First author surname and year of publication:

Name of first reviewer: K. Freeman *Name of second reviewer: A. Tsertsvadze*

Phase 1: State the review question:

Patients (setting, intended use of index test, presentation, prior testing): microbiology laboratory central or within hospital receiving samples from hospital and community of patients with diarrhea due to suspected gastrointestinal infection that are eligible for routine laboratory testing.
Index test(s): xTAG, FilmArray or Faecal Pathogens B assay kits handled and executed as instructed by the manufacturers using fresh samples of stool in medium
Reference standard and target condition: the target condition is diarrhoea caused by bacteria, viruses or parasites included in the Public Health England algorithm for routine screening of stool samples from people with diarrhoea and vomiting. The routine tests are not classed as reference standard. The ideal study would include a fair umpire test to solve discrepant results between conventional test and GPP test. The fair umpire test needs to be sufficiently different (unbiased and independent) from the GPP and comparator tests (e.g. exposure or treatment effect).

Phase 2: Draw a flow diagram for the primary study

See hard copy

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
+ Was only one sample per episode of diarrhoea included in the study?	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 comparator and verification method?	Yes/No/Unclear
+ If a threshold was used, was it pre-specified?	Yes/No/Unclear
+ Did all samples receive the index test?	Yes/No/Unclear
+ Was the index test undertaken as recommended by the manufacturer?	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: Comparator

A. Risk of Bias

Describe the comparator tests and how it was conducted and interpreted:

+ Were the comparator test results interpreted without knowledge of the results of the index test and verification method?	Yes/No/Unclear
+ If a threshold was used, was it pre-specified?	Yes/No/Unclear
+ Was culture performed on fresh (not previously frozen) samples?	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 comparator test, its conduct, or interpretation differ from the review question?	**CONCERN: LOW/HIGH/UNCLEAR**

DOMAIN 4: REFERENCE STANDARD

A. Risk of Bias

Describe the verification method 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
+ Was the references standard independent and unbiased?	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 5: FLOW AND TIMING

A. Risk of Bias

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

Describe the time interval and any intervention between index tests(s) and reference standard:

+ Was there an appropriate interval between index test(s) and comparator and reference standard (if applicable)?	Yes/No/Unclear
+ Did all discordant samples receive a reference standard?	Yes/No/Unclear
+ Did all patients receive the same reference standard?	Yes/No/Unclear
+ Did all samples receive the comparator methods for all pathogens considered in the study?	Yes/No/Unclear
+ Were all patients included in the analysis?	Yes/No/Unclear
Could the patient flow have introduced bias?	**RISK: LOW/HIGH/UNCLEAR**