NOTE: Please save this file locally before filling in the table, DO NOT work on the file within your internet browser as changes will not be saved. Adobe Acrobat Reader (available free here) is recommended for completion.

The ARRIVE guidelines 2.0: author checklist

The ARRIVE Essential 10

These items are the basic minimum to include in a manuscript. Without this information, readers and reviewers cannot assess the reliability of the findings.

Item		Recommendation	Section/ line number, or reason for not reporting
Study design	1	For each experiment, provide brief details of study design including: a. The groups being compared, including control groups. If no control group has been used, the rationale should be stated. b. The experimental unit (e.g. a single animal, litter, or cage of animals).	Materials and Methods/lines 123-135
Sample size	2	a. Specify the exact number of experimental units allocated to each group, and the total number in each experiment. Also indicate the total number of animals used. b. Explain how the sample size was decided. Provide details of any *a priori* sample size calculation, if done.	Materials and Methods/lines 123-135
Inclusion and exclusion criteria	3	a. Describe any criteria used for including and excluding animals (or experimental units) during the experiment, and data points during the analysis. Specify if these criteria were established *a priori.* If no criteria were set, state this explicitly. b. For each experimental group, report any animals, experimental units or data points not included in the analysis and explain why. If there were no exclusions, state so. c. For each analysis, report the exact value of *n* in each experimental group.	Materials and Methods/lines 136-139
Randomisation	4	a. State whether randomisation was used to allocate experimental units to control and treatment groups. If done, provide the method used to generate the randomisation sequence. b. Describe the strategy used to minimise potential confounders such as the order of treatments and measurements, or animal/cage location. If confounders were not controlled, state this explicitly.	This study was a self controlled study
Blinding	5	Describe who was aware of the group allocation at the different stages of the experiment (during the allocation, the conduct of the experiment, the outcome assessment, and the data analysis).	This study was a self controlled study
Outcome measures	6	a. Clearly define all outcome measures assessed (e.g. cell death, molecular markers, or behavioural changes). b. For hypothesis-testing studies, specify the primary outcome measure, i.e. the outcome measure that was used to determine the sample size.	Materials and Methods/lines 171-179, Materials and Methods/lines 196-201
Statistical methods	7	a. Provide details of the statistical methods used for each analysis, including software used. b. Describe any methods used to assess whether the data met the assumptions of the statistical approach, and what was done if the assumptions were not met.	Materials and Methods/lines 206-207
Experimental animals	8	a. Provide species-appropriate details of the animals used, including species, strain and substrain, sex, age or developmental stage, and, if relevant, weight. b. Provide further relevant information on the provenance of animals, health/immune status, genetic modification status, genotype, and any previous procedures.	Materials and Methods/lines 123-124, Firgue 3
Experimental procedures	9	For each experimental group, including controls, describe the procedures in enough detail to allow others to replicate them, including: a. What was done, how it was done and what was used. b. When and how often. c. Where (including detail of any acclimatisation periods). d. Why (provide rationale for procedures).	Materials and Methods/lines123 -151
Results	10	For each experiment conducted, including independent replications, report: a. Summary/descriptive statistics for each experimental group, with a measure of variability where applicable (e.g. mean and SD, or median and range). b. If applicable, the effect size with a confidence interval.	Materials and Methods/lines 234-257, Table 1-4

The Recommended Set

These items complement the Essential 10 and add important context to the study. Reporting the items in both sets represents best practice.

Item		Recommendation	Section/ line number, or reason for not reporting
Abstract	11	Provide an accurate summary of the research objectives, animal species, strain and sex, key methods, principal findings, and study conclusions.	Abstrct/lines 52-78
Background	12	a. Include sufficient scientific background to understand the rationale and context for the study, and explain the experimental approach. b. Explain how the animal species and model used address the scientific objectives and, where appropriate, the relevance to human biology.	Introduction/lines 84-119
Objectives	13	Clearly describe the research question, research objectives and, where appropriate, specific hypotheses being tested.	Introduction/lines 113-117
Ethical statement	14	Provide the name of the ethical review committee or equivalent that has approved the use of animals in this study, and any relevant licence or protocol numbers (if applicable). If ethical approval was not sought or granted, provide a justification.	Materials and Methods/line 123
Housing and husbandry	15	Provide details of housing and husbandry conditions, including any environmental enrichment.	Materials and Methods/lines 123-125
Animal care and monitoring	16	a. Describe any interventions or steps taken in the experimental protocols to reduce pain, suffering and distress. b. Report any expected or unexpected adverse events. c. Describe the humane endpoints established for the study, the signs that were monitored and the frequency of monitoring. If the study did not have humane endpoints, state this.	Materials and Methods/lines 141-142
Interpretation/ scientific implications	17	a. Interpret the results, taking into account the study objectives and hypotheses, current theory and other relevant studies in the literature. b. Comment on the study limitations including potential sources of bias, limitations of the animal model, and imprecision associated with the results.	Discussion/lines 266-355
Generalisability/ translation	18	Comment on whether, and how, the findings of this study are likely to generalise to other species or experimental conditions, including any relevance to human biology (where appropriate).	Discussion/329-340
Protocol registration	19	Provide a statement indicating whether a protocol (including the research question, key design features, and analysis plan) was prepared before the study, and if and where this protocol was registered.	Materials and Methods/line 123
Data access	20	Provide a statement describing if and where study data are available.	Yes (we can provide it when rational reasons to authors)
Declaration of interests	21	a. Declare any potential conflicts of interest, including financial and non-financial. If none exist, this should be stated. b. List all funding sources (including grant identifier) and the role of the funder(s) in the design, analysis and reporting of the study.	Footnote/lines 357-363

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STARD 2015

Section & Topic	Item No	Item	Reported on Page Number/ Line Number	Reported on Section/ Paragraph
TITLE OR ABSTRACT				
	1	Identification as a study of diagnostic accuracy using at least one measure of accuracy (such as sensitivity, specificity, predictive values, or AUC)	Page 3/Line 62-64	Abstract/Paragraph 2
ABSTRACT				
	2	Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts)	Page 3/Line 52-78	Abstract/Paragraph 1-4
INTRODUCTION				
	3	Scientific and clinical background, including the intended use and clinical role of the index test	Page 4-5/Line 84-112	Introduction/Paragraph 1-3
	4	Study objectives and hypotheses	Page 4-5/Line 113-117	Introduction/Paragraph 4
METHODS				
Study design	5	Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)	Page 6/line 123-129	Materials and Methods/Paragraph 1
Participants	6	Eligibility criteria	Page 6/Line 136-139	Materials and Methods/Paragraph 3
	7	On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)	Page 6/Line 136-139	Materials and Methods/Paragraph 3
	8	Where and when potentially eligible participants were identified (setting, location and dates)	Page 6/Line 136-139	Materials and Methods/Paragraph 3
	9	Whether participants formed a consecutive, random or convenience series	Page 6/Line 130-135	Materials and Methods/Paragraph 2
Test methods	10a	Index test, in sufficient detail to allow replication	Page 6-7/Line 124-139	Materials and Methods/Paragraph 1-3
	10b	Reference standard, in sufficient detail to allow replication	Page 9/Line 189-204	Materials and Methods/Paragraph 10
	11	Rationale for choosing the reference standard (if alternatives exist)	Page 9/Line 189-204	Materials and Methods/Paragraph 10
	12a	Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing pre-specified from exploratory	Page 8/Line 171-179	Materials and Methods/Paragraph 7
	12b	Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory	Page 9/Line 196-202	Materials and Methods/Paragraph 10
	13a	Whether clinical information and reference standard results were available to the performers/readers of the index test	Page 8/Line 168-171	Materials and Methods/Paragraph 7
	13b	Whether clinical information and index test results were available to the assessors of the reference standard	Page 9/Line 193-200	Materials and Methods/Paragraph 10

Analysis	14	Methods for estimating or comparing measures of diagnostic accuracy	Page 10/Line 212-217	Materials and Methods/Paragraph 11
	15	How indeterminate index test or reference standard results were handled	N/A	There was no indeterminate data in our study
	16	How missing data on the index test and reference standard were handled	N/A	There was no missing data in our study
	17	Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory	N/A	There was no comparative accuracy in our study
	18	Intended sample size and how it was determined	Page 6/Line 123-124	Materials and Methods/Paragraph 1
RESULTS				
Participants	19	Flow of participants, using a diagram	Figure 1	Figure 1
	20	Baseline demographic and clinical characteristics of participants	Figure 3	Figure 3
	21a	Distribution of severity of disease in those with the target condition	Figure 4	Figure 4
	21b	Distribution of alternative diagnoses in those without the target condition	N/A	There was no alternative diagnoses in our study
	22	Time interval and any clinical interventions between index test and reference standard	Page 6/Line 132-134,Page 9/Line 189-191	Materials and Methods/Paragraph 2, 10
Test results	23	Cross tabulation of the index test results (or their distribution) by the results of the reference standard	Page 11-12/Line 242-257	Results/Paragraph 4
	24	Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)	Page 11-12/Line 242-257	Results/Paragraph 4
	25	Any adverse events from performing the index test or the reference standard	N/A	There was no adverse events in our study
DISCUSSION				
	26	Study limitations, including sources of potential bias, statistical uncertainty, and generalisability	Page 16/Line 341-348	Discussion/Paragraph 7
	27	Implications for practice, including the intended use and clinical role of the index test	Page 16/Line 349-355	Discussion/Paragraph 8
OTHER INFORMATION				
	28	Registration number and name of registry	Page 6/line 123	Materials and Methods/Paragraph 1
	29	Where the full study protocol can be accessed	Yes (we can provide it when rational reasons to authors)	Yes (we can provide it when rational reasons to authors)
	30	Sources of funding and other support; role of funders	Page 17/Line 357-358	Acknowlegements/Paragraph 1

AIM

STARD stands for “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. Authors can use the list to write informative study reports. Editors and peer-reviewers can use it to evaluate whether the information has been included in manuscripts submitted for publication.

Explanation

A **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 stage, response or benefit from therapy, 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 these, or any other method for collecting information about the current health status of a patient.

The test whose accuracy is evaluated is called **index test**. A study can evaluate the accuracy of one or more index tests. Evaluating the ability of a medical test to correctly classify patients is typically 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. An accuracy study can rely on one or more reference standards.

If test results are 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** of the index test (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 (sometimes 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 around estimates of accuracy can then be calculated to quantify the statistical **precision** of the measurements.

If the index test results 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, authors can report a 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** informs in a single numerical value about the overall diagnostic accuracy of the index test.

The **intended use** 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 in the clinical pathway. 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.

Besides 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 staging or prognosis. The STARD list was not explicitly developed for these other outcomes, statistics, and study types, although most STARD items would still apply.

DEVELOPMENT

This 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 STARD was to select items 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. The list represents 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.

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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.