

Template¹ for summarising studies addressing diagnostic questions

Instructions to fill the table:

- When no element can be added under one or more heading, include the mention:
 - “Not applicable” when an item is not to be informed (according to the type of study);
 - “Not described” when an item must be informed but no information is given in the publication.
- Describe all the results given in the manuscript even if those are not relevant to the study aim.
- Refer to the addendum for added results calculated or reconstructed by the reviewer.

Name of Person completing template:

Date of completion:

HEADINGS	DESCRIPTION
Bibliographic citation	Use Vancouver style (Authors ² . Title. Journal name. Publication Date; Volume (Issue):Page Numbers) Insert the link to the publication.
Sources of funding and competing interest	Report: <ul style="list-style-type: none"> ➤ The source of funding cited in the paper: Write “Stated” or “Not Stated” and specify if any give name(s) of organisation or corporation. Specify if possible the source type (public research funds, NGO, government, Academic/university healthcare industry or other) ➤ Competing interests: Write “Stated” or “Not Stated” and specify if any
Setting	Multicenter, Country(ies), Healthcare setting,
Objective(s) of the study	Report, as cited by author(s), the objective(s) of the study including both primary and secondary aims, if applicable.
Questions addressed	Mention the <u>questions really addressed</u> ³ (e.g. include all questions even if only one is relevant for you at the moment, do not report questions planned to be addressed but on which no results are included) in the study including the following elements: <ul style="list-style-type: none"> ➤ Accuracy (comparison with a reference standard test) ➤ Reproducibility ➤ Cut-off determination ➤ Comparison of two or more tests
METHODS	

¹ Minimum data abstracted from a single study to allow consistent comparison across studies and to inform a group process in evidence synthesis.

² Limit to the first 6 authors and then add *et al.* If there is a society, it counts as an author.

³ Report all questions really addressed in the study, even if not expected in the aim.

HEADINGS	DESCRIPTION
Study design (cited by author or actual)	Specify the study design: Prospective study, randomized study, cross sectional study, retrospective study, cohort study, case control study, other. Precise if it's the design cited by author(s).
Reference standard test	Describe the reference standard test: <ul style="list-style-type: none"> ➤ What (including the provider's name if applicable), by whom and how, when ➤ Cut-offs, categories of results ➤ Blinding (investigator) to clinical information and/or to index test results, if applicable
Diagnostic test(s) evaluated	Describe the reference standard test: <ul style="list-style-type: none"> ➤ What (including the provider's name if applicable), by whom and how, when ➤ Cut-offs, categories of results ➤ Blinding (investigator) to clinical information and/or to index test results, if applicable
Time interval and treatment(s) administered between the tests	Specify if any
Investigator(s) and assessor(s) training	Report the number, training and expertise of the people executing (investigators) and reading the evaluated test(s) and the reference standard test(s) (assessors)
Study population expected	Describe the: <ul style="list-style-type: none"> ➤ Aimed eligibility criteria (i.e. inclusion-exclusion criteria, stage/characteristics of the disease) ➤ Prevalence estimation of the disease in the general population ➤ Previous test(s) and/or treatment(s) undertaken
RESULTS	
Numbers	Report: <ul style="list-style-type: none"> ➤ Number of patients needed, involved and analysed ➤ Number of patients excluded and reasons (i.e. non-interpretable test(s) results, incomplete or missing data)
Patients and disease characteristics	Describe the actual population involved in the study: <ul style="list-style-type: none"> ➤ Patients: gender, age, risk factors,... ➤ Disease characteristics ➤ Include the prevalence estimation of the disease in the study population
Accuracy	Give <u>all available figures</u> (including sub-group figures) with 95% confidence intervals when available: <ul style="list-style-type: none"> ➤ Sensitivity (Se) ➤ Specificity (Sp) ➤ Positive Predictive Value (PPV) ➤ Negative Predictive Value (NPV) ➤ Likelihood ratios (LR⁺, LR⁻) ➤ Area under the ROC curve

HEADINGS	DESCRIPTION
Reproducibility	Give <u>all available figures</u> with 95% confidence intervals when available: <ul style="list-style-type: none"> ➤ Quantitative test: <ul style="list-style-type: none"> ○ Number of repetitions of the evaluated test ○ Extent of values tested ○ Bland & Altman agreement method ○ Intraclass correlation coefficient ➤ Qualitative test: <ul style="list-style-type: none"> ○ Inter-rater reliability ○ Test-retest reliability ○ Correlation coefficient
Cut-Off determination	Threshold tested, if any. Precise Se and Sp values corresponding to the cut-off selected
Comparison of two or more tests	<ul style="list-style-type: none"> ➤ Quantitative test: report the area under the ROC curve ➤ Qualitative test: report percentage comparison: IC, p values
Adverse effects	Describe adverse effects as reported in the paper, if any: from performing tests, related to participants to the tests or related to the results of the tests.
CRITICAL APPRAISAL OF THE STUDY QUALITY	
Authors conclusion	Report the authors' conclusion
Results validity	Discuss the validity of the results and potential bias present: <ul style="list-style-type: none"> ➤ Internal validity: study design, sample size, blinding, appropriateness of the reference standard test as a gold standard, limitations of the reference standard test (i.e. incomplete reference standard test), interpretation of the results (taking into account the study hypotheses), comment on patients lost to follow-up (if applicable), use of inappropriate statistical analysis, etc. ➤ External validity: setting, population involved, test used, etc. General comments, including own conclusion of the reviewer, if possible.
Other /Addendum Optional	Further comments made by the reviewer

The evidence table working group would appreciate to hear about any comments, questions, you may have on this template. Please send your feedback to the G-I-N Office: office@g-i-n.net

Special thanks for the development of this template are addressed to:

- Najoua Mlika-Cabanne (HAS, FR), Joint speaker
- Hans de Beer (CBO, NL)
- Rob Cook (Bazian, UK)
- Michel Laurence (HAS, FR)
- Robin Harbour (SIGN, UK)