

Additional file 11: Table S5. The list of Standards for Reporting of Diagnostic Accuracy Studies (STARD2015) recommendations followed in the present work.

| Section & Topic | No | Item | Reported on page # |
|----------------------------|------------|--|--|
| 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) | p. 1, 3 |
| ABSTRACT | 2 | Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts) | p. 1 |
| INTRODUCTION | 3 | Scientific and clinical background, including the intended use and clinical role of the index test | p. 2 |
| | 4 | Study objectives and hypotheses | p. 2 |
| METHODS | | | |
| <i>Study design</i> | 5 | Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study) | Introduction, p. 1 Methods, p. 2, 6 |
| <i>Participants</i> | 6 | Eligibility criteria | Methods, p. 2 |
| | 7 | On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry) | Methods, p. 2, 6 |
| | 8 | Where and when potentially eligible participants were identified (setting, location and dates) | Methods, p.6 |
| | 9 | Whether participants formed a consecutive, random or convenience series | Methods, p. 6 |
| <i>Test methods</i> | 10a | Index test, in sufficient detail to allow replication | Methods, p. 3, 4 |
| | 10b | Reference standard, in sufficient detail to allow replication | Methods, p. 3 |
| | 11 | Rationale for choosing the reference standard (if alternatives exist) | Methods, p. 3 |
| | 12a | Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing pre-specified from exploratory | Methods, p. 3, 5, 6 |
| | 12b | Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory | Methods, p. 3 |
| | 13a | Whether clinical information and reference standard results were available to the performers/readers of the index test | Methods, p. 3 |
| | 13b | Whether clinical information and index test results were available to the assessors of the reference standard | Methods, p. 3 |
| <i>Analysis</i> | 14 | Methods for estimating or comparing measures of diagnostic accuracy | Methods, p. 5, 6 |
| | 15 | How indeterminate index test or reference standard results were handled | NA |
| | 16 | How missing data on the index test and reference standard | NA |

| | | | |
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| | | were handled | |
| | 17 | Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory | NA |
| | 18 | Intended sample size and how it was determined | Methods, p. 2, 6 |
| RESULTS | | | |
| <i>Participants</i> | 19 | Flow of participants, using a diagram | Figure 1 |
| | 20 | Baseline demographic and clinical characteristics of participants | Table 1 |
| | 21a | Distribution of severity of disease in those with the target condition | Table 1 |
| | 21b | Distribution of alternative diagnoses in those without the target condition | NA |
| | 22 | Time interval and any clinical interventions between index test and reference standard | Methods, p. 2, 6 |
| <i>Test results</i> | 23 | Cross tabulation of the index test results (or their distribution) by the results of the reference standard | Figure 4c |
| | 24 | Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals) | Methods, p. 5-6 |
| | 25 | Any adverse events from performing the index test or the reference standard | NA |
| DISCUSSION | | | |
| | 26 | Study limitations, including sources of potential bias, statistical uncertainty, and generalisability | Discussion, p.13,14 |
| | 27 | Implications for practice, including the intended use and clinical role of the index test | Discussion, p.14 |
| OTHER INFORMATION | | | |
| | 28 | Registration number and name of registry | NA |
| | 29 | Where the full study protocol can be accessed | NA |
| | 30 | Sources of funding and other support; role of funders | Abstract, p.1 |