

## S4. Appendix

### Standards for the Reporting of Diagnostic Accuracy studies checklist

| Section                  | No  | Item   |
|--------------------------|-----|--|
| <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)   |
| <b>Abstract</b>          |     |  |
|                          | 2   | Structured summary of study design, methods, results and conclusions (for specific guidance, see STARD for Abstracts)                                  |
| <b>Introduction</b>      |     |  |
|                          | 3   | Scientific and clinical background, including the intended use and clinical role of the index test   |
|                          | 4   | Study objectives and hypotheses  |
| <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)     |
| Participants             | 6   | Eligibility criteria   |
|                          | 7   | On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)                 |
|                          | 8   | Where and when potentially eligible participants were identified (setting, location and dates)   |
|                          | 9   | Whether participants formed a consecutive, random or convenience series  |
| Test methods             | 10a | Index test, in sufficient detail to allow replication  |
|                          | 10b | Reference standard, in sufficient detail to allow replication  |
|                          | 11  | Rationale for choosing the reference standard (if alternatives exist)  |
|                          | 12a | Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing pre-specified from exploratory         |
|                          | 12b | Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory |
|                          | 13a | Whether clinical information and reference standard results were available to the performers or readers of the index test                              |
|                          | 13b | Whether clinical information and index test results were available to the assessors of the reference standard  |
| Analysis                 | 14  | Methods for estimating or comparing measures of diagnostic accuracy  |
|                          | 15  | How indeterminate index test or reference standard results were handled  |
|                          | 16  | How missing data on the index test and reference standard were handled   |
|                          | 17  | Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory  |
|                          | 18  | Intended sample size and how it was determined   |
| <b>Results</b>           |     |  |
| Participants             | 19  | Flow of participants, using a diagram  |
|                          | 20  | Baseline demographic and clinical characteristics of participants  |
|                          | 21a | Distribution of severity of disease in those with the target condition   |
|                          | 21b | Distribution of alternative diagnoses in those without the target condition  |
|                          | 22  | Time interval and any clinical interventions between index test and reference standard   |
| Test results             | 23  | Cross tabulation of the index test results (or their distribution) by the results of the reference standard  |
|                          | 24  | Estimates of diagnostic accuracy and their precision (such as 95% CIs)   |
|                          | 25  | Any adverse events from performing the index test or the reference standard  |
| <b>Discussion</b>        |     |  |
|                          | 26  | Study limitations, including sources of potential bias, statistical uncertainty and generalizability   |
|                          | 27  | Implications for practice, including the intended use and clinical role of the index test  |
| <b>Other information</b> |     |  |
|                          | 28  | Registration number and name of registry   |
|                          | 29  | Where the full study protocol can be accessed  |
|                          | 30  | Sources of funding and other support; role of funders  |