

# UK Standards for Microbiology Investigations

Investigation of Gastric Biopsies for *Helicobacter pylori*

**DRAFT - THIS DOCUMENT WAS CONSULTED ON BETWEEN 23 AUGUST - 15 NOVEMBER 2013**



## Acknowledgments

UK Standards for Microbiology Investigations (SMIs) are developed under the auspices of the Public Health England (PHE) working in partnership with the National Health Service (NHS), Public Health Wales and with the professional organisations whose logos are displayed below and listed on the website <http://www.hpa.org.uk/SMI/Partnerships>. SMIs are developed, reviewed and revised by various working groups which are overseen by a steering committee (see <http://www.hpa.org.uk/SMI/WorkingGroups>).

The contributions of many individuals in clinical, specialist and reference laboratories who have provided information and comments during the development of this document are acknowledged. We are grateful to the Medical Editors for editing the medical content.

We also acknowledge Dr Andy Lawson for his considerable specialist input.

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UK Standards for Microbiology Investigations are produced in association with:



**The Association for  
Clinical Biochemistry  
Microbiology Group**



**The Royal College of Pathologists**  
Pathology: the science behind the cure



## UK Standards for Microbiology Investigations<sup>#</sup>: Status

### Users of SMIs

Three groups of users have been identified for whom SMIs are especially relevant:

- SMIs are primarily intended as a general resource for practising professionals in the field operating in the field of laboratory medicine in the UK. Specialist advice should be obtained where necessary.
- SMIs provide clinicians with information about the standard of laboratory services they should expect for the investigation of infection in their patients and the documents provide information that aids the electronic ordering of appropriate tests from hospital wards.
- SMIs also provide commissioners of healthcare services with the standard of microbiology investigations they should be seeking as part of the clinical and public health care package for their population.

### Background to SMIs

SMIs comprise a collection of recommended algorithms and procedures covering all stages of the investigative process in microbiology from the pre-analytical (clinical syndrome) stage to the analytical (laboratory testing) and post analytical (result interpretation and reporting) stages.

Syndromic algorithms are supported by more detailed documents containing advice on the investigation of specific diseases and infections. Guidance notes cover the clinical background, differential diagnosis, and appropriate investigation of particular clinical conditions. Quality guidance notes describe essential laboratory methodologies which underpin quality, for example assay validation, quality assurance and understanding uncertainty of measurement.

Standardisation of the diagnostic process through the application of SMIs helps to assure the equivalence of investigation strategies in different laboratories across the UK and is essential for public health interventions, surveillance, and research and development activities. SMIs align advice on testing strategies with the UK diagnostic and public health agendas.

### Involvement of Professional Organisations

The development of SMIs is undertaken within PHE in partnership with the NHS, Public Health Wales and with professional organisations.

The list of participating organisations may be found at <http://www.hpa.org.uk/SMI/Partnerships>. Inclusion of an organisation's logo in an SMI implies support for the objectives and process of preparing SMIs. Representatives of professional organisations are members of the steering committee and working groups which develop SMIs, although the views of participants are not necessarily those of the entire organisation they represent.

SMIs are developed, reviewed and updated through a wide consultation process. The resulting documents reflect the majority view of contributors. SMIs are freely available to view at <http://www.hpa.org.uk/SMI> as controlled documents in Adobe PDF format.

<sup>#</sup> UK Standards for Microbiology Investigations were formerly known as National Standard Methods.

Microbiology is used as a generic term to include the two GMC-recognised specialties of Medical Microbiology (which includes Bacteriology, Mycology and Parasitology) and Medical Virology.

## Quality Assurance

The process for the development of SMIs is certified to ISO 9001:2008.

NHS Evidence has accredited the process used by PHE to produce SMIs. Accreditation is valid for three years from July 2011. The accreditation is applicable to all guidance produced since October 2009 using the processes described in the PHE's Standard Operating Procedure SW3026 (2009) version 6.

SMIs represent a good standard of practice to which all clinical and public health microbiology laboratories in the UK are expected to work. SMIs are well referenced and represent neither minimum standards of practice nor the highest level of complex laboratory investigation possible. In using SMIs, laboratories should take account of local requirements and undertake additional investigations where appropriate. SMIs help laboratories to meet accreditation requirements by promoting high quality practices which are auditable. SMIs also provide a reference point for method development. SMIs should be used in conjunction with other SMIs.

UK microbiology laboratories that do not use SMIs should be able to demonstrate at least equivalence in their testing methodologies.

The performance of SMIs depends on well trained staff and the quality of reagents and equipment used. Laboratories should ensure that all commercial and in-house tests have been validated and shown to be fit for purpose. Laboratories should participate in external quality assessment schemes and undertake relevant internal quality control procedures.

Whilst every care has been taken in the preparation of SMIs, PHE, its successor organisation(s) and any supporting organisation, shall, to the greatest extent possible under any applicable law, exclude liability for all losses, costs, claims, damages or expenses arising out of or connected with the use of an SMI or any information contained therein. If alterations are made to an SMI, it must be made clear where and by whom such changes have been made.

SMIs are the copyright of PHE which should be acknowledged where appropriate.

Microbial taxonomy is up to date at the time of full review.

## Equality and Information Governance

An Equality Impact Assessment on SMIs is available at <http://www.hpa.org.uk/SMI>.

PHE is a Caldicott compliant organisation. It seeks to take every possible precaution to prevent unauthorised disclosure of patient details and to ensure that patient-related records are kept under secure conditions.

## Suggested Citation for this Document

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<http://www.hpa.org.uk/SMI/pdf>.



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NICE has accredited the process used by the Public Health England to produce Standards for Microbiology Investigations. Accreditation is valid for 5 years from July 2011. More information on accreditation can be viewed at [www.nice.org.uk/accreditation](http://www.nice.org.uk/accreditation).

For full details on our accreditation visit: [www.nice.org.uk/accreditation](http://www.nice.org.uk/accreditation).

## Amendment Table

Each SMI method has an individual record of amendments. The current amendments are listed on this page. The amendment history is available from [standards@phe.gov.uk](mailto:standards@phe.gov.uk).

New or revised documents should be controlled within the laboratory in accordance with the local quality management system.

Amendment No/Date.	8/dd.mm.yy <tab+enter>
Issue no. discarded.	5.1
Insert Issue no.	de
Section(s) involved.	Amendment.

Amendment No/Date.	7/02.08.12
Issue no. discarded.	5
Insert Issue no.	5.1
Section(s) involved.	Amendment.
Whole document.	<p>Document presented in a new format.</p> <p>The term “CE marked leak proof container” is referenced to specific text in the EU in vitro Diagnostic Medical Devices Directive (98/79/EC Annex 1 B 2.1) and to the Directive itself EC<sup>1,2</sup>.</p> <p>Edited for clarity.</p> <p>Reorganisation of [some] text.</p> <p>Minor textual changes.</p>
Section on specimen collection, transport, storage and processing.	Reorganised. Previous numbering changed.
References.	Some references updated.

## Scope of Document

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### Type of Specimen

Gastric biopsy

### Scope

This SMI describes the primary diagnosis, processing and bacteriological investigation of gastric biopsies for *Helicobacter pylori*.

This SMI should be used in conjunction with other SMIs.

## Introduction

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In 1984 Warren and Marshall first proposed the association of *H. pylori* with peptic ulcer disease, and since then it has become established as the most clinically important species of *Helicobacter*<sup>3</sup>. It is recognized as the main cause of peptic ulcer disease and a major risk factor for gastric cancer<sup>4</sup>. *H. pylori* infection is also an independent risk factor for the development of atrophic gastritis, gastric ulcer disease, gastric adenocarcinomas, and gastric mucosa-associated lymphoid tissue (MALT) lymphomas<sup>4</sup>. The species establishes a chronic infection in the majority of infected people, represented by chronic gastritis. Prominent mucosal inflammation is often evident in the antrum (antrum-predominant gastritis), predisposing to hyperacidity and duodenal ulcer disease. Many patients infected with *H. pylori* have recurrent abdominal symptoms (non-ulcer dyspepsia) without ulcer disease, and there appears to be a clinical benefit in eradicating *H. pylori* in these patients<sup>5</sup>. Acute symptoms of gastritis and epigastric pain, nausea and vomiting may occur and usually subside, but hyperchlorhydria may persist for much longer.

The detection and diagnosis of *H. pylori* infections has been of great interest. Initially invasive techniques (for example, tissue biopsies) were used. However, with progress in the diagnostic field, (especially molecular biology) non-invasive techniques have also been proposed. Nevertheless the ideal method has yet to be proposed.

### Gastric Biopsies

Gastric biopsy is the specimen of choice for the culture of *H. pylori*. Attempts to culture from other specimens have a low success rate<sup>7</sup>. However, the collection of the biopsy is an invasive procedure and is not a cost effective means of diagnosing *H. pylori* infections.

The National Institute of Clinical Excellence (NICE) guidelines on dyspepsia states that a 'test and treat' strategy should be employed for cases of dyspepsia and suspected gastric and duodenal ulcer that have not previously been investigated<sup>5</sup>. Recommended tests include the urea breath test, stool antigen test or serology test where it has been locally validated. Following a positive result for *H. pylori* and eradication therapy consisting of a seven day course of a proton pump inhibitor (PPI) with clarithromycin and either amoxicillin or metronidazole is given and eradication is effective in 80-85% of the patients<sup>8</sup>. If eradication fails a fourteen day course with PPI, bismuth and two unused antibiotics is recommended<sup>8</sup>.

### Invasive Techniques

Invasive techniques for examination of gastric biopsies taken at endoscopy include<sup>6,9</sup>:

- Culture
- Histology
- Biopsy urease test

- Microscopy

## Culture

Culture of the organism is the most specific method and offers opportunity for conventional antimicrobial susceptibility testing. This is important in predicting and evaluating the efficacy of treatment, and in identifying re-infections. With the adoption of the 'test and treat' strategy as recommended by NICE, the main rationale for obtaining a biopsy for culture is to establish the susceptibility of the isolate.

## Histology

Histology examination is as sensitive as culture when detecting *H. pylori*, and has a high degree of specificity<sup>6</sup>. It is also a useful means of detecting culture-resistant *Helicobacter* species such as *Helicobacter heilmannii* and similar species which are uncommon causes of gastritis and ulcer.

Neither culture nor histology will provide a rapid diagnosis.

## Biopsy urease test

Biopsy urease test (or CLO test - Campylobacter-like organism test) is a rapid, sensitive and cost effective test. Positive results are often available within minutes but negative reporting may take a great deal longer, according to manufacturers' instructions. It is recommended for use in combination with either culture or histology, depending on local facilities. This test is often carried out in the endoscopy suite. Commercial kits are available which are highly accurate but also expensive.

## Microscopy

Organisms may be stained using Giemsa or Gram stains according to preference. Sensitivities of up to 90% have been reported if two biopsies are examined, but this method requires technical expertise<sup>7</sup>.

## Rapid Identification and Sensitivity Testing

### Nucleic Acid Amplification Techniques (NAATs)

NAATs has been used for the detection of *H. pylori* in various samples, although its role in routine diagnosis remains to be established. NAATs assays can provide added value in investigating culture-negative gastric biopsy specimens, particularly those from cases for which other clinical tests indicate an *H. pylori* infection<sup>10</sup>. A systematic study of primers for *H. pylori* detection found that the four best-performing assays each attained a detection limit of <100 CFU/mL from gastric tissue<sup>11</sup>. However, no assay had 100% specificity or sensitivity, and all produced false positives<sup>11</sup>.

### MALDI-TOF Mass Spectroscopy

This technology is promising for the identification of relatively unreactive bacteria such as *Helicobacter* species. Although it is probably more useful for non-pylori *Helicobacter* species (refer to [ID 26 Identification of \*Helicobacter\* species](#))<sup>12</sup>.

### Sensitivity testing

To improve the quality of sensitivity testing there has been a general movement away from performing direct sensitivities on clinical samples, although the British Society for Antimicrobial Chemotherapy (BSAC) does however recognise that the procedure is carried out in many laboratories as a means of providing rapid results<sup>13</sup>. Results should be interpreted with care, especially if the inoculum is lighter or heavier than the recommended semi-confluent growth. BSAC breakpoints can be accessed via the BSAC website<sup>13</sup>.



Alternatively, commercially available antibiotic gradient strips which evaluate the minimum inhibitory concentration (MIC) can be used<sup>14</sup>. The range of antibiotic strips available varies and is dependent on the producer.

The European *Helicobacter* study group recommends the following breakpoints for antibiotics used in *H. pylori* therapy; isolates are considered resistant when the MIC is greater than: clarithromycin (>1µg/mL); metronidazole (>8µg/mL); amoxicillin (>0.5µg/mL); tetracycline (>1µg/mL); rifampicin (>1µg/mL); and levofloxacin (>0.5µg/mL)<sup>15</sup>.

In the UK *H. pylori* is frequently resistant to metronidazole (20% to 80%). Clarithromycin resistance is less common in the general population (4% to 11%). Levofloxacin resistance is uncommon (~15%), but occurs due to the widespread use of fluoroquinolones. *H. pylori* is rarely resistant to amoxicillin, rifampicin and tetracycline (~3%). *H. pylori* can also be treated with rifabutin, a similar drug to rifampicin, but with different susceptibilities (resistance is extremely rare <1%), unfortunately rifabutin discs and antibiotic gradient strips are not presently available<sup>15</sup>.

## Non-invasive Techniques

Non-invasive techniques avoid having the need for expensive and invasive endoscopy and include:

- Serology
- Urea breath tests (UBTs)
- Stool antigen tests

### Serology

*H. pylori* infection induces a specific systemic immune response to multiple antigens, with only 2% of patients failing to seroconvert<sup>16</sup>. The immune response typically shows a transient rise in specific IgM antibodies followed by a rise in IgG and IgA antibodies that persists during infection. Serology is widely used in primary screening for *H. pylori* infection, as it is a simple, non-invasive test. A number of in-house and commercial kits have been developed over the past 20 years for antibody detection, with the essential laboratory technique being the standard enzyme-linked immunosorbent assay (ELISA). The performance and diagnostic utility of laboratory ELISA kits (have been critically evaluated in several reviews and meta-analyses<sup>16</sup>. Serology (ELISA) kits that measure IgG antibodies are recommended based on overall performance as an accurate means of diagnosing infection while office or near-patient testing serology kits are not well regarded and should not be used<sup>8</sup>.

### Urea breath tests (UBTs)

UBTs are considered to be the diagnostic gold standard<sup>17</sup>. Urea Breath Test utilise either a carbon radioactive isotope (<sup>14</sup>C) or a nonradioactive natural isotope (<sup>13</sup>C), which are ingested by the patient. The labelled CO<sub>2</sub> is absorbed by the blood and exhaled in expired air. The testing methodology and factors influencing the result, standardization, and application in different clinical settings have been comprehensively reviewed<sup>16</sup>. The use of the UBT has high diagnostic accuracy (>95%) and, where available, is consistently recommended for the diagnosis of *H. pylori*<sup>8</sup>.

### Stool Antigen Tests (HPStAg)

Stool antigen tests using an ELISA provide another valuable aid in the diagnosis of an active *H. pylori* infection. The test is easy to perform and has the advantage of being non-invasive. Since becoming commercially available, kits consisting of a polyclonal antibody fixed on micro-wells have been extensively evaluated on samples from adults and children and have proven to be an excellent diagnostic tool<sup>18,19</sup>. A systematic review of published data up to 2004 confirmed the value of such kits for primary pre-treatment as well as for follow-up post-treatment diagnosis<sup>18</sup>. Near-patient

testing serology (pregnancy test-style) kits are less reliable<sup>19</sup>. An evidence-based study suggests that ELISA HPStAg is the most cost-effective means of diagnosing *H. pylori* infection<sup>20</sup>.

## Technical Information/Limitations

### Specimen Containers<sup>1,2</sup>

SMLs use the term “CE marked leak proof container” to describe containers bearing the CE marking used for the collection and transport of clinical specimens. The requirements for specimen containers are given in the EU in vitro Diagnostic Medical Devices Directive (98/79/EC Annex 1B 2.1) which states: “The design must allow easy handling and, where necessary, reduce as far as possible contamination of, and leakage from, the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen. The manufacturing processes must be appropriate for these purposes”.

### Optimal Growth Requirements

Optimal growth requirements for the isolation of *H. pylori* are a moist, micro-aerobic atmosphere (5-7% O<sub>2</sub> and 5-10% CO<sub>2</sub>) at 35-37<sup>9</sup>. It should be noted that *H. pylori* recovery is significantly enhanced by the presence of hydrogen (3-5%), which is absent from the most widely available micro-aerobic atmosphere generating kits<sup>7,21,22</sup>. Micro-aerobic atmosphere generating kits that include hydrogen are available; alternatively other methods which introduce hydrogen into the system can be used (eg using a tailored gas supply). All methods should be validated prior to use.

There is no consensus on which medium that is best for the isolation of *H. pylori* although blood based media is preferred. Several have been described<sup>23-25</sup>. Blood-free media, containing alternative supplements, may not be as good for primary isolation. This SML recommends the use of Columbia Blood Agar (CBA) with 10% horse blood and Dent's selective agar<sup>26</sup>.

Antimicrobial supplements may be added to media to inhibit overgrowth with contaminating bacteria and fungi<sup>27</sup>. *H. pylori* is sensitive to clindamycin, cephalosporins and sodium desoxycholate, none of which should be used in the selective medium<sup>28</sup>. Contamination with moulds may be reduced by the incorporation of an antifungal agent to the medium such as cyclohexamide (100mg/L) and thorough cleaning of equipment before and after use. Autoclaving of jars previously contaminated with moulds is recommended. Best results are obtained if both selective and non-selective media are used<sup>29</sup>.

Cultures should be incubated for a minimum of 10 days, although colonies may be visible at 3 to 5 days<sup>9</sup>. Practically, it is convenient to examine the plates every 48 hours (typically on Monday, Wednesday and Friday). It is not good practice to expose the plates to air too regularly, and once examined they should be returned to the incubator or gas jar as soon as possible. Initially colonies are small (1 to 3mm diameter) and grey. Confirmation of *H. pylori* relies primarily on the rapid utilisation of urea (usually tested by stabbing colonies into a Christensen's urea slope) colonies are also oxidase and catalase positive. The characteristic "seagull" or spiral morphology in the Gram stained film is not always present, and the cells can appear as vaguely bendy rods or 'U' shapes. Gram stain with a dilute carbol fuchsin counterstain enhances morphology (refer to [TP 39 – Staining procedures](#)).

Homogenisation can be performed, but may be counterproductive as it is more time consuming and requires the use of a sterile tissue grinder (Griffiths grinder or an unbreakable alternative). Biopsies can be cut finely with a sterile scalpel.

# 1 Specimen Collection, Transport and Storage<sup>1,2</sup>

## 1.1 Safety Considerations<sup>30-41</sup>

Use aseptic technique.

Collect specimens in appropriate CE marked leak proof containers and transport specimens in sealed plastic bags.

Compliance with postal and transport regulations is essential.

## 1.2 Achieving Optimal Conditions

### 1.2.1 Time between specimen collection and processing<sup>8</sup>

Ideally biopsies should be taken before antimicrobial therapy is begun, but as NICE recommend a 'test and treat' strategy for the diagnosis of *H. pylori* most samples referred for culture will be due to treatment failure. A period of at least two weeks should have elapsed since the last dose of antimicrobial therapy before the collection of the specimen.

Specimens should be transported and processed as soon as possible<sup>42</sup>.

### 1.2.2 Special considerations to minimise deterioration

Specimens should be transported and processed as soon as possible (preferably within 6hr)<sup>9</sup>.

If processing is delayed, refrigeration is preferable to storage at ambient temperature<sup>43</sup>.

It is important to maintain a moist atmosphere during transport.

**Where culture is to be carried out within six hours<sup>9</sup>:**

The biopsy should be placed in a small, sterile container such as a bijou bottle, containing a small amount (approximately 100µL) of sterile isotonic saline to preserve moisture. Alternatively, Dent's transport medium can be used<sup>27</sup>.

**Note:** Sensitivity of the microscopy may be reduced if the biopsy is submerged in the saline, because mucus globules form and production of a satisfactory smear becomes difficult.

**Where delays of >6h are expected<sup>9,29</sup>:**

The biopsy should be covered with approximately 1mL brain heart infusion broth in a small sterile container, such as a bijou bottle, and stored at 4°C for up to 48h. Alternatively, Dent's transport medium can be used. Organisms will remain viable in Amies charcoal transport medium, but if this is used, care is required to ensure that the mucosa has not become detached from the rest of the biopsy<sup>27</sup>.

Biopsies may be stored for up to 6 months at -70°C in broth containing 20-25% glycerol although viability will be significantly reduced.

## 1 Correct Specimen Type and Method of Collection

Unless otherwise stated, swabs for bacterial and fungal culture should then be placed in Amies transport medium with charcoal<sup>44</sup>.

Collect specimens other than swabs into appropriate CE marked leak proof containers and place in sealed plastic bags.

Gastric biopsy specimens are usually taken from the gastric antrum at endoscopy, and sometimes from the corpus depending on location of inflammation. Duodenal biopsies will be taken in cases with duodenal ulcers.

## 1.4 Adequate Quantity and Appropriate Number of Specimens

Numbers and frequency of specimen collection are dependent on clinical condition of patient. At the discretion of the endoscopist as it depends on the individual patient.

## 2 Specimen Processing<sup>1,2</sup>

### 2.1 Safety Considerations<sup>30-41</sup>

Containment Level 2.

Laboratory procedures that give rise to infectious aerosols must be conducted in a microbiological safety cabinet<sup>33</sup>.

Refer to current guidance on the safe handling of all organisms documented in this [document](#).

The above guidance should be supplemented with local COSHH and risk assessments.

### 2.2 Test Selection

The biopsy urease test is often performed in the endoscopy suite; therefore only culture and microscopy may be required in the laboratory.

The order in which any or all of the tests are performed will be in accordance with local protocol.

### 2.3 Appearance

N/A

### 2.4 Microscopy

Refer to [TP 39 – Staining procedures](#).

Microscopy is carried out using carbol fuchsin or Sandiford's stain.

#### 2.4.1 Standard

Pick up the biopsy with a sterile swab and smear vigorously on to a clean microscope slide (a sterile slide is required if microscopy is performed before culture).

Staining and examination of the stained preparation need only be performed if the culture result is negative and the biopsy urease test positive. Gram or Giemsa stains are suitable.

### 2.5 Culture and Investigation

#### 2.5.1 Pre-treatment

N/A

#### 2.5.2 Specimen processing

Culture

The same swab containing the biopsy that was used for microscopy (if performed) should be used to inoculate each agar plate (see [Q 5 – Inoculation of culture media for bacteriology](#)).

For the isolation of individual colonies, spread inoculum with a sterile loop.

**Note:** The simultaneous subculture of known control strains of *H. pylori* is recommended, especially if susceptibility testing is to be performed.

The following control strains may be used<sup>15</sup>:

- Type strain – NCTC 11637.
- Metronidazole and Clarithromycin sensitive strain – NCTC 12455.
- Metronidazole and Clarithromycin resistant strain – NCTC 11637.

### Biopsy urease test

Squash the biopsy on the end of the swab into urease broth.

The swab should be broken off in the broth and left *in situ* throughout the test.

Incubate the urease broth at ambient temperature for up to 24hr.

### 2.5.3 Culture media, conditions and organisms

Clinical details/ conditions	Standard media	Incubation			Cultures read	Target organism
		Temp °C	Atmos	Time		
Gastritis Gastric biopsy	Dent's selective agar or alternative <i>H. pylori</i> selective agar*	35-37	Microaerobic Moist chamber, ideally containing hydrogen	10 d	Every 48hr	<i>H. pylori</i>
	Blood agar 10% horse blood	35-37	Microaerobic Moist chamber, ideally containing hydrogen	10 d	Every 48hr	
For these situations, add the following:						
Clinical details/ conditions	Supplementary media	Incubation			Cultures read	Target organism
		Temp °C	Atmos	Time		
Biopsy urease test if not already performed in endoscopy suite	Biopsy urease broth	ambient	air	24hr	hourly up to 6hr and again at 24hr	<i>H. pylori</i>
*GC selective agar may be used in absence of <i>H. pylori</i> media.						



## 2.6 Identification

Refer to individual SMLs for organism identification.

### 2.6.1 Minimum level of identification in the laboratory

[H. pylori](#) species level

## 2.7 Antimicrobial Susceptibility Testing

Refer to British Society for Antimicrobial Chemotherapy (BSAC) guidelines.

## 2.8 Referral to Reference Laboratories

Contact appropriate reference laboratory for information on the tests available, turn around times, transport procedure and any other requirements for sample submission. Information regarding specialist and reference laboratories is available via the following websites:

[HPA - Specialist and Reference Microbiology Tests and Services](#)

[Health Protection Scotland – Reference Laboratories](#)

[Belfast Health and Social Care Trust – Laboratory and Mortuary Services](#)

Organisms with unusual or unexpected resistance and whenever there is a laboratory or clinical problem or anomaly that requires elucidation should be sent to the appropriate reference laboratory.

## 2.9 Referral for Outbreak Investigations

N/A

# 3 Reporting Procedure

## 3.1 Microscopy

Gram stain (if performed)

Report presence or absence of *H. pylori*-like organisms.

### 3.1.1 Microscopy reporting time

N/A

## 3.2 Culture

The following are appropriate:

Culture

Positive report

*H. pylori* isolated.

Negative report

*H. pylori* not isolated.

Biopsy urease test

Report biopsy urease test result as positive or negative.

### 3.2.1 Culture reporting time

Clinically urgent culture results to be telephoned or sent electronically.

Culture result may take up to 12 days (15 days if antimicrobial susceptibility testing is required), but is usually available within 10 days.

### 3.3 Antimicrobial Susceptibility Testing

Report susceptibilities as clinically indicated. Prudent use of antimicrobials according to local and national protocols is recommended.

## 4 Notification to PHE<sup>45,46</sup>

The Health Protection (Notification) regulations 2010 require diagnostic laboratories to notify PHE when they identify the causative agents that are listed in Schedule 2 of the Regulations.

Notifications must be provided in writing, on paper or electronically, within seven days. Urgent cases should be notified orally and as soon as possible, recommended within 24 hours. These should be followed up by written notification within seven days.

For the purposes of the Notification Regulations, the recipient of laboratory notifications is the local PHE Health Protection Team. If a case has already been notified by a registered medical practitioner, the diagnostic laboratory is still required to notify the case if they identify any evidence of an infection caused by a notifiable causative agent.

Notification under the Health Protection (Notification) Regulations 2010 does not replace voluntary reporting to PHE. The vast majority of NHS laboratories voluntarily report a wide range of laboratory diagnoses of causative agents to PHE and many PHE Health Protection Teams have agreements with local laboratories for urgent reporting of some infections. This should continue.

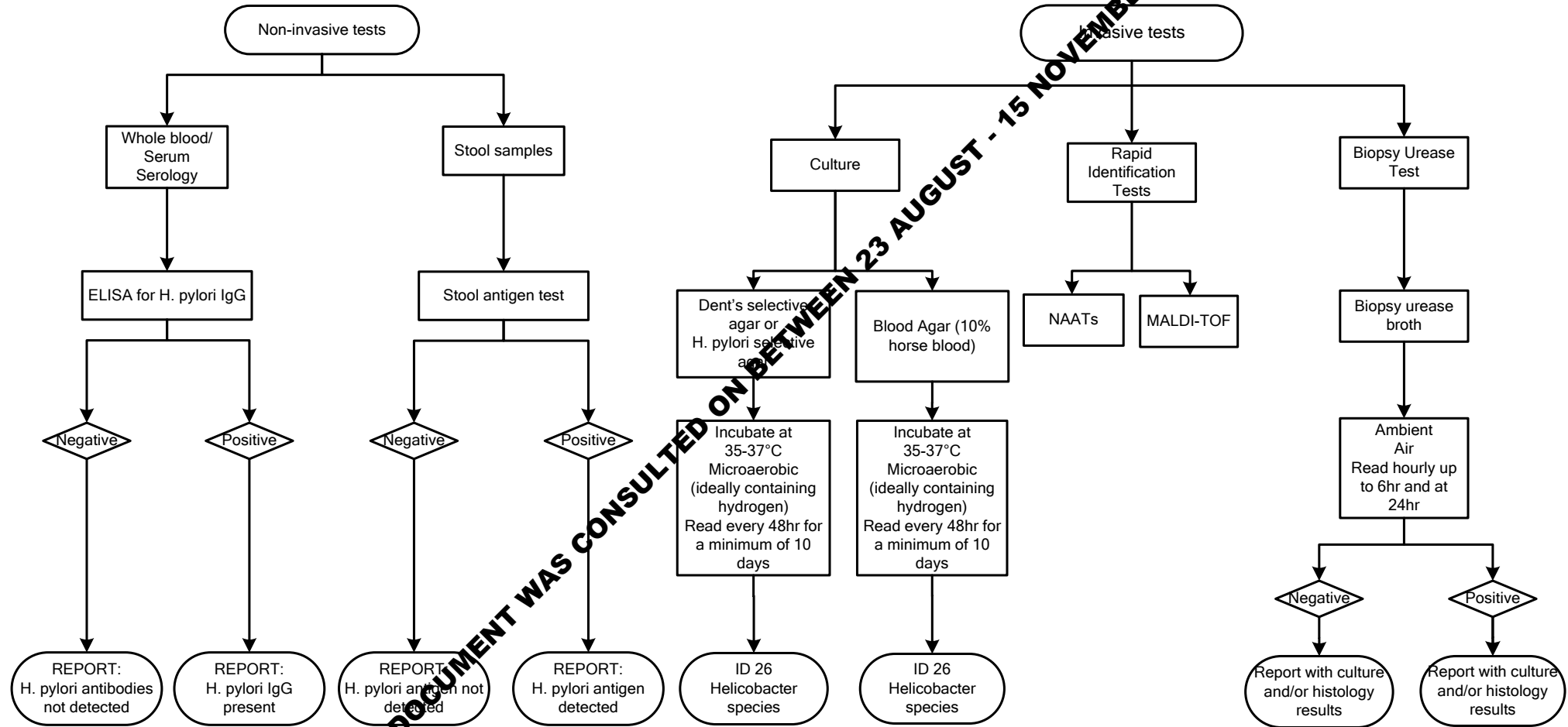
**Note:** The Health Protection Legislation Guidance (2010) includes reporting of HIV & STIs, HCAs and CJD under 'Notification Duties of Registered Medical Practitioners': it is not noted under 'Notification Duties of Diagnostic Laboratories'.

Other arrangements exist in Scotland<sup>47</sup> and Wales<sup>48</sup>.

Statutory notification of *H. pylori* is not required.

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Appendix: Gastric Biopsies for *Helicobacter pylori*



## References

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1. European Parliament. UK Standards for Microbiology Investigations (SMIs) use the term "CE marked leak proof container" to describe containers bearing the CE marking used for the collection and transport of clinical specimens. The requirements for specimen containers are given in the EU *in vitro* Diagnostic Medical Devices Directive (98/79/EC Annex 1 B 2.1) which states: "The design must allow easy handling and, where necessary, reduce as far as possible contamination of, and leakage from, the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen. The manufacturing processes must be appropriate for these purposes".
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