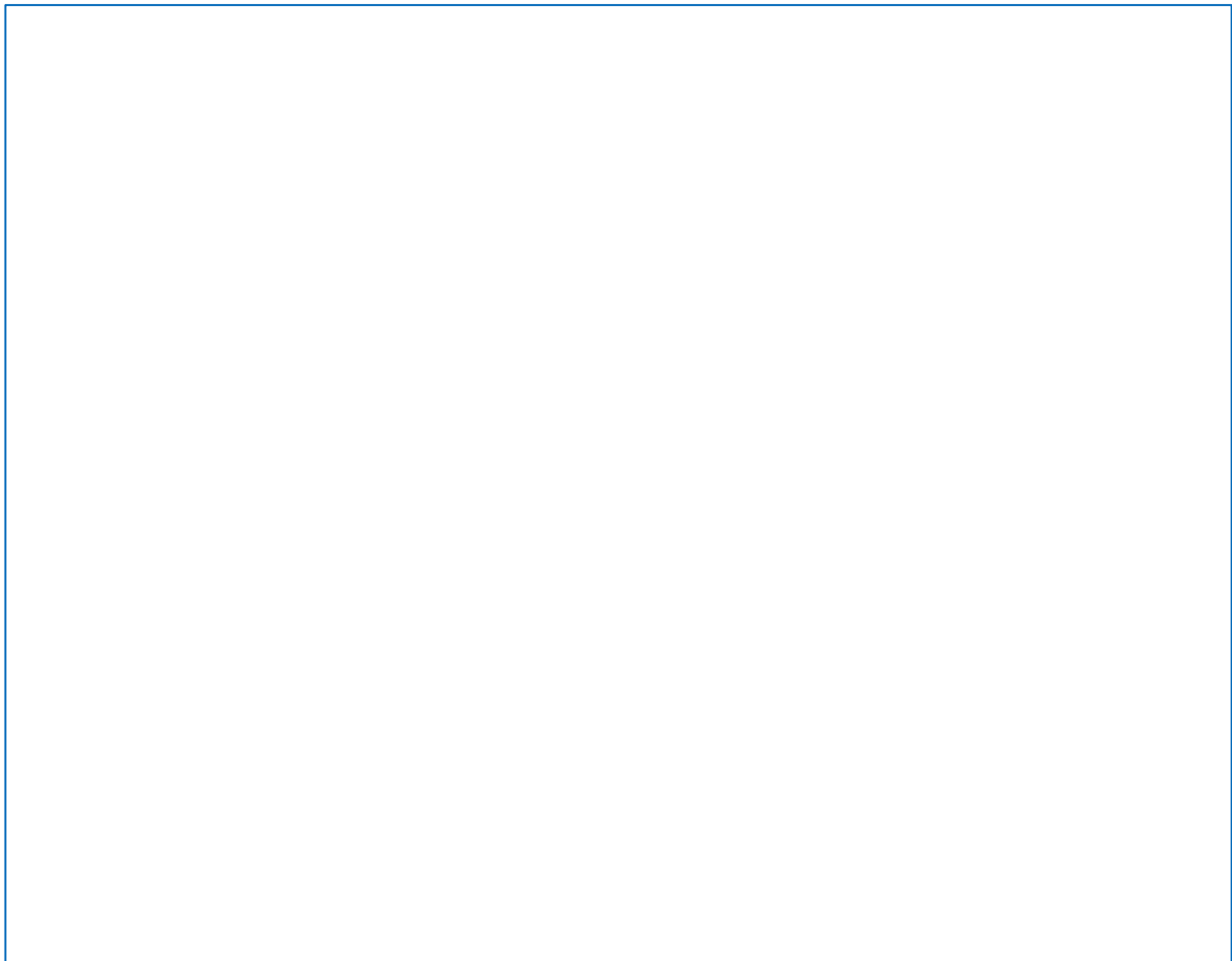# Appendix 4: QUADAS-2 Tool for the Quality Assessment of Diagnostic Accuracy Studies[13]

State the review question:

Patients (setting, intended use of index test, presentation, prior testing):
Index test(s):
Reference standard and target condition:

Draw a flow diagram for the primary study:

Risk of bias and applicability judgments

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)

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**	
Were the index test results interpreted without knowledge of the results of the reference standard?	

Domain 3: Reference standard

A. Risk of bias	
Describe the index test 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 knowledge of the results of the index test?	**Yes / No / Unclear**
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 the reference standard does not match the review question? **Concern: Low / High / Unclear**	

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) and reference standard?	**Yes / No / Unclear**
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**	