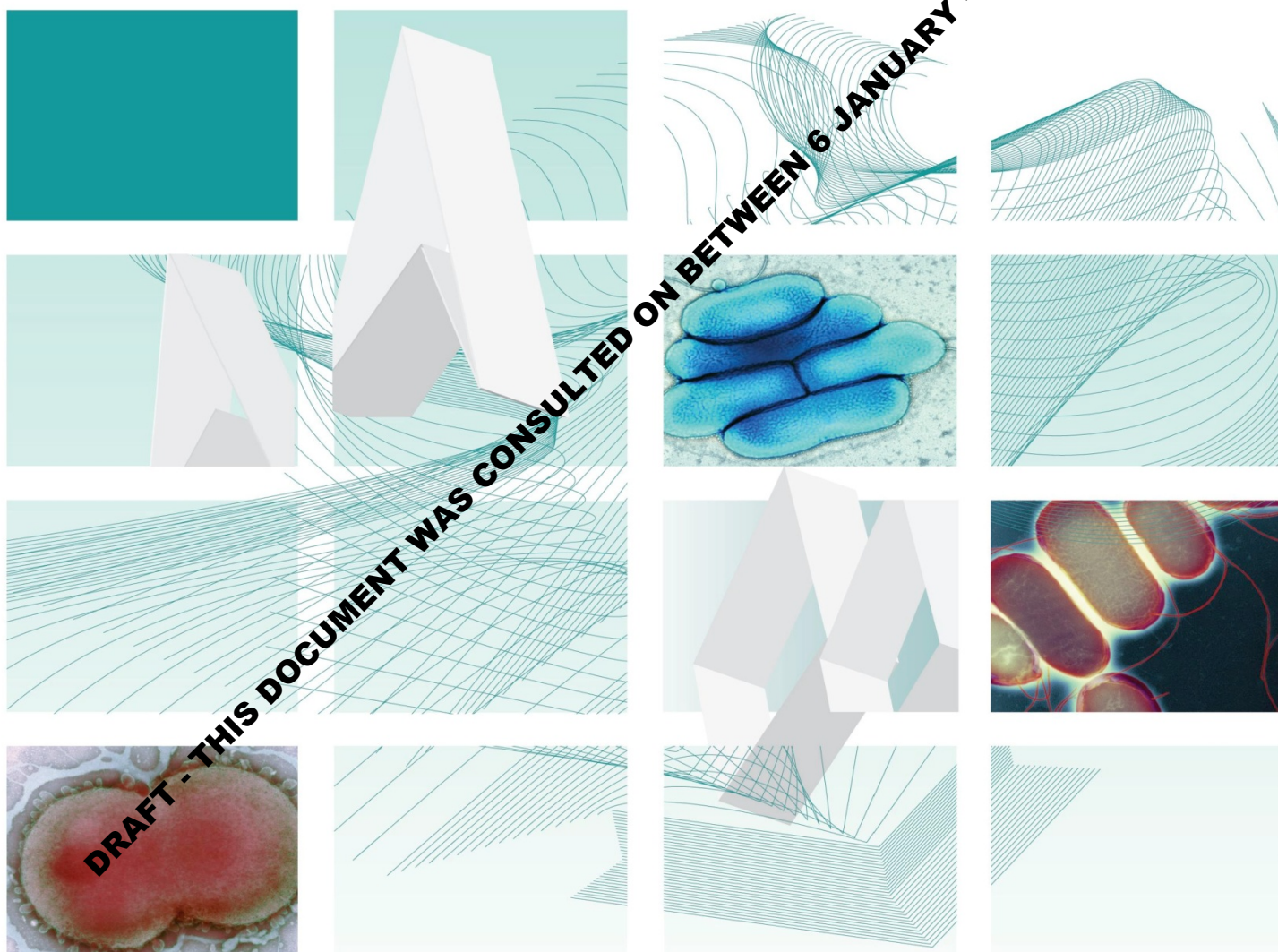




UK Standards for Microbiology Investigations

Investigation of tissues and biopsies from deep-seated sites and organs



Acknowledgments

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 <https://www.gov.uk/uk-standards-for-microbiology-investigations-smi-quality-and-consistency-in-clinical-laboratories>. SMIs are developed, reviewed and revised by various working groups which are overseen by a steering committee (see <https://www.gov.uk/government/groups/standards-for-microbiology-investigations-steering-committee>).

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:



The British Society for Antimicrobial Chemotherapy



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



Logos correct at time of publishing.

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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.

For full details on our accreditation visit: 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.

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

Amendment No/Date.	10/dd.mm.yy <tab+enter>
Issue no. discarded.	#.# <tab+enter>
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Section(s) involved	Amendment

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Section(s) involved	Amendment
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DRAFT - THIS DOCUMENT WAS CONSULTED ON BETWEEN 6 JANUARY - 26 JANUARY 2015

UK SMI[#]: Scope and Purpose

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 <https://www.gov.uk/uk-standards-for-microbiology-investigations-smi-quality-and-consistency-in-clinical-laboratories>. 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

[#] 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.

laboratories in the UK are expected to work. SMIs are NICE accredited 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. 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 <https://www.gov.uk/government/organisations/public-health-england/about/equality-and-diversity>.

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. (YYYY <tab+enter>). Investigation of tissues and biopsies from deep-seated sites and organs. UK Standards for Microbiology Investigations. B 17 Issue. <https://www.gov.uk/uk-standards-for-microbiology-investigations-smi-quality-and-consistency-in-clinical-laboratories>

Scope of Document

Type of Specimen

Tissue, biopsy

Scope

This SMI describes the processing and investigation of tissues and biopsies from deep-seated sites and organs for bacteria and fungi.

In addition to culture methods, rapid methods including NAAT may be used.

For further information regarding investigation of infections caused by fungi *Mycobacterium* species and parasites refer to:

[B 39 - Investigation of Dermatological Specimens for Superficial Mycoses](#)

[B 40 - Investigation of specimens for *Mycobacterium* species](#)

[B 31 - Investigation of Specimens other than Blood for Parasites](#)

The following samples are not included in this document:

Tissue associated with orthopaedic implant infection ([B 64 - Investigation of Prosthetic Joint Infection Samples](#)).

Bone and soft tissue associated with osteomyelitis ([B 42 - Investigation of Bone and Soft Tissue Associated with Osteomyelitis](#)).

Gastric biopsies (for the presence of *Helicobacter pylori*) ([B 55 - Investigation of Gastric Biopsies for *Helicobacter pylori*](#)).

This SMI should be used in conjunction with other SMIs.

Introduction

A biopsy may be defined as a portion of tissue removed from the living body for further examination. With the increasing sophistication of clinical imaging and sampling devices there are few organs in the human body that cannot be biopsied. Tissue obtained at operation is particularly precious as the sampling procedure may not be repeatable. Ideally these specimens should be discussed with the laboratory prior to sampling to ensure that transport and processing are timely and appropriate tests are performed.

Biopsies and other tissue samples are obtained in 3 main ways:

- As a closed procedure usually through the skin (eg needle biopsy). Percutaneous biopsy samples are associated with particular problems; they are often very small, may miss the infected lesion and may be contaminated with skin flora
- As an open procedure at operation (eg during debridement of devitalised or infected tissue). Tissue obtained at operation is generally more rewarding to deal with, particularly when the purpose of surgery is to remove infected tissue
- At post mortem (eg tissue from the lungs of a patient with pneumonia). In many cases the primary purpose of sampling is to obtain tissue for histological

examination. The microbiological yield from such samples is often low and they are commonly contaminated with enteric flora. Careful clinical interpretation of such isolates is required because they are often not significant

Biopsies may be taken from chronically infected tissues and so, in addition to investigation for bacterial infection, they will also require investigation for fungi, *Mycobacterium* species and parasites.

Histological investigation will often inform the decision to investigate for particular classes of infection. For instance, the presence of caseating granulomata should raise the suspicion of tuberculous infection; similar appearances may be caused by deep fungal infection on occasion.

Specific tissues

Aortic aneurysm contents

Aortic aneurysm contents may be sent for the exclusion of an infective cause¹.

Artificial materials

Artificial materials may also be sent to the laboratory for investigation. Such materials include prosthetic cardiac valves, pacemakers, grafts, artificial joints and tissue implants.

Brain biopsies

Brain biopsies may sometimes be taken to differentiate non-infectious conditions from infection.

Corneas

Corneas should be examined in cases where deep seated eye infection is suspected.

Donor heart valves or cornea rims

Donor heart valves or cornea rims need to be screened for bacterial infection prior to implantation.

Heart valves

Heart valves are submitted from patients with infective endocarditis undergoing valve replacement or at post mortem. Infected prosthetic valves may also be sent for culture. Where possible the results of these cultures should be correlated with blood cultures or serology.

Lung biopsies (percutaneous, bronchoscopic, surgical or post mortem)²

Lung biopsies are classified by the method of entry or the reason for biopsy. They may be useful for infections caused by bacteria including *Actinomyces* species, *Nocardia* species, *Legionella* species and *Mycobacterium* species and fungi, especially *Aspergillus* species, and *Pneumocystis jirovecii*. Pneumocystis pneumonia (PCP) occurs almost exclusively in patients who are immunocompromised. PCP may be diagnosed less invasively, but usually with reduced sensitivity, by processing induced sputum or bronchoalveolar lavage specimens.

Lymph nodes

Excised lymph nodes are submitted for investigation of lymphadenitis, particularly suspected mycobacterial lymphadenitis. The most common cause in children under 15 years old is mycobacteria other than *Mycobacterium tuberculosis* (non-tuberculous Mycobacterium (NTM)) notably *Mycobacterium avium-intracellulare*. However, *Mycobacterium tuberculosis* may also be isolated from these and older patients³. Other important causes of lymphadenitis are toxoplasmosis; cat scratch disease which is caused by *Bartonella henselae*, a Gram negative organism endemic among domestic cats; and lymphogranuloma venereum - a sexually transmitted chlamydial infection of the tropics. All of these conditions are perhaps best diagnosed by a combination of histological and serological investigations, coupled with molecular diagnostic testing where available (eg NAAT for Toxoplasma genome, offered by the Toxoplasma Reference Laboratory <https://www.gov.uk/government/collections/toxoplasma-reference-laboratory-trl>).

Placental specimens and products of conception

Products of conception and placental specimens are submitted for the investigation of septic abortion and listeriosis. *Listeria monocytogenes* may cause serious infection in pregnant women, neonatal infants and patients who are immunocompromised^{4,5}. In pregnant women septicaemia caused by *L. monocytogenes* presents as an acute febrile illness that may affect the fetus⁵. This may lead to systemic infection (granulomatosis infantisepticum), stillbirth and neonatal meningitis. Products of conception, placenta and neonatal screening swabs should be examined for this organism. Routine culture of vaginal swabs for *L. monocytogenes* is not usually performed although it may be useful in suspected cases. Blood cultures are indicated. Serological investigations have no place in the diagnosis of listeriosis (see [B 28 - Investigation of Genital Tract and Associated Specimens](#))⁴.

Septic abortion

Septic abortion may result in serious maternal morbidity and may be fatal⁵. Uterine perforation, presence of necrotic debris, and retained placental products can lead to infection. Most infections are polymicrobial and involve anaerobes. Clostridial sepsis complicating abortion is potentially lethal. *Clostridium* species are part of the normal vaginal flora in some women.

Skin biopsy

Skin biopsy may be submitted for the investigation of bacterial and fungal skin and soft tissue infection, and tissue parasites such as *Onchocerca volvulus*, *Mansonella streptocerca* and *Leishmania* species ([B 31 - Investigation of specimens other than blood for parasites](#)). They are also used to confirm cases of swimming pool or fish tank granuloma, a chronic skin infection which results from infection with *Mycobacterium marinum*, and is associated with injury and contact with water in swimmers and keepers of tropical fish⁶ ([B 40 - Investigation of specimens for Mycobacterium species](#)).

Technical Information/Limitations

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^{7,8}

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”.

Rapid methods

To reduce turnaround times, rapid identification and sensitivity tests may be performed in conjunction with routine methods where appropriate. A variety of rapid identification and sensitivity methods have been evaluated; these include molecular techniques and the Matrix Assisted Laser Desorption Ionisation Time-of-Flight (MALDI-TOF)^{9,10}. It is important to ensure that fresh cultures of pure single isolates are tested to avoid reporting misleading results.

Laboratories should follow manufacturers' instructions and all rapid tests must be validated and be shown to be fit for purpose prior to use.

1 Safety Considerations^{7,8,11-25}

1.1 Specimen Collection, Transport and Storage^{7,8,11-14}

Use aseptic technique.

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

Compliance with postal, transport and storage regulations is essential.

1.2 Specimen Processing^{7,8,11-25}

Containment Level 2.

Laboratory procedures that give rise to infectious aerosols must be conducted in a microbiological safety cabinet¹⁷.

Where infection with a Hazard Group 3 organism eg *Mycobacteria tuberculosis*, *Brucella abortus*, *Histoplasma capsulatum*, *Coccidioides* species, *Blastomyces dermatitidis*, *Paracoccidioides brasiliensis*, *Penicillium marneffei*, *Cladophialophora* species, *Fonsecea* species and *Rhinocladiella mackenziei* is suspected, all specimens must be processed in a microbiological safety cabinet under full Containment Level 3 conditions.

It is recommended that all Gram-negative coccobacilli from should be processed in a Class I or Class II microbiological safety cabinet until Hazard Group 3 pathogens (ie *Brucella*) have been definitively excluded²⁶.

Specimen from brain abscesses or from any site in a patient with a travel history to Africa, Asia, America or the Middle East to cover *Rhinocladiella mackenziei*²⁷), must be processed in a microbiological safety cabinet under full Containment Level 3 conditions.

Grinding and homogenisation of all specimens must be undertaken in a microbiological safety cabinet.

Wherever possible, the use of sterile scissors is recommended in preference to a scalpel blade.

Specimen containers must also be placed in a suitable holder.

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.

Specimen Collection

2.1 Type of Specimens

Tissue

Biopsy

2.2 Optimal Time and Method of Collection²⁸

For safety considerations refer to Section 1.1.

Collect specimens before antimicrobial therapy where possible²⁸.

A medical practitioner will collect the specimen.

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

General

If specimen is small, place it in sterile water to prevent desiccation.

Note: Specimens received in formol-saline are not suitable for culture.

Note: Ensure that the retention and disposal of tissues complies with the Human Tissue Act 2004.

Suspected *Legionella* species (Lung Tissue and Biopsy)

If specimen is small place it in sterile water to prevent desiccation.

Note 1: This would not be appropriate for specimens undergoing processing for diagnosis by molecular methods

Note 2: Avoid the use of saline, as it is known to be inhibitory to *Legionella* species

2.3 Adequate Quantity and Appropriate Number of Specimens²⁸

The specimen should, ideally, be large enough to carry out all microscopy preparations and cultures.

Minimum specimen size will depend on the number of investigations requested.

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

3 Specimen Transport and Storage^{7,8}

3.1 Optimal Transport and Storage Conditions

For safety considerations refer to Section 1.1.

Specimens should be transported and processed as soon as possible²⁸.

If processing is delayed, refrigeration is preferable to storage at ambient temperature²⁸

The volume of the specimen influences the transport time that is acceptable. Larger pieces of tissue maintain the viability of anaerobes for longer²⁹.

Note: It is recommended that all specimens of tissue and biopsy from suspected cases of legionellosis are stored at -20°C, until the final report is issued, as overgrowth with non-legionella bacteria may necessitate retesting of the original specimen.

4 Specimen Processing/Procedure^{7,8}

4.1 Test Selection

Select a representative portion of specimen for appropriate procedures such as culture for fungi ([B 39 - Investigation of dermatological specimens for superficial mycoses](#)) and *Mycobacterium* species ([B 40 - Investigation of specimens for](#)

[Mycobacterium species](#)), and examination for parasites ([B 31 - Investigation of specimens other than blood for parasites](#)) depending on clinical details.

If there is insufficient specimen for all investigations, they should be prioritised according to clinical indications after consultation with a medical microbiologist.

4.2 Appearance

N/A

4.3 Sample Preparation

For safety considerations refer to Section 1.2.

4.3.1 Pre-treatment

Standard

Grind or homogenise specimen with, as appropriate, using a sterile tissue grinder (Ballotini beads), a sterile scalpel or (preferably) sterile scissors and petri dish. The addition of a small volume (approximately 0.5 mL) of sterile, filtered water, saline, peptone or broth will aid the homogenisation process.

All grinding or homogenisation should be performed in a Class II exhaust protective cabinet.

Note: Surgically obtained specimens for fungal culture should be cut (finely sliced) rather than homogenised³⁰.

4.3.2 Supplementary

N/A

4.4 Microscopy

4.4.1 Standard

N/A

4.4.2 Supplementary

Gram Stain

Homogenised specimens

(See Section 4.3.1 for method of homogenisation).

Place one drop of specimen on to a clean microscope slide with a sterile pipette.

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

Non-homogenised specimens

Prepare a touch preparation - use sterile forceps to grasp pieces of specimen, touch the sides of one or more pieces of the specimen to a clean microscope slide for Gram staining. Group the touch preparations together for easier examination. This sample should not be used for culture.

See [TP 39 - Staining procedures](#).

Fluorescent staining technique

For suspected *Legionella* species (lung tissue and biopsies) homogenise specimens as in section 4.3.1.

Using a sterile pipette place one drop of homogenised specimen onto a clean PTFE microscope slide.

Spread the drop with a sterile loop to make a thin smear for fluorescent staining.

Follow kit manufacturers' instructions.

4.5 Culture and Investigation

Homogenised specimens

Inoculate each agar plate and enrichment broth with homogenised or ground specimen (see [Q 5 – Inoculation of culture media for bacteriology](#)).

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

Non-homogenised specimens

Inoculate each agar plate with the cut pieces of tissue (see [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			Culture s read	Target organism(s))
			Temp. °C	Atmos.	Time		
All clinical conditions	Tissue Biopsy	Blood agar	35-37	5-10% CO ₂	40-40hr	daily	Any organism
		CLED/ MacConkey agar	35-37	Air	18-24hr	≥18hr	
		Selective anaerobic agar	35-37	Anaerobic	5d	≥40hr and at 5d	Anaerobes
		Fastidious anaerobic, cooked meat broth or equivalent. Subculture if evidence of growth (≥40hr), or at day 5 to above media (excluding MacConkey agar)	35-37 35-37	Air As above	Up to 5d As above	N/A As Above	Any organism

Investigation of tissues and biopsies from deep-seated sites and organs

	For these situations, add the following:						
Clinical details/ conditions	Specimen	Supplementary media	Incubation			Culture s read	Target organism(s)
			Temp. °C	Atmos.	Time		
If microscopy suggestive of mixed infection	Tissue Biopsy	Selective anaerobic agar with metronidazole disc 5µg	35-37	Anaerobic	5d	≥40hr and at 5d	Anaerobes
Actinomycosis	Tissue Biopsy	Blood agar supplemented with metronidazole and nalidixic acid	35-37	Anaerobic	10d	≥40hr, at 7d and 10d	<i>Actinomyces</i> species
Immunocompromised, or suspected fungal infection	Tissue Biopsy	Sabouraud agar	35-37 and 25-30	Air	14d	daily [#]	Yeasts Moulds
Mycetoma	Tissue Biopsy	Lowenstein-Jensen slope / Blood agar	35-37	Air	up to 28d	every 3-4 days	Aerobic <i>Actinomycetes</i> species
Nocardiosis	Tissue Biopsy	Blood agar	35-37	Air	Up to 7d	3d and 7d	<i>Nocardia</i> species
Suspected Legionellosis	Tissue Biopsy	BMPA or BCYEA or alternative Legionella agar	35-37	Moist Atmos	Up to 10d	3d, 7d and 10d	<i>Legionella</i> species
Optional media:							
When clinical details or when microscopy suggestive of mixed infection or dependent on local policy	Tissue Biopsy	Saphylococci/Streptococci selective agar or Manitol Salt Agar	35-37	Air	40-48hr	daily	<i>S. aureus</i> Streptococci
Other organisms for consideration – Fungi (B 39 - Investigation of dermatological specimens for superficial mycoses), <i>H. pylori</i> (B 35 - Investigation of gastric biopsies for Helicobacter pylori), <i>Listeria</i> species, <i>Mycobacterium</i> species (B 40 - Investigation of specimens for Mycobacterium species) and parasites (B 31 - Investigation of specimens other than blood for parasites).							
[#] Agents of exotic imported mycoses eg <i>Histoplasma capsulatum</i> may take up to 8 weeks to grow; adequate humidification of incubators will be necessary ^{31,32} .							

4.6 Identification

Refer to individual SMIs for organism identification.

4.6.1 Minimum level of identification in the laboratory

Actinomycetes	genus level ID 10 – Identification of aerobic Actinomycetes species ID 15 – Identification of anaerobic Actinomycetes species
Anaerobes	"anaerobes" level ID 8 - Identification of Clostridium species
β-haemolytic streptococci	species level
Coagulase negative staphylococci	"coagulase-negative" level
Enterobacteriaceae	"coliforms" level
Pseudomonads	"pseudomonads" level
S. aureus	species level (consider Panton-Valentine leukocidin (PVL) and toxin testing if appropriate clinical details)
S. anginosus group	<i>S. anginosus</i> group level
Yeast	species level
Mould	species level
Legionella species	species level B 47 - Investigation of specimens for Legionella species
Mycobacterium species	species level B 40 - Investigation of specimens for Mycobacterium species
Parasites	species level B 31 - Investigation of specimens other than blood for parasites

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

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

4.9 Referral to Reference Laboratories

For information on the tests offered, turnaround 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, turnaround times, transport procedure and any other requirements for sample submission:

England and Wales

<https://www.gov.uk/specialist-and-reference-microbiology-laboratory-tests-and-services>

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

5.1 Microscopy

Gram stain

Report on WBCs and organisms detected.

Immunofluorescence

Legionella pneumophila detected by immunofluorescence or

Legionella pneumophila not detected by immunofluorescence

5.1.1 Microscopy reporting time

Urgent microscopy should be released immediately, following local policy.

Written or computer generated reports should follow preliminary/verbal reports within 24-72hrs.

5.2 Culture

The following results should be reported:

- clinically significant organisms isolated
- other growth with appropriate comment, eg No significant growth
- absence of growth

Also, report results of supplementary investigations.

5.2.1 Culture reporting time

Clinically urgent results should be telephoned or sent electronically or according to local protocols.

Preliminary positive culture reports should be telephoned or sent electronically stating, if appropriate, that a further report will be issued.

Final written or computer generated reports should follow preliminary/verbal reports on the same day as confirmation where possible, and within a 24 to 72hr.

Legionella

Final written or computer generated reports should follow preliminary/verbal reports within 3 - 10 days 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^{33,34} or Equivalent in the Devolved Administrations³⁵⁻³⁸

The Health Protection (Notification) regulations 2010 require diagnostic laboratories to notify Public Health England (PHE) when they identify the causative agent 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.

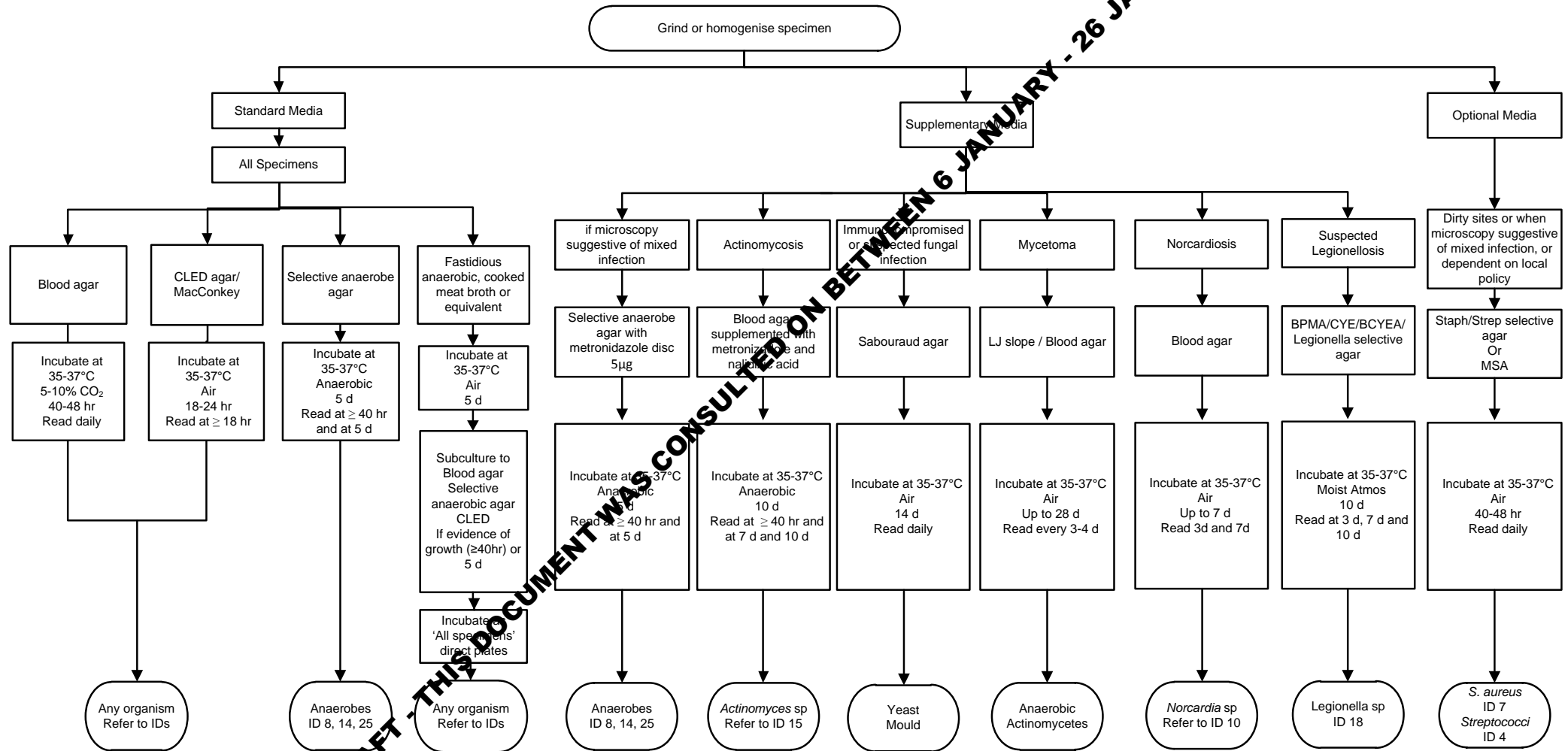
Notification under the Health Protection (Notification) Regulations 2010 does not replace voluntary reporting to PHE. The vast majority of NHS laboratories voluntarily report a wide range of laboratory diagnoses of causative agents to PHE and many PHE Health protection Teams have agreements with local 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 (HCIs) and Creutzfeldt–Jakob disease (CJD) under 'Notification Duties of Registered Medical Practitioners': it is not noted under 'Notification Duties of Diagnostic Laboratories'.

<https://www.gov.uk/government/organisations/public-health-england/about/our-governance#health-protection-regulations-2010>

Other arrangements exist in [Scotland](#)^{35,36}, [Wales](#)³⁷ and [Northern Ireland](#)³⁸.

Appendix: Investigation of tissues and biopsies from deep-seated sites and organs



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