

## STARD 2015

| Section & Topic          | Item No | Item   | Reported on Page Number/ Line Number | Reported on Section/ Paragraph |
|--------------------------|---------|--|--------------------------------------|--------------------------------|
| <b>TITLE OR ABSTRACT</b> |         |  |                                      |                                |
|                          | 1       | Identification as a study of diagnostic accuracy using at least one measure of accuracy (such as sensitivity, specificity, predictive values, or AUC)  | pg.2, line 75<br>pg. 3, lines 89-90  | Abstract                       |
| <b>ABSTRACT</b>          |         |  |                                      |                                |
|                          | 2       | Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts)                                 | page 2, line 71                      | abstract, results              |
| <b>INTRODUCTION</b>      |         |  |                                      |                                |
|                          | 3       | Scientific and clinical background, including the intended use and clinical role of the index test   | pgs 5-7, lines 100-156               | introduction                   |
|                          | 4       | Study objectives and hypotheses  | page 7, lines 150-156.               | introduction                   |
| <b>METHODS</b>           |         |  |                                      |                                |
| Study design             | 5       | Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)     | page 7, line 119                     | methods                        |
| Participants             | 6       | Eligibility criteria   | pgs 7-8, Lines 165-172.              | methods                        |
|                          | 7       | On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)                 | page 7 167-172.                      | methods                        |
|                          | 8       | Where and when potentially eligible participants were identified (setting, location and dates)   | page 7, lines 168-172                | methods                        |
|                          | 9       | Whether participants formed a consecutive, random or convenience series  | pages 7, lines 168-172               | methods                        |
| Test methods             | 10a     | Index test, in sufficient detail to allow replication  | lines 193-197, pg 9                  | methods                        |
|                          | 10b     | Reference standard, in sufficient detail to allow replication  | lines 193-197, pg 9                  | methods                        |
|                          | 11      | Rationale for choosing the reference standard (if alternatives exist)  | lines 108-112, pg 5                  | introduction                   |
|                          | 12a     | Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing pre-specified from exploratory         | lines 200-202, pg 9                  | methods                        |
|                          | 12b     | Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory | lines 200-202, pg 9                  | methods                        |
|                          | 13a     | Whether clinical information and reference standard results were available to the performers/readers of the index test                                 | line 202, pg 9                       | methods                        |
|                          | 13b     | Whether clinical information and index test results were available to the assessors of the reference standard  | line 202, pg 9                       | methods                        |

|                          |     |   |                        |                       |
|--------------------------|-----|---|------------------------|-----------------------|
| Analysis                 | 14  | Methods for estimating or comparing measures of diagnostic accuracy   | lines 218-232, page 10 | methods               |
|                          | 15  | How indeterminate index test or reference standard results were handled                                     | lines 222-235, pg 10   | methods               |
|                          | 16  | How missing data on the index test and reference standard were handled                                      | lines 222-235, pg 10   | methods               |
|                          | 17  | Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory           | lines 199-204, pg 9    | methods               |
|                          | 18  | Intended sample size and how it was determined  | lines 186-191, pg 8    | methods               |
| <b>RESULTS</b>           |     |   |                        |                       |
| Participants             | 19  | Flow of participants, using a diagram   | n/a                    | n/a                   |
|                          | 20  | Baseline demographic and clinical characteristics of participants   | lines 235-40, page 11  | results               |
|                          | 21a | Distribution of severity of disease in those with the target condition                                      | lines 238-268, pg 11-2 | results               |
|                          | 21b | Distribution of alternative diagnoses in those without the target condition                                 | lines 238-43, page 11  | results               |
|                          | 22  | Time interval and any clinical interventions between index test and reference standard                      | n/a                    | n/a                   |
| Test results             | 23  | Cross tabulation of the index test results (or their distribution) by the results of the reference standard | appendix               | appendix              |
|                          | 24  | Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)                     | pg 27, line 538        | Tables 5 and 6        |
|                          | 25  | Any adverse events from performing the index test or the reference standard                                 | n/a                    | n/a                   |
| <b>DISCUSSION</b>        |     |   |                        |                       |
|                          | 26  | Study limitations, including sources of potential bias, statistical uncertainty, and generalisability       | lines 319-38, pp 14-15 | discussion            |
|                          | 27  | Implications for practice, including the intended use and clinical role of the index test                   | lines 363-74, pp 16-17 | discussion/conclusion |
| <b>OTHER INFORMATION</b> |     |   |                        |                       |
|                          | 28  | Registration number and name of registry  | n/a                    | n/a                   |
|                          | 29  | Where the full study protocol can be accessed   | n/a                    | n/a                   |
|                          | 30  | Sources of funding and other support; role of funders   | n/a                    | n/a                   |

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\*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copyediting and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.