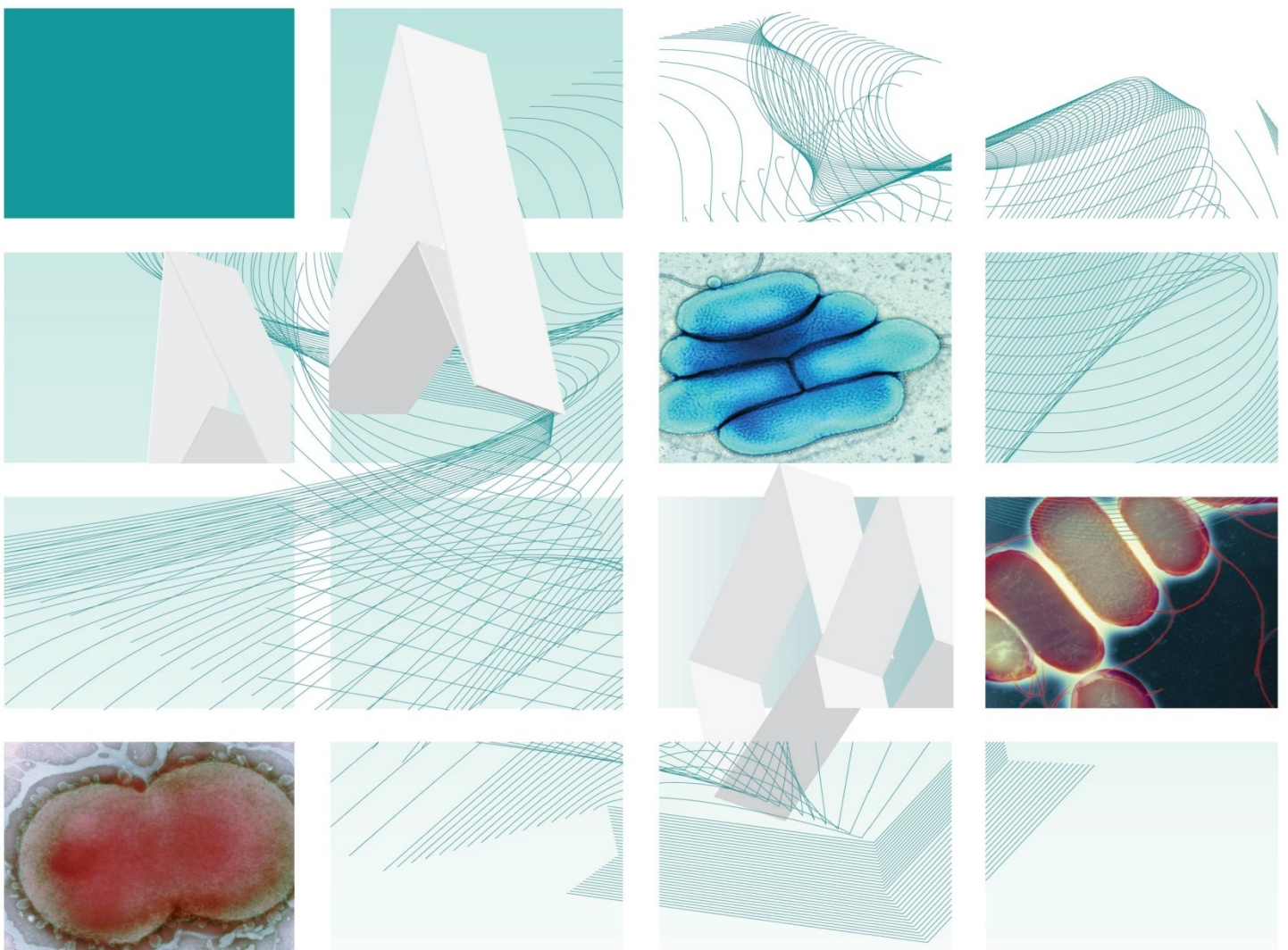




# UK Standards for Microbiology Investigations

## Investigation of Ear Infections and Associated Specimens



## Acknowledgments

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UK Standards for Microbiology Investigations (SMIs) are developed under the auspices of 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.

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UK Standards for Microbiology Investigations are produced in association with:



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SCOTTISH MICROBIOLOGY  
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**BIAMA**  
British Infection Association

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NICE has accredited the process used by 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

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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.	13/04.06.14
Issue no. discarded.	8.4
Insert Issue no.	9
<b>Section(s) involved</b>	<b>Amendment</b>
Whole document.	Document has been transferred to a new template to reflect the Health Protection Agency's transition to Public Health England. Front page has been redesigned. Status page has been renamed as Scope and Purpose and updated as appropriate. Professional body logos have been reviewed and updated. Standard safety and notification references have been reviewed and updated.
Introduction.	Specific sections on "Mycotic infections" and "Other Organisms" removed.
References.	References reviewed and updated.

Amendment No/Date.	12/29.03.12
Issue no. discarded.	8.3
Insert Issue no.	8.4
<b>Section(s) involved</b>	<b>Amendment</b>
Whole document.	Document transferred to an updated template.



## UK SMI<sup>#</sup>: Scope and Purpose

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### Users of SMIs

Primarily, SMIs are intended as a general resource for practising professionals operating in the field of laboratory medicine and infection specialties in the UK. SMIs also provide clinicians with information about the available test repertoire and the standard of laboratory services they should expect for the investigation of infection in their patients, as well as providing information that aids the electronic ordering of appropriate tests. The documents also provide commissioners of healthcare services with the appropriateness and 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 laboratory processes which underpin quality, for example assay validation.

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 surveillance, research and development activities.

### Equal Partnership Working

SMIs are developed in equal partnership with PHE, NHS, Royal College of Pathologists and professional societies. The list of participating societies may be found at <http://www.hpa.org.uk/SMI/Partnerships>. Inclusion of a logo in an SMI indicates participation of the society in equal partnership and support for the objectives and process of preparing SMIs. Nominees of professional societies are members of the Steering Committee and Working Groups which develop SMIs. The views of nominees cannot be rigorously representative of the members of their nominating organisations nor the corporate views of their organisations. Nominees act as a conduit for two way reporting and dialogue. Representative views are sought through the consultation process. SMIs are developed, reviewed and updated through a wide consultation process.

### Quality Assurance

NICE has accredited the process used by the SMI Working Groups to produce SMIs. The accreditation is applicable to all guidance produced since October 2009. The process for the development of SMIs is certified to ISO 9001:2008. 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 NICE accredited and represent

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<sup>#</sup>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.

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. The performance of SMIs depends on competent staff and appropriate quality reagents and equipment. 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.

### **Patient and Public Involvement**

The SMI Working Groups are committed to patient and public involvement in the development of SMIs. By involving the public, health professionals, scientists and voluntary organisations the resulting SMI will be robust and meet the needs of the user. An opportunity is given to members of the public to contribute to consultations through our open access website.

### **Information Governance and Equality**

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. The development of SMIs are subject to PHE Equality objectives

[http://www.hpa.org.uk/webc/HPAwebFile/HPAweb\\_C/1317133470313](http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1317133470313).

The SMI Working Groups are committed to achieving the equality objectives by effective consultation with members of the public, partners, stakeholders and specialist interest groups.

### **Legal Statement**

Whilst every care has been taken in the preparation of SMIs, PHE 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.

The evidence base and microbial taxonomy for the SMI is as complete as possible at the time of issue. Any omissions and new material will be considered at the next review. These standards can only be superseded by revisions of the standard, legislative action, or by NICE accredited guidance.

SMIs are Crown copyright which should be acknowledged where appropriate.

### **Suggested Citation for this Document**

Public Health England. (2014). Investigation of Ear Infections and Associated Specimens. UK Standards for Microbiology Investigations. B 1 Issue 9.

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

## Scope of Document

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### Type of Specimen

Ear swab, middle ear effusion

For investigation of fungal infection, scrapings of material from the ear canal are preferred although swabs can also be used.

### Scope

This document describes the bacteriological and mycological investigation of ear swabs and associated specimens.

This SMI should be used in conjunction with other SMIs.

## Introduction

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### Otitis Externa<sup>1,2</sup>

In general, infection of the external auditory canal resembles infection of skin and soft tissue elsewhere. However, there are some notable differences. The canal is narrow and, as a result, foreign materials and fluid that enter can become trapped, causing irritation and maceration of the superficial tissues. Otitis externa can be subdivided into categories: acute localised; acute diffuse; chronic; and invasive ('malignant'). However, except for invasive, they are rarely differentiated as such in clinical practice.

#### Acute localised otitis externa

Acute localised otitis externa is usually caused by *Staphylococcus aureus* and may result in a furuncle or pustule of a hair follicle. Erysipelas due to Group A *Streptococcus* may be found in the concha and canal.

#### Acute diffuse otitis externa

Acute diffuse otitis externa is a common disease in adults with frequent recurrence of infections. It is also known as "swimmer's ear" and is mainly encountered in hot, humid conditions. Many different bacteria cause this infection, the most common being *Pseudomonas aeruginosa* and *S. aureus*. Anaerobes are frequently associated with polymicrobial infections. Anaerobes involved in ear infections usually originate from the oropharynx.

#### Chronic otitis externa

Chronic otitis externa is due to colonisation with Enterobacteriaceae and fungi best treated by topical cleansing, and not with antibiotics.

#### Malignant otitis externa

Clinically the most important condition to identify is invasive ('malignant') otitis externa. Malignant otitis externa is a severe necrotising infection that spreads from the squamous epithelium of the canal into surrounding soft tissues, blood vessels, cartilage and bone. Patients at risk include people with diabetes, the elderly and patients who are immunocompromised. It is a life-threatening condition with significant risk of neurological involvement and facial nerve paralysis. It is almost always caused by *P. aeruginosa*.

## Otitis Media<sup>3</sup>

Otitis media covers a broad spectrum of disease, which includes acute otitis media and chronic suppurative otitis media, both these conditions are covered in more detail below. Although uncommon in adults, the causative organisms and treatment of otitis media are the same as in children. As uptake of the pneumococcal vaccination has become more widespread the causative organisms for this condition have changed<sup>4</sup>.

An external ear swab is not useful in the investigation of otitis media unless there is perforation of the eardrum. Tympanocentesis, to sample middle ear effusion, is rarely justified.

### Acute otitis media<sup>4</sup>

Acute otitis media infection is defined by the co-existence of fluid in the middle ear and signs and symptoms of acute illness. It occurs when oropharyngeal flora ascend the eustachian tube and are not eliminated by the defence mechanisms of the middle ear. Organisms that cause this type of infection are *Streptococcus pneumoniae*, *Haemophilus influenza* and *Moraxella catarrhalis*. Less frequent causes are *Streptococcus pyogenes*, *S. aureus*, and Gram negative bacilli. Respiratory viruses have been isolated and have a role in the aetiology of otitis media especially in children<sup>5</sup>.

### Chronic suppurative otitis media<sup>4</sup>

Chronic suppurative infections are very destructive, persistent and can produce irreversible adverse outcomes such as hearing loss. The most common bacterial isolates are pseudomonads closely followed by meticillin resistant *Staphylococcus aureus* (MRSA), with anaerobic bacteria found in 25% of patients. *P. aeruginosa* usually only colonises the ear canal and is rarely isolated from the middle ear.

## Technical Information/Limitations

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### Limitations of UK SMIs

The recommendations made in UK SMIs are based on evidence (eg sensitivity and specificity) where available, expert opinion and pragmatism, with consideration also being given to available resources. Laboratories should take account of local requirements and undertake additional investigations where appropriate. Prior to use, laboratories should ensure that all commercial and in-house tests have been validated and are fit for purpose.

### Selective Media in Screening Procedures

Selective media which does not support the growth of all circulating strains of organisms may be recommended based on the evidence available. A balance therefore must be sought between available evidence, and available resources required if more than one media plate is used.

### Specimen Containers<sup>6,7</sup>

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”.

# 1 Safety Considerations<sup>6-22</sup>

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## 1.1 Specimen Collection, Transport and Storage<sup>6-11</sup>

Use aseptic technique.

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

Collect swabs into appropriate transport medium and transport medium in sealed plastic bags.

For investigation of fungal infection, use an appropriate method to transport scrapings of material from the ear canal.

Compliance with postal, transport and storage regulations is essential.

## 1.2 Specimen Processing<sup>6-22</sup>

Containment Level 2.

Laboratory procedures that give rise to infectious aerosols must be conducted in a microbiological safety cabinet<sup>14</sup>.

Refer to current guidance on the safe handling of all organisms documented in this SMI.

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

# 2 Specimen Collection

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## 2.1 Type of Specimens

Ear swab, middle ear effusion

## 2.2 Optimal Time and Method of Collection

For safety considerations refer to Section 1.1.

Unless otherwise stated, swabs for bacterial and fungal culture should then be placed in appropriate transport medium<sup>23-27</sup>.

Swab any pus or exudates.

For investigation of fungal infection, scrapings of material from the ear canal are preferred although swabs can also be used.

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

## 2.3 Adequate Quantity and Appropriate Number of Specimens<sup>28</sup>

Numbers and frequency of specimen collection are dependent on clinical condition of patient.

## 3 Specimen Transport and Storage<sup>6,7</sup>

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### 3.1 Optimal Transport and Storage Conditions

Collect specimens before antimicrobial therapy where possible<sup>28</sup>.

Specimens should be transported and processed as soon as possible<sup>28</sup>.

If processing is delayed, refrigeration is preferable to storage at ambient temperature.

## 4 Specimen Processing/Procedure<sup>6,7</sup>

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### 4.1 Test Selection

N/A

### 4.2 Appearance

N/A

### 4.3 Sample Preparation

N/A

### 4.4 Microscopy

#### 4.4.1 Standard

(Refer to [TP 39 – Staining Procedures](#))

Gram stained smear if middle ear effusion is sent.

Using a sterile pipette place one drop of fluid on a clean microscope slide.

Spread this with a sterile loop to make a thin smear for Gram staining.

### 4.5 Culture and Investigation

#### Swabs

Inoculate each agar plate with swab (refer to [Q 5 - Inoculation of Culture Media for Bacteriology](#)).

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

Swabs taken from the nasopharynx for diagnosis of ear infections are inappropriate and should be discarded according to local protocols.

#### Middle ear effusion

Using a sterile pipette inoculate each agar plate with specimen (refer to [Q 5 - Inoculation of Culture Media for Bacteriology](#)).

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

## 4.5.1 Culture media, conditions and organisms

Clinical details/ conditions	Specimen	Standard media	Incubation			Cultures read	Target organism(s)
			Temp °C	Atmos	Time		
Otitis externa  Otitis media	All swabs	Chocolate agar with bacitracin*	35-37	5-10 % CO <sub>2</sub>	40-48hr	daily	<i>H. influenzae</i> <i>M. catarrhalis</i> <i>S. pneumoniae</i>  Other organisms in pure growth may be significant
		Staph/strep selective agar	35-37	air	40-48hr	daily	Lancefield group A streptococcus <i>S. aureus</i>
		Neomycin fastidious anaerobe agar with metronidazole 5µg disc**	35-37	anaerobic	48hr	≥40hr	Anaerobes <sup>29</sup>
		CLED or MacConkey agar	35-37	air	16-24hr	≥16hr	Enterobacteriaceae Pseudomonads
		Sabouraud agar	35-37	air	40-48hr <sup>†</sup>	≥40hr	Fungi
Middle ear effusion	Middle ear effusion	Chocolate agar	35-37	5-10 % CO <sub>2</sub>	40-48hr	daily	Any organism
		Fastidious anaerobe agar with metronidazole 5µg disc	35-37	anaerobic	7-14d	≥40hr	Anaerobes <sup>29</sup>
Clinical details/ conditions	Specimen	Optional media	Incubation			Cultures read	Target organism(s)
			Temp °C	Atmos	Time		
See*  Otitis externa  Otitis media	All swabs	Blood agar	35-37	5-10% CO <sub>2</sub>	40-48hr	daily	<i>M. catarrhalis</i> <i>S. pneumoniae</i>

\*may include either a bacitracin 10 unit disc or bacitracin incorporated in the agar<sup>30</sup>. When bacitracin is incorporated in to the plate a separate blood agar plate will need to be put up to detect *M. catarrhalis* and *S. pneumoniae*.

\*\* this should be done for Otitis media cases only.

**Note:** if chocolate agar with bacitracin incorporated into the agar is used then blood agar incubated in 5-10% CO<sub>2</sub> must be included for the isolation of *M. catarrhalis* and *S. pneumoniae*.

†incubation may be extended to 5 days. In such cases plates should be read at ≥40hr and then left in the incubator/cabinet until day 5. Certain opportunistic pathogens will require extended incubation.

In patients coming from endemic regions a tuberculous granuloma of the middle ear should be considered and

appropriate cultures set up see [B 40 – Investigation of Specimens for \*Mycobacterium\* species](#).

## 4.6 Identification

Refer to individual SMIs for organism identification.

### 4.6.1 Minimum level of identification in the laboratory

Anaerobes	"anaerobes" level or mixed "anaerobes" level
<a href="#">Enterobacteriaceae</a>	"coliform" level
<a href="#">Fungi</a>	genus level
<a href="#">H. influenzae</a>	species level
<a href="#">β-haemolytic streptococci</a>	Lancefield group level
<a href="#">M. catarrhalis</a>	species level
<a href="#">Neisseria</a>	species level
<a href="#">Pseudomonas species</a>	"pseudomonads" level
<a href="#">S. aureus</a>	species level
<a href="#">S. pneumoniae</a>	species level
Yeasts	"yeasts" level

Organisms may be further identified if this is clinically or epidemiologically indicated.

## 4.7 Antimicrobial Susceptibility Testing

Refer to [British Society for Antimicrobial Chemotherapy \(BSAC\)](#) and/or [EUCAST](#) guidelines.

## 4.8 Referral for Outbreak Investigations

N/A

## 4.9 Referral to Reference Laboratories

For information on the tests offered, turn around times, transport procedure and the other requirements of the reference laboratory [click here for user manuals and request forms](#).

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.

Contact appropriate devolved national reference laboratory for information on the tests available, turn around times, transport procedure and any other requirements for sample submission:

England and Wales

<http://www.hpa.org.uk/webw/HPAweb&Page&HPAwebAutoListName/Page/1158313434370?p=1158313434370>

Scotland

<http://www.hps.scot.nhs.uk/reflab/index.aspx>



Northern Ireland

<http://www.publichealth.hscni.net/directorate-public-health/health-protection>

## 5 Reporting Procedure

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### 5.1 Microscopy

Middle ear effusion, report on WBCs and organisms detected.

#### 5.1.1 Microscopy reporting time

Urgent microscopy results to be telephoned or sent electronically when available.

Written report, 16–72hr.

### 5.2 Culture

Report clinically significant organisms isolated **or**

Report other growth, eg no significant growth **or**

Report absence of growth.

#### 5.2.1 Culture reporting time

Clinically urgent culture results to be telephoned or sent electronically when available.

Written report, 16–72hr stating, if appropriate, that a further report will be issued.

### 5.3 Antimicrobial Susceptibility Testing

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

## 6 Notification to PHE<sup>31,32</sup> or Equivalent in the Devolved Administrations<sup>33-36</sup>

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The Health Protection (Notification) regulations 2010 require diagnostic laboratories to notify Public Health England (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.

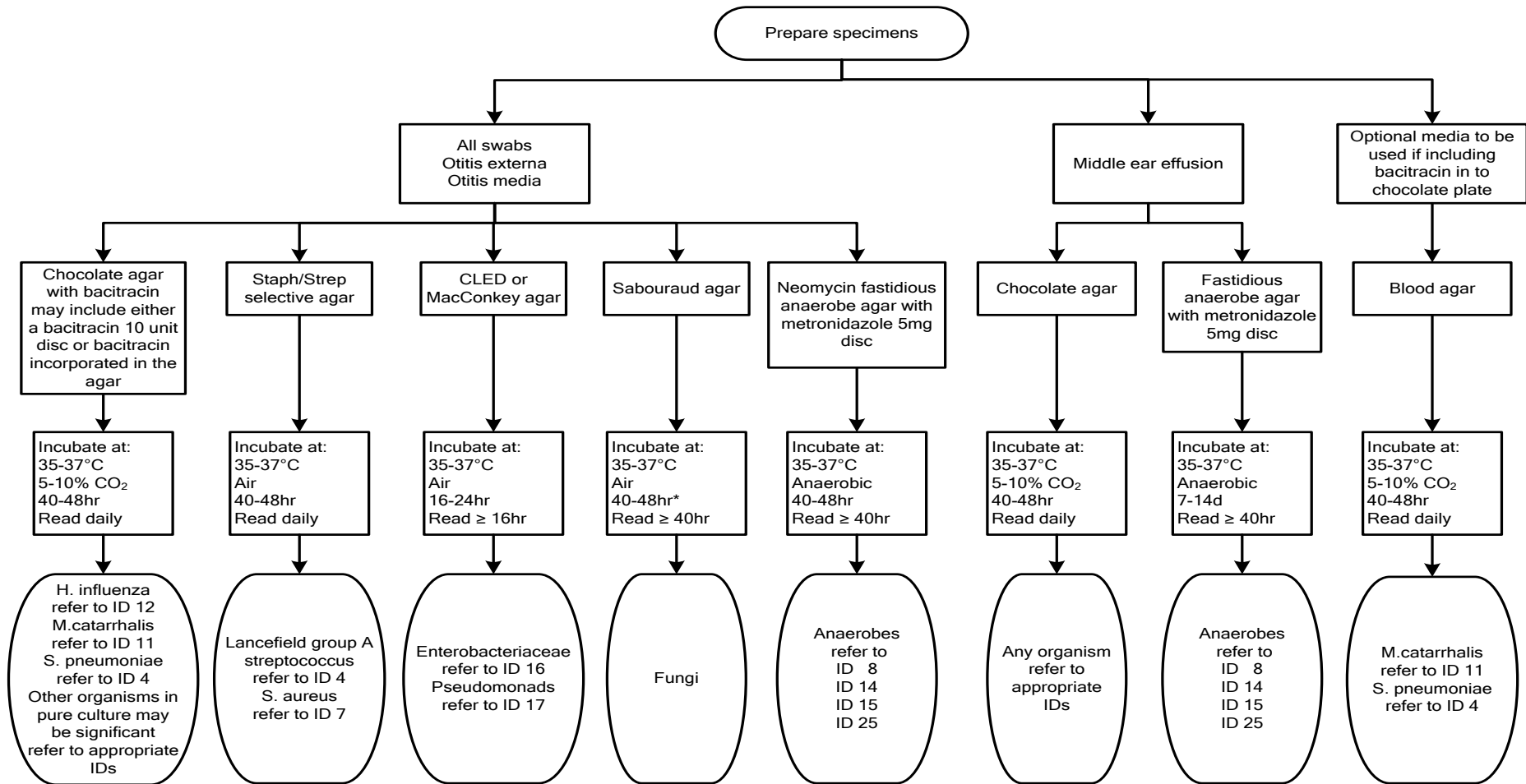
Notification under the Health Protection (Notification) Regulations 2010 does not replace voluntary reporting to PHE. The vast majority of NHS laboratories voluntarily report a wide range of laboratory diagnoses of causative agents to PHE and many PHE Health protection Teams have agreements with local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

**Note:** The Health Protection Legislation Guidance (2010) includes reporting of Human Immunodeficiency Virus (HIV) & Sexually Transmitted Infections (STIs), Healthcare Associated Infections (HCAs) and Creutzfeldt–Jakob disease (CJD) under ‘Notification Duties of Registered Medical Practitioners’: it is not noted under ‘Notification Duties of Diagnostic Laboratories’.

<http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/HealthProtectionRegulations>

Other arrangements exist in [Scotland](#)<sup>33,34</sup>, [Wales](#)<sup>35</sup> and [Northern Ireland](#)<sup>36</sup>.

## Appendix: Investigation of Ear Swabs and Associated Specimens



\*Incubation may be extended to 5 days. In such cases plates should be read at <sup>3</sup> 40hr and then left in the incubator / cabinet until day 5.

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