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Non-invasive diagnostic tests for *Helicobacter pylori* infection (Review)

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[Diagnostic Test Accuracy Review]

Non-invasive diagnostic tests for *Helicobacter pylori* infection

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ABSTRACT

Background

Helicobacter pylori (*H pylori*) infection has been implicated in a number of malignancies and non-malignant conditions including peptic ulcers, non-ulcer dyspepsia, recurrent peptic ulcer bleeding, unexplained iron deficiency anaemia, idiopathic thrombocytopaenia purpura, and colorectal adenomas. The confirmatory diagnosis of *H pylori* is by endoscopic biopsy, followed by histopathological examination using haemotoxylin and eosin (H & E) stain or special stains such as Giemsa stain and Warthin-Starry stain. Special stains are more accurate than H & E stain. There is significant uncertainty about the diagnostic accuracy of non-invasive tests for diagnosis of *H pylori*.

Objectives

To compare the diagnostic accuracy of urea breath test, serology, and stool antigen test, used alone or in combination, for diagnosis of *H pylori* infection in symptomatic and asymptomatic people, so that eradication therapy for *H pylori* can be started.

Search methods

We searched MEDLINE, Embase, the Science Citation Index and the National Institute for Health Research Health Technology Assessment Database on 4 March 2016. We screened references in the included studies to identify additional studies. We also conducted citation searches of relevant studies, most recently on 4 December 2016. We did not restrict studies by language or publication status, or whether data were collected prospectively or retrospectively.

Selection criteria

We included diagnostic accuracy studies that evaluated at least one of the index tests (urea breath test using isotopes such as ^{13}C or ^{14}C, serology and stool antigen test) against the reference standard (histopathological examination using H & E stain, special stains or immunohistochemical stain) in people suspected of having *H pylori* infection.

Data collection and analysis

Two review authors independently screened the references to identify relevant studies and independently extracted data. We assessed the methodological quality of studies using the QUADAS-2 tool. We performed meta-analysis by using the hierarchical summary receiver operating characteristic (HSROC) model to estimate and compare SROC curves. Where appropriate, we used bivariate or univariate logistic regression models to estimate summary sensitivities and specificities.

Main results

We included 101 studies involving 11,003 participants, of which 5839 participants (53.1%) had *H pylori* infection. The prevalence of *H pylori* infection in the studies ranged from 15.2% to 94.7%, with a median prevalence of 53.7% (interquartile range 42.0% to 66.5%). Most of the studies (57%) included participants with dyspepsia and 53 studies excluded participants who recently had proton pump inhibitors or antibiotics.There was at least an unclear risk of bias or unclear applicability concern for each study.

Of the 101 studies, 15 compared the accuracy of two index tests and two studies compared the accuracy of three index tests. Thirty-four studies (4242 participants) evaluated serology; 29 studies (2988 participants) evaluated stool antigen test; 34 studies (3139 participants) evaluated urea breath test-^{13}C; 21 studies (1810 participants) evaluated urea breath test-^{14}C; and two studies (127 participants) evaluated urea breath test but did not report the isotope used. The thresholds used to define test positivity and the staining techniques used for histopathological examination (reference standard) varied between studies. Due to sparse data for each threshold reported, it was not possible to identify the best threshold for each test.

Using data from 99 studies in an indirect test comparison, there was statistical evidence of a difference in diagnostic accuracy between urea breath test-^{13}C, urea breath test-^{14}C, serology and stool antigen test (P = 0.024). The diagnostic odds ratios for urea breath test-^{13}C, urea breath test-^{14}C, serology, and stool antigen test were 153 (95% confidence interval (CI) 73.7 to 316), 105 (95% CI 74.0 to 150), 47.4 (95% CI 25.5 to 88.1) and 45.1 (95% CI 24.2 to 84.1). The sensitivity (95% CI) estimated at a fixed specificity of 0.90 (median from studies across the four tests), was 0.94 (95% CI 0.89 to 0.97) for urea breath test-^{13}C, 0.92 (95% CI 0.89 to 0.94) for urea breath test-^{14}C, 0.84 (95% CI 0.74 to 0.91) for serology, and 0.83 (95% CI 0.73 to 0.90) for stool antigen test. This implies that on average, given a specificity of 0.90 and prevalence of 53.7% (median specificity and prevalence in the studies), out of 1000 people tested for *H pylori* infection, there will be 46 false positives (people without *H pylori* infection who will be diagnosed as having *H pylori i*nfection). In this hypothetical cohort, urea breath test-^{13}C, urea breath test-^{14}C, serology, and stool antigen test will give 30 (95% CI 15 to 58), 42 (95% CI 30 to 58), 86 (95% CI 50 to 140), and 89 (95% CI 52 to 146) false negatives respectively (people with *H pylori* infection for whom the diagnosis of *H pylori* will be missed).

Direct comparisons were based on few head-to-head studies. The ratios of diagnostic odds ratios (DORs) were 0.68 (95% CI 0.12 to 3.70; P = 0.56) for urea breath test-^{13}C versus serology (seven studies), and 0.88 (95% CI 0.14 to 5.56; P = 0.84) for urea breath test-^{13}C versus stool antigen test (seven studies). The 95% CIs of these estimates overlap with those of the ratios of DORs from the indirect comparison. Data were limited or unavailable for meta-analysis of other direct comparisons.

Authors' conclusions

In people without a history of gastrectomy and those who have not recently had antibiotics or proton ,pump inhibitors, urea breath tests had high diagnostic accuracy while serology and stool antigen tests were less accurate for diagnosis of *Helicobacter pylori* infection.This is based on an indirect test comparison (with potential for bias due to confounding), as evidence from direct comparisons was limited or unavailable. The thresholds used for these tests were highly variable and we were unable to identify specific thresholds that might be useful in clinical practice.

We need further comparative studies of high methodological quality to obtain more reliable evidence of relative accuracy between the tests. Such studies should be conducted prospectively in a representative spectrum of participants and clearly reported to ensure low risk of bias. Most importantly, studies should prespecify and clearly report thresholds used, and should avoid inappropriate exclusions.

PLAIN LANGUAGE SUMMARY

Accuracy of different non-invasive methods for identifying *Helicobacter pylori*

Why is it important to know whether someone has *Helicobacter pylori*?

Helicobacter pylori (H pylori) is a type of bacteria which may be present in the stomach of some people. *H pylori* is believed to cause a number of cancers, including stomach cancer, pancreatic cancer, and throat cancer. *H pylori* is also linked with other diseases including stomach ulcers, heart burn, and a bloated feeling. If *H pylori* is found in an individual, appropriate treatment can be started.

What is the aim of this review?

To compare the accuracy of three different types of test for *H pylori.* These are: urea breath tests, blood tests (the specific blood test is called serology), and stool tests (in faeces).

What was studied in this review?

There are two types of urea breath test which use two different forms of carbon known as ^{13}C and ^{14}C, as well as multiple versions of serology and stool tests.

What are the main results of the review?

We found 101 studies which included 11,003 people who were tested for *H pylori*. Of these 11,003 participants, 5839 (53.1%) had *H pylori* infection. All the studies used one of the three tests listed above and compared these test results with the diagnosis given by endoscopic biopsy. Endoscopic biopsy involves obtaining tissue from the stomach using a thin flexible tube introduced through the mouth and testing for the presence of *H pylori* under the microscope. It is currently the most accurate available test, however it causes physical discomfort to the patient, with associated risks for harm. This is in contrast to the alternative non-invasive tests in this review which are significantly less uncomfortable and have minimal or no risk of harm, making them desirable alternatives if they can be shown to be as accurate at diagnosing *H pylori* as endoscopic biopsy. Most of the studies included participants with heart burn or similar problems in the stomach and excluded participants who had previously undergone partial removal of the stomach and those having treatment for *H pylori*.

Thirty-four studies (4242 participants) used serology; 29 studies (2988 participants) used stool antigen test; 34 studies (3139 participants) used urea breath test-^{13}C; 21 studies (1810 participants) used urea breath test-^{14}C; and two studies (127 participants) used urea breath test but did not report the type of carbon used. Studies varied in the limit they used before saying a test was positive for *H pylori* infection and the type of stains used to examine the biopsy material. When we looked at all the data we found that urea breath tests were more accurate than blood and stool tests. The results mean that, on average, if 1000 people are tested, there will be 46 people without *H pylori* who will be misdiagnosed as having *H pylori*. Also, there will be 30, 42, 86, and 89 people with *H pylori* infection for whom the diagnosis of *H pylori* infection will be missed by urea breath test-^{13}C, urea breath test-^{14}C, serology, and stool antigen test, respectively. When we looked at the seven studies which compared urea breath test-^{13}C and serology, or urea breath test-^{13}C and stool antigen tests in the same participants, the results were uncertain and we cannot tell which test is more accurate.

How reliable are the results of the studies?

Except for one study, all the studies were of poor methodological quality, which makes their results unreliable.

Who do the results of this review apply to?

These results apply to children and adults with suspected *H pylori* infection, but only in those who have not previously undergone stomach operations and those who have not recently had antibiotics or treatment for *H pylori* infection.

What are the implications of this review?

Urea breath tests, blood tests, and stool tests may be suitable for identifying whether someone has *H pylori* infection. However, the level of the result of urea breath test, blood test, or stool test which should be used to make a diagnosis of *H pylori* infection remains unclear.

How up-to-date is the review?

We performed a thorough literature search for studies reporting the accuracy of these different tests until 4 March 2016.

SUMMARY OF FINDINGS

Summary of findings 1. Performance of non-invasive tests for diagnosis of *H pylori* infection

What is the best non-invasive test for diagnosis of *H pylori* infection?

Population	Children and adults with gastrointestinal symptoms
Setting	Primary care setting
Index tests	Urea breath test-^{13}C, Urea breath test-^{14}C, serology, and stool antigen test
Threshold	Various thresholds were used for each test
Role and purpose of test	Screening and diagnosis of *H pylori*
Reference standard	Endoscopic biopsy with Haemotoxylin & Eosin stain, special stains, or combination of Haemotoxylin & Eosin and special stains
Quality of evidence	Risk of bias was generally high or unclear with respect to the selection of participants, and the conduct and interpretation of the index tests and reference standard. Applicability concerns were also generally high or unclear with respect to selection of participants
Limitations	There was heterogeneity in thresholds and reference standards. Studies did not often prespecify or clearly report thresholds used
Pre-test probability (prevalence of *Helicobacter pylori*)	Median (interquartile range) = 53.7% (42.0% to 66.5%)

Index test	Number of participants (studies)	Diagnostic odds ratio (95% CI)	Sensitivity (95% CI) at fixed specificity of 0.90[1]	Missed *H pylori* cases per 1000 people tested (95% CI)[2]
Urea breath test-^{13}C	3139 participants (34 studies)	153 (95% CI 73.7 to 316)	0.94 (0.89 to 0.97)	30 (15 to 58)
Urea breath test-^{14}C	1810 participants (21 studies)	105 (95% CI 74.0 to 150)	0.92 (0.89 to 0.94)	42 (30 to 58)
Serology	4242 participants (34 studies)	47.4 (95% CI 25.5 to 88.1)	0.84 (0.74 to 0.91)	86 (50 to 140)
Stool antigen test	2988 participants (29 studies)	45.1 (95% CI 24.2 to 84.1)	0.83 (0.73 to 0.90)	89 (52 to 146)

Comparison of non-invasive tests for *H pylori* infection

Based on an indirect comparison of the four tests using all the studies, there was statistical evidence of a difference in diagnostic accuracy (P = 0.024). Direct comparisons were based on few head-to-head studies. The ratios of diagnostic odds ratios (95% CI; P value) were 0.68 (95% CI 0.12 to 3.70; P = 0.56) for urea breath test-^{13}C versus serology (seven studies), and 0.88 (95% CI 0.14 to 5.56; P = 0.84) for urea breath test-^{13}C versus stool antigen test (seven studies). The 95% confidence intervals of these estimates overlap with

those of the ratios of diagnostic odds ratios from the indirect comparison. Data were limited or unavailable for meta-analysis of other direct comparisons.

Conclusions

In people with no history of gastrectomy and those who have not recently had antibiotics or proton pump inhibitors, urea breath tests had high diagnostic accuracy while serology and stool antigen tests had lower accuracy to detect *H pylori* infection. Although susceptible to bias due to confounding, this conclusion is based on evidence from indirect test comparisons as evidence from direct comparisons was based on few studies or was unavailable. It should be noted that studies were generally of poor methodological quality. The thresholds used for the tests were highly variable and there is currently insufficient evidence to recommend specific thresholds for use in clinical practice.

[1]The sensitivities were estimated along the SROC curves at the median specificity across the studies included for the four tests.
[2]Based on the sensitivity estimated at the median specificity of 0.90, and the median prevalence of 53.7% from the included studies, the numbers of missed *H pylori* cases were calculated using a hypothetical cohort of 1000 people suspected of having *H pylori* infection. The 95% CI for the number of missed cases is from the 95% CI for sensitivity. For a specificity of 0.90 and prevalence of 53.7%, there will be 46 false positives. See Table 3 for results for other values of specificity and prevalence.

BACKGROUND

Helicobacter pylori (H pylori) is a gram negative spiral bacterium (NCBI 2014). Approximately 13% to 81% of people have *H pylori* infection (Peleteiro 2014). Prevalence of the bacterium varies according to age (generally increasing with age, although infection rates tend to fall among older age groups in some Latin American and Northeast Asian countries); region (lower infection rates are seen in Australia and the UK, while higher rates are reported in Chile, China, Japan, Korea, and Latvia); race (more prevalent amongst Afrocarribeans compared to white people); and socioeconomic class (more common in poorer settings) (Graham 1991; Laszewicz 2014; Muhsen 2012; Peleteiro 2014).

Based on observational studies, *H pylori* infection has been implicated in a number of malignancies, including gastric cancer, premalignant lesions of the stomach (atrophic gastritis and intestinal metaplasia), gastric lymphoma, pancreatic cancer, colorectal cancer, and laryngeal cancer (Huang 1998; Huang 2003; Wu 2013; Xiao 2013; Xue 2001; Zhuo 2008). However, *H pylori* is associated with a lower incidence of oesophageal adenocarcinomas (Islami 2008). *H pylori* is also associated with a number of non-malignant conditions, including peptic ulcers, non-ulcer dyspepsia, recurrent peptic ulcer bleeding, unexplained iron deficiency anaemia, idiopathic thrombocytopaenia purpura, and colorectal adenomas (DuBois 2005; Franchini 2007; Gisbert 2004b; Huang 2002; Jaakkimainen 1999; Wu 2013).

Although a number of pathogenic factors such as cytotoxin-associated gene A (CagA), vacuolating cytotoxin A (VacA), and blood group antigen binding adhesin (BabA) are associated with increased virulence of *H pylori* (Huang 2003; Malfertheiner 2012), detection of these pathogenic factors currently has no role in the management of *H pylori* infection (Malfertheiner 2012). The recommended initial treatment for *H pylori* infection is with a combination of a proton pump inhibitor, clarithromycin, and amoxicillin or metronidazole (triple therapy) in regions with low resistance to clarithromycin (< 20% resistance rate in the area), and the triple therapy along with bismuth (quadruple therapy) in regions with high resistance to clarithromycin (> 20% resistance rate in the area) (Malfertheiner 2012). If this results in failure of eradication, bismuth-quadruple therapy or levofloxacin-triple therapy (replacement of clarithromycin with levofloxacin in the classical triple therapy) when triple therapy was used as the initial treatment and levofloxacin-triple therapy when bismuth quadruple therapy was used as the initial treatment is recommended (Malfertheiner 2012). If even this treatment fails to eradicate *H pylori*, then further treatment should be based on antibiotic susceptibility (Malfertheiner 2012). Eradication of *H pylori* might lead to a decrease in malignant and non-malignant conditions associated with *H pylori* infection. Adverse events related to *H pylori* treatment include taste disturbance, diarrhoea, nausea, headache, skin rash, abdominal pain, dizziness, bloating, myalgias (muscle pain), and constipation (Ye 2014).

A glossary of terms is included in Appendix 1.

Target condition being diagnosed

Helicobacter pylori infection.

Index test(s)

Urea breath test

The urea breath test is based on the presence of urease enzyme in live *H pylori* which breaks down urea into ammonia and carbon dioxide (McNulty 2005; Ricci 2007). After ingestion of urea labelled with either ^{13}C or ^{14}C, breath samples are collected for up to 30 minutes by exhaling into a carbon dioxide-trapping agent (Ricci 2007). The urea breath test is performed by the clinician or the clinician's assistant. The thresholds used include the percentage of carbon recovered during the collection time or counts per minute (Ferwana 2015). Threshold levels above 4% or 5% are commonly used to diagnose *H pylori* infection (Ferwana 2015). A wide range of threshold counts per minute, ranging from more than 25 counts per minute to 1000 counts per minute, have been used for diagnosis of *H pylori* infection (Ferwana 2015).

Serology

These tests are based on circulating antibodies to *H pylori*. There are three main methods for these tests: the enzyme-linked immunosorbent assay (ELISA) test, latex agglutination tests, and Western blotting (Ricci 2007). Of these, ELISA is the most commonly used method. Total immunoglobulin, immunoglobulin subtypes, and antibody response to specific antigens can all be tested. Since they do not require any special equipment, they can be easily performed (Ricci 2007). However, serology may be positive because of the presence of active infection at the time of the test, previous infection, or because of non-specific cross-reacting antibodies (McNulty 2005). Tests that use whole blood (rather than serum) and other bedside tests (using a bedside centrifuge) are also available, although these whole-blood tests and bedside serum tests are generally considered unreliable (Ricci 2007). Routine serum tests are performed by the laboratory technician and interpreted by the clinician. The bedside serum tests and whole-blood tests are performed by the clinician or the clinician's assistant. Different researchers evaluating the prevalence of *H pylori* have used different thresholds to define the positivity of serology, for example Lindsetmo 2008 used a titre ≥ 300 while Granberg 1993 used a titre ≥ 500.

Stool antigen tests

These tests use monoclonal and polyclonal antibodies to detect the presence of *H pylori* antigen in stools and active *H pylori* infection can be diagnosed (McNulty 2005; Ricci 2007). Serum tests are performed by the laboratory technician and interpreted by the clinician. Several thresholds have been used for other tests, for example, an optical density of ≥ 0.15, ≥ 0.16, and ≥ 0.19 have all been used as thresholds for diagnosis of *H pylori* using monoclonal antibodies for stool antigen tests.

Clinical pathway

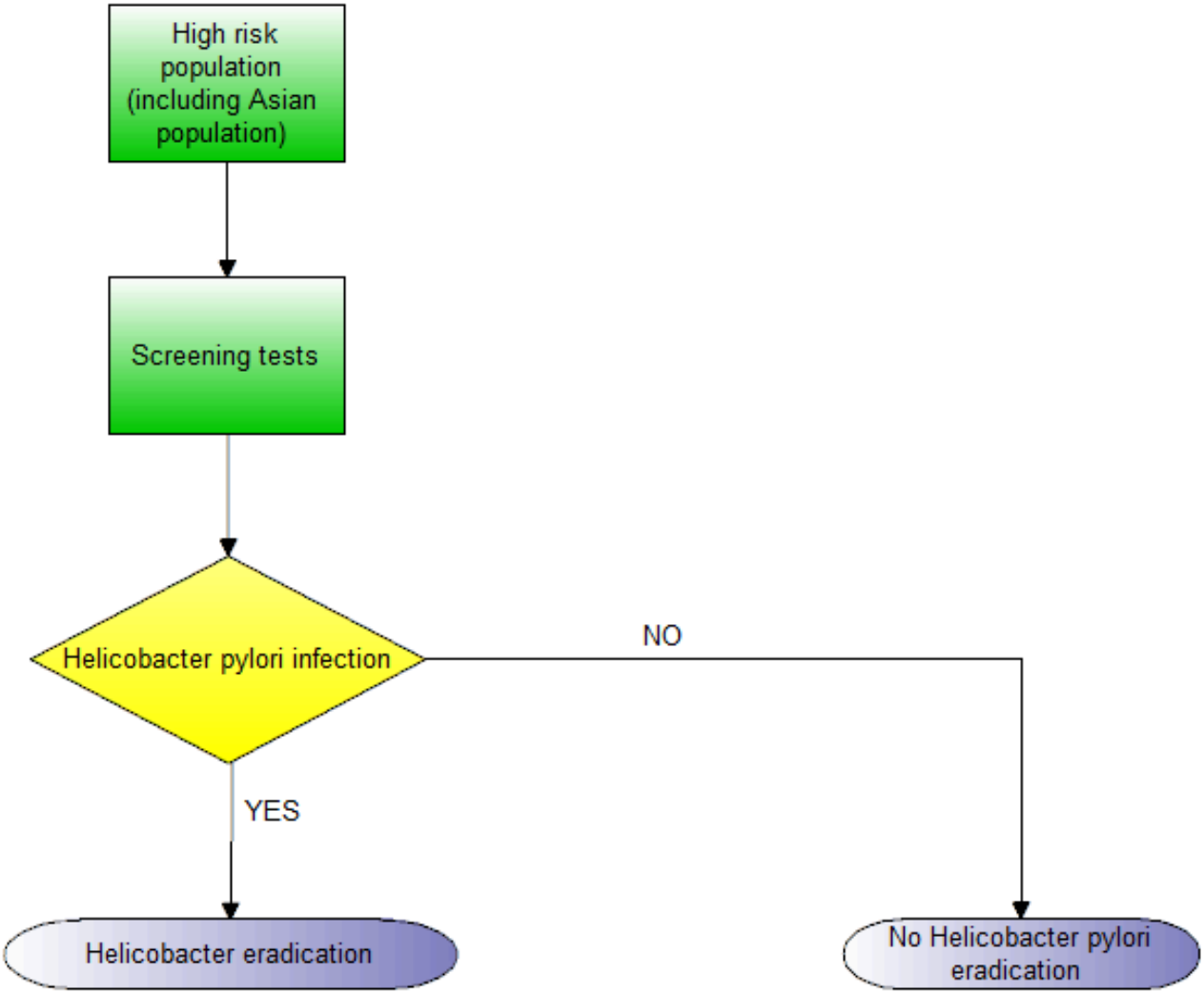
Evidence from randomised controlled trials (RCTs) showed that screening and eradication programmes for *H pylori* in populations at high risk of gastric cancer (e.g. East Asians) lowered the incidence of gastric cancer (Ford 2014). The Asia-Pacific Gastric Cancer Consensus conference recommended that screening and eradication of *H pylori* was advisable in populations in countries at high risk of gastric cancer (i.e. Japan and Korea) (Talley 2008). The updated European Helicobacter Study Group (EHSG) Fourth Maastricht/Florence Consensus Conference guidelines suggest that

people should be tested for *H pylori,* and eradication of *H pylori* (when present) has been recommended for the following conditions (Malfertheiner 2012):

1. People at high risk of gastric cancer.
2. Adults with dyspepsia with a locally-determined age cut-off point (depending on local incidence of gastric cancer in different age groups), and without 'alarm' symptoms or signs associated with an increased risk of gastric cancer such as weight loss, dysphagia, upper gastrointestinal bleeding, abdominal mass, or iron deficient anaemia.
3. Unexplained iron deficiency anaemia.
4. Idiopathic thrombocytopenic purpura.
5. Uninvestigated young patients with dyspepsia should also be considered for testing for *H pylori* when the prevalence of *H pylori* is high (≥ 20%).

The clinical pathway is shown in Figure 1.

Figure 1. Clinical pathway



Prior test(s)

The index tests can be performed without any prior test.

Role of index test(s)

The index tests are used for screening and diagnosis of *H pylori*.

Alternative test(s)

Other tests used in the screening and diagnosis of *H pylori* infection include non-invasive saliva and urine antigen-based tests (Ricci 2007), and invasive gastric biopsy followed by Campylobacter-like organism (CLO) test, culture, histology, and polymerase chain reaction (PCR) (Van Doorn 2000). We do not include non-invasive saliva and urine antigen-based tests in this review because these tests are not commonly used (Ricci 2007).

Rationale

Testing for *H pylori* and eradication of *H pylori* have been recommended for a number of population groups (Clinical pathway). These tests have to be non-invasive so that a large number of people can be tested. People with undetected *H pylori* continue to be at high risk of gastric cancer or continue to have

dyspepsia, anaemia, or purpura. Overdiagnosis (false positive test results) of *H pylori* means that patients are subject to unnecessary adverse events related to eradication therapy (approximately 27% of patients receiving eradication therapy develop mild adverse events such as bitter taste, nausea, diarrhoea, etc.). Comparing the diagnostic accuracy of different index tests will highlight the best test for the diagnosis of *H pylori* infection.

OBJECTIVES

To compare the diagnostic accuracy of urea breath test, serology, and stool antigen test, alone or in combination, for diagnosis of *H pylori* infection in symptomatic and asymptomatic people, so that eradication therapy for *H pylori* can be started.

Secondary objectives

To investigate the following potential sources of heterogeneity: type of reference standard, risk of bias, publication status, prospective versus retrospective studies, symptomatic versus asymptomatic participants, recent or current use of proton pump inhibitors or antibiotics, different subtypes of tests, and the interval between the index test and reference standard.

METHODS

Criteria for considering studies for this review

Types of studies

We include studies that evaluate the accuracy of the index tests in the appropriate patient population (see Participants), regardless of language or publication status, or whether data were collected prospectively or retrospectively. However, we exclude reports that describe how the diagnosis of *H pylori* was made in an individual patient or group of patients, and which do not provide sufficient diagnostic test accuracy data (i.e. the number of true positives, false positives, false negatives, and true negatives). We also exclude case-control studies because these are prone to bias (Whiting 2011).

Participants

Symptomatic and asymptomatic people in whom *H pylori* infection status is sought so that eradication therapy for *H pylori* can be started. We exclude studies that included only people with acute upper gastrointestinal bleeding because such patients are likely to undergo endoscopy and invasive testing can be performed, if required.

Index tests

Urea breath test-^{14}C, urea breath test-^{13}C, serology, and stool antigen test, alone or in combination. We included only initial testing and excluded repeat testing (monitoring success of treatment), since diagnostic accuracy may vary depending on the purpose of testing (Ricci 2007).

Target conditions

H pylori infection.

Reference standards

There is no gold standard for diagnosis of *H pylori* infection and the diagnosis is made by a combination of tests following endoscopic biopsy; endoscopic biopsy followed by histology, endoscopic biopsy followed by polymerase chain reaction (PCR), and endoscopic biopsy followed by rapid urease testing all have excellent sensitivity and specificity (Chey 2007). However, PCR methodology is not standardised across laboratories (Chey 2007); it is an unreliable reference standard. Endoscopic biopsy followed by rapid urease testing has poor sensitivity following treatment with proton pump inhibitors (Chey 2007). Endoscopic biopsy with culture has high specificity but poor sensitivity (Chey 2007). We therefore considered only endoscopic biopsy followed by histology (using haemotoxylin and eosin (H & E) stain, special histological stains such as Giemsa stain and Warthin-Starry stain, or immunohistochemical stain) as the reference standard in this review.

Immunohistochemical stains are more accurate than special stains, while special stains and immunohistochemical stains are thought to have better specificity than H & E stains for diagnosis of *H pylori* infection (Laine 1997; Lee 2015b). For this reason,we considered endoscopic biopsy with histology using immunohistochemical stain as the best reference standard, and endoscopic biopsy with histology using H & E stain as the worst reference standard.

Search methods for identification of studies

We included all studies, irrespective of the language of publication and publication status. If we found articles in languages other than English, we obtained translations.

Electronic searches

We searched the following databases.

1. MEDLINE via OvidSP (January 1946 to 4 March 2016) (Appendix 2).
2. Embase via OvidSP (January 1947 to 4 March 2016) (Appendix 3).
3. Science Citation Index Expanded via Thomson Reuters Web of Science (January 1980 to 4 March 2016) (Appendix 4).
4. National Institute for Health Research (NIHR HTA) via Centre for Reviews and Dissemination, University of York. (www.crd.york.ac.uk/CRDWeb/) (4 March 2016) (Appendix 5).

Searching other resources

To identify additional studies, we examined references in the included studies to see if any might be relevant. We also searched for articles related to the included studies by using the 'related search' function in MEDLINE (OvidSP) and Embase (OvidSP). We conducted a 'citing reference' search (by searching articles which cited the included articles) (Sampson 2008) in MEDLINE (OvidSP) and Embase (OvidSP) on 4 December 2016.

Data collection and analysis

Selection of studies

Two review authors (KG and LB, SS, or AS) independently searched the references to identify relevant studies. We obtained the full text for references considered relevant by at least one of the two review authors. Two review authors independently screened the full-text papers against the inclusion criteria, resolving any differences in study selection by discussion. We attempted to contact study authors if there were doubts about the eligibility of a study.

Data extraction and management

Two review authors (KG and LB, SS, or AS) independently extracted the following data from each included study, using a pre-piloted data extraction form, and resolving differences by discussion.

1. First author.
2. Year of publication.
3. Study design (prospective or retrospective cohort studies; cross-sectional studies or randomised controlled trials).
4. Inclusion and exclusion criteria for individual studies.
5. Total number of participants.
6. Number of female participants.
7. Average age of the participants.
8. Initial testing versus testing after eradication.
9. Number of people with bleeding ulcers, gastric atrophy, lymphoma, and recent or current use of proton pump inhibitors or antibiotics.
10. Number of symptomatic participants.
11. Tests carried out prior to the index test.
12. Description of the index test.
13. Threshold used for the index test.
14. Reference standard.
15. Number of true positives, false positives, false negatives, and true negatives (i.e. 2 x 2 data) at each threshold reported.

If a study reported multiple index tests, we extracted the 2 x 2 data for each index test at each threshold. For studies that reported test accuracy for different reference standards, we extracted 2 x 2 data for only one of the reference standards. For this purpose, due to the accuracy of the stains, we preferred the immunohistochemical stain over special stains, which in turn we preferred over the H & E stain.

Although the number of uninterpretable index test results may provide information on the applicability of the tests in clinical practice and may affect the cost effectiveness of a test, we had planned to exclude patients with uninterpretable index test results from the meta-analyses. We made this decision because in clinical practice uninterpretable index test results would result in additional testing. Nevertheless, we would have extracted and reported such data if available from the studies.

If we suspected an overlap of participants between multiple reports due to common study authors and centres, we planned to contact the study authors for clarification; however, this was not required, since we could identify multiple reports of the same study using the information provided in the reports. We sought further information from study authors, if necessary.

Assessment of methodological quality

Two review authors independently assessed study quality using the QUADAS-2 tool (Whiting 2006; Whiting 2011), resolving differences by discussion. The criteria used for the assessment are shown in Appendix 6. We considered studies classified as 'low risk of bias' and 'low concern' in all the domains of the QUADAS-2 tool as studies with high methodological quality. It must be noted here that 'risk of bias' refers to internal validity (i.e. whether there were systematic errors in performing the study with respect to the particular domain), while 'applicability concern' refers to external validity (i.e. whether there were concerns that the population, index test or reference standard used in the studies matched the review question).

Statistical analysis and data synthesis

We plotted study estimates of sensitivity and specificity on forest plots and in receiver operating characteristic (ROC) space to explore between-study variation in the accuracy of each test. We examined the thresholds reported for each test and the reference standards used. Due to between-study variation in thresholds, we performed meta-analyses by using the hierarchical summary receiver operating characteristics (HSROC) model to estimate SROC curves (Rutter 2001). For these analyses, if a study reported test accuracy at multiple thresholds, we selected the threshold used by the study authors for their primary analysis.

Prior to comparative meta-analyses of the tests, we performed meta-analysis of each test separately for preliminary investigation of the shape of the SROC curve of each test and to assess heterogeneity in test performance. We used this approach to understand the data and to guide modelling assumptions we may need to make in the comparative meta-analysis. These preliminary analyses were done noting the availability of comparative studies. To compare the accuracy of the index tests, we added test type as a covariate to the HSROC model (Macaskill 2013). For the indirect comparison where we used all available data (i.e. not restricted to comparative studies), we assessed the effect of test type on the accuracy, threshold, and shape parameters of the HSROC model. We also explored the effect of test type on the variance of the random effects for accuracy and threshold. To determine the final meta-analytic model, we used likelihood ratio tests to assess model fit. Likelihood ratio tests were also used to determine the statistical significance of differences in test accuracy. When SROC curves are symmetric (i.e. HSROC model without the shape parameter), each curve can be described using the diagnostic odds ratio (DOR) to quantify the accuracy of the test. We used the ratio of DORs as a summary of the relative accuracy of two tests.

Summary sensitivities and specificities can be obtained from a HSROC model but they are not clinically interpretable here because we included studies with different thresholds. We therefore estimated sensitivities at points on the SROC curves that correspond to the lower quartile, median and upper quartile of the specificities from the studies included in the meta-analysis. When comparative studies that had evaluated two tests head-to-head were available, we performed direct comparisons of the tests (Takwoingi 2013). For these analyses, we fitted HSROC models with symmetric SROC curves, as the available data were insufficient for reliable estimation of the shape of the SROC curves (Takwoingi 2017).

If there were at least two studies that reported the accuracy of a test at the same threshold, we considered meta-analysis to obtain summary estimates of sensitivity and specificity. Due to the small number of studies in these analyses, we performed meta-analyses using univariate fixed-effect or random-effects logistic regression models, depending on the extent of heterogeneity observed in forest plots and in ROC space (Takwoingi 2017). When there were only two or three studies at the same threshold, and little or no heterogeneity observed in ROC space, we used univariate fixed-effect logistic regression models to pool sensitivities and specificities separately. When there were two or three studies and we observed heterogeneity, we did not perform meta-analysis,

as random-effects models would be more appropriate in such situations. However, random effects cannot be reliably estimated with very few studies.

We performed meta-analyses using the NLMIXED procedure in SAS.

Investigations of heterogeneity

We used forest plots and scatter plots of sensitivity against specificity for preliminary investigation of potential sources of heterogeneity such as:

1. Type of reference standard (different histological stains).
2. Studies at low risk of bias in all the QUADAS-2 domains versus those at unclear or high risk of bias.
3. Full-text publications versus abstracts (may provide insight into publication bias if there is an association between the results of a study and full publication of the study) (Eloubeidi 2001).
4. Prospective versus retrospective studies.
5. Symptomatic versus asymptomatic participants.
6. Recent or current use of proton pump inhibitors or antibiotics, as these patients are at higher risk of false negative results for the urea breath test and stool antigen test, with serology being the only non-invasive test unaffected by the use of proton pump inhibitors or antibiotics (Malfertheiner 2012; Ricci 2007).
7. Different subtypes of tests (ELISA, latex agglutination test, and Western blot methods of serological tests; formal serological tests versus bedside serological tests; and monoclonal versus polyclonal antibodies for stool antigen tests).
8. Interval between index test and reference standard. Resolution of *H pylori* infection in people with *H pylori* infection (usually with treatment) and infection in those without *H pylori* infection may occur if there was a long interval between the index test and reference standard.

We formally investigated heterogeneity for each test by adding a covariate to a HSROC model (meta-regression). We used likelihood ratio tests to assess the statistical significance of differences in test accuracy by comparing models with and without the covariate.

Sensitivity analyses

We planned to examine the impact of data inconsistencies on the meta-analytic findings. For example, if test accuracy data reported in the text of a paper differed from those in the figures, we planned to assess the impact of using different data in sensitivity analyses; however, we did not find such inconsistencies.

Assessment of reporting bias

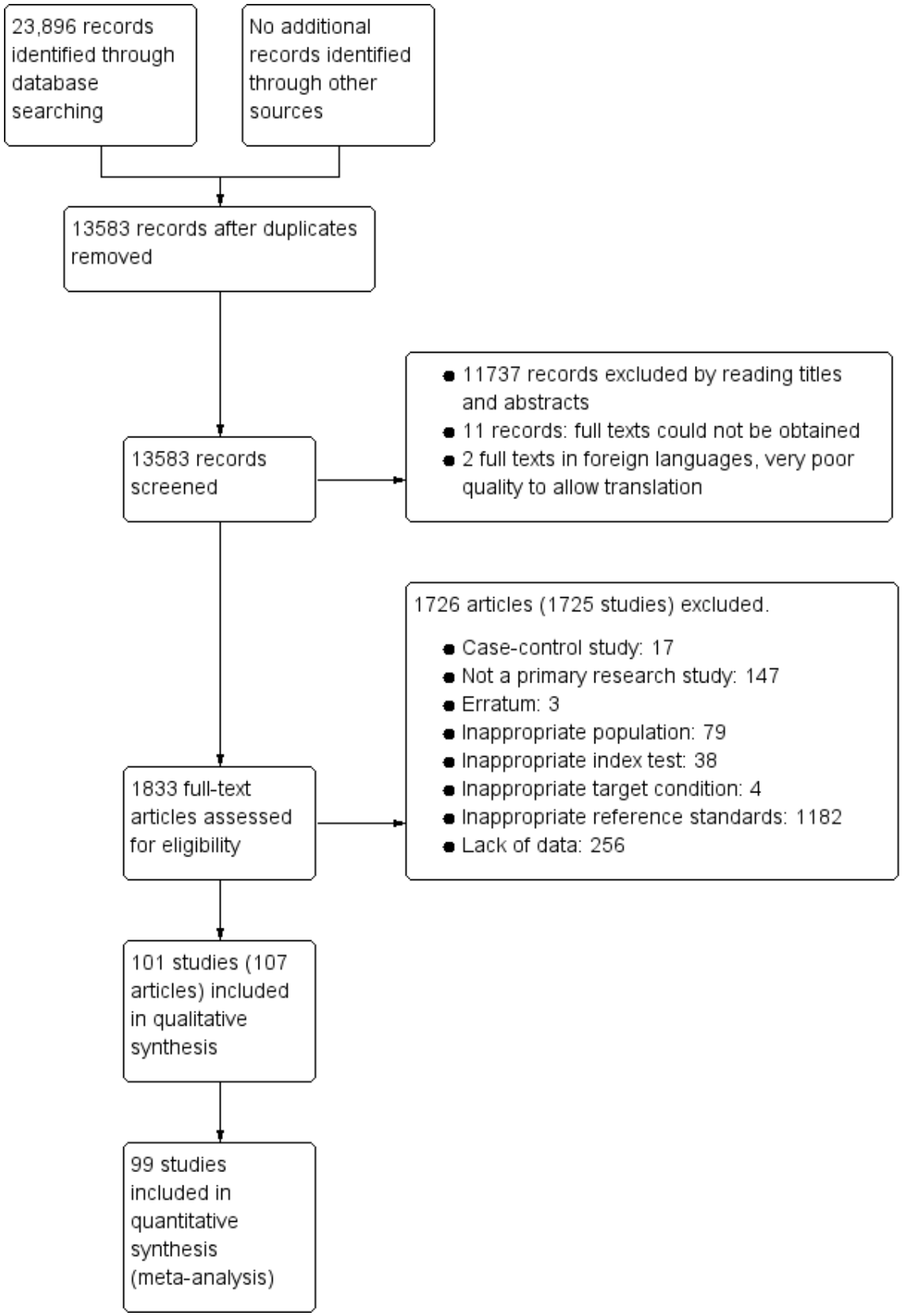
Due to limited data, we were unable to formally investigate whether test accuracy differed between studies that were published as full texts and those available only as abstracts.

RESULTS

Results of the search

We identified 23,896 references through electronic searches of MEDLINE, Embase, Science Citation Index, and NIHR HTA. We did not identify additional references through other searches. The flow of studies through the screening process is shown in Figure 2. After removing 10,313 duplicates, there were 13,583 references. Of these, we dropped 11,737 irrelevant references through reading the titles and abstracts. We could not obtain the full text of 11 references. The quality of copies of two references was too poor to allow translation and we were unable to obtain better copies. We assessed the full text of the remaining 1833 references. We excluded 1728 references (1727 studies) for reasons stated in Appendix 7 (also see Characteristics of excluded studies below). The remaining 107 references (101 studies) met our inclusion criteria. Two references reported diagnostic accuracy data separately for people who underwent gastrectomy and those who did not undergo gastrectomy, and so we considered these subgroups as separate studies (Adamopoulos 2009a; Adamopoulos 2009b; Sheu 1998a; Sheu 1998b).

Figure 2. Study flow diagram.



Characteristics of included studies

We summarise the characteristics of the 101 included studies in the Characteristics of included studies table. The studies included 11,003 participants, of which 5839 participants (53.1%) had *H pylori* infection. The prevalence of *H pylori* infection ranged from 15.2% to 94.7% with a median of 53.7% (interquartile range: 42.0% to 66.5%).

Of the 101 studies, 34 evaluated urea breath test-^{13}C; 21 evaluated urea breath test-^{14}C; two evaluated urea breath test but did not report the isotope used; 34 evaluated serology; and 29 evaluated stool antigen test. Seventeen studies evaluated more than one test. Of these, 15 evaluated two tests (Dede 2015; El-Din 2013; Eltumi 1999; Hafeez 2007; Inelmen 2004; Korstanje 2006; Kuloglu 2008; Lahner 2004; Lottspeich 2007; Mansour-Ghanaei 2011; Ogata 2001; Soomro 2012; Vandenplas 1992; Yoshimura 2001; Yu 2001), and two evaluated three tests (Monteiro 2001a; Salles-Montaudon 2002). Studies used different thresholds, with 15 studies reporting test accuracy at more than one threshold (Chey 1998; Dede 2015; Delvin 1999; Formichella 2013; Ladas 2002a; Mana 2001a; Misawa 1998; Monteiro 2001a; Morales 1995; Noguera 1998; Novis 1991; Ozturk 2003; Trevisani 2005; Weiss 1994; Yu 2001).

Eleven studies were prospective (Adamopoulos 2009a; Adamopoulos 2009b; Al-Fadda 2000; Arikan 2004; Dede 2015; Eltumi 1999; Fallone 1995; Kalach 1998a; Kuloglu 2008; Ogata 2001; Qadeer 2009); six studies were retrospective (Bosso 2000; Czerwionka-Szaflarska 2007; Graham 1996a; Iqbal 2013; Mion 1994; Wardi 2012), while the remaining 84 studies did not state whether they were prospective or retrospective studies. Six studies were published as abstracts only (Han 2012; Mohammadian 2007; Rathbone 1986; Sheu 1998a; Sheu 1998b; Thobani 1995), and the remaining 95 were full-text publications.

Fourteen studies included only children (Argentieri 2007; Behrens 1999; Czerwionka-Szaflarska 2007; Delvin 1999; Dinler 1999; Eltumi 1999; Hafeez 2007; Kalach 1998a; Kuloglu 2008; Lottspeich 2007; Ogata 2001; Rafeey 2007; Vandenplas 1992; Yoshimura 2001). Five studies clearly included only adults (Atli 2012; Chen 1991; Kamel 2011; Safe 1993; Salles-Montaudon 2002). Although not clearly specified in the remaining 82 studies, it appeared that most or all of the participants were adults. The mean or median age of the participants included in these studies ranged between 31 years and 85 years in the 45 studies that reported this information. One study included only participants without symptoms (Wang 2008). Fifty-eight studies included only participants with symptoms, usually abdominal pain or dyspepsia (Adamopoulos 2009a; Adamopoulos 2009b; Aguilar 2007; Al-Fadda 2000; Allardyce 1997; Behrens 1999; Bosso 2000; Ceken 2011; Chen 1991; Czerwionka-Szaflarska 2007; D'Elios 2000; Delvin 1999; Dinler 1999; Ekesbo 2006; El-Din 2013; El-Mekki 2011; El-Nasr 2003; Eltumi 1999; Fanti 1999; Faruqui 2007; Ferrara 1998; Germana 2001; Guo 2011; Gurbuz 2005; Hafeez 2007; Jordaan 2008; Kamel 2011; Kuloglu 2008; Ladas 2002a; Lahner 2004; Lee 1998; Lottspeich 2007; Mansour-Ghanaei 2011; Mion 1994; Misawa 1998; Mohammadian 2007; Morales 1995; Novis 1991; Ogata 2001; Ozturk 2003; Peitz 2001; Qadeer 2009; Rafeey 2007; Rasool 2007; Rathbone 1986; Safe 1993; Scuderi 2000; Segamwenge 2014; Selcukcan 2011; Sharbatdaran 2013; Sheu 1998a; Soomro 2012; Surveyor 1989; Thobani 1995; Vandenplas 1992; Villalobos 1992; Weiss 1994; Yoshimura 2001). The remaining 42 studies did not report the type of participants included. Five studies included only participants who had previously undergone gastrectomy (Adamopoulos 2009b; Lombardo 2003; Schilling 2001; Sheu 1998b; Wardi 2012). Two studies included only participants with atrophic gastritis (Korstanje 2006; Ogata 2001). It was clear that participants who received recent proton pump inhibitors or antibiotics were excluded from 53 studies (Ceken 2011; Chey 1998; Debongnie 1991; D'Elios 2000; Delvin 1999; Duan 1999; El-Mekki 2011; El-Nasr 2003; Eltumi 1999; Fallone 1996; Fanti 1999; Ferrara 1998; Formichella 2013; Germana 2001; Guo 2011; Gurbuz 2005; Jekarl 2013; Jensen 1998; Jordaan 2008; Kalach 1998a; Kim 2016; Kuloglu 2008; Ladas 2002a; Lahner 2004; Lee 1998; Lombardo 2003; Lottspeich 2007; Mana 2001a; Mansour-Ghanaei 2011; Monteiro 2001a; Ogata 2001; Ozturk 2003; Peitz 2001; Peura 1996; Puspok 1999; Qadeer 2009; Rafeey 2007; Rasool 2007; Schilling 2001; Segamwenge 2014; Selcukcan 2011; Sharbatdaran 2013; Shin 2009; Tiwari 2014; Trevisani 2005; Vandenplas 1992; Villalobos 1992; Wang 2008; Weiss 1994; Yan 2003; Yoshimura 2001; Yu 1999; Yu 2001). It was not clear whether such participants were included or excluded in the remaining 48 studies.

Thirty-two studies used H & E stain as a reference standard (Aguilar 2007; Al-Fadda 2000; Arikan 2004; Atli 2012; Behrens 1999; Ceken 2011; Chen 1991; Chey 1998; Czerwionka-Szaflarska 2007; D'Elios 2000; Dinler 1999; Eggers 1990; El-Nasr 2003; Fallone 1996; Faruqui 2007; Graham 1996a; Gramley 1999; Gurbuz 2005; Iqbal 2013; Jordaan 2008; Kalach 1998a; Kamel 2011; Lee 1998; Logan 1991a; Noguera 1998; Puspok 1999; Segamwenge 2014; Selcukcan 2011; Sheu 1998a; Sheu 1998b; Tiwari 2014; Yu 2001); 24 studies used special stains such as Warthin-Starry stain, Giemsa stain, or silver stain (Argentieri 2007; Bosso 2000; El-Din 2013; Fallone 1995; Guo 2011; Hafeez 2007; Han 2012; Ivanova 2010; Kim 2016; Ladas 2002a; Lahner 2004; Mion 1994; Mohammadian 2007; Morales 1995; Novis 1991; Ozturk 2003; Peura 1996; Qadeer 2009; Schilling 2001; Scuderi 2000; Shin 2009; Soomro 2012; Villalobos 1992; Yan 2003); two studies used immunohistochemical staining (Ekesbo 2006; Misawa 1998); and the remaining 43 studies used a combination of different stains.

The interval between the index test and reference standard was reported only in 21 studies. The interval was less than two weeks in 19 of the 21 studies (Adamopoulos 2009a; Adamopoulos 2009b; Bosso 2000; Debongnie 1991; Duan 1999; Fallone 1995; Fallone 1996; Formichella 2013; Gurbuz 2005; Hafeez 2007; Lahner 2004; Lee 1998; Logan 1991a; Lottspeich 2007; Mansour-Ghanaei 2011; Mion 1994; Ozturk 2003; Peura 1996; Safe 1993), and was between 15 days and 23 days in one study (Dede 2015); it was within 30 days in the remaining study (Lombardo 2003).

Characteristics of excluded studies

We excluded 1726 references (1725 studies). The reason for exclusion is stated for each study in Appendix 7 and summarised below.

- Case-control study: 17
- Not a primary research study: 147
- Erratum: 3
- Inappropriate population: 79
  - In monitoring: 33
  - Not in humans: 1
  - Only in *H pylori* negative people: 2
  - Only in *H pylori* positive people: 39
  - Only in people with gastrointestinal bleeding: 2

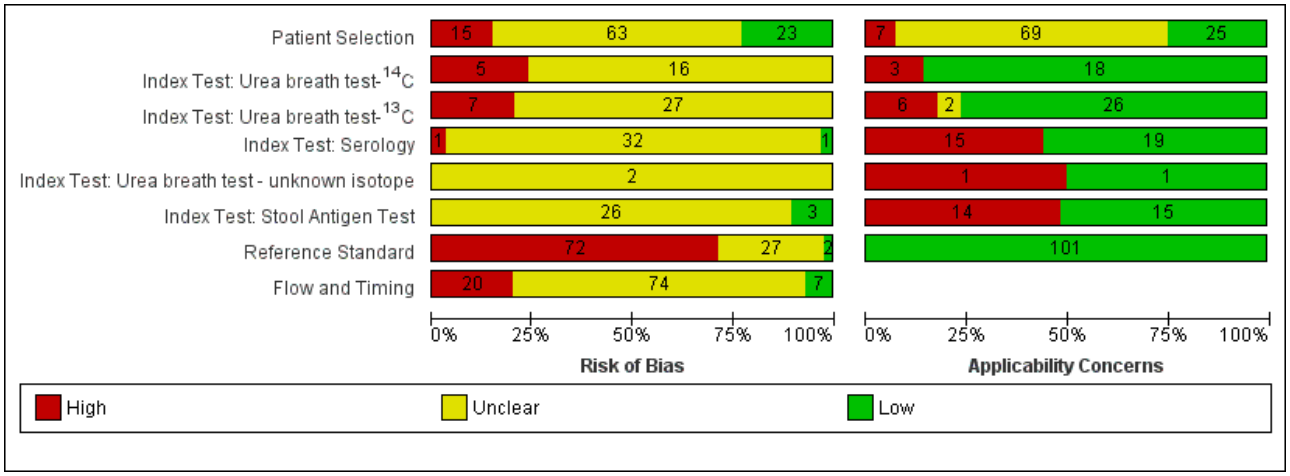
- Selection of participants was based on the results of other *H pylori* tests: 1
- Includes people who were being monitored for *H pylori* status: 1

- Inappropriate index test: 38
- Inappropriate target condition: 4
- Inappropriate reference standards: 1182
- Lack of data: 256
  - Insufficient diagnostic test accuracy data: 25
  - No diagnostic accuracy data: 42
  - Not a diagnostic test accuracy study of non-invasive *H pylori* diagnosis: 188
  - Incorrect data (correct information could not be obtained): 1

Methodological quality of included studies

The methodological quality of the included studies is summarised across all studies in Figure 3. None of the included studies was of high methodological quality (i.e. low risk of bias in all the domains). Appendix 8 shows the results for individual studies for urea breath test-^{13}C, urea breath test-^{14}C, serology and the stool antigen test, respectively.

Figure 3. Risk of bias and applicability concerns graph: review authors' judgements about each domain presented as percentages across included studies. For each domain, the numbers shown on the bar represent the number of studies that were scored as high, unclear or low in terms of risk of bias or applicability concern.



Patient selection domain

In the patient selection domain, 23, 15 and 63 studies were at low, high and unclear risk of bias, respectively. All 15 studies were at high risk of bias because they did not include a consecutive or random series of participants.

Twenty-five, seven and 69 studies were of low, high and unclear applicability concern. In the 69 studies of unclear applicability concern it was not clear whether participants similar to those seen in the clinical setting where the test is used were excluded, while the seven studies of high concern clearly excluded such participants. In these seven studies, only people who had undergone gastrectomy or those with atrophic gastritis were included.

Index test domain

In the index test domain, studies generally had an unclear risk of bias because it was unclear whether the index test results were interpreted without the knowledge of the results of the reference standard, and/or it was unclear whether a threshold was prespecified.

Urea breath test

None of the studies that evaluated the urea breath test (^{13}C, ^{14}C, or unknown isotope) were at low risk of bias. The risk of bias was unclear in the two studies that did not report the type of isotope (Han 2012; Lombardo 2003). Of the 34 studies that evaluated urea breath test-^{13}C, seven (21%) had a high risk of bias while 27 (79%) had unclear risk of bias. There were 21 studies of urea breath test-^{14}C, 16 (76%) of which had unclear risk of bias while five (24%) had high risk of bias.

For the two studies with unknown isotope, applicability concern was high in one study and low in the other. Of the 34 urea breath test-^{13}C studies, applicability concerns were unclear for two (6%) studies, high for six (18%) studies and low for 26 (76%) studies. For urea breath test-^{14}C, applicability concerns were generally low (18/21; 86%) with only three studies having high applicability concerns (Selcukcan 2011; Surveyor 1989; Yu 1999) .

Serology

One study (Ladas 2002a), had a low risk of bias.and another study (Rathbone 1986), had a high risk of bias. The risk of bias for the remaining 32 (94%) studies was unclear. Applicability concerns were low in 19 (56%) studies and high in 15 (44%) studies.

Stool antigen test

None of the 29 studies had a high risk of bias. Most of the studies (26/29; 90%) had an unclear risk of bias; three studies (Islam 2005; Kuloglu 2008; Sharbatdaran 2013), had a low risk of bias. All the studies were of low applicability concern.

Reference standard domain

Two studies were at low risk of bias in the reference standard domain (Fallone 1995; Ladas 2002a). For 27 studies, the risk of bias was unclear because it was not clear whether reference standard results were interpreted without knowledge of the results of the index tests. The remaining 72 studies were at high risk of bias because the reference standard was endoscopic biopsy with H & E stain in some or all participants.

All the studies were of low applicability concern.

Flow and timing domain

Seven studies were at low risk of bias in the flow and timing domain. The risk of bias was unclear for 74 studies because the interval between the index test and reference standard was unclear or it was unclear whether all participants were included in the analysis. The remaining 20 studies were at high risk of bias because some participants were clearly excluded from the analysis. These studies did not report the reference standard results for the excluded participants. None of the studies reported indeterminate results (i.e. there were no indeterminate index test results in studies which provided a clear participant flow and none of the exclusions were due to indeterminate index test results).

Findings

Urea breath test-^{13}C

The 34 studies of urea breath test-^{13}C included 3139 participants, of whom 1526 had *H pylori* infection (Figure 4). The threshold used in six studies was either unknown (Eggers 1990; Monteiro 2001a), or unclear (Sheu 1998a; Sheu 1998b; Vandenplas 1992; Wardi 2012). At the most commonly reported threshold of delta over baseline > 4% (30 minutes after administration of urea), the summary sensitivity (95% confidence interval (CI)) and specificity (95% CI) from 10 studies (958 participants) were 0.95 (95% CI 0.79 to 0.99) and 0.95 (95% CI 0.87 to 0.98). Other thresholds were used by a limited number of studies (Figure 5; Appendix 9). When possible we performed meta-analysis to estimate summary sensitivities and specificities at these common thresholds. The results are presented in Table 1.

Figure 4. Forest plot of urea breath test-^{13}C.FN = false negative; FP = false positive; TN = true negative; TP = true positive. The forest plot shows an estimate of sensitivity and specificity from each study and the threshold used. Studies are sorted by threshold, sensitivity and specificity. For threshold, the number of minutes in brackets is the time after administration of urea.

Study	TP	FP	FN	TN	Threshold	Sensitivity (95% CI)	Specificity (95% CI)
Mion 1994	32	6	1	56	> +3 delta 0/00 (30 mins)	0.97 [0.84, 1.00]	0.90 [0.80, 0.96]
Ogata 2001	22	8	1	16	>3% excretion (time unknown)	0.96 [0.78, 1.00]	0.67 [0.45, 0.84]
Epple 1997	74	7	3	42	>Mean +2 SDs above normal (30 mins)	0.96 [0.89, 0.99]	0.86 [0.73, 0.94]
Logan 1991a	31	0	3	16	>Mean +3 SDs above normal (60 mins)	0.91 [0.76, 0.98]	1.00 [0.79, 1.00]
Kim 2016	54	18	4	31	DOB >2.5% (20 mins)	0.93 [0.83, 0.98]	0.63 [0.48, 0.77]
Yu 2001	12	3	4	13	DOB >2.8% (15 mins)	0.75 [0.48, 0.93]	0.81 [0.54, 0.96]
Yoshimura 2001	42	3	2	25	DOB >3.0% (20 & 30 mins)	0.95 [0.85, 0.99]	0.89 [0.72, 0.98]
Mana 2001a	84	6	0	92	DOB >3.0% (30 mins)	1.00 [0.96, 1.00]	0.94 [0.87, 0.98]
Delvin 1999	12	0	0	67	DOB >3.0% (30 mins)	1.00 [0.74, 1.00]	1.00 [0.95, 1.00]
Salles-Montaudon 2002	18	19	6	64	DOB >3.5% (30 mins)	0.75 [0.53, 0.90]	0.77 [0.67, 0.86]
Czerwionka-Szaflarska 2007	21	5	10	64	DOB >4.0 % (time unknown)	0.68 [0.49, 0.83]	0.93 [0.84, 0.98]
Hafeez 2007	31	8	3	12	DOB >4.0% (10/ 20/ 30 mins)	0.91 [0.76, 0.98]	0.60 [0.36, 0.81]
Adamopoulos 2009b	6	0	9	16	DOB >4.0% (30 mins)	0.40 [0.16, 0.68]	1.00 [0.79, 1.00]
Schilling 2001	13	3	12	40	DOB >4.0% (30 mins)	0.52 [0.31, 0.72]	0.93 [0.81, 0.99]
Korstanje 2006	5	3	1	11	DOB >4.0% (30 mins)	0.83 [0.36, 1.00]	0.79 [0.49, 0.95]
Bosso 2000	32	6	1	56	DOB >4.0% (30 mins)	0.97 [0.84, 1.00]	0.90 [0.80, 0.96]
D'Elios 2000	113	2	3	138	DOB >4.0% (30 mins)	0.97 [0.93, 0.99]	0.99 [0.95, 1.00]
Germana 2001	54	1	1	44	DOB >4.0% (30 mins)	0.98 [0.90, 1.00]	0.98 [0.88, 1.00]
Fallone 1995	23	1	0	26	DOB >4.0% (30 mins)	1.00 [0.85, 1.00]	0.96 [0.81, 1.00]
Adamopoulos 2009a	43	1	0	29	DOB >4.0% (30 mins)	1.00 [0.92, 1.00]	0.97 [0.83, 1.00]
Lahner 2004	5	3	5	14	DOB >4.5% (15 & 30 mins)	0.50 [0.19, 0.81]	0.82 [0.57, 0.96]
Jordaan 2008	55	3	5	40	DOB >4.5% (time unknown)	0.92 [0.82, 0.97]	0.93 [0.81, 0.99]
Duan 1999	96	5	7	41	DOB >5 per thousand (30 mins)	0.93 [0.86, 0.97]	0.89 [0.76, 0.96]
Eltumi 1999	17	3	2	28	DOB >5 units/ml (40 mins)	0.89 [0.67, 0.99]	0.90 [0.74, 0.98]
Behrens 1999	129	7	7	98	DOB >5.0% (30 & 60 mins)	0.95 [0.90, 0.98]	0.93 [0.87, 0.97]
Inelmen 2004	41	7	13	61	DOB >5.0% (30 mins)	0.76 [0.62, 0.87]	0.90 [0.80, 0.96]
Lottspeich 2007	41	0	0	15	DOB >5.0% (30 mins)	1.00 [0.91, 1.00]	1.00 [0.78, 1.00]
Lee 1998	46	1	1	23	DOB >6% (30 mins)	0.98 [0.89, 1.00]	0.96 [0.79, 1.00]
Sheu 1998b	20	0	14	32	Unclear	0.59 [0.41, 0.75]	1.00 [0.89, 1.00]
Wardi 2012	9	6	5	56	Unclear	0.64 [0.35, 0.87]	0.90 [0.80, 0.96]
Vandenplas 1992	24	5	3	63	Unclear	0.89 [0.71, 0.98]	0.93 [0.84, 0.98]
Sheu 1998a	106	1	2	26	Unclear	0.98 [0.93, 1.00]	0.96 [0.81, 1.00]
Monteiro 2001a	43	2	3	56	Unknown	0.93 [0.82, 0.99]	0.97 [0.88, 1.00]
Eggers 1990	41	31	0	28	Unknown	1.00 [0.91, 1.00]	0.47 [0.34, 0.61]

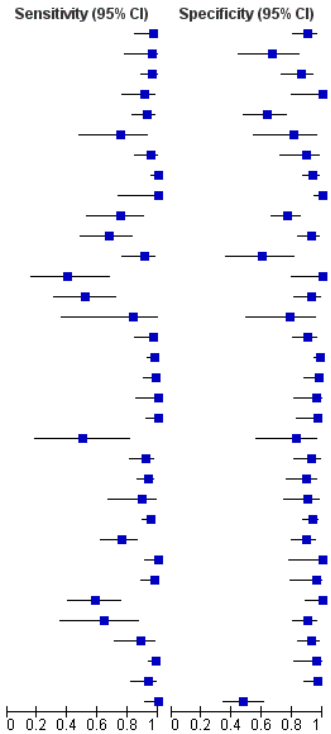
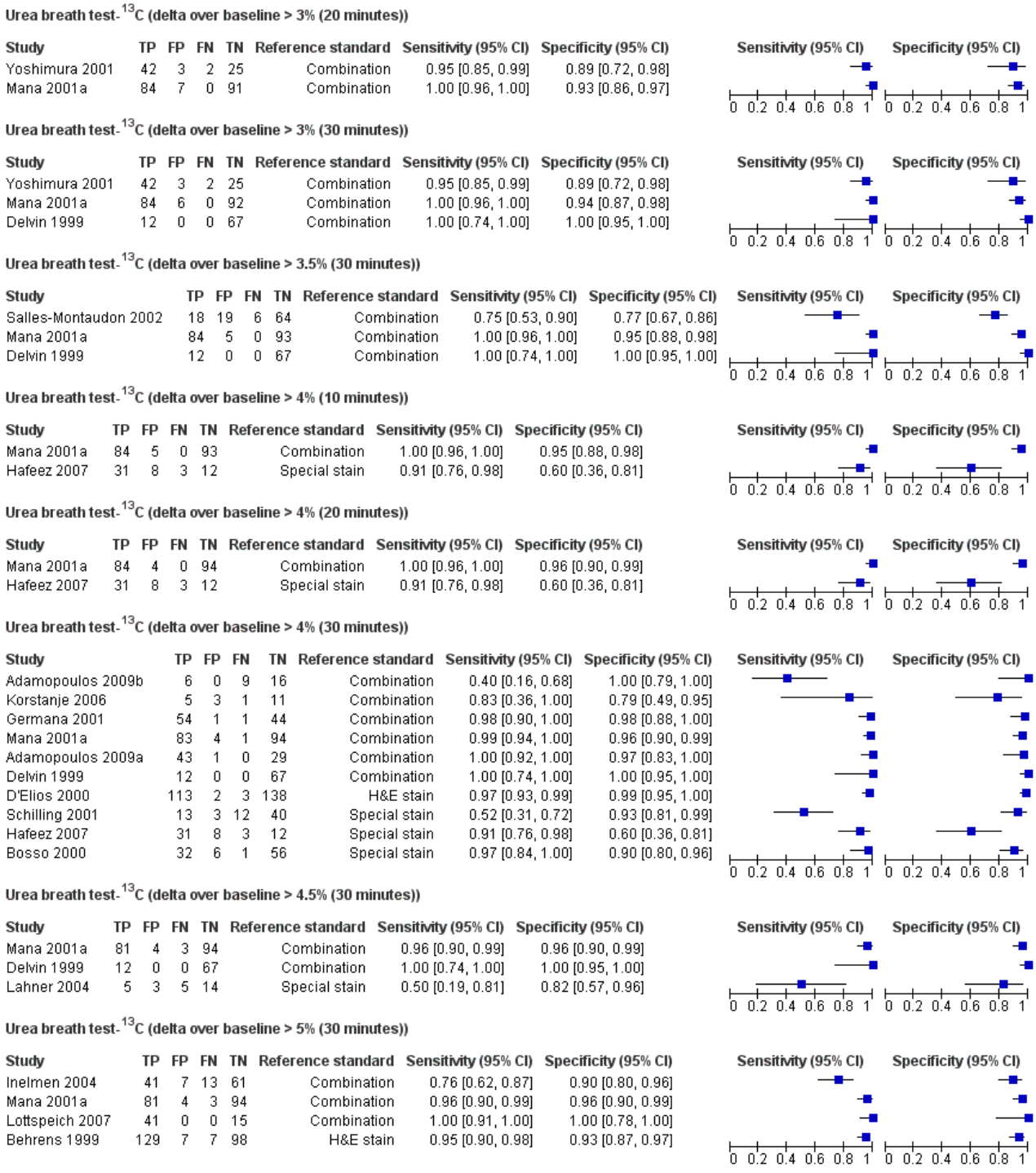


Figure 5. Forest plot of urea breath test-^{13}C at commonly reported thresholds. FN = false negative; FP = false positive; TN = true negative; TP = true positive. Thresholds are shown in brackets and the number of minutes in brackets is the time after administration of urea.



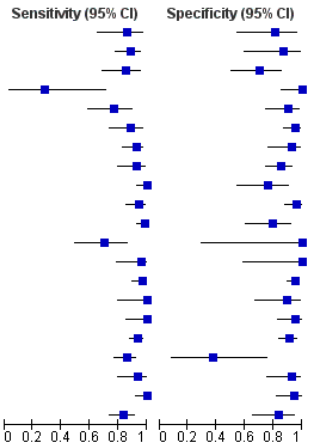
Urea breath test-^{14}C

Figure 6 shows the 21 studies of urea breath test-^{14}C. The studies included 1810 participants (involving 1018 *H pylori* cases). Three studies did not state the thresholds used (Selcukcan 2011; Surveyor 1989; Yu 1999). The two most commonly used thresholds were counts per minute > 50 (10 minutes after administration of urea) in six studies (471 participants) and disintegrations per minute >

200 (10 minutes) in four studies (296 participants) (Table 1). Test accuracy results for other thresholds are shown in Appendix 9. The summary sensitivity (95% CI) and specificity (95% CI) at the counts per minute > 50 threshold were 0.89 (95% CI 0.55 to 0.98) and 0.91 (95% CI 0.79 to 0.96). For the disintegrations per minute > 200 threshold, the summary sensitivity (95% CI) and specificity (95% CI) were 0.95 (95% CI 0.33 to 1.00) and 0.95 (95% CI 0.80 to 0.99).

Figure 6. Forest plot of urea breath test-^{14}C. FN = false negative; FP = false positive; TN = true negative; TP = true positive. The forest plot shows an estimate of sensitivity and specificity from each study and the threshold used. Studies are sorted by threshold, sensitivity and specificity. For threshold, the number of minutes in brackets is the time after administration of urea.

Study	TP	FP	FN	TN	Threshold	Reference standard	Sensitivity (95% CI)	Specificity (95% CI)
Noguera 1998	19	3	3	13	>1% excretion (10 mins)	H&E stain	0.86 [0.65, 0.97]	0.81 [0.54, 0.96]
Novis 1991	54	2	7	13	>4.7% excretion (15 mins)	Special stain	0.89 [0.78, 0.95]	0.87 [0.60, 0.98]
Al-Fadda 2000	29	9	5	21	CO2 recovery >0.55 (20 mins)	H&E stain	0.85 [0.69, 0.95]	0.70 [0.51, 0.85]
Dede 2015	2	0	5	23	CPM >50 (10 mins)	Combination	0.29 [0.04, 0.71]	1.00 [0.85, 1.00]
Gurbuz 2005	26	3	8	28	CPM >50 (10 mins)	H&E stain	0.76 [0.59, 0.89]	0.90 [0.74, 0.98]
Atli 2012	32	3	4	61	CPM >50 (10 mins)	H&E stain	0.89 [0.74, 0.97]	0.95 [0.87, 0.99]
Rasool 2007	61	2	5	26	CPM >50 (10 mins)	Combination	0.92 [0.83, 0.97]	0.93 [0.76, 0.99]
Kuloglu 2008	37	10	3	59	CPM >50 (10 mins)	Combination	0.93 [0.80, 0.98]	0.86 [0.75, 0.93]
Ozturk 2003	48	6	0	19	CPM >50 (10 mins)	Special stain	1.00 [0.93, 1.00]	0.76 [0.55, 0.91]
Mansour-Ghanaei 2011	65	2	4	54	CPM >50 (15 mins)	Combination	0.94 [0.86, 0.98]	0.96 [0.88, 1.00]
Villalobos 1992	75	6	1	23	DPM >1.6% (60 mins)	Special stain	0.99 [0.93, 1.00]	0.79 [0.60, 0.92]
Tiwari 2014	19	0	8	3	DPM >200 (10 mins)	H&E stain	0.70 [0.50, 0.86]	1.00 [0.29, 1.00]
Aguilar 2007	23	0	1	7	DPM >200 (10 mins)	H&E stain	0.96 [0.79, 1.00]	1.00 [0.59, 1.00]
Peura 1996	63	7	2	128	DPM >200 (10 mins)	Special stain	0.97 [0.89, 1.00]	0.95 [0.90, 0.98]
Jensen 1998	16	2	0	17	DPM >200 (10 mins)	Combination	1.00 [0.79, 1.00]	0.89 [0.67, 0.99]
Allardyce 1997	24	2	0	37	DPM >49 (time unknown)	Combination	1.00 [0.86, 1.00]	0.95 [0.83, 0.99]
Debongnie 1991	119	9	8	92	Specific activity >0.3% (10 mins)	Combination	0.94 [0.88, 0.97]	0.91 [0.84, 0.96]
Selcukcan 2011	79	5	13	3	Unknown	H&E stain	0.86 [0.77, 0.92]	0.38 [0.09, 0.76]
Surveyor 1989	30	2	2	25	Unknown	Combination	0.94 [0.79, 0.99]	0.93 [0.76, 0.99]
Yu 1999	44	2	0	35	Unknown	Combination	1.00 [0.92, 1.00]	0.95 [0.82, 0.99]
Morales 1995	62	5	12	25	≥1.6% excretion (time unknown)	Special stain	0.84 [0.73, 0.91]	0.83 [0.65, 0.94]

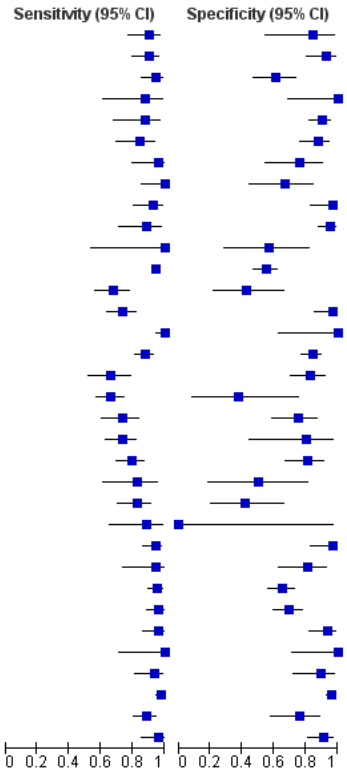


Serology

Serology was evaluated in 34 studies with a total of 4242 participants, of whom 2477 had *H pylori* infection (Figure 7). There was considerable variation in the thresholds used but 14 (41%) studies did not state the thresholds used. A threshold of > 7 units/ml was used in two studies (Iqbal 2013; Ogata 2001), involving 97 participants, and two studies involving 234 participants (Ladas 2002a; Monteiro 2001a) used a threshold of ≥ 300 units (Table 1). The summary sensitivity (95% CI) and specificity (95% CI) at the > 7 units/mL threshold were 0.98 (95% CI 0.74 to 1.00) and 0.71 (95% CI 0.51 to 0.86), and 0.91 (95% CI 0.82 to 0.96) and 0.86 (95% CI 0.72 to 0.93) for the ≥ 300 units threshold.

Figure 7. Forest plot of serology. FN = false negative; FP = false positive; SD = standard deviation; TN = true negative; TP = true positive. The forest plot shows an estimate of sensitivity and specificity from each study and the threshold used. Studies are sorted by threshold, sensitivity and specificity. Other threshold is staining of a 120kDa protein (CagA) gel band and/or at least two of five proteins between 28–33 kDa.

Study	TP	FP	FN	TN	Threshold	Sensitivity (95% CI)	Specificity (95% CI)
El-Mekki 2011	38	2	4	11	> 1 units/ml	0.90 [0.77, 0.97]	0.85 [0.55, 0.98]
Safe 1993	53	3	6	38	>10 units/ml	0.90 [0.79, 0.96]	0.93 [0.80, 0.98]
Mansour-Ghanaei 2011	65	22	4	34	>11 IU	0.94 [0.86, 0.98]	0.61 [0.47, 0.74]
Thobani 1995	14	0	2	10	>2 units	0.88 [0.62, 0.98]	1.00 [0.69, 1.00]
Salles-Montaudon 2002	21	8	3	75	>300 Units	0.88 [0.68, 0.97]	0.90 [0.82, 0.96]
Kalach 1998a	37	7	7	49	>6 IU /ml	0.84 [0.70, 0.93]	0.88 [0.76, 0.95]
Iqbal 2013	24	6	1	19	>7 units/ml	0.96 [0.80, 1.00]	0.76 [0.55, 0.91]
Ogata 2001	23	8	0	16	>7 units/ml	1.00 [0.85, 1.00]	0.67 [0.45, 0.84]
Rathbone 1986	39	1	3	30	>Mean +2 SDs above normal	0.93 [0.81, 0.99]	0.97 [0.83, 1.00]
Vandenplas 1992	24	3	3	65	>Mean +3 SDs above normal	0.89 [0.71, 0.98]	0.96 [0.88, 0.99]
Korstanje 2006	6	6	0	8	Absorbance (WL unknown) >0.320	1.00 [0.54, 1.00]	0.57 [0.29, 0.82]
Shin 2009	449	80	25	97	Absorbance 450 nm >0.406	0.95 [0.92, 0.97]	0.55 [0.47, 0.62]
Chen 1991	51	12	24	9	Agglutination (within 3 minutes)	0.68 [0.56, 0.78]	0.43 [0.22, 0.66]
Ekesbo 2006	67	1	24	34	Other	0.74 [0.63, 0.82]	0.97 [0.85, 1.00]
Graham 1996a	67	0	0	8	Pink line	1.00 [0.95, 1.00]	1.00 [0.63, 1.00]
Chey 1998	115	25	16	131	Two red lines	0.88 [0.81, 0.93]	0.84 [0.77, 0.89]
Fallone 1996	35	9	18	44	Unknown	0.66 [0.52, 0.78]	0.83 [0.70, 0.92]
Wang 2008	76	5	39	3	Unknown	0.66 [0.57, 0.75]	0.38 [0.09, 0.76]
Ferrara 1998	44	10	16	30	Unknown	0.73 [0.60, 0.84]	0.75 [0.59, 0.87]
Soomro 2012	66	2	24	8	Unknown	0.73 [0.63, 0.82]	0.80 [0.44, 0.97]
Peitz 2001	77	9	20	39	Unknown	0.79 [0.70, 0.87]	0.81 [0.67, 0.91]
Ivanova 2010	19	5	4	5	Unknown	0.83 [0.61, 0.95]	0.50 [0.19, 0.81]
Dinler 1999	48	11	10	8	Unknown	0.83 [0.71, 0.91]	0.42 [0.20, 0.67]
El-Din 2013	16	1	2	0	Unknown	0.89 [0.65, 0.99]	0.00 [0.00, 0.97]
Misawa 1998	79	1	5	29	Unknown	0.94 [0.87, 0.98]	0.97 [0.83, 1.00]
Eltumi 1999	18	6	1	25	Unknown	0.95 [0.74, 1.00]	0.81 [0.63, 0.93]
Luthra 1998	107	45	5	83	Unknown	0.96 [0.90, 0.99]	0.65 [0.56, 0.73]
Mohammadian 2007	72	32	3	72	Unknown	0.96 [0.89, 0.99]	0.69 [0.59, 0.78]
Weiss 1994	48	3	2	42	Unknown	0.96 [0.86, 1.00]	0.93 [0.82, 0.99]
Gramley 1999	11	0	0	11	Unknown	1.00 [0.72, 1.00]	1.00 [0.72, 1.00]
Yoshimura 2001	41	3	3	25	≥1.8 units	0.93 [0.81, 0.99]	0.89 [0.72, 0.98]
Formichella 2013	205	11	5	279	≥2 or more antigens	0.98 [0.95, 0.99]	0.96 [0.93, 0.98]
Ladas 2002a	86	8	11	25	≥300 units	0.89 [0.81, 0.94]	0.76 [0.58, 0.89]
Monteiro 2001a	44	5	2	53	≥300 units	0.96 [0.85, 0.99]	0.91 [0.81, 0.97]

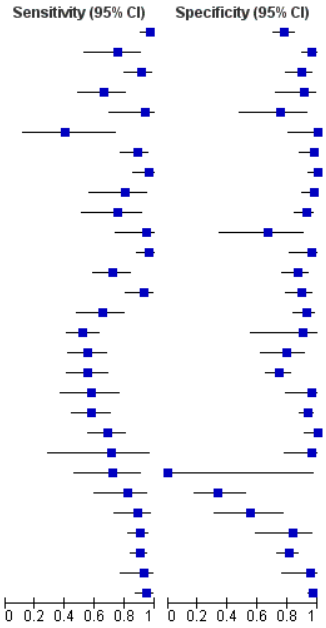


Stool antigen test

Twenty-nine studies assessed the stool antigen test in 2988 participants (including 1311 *H pylori* cases) (Figure 8). The threshold used was unknown in almost half of the studies (14/29, 48%). None of the thresholds reported were used by more than one study. Summary estimates of sensitivity and specificity were therefore not obtained at a common threshold.

Figure 8. Forest plot of stool antigen test. FN = false negative; FP = false positive; TN = true negative; TP = true positive; WL = wavelength. The forest plot shows an estimate of sensitivity and specificity from each study and the threshold used. Studies are sorted by threshold, sensitivity and specificity.

Study	TP	FP	FN	TN	Threshold	Sensitivity (95% CI)	Specificity (95% CI)
Jekarl 2013	71	30	2	106	Absence of yellow	0.97 [0.90, 1.00]	0.78 [0.70, 0.85]
Salles-Montaudon 2002	18	3	6	80	Absorbance (WL unknown) >0.160	0.75 [0.53, 0.90]	0.96 [0.90, 0.99]
Monteiro 2001a	42	6	4	52	Absorbance (WL unknown) ≥0.160	0.91 [0.79, 0.98]	0.90 [0.79, 0.96]
Sharbatdaran 2013	25	2	13	21	Absorbance 450 nm > +0.1 of negative control	0.66 [0.49, 0.80]	0.91 [0.72, 0.99]
Yu 2001	15	4	1	12	Absorbance 450 nm >0.140	0.94 [0.70, 1.00]	0.75 [0.48, 0.93]
Lahner 2004	4	0	6	17	Absorbance 450 nm ≥0.160	0.40 [0.12, 0.74]	1.00 [0.80, 1.00]
Trevisani 2005	52	1	7	44	Absorbance 450 nm ≥0.190	0.88 [0.77, 0.95]	0.98 [0.88, 1.00]
Lottspeich 2007	44	0	2	54	Absorbance 450/620 nm to 650 nm ≥0.150	0.96 [0.85, 0.99]	1.00 [0.93, 1.00]
Puspok 1999	16	1	4	51	Absorbance 450/620 nm ≥0.100	0.80 [0.56, 0.94]	0.98 [0.90, 1.00]
Islam 2005	15	7	5	85	Absorbance 450/630 nm >0.120	0.75 [0.51, 0.91]	0.92 [0.85, 0.97]
Yan 2003	18	4	1	8	Absorbance 450/630 nm >0.120	0.95 [0.74, 1.00]	0.67 [0.35, 0.90]
Fanti 1999	54	1	2	27	Absorbance 450/630 nm >0.150	0.96 [0.88, 1.00]	0.96 [0.82, 1.00]
Inelmen 2004	39	9	15	59	Definite yellow colour	0.72 [0.58, 0.84]	0.87 [0.76, 0.94]
Qadeer 2009	39	6	3	52	Pink-red band (time unknown)	0.93 [0.81, 0.99]	0.90 [0.79, 0.96]
Kuloglu 2008	26	5	14	64	Pink-red band (within 10 mins)	0.65 [0.48, 0.79]	0.93 [0.84, 0.98]
Soomro 2012	47	1	43	9	Unknown	0.52 [0.41, 0.63]	0.90 [0.55, 1.00]
Rafeey 2007	34	7	28	27	Unknown	0.55 [0.42, 0.68]	0.79 [0.62, 0.91]
Segamwenge 2014	30	29	24	84	Unknown	0.56 [0.41, 0.69]	0.74 [0.65, 0.82]
El-Nasr 2003	15	1	11	23	Unknown	0.58 [0.37, 0.77]	0.96 [0.79, 1.00]
Argentieri 2007	37	10	27	141	Unknown	0.58 [0.45, 0.70]	0.93 [0.88, 0.97]
Ceken 2011	42	0	19	39	Unknown	0.69 [0.56, 0.80]	1.00 [0.91, 1.00]
Dede 2015	5	1	2	22	Unknown	0.71 [0.29, 0.96]	0.96 [0.78, 1.00]
El-Din 2013	13	1	5	0	Unknown	0.72 [0.47, 0.90]	0.00 [0.00, 0.97]
Kamel 2011	18	22	4	11	Unknown	0.82 [0.60, 0.95]	0.33 [0.18, 0.52]
Hafeez 2007	30	9	4	11	Unknown	0.88 [0.73, 0.97]	0.55 [0.32, 0.77]
Arikan 2004	74	3	8	15	Unknown	0.90 [0.82, 0.96]	0.83 [0.59, 0.96]
Scuderi 2000	113	24	12	101	Unknown	0.90 [0.84, 0.95]	0.81 [0.73, 0.87]
Faruqui 2007	27	1	2	20	Unknown	0.93 [0.77, 0.99]	0.95 [0.76, 1.00]
Guo 2011	70	8	4	246	Unknown	0.95 [0.87, 0.99]	0.97 [0.94, 0.99]



Comparative accuracy of non-invasive tests for H pylori infection

Comparison based on all studies (Indirect test comparison)

Across the four tests (urea breath test-^{13}C, urea breath test-^{14}C, serology and stool antigen test) 99 studies (5694 cases; 10799 participants) were included in this comparative meta-analysis (Figure 9). Preliminary assessment of each test separately indicated there was no significant association between test accuracy and threshold, and so a symmetric SROC curve is plausible for each test. Based on these preliminary assessments, and likelihood ratio tests comparing different HSROC meta-regression models with covariate terms for test type and examination of the variance parameters in these models, the final model we fitted allowed for differences in accuracy and threshold as random effects (i.e. unequal variances for the random effects) with symmetric SROC curves for the tests. Overall, there was statistical evidence of a difference in accuracy (P = 0.024). The DORs (95% CI) for urea breath test-^{13}C, urea breath test-^{14}C, serology and stool antigen test were 153 (95% CI 73.7 to 316), 105 (95% CI 74.0 to 150), 47.4 (95% CI 25.5 to 88.1) and 45.1 (95% CI 24.2 to 84.1) respectively (Table 2). The accuracy of urea breath tests (^{13}C and ^{14}C) was significantly higher than that of serology and stool antigen test. For example, the ratio of DORs (95%) for urea breath test-^{13}C compared to serology was 3.22 (95% CI 1.24 to 8.37), P = 0.017.

Figure 9. Summary ROC plot of non-invasive tests for *H pylori* infection. The SROC curves for the four tests are parallel. The curve for each test is drawn within the range of estimates of specificity from the studies included for the test.

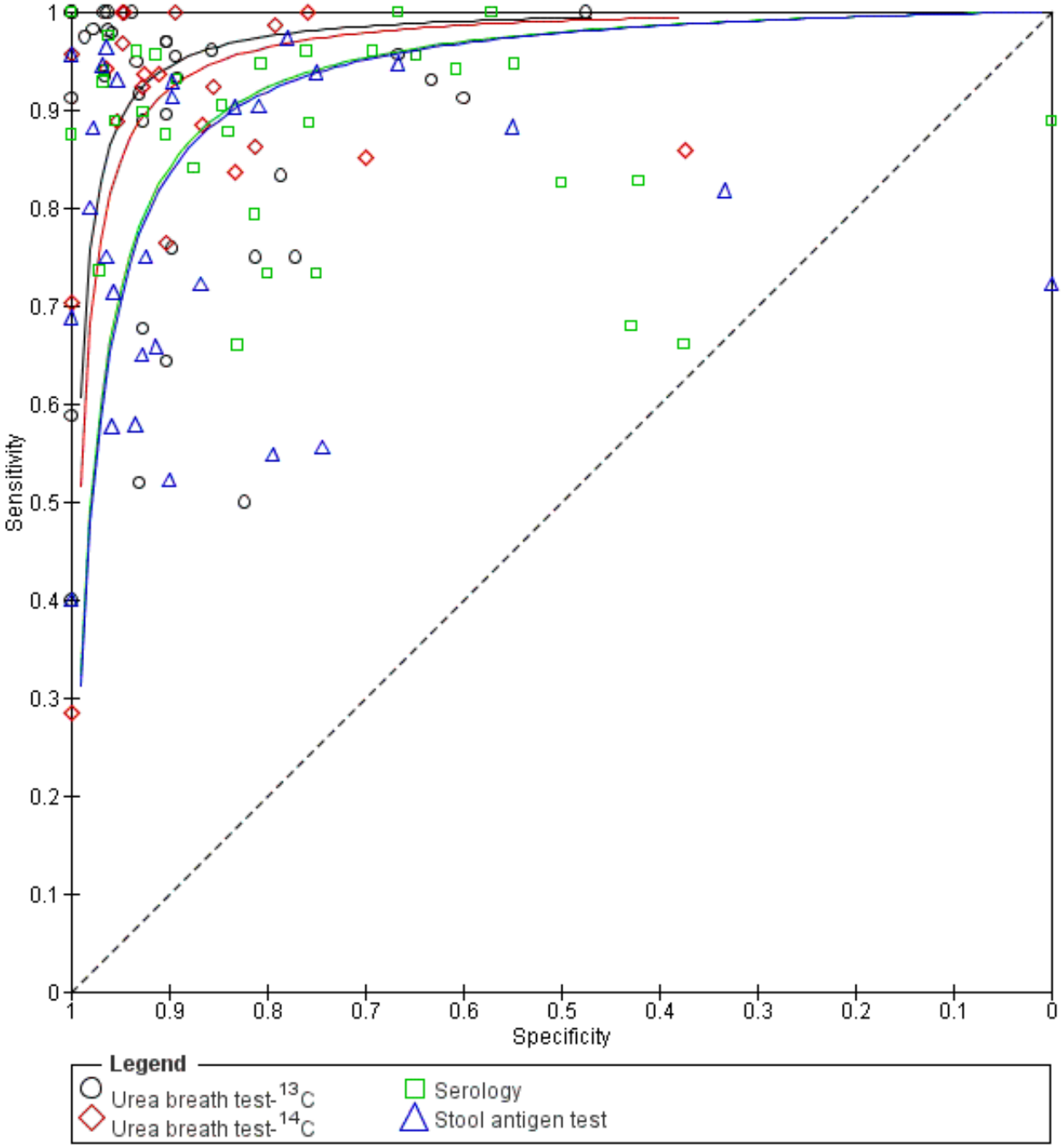


Table 3 shows the clinical implications of using each of the four tests in a hypothetical cohort of 1000 people with different levels of prevalence of *H pylori* infection. For example, given a prevalence of 53.7% and a specificity of 0.90, 46 people who do not have *H pylori* infection will be treated and urea breath test-^{13}C, urea breath test-^{14}C, serology and stool antigen test will miss 30, 42, 86 and 89 people respectively who have *H pylori* infection.

Direct comparisons (restricted to comparative studies)

Direct comparisons were based on few studies. Table 4 shows the number of studies (*N*) for each pairwise comparison and, where meta-analysis was possible, the ratio of DORs with 95% CIs and P value. There were no comparative studies of urea breath test-^{13}C and urea breath test-^{14}C. All other comparisons were based on seven or fewer studies. Each pair of tests were evaluated as follows:

- Urea breath test-^{13}C versus serology (Figure 10): seven studies (Eltumi 1999; Korstanje 2006; Monteiro 2001a; Ogata 2001; Salles-Montaudon 2002; Vandenplas 1992; Yoshimura 2001).
- Urea breath test-^{13}C versus stool antigen test (Figure 11): seven studies (Hafeez 2007; Inelmen 2004; Lahner 2004; Lottspeich 2007; Monteiro 2001a; Salles-Montaudon 2002; Yu 2001).
- Urea breath test-^{14}C versus serology: two studies (Dede 2015; Kuloglu 2008).
- Urea breath test-^{14}C versus serology: one study (Mansour-Ghanaei 2011).
- Serology versus stool antigen test: four studies (El-Din 2013; Monteiro 2001a; Salles-Montaudon 2002; Soomro 2012).

Figure 10. Summary ROC plot of direct comparisons of urea breath test-^{13}C and serology. Each summary curve was drawn restricted to the range of specificities for each test. The size of each symbol was scaled according to the precision of sensitivity and specificity in the study. A dotted line joins the pair of points for the two tests from each study.

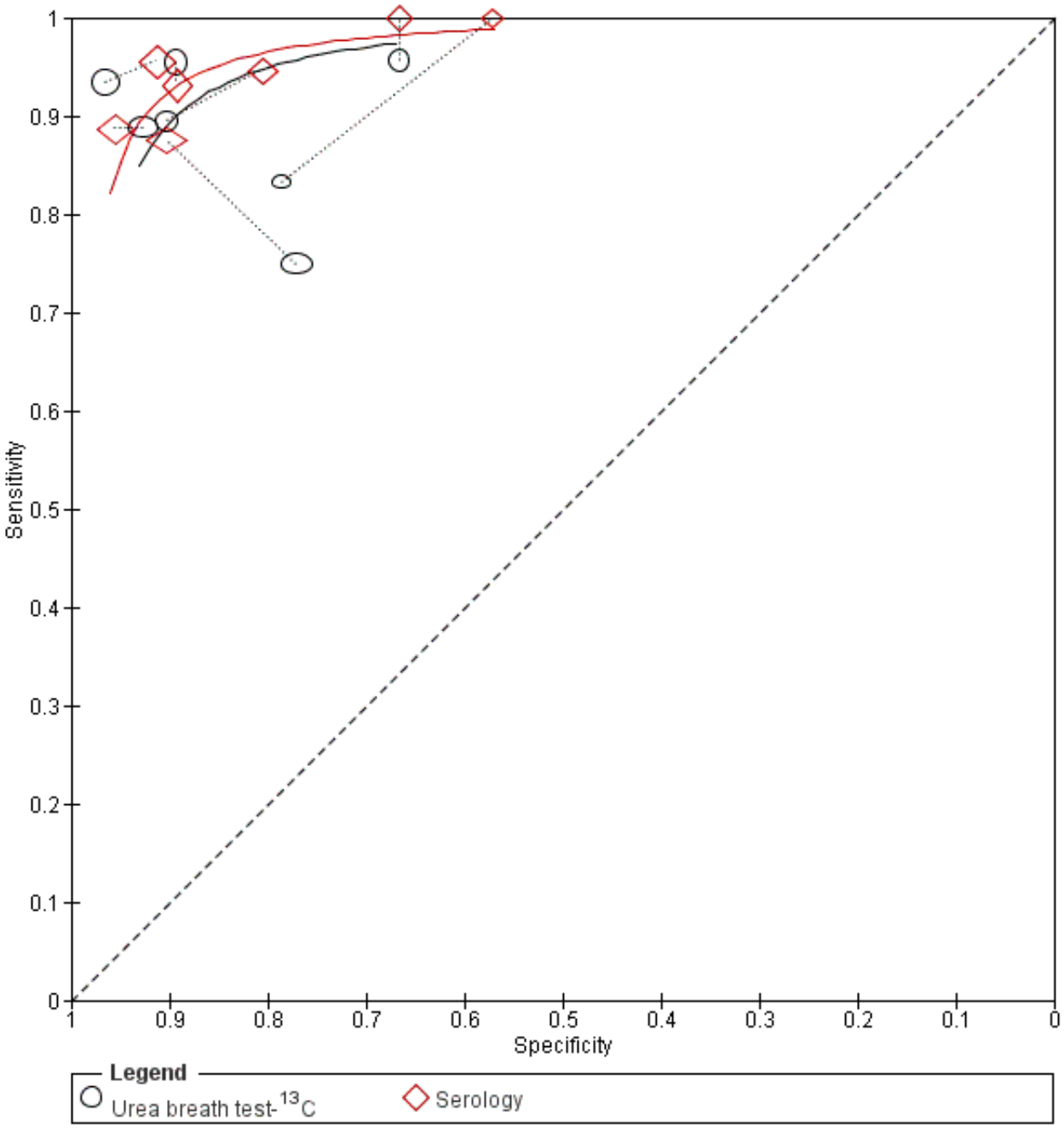
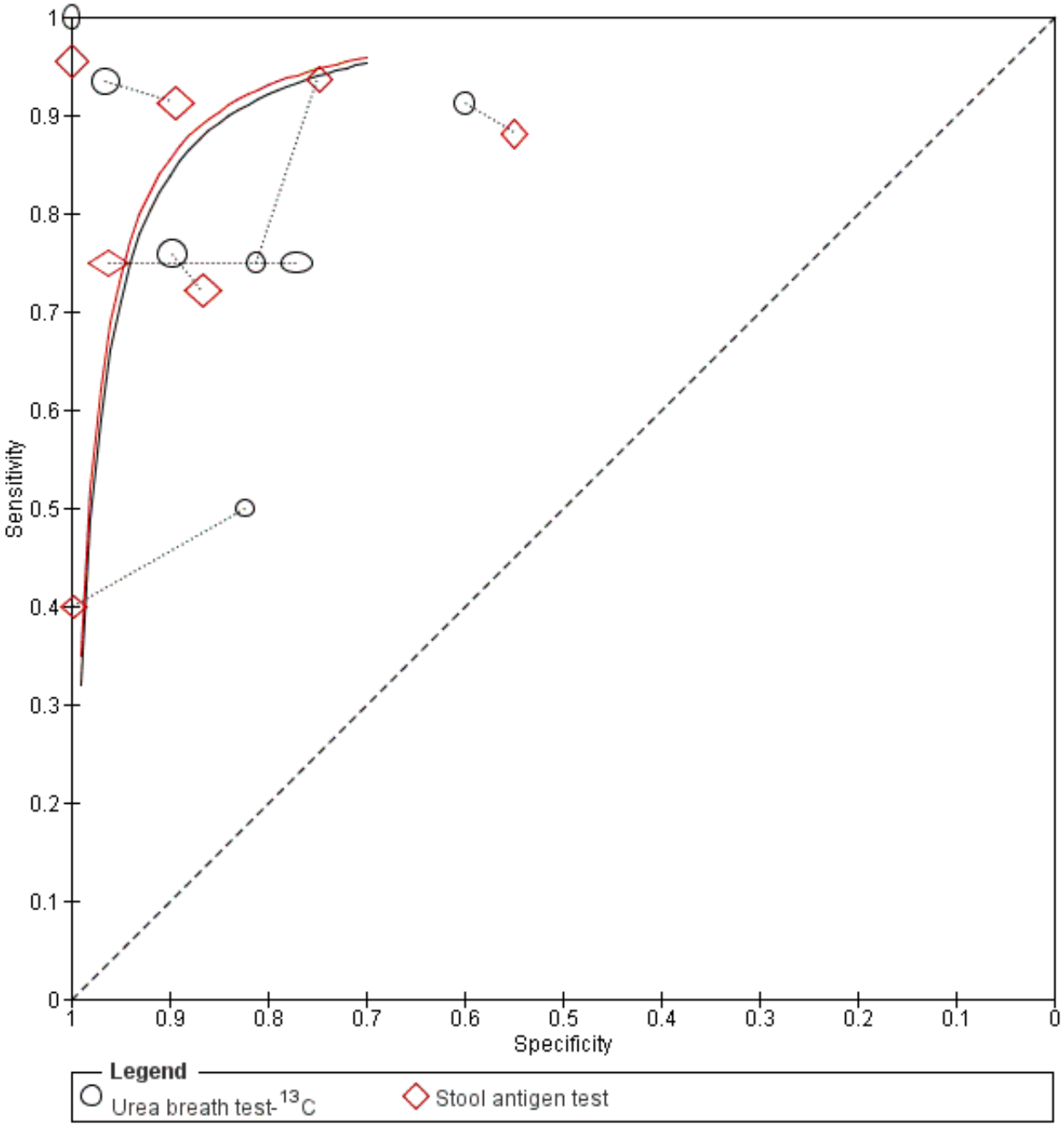


Figure 11. Summary ROC plot of direct comparisons of urea breath test-^{13}C and stool antigen test. Each summary curve was drawn restricted to the range of specificities for each test. The size of each symbol was scaled according to the precision of sensitivity and specificity in the study. A dotted line joins the pair of points for the two tests from each study.



The ratios of DORs (95% CI; P value) were 0.68 (95% CI 0.12 to 3.70; P = 0.56) for urea breath test-^{13}C versus serology, and 0.88 (95% CI 0.14 to 5.56; P = 0.84) for urea breath test-^{13}C versus stool antigen test. Due to paucity of data and substantial heterogeneity observed in ROC space which precluded the use of simpler meta-analytic models, meta-analyses were not possible for the other two test comparisons that had more than one study. For the single study of urea breath test-^{14}C versus serology (Mansour-Ghanaei 2011), both tests had similar sensitivity, but specificity was higher for urea breath test-^{14}C than for serology.

Investigation of heterogeneity

We were unable to investigate subtype of tests because most of the serological tests were ELISA (17/20 (85%) studies that provided the type of serology test) and most studies (24/29 (83%) studies) did not report whether monoclonal or polyclonal antibodies were used for stool antigen tests. Studies did not report the precise interval between index test and reference standard (unless they were performed on the same day), i.e. many studies did not report the interval at all, while some reported that the tests were performed within a few days of each other without stating the exact time interval. Of those that reported the interval, only two studies had an interval of more than two weeks (Dede 2015; Lombardo 2003). For each of the four tests, Appendix 10 shows the number of studies in each subgroup of other factors we had planned to investigate. Given the availability of data, we were only able to perform meta-regression to investigate the effect of reference standard on the accuracy of each test. Of the 99 studies, 42 (42%) used a combination of stains and there were few data for Immunohistochemical stains (2/99; 2%). The analyses were therefore limited to comparisons of H & E stain versus special stain for each test (Appendix 11). Although the effect of reference standard was not consistent across tests, there was no statistical evidence of a difference in test accuracy for any of the tests. For urea breath test-^{14}C, the DOR for special stain was higher than for H & E stain, while for the other tests the DOR of both types of stain were similar or higher for H & E (Appendix 11).

DISCUSSION

Summary of main results

We included 101 studies (11,003 participants) that evaluated the diagnostic accuracy of different non-invasive methods for the diagnosis of *H pylori*. Of these 11,003 participants, 5839 participants (53.1%) had *H pylori* infection. The prevalence of *H pylori* infection ranged from 15.2% to 94.7%. The median prevalence was 53.7% (lower quartile: 42.0% and upper quartile: 66.5%).

The summary of results for urea breath test-^{13}C, urea breath test-^{14}C, serology and stool antigen test is given in Summary of findings 1. The studies used different thresholds and reference standards. As a result, there were few data for pooling sensitivities and specificities at specific thresholds, and we mainly estimated and compared SROC curves. The test comparison based on all available data (99 studies) for the four tests showed a statistically significant difference in diagnostic accuracy between the test (P = 0.024). There was no statistical evidence of a difference in diagnostic accuracy between urea breath test-^{13}C and urea breath test-^{14}C, while serology and stool antigen test were inferior to both urea breath tests. Direct comparisons are more reliable than indirect comparisons, due to the potential for confounding in indirect comparisons (Takwoingi 2013). However, we found few head-to-head studies and meta-analysis was possible for only two pairwise comparisons (urea breath test-^{13}C versus serology, seven studies; and urea breath test-^{13}C versus stool antigen test, seven studies).

Most of the tests that used visual assessment (for example, appearance of a pink-red line) were stool antigen tests, although some serology tests also used visual assessment. Some serology and stool antigen tests are therefore easy to use (stool antigen test is easier to use as described below), but low diagnostic accuracy is a disadvantage when compared to urea breath tests. Urea breath test is a cumbersome test and involves the use of radioisotopes; however, urea breath test-^{13}C may be the most accurate test among the non-invasive tests. This has implications in the screening of individuals for *H pylori* as a decision has to be made regarding the use of a cumbersome and relatively costly test but with good diagnostic accuracy versus cheap tests that can be performed easily but with lower diagnostic accuracy. A further decision to make if one opts for easy-to-use tests is the threshold at which the test should be used. For example, one can use a threshold that provides higher sensitivity (at the cost of lower specificity, necessitating endoscopic biopsy confirmation or treatment) or a threshold that provides higher specificity (at the cost of lower sensitivity, resulting in people with *H pylori* not being treated). Although at first sight it appears that the treatment for *H pylori* is relatively harmless and one would prefer a threshold at which the test has higher sensitivity rather than higher specificity, the decision to give antibiotics is not a straightforward one, because of the association between unnecessary antibiotic use and development of antimicrobial resistance (Llor 2014). Serology and stool antigen test have similar diagnostic test accuracy and the choice between the two may be made based on ease of carrying out the tests. Only one study included in this review used whole blood for performing serology (Chey 1998). Even this test required a laboratory technician to interpret the test result (Chey 1998). So, there are no bedside tests available for serology testing. On the other hand, bedside kits with easy interpretation by colour changes are available for stool antigen tests, making them easy to administer (Inelmen 2004; Jekarl 2013; Kuloglu 2008; Qadeer 2009; Trevisani 2005). A cost-effectiveness study may clarify the most cost-effective non-invasive test in people with suspected *H pylori*, but it is difficult to factor in the price of antimicrobial resistance to an individual as the price of antimicrobial resistance is paid by future generations (through increased mortality and decreased productivity), rather than the individual for whom the treatment decision has to be made (Taylor 2014).

Strengths and weaknesses of the review

We conducted a thorough literature search and included full-text publications and abstracts without any language restrictions. There are currently no reliable search strategies to identify diagnostic test accuracy studies (Beynon 2013). We did not use any diagnostic filter in our search strategy, thereby ensuring that studies on the topic were identified. Two review authors independently identified and extracted data from the studies, potentially decreasing errors related to single data extraction. PCR methodology is not standardised across laboratories and it is an unreliable reference standard (Chey 2007). Endoscopic biopsy followed by rapid urease testing has poor sensitivity following treatment with proton pump inhibitors, and endoscopic biopsy with culture has high specificity but poor sensitivity (Chey 2007). We used a strict reference standard (histology) which is likely to diagnose the target condition with a high degree of accuracy. These are the major strengths of the review.

A major limitation was the diversity of thresholds used in the studies. As a result, data were sparse for each threshold, which limited estimation of summary sensitivities and specificities. Therefore there is insufficient evidence to recommend specific thresholds for each of the tests. Nonetheless, we were able to estimate and compare SROC curves by including studies with

different thresholds. There was a high proportion of studies at high risk of bias and with high concern regarding applicability in all the four domains of the QUADAS-2 tool. This makes the validity and applicability of the results questionable. The major concerns were lack of reporting of the threshold used or when the thresholds were reported, there was no information to judge whether the thresholds were prespecified. Despite the lack of statistical evidence of an effect of type of reference standard on test accuracy, as there were few studies for each subgroup and other differences between studies, we cannot conclude that diagnostic accuracy does not depend on type of reference standard.

Comparison with other systematic reviews

We identified several relevant systematic reviews (Ferwana 2015; Gisbert 2001; Gisbert 2004a; Loy 1996; Zhou 2014; Zhou 2017). The findings from this review support those of Zhou 2017, and Ferwana 2015, that urea breath test has high diagnostic accuracy and that there was significant heterogeneity in the diagnostic accuracy of the urea breath test (Zhou 2017). Our findings agree with those of Zhou 2014 that stool antigen test has only modest diagnostic test accuracy. The review findings are contrary to those of Gisbert 2001, and Gisbert 2004a, which suggested that stool antigen tests are highly accurate. This difference may be due to the strict reference standards that we used in this review and how we handled the issue of heterogeneity in thresholds. In agreement with the findings of Loy 1996, the role of serology in clinical practice is uncertain, as stool antigen tests provide equivalent diagnostic accuracy to serology and are easier to interpret.

Applicability of findings to the review question

This review included adults and children who underwent non-invasive tests for the diagnosis of *H pylori*. Most of the studies included only symptomatic people and so the findings of this review are applicable only to people with symptoms. Most studies excluded people who had previous gastrectomy and those who had recent antibiotics or proton pump inhibitors. Hence, the findings of this review are not applicable in these populations.

AUTHORS' CONCLUSIONS

Implications for practice

In people with no history of gastrectomy and those who have not recently had antibiotics or proton pump inhibitors, urea breath tests had high diagnostic accuracy while serology and stool antigen tests had lower accuracy to detect *H pylori* infection. Although susceptible to bias due to confounding, this conclusion is based on evidence from indirect test comparisons, as evidence from direct comparisons was based on few studies or was unavailable. There was high or unclear risk of bias for many studies with respect to the selection of participants, and the conduct and interpretation of the index tests and reference standard. The thresholds used for these tests were highly variable, thus there is insufficient evidence to identify specific thresholds that might be useful in clinical practice.

Implications for research

Further comparative studies of high methodological quality are necessary to obtain more reliable evidence of accuracy between the tests (urea breath tests, serology, and stool antigen tests) in people with upper gastrointestinal symptoms and people without any symptoms suggestive of *H pylori*. Such studies should be conducted prospectively in a representative spectrum of participants, and be clearly reported to ensure low risk of bias. Most importantly, studies should pre-specify and clearly report the thresholds used, should apply appropriate reference standards such as endoscopic biopsy with special stains, and should avoid inappropriate exclusions.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Adamopoulos 2009a

Study characteristics	
Patient sampling	Type of study: prospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 73 Female: 24 (33%) Age: 63 years Presentation: 1. People who had undergone endoscopy (for various indications) Setting: secondary care, Greece
Index tests	Index test: urea breath test -^{13}C Further details: Technical specifications: manufacturer - Infai Institut für Biomedizinische; Analytik & NMR-Imaging GmbH, Bochum Performed by: not stated Criteria for positive diagnosis: delta over baseline > 4.0% (30 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and histopathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)
Comparative	
Notes	

Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		

Adamopoulos 2009a *(Continued)*

Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	**Low**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Unclear**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Low	

Adamopoulos 2009b

Study characteristics	
Patient sampling	Type of study: prospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 31 Female: 8 (25.8%) Age: 71 years Presentation: 1. People who had undergone Billroth II gastrectomy and endoscopy (for various indications) Setting: secondary, Greece
Index tests	Index test: urea breath test-^{13}C Further details: Technical specifications: manufacturer - Infai Institut für Biomedizinische; Analytik & NMR-Imaging GmbH, Bochum

Adamopoulos 2009b *(Continued)*

	Performed by: not stated Criteria for positive diagnosis: delta over baseline > 4.0% (30 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and histopathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	**High**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Unclear**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		

Adamopoulos 2009b *(Continued)*

Did all patients receive the same reference standard?	Yes	
Were all patients included in the analysis?	Yes	
		Low

Aguilar 2007

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 31 Female: 5 (16.1%) Age: not stated Presentation: 1. Dyspepsia Setting: secondary care, Peru
Index tests	Index test: urea breath test-^{14}C Further details: Technical specifications: Not stated Performed by: Not stated Criteria for positive diagnosis: disintegrations per minute > 200 (10 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: Not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		

Aguilar 2007 *(Continued)*

Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Low**
DOMAIN 2: Index Test Urea breath test-^{14}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Al-Fadda 2000

Study characteristics	
Patient sampling	Type of study: prospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 64 Female: not stated Age: not stated Presentation: 1. Patients with upper gastroinstestinal symptoms Setting: secondary care, Peru
Index tests	Index test: urea breath test-^{14}C Further details: Technical specifications: Not stated Performed by: Not stated Criteria for positive diagnosis: CO^2 recovery > 0.55 (20 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection

Al-Fadda 2000 *(Continued)*

	Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: Not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Low**
DOMAIN 2: Index Test Urea breath test-^{14}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		

Al-Fadda 2000 *(Continued)*

		Unclear	

Allardyce 1997

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process		
Patient characteristics and setting	Sample size: 63 Female: 26 (41.3%) Age: not stated Presentation: 1. Dyspepsia Setting: secondary care, New Zealand		
Index tests	Index test: urea breath test-^{14}C Further details: Technical specifications: Not stated Performed by: Not stated Criteria for positive diagnosis: disintegrations per minute > 49 (time not stated)		
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: Not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Low**

Allardyce 1997 *(Continued)*

DOMAIN 2: Index Test Urea breath test-^{14}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	No		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Argentieri 2007

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 215 Female: not stated Age: not stated Presentation: 1. Children undergoing upper gastrointestinal endoscopy Exclusion: 1. Recent *H pylori* treatment Setting: secondary care, Italy
Index tests	Index test: stool antigen test Further details: Technical specifications: Premier Platinum HpSA Performed by: Not stated Criteria for positive diagnosis: Not stated
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: Not stated

Argentieri 2007 *(Continued)*

	Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Arikan 2004

Study characteristics			
Patient sampling	Type of study: prospective study Consecutive or random sample: unclear sampling process		
Patient characteristics and setting	Sample size: 100 Female: not stated Age: not stated Presentation: 1. Patients undergoing endoscopy Exclusion: 1. Malignancy 2. Taken antibiotics or proton pump inhibitors in last 2 weeks Setting: secondary care, Turkey		
Index tests	Index test: stool antigen test Further details: Technical specifications: Premier Platinum HpSA Performed by: Not stated Criteria for positive diagnosis: Not stated		
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: Not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Stool Antigen Test			

Arikan 2004 *(Continued)*

Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Atli 2012

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 100 Female: 57 (57%) Age: 71 years Presentation: 1. Patients with dyspepsia and symptoms or signs related to peptic ulcer > 65 years of age Exclusion: 1. Patients who had taken antibiotics or anti-ulcer treatment in the past 2 weeks 2. Advanced dementia 3. Cerbrovascular disease 4. Advanced respiratory problems 5. Alarm symptoms for malignancy Setting: secondary setting, Turkey
Index tests	Index test: urea breath test-^{14}C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: counts per minute > 50 (10 minutes)

Atli 2012 *(Continued)*

Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{14}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		

Atli 2012 *(Continued)*

Did all patients receive the same reference standard?	Yes
Were all patients included in the analysis?	Unclear
	Unclear

Behrens 1999

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 252 Female: not stated Age: not stated Presentation: 1. Children (3 years to 18 years) with abdominal pain, nausea, or vomiting Exclusion criteria: 1. Previous treatment with antibiotics or proton pump inhibitors 2. WBC < 3500/microlitre or platelets < 100,000/microlitre Setting: secondary setting, Germany
Index tests	Index test: urea breath test -^{13}C Further details: Technical specifications: Promochem, Wesel Performed by: not stated Criteria for positive diagnosis: delta over baseline > 5.0% (30 minutes and 60 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		

Behrens 1999 *(Continued)*

Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Bosso 2000

Study characteristics	
Patient sampling	Type of study: retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 95 Female: not stated Age: not stated Presentation: 1. Patients with upper abdominal symptoms Exclusion: 1. Patients with previous gastric surgery Setting: secondary care, France

Bosso 2000 *(Continued)*

Index tests	Index test: urea breath test -^{13}C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: delta over baseline > 4.0% (30 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with Warthin-Starry stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	No		
		High	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	**Low**
DOMAIN 4: Flow and Timing			

Bosso 2000 *(Continued)*

Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Ceken 2011

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process		
Patient characteristics and setting	Sample size: 100 Female: 67 (67%) Age: 48 years Presentation: 1. Patients with dyspepsia Exclusion: 1. Antibiotics or anti-ulcer treatment within last 4 weeks 2. Gastric surgery Setting: secondary care, France		
Index tests	Index test: stool antigen test Further details: Technical specifications: Helicobacter Antigen Quick Castte Performed by: not stated Criteria for positive diagnosis: not stated		
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			

Ceken 2011 *(Continued)*

Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Chen 1991

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 96 Female: not stated Age: not stated Presentation: 1. Adult patients with dyspepsia Setting: secondary care, China
Index tests	Index test: serology

Chen 1991 *(Continued)*

	Further details: Technical specifications: Pyloriset Performed by: not stated Criteria for positive diagnosis: presence of agglutination (within 3 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	**Low**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			

Chen 1991 *(Continued)*

Was there an appropriate interval between index test and reference standard?	Unclear
Did all patients receive the same reference standard?	Yes
Were all patients included in the analysis?	Yes
	Unclear

Chey 1998

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 287 Female: 140 (48.8%) Age: 53 years Presentation: 1. People undergoing endoscopy Exclusion: 1. Recent treatment for *H pylori* or anti-ulcer treatment Setting: Variable settings, USA
Index tests	Index test 1a: serology Further details: Technical specifications: HM-CAP (Enteric Products Inc.) Performed by: not stated Criteria for positive diagnosis: not stated Index test 1b: serology (serum) Further details: Technical specifications: Hp Chek (Chem Trak) Performed by: not stated Criteria for positive diagnosis: 2 red lines Index test 1c: serology (whole blood) Further details: same as for index test 2
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	
Methodological quality	

Chey 1998 *(Continued)*

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Unclear	

Czerwionka-Szaflarska 2007

Study characteristics	
Patient sampling	Type of study: retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 100 Female: 66 (66%)

Czerwionka-Szaflarska 2007 *(Continued)*

	Age: 13 years Presentation: 1. Children with gastrointestinal disorders Setting: secondary care, Poland
Index tests	Index test: urea breath test-^{13}C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: delta over baseline > 4.0 % (time not stated)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		

Czerwionka-Szaflarska 2007 *(Continued)*

Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

D'Elios 2000

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 256 Female: not stated Age: not stated Presentation: 1. Patients with dyspepsia Exlusion: 1. Gastric surgery 2. Recent treatment for ulcer or *H pylori* 3. Pulmonary failure Setting: secondary care, Italy
Index tests	Index test: urea breath test-^{13}C Further details: Technical specifications: AB Analitica Performed by: not stated Criteria for positive diagnosis: delta over baseline > 4.0% (30 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)
Comparative	
Notes	

D'Elios 2000 *(Continued)*

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	**Low**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Unclear	

Debongnie 1991

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: neither - patients with previous gastric surgery excluded

Debongnie 1991 *(Continued)*

Patient characteristics and setting	Sample size: 230 Female: not stated Age: not stated Presentation: 1. Patients referred for upper gastrointestinal surgery Excluded: 1. Gastric surgery 2. Haematologic disease 3. Immunodeficiency 4. Gastric cancer 5. Recent treatment for ulcer or *H pylori* 6. Atrophic gastritis Setting: secondary care, Belgium
Index tests	Index test: urea breath test-^{14}C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: specific activity > 0.3% (10 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Cresyl Violet stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 27 (11.7%)
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		High	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{14}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	No		

Debongnie 1991 *(Continued)*

		High	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		

		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		

	High

Dede 2015

Study characteristics	
Patient sampling	Type of study: prospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 30 Female: 8 (26.7%) Age: 55 years Presentation: 1. Patients who had undergone partial gastrectomy Setting: secondary care, Turkey
Index tests	Index test 1: stool antigen test Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated Index test 2: urea breath test-^{14}C Further details: Technical specifications: Heliprobe System, Kibion AB Performed by: not stated Different criteria for positive diagnosis: • Counts per minute > 23 (10 minutes) • Counts per minute > 29 (30 minutes) • Counts per minute > 35 (20 minutes) • Counts per minute > 50 (10 minutes)

Dede 2015 *(Continued)*

- Counts per minute > 50 (20 minutes)
- Counts per minute > 50 (30 minutes)

Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and modified Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{14}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	No		
		High	**Low**
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	**High**
DOMAIN 3: Reference Standard			

Dede 2015 *(Continued)*

Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	No		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		High	

Delvin 1999

Study characteristics	
Patient sampling	Type of study: prospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 79 Female: not stated Age: not stated Presentation: 1. Children with gastrointestinal symptoms Exclusion: 1. Chilren with functional abdominal pain 2. Anti-ulcer or *H pylori* treatment in last 6 weeks Setting: secondary care, Canada
Index tests	Index test 1: urea breath test-^{13}C Further details: Technical specifications: Dia 13-Helico; Dianatec iso Performed by: not stated Different criteria for positive diagnosis: • Delta over baseline > 2.0% (30 minutes) • Delta over baseline > 2.5% (30 minutes) • Delta over baseline > 3.0% (30 minutes) • Delta over baseline > 3.5% (30 minutes) • Delta over baseline > 4.0% (30 minutes) • Delta over baseline > 4.5% (30 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Warthin-Starry stain Further details: Technical specifications: not stated

Delvin 1999 *(Continued)*

	Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	**Low**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
If a threshold was used, was it pre-specified?	No		
		High	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		

Delvin 1999 *(Continued)*

	Unclear

Dinler 1999

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 77 Female: 48 (62.3%) Age: 13 years Presentation: 1. Children with recurrent abdominal pain Setting: secondary care, Turkey
Index tests	Index test: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Serology			

Dinler 1999 *(Continued)*

Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Duan 1999

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 149 Female: 35 (23.5%) Age: 44 years Presentation: 1. Patients with gastritis or gastric ulcer Exclusion: 1. Treatment with antibiotics or bismuth in the previous 2 months 2. Previous gastric surgery or gastric cancer Setting: secondary care, China
Index tests	Index test: urea breath test-^{13}C Further details: Technical specifications: Finniga, MAT-252, USA Performed by: not stated Criteria for positive diagnosis: delta over baseline > 5 per thousand (30 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Warthin-Starry stain Further details: Technical specifications: not stated

Duan 1999 *(Continued)*

	Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		

Duan 1999 *(Continued)*

		Unclear	

Eggers 1990

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process		
Patient characteristics and setting	Sample size: 100 Female: not stated Age: not stated Presentation: 1. Patients undergoing endoscopy Setting: secondary care, Germany		
Index tests	Index test: urea breath test-^{13}C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated		
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 8 (7.4%)		
Comparative			
Notes			
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{13}C			

Eggers 1990 *(Continued)*

Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Ekesbo 2006

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: neither - patients with previous gastric surgery excluded
Patient characteristics and setting	Sample size: 126 Female: not stated Age: not stated Presentation: 1. Patients undergoing gastroscopy for dyspepsia or gastrointestinal bleeding Setting: primary care, Sweden
Index tests	Index test: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: staining of a 120 kilodalton protein gel band and/or at least 2 of 5 proteins between 28 – 33 kilodaltons
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with immunostaining Further details: Technical specifications: not stated Performed by: endoscopist and pathologist

Ekesbo 2006 *(Continued)*

	Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 40 (24.1%)
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		High	**Unclear**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

El-Din 2013

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: neither - patients without pathologic data excluded
Patient characteristics and setting	Sample size: 19 Female: 6 (31.6%) Age: 47 years Presentation: 1. Patients with upper gastrointestinal disorders Setting: secondary care, Egypt
Index tests	Index test 1: serology Further details: Technical specifications: Ridascreen Performed by: not stated Criteria for positive diagnosis: not stated Index test 2: stool antigen test Further details: Technical specifications: Immunodiagnostik AG Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 33 (63.5%)
Comparative	
Notes	

Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		High	**Unclear**

El-Din 2013 *(Continued)*

DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

El-Mekki 2011

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 55 Female: 35 (63.6%) Age: 37 years Presentation: 1. Patients with dyspepsia Setting: secondary care, Saudi Arabia
Index tests	Index test: serology Further details:

El-Mekki 2011 *(Continued)*

	Technical specifications: HeliSAL TM serum Performed by: not stated Criteria for positive diagnosis: > 1 units/ml
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	**Low**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			

El-Mekki 2011 *(Continued)*

Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Unclear	

El-Nasr 2003

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process		
Patient characteristics and setting	Sample size: 50 Female: 16 (32%) Age: 36 years Presentation: 1. Patients with dyspepsia Setting: secondary care, Egypt		
Index tests	Index test: stool antigen test Further details: Technical specifications: Premier Platinum HpSA, Meridien Diagnostics Performed by: not stated Criteria for positive diagnosis: not stated		
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			

Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		

El-Nasr 2003 *(Continued)*

Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Eltumi 1999

Study characteristics	
Patient sampling	Type of study: prospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 50 Female: 17 (34%) Age: 11 years Presentation: 1. Children referred for endoscopy Exclusion: 1. Recent treatment for *H pylori* Setting: Tertiary care, UK
Index tests	Index test 1: urea breath test-^{13}C Further details: Technical specifications: not stated

Eltumi 1999 *(Continued)*

	Performed by: not stated Criteria for positive diagnosis: delta over baseline > 5 units/ml (40 minutes) Index test 2: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Warthin-Starry stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		

Eltumi 1999 *(Continued)*

		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Epple 1997

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 126 Female: 70 (55.6%) Age: 48 years Presentation: 1. Patients undergoing routine endoscopy Exclusion: 1. Gastric cancer 2. Previous gastric surgery Setting: secondary care, Germany
Index tests	Index test: urea breath test-^{13}C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: > Mean + 2 standard deviations above normal level (30 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Warthin-Starry stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy

Epple 1997 *(Continued)*

Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	**Low**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	No		
		High	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Low	

Fallone 1995

Study characteristics			
Patient sampling	Type of study: prospective study Consecutive or random sample: consecutive patients		
Patient characteristics and setting	Sample size: 50 Female: not stated Age: not stated Presentation: 1. Patients undergoing endoscopy Exclusion 1. Conditions that would make gastric biopsy dangerous 2. Lactating 3. Pregnant or women of child-bearing potential who were not using adequate control Setting: secondary care, Canada		
Index tests	Index test: urea breath test-^{13}C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: > 1.5% excretion (15 minutes)		
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with Silver stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 4 (7.4%)		
Comparative			
Notes			
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{13}C			

Fallone 1995 *(Continued)*

Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		Low	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Fallone 1996

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 106 Female: 51 (48.1%) Age: 54 years Presentation: 1. Patients undergoing endoscopy Exclusion: 1. Recent treatment for *H pylori* Setting: secondary care, Canada
Index tests	Index test: serology Further details: Technical specifications: HeliSAL TM serum Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist

Fallone 1996 *(Continued)*

	Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	**Low**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Low	

Fanti 1999

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 84 Female: 45 (53.6%) Age: 50 years Presentation: 1. Patients with dyspepsia 2. Not on current treatment for *H pylori* or ulcers Setting: secondary care, Italy
Index tests	Index test: stool antigen test Further details: Technical specifications: Premier Platinum HpSA (Meridian Diagnostics) Performed by: not stated Criteria for positive diagnosis: Absorbance 450/630 nm > 0.150
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		

Fanti 1999 *(Continued)*

		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Faruqui 2007

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 50 Female: 26 (52%) Age: 36 years Presentation: 1. Patients with dyspepsia despite anti-ulcer treatment Exclusion: 1. Myocardial infarction in the last 6 months 2. Cardiac failure 3. Bleeding diathesis Setting: secondary care, Pakistan
Index tests	Index test: stool antigen test Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy

Faruqui 2007 *(Continued)*

Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Ferrara 1998

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process		
Patient characteristics and setting	Sample size: 100 Female: 56 (56%) Age: not stated Presentation: 1. Patients with dyspepsia 2. Not on current treatment for *H pylori* Setting: secondary care, Italy		
Index tests	Index test: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated		
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		

Ferrara 1998 *(Continued)*

If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Formichella 2013

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 500 Female: 263 (52.6%) Age: 50 years Presentation: 1. Patients undergoing routine endoscopy Exclusion: 1. Undergone *H pylori* eradication therapy 2. Active immunosuppressive therapy 3. Suffering from malignant diseases Setting: secondary care, Germany
Index tests	Index test 1a: serology Further details: Technical specifications: recomWell ELISA (Mikrogen) Performed by: not stated Criteria for positive diagnosis: not stated Index test 1b: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: 2 or more antigens Index test 1c: serology

Formichella 2013 *(Continued)*

	Further details: Technical specifications: Immunoblot Helicobacter (Mikrogen) Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain, Warthin-Starry stain, and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**

Formichella 2013 *(Continued)*

DOMAIN 4: Flow and Timing		
Was there an appropriate interval between index test and reference standard?	Yes	
Did all patients receive the same reference standard?	Yes	
Were all patients included in the analysis?	Unclear	
		Unclear

Germana 2001

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 100 Female: 52 (52%) Age: 51 years Presentation: 1. Patients with dyspepsia 2. Not on current treatment for *H pylori* Setting: secondary care, Italy
Index tests	Index test: urea breath test-^{13}C Further details: Technical specifications: Wagner Analysen - Tecturik Performed by: not stated Criteria for positive diagnosis: delta over baseline > 4.0% (30 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and immunohistochemical stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			

Germana 2001 *(Continued)*

Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Graham 1996a

Study characteristics	
Patient sampling	Type of study: retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 75 Female: not stated Age: not stated Presentation: 1. Patients undergoing screening for *H pylori* and who underwent endoscopy Setting: secondary care, USA

Graham 1996a *(Continued)*

Index tests	Index test: serology Further details: Technical specifications: FlexSure HP Performed by: not stated Criteria for positive diagnosis: pink line
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 476 (86.4%)
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**

Graham 1996a *(Continued)*

DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Gramley 1999

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients		
Patient characteristics and setting	Sample size: 22 Female: not stated Age: not stated Presentation: 1. Patients undergoing endoscopy Setting: secondary care, USA		
Index tests	Index test: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated		
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)		
Comparative			
Notes			
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			

Gramley 1999 *(Continued)*

Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	**Low**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Unclear	

Guo 2011

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 328 Female: 90 (27.4%) Age: 47 years Presentation: 1. Patients with gastrointestinal symptoms 2. No previous treatment or stopped treatment for *H pylori* Setting: secondary care, China
Index tests	Index test: stool antigen test

Guo 2011 *(Continued)*

	Further details: Technical specifications: Kyowa pharmaceutical Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with silver stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	**Low**
DOMAIN 4: Flow and Timing			

Guo 2011 *(Continued)*

Was there an appropriate interval between index test and reference standard?	Unclear	
Did all patients receive the same reference standard?	Yes	
Were all patients included in the analysis?	Unclear	
		Unclear

Gurbuz 2005

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: neither - patients with previous gastric surgery excluded
Patient characteristics and setting	Sample size: 65 Female: 45 (69.2%) Age: not stated Presentation: 1. Patients undergoing routine endoscopy Exclusion: 1. Undergone *H pylori* eradication therapy 2. Pregnancy or lactation 3. Prior gastric surgery Setting: secondary care, Turkey
Index tests	Index test: urea breath test-^{14}C Further details: Technical specifications: Heliprobe system Performed by: not stated Criteria for positive diagnosis: Counts per minute > 50 (10 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 3 (4.4%)
Comparative	
Notes	

Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			

Gurbuz 2005 *(Continued)*

Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		High	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{14}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Hafeez 2007

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: neither - patients with inadequate breath samples excluded
Patient characteristics and setting	Sample size: 60 Female: not stated Age: not stated Presentation: 1. Children with gastrointestinal symptoms Setting: secondary care, Pakistan

Hafeez 2007 *(Continued)*

Index tests	Index test 1: urea breath test-^{13}C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: delta over baseline > 4.0% (10 minutes, 20 minutes, and 30 minutes) Index test 2: stool antigen test Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 6 (10%)
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		High	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		

Hafeez 2007 *(Continued)*

If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Han 2012

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 99 Female: not stated Age: not stated Presentation: 1. Patients who had undergone urea breath tests and endoscopy Setting: secondary care, South Korea
Index tests	Index test: urea breath test - unknown isotope Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated

Han 2012 *(Continued)*

Comparative			
Notes			
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Urea breath test - unknown isotope			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Inelmen 2004

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study

Inelmen 2004 *(Continued)*

	Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 122 Female: 81 (66.4%) Age: 80 years Presentation: 1. Patients undergoing upper gastrointestinal endoscopy Setting: secondary care, Italy
Index tests	Index test 1: urea breath test-^{13}C Further details: Technical specifications: BreathQuality-UBT 13C-Urea Kit, Zeta Farmaceutici SpA Performed by: not stated Criteria for positive diagnosis: delta over baseline > 5.0% (30 minutes) Index test 2: stool antigen test Further details: Technical specifications: Premier Platinum HpSA (Meridian Diagnostics) Performed by: not stated Criteria for positive diagnosis: definite yellow colour
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	**Low**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		

Inelmen 2004 *(Continued)*

If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Unclear	

Iqbal 2013

Study characteristics	
Patient sampling	Type of study: retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 50 Female: 19 (38%) Age: 41 years Presentation: 1. Patients who underwent upper gastrointestinal endoscopy Setting: secondary care, Pakistan
Index tests	Index test: serology Further details: Technical specifications: HpG screen ELISA kit Performed by: not stated Criteria for positive diagnosis: > 7 units/ml

Iqbal 2013 *(Continued)*

Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		

Iqbal 2013 *(Continued)*

Were all patients included in the analysis?	Unclear
	Unclear

Islam 2005

Study characteristics	
Patient sampling	Type of study: prospective study Consecutive or random sample: neither - patients without stool samples excluded
Patient characteristics and setting	Sample size: 112 Female: not stated Age: not stated Presentation: 1. Patients undergoing upper gastrointestinal endoscopy Setting: secondary care, New Zealand
Index tests	Index test: stool antigen test Further details: Technical specifications: Premier Platinum HpSA (Meridian Diagnostics) Performed by: pathologists Criteria for positive diagnosis: Absorbance 450/630 nm > 0.120
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Immunoperoxidase stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 15 (11.8%)
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		

Islam 2005 *(Continued)*

		High	**Unclear**
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
If a threshold was used, was it pre-specified?	Yes		
		Low	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Ivanova 2010

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 33 Female: 16 (48.5%) Age: 42 years Presentation: 1. Patients undergoing upper gastrointestinal endoscopy Setting: secondary care, Bulgaria
Index tests	Index test: serology Further details: Technical specifications: Rapid HP, US Meds Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with Giemsa stain Further details:

Ivanova 2010 *(Continued)*

	Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Jekarl 2013

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: neither - patients with a recent antibiotic treatment were excluded
Patient characteristics and setting	Sample size: 209 Female: 85 (40.7%) Age: not stated Presentation: 1. Patients undergoing routine health check-up and upper gastrointestinal endoscopy Exclusion: 1. Recent ulcer or *H pylori* treatment 2. Previous gastric surgery 3. Previous gastric cancer Setting: secondary care, Korea
Index tests	Index test: stool antigen test Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: Absence of yellow
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Warthin-Starry stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 57 (21.4%)
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		High	**Unclear**
DOMAIN 2: Index Test Stool Antigen Test			

Jekarl 2013 *(Continued)*

Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Jensen 1998

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear
Patient characteristics and setting	Sample size: 35 Female: not stated Age: not stated Presentation: 1. Patients referred for endoscopy Exclusion: Recent *H pylori* treatment Setting: secondary care, USA
Index tests	Index test: urea breath test-^{14}C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: disintegrations per minute > 200 (10 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain

Jensen 1998 *(Continued)*

	Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 7 (16.7%)
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{14}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		

Jensen 1998 *(Continued)*

	High

Jordaan 2008

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: neither - patients with previous gastrointestinal surgery excluded
Patient characteristics and setting	Sample size: 103 Female: not stated Age: not stated Presentation: 1. Patients with dyspepsia Exclusion criteria: 1. Recent *H pylori* therapy 2. Major gastrointestinal surgery Setting: secondary care, South Africa
Index tests	Index test: urea breath test-^{13}C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: delta over baseline > 4.5% (time not stated)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 8 (7.2%)
Comparative	
Notes	

Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		

Jordaan 2008 *(Continued)*

		High	Unclear
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Kalach 1998a

Study characteristics	
Patient sampling	Type of study: prospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 100 Female: 35 (35%) Age: 11 years Presentation: 1. Children undergoing upper gastrointestinal endoscopy for recurrent epigastric pain or upper GI tract disorders Exclusion: 1. Recent *H pylori* treatment Setting: secondary care, France
Index tests	Index test: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: > 6 IU /ml

Kalach 1998a *(Continued)*

Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		

Kalach 1998a *(Continued)*

Were all patients included in the analysis?	Unclear		
		Unclear	

Kamel 2011

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process		
Patient characteristics and setting	Sample size: 55 Female: not stated Age: 67 years Presentation: 1. Older adults with dyspepsia and no gastrointestinal bleeding Setting: secondary care, Egypt		
Index tests	Index test: stool antigen test Further details: Technical specifications: CerTest *H pylori* Card Performed by: not stated Criteria for positive diagnosis: not stated		
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			

Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**

Kamel 2011 *(Continued)*

DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Kim 2016

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 107 Female: 56 (52.3%) Age: 41 years Presentation: 1. Patients undergoing upper gastrointestinal endoscopy Exclusion: 1. Recent *H pylori* treatment Setting: secondary care, South Korea
Index tests	Index test: urea breath test-^{13}C Further details: Technical specifications: UbiT-IR300 apparatus Performed by: not stated Criteria for positive diagnosis: delta over baseline > 2.5% (20 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated

Kim 2016 *(Continued)*

	Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Korstanje 2006

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 20 Female: 9 (45%) Age: 68 years Presentation: 1. Patients with atrophic gastritis Setting: primary care, Netherlands
Index tests	Index test 1: urea breath test-^{13}C Further details: Technical specifications: INFAI, Bochum, Germany Performed by: not stated Criteria for positive diagnosis: delta over baseline > 4.0% (30 minutes) Index test 2: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: Absorbance (wavelength not stated) > 0.320
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**High**
DOMAIN 2: Index Test Urea breath test-^{13}C			

Korstanje 2006 *(Continued)*

Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Kuloglu 2008

Study characteristics	
Patient sampling	Type of study: prospective study Consecutive or random sample: neither - patients without a either a stool sample or a breath sample excluded
Patient characteristics and setting	Sample size: 109 Female: 58 (53.2%) Age: 12 years Presentation: 1. Children with symptoms suggestive of *H pylori* infection Exclusion criteria: 1. Recent *H pylori* treatment Setting: secondary care, Turkey
Index tests	Index test 1: urea breath test-^{14}C

Kuloglu 2008 *(Continued)*

	Further details: Technical specifications: Heliprobe BreathCard Performed by: not stated Criteria for positive diagnosis: Counts per minute > 50 (10 minutes) Index test 2: stool antigen test Further details: Technical specifications: Rapid HpSA test (LİNEAR Chemical) Performed by: not stated Criteria for positive diagnosis: pinkish red band (within 10 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 16 (12.8%)
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		High	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{14}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
If a threshold was used, was it pre-specified?	Yes		

Kuloglu 2008 *(Continued)*

		Low	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Ladas 2002a

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 130 Female: 48 (36.9%) Age: 50 years Presentation: 1. Patients with dyspepsia Exclusion: 1. Recent *H pylori* therapy 2. Malignancy 3. Pregnancy 4. Gastric surgery Setting: secondary care, Greece
Index tests	Index test 1a: serology Further details: Technical specifications: Pyloriset EIA-G Performed by: not stated Criteria for positive diagnosis: ≥ 300 Index test 1b: serology Further details: Technical specifications: Milenia H Pylori IgG Performed by: not stated Criteria for positive diagnosis: ≥ 44
Target condition and reference standard(s)	Target condition: *H pylori* infection

Ladas 2002a *(Continued)*

	Reference standard: endoscopic biopsy with Giemsa and Warthin-Starry stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	**Low**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
If a threshold was used, was it pre-specified?	Yes		
		Low	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		Low	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		

Ladas 2002a *(Continued)*

Were all patients included in the analysis?	Yes
	Unclear

Lahner 2004

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 27 Female: 19 (70.4%) Age: 52 years Presentation: 1. Patients with atrophic gastritis Exclusion criteria: 1. Gastric surgery 2. Gastric malignancy 3. Recent *H pylori* treatment 4. Diarrhoea 5. Constipation Setting: not stated
Index tests	Index test 1: urea breath test-^{13}C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: delta over baseline > 4.5% (15 minutes and 30 minutes) Index test 2: stool antigen test Further details: Technical specifications: HpSA, Meridian Performed by: not stated Criteria for positive diagnosis: Absorbance 450 nm ≥ 0.160
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**

Lahner 2004 *(Continued)*

DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	**Low**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Low	

Lee 1998

Study characteristics

Lee 1998 *(Continued)*

Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 71 Female: not stated Age: not stated Presentation: 1. Patients undergoing endoscopy for duodenitis, gastritis, duodenal ulcer, gastric ulcer Exclusion criteria: 1. Recent *H pylori* treatment Setting: secondary care, Singapore
Index tests	Index test: urea breath test-^{13}C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: delta over baseline > 6% (30 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	**Low**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
If a threshold was used, was it pre-specified?	Unclear		

Lee 1998 *(Continued)*

		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Low	

Logan 1991a

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 50 Female: 24 (48%) Age: 51 years Presentation: 1. Patients undergoing upper gastrointestinal endoscopy Exclusion criteria: 1. Recent *H pylori* infection 2. Previous gastric surgery Setting: secondary care, UK
Index tests	Index test: urea breath test-^{13}C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: > Mean + 3 standard deviations above normal level (60 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated

Logan 1991a *(Continued)*

	Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	No		
If a threshold was used, was it pre-specified?	No		
		High	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Lombardo 2003

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: neither - histology performed in a subset of patients
Patient characteristics and setting	Sample size: 28 Female: not stated Age: not stated Presentation: 1. Patients who had undergone gastrectomy Setting: secondary care, Italy
Index tests	Index test: urea breath test - unknown isotope Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: delta over baseline > 4 per ml (at 5-minute intervals up to 30 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 72 (72%)
Comparative	
Notes	

Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		High	**High**
DOMAIN 2: Index Test Urea breath test - unknown isotope			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		

Lombardo 2003 *(Continued)*

		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	No		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Lottspeich 2007

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: neither - patients with recent antibiotic treatment were excluded
Patient characteristics and setting	Sample size: 56 for urea breath test, 100 for stool antigen test Female: not stated Age: 10 years Presentation: 1. Children with abdominal symptoms undergoing endoscopy Exclusion criteria: 1. Recent *H pylori* treatment Setting: secondary care, Germany
Index tests	Index test 1: urea breath test-^{13}C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: delta over baseline > 5.0% (30 minutes) Index test 2: stool antigen test Further details: Technical specifications: IDEIA HpStAR assay (DakoCytomation) Performed by: not stated Criteria for positive diagnosis: Absorbance 450/620 nm to 650 nm ≥ 0.150
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain or Giemsa stain Further details:

Lottspeich 2007 *(Continued)*

	Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 44 (44%) for urea breath test; 0 (0%) for stool antigen test
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		High	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		

Lottspeich 2007 *(Continued)*

		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Luthra 1998

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 240 Female: not stated Age: not stated Presentation: 1. Patients undergoing upper gastrointestinal endoscopy Excluded: 1. People with upper GI bleeding 2. People with coagulation abnormalities Setting: not stated
Index tests	Index test: serology Further details: Technical specifications: Pyloristat (BioWhittaker) Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain, immunostain, or Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	
Methodological quality	

Luthra 1998 *(Continued)*

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Mana 2001a

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 182 Female: not stated Age: not stated

Mana 2001a *(Continued)*

	Presentation: 1. Patients undergoing upper gastrointestinal endoscopy 2. People not taking *H pylori* medication Setting: secondary care, Belgium
Index tests	Index test 1: urea breath test-^{13}C Further details: Technical specifications: not stated Performed by: not stated Multiple criteria for positive diagnosis: • Delta over baseline > 3.0% (10 minutes) • Delta over baseline > 3.0% (20 minutes) • Delta over baseline > 3.0% (30 minutes) • Delta over baseline > 3.5% (10 minutes) • Delta over baseline > 3.5% (20 minutes) • Delta over baseline > 3.5% (30 minutes) • Delta over baseline > 4.0% (10 minutes) • Delta over baseline > 4.0% (20 minutes) • Delta over baseline > 4.0% (30 minutes) • Delta over baseline > 4.5% (10 minutes) • Delta over baseline > 4.5% (20 minutes) • Delta over baseline > 4.5% (30 minutes) • Delta over baseline > 5.0% (10 minutes) • Delta over baseline > 5.0% (20 minutes) • Delta over baseline > 5.0% (30 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with immunohistochemistry and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		

Mana 2001a *(Continued)*

		Low	**Low**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	No		
		High	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Unclear	

Mansour-Ghanaei 2011

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 125 Female: 65 (52%) Age: 36 years Presentation: 1. Patients with dyspepsia Exclusion: 1. Recent or past *H pylori* eradication 2. Pregnancy 3. Severe cardiopulmonary disorders or other life-threatening illnesses Setting: secondary care, Iran
Index tests	Index test 1: urea breath test-^{14}C

Mansour-Ghanaei 2011 *(Continued)*

	Further details: Technical specifications: Heliprobe BreathCard Performed by: not stated Criteria for positive diagnosis: Counts per minute > 50 (15 minutes) Index test 2: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: > 11 IU
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	**Low**
DOMAIN 2: Index Test Urea breath test-^{14}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	No		
		High	**Low**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		

Mansour-Ghanaei 2011 *(Continued)*

		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Low	

Mion 1994

Study characteristics	
Patient sampling	Type of study: retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 95 Female: not stated Age: not stated Presentation: 1. Patients with upper abdominal symptoms Exclusion: 1. Patients with previous gastric surgery Setting: secondary care, France
Index tests	Index test: urea breath test-^{13}C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: > + 3 delta 0/00 (30 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with Warthin-Starry stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated

Mion 1994 *(Continued)*

	Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	No		
		High	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Misawa 1998

Study characteristics

Misawa 1998 *(Continued)*

Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 114 Female: 46 (40.4%) Age: not stated Presentation: 1. Patients with gastritis, gastric, or duodenal ulcers Setting: secondary care, Japan
Index tests	Index test 1a: serology (IgA) Further details: Technical specifications: GAP-IgA (BioMerica) Performed by: not stated Criteria for positive diagnosis: not stated Index test 1b: serology (IgG) Further details: Technical specifications: GAP-IgG (BioMerica) Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with immunostaining (Carnoy's solution) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		

Misawa 1998 *(Continued)*

If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Mohammadian 2007

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 179 Female: 108 (60.3%) Age: 54 years Presentation: 1. Patients undergoing endoscopy for gastrointestinal problems Setting: secondary care, Iran
Index tests	Index test: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated

Mohammadian 2007 *(Continued)*

	Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Monteiro 2001a

Study characteristics

Monteiro 2001a *(Continued)*

Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 104 Female: not stated Age: not stated Presentation: 1. Patients undergoing endoscopy Exclusion criteria: 1. Recent *H pylori* therapy 2. Bleeding disorders or other conditions with contraindication for endoscopy or biopsy Setting: secondary care, France
Index tests	Index test 1: urea breath test-^{13}C Further details: Technical specifications: ABCA, Europa Scientific Performed by: not stated Criteria for positive diagnosis: not stated Index test 2a: serology Further details: Technical specifications: Pyloriset EIA Kit (Orion Diagnostica) Performed by: not stated Criteria for positive diagnosis: > = 300 Index test 2b: serology Further details: Technical specifications: Helicoblot Immunoblot kit Performed by: not stated Criteria for positive diagnosis: not stated Index test 3: stool antigen test Further details: Technical specifications: Premier Platinum HpSA, Meridian Performed by: not stated Criteria for positive diagnosis: Absorbance (wavelength not reported) > = 0.160
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			

Monteiro 2001a *(Continued)*

Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	**Low**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		

Monteiro 2001a *(Continued)*

Were all patients included in the analysis?	Unclear
	Unclear

Morales 1995

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 104 Female: 52 (50%) Age: 50 years Presentation: 1. Patients with upper abdominal symptoms Setting: Outpatients, Mexico
Index tests	Index test 1: urea breath test-^{14}C Further details: Technical specifications: not stated Performed by: not stated Multiple criteria for positive diagnosis: First criterion: ≥ 1.6% excretion (time not stated) Second criterion: not stated
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with Warthin-Starry stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		

Morales 1995 *(Continued)*

		Unclear	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{14}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	No		
		High	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Noguera 1998

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear
Patient characteristics and setting	Sample size: 38 Female: not stated Age: not stated Presentation: 1. Patients undergoing urea breath tests and endoscopic biopsy Setting: secondary care, Argentina
Index tests	Index test 1: urea breath test-^{13}C Further details: Technical specifications: not stated Performed by: not stated Multiple criteria for positive diagnosis: • > 1% excretion (10 minutes) • > 1% excretion (20 minutes)

Noguera 1998 *(Continued)*

	• > 1% excretion (30 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 87 (69.6%)
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{14}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		

Noguera 1998 *(Continued)*

Did all patients receive the same reference standard?	Yes	
Were all patients included in the analysis?	No	
		High

Novis 1991

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 76 Female: not stated Age: not stated Presentation: 1. Patients undergoing endoscopy for gastrointestinal symptoms Setting: secondary care, Israel
Index tests	Index test 1: urea breath test-^{14}C Further details: Technical specifications: not stated Performed by: not stated Multiple criteria for positive diagnosis: • > 4.7% excretion (5 minutes) • > 4.7% excretion (10 minutes) • > 4.7% excretion (15 minutes) • > 4.7% excretion (20 minutes) • > 4.7% excretion (25 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			

Novis 1991 *(Continued)*

Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{14}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	No		
		High	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Ogata 2001

Study characteristics	
Patient sampling	Type of study: prospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 47 Female: 27 (57.4%) Age: 12 years Presentation: 1. Children with dyspepsia undergoing endoscopy Exclusion: 1. Recent *H pylori* treatment 2. Immunosuppressive treatment or chemotherapy

Ogata 2001 *(Continued)*

	3. Extradigestive disease Setting: secondary care, Brazil
Index tests	Index test 1: urea breath test-^{13}C Further details: Technical specifications: Isomed Performed by: not stated Criteria for positive diagnosis: > 3% excretion (time not stated) Index test 2: serology Further details: Technical specifications: Cobas Core II (Roche) Performed by: not stated Criteria for positive diagnosis: > 7 U/ml
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**High**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 2: Index Test Serology			

Ogata 2001 *(Continued)*

Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Ozturk 2003

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 73 Female: 56 (74.6%) Age: 41 years Presentation: 1. Patients with dyspepsia Setting: secondary care, Turkey
Index tests	Index test 1a: urea breath test-^{14}C Further details: Technical specifications: Heliprobe BreathCard Performed by: not stated Criteria for positive diagnosis: Counts per minute > 50 (10 minutes) Index test 1b: urea breath test-^{14}C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: disintegrations per minute > 100 (10 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection

Ozturk 2003 *(Continued)*

	Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{14}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		

Ozturk 2003 *(Continued)*

Were all patients included in the analysis?	Unclear
	Unclear

Peitz 2001

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 145 Female: 87 (60%) Age: 59 years Presentation: 1. Patients with dyspepsia Exclusion criteria: 1. Recent *H pylori* treatment 2. Recent NSAID treatment 3. Previous gastric surgery 4. Clotting disorders Setting: secondary care, Germany
Index tests	Index test: serology Further details: Technical specifications: Helisa Rapid Whole Blood Test (Cortecs Diagnostics Ltd) Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)
Comparative	
Notes	

Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		

Peitz 2001 *(Continued)*

Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	**Low**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Unclear	

Peura 1996

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 200 Female: 118 (59%) Age: not stated Presentation: 1. Patients undergoing endoscopy Exclusion criteria: 1. Recent *H pylori* treatment 2. Gastric surgery Setting: secondary care, USA
Index tests	Index test: urea breath test-^{14}C

Peura 1996 *(Continued)*

	Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: disintegrations per minute > 200 (10 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{14}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	**Low**
DOMAIN 4: Flow and Timing			

Peura 1996 *(Continued)*

Was there an appropriate interval between index test and reference standard?	Yes	
Did all patients receive the same reference standard?	Yes	
Were all patients included in the analysis?	Unclear	
		Unclear

Puspok 1999

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients		
Patient characteristics and setting	Sample size: 72 Female: 42 (58.3%) Age: 55 years Presentation: 1. Patients undergoing endoscopy Exclusion criteria: 1. Recent *H pylori* treatment Setting: secondary care, Austria		
Index tests	Index test: stool antigen test Further details: Technical specifications: Premier Platinum HpSA (Meridian Diagnostics) Performed by: not stated Criteria for positive diagnosis: Absorbance 450/620 nm ≥ 0.100		
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)		
Comparative			
Notes			
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			

Puspok 1999 *(Continued)*

Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	**Low**
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Unclear	

Qadeer 2009

Study characteristics	
Patient sampling	Type of study: prospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 100 Female: 50 (50%) Age: 39 years Presentation: 1. Patients with dyspepsia Exlusion criteria: 1. Recent *H pylori* therapy 2. Not on anti-coagulant therapy

Qadeer 2009 *(Continued)*

	3. Oral anticoagulants or NSAID treatment Setting: secondary care, Pakistan
Index tests	Index test: stool antigen test Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: pink-red band
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	**Low**

Qadeer 2009 *(Continued)*

DOMAIN 4: Flow and Timing		
Was there an appropriate interval between index test and reference standard?	Unclear	
Did all patients receive the same reference standard?	Yes	
Were all patients included in the analysis?	Unclear	
		Unclear

Rafeey 2007

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 96 Female: 31 (32.3%) Age: 8 years Presentation: 1. Children with dyspepsia or abdominal pain Exclusion criteria: 1. Recent *H pylori* treatment 2. Diarrhoea Setting: secondary care, Iran
Index tests	Index test: stool antigen test Further details: Technical specifications: Equipar HPSA test Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**

Rafeey 2007 *(Continued)*

DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Rasool 2007

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 94 Female: 34 (36.2%) Age: 41 years Presentation: 1. Patients with dyspepsia Exclusion criteria:

Rasool 2007 *(Continued)*

	1. Recent *H pylori* treatment 2. Pregnancy 3. Gastric surgery Setting: secondary care, Pakistan
Index tests	Index test: urea breath test Further details: Technical specifications: Heliprobe BreathCard Performed by: not stated Criteria for positive diagnosis: Counts per minute > 50 (10 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	**Low**
DOMAIN 2: Index Test Urea breath test-^{14}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		

Rasool 2007 *(Continued)*

		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Rathbone 1986

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 73 Female: not stated Age: not stated Presentation: 1. Patients with dyspepsia Setting: secondary care, UK
Index tests	Index test: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: > Mean + 2 standard deviations above normal level
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**

Rathbone 1986 *(Continued)*

DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	No		
		High	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Safe 1993

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 100 Female: 59 (59%) Age: 72 years Presentation: 1. Elderly dyspeptic patients Setting: secondary care, UK

Safe 1993 *(Continued)*

Index tests	Index test: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: > 10 units/ml
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**

Safe 1993 *(Continued)*

DOMAIN 4: Flow and Timing		
Was there an appropriate interval between index test and reference standard?	Yes	
Did all patients receive the same reference standard?	Yes	
Were all patients included in the analysis?	Unclear	
		Unclear

Salles-Montaudon 2002

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 107 Female: 71 (66.4%) Age: 85 years Presentation: 1. Adults > 75 years Exclusion criteria: 1. Contraindication to biopsy Setting: secondary care, Switzerland
Index tests	Index test 1: urea breath test-^{13}C Further details: Technical specifications: ABCA, Europa Scientific Performed by: not stated Criteria for positive diagnosis: delta over baseline > 3.5% (30 minutes) Index test 2: serology Further details: Technical specifications: Pyloriset EIA Kit (Orion Diagnostica) Performed by: not stated Criteria for positive diagnosis: > 300 Units Index test 3: stool antigen test Further details: Technical specifications: Premier Platinum HpSA, Meridian Performed by: not stated Criteria for positive diagnosis: Absorbance (wavelength not reported) > 0.160
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated

Salles-Montaudon 2002 *(Continued)*

Comparative
Notes

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**

Salles-Montaudon 2002 *(Continued)*

DOMAIN 4: Flow and Timing		
Was there an appropriate interval between index test and reference standard?	Unclear	
Did all patients receive the same reference standard?	Yes	
Were all patients included in the analysis?	Unclear	
		Unclear

Schilling 2001

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 68 Female: 20 (29.4%) Age: 62 years Presentation: 1. Patients with partial gastric resection Exclusion criteria: Recent *H pylori* treatment Setting: secondary care, Germany
Index tests	Index test: urea breath test-^{13}C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: delta over baseline > 4.0% (30 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with Warthin-Starry stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			

Schilling 2001 *(Continued)*

Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**High**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Scuderi 2000

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 250 Female: 127 (50.8%) Age: 58 years Presentation: 1. Patients with dyspeptic symptoms Setting: secondary care, Italy
Index tests	Index test: stool antigen test

Scuderi 2000 *(Continued)*

	Further details: Technical specifications: Premier Platinum HpSA (Meridian Diagnostics) Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	**Low**
DOMAIN 4: Flow and Timing			

Scuderi 2000 *(Continued)*

Was there an appropriate interval between index test and reference standard?	Unclear
Did all patients receive the same reference standard?	Yes
Were all patients included in the analysis?	Unclear
	Unclear

Segamwenge 2014

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: neither - patients with recent antibiotic treatment were excluded
Patient characteristics and setting	Sample size: 160 Female: not stated Age: not stated Presentation: 1. Patients with dyspepsia Exclusion criteria 1. Could not tolerate endoscopy 2. Recent *H pylori* treatment 3. Pain attributable to pancreas or liver 4. NSAID-related dyspepsia Setting: secondary care, Italy
Index tests	Index test: stool antigen test Further details: Technical specifications: Rapid strip HPSA (Meridian Bioscience) Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			

Segamwenge 2014 *(Continued)*

Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		High	**Unclear**
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Selcukcan 2011

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 100 Female: 47 (47%) Age: not stated Presentation: 1. Infants undergoing endoscopy Exclusion criteria:

Selcukcan 2011 *(Continued)*

	1. No recent H pylori treatment Setting: secondary care, Turkey
Index tests	Index test: urea breath test-^{14}C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{14}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		

Selcukcan 2011 *(Continued)*

		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Sharbatdaran 2013

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 61 Female: 36 (59%) Age: 31 years Presentation: 1. Patients with dyspepsia Exclusion criteria: 1. Recent *H pylori* infection 2. Gastric cancer 3. Bleeding during endoscopy Setting: secondary care, Iran
Index tests	Index test: stool antigen test Further details: Technical specifications: GA Generic Assay Performed by: not stated Criteria for positive diagnosis: Absorbance 450 nm > + 0.1 of negative control
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)
Comparative	
Notes	
Methodological quality	

Sharbatdaran 2013 *(Continued)*

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	**Low**
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
If a threshold was used, was it pre-specified?	Yes		
		Low	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Unclear	

Sheu 1998a

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 135 Female: not stated Age: not stated Presentation:

Sheu 1998a *(Continued)*

	1. Patients with dyspepsia Setting: secondary care, Mexico
Index tests	Index test: urea breath test-^{13}C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not clearly stated
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		

Sheu 1998a *(Continued)*

		High	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Sheu 1998b

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 66 Female: not stated Age: not stated Presentation: 1. Patients with gastrectomy Setting: secondary care, Mexico
Index tests	Index test: urea breath test-^{13}C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not clearly stated
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			

Sheu 1998b *(Continued)*

Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**High**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Shin 2009

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 651 Female: 254 (39%) Age: 58 years Presentation: 1. Patients undergoing endoscopy Exclusion criteria: 1. Recent *H pylori* treatment 2. Chronic medication 3. Gastric surgery

Shin 2009 *(Continued)*

	Setting: secondary care, South Korea
Index tests	Index test: serology Further details: Technical specifications: Genedia *H pylori* Performed by: not stated Criteria for positive diagnosis: Absorbance 450 nm > 0.406
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	**Low**

Shin 2009 *(Continued)*

DOMAIN 4: Flow and Timing	
Was there an appropriate interval between index test and reference standard?	Unclear
Did all patients receive the same reference standard?	Yes
Were all patients included in the analysis?	Unclear
	Unclear

Soomro 2012

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 100 Female: 44 (44%) Age: not stated Presentation: 1. Patients undergoing endoscopic biopsy for dyspepsia or gastritis Setting: secondary care, Pakistan
Index tests	Index test: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated Index test: stool antigen test Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	
Methodological quality	

Soomro 2012 *(Continued)*

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Surveyor 1989

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 63 Female: 30 (47.8%) Age: 59 years Presentation: 1. Patients with symptoms related to upper gastrointestinal tract undergoing endoscopy Setting: secondary care, Australia
Index tests	Index test: urea breath test-^{14}C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain, Warthin-Starry stain, and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)
Comparative	
Notes	

Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	**Low**
DOMAIN 2: Index Test Urea breath test-^{14}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		

Surveyor 1989 *(Continued)*

		Unclear	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Unclear	

Thobani 1995

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 26 Female: not stated Age: not stated Presentation: 1. Patients with upper gastrointestinal symptoms Setting: secondary care, Pakistan
Index tests	Index test: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: > 2
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated

Thobani 1995 *(Continued)*

Comparative			
Notes			
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Tiwari 2014

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study

Tiwari 2014 *(Continued)*

	Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 30 Female: 25 (83.3%) Age: not stated Presentation: 1. Patients undergoing endoscopy Exclusion criteria: 1. Recent *H pylori* treatment Setting: secondary care, India
Index tests	Index test: urea breath test-^{14}C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: disintegrations per minute > 200 (10 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy (staining not reported, probably H & E) Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{14}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**

Tiwari 2014 *(Continued)*

DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Trevisani 2005

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 105 Female: 50 (47.6%) Age: 58 years Presentation: 1. Patients referred to endoscopy centre Exclusion criteria: 1. Recent *H pylori* treatment 2. Pregnancy or lactation 3. Steroids or NSAID treatment 4. Prior gastric surgery 5. Bleeding peptic ulcer 6. Severe concomitant diseases Setting: secondary care, Italy
Index tests	Index test 1a: stool antigen test Further details: Technical specifications: Amplified IDEA Hp StAR Performed by: doctor Criteria for positive diagnosis: Absorbance 450 nm ≥ 0.190 Index test 1b: stool antigen test Further details: Technical specifications: Immunocard Stat Performed by: doctor Criteria for positive diagnosis: pink red band (5 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection

Trevisani 2005 *(Continued)*

	Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		

Trevisani 2005 *(Continued)*

Did all patients receive the same reference standard?	Yes
Were all patients included in the analysis?	Unclear
	Unclear

Vandenplas 1992

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 95 Female: 50 (52.6%) Age: 9 years Presentation: 1. Children with chronic abdominal pain Exclusion criteria: 1. Recent *H pylori* treatment Setting: secondary care, Belgium
Index tests	Index test 1: urea breath test-^{13}C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not clearly stated Index test 2: serology Further details: Technical specifications: Malakit Helicobacter pylori (Biolab) Performed by: not stated Criteria for positive diagnosis: > Mean + 3 standard deviations above normal level
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**

Vandenplas 1992 *(Continued)*

DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	**Low**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Unclear	

Villalobos 1992

Study characteristics

Villalobos 1992 *(Continued)*

Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 105 Female: 69 (65.7%) Age: not stated Presentation: 1. Patients with dyspepsia Excluded: 1. Recent *H pylori* treatment 2. Patients taking steroids 3. Patients with coagulopathy 4. Patients allergic to penicillin 5. Pregnancy or lactation Setting: secondary care, Mexico
Index tests	Index test: urea breath test-^{14}C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: disintegrations per minute > 1.6% (60 minutes)
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{14}C			

Villalobos 1992 *(Continued)*

Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Wang 2008

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: neither - patients with recent antibiotic treatment were excluded
Patient characteristics and setting	Sample size: 123 Female: 69 (56.1%) Age: 48 years Presentation: 1. Asymptomatic individuals Exclusion criteria: 1. Recent *H pylori* therapy 2. Gastric surgery Setting: secondary care, Italy
Index tests	Index test: serology Further details: Technical specifications: Assure *H pylori* Rapid Test (CIM-test, Genelabs Diagnostics Ltd) Performed by: not stated Criteria for positive diagnosis: not stated

Wang 2008 *(Continued)*

Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain, Warthin-Starry stain, and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 214 (63.5%)
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		High	**Unclear**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		

Wang 2008 *(Continued)*

Were all patients included in the analysis?	No		
		High	

Wardi 2012

Study characteristics			
Patient sampling	Type of study: retrospective study Consecutive or random sample: unclear sampling process		
Patient characteristics and setting	Sample size: 76 Female: 15 (19.7%) Age: 70 years Presentation: 1. Patients with partial gastrectomy Setting: secondary care, Israel		
Index tests	Index test: urea breath test - C13 Further details: Technical specifications: BreathID Performed by: not stated Criteria for positive diagnosis: not clearly stated		
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated		
Comparative			
Notes			
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**High**

Wardi 2012 *(Continued)*

DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	No		
		High	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Weiss 1994

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 95 Female: not stated Age: not stated Presentation: 1. Patients with abdominal pain Exclusion criteria: 1. Recent *H pylori* treatment Setting: secondary care, USA
Index tests	Index test 1a: serology Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated Index test 1b: serology Further details: Technical specifications: Cobas Core anti-*H pylori* (Roche) Performed by: not stated

Weiss 1994 *(Continued)*

	Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		

Weiss 1994 *(Continued)*

Did all patients receive the same reference standard?	Yes
Were all patients included in the analysis?	Unclear
	Unclear

Yan 2003

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: neither - patients with recent antibiotic treatment were excluded
Patient characteristics and setting	Sample size: 31 Female: not stated Age: not stated Presentation: 1. Patients undergoing endoscopy Exclusion criteria: 1. Recent *H pylori* treatment Setting: secondary care, China
Index tests	Index test: stool antigen test Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: Absorbance 450/630 nm ≥ 0.120
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with Warthin-Starry stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 32 (50.8%)
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		

Yan 2003 *(Continued)*

Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		High	**Unclear**
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Yoshimura 2001

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: unclear sampling process
Patient characteristics and setting	Sample size: 72 Female: 34 (47.2%) Age: 13 years Presentation: 1. Children undergoing endoscopy for symptoms such as anaemia and abdominal pain Exclusion criteria: 1. Recent *H pylori* treatment Setting: secondary care, Japan
Index tests	Index test 1: urea breath test-^{13}C

Yoshimura 2001 *(Continued)*

	Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: delta over baseline > 3.0% (20 minutes and 30 minutes) Index test 2: serology Further details: Technical specifications: HM-CAP Anti-*H pylori*-EIA; Kyowa Medics Performed by: not stated Criteria for positive diagnosis: ≥ 1.8
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Giemsa stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: not stated
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		Unclear	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	**Low**
DOMAIN 2: Index Test Serology			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		

Yoshimura 2001 *(Continued)*

		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		
		Unclear	

Yu 1999

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study Consecutive or random sample: neither - patients with recent antibiotic treatment were excluded
Patient characteristics and setting	Sample size: 88 Female: not stated Age: not stated Presentation: 1. Patients undergoing endoscopy Exclusion criteria: 1. Recent *H pylori* treatment Setting: secondary care, Singapore
Index tests	Index test: urea breath test-^{14}C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: not stated
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain and Warthin-Starry stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy

Yu 1999 *(Continued)*

Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 16 (16.5%)
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
		High	**Unclear**
DOMAIN 2: Index Test Urea breath test-^{14}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	**High**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		
		High	

Yu 2001

Study characteristics	
Patient sampling	Type of study: retrospective study Consecutive or random sample: consecutive patients
Patient characteristics and setting	Sample size: 32 Female: 14 (43.8%) Age: 51 years Presentation: 1. Patients undergoing endoscopy Exclusion criteria: 1. Recent *H pylori* treatment 2. Gastric surgery Setting: secondary care, Taiwan, China
Index tests	Index test 1: urea breath test-^{13}C Further details: Technical specifications: not stated Performed by: not stated Criteria for positive diagnosis: delta over baseline > 2.8% (15 minutes) Index test 2: stool antigen test Further details: Technical specifications: Premier Platinum HpSA, Meridian Performed by: not stated Multiple criteria for positive diagnosis: • Absorbance 450 nm > 0.140 • Visual assessment by gastroenterologists
Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with H & E stain Further details: Technical specifications: not stated Performed by: endoscopist and pathologist Criteria for positive diagnosis: presence of *H pylori* in biopsy
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated Number of patients who were excluded from the analysis: 0 (0%)
Comparative	
Notes	

Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		

Yu 2001 *(Continued)*

Did the study avoid inappropriate exclusions?	Yes		
		Low	**Low**
DOMAIN 2: Index Test Urea breath test-^{13}C			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Yes		
		Unclear	**Low**
DOMAIN 2: Index Test Stool Antigen Test			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
If a threshold was used, was it pre-specified?	Unclear		
		Unclear	**Low**
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		High	**Low**
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
		Unclear	

CO2 - carbon dioxide;
H & E stain - haematoxylin and eosin stain;
HpSA - *H pylori* stool antigen;
IgA - immunoglobulin A;
IgG - immunoglobulin G;
NMR - nuclear magnetic resonance;
NSAID - non-steroidal anti-inflammatory
WBC - white blood cell
All other acronyms and abbreviations are the full title of either products or companies producing products included in the study.

Characteristics of studies awaiting classification *[ordered by study ID]*

Buhigas-Garcia 2008

Study characteristics	
Patient sampling	
Patient characteristics and setting	
Index tests	urea breath test-^{13}C
Target condition and reference standard(s)	
Flow and timing	
Comparative	
Notes	

Fazeli 2004

Study characteristics	
Patient sampling	
Patient characteristics and setting	
Index tests	salivary test, potential index tests of interest
Target condition and reference standard(s)	
Flow and timing	
Comparative	
Notes	

Fuke 2009

Study characteristics	
Patient sampling	
Patient characteristics and setting	
Index tests	serology
Target condition and reference standard(s)	
Flow and timing	
Comparative	
Notes	

Glupczynski 1991

Study characteristics	
Patient sampling	
Patient characteristics and setting	
Index tests	urea breath test-^{13}C
Target condition and reference standard(s)	
Flow and timing	
Comparative	
Notes	

Karczewska 1997

Study characteristics	
Patient sampling	
Patient characteristics and setting	
Index tests	serology
Target condition and reference standard(s)	
Flow and timing	
Comparative	
Notes	

Kushch 2014

Study characteristics	
Patient sampling	
Patient characteristics and setting	
Index tests	unclear
Target condition and reference standard(s)	
Flow and timing	
Comparative	

Kushch 2014 *(Continued)*

Notes

Lappas 1997

Study characteristics	
Patient sampling	
Patient characteristics and setting	
Index tests	salivary test, potential index tests of interest
Target condition and reference standard(s)	
Flow and timing	
Comparative	
Notes	

Lee 1999a

Study characteristics	
Patient sampling	
Patient characteristics and setting	
Index tests	urea breath test-^{13}C
Target condition and reference standard(s)	
Flow and timing	
Comparative	
Notes	

Martin-de-Argila 1997

Study characteristics	
Patient sampling	
Patient characteristics and setting	
Index tests	serology
Target condition and reference standard(s)	

Martin-de-Argila 1997 *(Continued)*

Flow and timing	
Comparative	
Notes	

Mason 1997

Study characteristics	
Patient sampling	
Patient characteristics and setting	
Index tests	urea breath test
Target condition and reference standard(s)	
Flow and timing	
Comparative	
Notes	

Thong-Ngam 2011

Study characteristics	
Patient sampling	
Patient characteristics and setting	
Index tests	serology
Target condition and reference standard(s)	
Flow and timing	
Comparative	
Notes	

Tokunaga 2005a

Study characteristics	
Patient sampling	
Patient characteristics and setting	

Tokunaga 2005a *(Continued)*

Index tests	urea breath test
Target condition and reference standard(s)	
Flow and timing	
Comparative	
Notes	

Xu 1995

Study characteristics	
Patient sampling	
Patient characteristics and setting	
Index tests	urea breath test-^{13}C
Target condition and reference standard(s)	
Flow and timing	
Comparative	
Notes	

D A T A

Presented below are all the data for all of the tests entered into the review.

Table Tests. Data tables by test

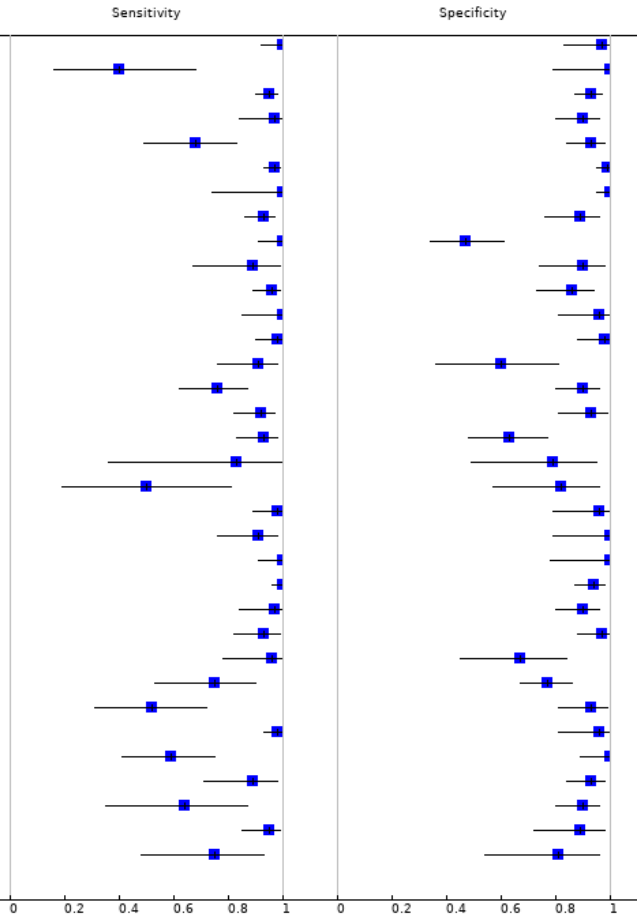
Test	No. of studies	No. of participants
1 Urea breath test-^{13}C	34	3139
2 Urea breath test-^{14}C	21	1810
3 Urea breath test - Unknown isotope	2	127
4 Serology	34	4242
5 Stool antigen test	29	2988
6 Urea breath test-^{13}C (delta over baseline > 3% (20 minutes))	2	254
7 Urea breath test-^{13}C (delta over baseline > 3% (30 minutes))	3	333

Test	No. of studies	No. of participants
8 Urea breath test-^{13}C (delta over baseline > 3.5% (30 minutes))	3	368
9 Urea breath test-^{13}C (delta over baseline > 4% (10 minutes))	2	236
10 Urea breath test-^{13}C (delta over baseline > 4% (20 minutes))	2	236
11 Urea breath test-^{13}C (delta over baseline > 4% (30 minutes))	10	958
12 Urea breath test-^{13}C (delta over baseline > 4.5% (30 minutes))	3	288
13 Urea breath test-^{13}C (delta over baseline > 5% (30 minutes))	4	601
14 Urea breath test-^{14}C (counts per minute > 50)	6	471
15 Urea breath test-^{14}C (disintegrations per minute > 200)	4	296
16 Serology > 7 units/ml	2	97
17 Serology ≥300 units	2	234

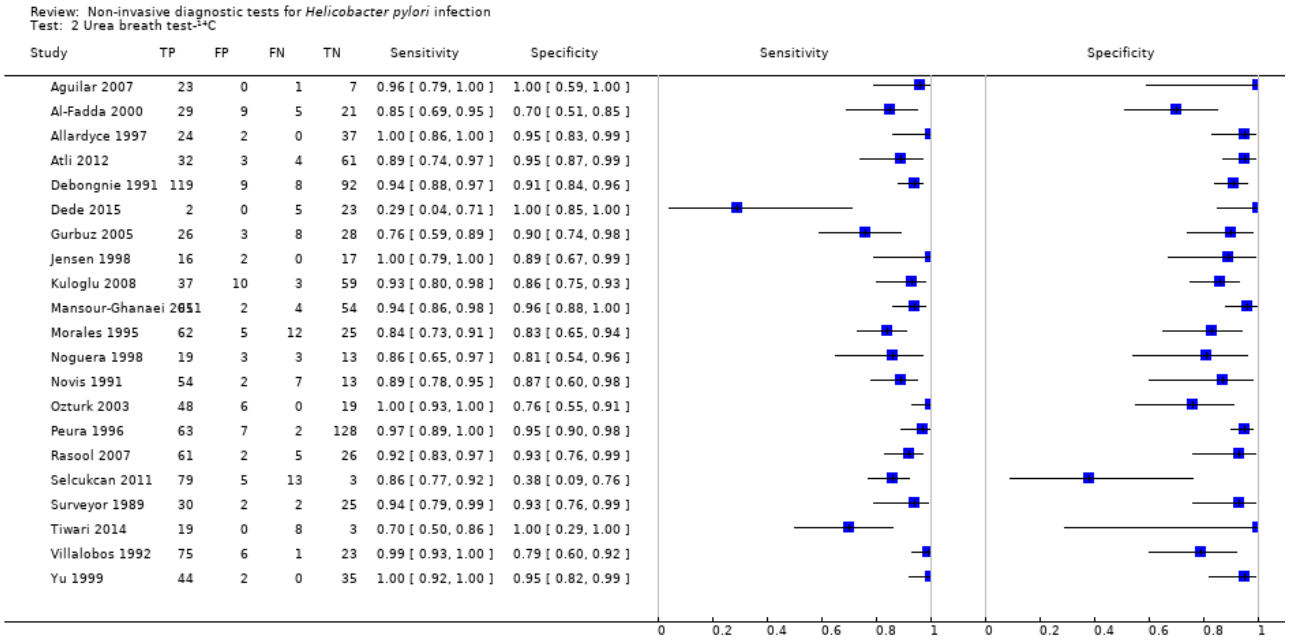
Test 1. Urea breath test-^{13}C.

Review: Non-invasive diagnostic tests for *Helicobacter pylori* infection
Test: 1 Urea breath test-^{13}C

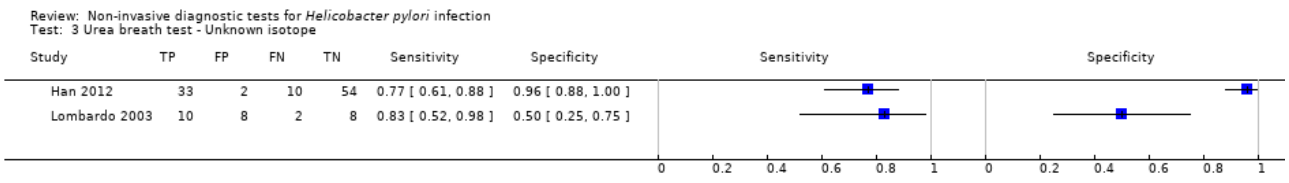
Study	TP	FP	FN	TN	Sensitivity	Specificity
Adamopoulos 2009a	43	1	0	29	1.00 [0.92, 1.00]	0.97 [0.83, 1.00]
Adamopoulos 2009b	6	0	9	16	0.40 [0.16, 0.68]	1.00 [0.79, 1.00]
Behrens 1999	129	7	7	98	0.95 [0.90, 0.98]	0.93 [0.87, 0.97]
Bosso 2000	32	6	1	56	0.97 [0.84, 1.00]	0.90 [0.80, 0.96]
Czerwionka-Szaflarska 2007	11	5	10	64	0.68 [0.49, 0.83]	0.93 [0.84, 0.98]
D'Elios 2000	113	2	3	138	0.97 [0.93, 0.99]	0.99 [0.95, 1.00]
Delvin 1999	12	0	0	67	1.00 [0.74, 1.00]	1.00 [0.95, 1.00]
Duan 1999	96	5	7	41	0.93 [0.86, 0.97]	0.89 [0.76, 0.96]
Eggers 1990	41	31	0	28	1.00 [0.91, 1.00]	0.47 [0.34, 0.61]
Eltumi 1999	17	3	2	28	0.89 [0.67, 0.99]	0.90 [0.74, 0.98]
Epple 1997	74	7	3	42	0.96 [0.89, 0.99]	0.86 [0.73, 0.94]
Fallone 1995	23	1	0	26	1.00 [0.85, 1.00]	0.96 [0.81, 1.00]
Germana 2001	54	1	1	44	0.98 [0.90, 1.00]	0.98 [0.88, 1.00]
Hafeez 2007	31	8	3	12	0.91 [0.76, 0.98]	0.60 [0.36, 0.81]
Inelmen 2004	41	7	13	61	0.76 [0.62, 0.87]	0.90 [0.80, 0.96]
Jordaan 2008	55	3	5	40	0.92 [0.82, 0.97]	0.93 [0.81, 0.99]
Kim 2016	54	18	4	31	0.93 [0.83, 0.98]	0.63 [0.48, 0.77]
Korstanje 2006	5	3	1	11	0.83 [0.36, 1.00]	0.79 [0.49, 0.95]
Lahner 2004	5	3	5	14	0.50 [0.19, 0.81]	0.82 [0.57, 0.96]
Lee 1998	46	1	1	23	0.98 [0.89, 1.00]	0.96 [0.79, 1.00]
Logan 1991a	31	0	3	16	0.91 [0.76, 0.98]	1.00 [0.79, 1.00]
Lottspeich 2007	41	0	0	15	1.00 [0.91, 1.00]	1.00 [0.78, 1.00]
Mana 2001a	84	6	0	92	1.00 [0.96, 1.00]	0.94 [0.87, 0.98]
Mion 1994	32	6	1	56	0.97 [0.84, 1.00]	0.90 [0.80, 0.96]
Monteiro 2001a	43	2	3	56	0.93 [0.82, 0.99]	0.97 [0.88, 1.00]
Ogata 2001	22	8	1	16	0.96 [0.78, 1.00]	0.67 [0.45, 0.84]
Salles-Montaudon 2002	102	19	6	64	0.75 [0.53, 0.90]	0.77 [0.67, 0.86]
Schilling 2001	13	3	12	40	0.52 [0.31, 0.72]	0.93 [0.81, 0.99]
Sheu 1998a	106	1	2	26	0.98 [0.93, 1.00]	0.96 [0.81, 1.00]
Sheu 1998b	20	0	14	32	0.59 [0.41, 0.75]	1.00 [0.89, 1.00]
Vandenplas 1992	24	5	3	63	0.89 [0.71, 0.98]	0.93 [0.84, 0.98]
Wardi 2012	9	6	5	56	0.64 [0.35, 0.87]	0.90 [0.80, 0.96]
Yoshimura 2001	42	3	2	25	0.95 [0.85, 0.99]	0.89 [0.72, 0.98]
Yu 2001	12	3	4	13	0.75 [0.48, 0.93]	0.81 [0.54, 0.96]



Test 2. Urea breath test-^{14}C.



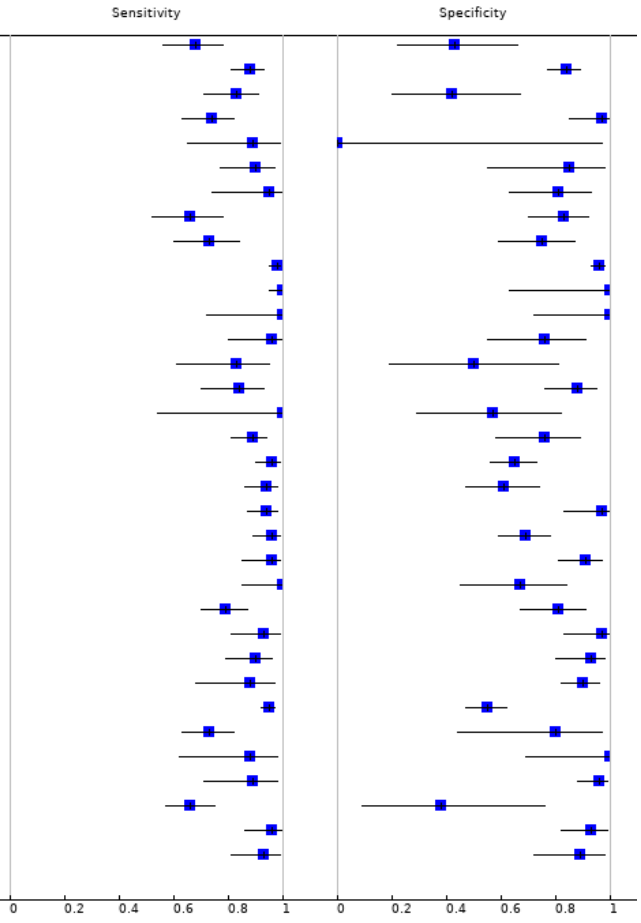
Test 3. Urea breath test - Unknown isotope.



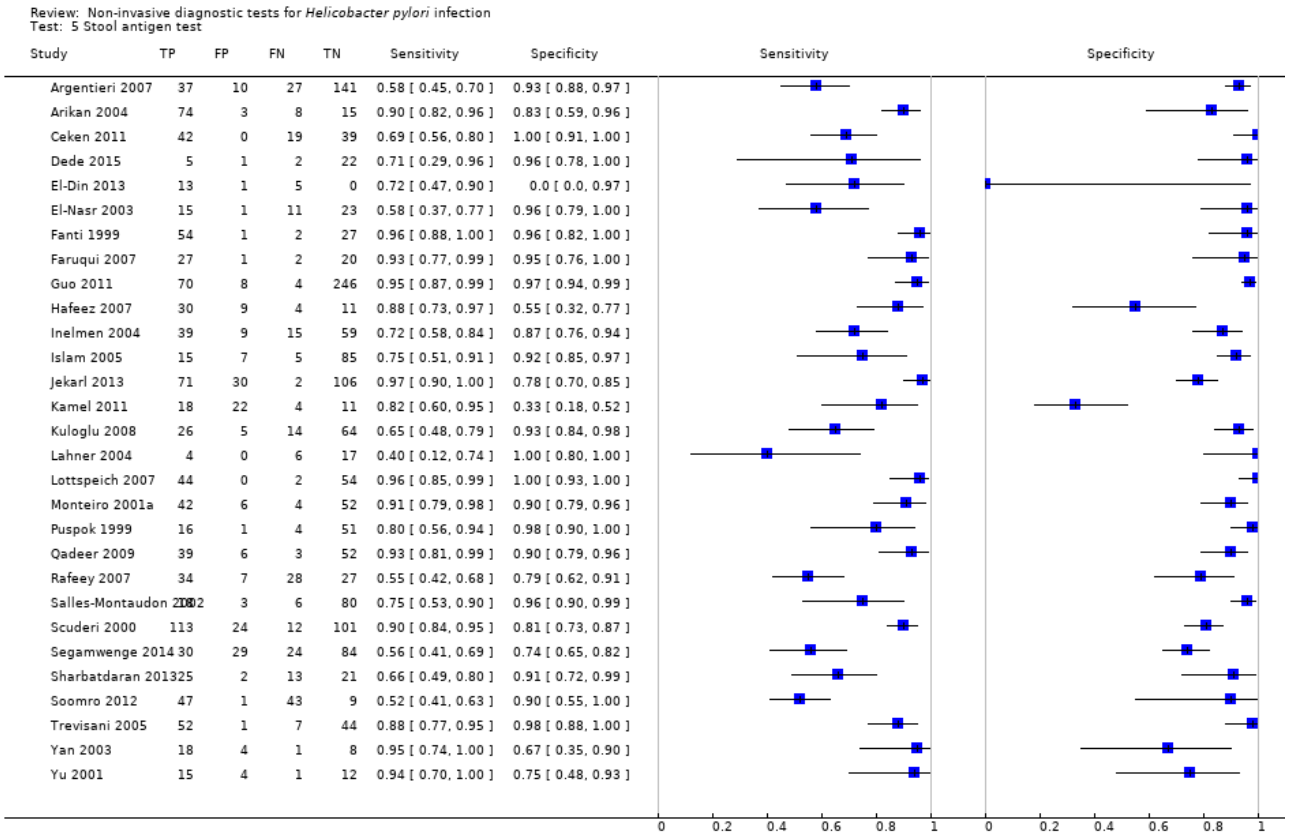
Test 4. Serology.

Review: Non-invasive diagnostic tests for *Helicobacter pylori* infection
Test: 4 Serology

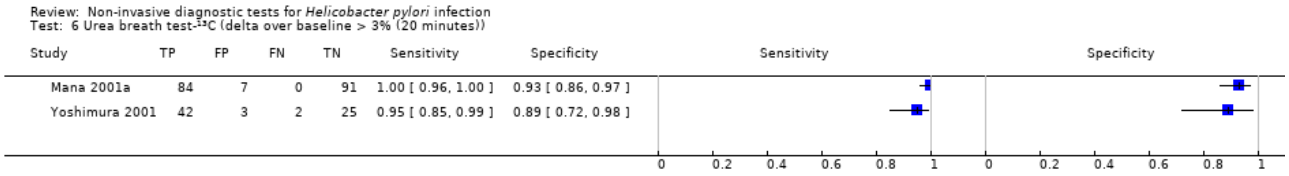
Study	TP	FP	FN	TN	Sensitivity	Specificity
Chen 1991	51	12	24	9	0.68 [0.56, 0.78]	0.43 [0.22, 0.66]
Chey 1998	115	25	16	131	0.88 [0.81, 0.93]	0.84 [0.77, 0.89]
Dinler 1999	48	11	10	8	0.83 [0.71, 0.91]	0.42 [0.20, 0.67]
Ekesbo 2006	67	1	24	34	0.74 [0.63, 0.82]	0.97 [0.85, 1.00]
El-Din 2013	16	1	2	0	0.89 [0.65, 0.99]	0.0 [0.0, 0.97]
El-Mekki 2011	38	2	4	11	0.90 [0.77, 0.97]	0.85 [0.55, 0.98]
Eltumi 1999	18	6	1	25	0.95 [0.74, 1.00]	0.81 [0.63, 0.93]
Fallone 1996	35	9	18	44	0.66 [0.52, 0.78]	0.83 [0.70, 0.92]
Ferrara 1998	44	10	16	30	0.73 [0.60, 0.84]	0.75 [0.59, 0.87]
Formichella 2013	205	11	5	279	0.98 [0.95, 0.99]	0.96 [0.93, 0.98]
Graham 1996a	67	0	0	8	1.00 [0.95, 1.00]	1.00 [0.63, 1.00]
Gramley 1999	11	0	0	11	1.00 [0.72, 1.00]	1.00 [0.72, 1.00]
Iqbal 2013	24	6	1	19	0.96 [0.80, 1.00]	0.76 [0.55, 0.91]
Ivanova 2010	19	5	4	5	0.83 [0.61, 0.95]	0.50 [0.19, 0.81]
Kalach 1998a	37	7	7	49	0.84 [0.70, 0.93]	0.88 [0.76, 0.95]
Korstanje 2006	6	6	0	8	1.00 [0.54, 1.00]	0.57 [0.29, 0.82]
Ladas 2002a	86	8	11	25	0.89 [0.81, 0.94]	0.76 [0.58, 0.89]
Luthra 1998	107	45	5	83	0.96 [0.90, 0.99]	0.65 [0.56, 0.73]
Mansour-Ghanaei 2011	261	22	4	34	0.94 [0.86, 0.98]	0.61 [0.47, 0.74]
Misawa 1998	79	1	5	29	0.94 [0.87, 0.98]	0.97 [0.83, 1.00]
Mohammadian 2007	72	32	3	72	0.96 [0.89, 0.99]	0.69 [0.59, 0.78]
Monteiro 2001a	44	5	2	53	0.96 [0.85, 0.99]	0.91 [0.81, 0.97]
Ogata 2001	23	8	0	16	1.00 [0.85, 1.00]	0.67 [0.45, 0.84]
Peitz 2001	77	9	20	39	0.79 [0.70, 0.87]	0.81 [0.67, 0.91]
Rathbone 1986	39	1	3	30	0.93 [0.81, 0.99]	0.97 [0.83, 1.00]
Safe 1993	53	3	6	38	0.90 [0.79, 0.96]	0.93 [0.80, 0.98]
Salles-Montaudon 2002	202	8	3	75	0.88 [0.68, 0.97]	0.90 [0.82, 0.96]
Shin 2009	449	80	25	97	0.95 [0.92, 0.97]	0.55 [0.47, 0.62]
Soomro 2012	66	2	24	8	0.73 [0.63, 0.82]	0.80 [0.44, 0.97]
Thobani 1995	14	0	2	10	0.88 [0.62, 0.98]	1.00 [0.69, 1.00]
Vandenplas 1992	24	3	3	65	0.89 [0.71, 0.98]	0.96 [0.88, 0.99]
Wang 2008	76	5	39	3	0.66 [0.57, 0.75]	0.38 [0.09, 0.76]
Weiss 1994	48	3	2	42	0.96 [0.86, 1.00]	0.93 [0.82, 0.99]
Yoshimura 2001	41	3	3	25	0.93 [0.81, 0.99]	0.89 [0.72, 0.98]



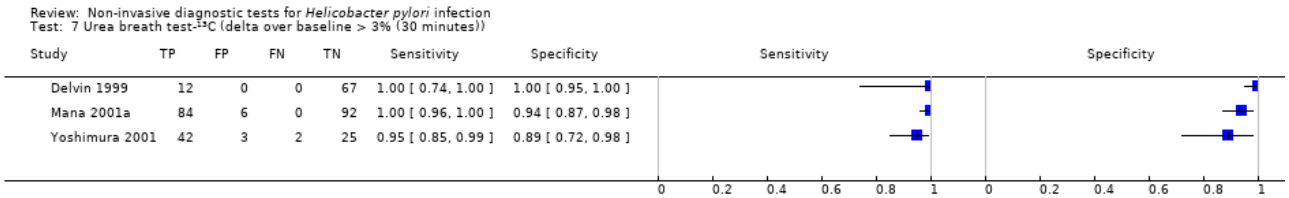
Test 5. Stool antigen test.



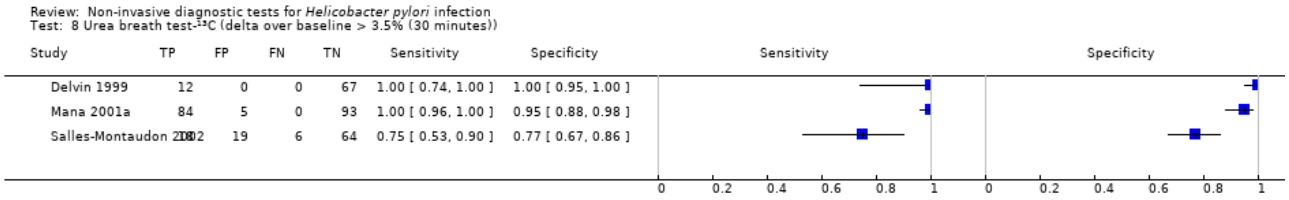
Test 6. Urea breath test-^{13}C (delta over baseline > 3% (20 minutes)).



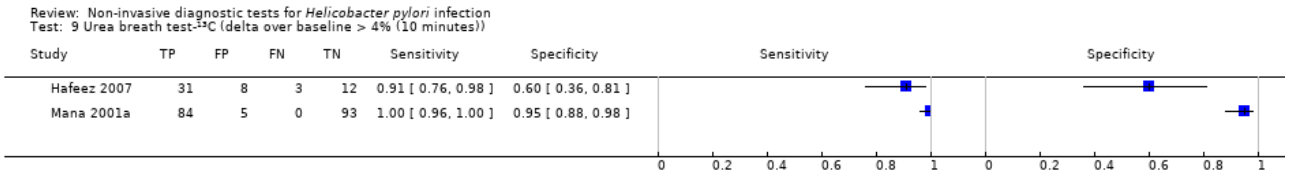
Test 7. Urea breath test-^{13}C (delta over baseline > 3% (30 minutes)).



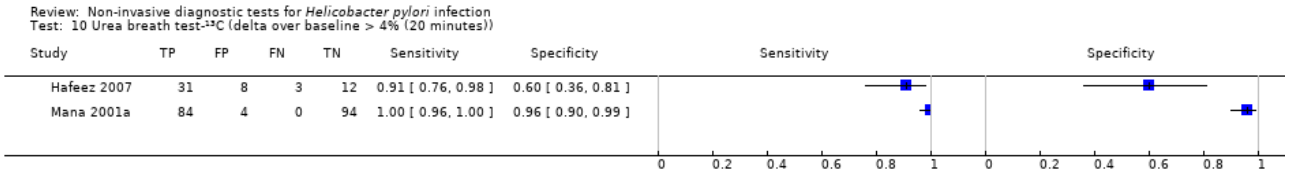
Test 8. Urea breath test-^{13}C (delta over baseline > 3.5% (30 minutes)).



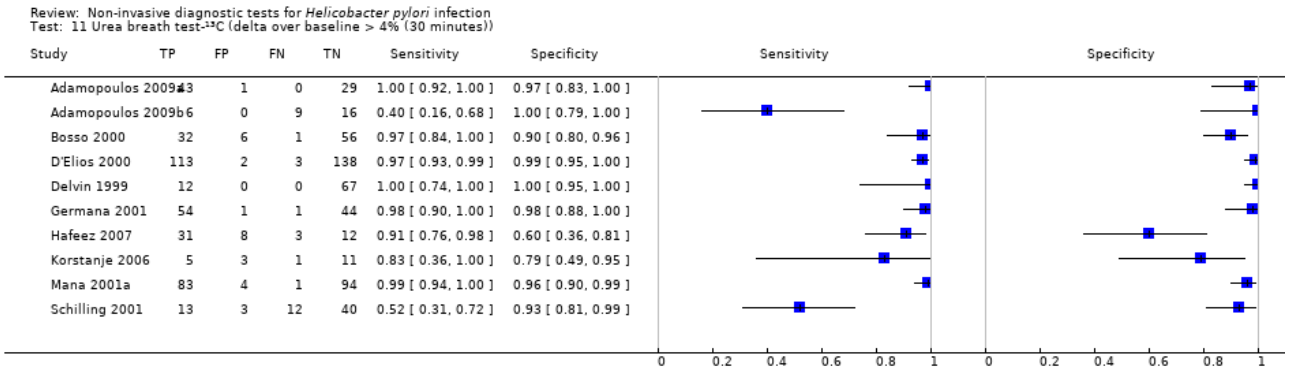
Test 9. Urea breath test-^{13}C (delta over baseline > 4% (10 minutes)).



Test 10. Urea breath test-^{13}C (delta over baseline > 4% (20 minutes)).



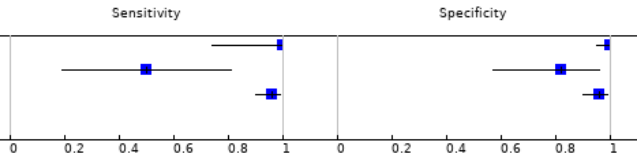
Test 11. Urea breath test-^{13}C (delta over baseline > 4% (30 minutes)).



Test 12. Urea breath test-^{13}C (delta over baseline > 4.5% (30 minutes)).

Review: Non-invasive diagnostic tests for *Helicobacter pylori* infection
Test: 12 Urea breath test-^{13}C (delta over baseline > 4.5% (30 minutes))

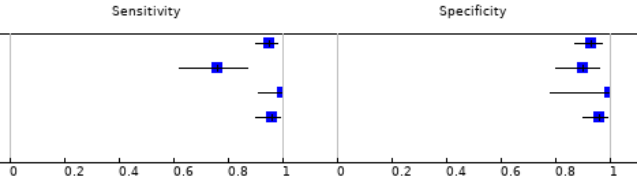
Study	TP	FP	FN	TN	Sensitivity	Specificity
Delvin 1999	12	0	0	67	1.00 [0.74, 1.00]	1.00 [0.95, 1.00]
Lahner 2004	5	3	5	14	0.50 [0.19, 0.81]	0.82 [0.57, 0.96]
Mana 2001a	81	4	3	94	0.96 [0.90, 0.99]	0.96 [0.90, 0.99]



Test 13. Urea breath test-^{13}C (delta over baseline > 5% (30 minutes)).

Review: Non-invasive diagnostic tests for *Helicobacter pylori* infection
Test: 13 Urea breath test-^{13}C (delta over baseline > 5% (30 minutes))

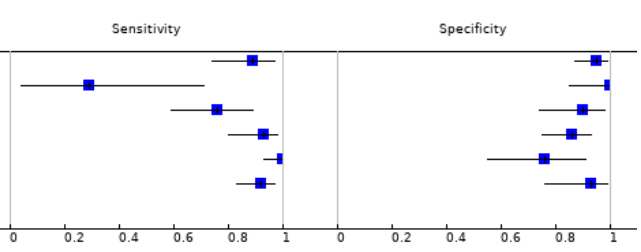
Study	TP	FP	FN	TN	Sensitivity	Specificity
Behrens 1999	129	7	7	98	0.95 [0.90, 0.98]	0.93 [0.87, 0.97]
Inelmen 2004	41	7	13	61	0.76 [0.62, 0.87]	0.90 [0.80, 0.96]
Lottspeich 2007	41	0	0	15	1.00 [0.91, 1.00]	1.00 [0.78, 1.00]
Mana 2001a	81	4	3	94	0.96 [0.90, 0.99]	0.96 [0.90, 0.99]



Test 14. Urea breath test-^{14}C (counts per minute > 50).

Review: Non-invasive diagnostic tests for *Helicobacter pylori* infection
Test: 14 Urea breath test-^{14}C (counts per minute > 50)

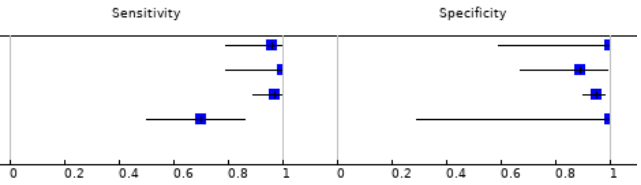
Study	TP	FP	FN	TN	Sensitivity	Specificity
Atli 2012	32	3	4	61	0.89 [0.74, 0.97]	0.95 [0.87, 0.99]
Dede 2015	2	0	5	23	0.29 [0.04, 0.71]	1.00 [0.85, 1.00]
Gurbuz 2005	26	3	8	28	0.76 [0.59, 0.89]	0.90 [0.74, 0.98]
Kuloglu 2008	37	10	3	59	0.93 [0.80, 0.98]	0.86 [0.75, 0.93]
Ozturk 2003	48	6	0	19	1.00 [0.93, 1.00]	0.76 [0.55, 0.91]
Rasool 2007	61	2	5	26	0.92 [0.83, 0.97]	0.93 [0.76, 0.99]



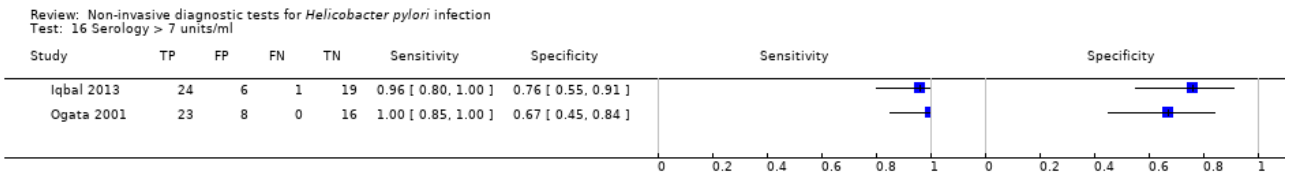
Test 15. Urea breath test-^{14}C (disintegrations per minute > 200).

Review: Non-invasive diagnostic tests for *Helicobacter pylori* infection
Test: 15 Urea breath test-^{14}C (disintegrations per minute > 200)

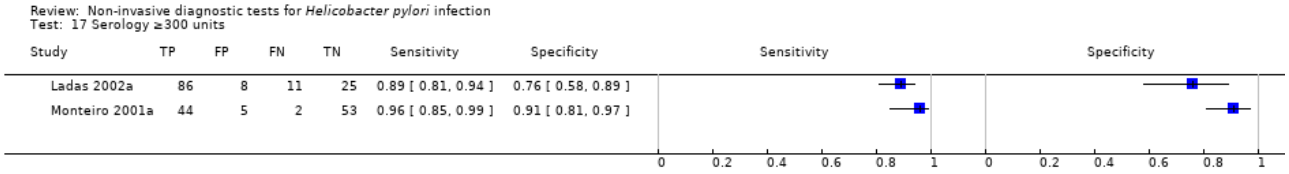
Study	TP	FP	FN	TN	Sensitivity	Specificity
Aguilar 2007	23	0	1	7	0.96 [0.79, 1.00]	1.00 [0.59, 1.00]
Jensen 1998	16	2	0	17	1.00 [0.79, 1.00]	0.89 [0.67, 0.99]
Peura 1996	63	7	2	128	0.97 [0.89, 1.00]	0.95 [0.90, 0.98]
Tiwari 2014	19	0	8	3	0.70 [0.50, 0.86]	1.00 [0.29, 1.00]



Test 16. Serology > 7 units/ml.



Test 17. Serology ≥300 units.



ADDITIONAL TABLES

Table 1. Summary of results at thresholds commonly reported for urea breath test-^{13}C, urea breath test-^{14}C and serology

Threshold	Studies	Number of participants (cases)	Sensitivity (95% CI)	Specificity (95% CI)
Urea breath test-^{13}C				
Delta over baseline > 3% (20 minutes)	2	254 (128)	0.98 (0.90 to 1.00)	0.92 (0.82 to 0.97)
Delta over baseline > 3% (30 minutes)	3	333 (140)	0.99 (0.92 to 1.00)	0.95 (0.90 to 0.98)
Delta over baseline > 3.5% (30 minutes)	3	368 (120)	0.75 to 1.00	0.77 to 1.00
Delta over baseline > 4% (10 minutes)	2	236 (118)	0.91 to 1.00	0.60 to 0.95
Delta over baseline > 4% (20 minutes)	2	236 (118)	0.91 to 1.00	0.60 to 0.96
Delta over baseline > 4% (30 minutes)	10	958 (423)	0.95 (0.79 to 0.99)	0.95 (0.87 to 0.98)
Delta over baseline > 4.5% (30 minutes)	3	288 (106)	0.50 to 0.96	0.82 to 0.96
Delta over baseline > 5% (30 minutes)	4	601 (315)	0.95 (0.49 to 1.00)	0.94 (0.84 to 0.98)
Urea breath test-^{14}C				
Counts per minute > 50 (10 minutes)	6	471 (231)	0.89 (0.55 to 0.98)	0.91 (0.79 to 0.96)
Disintegrations per minute > 200 (10 minutes)	4	296 (132)	0.95 (0.33 to 1.00)	0.95 (0.80 to 0.99)
Serology				
> 7 units/ml	2	97 (48)	0.98 (0.74 to 1.00)	0.71 (0.51 to 0.86)

Table 1. Summary of results at thresholds commonly reported for urea breath test-^{13}C, urea breath test-^{14}C and serology *(Continued)*

≥ 300 unit	2	234 (143)	0.91 (0.82 to 0.96)	0.86 (0.72 to 0.93)

Tests evaluated at the same threshold by more than one study are presented in the table. When there were two or three studies at the same threshold, and little or no heterogeneity was observed in ROC space, estimates of summary sensitivity and summary specificity were obtained by using univariate fixed-effect logistic regression models to pool sensitivities and specificities separately. When there were two or three studies and we observed heterogeneity, we did not perform meta-analysis but report the range of the sensitivities and specificities.

Table 2. Indirect comparison of the accuracy of non-invasive tests for *H pylori* infection

Index tests	Studies; participants (*H pylori* present)	DOR (95% CI)	Ratio of diagnostic odds ratios (95% CI), P value		
			Urea breath test-^{13}C	Urea breath test-^{14}C	Serology
Urea breath test-^{13}C	34; 3139 (1526)	153 (73.7 to 316)	-	-	-
Urea breath test-^{14}C	21; 1810 (1018)	105 (74.0 to 150)	1.45 (0.65 to 3.26), P = 0.36	-	-
Serology	34; 4242 (2477)	47.4 (25.5 to 88.1)	3.22 (1.24 to 8.37), P = 0.017	2.22 (1.09 to 4.51), P = 0.028	-
Stool antigen test	29; 2988 (1311)	45.1 (24.2 to 84.1)	3.39 (1.30 to 8.83), P = 0.013	2.33 (1.14 to 4.76), P = 0.020	1.05 (0.44 to 2.53), P = 0.91

The indirect comparison included all studies that evaluated at least one of the four tests, i.e. all available data. The ratio of diagnostic odds ratios is the diagnostic odds ratio (DOR) of the test in the column divided by the DOR of the test in the row. If the ratio is greater than one, then the test in the column is more accurate than the test in the row; if the ratio is less than one, the test in the row is more accurate than the test in the column.

Table 3. Accuracy of non-invasive tests for *H pylori* infection at different levels of prevalence

Prevalence (%)	Specificity	False positives[1]	Test	Sensitivity (95% CI)	Missed cases (95% CI)
42.0	0.79	122	Urea breath test-^{13}C	0.98 (0.95 to 0.99)	10 (5 to 20)
			Urea breath test-^{14}C	0.97 (0.95 to 0.98)	15 (10 to 20)
			Serology	0.93 (0.87 to 0.96)	31 (17 to 54)
			Stool antigen test	0.92 (0.87 to 0.96)	32 (18 to 57)
53.7	0.79	97	Urea breath test-^{13}C	0.98 (0.95 to 0.99)	13 (6 to 26)
			Urea breath test-^{14}C	0.97 (0.95 to 0.98)	19 (13 to 26)
			Serology	0.93 (0.87 to 0.96)	39 (22 to 69)

Table 3. Accuracy of non-invasive tests for *H pylori* infection at different levels of prevalence *(Continued)*

			Stool antigen test	0.92 (0.87 to 0.96)	41 (23 to 72)
66.5	0.79	70	Urea breath test-^{13}C	0.98 (0.95 to 0.99)	16 (8 to 32)
			Urea breath test-^{14}C	0.97 (0.95 to 0.98)	23 (16 to 32)
			Serology	0.93 (0.87 to 0.96)	49 (27 to 85)
			Stool antigen test	0.92 (0.87 to 0.96)	51 (28 to 89)
42.0	0.90	58	Urea breath test-^{13}C	0.94 (0.89 to 0.97)	23 (12 to 46)
			Urea breath test-^{14}C	0.92 (0.89 to 0.94)	33 (24 to 46)
			Serology	0.84 (0.74 to 0.91)	67 (39 to 110)
			Stool antigen test	0.83 (0.73 to 0.90)	70 (41 to 114)
53.7	0.90	46	Urea breath test-^{13}C	0.94 (0.89 to 0.97)	30 (15 to 58)
			Urea breath test-^{14}C	0.92 (0.89 to 0.94)	42 (30 to 58)
			Serology	0.84 (0.74 to 0.91)	86 (50 to 140)
			Stool antigen test	0.83 (0.73 to 0.90)	89 (52 to 146)
66.5	0.90	34	Urea breath test-^{13}C	0.94 (0.89 to 0.97)	37 (18 to 72)
			Urea breath test-^{14}C	0.92 (0.89 to 0.94)	53 (38 to 72)
			Serology	0.84 (0.74 to 0.91)	106 (62 to 173)
			Stool antigen test	0.83 (0.73 to 0.90)	111 (64 to 180)
42.0	0.96	23	Urea breath test-^{13}C	0.86 (0.75 to 0.93)	57 (30 to 103)
			Urea breath test-^{14}C	0.81 (0.76 to 0.86)	78 (58 to 103)
			Serology	0.66 (0.52 to 0.79)	141 (90 to 204)
			Stool antigen test	0.65 (0.50 to 0.78)	146 (93 to 209)
53.7	0.96	19	Urea breath test-^{13}C	0.86 (0.75 to 0.93)	73 (38 to 132)
			Urea breath test-^{14}C	0.81 (0.76 to 0.86)	100 (74 to 132)
			Serology	0.66 (0.52 to 0.79)	181 (115 to 260)
			Stool antigen test	0.65 (0.50 to 0.78)	187 (119 to 267)
66.5	0.96	13	Urea breath test-^{13}C	0.86 (0.75 to 0.93)	90 (47 to 163)
			Urea breath test-^{14}C	0.81 (0.76 to 0.86)	124 (92 to 163)
			Serology	0.66 (0.52 to 0.79)	224 (142 to 322)

Table 3. Accuracy of non-invasive tests for *H pylori* infection at different levels of prevalence *(Continued)*

	Stool antigen test	0.65 (0.50 to 0.78)	231 (148 to 331)

[1]Average number of participants who are diagnosed with *H pylori* infection but do not have the infection per 1000 tested.
The sensitivities were estimated from the SROC curves at fixed values (lower quartile, median and upper quartile) of specificity from the included studies across all tests. Based on these sensitivities and specificities, and quartiles of prevalence from the included studies (across all tests), the numbers of missed *H pylori* cases and false positives (i.e. overdiagnosed people) were calculated using a hypothetical cohort of 1000 people suspected of having *H pylori* infection.

Table 4. Direct comparison of the accuracy of non-invasive tests for *H pylori* infection

Test	Urea breath test-^{13}C	Urea breath test-^{14}C	Serology
Urea breath test-^{13}C	-	-	-
Urea breath test-^{14}C	N = 0	-	-
Serology	N = 7 DOR (95% CI) of urea breath test-^{13}C = 74.8 (95% CI 17.8 to 314) DOR (95% CI) of serology = 111 (95% CI 41.2 to 297) RDORs (95% CI) of urea breath test-^{13}C versus serology, P value = 0.68 (95% CI 0.12 to 3.70), P = 0.56	N = 1	-
Stool antigen test	N = 7 DOR (95% CI) of urea breath test-^{13}C = 46.6 (95% CI 3.30 to 658) DOR (95% CI) of stool antigen test = 53.0 (95% CI 5.34 to 527) RDORs (95% CI) of urea breath test-^{13}C versus stool antigen test, P value = 0.88 (95% CI 0.14 to 5.56), P = 0.84	N = 2	N = 4

DOR = diagnostic odds ratio; N = number of studies; RDORs = ratio of diagnostic odds ratios.
Due to paucity of data and substantial heterogeneity observed in ROC space which precluded the use of simpler meta-analytic models, meta-analyses were not possible for two test comparisons that had more than one study. For the single study of urea breath test-^{14}C versus serology (Mansour-Ghanaei 2011), both tests had similar sensitivity, but specificity was higher for urea breath test-^{14}C than for serology. The ratio of diagnostic odds ratios is the DOR of the test in the column divided by the DOR of the test in the row. If the ratio is greater than one, then the test in the column is more accurate than the test in the row; if the ratio is less than one, the test in the row is more accurate than the test in the column.

APPENDICES

Appendix 1. Glossary

Adenomas: a non-cancerous growth arising from the glands and has a structure similar to glands

Anaemia: a condition in which there is a deficiency of red cells or of haemoglobin in the blood, resulting in pallor and weariness

Asymptomatic: without symptoms

Atrophic gastritis: chronic inflammation of the stomach lining, leading to loss of cells lining the stomach usually and their replacement with scar tissue and cell types which line the small bowel

Dyspepsia: indigestion

Eradication: removal (of)

Flatulence: passing wind excessively

Gastrectomy: partial removal of stomach

Heterogeneity: (in this context) different results in different studies

Heterogeneity: differences in results between studies

Idiopathic thrombocytopaenia purpura: purpura (purplish spots or patches on the skin and inner lining of the mouth) resulting from bleeding due to a reduction in circulating blood platelets caused by antibodies against platelets

Isotopes: atoms of an element with different numbers of neutrons (a part of atom)

Laryngeal: related to voice-box (throat)

Lymphoma: is a form of cancer of the lymphocytes, a type of white blood cells, which normally defend the body against harmful micro-organisms such as bacteria, virus, and fungi

Malignancies: cancers

Meta-analysis: combining the results of individual studies to provide a single average result

Pathogenic: causing disease

Quartile: each of four equal groups into which a population can be divided

Serology: blood tests to test the presence of antibodies (substances produced by white cells to defend the body against harmful micro-organisms such as bacteria)

Stool antigen test: a laboratory test of stool to diagnose *H plyori* infection

Urea breath test: a laboratory test of breath to diagnose *H pylori* infection

Appendix 2. MEDLINE search strategy

1. exp *Helicobacter pylori*/ or Helicobacter/

2. (pylori or pyloridis).mp.

3. Helicobacter.mp.

4. HP.mp.

5. Campylobacter.mp.

6. 1 or 2 or 3 or 4 or 5

7. exp Breath Tests/

8. (breath adj3 test).mp.

9. exp Enzyme-Linked Immunosorbent Assay/

10. (Enzyme-Linked Immunosorbent Assay or ELISA).mp.

11. exp Blotting, Western/

12. (Western adj1 (blot or blotting or immunoblot or immunoblotting)).mp.

13. Latex Fixation Tests/

14. ("latex agglutination test" or "latex fixation test" or LAT).mp.

15. ((stool or "stool antigen" or feces or faeces or fecal or faecal) adj3 test).mp.

16. 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15

17. 6 and 16

18. exp animals/ not humans.sh.

19. 17 not 18

Appendix 3. Embase search strategy

1. exp *Helicobacter pylori*/ or Helicobacter/

2. Helicobacter.mp.

3. (pylori or pyloridis or HP).mp.

4. Campylobacter.mp.

5. 1 or 2 or 3 or 4

6. urea breath test/

7. (breath adj3 test).mp.

8. enzyme linked immunosorbent assay/

9. (Enzyme-Linked Immunosorbent Assay or ELISA).mp.

10.Western blotting/

11. (Western adj1 (blot or blotting or immunoblot or immunoblotting)).mp.

12. latex agglutination test/

13. ("latex agglutination test" or "latex fixation test" or LAT).mp.

14. exp feces analysis/

15. ((stool or "stool antigen" or feces or faeces or fecal or faecal) adj3 test).mp.

16. 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15

17. 5 and 16

18. exp animal/ not exp human/

19. 17 not 18

Appendix 4. Science Citation Index search strategy

#1 TS=(pylori or pyloridis or Helicobacter or HP or Campylobacter)

#2 TS=("breath test" or Enzyme-Linked Immunosorbent Assay or ELISA or "Western blot" or "Western blotting" or "Western Immunoblot" or "Western Immunoblotting" or ("latex agglutination test" or "latex fixation test" or LAT) or "stool test" or "stool antigen test" or "feces test" or "faeces test" or "fecal test" or "faecal test")

#3 #1 AND #2

Appendix 5. National Institute for Health Research - Health Technology Assessment

Helicobacter pylori and accuracy

Appendix 6. Criteria for assessment of risk of bias and applicability concerns

Domain 1: Patient selection	Patient sampling	Symptomatic people and asymptomatic people in whom *H pylori* infection status is sought so that eradication therapy for *H pylori* can be started

(Continued)

	Was a consecutive or random sample of patients enrolled?	Yes: If a consecutive sample or a random sample of symptomatic people and asymptomatic people in whom *H pylori* infection status is sought was included in the study No: If a consecutive sample or a random sample of symptomatic people and asymptomatic people in whom *H pylori* infection status is sought was not included in the study Unclear: If this information was not available
	Was a case-control design avoided?	Yes: If a cohort of symptomatic people and asymptomatic people in whom *H pylori* infection status was sought were studied No: If people with *H pylori* infection were compared with people without *H pylori* infection (controls). Such studies were excluded Unclear: As anticipated, we were able to determine whether the design was case-control. So, all studies included in the review to be classified as 'yes' for this item
	Did the study avoid inappropriate exclusions?	Yes: If all symptomatic people and asymptomatic people in whom *H pylori* infection status was sought were included No: If the study excluded patients based on high probability of false negative results (for example, people with bleeding ulcers, gastric atrophy, lymphoma, and recent or current use of proton pump inhibitors or antibiotics) Unclear: If this information was not available
	Could the selection of patients have introduced bias?	Low risk of bias: If 'yes' classification for all the above three questions; high risk of bias: if 'no' classification for any of the above three questions; unclear risk of bias: if 'unclear' classification for any of the above three questions, but without a 'no' classification for any of the above three questions
	Patient characteristics and setting	Yes: If all symptomatic people and asymptomatic people in whom *H pylori* infection status was sought were included No: If a proportion of symptomatic people and asymptomatic people in whom *H pylori* infection status was sought were excluded on the basis of the high probability of false negative results (for example, people with bleeding ulcers, gastric atrophy, lymphoma, and recent or current use of proton pump inhibitors or antibiotics) Unclear: If it was not clear whether the patients have been included on the basis of the probability of *H pylori* infection
	Are there concerns that the included patients and setting do not match the review question?	Low concern: if the patient characteristics and setting were classified as 'yes'; unclear concern: if the patient characteristics and setting were classified as 'unclear'; high concern: if the patient characteristics and setting were classified as 'no'
Domain 2: Index test	Index test(s)	Urea breath test, serology, and stool antigen test
	Were the index test results interpreted without knowledge of the results of the reference standard?	Yes: If the index test was conducted and interpreted without the knowledge of the results of the reference standard No: If the index test was interpreted with the knowledge of the results of the reference standard Unclear: If it is not clear whether the index test was interpreted without the knowledge of the results of the reference standard
	If a threshold was used, was it prespecified?	Yes: if a prespecified threshold was used No: if a prespecified threshold was not used Unclear: if it was not clear whether the threshold used was prespecified

(Continued)

	Could the conduct or interpretation of the index test have introduced bias?	Low risk of bias: If 'yes' classification for both questions above; high risk of bias: if 'no' classification for any of the above two questions; unclear risk of bias: if 'unclear' classification for any of the above two questions, but without a 'no' classification for any of the above two questions
	Are there concerns that the index test, its conduct, or interpretation differ from the review question?	Low concern: If the criteria for a positive index test was clearly stated; high concern: if the criteria for a positive index test was not stated
Domain 3: Target condition and reference standard	Target condition and reference standard(s)	Target condition: *H pylori* infection Reference standard: endoscopic biopsy with histology
	Is the reference standard likely to correctly classify the target condition?	Yes: If *H pylori* infection was confirmed by endoscopic biopsy with special stains or immunohistochemical stains No: If the reference standard was endoscopic biopsy with haemotoxylin and eosin stain in some or all participants Unclear: If the reference standard was not described adequately. Such studies were excluded
	Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes: If the reference standard was interpreted without the knowledge of the results of the index test No: If the reference standard was interpreted with the knowledge of the results of the index test Unclear: It was not clear if the reference standard was interpreted without the knowledge of the results of the index test
	Could the reference standard, its conduct, or its interpretation have introduced bias?	Low risk of bias: If 'yes' classification for both questions above; high risk of bias: if 'no' classification for any of the above two questions; unclear risk of bias: if 'unclear' classification for any of the above two questions, but without a 'no' classification for any of the above two questions
	Are there concerns that the target condition (as defined by the reference standard) does not match the question?	Considering the inclusion criteria for this review, all the included studies were classified as 'low concern' as anticipated
Domain 4: Flow and timing	Flow and timing	People with *H pylori* infection may have resolution of infection (usually with treatment) and people without *H pylori* infection may get infected with *H pylori* if there is a long delay between the index test and reference standard. An arbitrary two weeks were chosen as acceptable delay between the index test and reference standard
	Was there an appropriate interval between index test and reference standard?	Yes: If the time interval between index test and reference standard was less than two weeks No: If the time interval between index test and reference standard was more than two weeks, or if any treatment for *H pylori* had been performed Unclear: If the time interval between index test and reference standard was unclear or it was not clear if any treatment for *H pylori* had been performed
	Did all patients receive a reference standard?	Yes: If all patients received a reference standard No: If some of the patients did not receive a reference standard. Such studies were excluded

(Continued)

	Unclear: If it was not clear whether all patients received a reference standard. Such studies were excluded Therefore, all studies included in the review were classified as 'yes' for this item
Did all patients receive the same reference standard?	Yes: If all the patients received the same reference standard No: If different patients received different reference standards Unclear: If this information was not clear
Were all patients included in the analysis?	Yes: If all the patients were included in the analysis, irrespective of whether the results were uninterpretable No: If some patients were excluded from the analysis because of uninterpretable results Unclear: If this information was not clear
Could the patient flow have introduced bias?	Low risk of bias: If 'yes' classification for all the above four questions; high risk of bias: if 'no' classification for any of the above four questions; unclear risk of bias: if 'unclear' classification for any of the above four questions, but without a 'no' classification for any of the above four questions

Appendix 7. Characteristics of excluded studies

We excluded 1728 references (1727 studies) for the following reasons.

Case-control study (17): Alarcón-Rivera 2011; Benjamin 2012; Cao 2012; De Pascalis 1999; Doweck 1997; Dun 2001; Enroth 2002; Figura 1994; Gao 2015; Gerstenecker 1992; Klein 1996; Marshall 1988c; Mattar 1999; Nishizono 1998; Pantoflickova 2000; Roggero 2002; Veijola 2005b

Not a primary research study (147): Abadi 2011; Abut 2006; Adamek 1995; Adamsson 2000; Alpert 1989; Anania 2008; Anonymous 1997; Anonymous 2000; Anonymous 2002a; Anonymous 2002b; Anonymous 2004; Arents 2002; Atherton 1994; Attumi 2011; Barthel 1990; Bateson 1991; Bazzoli 1997b; Bazzoli 1998; Bazzoli 1999; Bellon 2004; Bergmann 1997; Blancas 2004; Blum 1997; Bornschein 2011; Braden 1991; Braden 1992; Braden 2001b; Braden 2007; Braden 2012; Bravos 2000; Breslin 1997; Brown 1993; Calam 1994; Calvet 2015; Canard 2003; Caspary 1995; Chey 2000b; Chiba 1999; Ching 1991b; Ciok 2003; Cirak 2007; Continibali 1991; Corti 2007; Couturier 2014; Cutler 1995b; Cutler 1997; De Argila 2001; De Boer 1995; Dewan 2000; Di Rienzo 2013; Dorta 2005; Drumm 1999; Dyrla 2015; Ebell 1998; Elbast 1999; Elitsur 2005; Falk 1997; Fallone 2000; Farkkila 1996; Ferwana 2015; Fukuda 2002; Fukuda 2003a; Fukuda 2003b; Garcia 1996; Garcia 2006; Gatta 2003a; Gisbert 2000b; Gisbert 2006a; Gisbert 2006b; Gisbert 2006h; Gold 2000; Gold 2014; Gonzalez 2004; Goto 1998; Gottrand 2001; Graham 2000; Graham 2001c; Graham 2010; Guo 2005; Guslandi 2000; Harris 1995; Harris 1998; Hart 1999; Hawtin 1999; Heenan 1989; Hirschl 2005; Ho 2000; Hong 2008; Hoshiya 2001; Hsu 2010; Imperiale 1996; Janssen 2001; Jones 1997b; Kabir 2001; Kalach 1998b; Karakus 2013; Katelaris 1997; Kato 2005b; Kato 2005c; Kato 2010; Laheij 2006; Ling 2013; Malfertheiner 2005; Mana 2000a; Mana 2001b; Megraud 1988; Miftahussurur 2016; Mion 1996; Newell 1989b; Nightingale 1996; Nishikawa 1999; Oderda 1998a; Oderda 2004; Parente 2001; Parente 2002b; Pattison 1996; Payne 2006; Perez 1998; Perri 1995; Perri 2000; Radke 1997; Raedsch 1992; Ratnaraj 2015; Rauws 1987; Rauws 1989b; Satoh 1993; Seo 2004; Seo 2013; Shiba 1998; Snyder 1999; Stirling 1995; Takagi 2002; Tamura 2001; Trevisani 2002; Vaira 1989; Vaira 2000a; Vaira 2000b; Vakil 2000b; Wadstrom 1994; Westblom 1999; Wildgrube 1995; Yakoob 2014; Yamamoto 2008; Zagari 2003; Zhang 2002; Zhelezova 2006; Zhou 2014

Erratum (3): Altindis 2002b; Altindis 2003; Ballam 2000b

Inappropriate population (79)

- **In monitoring** (33): Al-Assi 1999; Balcilar 2012; Bilardi 2002; Bommelaer 2001; Cutler 1996; Fraser 2003; Gisbert 1999c; Hirschl 1996; Houben 1998; Isomoto 2003; Kato 2000a; Kato 2003b; Kato 2005a; Koizumi 2003; Labenz 1997; Makristathis 2000; Mansour-Ghanaei 2013; Miwa 1998a; Odaka 2002; Oderda 1998b; Osaki 2008; Ploier 1997; Quesada 2006a; Richter 2002; Rollan 1997; Sharma 1999; Shimoyama 2009b; Shimoyama 2011; Sorberg 1997; Thijs 1994; Vaira 1999b; Van't Hoff 2000; Zipser 2000
- **Not in humans** (1): Foertsch 2010
- **Only in *H pylori* negative people** (2): Hahn 2000; Urita 2006
- **Only in *H pylori* positive people** (39): Ahmed 2005; Alam 2013; Crabtree 1990; Crabtree 1991a; Crabtree 1991b; Cremonini 2005; Janus 1991; Kopanski 1997; Kryvy 2012; Mirbagheri 2005; Parente 2000a; Parente 2000b; Parente 2002a; Park 2001; Pathak 2012; Perri 1994; Polat 2010; Ren 2010; Savarino 2000b; Shimoyama 1996; Shimoyama 2010; Shirin 2005; Sicinschi 2003a; Slomianski 1994; Slomianski

1995; Sue 1996; Thongbai 2007; Valle 1997; Van der Est 1990; Van der Wouden 1999; Van Zanten 1998; Van Zanten 1999; Van Zwet 1992; Van Zwet 1994; Veijola 2005a; Weingart 2003; Weingart 2004; Yoo 2007; Zagari 2005

- **Only in people with gastrointestinal bleeding** (2): Liao 2003; Van Leerdam 2003
- **Selection of patients was based on the results of other *H pylori* tests** (1): Falsafi 2014
- **Includes people who were being monitored for *H pylori* status** (1): Lin 1992

Inappropriate index test (38): Aguilar-Soto 2004; Alan 2014; Bathe 1996; Boyanova 2003; Busro 2013; Chey 1999b; Chou 1997; Datta 2005; Del Pozo Garcia 2006; Dietz 2001; Elitsur 1999b; El-Zimaity 1998; Garces 2012; Ho 2004; Ismail 2016; Isomoto 2006; Jolley 2007; Kolts 1993; Koumi 2011; Kuo 2002; Li 1996; Loeb 1997; Niv 1998; Notarnicola 1996; Olsson 1993; Rogge 1995; Sayed 2011; Schilling 2003; Shimada 1994; Smith 2010; Smith 2012; Suto 2000a; Tokunaga 1998; Tokunaga 2000; Urita 2000; Urita 2004b; Urita 2007a

Inappropriate target condition (4): Ang 2007b; Lee 2013; Ploier 1996; Witt 1990

Inappropriate reference standards (1182): Abdulqawi 2012; Abu 2015; Abukhadir 1998; Abu-Sbeih 2014; Aceti 1989; Adachi 2002; Adamek 1994; Adiloglu 2007; Agha-Amiri 1999a; Agha-Amiri 1999b; Agha-Amiri 2001; Agudo 2009a; Agudo 2009b; Aguemon 2004; Ahuja 1998; Aje 2010; Aksoy 2003; Aktepe 2011; Alavi 1996b; Albrecht 2012; Alcalde 1994; Alemohammad 1993; Al-Humayed 2008; Ali 1997; Ali 1998; Altindis 2002a; Amendola 2002; Anania 2007; Andersen 1998; Anderson 1993; Andrews 2003; Ang 2007a; Anonymous 1989; Antoine 1995; Antos 2005; Arboleda 2013; Archimandritis 2001; Arents 2001; Arinton 2011; Arita 1982; Arj 2012; Arora 2003; Artiko 2004; Asante 1998; Asfeldt 2004; Ashraf 1999; Atherton 1992; Attallah 2004; Aucher 1998; Auroux 1998; Aziz 2014; Bakka 2002; Ballam 1998; Ballam 2000a; Balon 1997; Baqai 2003; Barbosa 2003; Baryshnikova 2009; Baryshnikova 2012; Baryshnikova 2013; Basso 1999; Bazaz 2005; Bazzoli 1995; Bazzoli 2000; Befrits 1993; Beiki 2005; Bell 1987; Bener 2002; Benito 1999; Bergey 2003; Bermejo 2000a; Bermejo 2000b; Bermejo 2002; Bessede 2011; Best 1992; Best 1994; Bhewa 2007; Bielanski 1996a; Bielanski 1996b; Bielanski 1996c; Bielanski 1997b; Bielanski 1998; Bielanski 1999; Biemond 1997; Billaud 1996; Bjorneklett 1989; Blairon 2009; Blanco 2008; Blanco 2009; Blecker 1993b; Blecker 1993c; Blecker 1993d; Blecker 1993e; Blecker 1993f; Blecker 1994a; Blecker 1994c; Blecker 1994d; Blecker 1995a; Blecker 1995b; Bode 2000; Bode 2001; Bode 2002; Bodger 1999; Bodhidatta 1993; Bolton 1989a; Bolton 1989b; Bonamico 2004; Bongermino 2010; Booka 2005; Borody 2012; Borody 2013; Boudjella 2009; Boukthir 2005; Boyanova 2013; Braden 1993; Braden 1994a; Braden 1994b; Braden 1996; Braden 1999; Braden 2000a; Braden 2000b; Braden 2000c; Braden 2001a; Bravo 1999; Brennan 2015a; Brennan 2015b; Breslin 1998; Breslin 2000; Bretagne 1998; Briedigkeit 1992; Britto 2002; Brmbolic 1997; Bruce 2005; Bruden 2011; Bruning 2002; Brunner 1989; Buchan 2013; Buhling 2004; Burucoa 2013; Cadranel 1998; Cagdas 2012; Caglar 1999; Calvet 1999; Calvet 2002a; Calvet 2002b; Calvet 2002c; Calvet 2003; Calvet 2005; Calvet 2009; Calvet 2010a; Calvet 2010b; Calvo 2013; Camargos 2003; Camorlinga-Ponce 1998; Campuzano-Maya 2007; Canete 2002; Canete 2003; Cardenas 2006; Cardenas 2008; Cardinali 2003; Carrasco 1998; Caselli 1999; Casswall 1999; Castro 2004; Castro-Fernandez 2004; Cave 1999; Chacon 1995; Chang 1999; Chang 2002; Chattopadhyay 2002; Chattopadhyay 2004; Checchi 2000; Chen 1996; Chen 1997; Chen 2000; Chen 2001a; Chen 2001b; Chen 2002a; Chen 2002b; Chen 2003; Cheng 2004; Cherian 2008; Chey 1997a; Chey 1999a; Chey 2000a; Ching 1991a; Ching 1993; Chisholm 2004; Chmiela 2003; Cho 2000; Cho 2003; Choi 2010; Choi 2011; Christie 1996; Chua 2002; Chung 2001a; Chvalova 1990; Clancy 1994; Cockburn 2001; Coelho 1990; Coelho 1997; Coelho 1999; Coelho 2003; Coelho 2009a; Coelho 2009b; Coelho 2011; Cohen 1999; Colaiocco 1999; Connor 1999; Conti-Nibali 1990; Contreras 2006; Coombs 2001; Corvaglia 1997; Corvaglia 1999; Costa 2001; Crespo 2009; Crispino 2013; Cullen 2002; Cunningham 2010; Cutler 1993; Cutler 1995a; Cutler 1998; Cutler 1999; Da Silva 2010; Dahlberg 1998; Daino 2015; Dan 2013; Danielli 1993; Day 2002; Day 2003; De Angelis 2007; De Bustillo 1998; De Carvalho 2003; De Giacomo 1991; De Laat 2001; De Oliveira 1999; Deankanob 2006; Debongnie 1993; Deguchi 2009; Del Zompo 2014; Delaney 2003; Demiray 2006; Demiray 2012; Demiray-Gurbuz 2012; Demirturk 2003; Desroches 1997; Dhar 1998; Dhesi 2015; Di Fulvio 2003; Di Mario 2009; Di Mario 2010; Di Silvio 1998; Dill 1989; Dill 1990; Ding 1993; Ding 2000; Dolek 2007; Dominguez 2006; Dominguezmunoz 1995; Domínguez-Muñoz 1997; Donati 1997; Dondi 2006; Dore 2004; Douraghi 2013; Drew 1988; Drzymala-Czy 2014; Du 2004; Duan 1994; Duggan 1998; Duggan 1999; Dulbecco 2001; Dulbecco 2003; Dumont 1989; Durdal 2002; Dy-Limquiaco 2006; Edwards 1997; Elitsur 1997; Elitsur 2004; Elitsur 2009; Ellenrieder 1997; Elnujumi 1991; El-Nujumi 1996; El-Nujumi 1998; El-Zaatari 1995; Endtz 2000; Engberg 2003; Engstrand 1992; Enroth 1997a; Enroth 1997b; Erzin 2004; Erzin 2005; Evans 1989; Everts 1996; Faigel 1996a; Faigel 1996b; Faigel 2000; Fakhrjou 2011; Falaknazi 2010; Fallone 1998; Falsafi 2005; Falsafi 2009; Fanti 2001; Fazulzyanova 2012; Fazzio 1995; Feldman 1995; Felz 1997; Ferrante 1999; Festi 1999; Feteih 2009; Feydt-Schmidt 2002; Figura 2005; Figura 2014; Finderle 2013; Fontana 2000; Forne 2000; Fox 1989; Fraser 1996b; Frenck 2006; Fry 2005; Fujisawa 2001; Fukuda 1996; Fukuda 2005; Fukuda 2006; Fusconi 1999; Galleguillos 1998; Gallo 2001; Ganga-Zandzou 2001; Garcia 2000; Garcia-Diaz 2002; Garza-Gonzalez 2003; Gatta 2003b; Gatta 2003c; Gatta 2003d; Gatta 2004a; Gatta 2004b; Gatta 2006; Gatta 2010a; Gatta 2010b; Gatta 2011; Gerards 1999; Ghasemian 2005; Ghoshal 2010; Gilger 2002; Gill 2007; Girdalidze 2013; Gisbert 1999a; Gisbert 1999b; Gisbert 2000a; Gisbert 2000c; Gisbert 2000d; Gisbert 2000e; Gisbert 2000f; Gisbert 2000g; Gisbert 2001; Gisbert 2002a; Gisbert 2002b; Gisbert 2002c; Gisbert 2002d; Gisbert 2003a; Gisbert 2003b; Gisbert 2004a; Gisbert 2006c; Gisbert 2006d; Gisbert 2006e; Gisbert 2006f; Gisbert 2006g; Gisbert 2007; Glassman 1990; Glupczynski 1992; Gobert 1989; Goel 2003; Goh 1995; Gomes 2002; Gomes 2005; Gomez 2000; Gomollon 2003; Gonzalez 2007; Gonzalez 2013; Gonzalez-Cuevas 2001; Good 1991; Goodwin 1987; Gosciniak 1993; Gosciniak 1996; Gosciniak 2000; Gosciniak 2002; Gosciniak 2003; Goto 1995; Graham 1986; Graham 1987; Graham 1996b; Graham 2001a; Graham 2001b; Grino 2001; Grino 2003; Grossi 2000; Guell 2006; Guja 1999; Gulcan 2005; Gupta 2003; Gurbuz 2009; Gutierrez 1999; Gutierrez 2005; Hackelsberger 1998; Haggerty 2005; Hamlet 1995; Hamlet 1999; Han 2006; Hanvivatvong 2004; Hanvivatvong 2006; Harries 1992; Harrison 1998; Hartmann 2003; Hashemi 2008; Hauser 2006; Havlasova 1998; Hawthorne 1999; Hayashi 2003; Heaney 1998; Heanhean 2013; Hegedus 2002; Helvaci 1993; Henze 1988; Henze 1989; Henze 1990; Hidaka 2010; Higazy 2000; Hildebrand 1997; Hino 2004; Hirschl 1991; Hirschl 1993; Ho 1996; Hoang 2006; Hoek 1992; Hollenz 1999; Hooton 2006; Houben 1999; Hu 1995; Hu 2000; Hu 2007; Hu 2011; Huang 1993; Huang 1996; Huang 2000; Huelin 1996; Hung 2002; Hung 2010; Husson 2000; Ibrahim 2012; Ichinose 1998; Ignys 2006; Ilan 1998; Imrie 2001; Iranikhah 2013; Ishihara 2000; Ishizuka 1999; Isomoto 2002; Israeli 2003; Ito 2005; Iwanczak 2005; Jadresin 2000; Jalali 1988; Jensen 1993; Ji 1993; Jiang 2004; Jo 2008; Jo 2014; Johnston 1998; Jonaitis 2007; Jones 1997a; Jones

2007; Juhasz 2000; Juncal 1998; Kajiwara 1997; Kajiwara 1998; Kakinoki 2001; Kaklikkaya 2006; Kalach 1996; Kalach 2005; Kalach 2009; Kalem 2010; Kang 1999; Kannath 2007; Kao 1993; Kaore 2012; Kaptan 2009; Karsligil 2010; Kasho 1996; Kassa 1996; Katelaris 1998; Kato 1997; Kato 1998; Kato 1999; Kato 2000b; Kato 2000c; Kato 2001a; Kato 2001b; Kato 2001c; Kato 2002a; Kato 2002b; Kato 2002c; Kato 2002d; Kato 2002e; Kato 2003a; Kato 2004a; Kato 2004b; Kato 2004c; Kato 2007; Katsuragi 1998; Kaul 1998; Kawai 2008; Kawakami 2002; Kazemi 2011; Kearney 1999; Kearney 2002; Ken 2013; Kesli 2010; Khafri 2005; Khalifehgholi 2013; Kharchenko 2012; Khorovskaya 2003; Kias 2011; Kikuchi 1999; Kim 1996; Kim 1997; Kim 1999; Kim 2001; Kim 2002; Kim 2009; Kim 2012; Kim 2013; Kim 2014; Kindermann 2000; Kindermann 2001a; Kindermann 2001b; Kishkun 2002; Klyucharova 2013; Kobayashi 2002; Kodama 2004; Kodama 2012; Kokkola 2000; Koletzko 1995; Koletzko 2003; Kolho 2002; Kolho 2006; Kolt 1997; Kondo 2000; Konorev 2013; Konstantopoulos 2001; Konturek 1999; Kopacova 1999; Kopacova 2005; Kopanski 1996; Korkmaz 2013; Korkmaz 2015; Korzonek 1997; Kountouras 1996; Kowalski 1990; Kozaiwa 1997; Kozlov 2006; Krausse 2008; Kroser 1998; Krumbiegel 2000a; Krumbiegel 2000b; Kuang 1998; Kubota 2002; Kubota 2003; Kumbhari 2012; Kumbhari 2013; Kuo 2005; Kushch 2009; Kwon 2004; Kwon 2015; Kyrlagkitsis 2007; Labenz 1996; Ladas 2000; Ladas 2002b; Lahaie 1995; Lai 1997; Laine 1999; Langhorst 2002; Larras 2009; Lee 1999; Lee 2000a; Lee 2000b; Lee 2003; Lee 2014; Lee 2015a; Leja 2009; Lelwala 1990; Leodolter 1997; Leodolter 1998a; Leodolter 1998b; Leodolter 1999a; Leodolter 1999b; Leodolter 2000; Leodolter 2001a; Leodolter 2001b; Leodolter 2001c; Leodolter 2002; Leodolter 2003a; Leodolter 2003b; Leodolter 2004; Lepper 2004; Lerang 1998a; Lerang 1998b; Leszczynska 2009; Leung 1998a; Leung 1998b; Leung 1999; Leung 2001; Leunk 1990; Levine 2004a; Levine 2004b; Lew 1999; Lewin-van 1999; Lewis 1997; Li 1995; Li 2004; Liao 2002; Lie 2012; Lim 2005; Lin 2004a; Lin 2004b; Lin 2004c; Lin 2015; Lindsetmo 2008; Liquornik 1998; Liston 1996; Liu 2002; Lo 2005; Locatelli 2004; Loffeld 1989; Loffeld 1993; Logan 1990; Logan 1991b; Lombardo 1999; Lopez 2001; Lopez 2004; Lopez-Brea 1998; Lotterer 1991; Lotterer 1993a; Lotterer 1993b; Lozniewski 1996; Lu 2005; Lu 2006; Lucio 1999; Luzza 1995; Luzza 1997; Luzza 2000; Ma 2006; Maaroos 2004; Machado 2004; Machado 2006; MacKay 2003; Madico 1995; Mahmood 2010; Maity 2014; Makristathis 1998; Malaty 1996; Malaty 2000; Malaty 2002; Malfertheiner 1988; Malfertheiner 2002; Mana 2000b; Mana 2005; Manes 2000; Manes 2001; Manes 2005; Marchildon 1996; Marchildon 1999; Marchildon 2003; Marshall 1988a; Marshall 1988b; Marshall 1991; Marusic 2006; Masoero 2000; Matougui 2007; Matsuda 2003a; Matsuda 2003b; Matsukura 1995; Matsukura 2004; Matsuo 2000; Mattar 2014; Mauro 2006a; Mauro 2006b; McColl 2003; McNamara 1999; McNulty 1999; Mediero 2007; Megraud 2000; Megraud 2005; Mehrazma 2014; Meijer 1997; Mendall 1992; Menegatti 1997a; Menegatti 1997b; Metz 1998; Metz 2000; Midolo 1995; Minoli 1998; Mion 1997a; Mion 1997b; Mion 2001; Miwa 1997; Miwa 1998b; Miwa 1999; Miwa 2000; Miwa 2001; Mizukami 1994; Moayyedi 1997; Mock 1999; Mohammadi 2008; Moncayo 2006; Monteiro 2001b; Morales 2002; Moshkowitz 1993; Motta 2009; Moulton-Barrett 1993; Mowat 1997; Mowat 1998; Mrevlje 2012; Muhsen 2006; Muñoz 1998; Muñoz 1999; Munster 1993; Murakami 2003; Murakami 2011; Murata 2002; Murphy 2015; Myllyniemi 2007; Myllyniemi 2008; Nagahara 2003; Nair 1995; Nakata 1995; Nakata 2004; Nakayama 2004; Navarro 1992; Negayama 1992; Negrini 1992; Newell 1988; Newell 1991; Ng 2002; Ng 2013; Nguyen 2008a; Nguyen 2008b; Nguyen 2010; Nguyen 2013; Ni 2000; Nijevitch 2001; Nilius 2001; Nishikawa 1996; Nishikawa 2000; Noguchi 2007; Nugalieva 2006; Nurgalieva 2003; Nurgalieva 2008; Nysaeter 1992; Obata 2003; Obradovic 2001; Oderda 1989; Oderda 1999; Oderda 2000; Ogunc 2003; Ohara 1995; Ohara 1996; Ohara 1997; Ohara 1998a; Ohara 1998b; Ohara 2004; Ohkura 1998; Ohkura 2000; Oksanen 1997; Oksanen 1998; Oksanen 2001; Okuda 2002; Okuda 2004; Okuda 2005; Okuda 2010; Okuda 2013; Okuda 2014; Olafsson 2012; Oleastro 2000; Oleastro 2002; Oliaro 2000; Omorogbe 2015; Ong 1993; Opekun 2002; Opekun 2006; Ormand 1990; Ortiz-Olvera 2007; Osman 2014; Osoba 2004; Ou 2013; Ozdemir 2008; Ozturk 2009; Pacheco 2001; Pacheco 2013; Paimela 2006; Palka 2010; Pandya 2014; Pantoflickova 1999; Pantoflickova 2003; Paoluzi 2001; Parejo 1998; Park 2006; Park 2009; Park 2015; Parolova 2012; Patel 1994; Pathak 1992; Pathak 1994; Pathak 2008; Pathak 2011; Pathak 2013; Pathak 2014; Pattison 1997; Pavlitou 1998; Pavlitou 2000; Pawar 2014; Peitz 2000; Peitz 2003; Peitz 2004; Pena 1989; Peng 2000a; Peng 2000b; Peng 2001a; Peng 2001b; Peng 2002; Peng 2003; Peng 2005; Peng 2009; Perets 2014; Perets 2015; Perez 1996; Perezperez 1994; Perna 2002; Perna 2005; Perri 1997a; Perri 1997b; Perri 1998a; Perri 1998b; Perri 1998c; Perri 2002a; Perri 2002c; Perri 2005; Petrovic 2011; Pettersson 2001; Pianko 1999; Pilotto 1999; Pilotto 2000a; Pilotto 2000b; Pilotto 2002; Plebani 1999; Ploier 1995; Pons 2014; Porter 2009a; Porter 2009b; Portorreal 2002; Posteraro 2006; Pourakbari 2011a; Pourakbari 2011b; Pourakbari 2013; Prabakaran 1997; Prell 2009; Prieto 1994; Pronovost 1994; Przyklenk 1990; Pu 2005; Puolakkainen 1997; Puz 2006; Puz 2008; Qibi 2008; Quach 2014; Queiroz 1999; Queiroz 2000; Queiroz 2013; Queralt 2005; Quesada 2006b; Rabbe 1988; Rae 1995; Raguza 2005; Raguza 2010; Rahman 2008; Raju 1994; Ramírez-Lázaro 2011; Ramírez-Lázaro 2015; Rao 2001; Rauws 1989a; Rauws 1989c; Raymond 1999; Raymond 2000; Razaghi 2010; Rechcinski 1997; Redéen 2011; Rehnberg 2001; Reilly 1997; Ren 2005; Reynders 2012; Riaz 2011; Riepl 2000; Ritchie 2009; Rocha 1998; Rocha 2002; Rocha 2004; Roma-Giannikou 2010; Romaozinho 2011; Roth 2001; Rothenbacher 2000a; Rothenbacher 2000b; Rowland 1997a; Rowland 1997b; Sabbi 2005; Sadowski 1998; Saez 2012; Saffari 2003; Salama 1993; Salles-Montaudon 2001; Salomaa-Rasanen 2004; Saltik 2001; Saltik 2003; Sanches 2013; Saneian 2013; Sano 2004; Santogade 1990; Sarker 2003; Sastry 1997; Sato 2012; Savarino 1999; Savarino 2000a; Savarino 2001; Savio 1999; Sawada 2001; Scherbakov 2001; Schmitt 1996; Schuman 1995; Schumann 2006; Schwarzer 2007; Sedlackova 1992; Sen 2005; Sen 2011; Serrano 2008; Sfarti 2009; Shaikh 2005; Sharma 1995; Sharma 1997; She 2009; Sheikhian 2007; Shepherd 2000; Sheu 1997; Sheu 1999a; Sheu 1999b; Sheu 2000a; Sheu 2000b; Sheu 2000c; Sheu 2002; Shimizu 2003a; Shimizu 2003b; Shimoyama 2009a; Shimoyama 2015; Shirin 2001; Shirin 2003; Shukla 2012; Sicinschi 2003b; Siddiqui 2010; Silva 2009; Sito 1994; Slade 1999; Slater 2004; Smith 2006; Sobala 1991; Sokucu 2002; Song 2000; Song 2014; Sonmezoglu 2005; Steen 1995; Stege 2010; Sternberg 1997; Stojkovic 2011; Stone 1997; Storskrubb 2005; Stray-Pedersen 2007; Stuppy 2010; Stuppy 2011; Sudraba 2010; Sudraba 2011; Sugiyama 1991; Sujatha 2013; Sukhanov 2011; 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Van Der Ende 1999; Van Der Hulst 1999; Van der Hulst 1999; Van der Voort 1998; Van der Voort 1999; Van Doorn 2001; Van Leerdam 2002; Vannella 2009; Vargas 2013; Vaz Coelho 2005; Vecsei 2010; Veenendaal 1995; Veijola 2008; Velayos 2012; Veldhuyzen 1990; Veldhuyzen 1991; Vincent 1999; Vinette 2004; Vivas 1993; Von Wulffen 1988b; Von Wulffen 1993; Vyas 1994; Wallace 2006; Wang 1998; Wang 2000; Wang 2001; Wang 2002; Wang 2003; Wang 2015a; Wang 2015b; Watanabe 2001; Watanabe 2013; Weijnen 2001a; Weijnen 2001b; Westblom 1992; Wilcox 1996; Wildner-Christensen 2002; Wilson 2008; Winiarski 2003b; Winiarski 2003a; Wirtheim 2001; Wisniewska 2002a; Wisniewska 2002b; Wisniewska 2006; Wong 1999; Wong 2000a; Wong 2000b; Wong 2000c; Wong 2001a; Wong 2001b; Wong 2003a; Wong 2003b; Wong 2003c; Wu 1992; Wu 2001a; Wu 2001b; Wu 2003; Wu 2004; Wu 2006a; Wu 2006b; Xia 2000a; Xia 2000b; Xia 2002; Xiao 1991; Yachi 1991; Yakoob 2008; Yamakawa 1993; Yamamoto 1995; Yamamoto 1996; Yamamoto 2000; Yamamoto 2003; Yamamoto 2005; Yamaoka 1998; Yamasaki 2004; Yamashiro 1995; Yan 2010; Yanez 2000; Yang 2005; Yang 2007; Yang 2008a; Yang 2008b; Yang 2015; Yasuda 2009; Ye 2005; Yee 2002; Yilmaz 2006; Yin 2015; Yokota 1990; Yong 2006; Yoshida 1993; Yoshida 2000; Young 1995; Young 1996; Zagari 1998; Zagari 2012; Zalabska 2010; Zambon 2004; Zanetti 2002; Zaremba 1995; Zawadzka-Gralec 2009; Zhang 1990; Zhang 2007; Zheng 2004; Zhou 1996; Zhu 2002a; Zhu 2002b; Zhukhovitskii 2005; Zubillaga 1997; Zubillaga 1999

Lack of data (256)

- **Insufficient diagnostic test accuracy data** (25): Allerberger 1996; Baryshnikova 2014; Bilal 2007; Capurso 2006; Casellas 1999; Chehter 2013; Cinar 2004; De Arruda 2001; Faigel 2001; Folwaczny 1999; Formichella 2012; Goettner 2012; Gonzalez 2003; Groves 1997; Herold 2002; Hilker 1994; Hirschl 1990; Konorev 2014; Mendoza 2006; Neri 1999; Neumann 2010; Neumann 2011; Neumann 2012; Reshetnikov 2007; Urita 2007b
- **No diagnostic accuracy data** (42): Abdullah 1997a; Alem 2002; Bazzoli 1994; Bazzoli 1996; Bojko 1997; Brandi 2006; Brennan 1991; Cacoullis 1991; Cai 2010; Caporali 2003; Cevrioglu 2004; Chang 2000; Chiang 2010; Chong 1995; Cremonini 2000; Czkwianianc 1997; Dowlatshahi 2002; Elitsur 2000; Garza-Gonzalez 2002; Gisbert 1996; Gisbert 2005; Gong 2010; He 1997; Hegedus 2001a; Hegedus 2001b; Herbrink 1988; Iijima 1998; Ilga 2008; Inaba 2002; Jabbari 2009; Jung 2002; Matthews 2000; Matthews 2005; Mitchell 1988; Naruki 1996; Nishi 1998; Oak 2011; Rapoport 2014; Rasheed 2014; Rejchrt 2004; Schaefer 1999; Smith 2009
- **Not a diagnostic test accuracy study of non-invasive *H pylori* diagnosis** (188): Abdullah 1997b; Adamczyk 2013; Adiloglu 2003; Aguemon 2005; Alavi 1996a; Andersen 1989; Anonymous 1996; Antico 2010; Anwar 2012; Asaka 1988; Asaki 1996; Aulia 2009; Baranskaia 2006; Basinska 2005; Bassler 1992; Bateson 2001; Bauernfeind 1989; Bazzoli 1997a; Bekmen 2008; Bell 1991; Bennedsen 1998; Bennett 2006; Berger 2002; Berker 2003; Berning 2009; Bertschinger 1992; Besherdas 2000; Bielanski 1997a; Bielanski 2000; Bindayna 2006; Birkenfeld 2004; Blashenkov 2013; Bleau 1998; Blecker 1992a; Blecker 1992b; Blecker 1993a; Blecker 1993g; Blecker 1994b; Bode 1998; Bohn 1994; Bolton 1997; Bordin 2013; Braden 1997; Buchvald 1993; Bures 2000; Butler 2000; Buyukbaba-Boral 2005; Buzas 2001; Buzas 2008; Chalkias 2011; Chang 2003; Chang 2012; Chang 2013; Chen 1994; Chen 2009a; Chen 2009b; Chey 1997b; Cho 2008; Chong 1994; Christensen 1992; Chung 2001b; Churchill 1998; Clayton 1992; Collins 1992; Con 2007; Cooreman 1990; Cullen 1992; Czinn 1991; Datta 2003; Dediste 2003; Demir 2001; Devenish 2005; Djurasinovic 2014; Dmitrienko 2009; Dmitrienko 2011; Donati 2000; Dong 2015; Dore 1997; Dore 2003; Dou 2008; Ebara 2000; Elitsur 1999a; Faulde 1991; Fayaz 2014; Fayed 2008; Floch 2012; Fowora 2012; Fradkin 1997; Franceschi 1999; Fraser 1996a; Fraser 1997; Fraser 1998; Fruehauf 2003; Fukuda 2007; Fukuda 2009; Fusconi 1997; Gangaidzo 1995; Geletneky 1996; Gemignani 2013; Gene 2000; Ghosh 2014; Gisbert 1997; Gobert 1988; Goji 2015; Gomez 2011; Gomez-Camarasa 2014; Gong 2014; Gonzalez 2012; Gotoh 1997; Grossi 2012; Grotowski 1998; Groves 2002; Guducuoglu 2010; Gunay 2009; Guven 2011; Harde 2008; Harde 2010; Hartman 1992; Hassan 2013; Huijsdens 2004; Hynes 1998; Hynes 2000; Ierardi 2002; Ierfone 2003; Ito 2002; Jaff 2011; Jafri 2010; Jaime 2013; Jain 1999; Jane 1999; Janjetic 2010; Janjetic 2011; Janjetic 2015; Janulaityte 1998; Jarbol 2006; Johansen 2004; Jung 2013; Kessenich 2012; Kist 1999; Klein 1999; Koca 2005; Kokkola 1998; Kopanski 1993a; Kopanski 1993b; Kopanski 2002; Kubo 2001; Lamarque 1996; Lassnig 1988; Lemus 2004; Leodolter 2005; Mahony 1988; Marshall 1999; Massarrat 2012; McColl 1997; Meltzer 2013; Miehlke 1996; Murugesan 2011; Nakagawa 1995; Newell 1989a; Nguyen 2012; Niv 2000; Niv 2003; O'Connor 2010; Perez-Perez 1997; Perri 2002b; Perrone 2005; Potashov 1996; Presecki 1997; Salih 2013; Sharma 2015; Shimoyama 2014; Shmuely 2007; Shuber 2002; Smith 2011; Stermer 1997; Taylor 1987; Tormo 2013; Van Bohemen 1988; Van Bohemen 1989; Vesna 2005; Von Wulffen 1988a; Von Wulffen 1989; Vorobjova 1991; Werdmuller 1998; Xie 2008a; Xie 2008b; Zhang 2006; Zhou 2000
- **Incorrect data (correct information could not be obtained)** (1): Hilker 1996

Appendix 8. Risk of bias and applicability concerns summary for each study included for urea breath test-^{13}C, urea breath test-^{14}C, serology and the stool antigen test

Figure 12; Figure 13; Figure 14; Figure 15

Figure 12. Risk of bias and applicability concerns summary: review authors' judgements about each domain for each study included for urea breath test-^{13}C

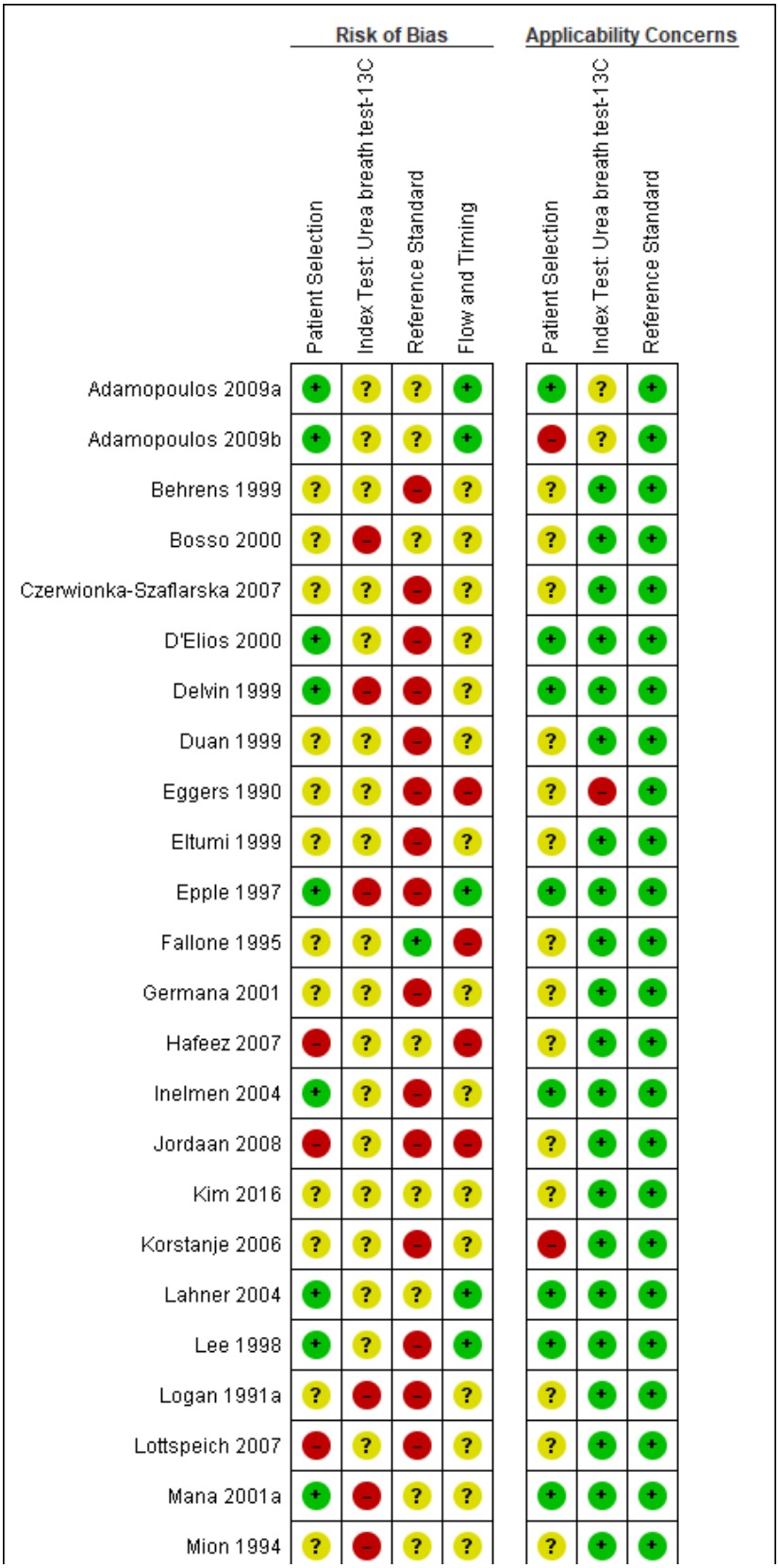


Figure 12. (Continued)

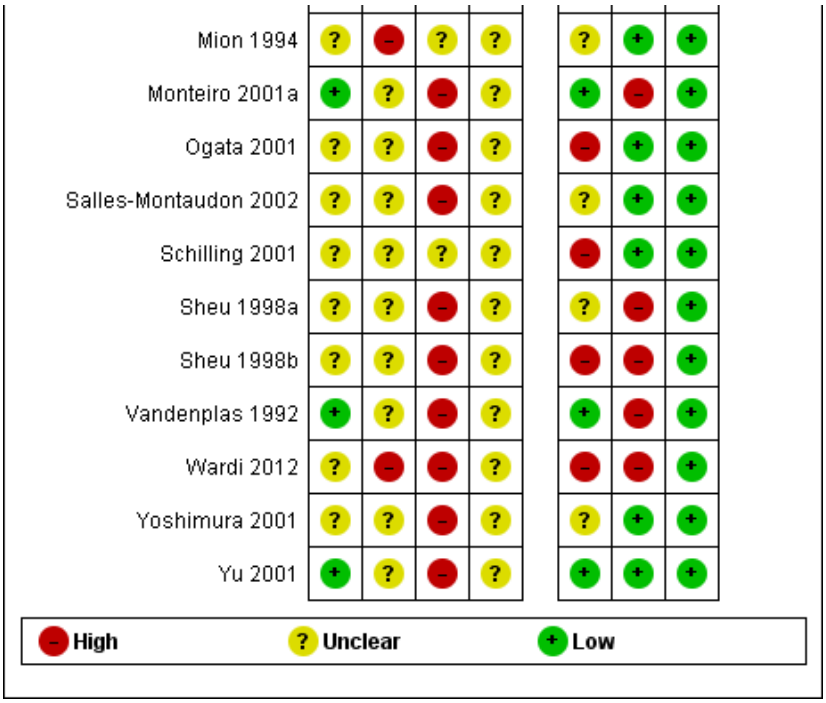


Figure 13. Risk of bias and applicability concerns summary: review authors' judgements about each domain for each study included for urea breath test-^{14}C.

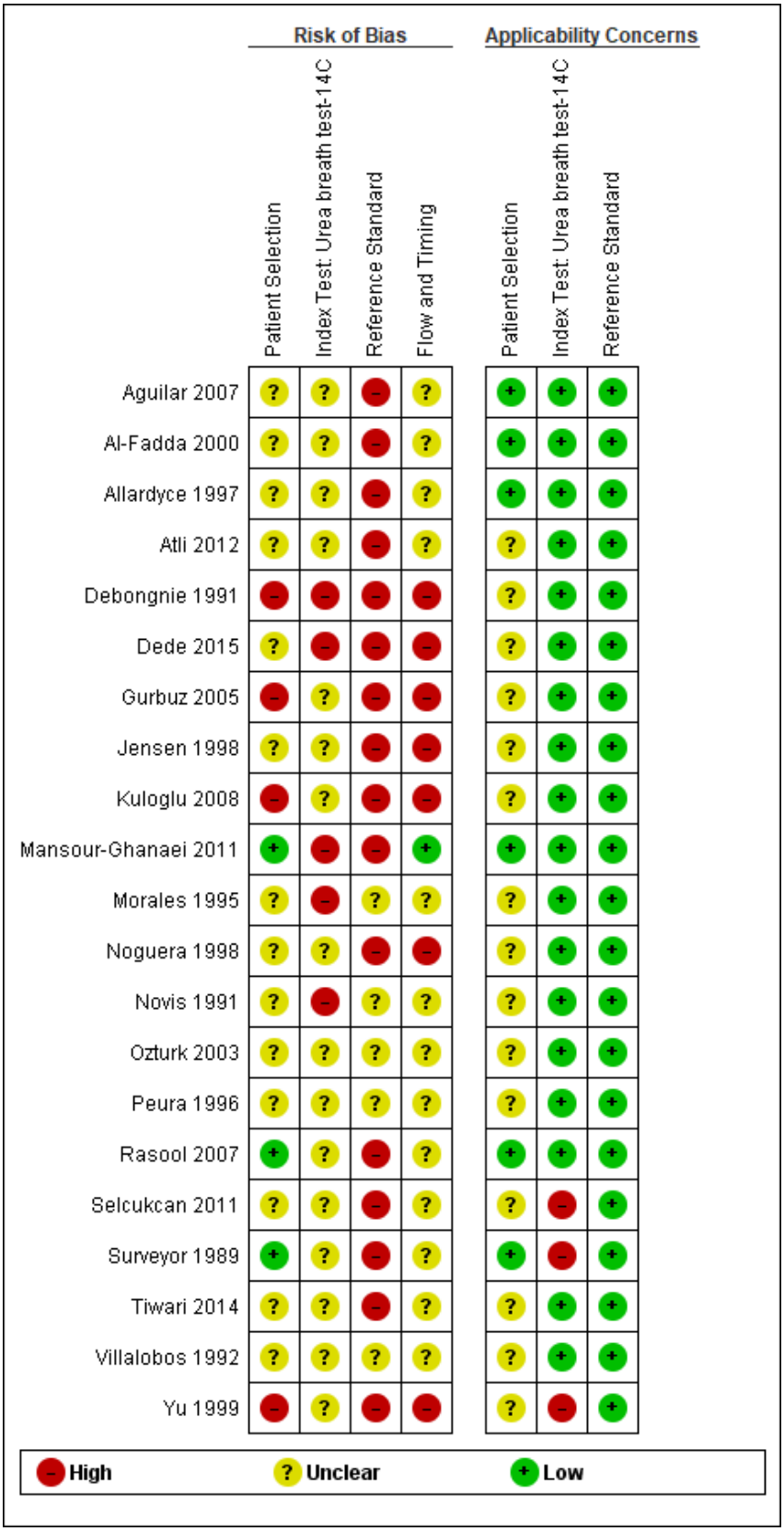


Figure 14. Risk of bias and applicability concerns summary: review authors' judgements about each domain for each study included for serology

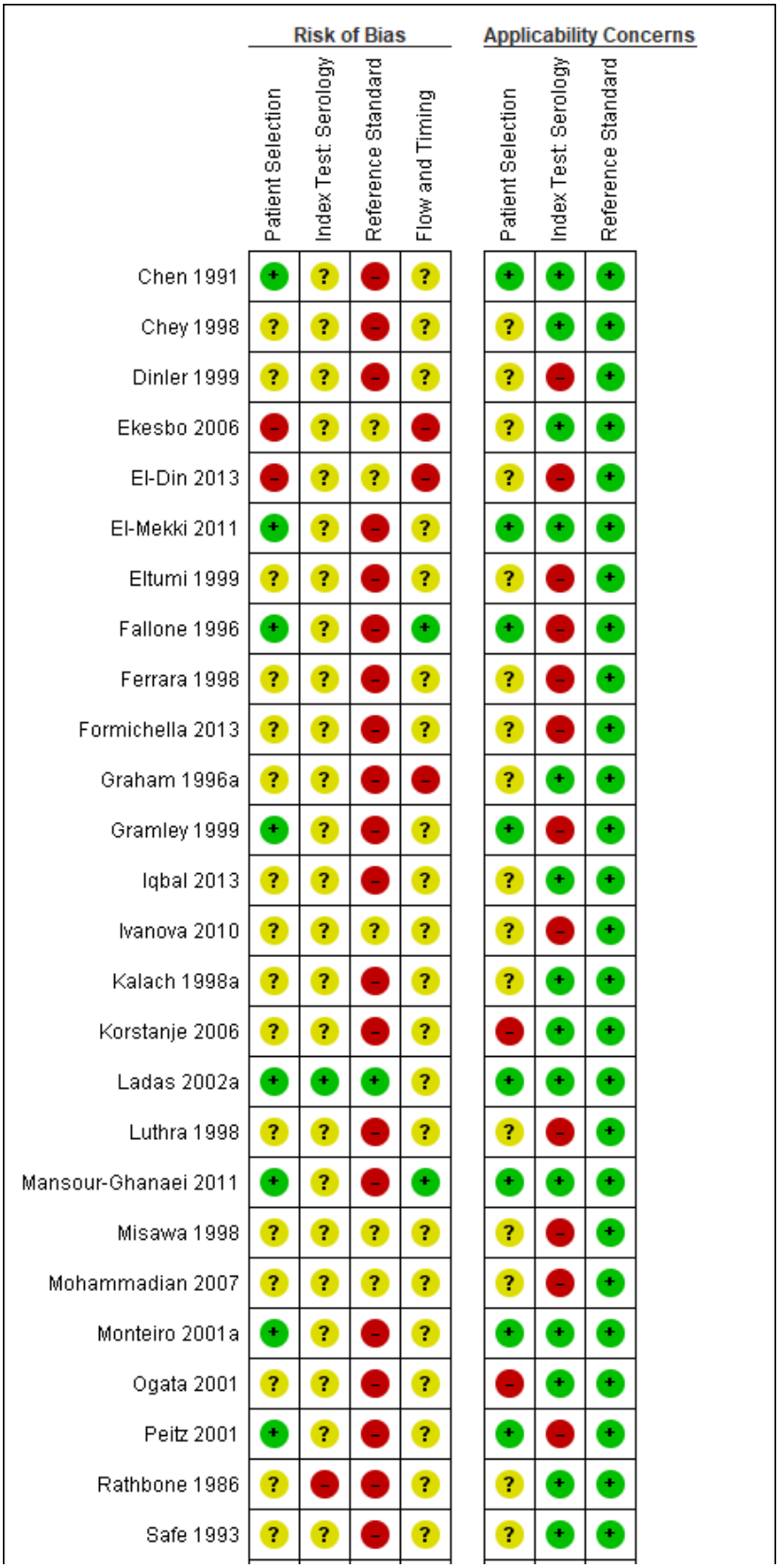


Figure 14. (Continued)

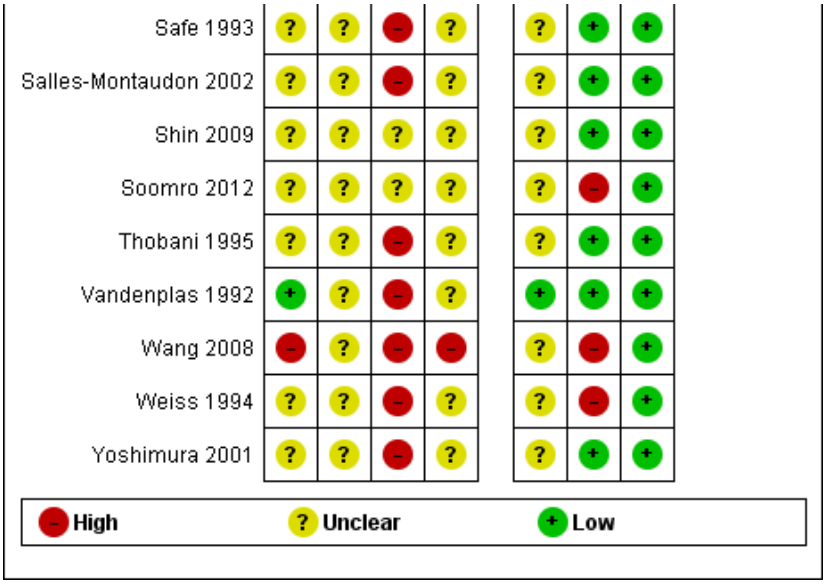


Figure 15. Risk of bias and applicability concerns summary: review authors' judgements about each domain for each study included for the stool antigen test

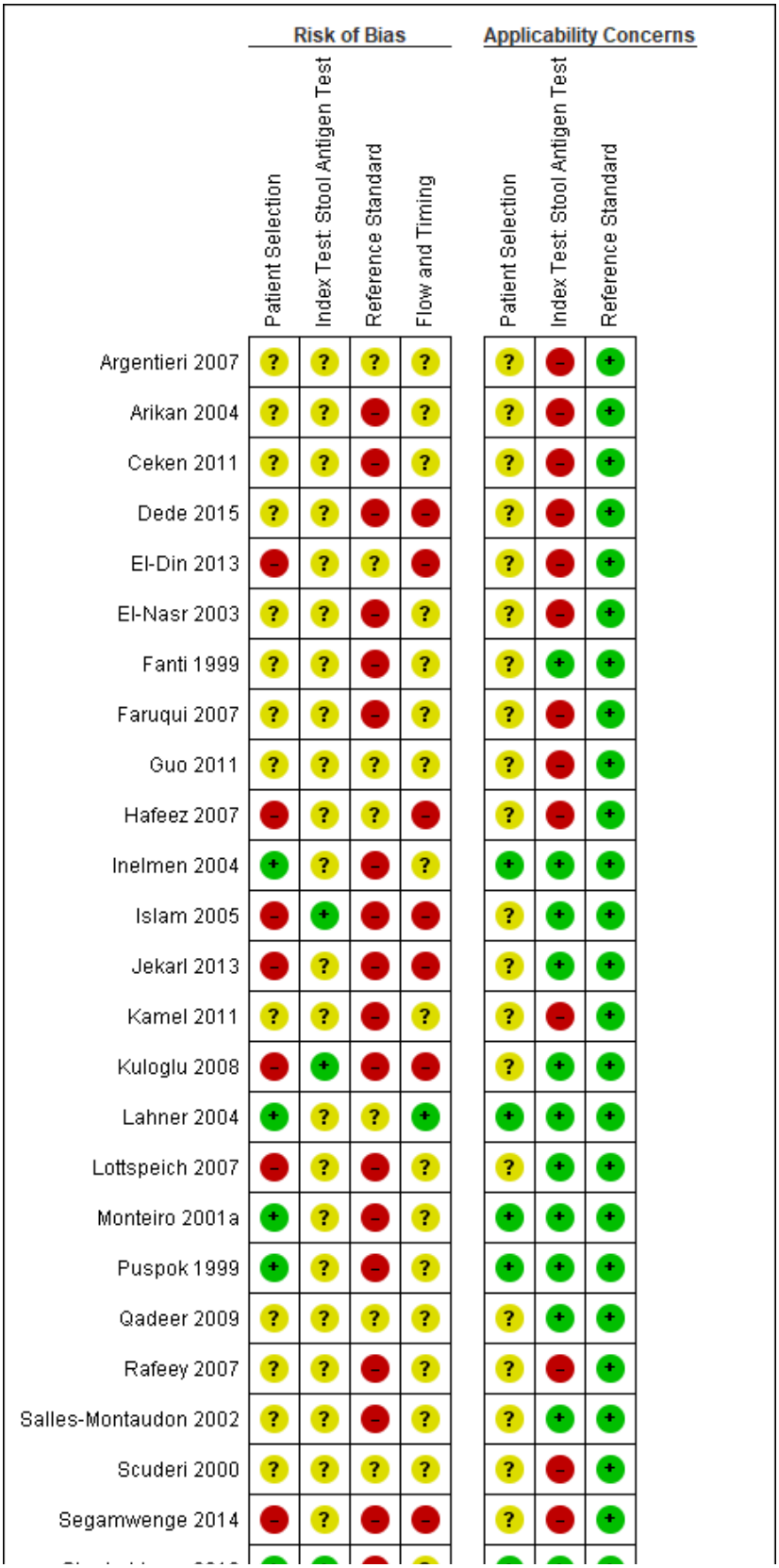
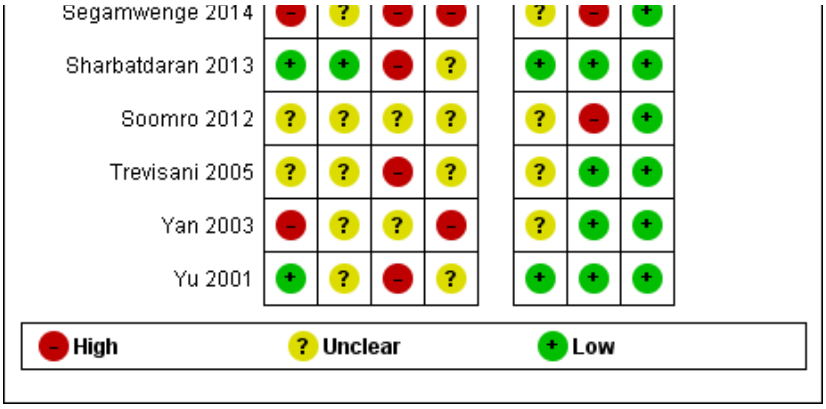


Figure 15. (Continued)



Appendix 9. Individual study results of test accuracy at other thresholds (grouped by test)

Study name	Threshold	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Urea breath test-^{13}C							
Delvin 1999	DOB > 2.0% (30 minutes)	12	5	0	62	1.00 [0.74, 1.00]	0.93 [0.83, 0.98]
Delvin 1999	DOB > 2.5% (30 minutes)	12	2	0	65	1.00 [0.74, 1.00]	0.97 [0.90, 1.00]
Delvin 1999	DOB > 3.5% (30 minutes)	12	0	0	67	1.00 [0.74, 1.00]	1.00 [0.95, 1.00]
Delvin 1999	DOB > 4.0% (30 minutes)	12	0	0	67	1.00 [0.74, 1.00]	1.00 [0.95, 1.00]
Delvin 1999	DOB > 4.5% (30 minutes)	12	0	0	67	1.00 [0.74, 1.00]	1.00 [0.95, 1.00]
Inelmen 2004	DOB > 5.0% (30 minutes)	41	7	13	61	0.76 [0.62, 0.87]	0.90 [0.80, 0.96]
Mana 2001a	DOB > 3.0% (10 minutes)	84	9	0	89	1.00 [0.96, 1.00]	0.91 [0.83, 0.96]
Mana 2001a	DOB > 3.0% (20 minutes)	84	7	0	91	1.00 [0.96, 1.00]	0.93 [0.86, 0.97]
Mana 2001a	DOB > 3.5% (10 minutes)	84	7	0	91	1.00 [0.96, 1.00]	0.93 [0.86, 0.97]
Mana 2001a	DOB > 3.5% (20 minutes)	84	5	0	93	1.00 [0.96, 1.00]	0.95 [0.88, 0.98]
Mana 2001a	DOB > 3.5% (30 minutes)	84	5	0	93	1.00 [0.96, 1.00]	0.95 [0.88, 0.98]
Mana 2001a	DOB > 4.0% (10 minutes)	84	5	0	93	1.00 [0.96, 1.00]	0.95 [0.88, 0.98]
Mana 2001a	DOB > 4.0% (20 minutes)	84	4	0	94	1.00 [0.96, 1.00]	0.96 [0.90, 0.99]
Mana 2001a	DOB > 4.0% (30 minutes)	83	4	1	94	0.99 [0.94, 1.00]	0.96 [0.90, 0.99]
Mana 2001a	DOB > 4.5% (10 minutes)	84	5	0	93	1.00 [0.96, 1.00]	0.95 [0.88, 0.98]
Mana 2001a	DOB > 4.5% (20 minutes)	84	4	0	94	1.00 [0.96, 1.00]	0.96 [0.90, 0.99]
Mana 2001a	DOB > 4.5% (30 minutes)	81	4	3	94	0.96 [0.90, 0.99]	0.96 [0.90, 0.99]
Mana 2001a	DOB > 5.0% (10 minutes)	84	5	0	93	1.00 [0.96, 1.00]	0.95 [0.88, 0.98]

(Continued)

Mana 2001a	DOB > 5.0% (20 minutes)	84	3	0	95	1.00 [0.96, 1.00]	0.97 [0.91, 0.99]
Mana 2001a	DOB > 5.0% (30 minutes)	81	4	3	94	0.96 [0.90, 0.99]	0.96 [0.90, 0.99]
Urea breath test-^{14}C							
Dede 2015	CPM > 23 (10 minutes)	6	3	1	20	0.86 [0.42, 1.00]	0.87 [0.66, 0.97]
Dede 2015	CPM > 29 (30 minutes)	5	0	2	23	0.71 [0.29, 0.96]	1.00 [0.85, 1.00]
Dede 2015	CPM > 35 (20 minutes)	6	0	1	23	0.86 [0.42, 1.00]	1.00 [0.85, 1.00]
Dede 2015	CPM > 50 (20 minutes)	4	0	3	23	0.57 [0.18, 0.90]	1.00 [0.85, 1.00]
Dede 2015	CPM > 50 (30 minutes)	5	0	2	23	0.71 [0.29, 0.96]	1.00 [0.85, 1.00]
Morales 1995	Not stated	64	5	10	25	0.86 [0.77, 0.93]	0.83 [0.65, 0.94]
Noguera 1998	> 1% excretion (20 minutes)	19	2	3	14	0.86 [0.65, 0.97]	0.88 [0.62, 0.98]
Noguera 1998	> 1% excretion (30 minutes)	15	1	7	15	0.68 [0.45, 0.86]	0.94 [0.70, 1.00]
Novis 1991	> 4.7% excretion (10 minutes)	55	2	6	13	0.90 [0.80, 0.96]	0.87 [0.60, 0.98]
Novis 1991	> 4.7% excretion (20 minutes)	50	2	11	13	0.82 [0.70, 0.91]	0.87 [0.60, 0.98]
Novis 1991	> 4.7% excretion (25 minutes)	52	2	9	13	0.85 [0.74, 0.93]	0.87 [0.60, 0.98]
Novis 1991	> 4.7% excretion (5 minutes)	59	3	2	12	0.97 [0.89, 1.00]	0.80 [0.52, 0.96]
Ozturk 2003	DPM > 100 (10 minutes)	48	5	0	20	1.00 [0.93, 1.00]	0.80 [0.59, 0.93]
Urea breath test - unknown isotope							
Han 2012	Not stated	33	2	10	54	0.77 [0.61, 0.88]	0.96 [0.88, 1.00]

(Continued)

Lombardo 2003	DOB > 4 per ml (at 5 minute intervals up to 30 minutes)	10	8	2	8	0.83 [0.52, 0.98]	0.50 [0.25, 0.75]
Serology							
Chey 1998	Not stated	128	33	3	123	0.98 [0.93, 1.00]	0.84 [0.77, 0.89]
Chey 1998	Two red lines	115	23	16	133	0.88 [0.81, 0.93]	0.85 [0.79, 0.90]
Formichella 2013	Not stated	181	13	29	277	0.86 [0.81, 0.91]	0.96 [0.92, 0.98]
Formichella 2013	Not stated	179	6	31	284	0.85 [0.80, 0.90]	0.98 [0.96, 0.99]
Ladas 2002a	≥44 units	89	10	8	23	0.92 [0.84, 0.96]	0.70 [0.51, 0.84]
Misawa 1998	Not stated	62	7	22	23	0.74 [0.63, 0.83]	0.77 [0.58, 0.90]
Monteiro 2001a	Not stated	44	5	2	53	0.96 [0.85, 0.99]	0.91 [0.81, 0.97]
Weiss 1994	Not stated	47	1	3	44	0.94 [0.83, 0.99]	0.98 [0.88, 1.00]
Stool antigen test							
Trevisani 2005	Pink red band (5 minutes)	50	4	9	41	0.85 [0.73, 0.93]	0.91 [0.79, 0.98]
Yu 2001	Visual assessment by gastroenterologists	15	4	1	12	0.94 [0.70, 1.00]	0.75 [0.48, 0.93]

CI = confidence interval; CPM = counts per minute; DOB = delta over baseline; DPM = disintegrations per minute; FN = false negative, FP = false positive; TN = true negative; TP = true positive.

For thresholds for urea breath tests, the number of minutes in brackets is the time after administration of urea.

Appendix 10. Availability of data on potential sources of heterogeneity

Characteristic	Test			
	Urea breath test C-13	Urea breath test C-14	Serology	Stool antigen test
Number of studies (*H pylori* cases/total)	34 (1526/3139)	21 (1018/1810)	34 (2477/4242)	29 (1311/2988)
Reference standard				
Haemotoxylin and eosin stain	10	7	8	8
Special histological stains	7	5	6	9
Immunohistochemical stain	0	0	2	0
Combination	17	9	18	12
Participant type				
Symptomatic	19	13	20	17
Asymptomatic	0	0	1	0
Both	0	1	1	0
Not stated	15	7	12	12
Recent, current proton pump inhibitor or antibiotic use				
Yes	0	0	0	0
No	18	13	17	19
Both	2	0	1	2
Not stated	14	8	16	8
Recruitment type				
Prospective	6	3	3	4
Retrospective	4	0	2	0
Not stated	24	18	29	25
Publication type				
Full text	32	21	31	29
Abstract	2	0	3	0
Subtype of tests*				
Serology subtypes				

(Continued)

ELISA	-	-	17	-
Latex agglutination test	-	-	1	-
Western blot	-	-	3	-
Not stated	-	-	17	-
Stool antigen subtypes				
Monoclonal antibody	-	-	-	2
Polyclonal antibody	-	-	-	3
Not stated	-	-	-	24
Risk of bias†				
Low	0	0	0	0
High	32	18	32	27
Unclear	2	3	2	2

*The same study can feature in more than one category depending upon the number of tests included in the study.

†Studies at low risk of bias in all the QUADAS-2 domains versus those at unclear or high risk of bias.

Appendix 11. Investigation of effect of reference standard on test accuracy

Test	Special stain		Haemotoxylin and eosin stain		P value*
	Studies; participants (*H pylori* cases)	DOR (95% CI)	Studies; participants (cases)	DOR (95% CI)	
Urea breath test-^{13}C	7; 496 (216)	59.5 (13.4, 265)	10; 1154 (623)	229 (62.3, 842)	0.30
Urea breath test-^{14}C	5; 558 (324)	123 (33.7, 446)	7; 428 (269)	33.1 (10.6, 103)	0.10
Serology	6; 1112 (777)	14.4 (2.98, 69.6)	8; 813 (464)	33.5 (7.86, 143)	0.22
Stool antigen test	9; 1124 (476)	33.2 (9.94, 111)	8; 626 (310)	33.0 (9.19, 118)	1.0

*P value from likelihood ratio test comparing models with and without the reference standard covariate.

DOR = diagnostic odds ratio.

CONTRIBUTIONS OF AUTHORS

LB, SS, AS, AG, BL, and KG identified studies and extracted data for the review. LB entered the characteristics of included and excluded studies. KG and YT analysed the data and wrote the review. MY provided critical comments for the review.

DECLARATIONS OF INTEREST

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LB: none known.

SS: none known.

AS: none known.

AG: none known.

BL: none known.

MY: is an Editor with the Cochrane Upper GI and Pancreatic Diseases (UGPD) Review Group. However, other UGPD Editors were responsible for the editorial processing of this review.

KS: none known.

YT: none known.

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

- We considered urea breath test-^{14}C and urea breath test-^{13}C as different index tests.
- Because of the paucity of data, we did not stratify the analysis by reference standard; however, we investigated reference standard as a potential source of heterogeneity.
- Because studies reported different thresholds and following recommendation from peer reviewers, we used the HSROC model for the primary analyses. For estimation of summary sensitivities and specificities at specific thresholds, we used univariate fixed- and random-effects logistic regression models due to paucity of data.
- We performed direct comparisons whenever possible, rather than deciding this on the basis of the number of studies.

INDEX TERMS

Medical Subject Headings (MeSH)

*Helicobacter pylori [immunology]; Antigens, Bacterial [analysis]; Biomarkers [analysis]; Breath Tests [*methods]; Feces [*chemistry]; Helicobacter Infections [blood] [*diagnosis] [epidemiology]; Prevalence; Urea [*analysis]

MeSH check words

Adult; Child; Humans