

CLSI Guidelines for References

Purpose of references

When statements of fact are presented in CLSI documents, the original source of the fact needs to be provided in a reference citation. References tell readers where to access more information regarding the subject, and they give credit to the original authors.

When are references needed?

The necessity and appropriate use of references can be a bit vague. In general, a statement of fact requires a citation to support the statement (examples might be a statistical test or a limitation in a proficiency testing material). A statement of committee recommendation for a best practice (ie, an informed opinion) does not need a reference. The areas in between “fact” and “informed opinion” are more challenging. A body of evidence that supports a best practice statement should have references to support the evidence on which a statement is based.

Number of references

CLSI aims to limit the number of references used in its documents (ie, 200 or fewer). Too many references can be burdensome for the committee and the CLSI staff to verify and for readers to evaluate or review. Often, review articles or newer publications will themselves refer to older publications that the readers can then look up if they choose. It is not necessary to include all the references that may be suitable to support a fact; rather, a single suitable reference for the fact is sufficient. CLSI encourages all committees to use as few references as possible while still including adequate references to provide proper citations to factual statements.

Types of references

CLSI encourages reference to information that is fully explained and disclosed. These references typically are from peer-reviewed journals, textbooks, public laws or regulations, and published standards and guidelines. Information from websites may be included when the website is that of a well-recognized, credible organization; however, information from blogs or other opinion sources should be avoided. CLSI does not permit the inclusion of information that is solely available in abstracts (or posters or other types of presentations) or by personal communication.

Reference formats

CLSI uses the *AMA Manual of Style* for reference citation formatting. Citation information for journal articles can be found at <https://pubmed.ncbi.nlm.nih.gov/>. Here are some examples of correct references:

1. Single-author journal article:

Dubin SB. Assessment ~~of fetal lung maturity~~: practice parameter. *Am J Clin Pathol.* 1998;110(6):723-732.

NOTE: When the title of a journal article contains two sentences or fragments (ie, two lines of text that contain a period on the end of each), CLSI style deletes the first period, replaces it with a colon, and lowercases the first word of the second sentence or fragment, as in the above example.

2. Multiple-author journal article:

Wijnberger LD, Huisjes AJ, Voorbij HA, Franx A, Bruinse HW, Mol BW. The accuracy of lamellar body count and lecithin/sphingomyelin ratio in the prediction of neonatal respiratory distress syndrome: a meta-analysis. *BJOG*. 2001;108(6):583-588.

NOTE: If more than six authors are listed, CLSI style lists the first three authors, followed by “et al.”

3. Chapter within a text:

Dubin SB. Fetal lung maturity assessment by determination of the lamellar body number density. In: Weinstein RS, ed. *Advances in Pathology and Laboratory Medicine*. Mosby; 1994:495-514.

NOTE: CLSI staff does not always have access to specific chapter titles, authors, and pagination, particularly for older books. Including this information up front provides valuable search criteria that CLSI staff can use to verify the citation.

4. Another standard or guideline:

CLSI. *Evaluation of Linearity of Quantitative Measurement Procedures*. 2nd ed. CLSI guideline EP06. Clinical and Laboratory Standards Institute; 2020.

ISO. *In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus*. ISO 15197. International Organization for Standardization; 2013.

5. Website:

US Food and Drug Administration. Critical path initiative. Accessed 22 February 2021.
<http://www.fda.gov/science-research/science-and-research-special-topics/critical-path-initiative>

Responsibilities of the Document Development Committee

The document development committee (DDC) members are responsible for ensuring the accuracy of all references. For revisions, it is necessary to determine whether newer references can replace older ones. The DDC members should read and verify each article or document referenced. The reference must contain the specific information and must be the original source of the information. Be sure that all the references are in the right order and that no reference is included twice.

References

Annesley TM. Giving credit: citations and references. *Clin Chem*. 2011;52(1):14-17.

Christiansen S, Iverson C, Flanagan A, et al. *AMA Manual of Style: A Guide for Authors and Editors*. 11th ed. Oxford University Press; 2020.

