.equator-network.org/ (last access: January 2021).
2. Ialongo C. Understanding the effect size and its measures. Biochemia Medica 2016;26:150–63.
3. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet 1986;8476:307-10.
4. Vidali M, Tronchin M, Dittadi R, per il Gruppo di Studio SIBioC - Medicina di Laboratorio "Statistica per il laboratorio. Protocollo per la comparazione di due metodi analitici di laboratorio. Biochim Clin 2016;40:129-42.
5. Lang TA, Altman DG. Basic statistical reporting for articles published in biomedical journals: the "Statistical Analyses and Methods in the Published Literature" or the SAMPL Guidelines. Int J Nurs Stud 2015;52:5-9.

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