

Item No	Item	Reported on Page Number/ Line Number	Re Se Pa
ABSTRACT			
	Identification as a study of diagnostic accuracy using at least one measure of accuracy (such as sensitivity, specificity, predictive values, or AUC)	Page2 Line24-27	Abstr
	Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts)	Page1-2 Line5-30	Abstr
	Scientific and clinical background, including the intended use and clinical role of the index test	Page2-3 Line42-75	Intro
	Study objectives and hypotheses	Page 4-5 Line 84-87	Intro
	Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)	Page 5 Line 105-16	Mate
	Eligibility criteria	Page 6 Line106-111	Mate
	On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)	Page 6 Line106-111	Mate
	Where and when potentially eligible participants were identified (setting, location and dates)	Page5 Line105-106	Mate
	Whether participants formed a consecutive, random or convenience series	Page5 Line105-16	Mate
0a	Index test, insufficient detail to allow replication	Page 7 Line 132-135	Mate Anal
0b	Reference standard, insufficient detail to allow replication	Page 7-8 Line 147-155	Mate Path
1	Rationale for choosing the reference standard (if alternatives exist)	None	No a
2a	Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing pre-specified from exploratory	Page 8 Line 167-169	Mate Statist
2b	Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory	Page 7 Line 147-148	Mate Path
3a	Whether clinical information and reference standard results were available to the performers/readers of the index test	Page 7 Line 135-139	Mate Anal

4	Methods for estimating or comparing measures of diagnostic accuracy	Page 8 Line 163-167	Mat Statis
5	How indeterminate index test or reference standard results were handled	Page 8 Line 163-167	Mat Statis
6	How missing data on the index test and reference standard were handled	None	No m
7	Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory	Page 8 Line 163-167	Mat Statis
8	Intended sample size and how it was determined	Page 5-6 Line 103-110	Mat

9	Flow of participants, using a diagram	Figure 1	Figur
10	Baseline demographic and clinical characteristics of participants	Page 28	Table
11a	Distribution of severity of disease in those with the target condition	Page 9 Line 189-192 Page 28 Table 3	Resu Patie
11b	Distribution of alternative diagnoses in those without the target condition	None	None
12	Time interval and any clinical interventions between index test and reference standard	Figure 1	Figur
13	Cross tabulation of the index test results (or their distribution) by the results of the reference standard	None	None
14	Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)	Page 11 Line 220-226	Resu and p
15	Any adverse events from performing the index test or the reference standard	None	None

16	Study limitations, including sources of potential bias, statistical uncertainty, and generalisability	Page 14 Line 293-302	Disc
17	Implications for practice, including the intended use and clinical role of the index test	Page 12-13 Line 259-262	Disc

INFORMATION

18	Registration number and name of registry	None	None
19	Where the full study protocol can be accessed	None	None
20	Sources of funding and other support; role of funders	Page 16 Line 322-325	Ackn

“Standards for Reporting Diagnostic accuracy studies”. This list of items was developed to contribute to the completeness and transparency of reporting of diagnostic accuracy studies. The list is intended to help authors write informative study reports. Editors and peer-reviewers can use it to evaluate whether the information has been included in manuscripts submitted for publication.

Diagnostic accuracy study evaluates the ability of one or more medical tests to correctly classify study participants as having a **target condition**. This can be a disease, a disease severity, or an event or condition in the future. A medical test can be an imaging procedure, a laboratory test, elements from history and physical examination, a combination of tests, or a combination of these. The test involves collecting information about the current health status of a patient.

Diagnostic accuracy is evaluated by comparing the results of the test to those of a **reference standard**. A study can evaluate the accuracy of one or more index tests. Evaluating the ability of a medical test to correctly classify patients is done by comparing the distribution of the index test results with those of the **reference standard**. The reference standard is the best available method for establishing the presence or absence of the target condition. A study can rely on one or more reference standards.

When a test result is categorized as either positive or negative, the cross tabulation of the index test results against those of the reference standard can be used to estimate the **sensitivity** (the proportion of participants with the target condition who have a positive index test), and its **specificity** (the proportion without the target condition who have a negative index test). From this cross tabulation (referred to as the contingency or “2x2” table), several other accuracy statistics can be estimated, such as the positive and negative **predictive values** of the test. Confidence intervals for these values can then be calculated to quantify the statistical **precision** of the measurements.

When a test result can take more than two values, categorization of test results as positive or negative requires a **test positivity cut-off**. When multiple such cut-offs can be defined, the receiver operating characteristic (ROC) curve which graphically represents the combination of sensitivity and specificity for each possible test positivity cut-off. The **area under the ROC curve** is a summary value about the overall diagnostic accuracy of the index test.

The **clinical role** of a medical test can be diagnosis, screening, staging, monitoring, surveillance, prediction or prognosis. The **clinical role** of a test explains its position relative to existing tests. A replacement test, for example, replaces an existing test. A triage test is used before an existing test; an add-on test is used after an existing test.

In addition to diagnostic accuracy, several other outcomes and statistics may be relevant in the evaluation of medical tests. Medical tests can also be used to classify patients for purposes other than diagnosis, such as prognosis. The STARD list was not explicitly developed for these other outcomes, statistics, and study types, although most STARD items would still apply.

INTRODUCTION

The STARD list was released in 2015. The 30 items were identified by an international expert group of methodologists, researchers, and editors. The guiding principle in the development of the list was that, when reported, would help readers to judge the potential for bias in the study, to appraise the applicability of the study findings and the validity of conclusions and recommendations. This is an update of the first version, which was published in 2003. More information can be found on <http://www.equator-network.org/reporting-guidelines/stard>.

For more information: <https://dx.doi.org/10.21037/qims-23-942>

The STARD list was provided upon initial submission, the page number/line number reported may be changed due to copyediting and formatting. In the published version. In this case, the section/paragraph may be used as an alternative reference.