

## STARD checklist for the reporting of studies of diagnostic accuracy

| Manuscript number and/or corresponding author name: |        |   |           |
|---|--------|---|-----------|
| Section and Topic                                   | Item # |   | On page # |
| TITLE/ABSTRACT/<br>KEYWORDS                         | 1      | Identify the article as a study of diagnostic accuracy (recommend MeSH heading 'sensitivity and specificity').  |           |
| INTRODUCTION  | 2      | State the research questions or study aims, such as estimating diagnostic accuracy or comparing accuracy between tests or across participant groups.  |           |
| METHODS   |        | Describe  |           |
| <i>Participants</i>                                 | 3      | The study population: The inclusion and exclusion criteria, setting and locations where the data were collected.  |           |
|   | 4      | Participant recruitment: Was recruitment based on presenting symptoms, results from previous tests, or the fact that the participants had received the index tests or the reference standard?   |           |
|   | 5      | Participant sampling: Was the study population a consecutive series of participants defined by the selection criteria in item 3 and 4? If not, specify how participants were further selected.  |           |
|   | 6      | Data collection: Was data collection planned before the index test and reference standard were performed (prospective study) or after (retrospective study)?  |           |
| <i>Test methods</i>                                 | 7      | The reference standard and its rationale.   |           |
|   | 8      | Technical specifications of material and methods involved including how and when measurements were taken, and/or cite references for index tests and reference standard.  |           |
|   | 9      | Definition of and rationale for the units, cutoffs and/or categories of the results of the index tests and the reference standard.  |           |
|   | 10     | The number, training and expertise of the persons executing and reading the index tests and the reference standard.   |           |
|   | 11     | Whether or not the readers of the index tests and reference standard were blind (masked) to the results of the other test and describe any other clinical information available to the readers.   |           |
| <i>Statistical methods</i>                          | 12     | Methods for calculating or comparing measures of diagnostic accuracy, and the statistical methods used to quantify uncertainty (e.g. 95% confidence intervals).   |           |
|   | 13     | Methods for calculating test reproducibility, if done.  |           |
| RESULTS   |        | Report  |           |
| <i>Participants</i>                                 | 14     | When study was done, including beginning and ending dates of recruitment.   |           |
|   | 15     | Clinical and demographic characteristics of the study population (e.g. age, sex, spectrum of presenting symptoms, comorbidity, current treatments, recruitment centers).  |           |
|   | 16     | The number of participants satisfying the criteria for inclusion that did or did not undergo the index tests and/or the reference standard; describe why participants failed to receive either test (a flow diagram is strongly recommended).       |           |
| <i>Test results</i>                                 | 17     | Time interval from the index tests to the reference standard, and any treatment administered between.   |           |
|   | 18     | Distribution of severity of disease (define criteria) in those with the target condition; other diagnoses in participants without the target condition.   |           |
|   | 19     | A cross tabulation of the results of the index tests (including indeterminate and missing results) by the results of the reference standard; for continuous results, the distribution of the test results by the results of the reference standard. |           |
|   | 20     | Any adverse events from performing the index tests or the reference standard.   |           |
| <i>Estimates</i>                                    | 21     | Estimates of diagnostic accuracy and measures of statistical uncertainty (e.g. 95% confidence intervals).   |           |
|   | 22     | How indeterminate results, missing responses and outliers of the index tests were handled.  |           |
|   | 23     | Estimates of variability of diagnostic accuracy between subgroups of participants, readers or centers, if done.   |           |
|   | 24     | Estimates of test reproducibility, typically imprecision (as CV) at 2 or 3 concentrations.  |           |
| DISCUSSION  | 25     | Discuss the clinical applicability of the study findings.   |           |