| Section & Topic   | No  | Item   | Reported on page<br># |
|-------------------|-----|--|-----------------------|
| TITLE OR ABSTRACT |     |  |                       |
|                   | 1   | Identification as a study of diagnostic accuracy using at least one measure of accuracy            | Page 1                |
|                   |     | (such as sensitivity, specificity, predictive values, or AUC)                                      |                       |
| ABSTRACT          |     |  |                       |
|                   | 2   | Structured summary of study design, methods, results, and conclusions                              | Page 3                |
|                   |     | (for specific guidance, see STARD for Abstracts)   |                       |
| INTRODUCTION      |     |  |                       |
|                   | 3   | Scientific and clinical background, including the intended use and clinical role of the index test | Page 3, 4             |
|                   | 4   | Study objectives and hypotheses  | Page 3, 4             |
| METHODS           |     |  |                       |
| Study design      | 5   | Whether data collection was planned before the index test and reference standard                   | Page 7, 19            |
|                   |     | were performed (prospective study) or after (retrospective study)                                  |                       |
| Participants      | 6   | Eligibility criteria   | Page 4, 5             |
|                   | 7   | On what basis potentially eligible participants were identified                                    | Page 4                |
|                   |     | (such as symptoms, results from previous tests, inclusion in registry)                             |                       |
|                   | 8   | Where and when potentially eligible participants were identified (setting, location and dates)     | Page 7, 19            |
|                   | 9   | Whether participants formed a consecutive, random or convenience series                            | Page 5, 6             |
| Test methods      | 10a | Index test, in sufficient detail to allow replication  | Page 7, 19            |
|                   | 10b | Reference standard, in sufficient detail to allow replication                                      | Page 19-22            |
|                   | 11  | Rationale for choosing the reference standard (if alternatives exist)                              | N/A                   |
|                   | 12a | Definition of and rationale for test positivity cut-offs or result categories                      | N/A                   |
|                   |     | of the index test, distinguishing pre-specified from exploratory                                   |                       |
|                   | 12b | Definition of and rationale for test positivity cut-offs or result categories                      | N/A                   |
|                   |     | of the reference standard, distinguishing pre-specified from exploratory                           |                       |
|                   | 13a | Whether clinical information and reference standard results were available                         | Page 19-22            |
|                   |     | to the performers/readers of the index test  | -                     |
|                   | 13b | Whether clinical information and index test results were available                                 | Page 19-22            |
|                   |     | to the assessors of the reference standard   | _                     |
| Analysis          | 14  | Methods for estimating or comparing measures of diagnostic accuracy                                | Page 7                |
|                   | 15  | How indeterminate index test or reference standard results were handled                            | Page 19-22            |
|                   | 16  | How missing data on the index test and reference standard were handled                             | Page 19-22            |
|                   | 17  | Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory  | Page 19-22            |
|                   | 18  | Intended sample size and how it was determined   | Page 18, 19           |
| RESULTS           |     |  | , j                   |
| Participants      | 19  | Flow of participants, using a diagram  | Page 5, 19            |
| Test results      | 20  | Baseline demographic and clinical characteristics of participants                                  | Page 19               |
|                   | 21a | Distribution of severity of disease in those with the target condition                             | Page 19               |
|                   | 21b | Distribution of alternative diagnoses in those without the target condition                        | N/A                   |
|                   | 22  | Time interval and any clinical interventions between index test and reference standard             | N/A                   |
|                   | 23  | Cross tabulation of the index test results (or their distribution)                                 | Page 20               |
|                   | 25  | by the results of the reference standard   | 1 age 20              |
|                   | 24  | Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)            | Page 20               |
|                   | 25  | Any adverse events from performing the index test or the reference standard                        | N/A                   |
| DISCUSSION        |     |  | ,,                    |
|                   | 26  | Study limitations, including sources of potential bias, statistical uncertainty, and               | Page 10, 12           |
|                   | 20  | generalisability   | 1 UBC 10, 12          |
|                   | 27  | Implications for practice, including the intended use and clinical role of the index test          | Page 11               |
| OTHER             | 21  | החקור מנוסדי זיסר ערמכוניב, הוכוענוווצ נדיב התבחעבע עצב מוע כווווכמו דטוב טו נדוב הועבא נפגנ       | L aRC TT              |
|                   |     |  |                       |
|                   | 70  | Pagistration number and name of registry   | Dago 4                |
|                   | 28  | Registration number and name of registry   | Page 4                |
|                   | 29  | Where the full study protocol can be accessed  | Page 13               |
|                   | 30  | Sources of funding and other support; role of funders  | Page 2                |

