

**Appendix 2.** QUADAS-2 checklist, a revised tool for the quality assessment of diagnostic accuracy studies (Whiting et al., 2011)

## QUADAS-2

### Phase 1: State the review question:

*Patients (setting, intended use of index test, presentation, prior testing):*

*Index test(s):*

*Reference standard and target condition:*

### Phase 2: Draw a flow diagram for the primary study

### Phase 3: Risk of bias and applicability judgments

*QUADAS-2 is structured so that 4 key domains are each rated in terms of the risk of bias and the concern regarding applicability to the research question (as defined above). Each key domain has a set of signalling questions to help reach the judgments regarding bias and applicability.*

## DOMAIN 1: PATIENT SELECTION

### A. Risk of Bias

Describe methods of patient selection:

- ❖ Was a consecutive or random sample of patients enrolled? Yes/No/Unclear
- ❖ Was a case-control design avoided? Yes/No/Unclear
- ❖ Did the study avoid inappropriate exclusions? Yes/No/Unclear

**Could the selection of patients have introduced bias? RISK: LOW/HIGH/UNCLEAR**

### B. Concerns regarding applicability

Describe included patients (prior testing, presentation, intended use of index test and setting):

**Is there concern that the included patients do not match the review question? CONCERN: LOW/HIGH/UNCLEAR**

## DOMAIN 2: INDEX TEST(S)

**If more than one index test was used, please complete for each test.**

### A. Risk of Bias

Describe the index test and how it was conducted and interpreted:

- ❖ Were the index test results interpreted without knowledge of the results of the reference standard? Yes/No/Unclear
  - ❖ If a threshold was used, was it pre-specified? Yes/No/Unclear
- Could the conduct or interpretation of the index test have introduced bias? RISK: LOW /HIGH/UNCLEAR**

### B. Concerns regarding applicability

**Is there concern that the index test, its conduct, or interpretation differ from the review question? CONCERN: LOW /HIGH/UNCLEAR**

### DOMAIN 3: REFERENCE STANDARD

#### A. Risk of Bias

Describe the reference standard and how it was conducted and interpreted:

- ❖ Is the reference standard likely to correctly classify the target condition? Yes/No/Unclear
- ❖ Were the reference standard results interpreted without Yes/No/Unclear knowledge of the results of the index test?

**Could the reference standard, its conduct, or its interpretation have introduced bias? RISK: LOW /HIGH/UNCLEAR**

#### B. Concerns regarding applicability

**Is there concern that the target condition as defined by CONCERN: LOW /HIGH/UNCLEAR the reference standard does not match the review question?**

### DOMAIN 4: FLOW AND TIMING

#### A. Risk of Bias

Describe any patients who did not receive the index test(s) and/or reference standard or who were excluded from the 2x2 table (refer to flow diagram):

Describe the time interval and any interventions between index test(s) and reference standard:

- ❖ Was there an appropriate interval between index test(s) Yes/No/Unclear and reference standard?
- ❖ Did all patients receive a reference standard? Yes/No/Unclear
- ❖ Did patients receive the same reference standard? Yes/No/Unclear
- ❖ Were all patients included in the analysis? Yes/No/Unclear **Could the patient flow have introduced bias? RISK: LOW /HIGH/UNCLEAR**

Whiting PF, Rutjes AW, Westwood ME, Mallett S, Deeks JJ, Reitsma JB, Leeflang MM, Sterne JA, Bossuyt PM. 2011. QUADAS-2: a revised tool for the quality assessment of diagnostic accuracy studies. Ann Intern Med. Oct 18;155:529-536. Epub 2011/10/19.