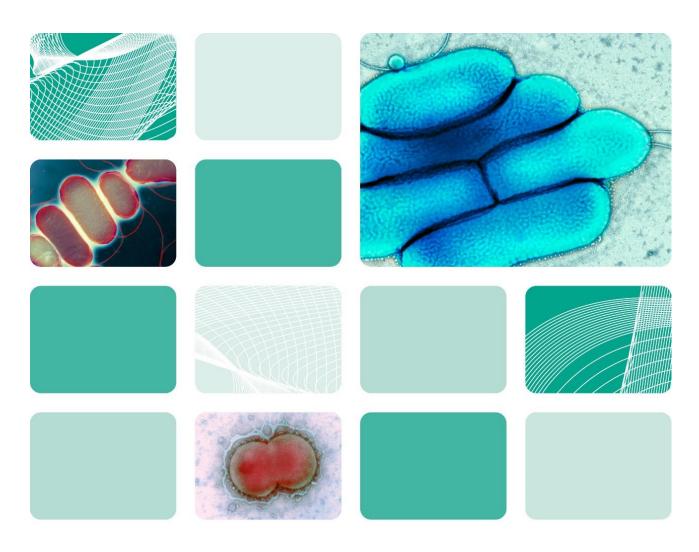


UK Standards for Microbiology Investigations

Investigation of tissues and biopsies from deepseated sites and organs



Acknowledgments

UK Standards for Microbiology Investigations (UK SMIs) are developed under the auspices of UKHSA working in partnership with the partner organisations whose logos are displayed below and listed on the UK SMI website. UK SMIs are developed, reviewed and revised by various working groups which are overseen by a 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.

UK SMIs are produced in association with:

Applied Microbiology International











































Displayed logos correct as of December 2024

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Amendment table

Each UK SMI document has an individual record of amendments. The amendments are listed on this page. The amendment history is available from standards@ukhsa.gov.uk.

Any alterations to this document should be controlled in accordance with the local document control process.

Amendment number/date	14/17.10.25			
Issue number discarded	6.3			
Insert issue number	6.4			
Section(s) involved	Amendment			
	This is an administrative point change.			
	The content of this UK SMI document has not changed.			
	The last scientific and clinical review was conducted on 05/01/2018.			
	Hyperlinks throughout document updated to Royal College of Pathologists website.			
Whole document.	Public Health England replaced with UK Health Security Agency throughout the document, including the updated Royal Coat of Arms.			
	Partner organisation logos updated.			
	Broken links to devolved administrations replaced.			
	References to NICE accreditation removed.			
	Scope and Purpose replaced with General and Scientific information to align with current UK SMI template.			
	'Public health responsibilities of diagnostic laboratories' section added.			

Amendment no/date.	13/05.01.18			
Issue no. discarded.	6.2			
Insert issue no.	6.3			
Section(s) involved	Amendment			

Amendment no/date.	12/10.01.17
Issue no. discarded.	6.1
Insert issue no.	6.2
Section(s) involved	Amendment

Amendment no/date.	11/13.12.16				
Issue no. discarded.	6				
Insert issue no.	6.1				
Section(s) involved	Amendment				
	Section 4.4.2 Supplementary				
	 Information has been updated on the preparation of tissue for examination in the case of suspected fungal infections along with a link to B 39 document for more information. 				
Specimen processing/procedure.	Section 4.5.1 (culture media, conditions and organisms) media and incubation updated.				
	 For Nocardiosis, the incubation temperature, atmosphere and time has been updated to reflect what is in the other UK SMI documents. For Legionella species, the incubation atmosphere has been updated. Footnotes have been added for clarity. 				
Appendix.	Updated to reflect section 4.5.1.				

Amendment no/date.	10/08.04.16			
Issue no. discarded.	5.3			
Insert issue no.	6			
Section(s) involved	Amendment			
Section(s) involved	Amenament			
Section(s) involved	Hyperlinks updated to gov.uk.			

	References reviewed throughout.				
	Addition of lung tissue and biopsy for suspected				
	infection with Legionella species.				
Page 2.	Updated logos added.				
Scope.	Scope updated to include rapid methods and links to relevant SMIs.				
	Reorganised for clarity. Specific tissue types placed into alphabetical order.				
Introduction.	Information regarding skin infection streamlined and information include in B11 – Investigation of swabs from skin and soft tissue infections.				
Technical information/limitations.	Section on rapid methods included.				
	Safety considerations regarding Hazard Group 3 organisms amended.				
Safety considerations.	It is recommended that all Gram-negative coccobacilli from sterile sites should be processed in a Class I or Class II microbiological safety cabinet until Hazard Group 3 pathogens (ie Brucella) have been definitively excluded.				
Specimen processing.	Samples for mycological examination must not be homogenised/ground.				
	Ideally, all grinding or homogenisation should be performed in a Class II exhaust protective cabinet.				
	Surgically obtained specimens for fungal culture should be cut (finely sliced) rather than homogenised.				
	Addition of fluorescent staining technique.				
Specimen processing/procedure.	Section 4.5.1 (culture media, conditions and organisms) media and incubation updated.				
, <u>,</u>	 Immunocompromised/suspected fungal infection changed to Sabouraud agar slope + chloramphenicol (35-37°C 14d incubation, 28-30°C 28d incubation). Mycetoma addition of Sabouraud agar slope + chloramphenicol. Nocardiosis blood agar 35-37°C up to 7d. Addition of Legionella species BMPA or alternative 35-37°C up to 10d. 				

	 Mixed infection/local policy, addition of Mannitol Salt Agar.
	Section 4.6.1 (minimum level of identification) level of identification updated for β haemolytic streptococci, coagulase negative streptococci, enterobacteriaceae and pseudomonas. Consider sending staphylococci isolates from post mortem samples for toxin testing.
Reporting procedure.	Culture reporting statement updated.
Appendix.	Updated to reflect section 4.5.1.

1 General information

View general information related to UK SMIs.

2 Scientific information

View scientific information related to UK SMIs.

3 Scope of document

3.1 Type of specimen

Tissue, biopsy

This UK 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:

UK SMI B 39 - Investigation of dermatological specimens for superficial mycoses

UK SMI B 40 - Investigation of specimens for Mycobacterium species

UK SMI 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 (<u>UK SMI B 44 - Investigation of prosthetic joint infection samples</u>).

Bone and soft tissue associated with osteomyelitis (<u>UK SMI B 42 - Investigation of bone and soft tissue associated with osteomyelitis</u>).

Gastric biopsies (for the presence of *Helicobacter pylori*) (<u>UK SMI B 55 - Investigation of infectious causes of dyspepsia</u>).

This UK SMI should be used in conjunction with other UK SMIs.

4 Introduction

A biopsy may be defined as a portion of tissue removed from the 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

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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 may 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.

Tissues and biopsies are not easily repeatable specimens thus prolonged storage (1 month) of residual specimens may be critical in enabling the arrangement of any further appropriate investigations such as mycobacterial cultures or referral for 16S rDNA PCR.

4.1 Specific tissues¹

Aortic aneurysm contents

Aortic aneurysm contents may be sent for the exclusion of an infective cause².

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. Refer to: UK SMI B 2 - Investigation of bacterial eye infections.

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

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culture. Where possible the results of these cultures should be correlated with blood cultures or serology.

In recent years PCR has been found useful in the diagnosis of infective endocarditis, detecting *Coxiella 10urnetiid* in heart valve samples^{3,4}. Duplex PCR has been successfully used to differentiate between *Coxiella 10urnetiid* and other causes of infective endocarditis⁵.

Lung biopsies (percutaneous, bronchoscopic, surgical or post mortem)⁶

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 (usually with reduced sensitivity) by processing induced sputum or bronchoalveolar lavage specimens. Refer to <u>UK SMI B 57 – Investigation of bronchoalveolar lavage</u>, sputum and associated 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 patients⁷. 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 infection⁸. 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^{9,10}. In pregnant women septicaemia caused by *L. monocytogenes* presents as an acute febrile illness that may affect the fetus¹⁰. 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 listeriosis⁹.

Septic abortion may result in serious maternal morbidity and may be fatal¹⁰. 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 biopsies

Skin biopsies 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 (<u>UK SMI B 31 – Investigation of specimens other than blood for parasites</u>). 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 for swimmers and keepers of tropical fish¹¹ (<u>UK SMI B 40 – Investigation of specimens for Mycobacterium species</u>).

Necrotising fasciitis is limited by the deep fascia. The infection spreads widely and rapidly due to the absence of internal barriers in the fascia. The infection can be fatal in a very short time. Some cases occur post-operatively or in patients with underlying clinical conditions such as malignancy. Some authorities consider that it exists as two types. Type I is due to infection by a polymicrobial mixture with aerobic and anaerobic organisms (group A streptococci, anaerobes, *S. aureus* and members of the Enterobacteriaceae). Type II (haemolytic streptococcal gangrene) is due to infection with group A streptococci¹².

5 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^{13,14}

UK 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 improve sensitivity and 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 matrix assisted laser desorption ionisation time-of-flight mass spectrometry (MALDI-TOF MS)¹⁵⁻¹⁷. 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.

6 Safety considerations^{13,14,18-32}

6.1 Specimen collection, transport and storage 13,14,18-21

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.

6.2 Specimen processing 13,14,18-32

Containment Level 2.

Where infection with a Hazard Group 3 organism eg *Mycobacterium tuberculosis*, *Brucella abortus*, *Histoplasma capsulatum*, *Coccidioides* species, *Blastomyces dermatitidis*, *Paracoccidioides brasiliensis*, *Talaromyces* (previously *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 sterile sites should be processed in a Class I or Class II microbiological safety cabinet until Hazard Group 3 pathogens (ie *Brucella*) have been definitively excluded³³.

Laboratory procedures that give rise to infectious aerosols must be conducted in a microbiological safety cabinet²⁴.

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.

Note: Samples for mycological examination must not be homogenised/ground.

Specimen containers must also be placed in a suitable holder.

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

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

7 Specimen collection

7.1 Type of specimens

Tissue, biopsy

7.2 Optimal time and method of collection¹

For safety considerations refer to Section 6.1.

Collect specimens before antimicrobial therapy where possible¹.

A medical practitioner will normally 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: This would not be appropriate for specimens undergoing processing for diagnosis by molecular methods.

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

7.3 Adequate quantity and appropriate number of specimens¹

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.

8 Specimen transport and storage^{13,14}

8.1 Optimal transport and storage conditions

For safety considerations refer to Section 6.1.

Specimens should be transported and processed as soon as possible¹.

If processing is delayed, refrigeration is preferable to storage at ambient temperature¹.

The volume of the specimen influences the transport time that is acceptable. Larger pieces of tissue maintain the viability of anaerobes for longer³⁴.

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Tissues and biopsies are not easily repeatable specimens thus prolonged storage (1 month) of residual specimens may be critical in enabling the arrangement of any further appropriate investigations such as mycobacterial cultures or referral for 16S rDNA PCR.

9 Specimen processing/procedure^{13,14}

9.1 Test selection

Select a representative portion of specimen for appropriate procedures such as culture for fungi (<u>UK SMI B 39 - Investigation of dermatological specimens for superficial mycoses</u>) and *Mycobacterium* species (<u>UK SMI B 40 - Investigation of specimens for Mycobacterium species</u>), and examination for parasites (<u>UK SMI B 31 - Investigation of specimens other than blood for parasites</u>) 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.

9.2 Appearance

N/A

9.3 Sample preparation

For safety considerations refer to Section 6.2.

9.3.1 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 0.5mL) of sterile, filtered water, saline, peptone or broth will aid the homogenisation process.

Ideally, 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 homogenised³⁵.

9.3.2 Supplementary

N/A

9.4 Microscopy

9.4.1 Standard

N/A

9.4.2 Supplementary

Gram stain

Homogenised specimens

(See section 9.3.1 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 UK SMI TP 39 - Staining procedures.

Fluorescent staining technique

Follow kit manufacturers' instructions.

Legionella

For suspected *Legionella* species (lung tissue and biopsies) homogenise specimens as in section 9.3.1.

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.

Suspected fungal infections

For suspected fungal infections finely cut specimens as in section 9.3.1.

Place a small portion of tissue in a sterile Eppendorf tube and add equal proportions of 10-30% KOH and Calcofluor white (0.1%) solution. Leave to digest for at least 20 min or less at room temperature. After digestion, the tissue should be squashed to produce a single layer of cells.

Using a sterile pipette, place the digested tissue on a glass slide, and examine under a fluorescent microscope. Note the type of structures seen to correlate with subsequent culture results ie pseudohyphae, true hyphae, yeast forms, other fungal elements.

For more information, refer to <u>UK SMI TP 39 - Staining procedures</u> and <u>UK SMI B 39 - Investigation of dermatological specimens for superficial mycoses.</u>

9.5 Culture and investigation

Homogenised specimens

Inoculate each agar plate and enrichment broth with homogenised or ground specimen (see UK SMI 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 <u>UK SMI Q 5 – Inoculation of culture media for bacteriology</u>).

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

9.5.1 Culture media, conditions and organisms

Clinical details/	Specimen	Standard media		Incubation		Cultures read	Target
conditions			Temp. °C	Atmos.	Time	read	organism(s)
	Tissue Biopsy	Blood agar	35-37	5-10% CO ₂	40- 48hr	daily	
		CLED/	35-37	Air	18- 24hr	≥18hr	Any organism
		MacConkey agar			24111		
		Selective anaerobic agar	35-37	Anaerobic	5d	≥40hr and at 5d	Anaerobes
All clinical conditions		Fastidious anaerobic, cooked meat broth or equivalent.	35-37	Air	Up to 5d	N/A	
		Subculture if evidence of growth (≥40hr), or at day 5	35-37	As above	As above	As above	Any organism
		to above media (excluding MacConkey agar)					
	For these situations, add the following:						
Clinical details/	Specimen	Supplementary media		Incubation		Cultures read	Target organism(s)
conditions			Temp. °C	Atmos.	Time	Toda	o. gao(o)
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	Actinomyces species
Immunocompro	Tissue	Sabouraud agar slope +	35-37	Air	14d	daily#	Yeasts
mised, or suspected fungal infection	Biopsy	chloramphenicol	and 28-30		28d		Moulds
Mycetoma	Tissue Biopsy	Lowenstein- Jensen slope / Blood agar or	35-37	Air	up to	Every 3-	Aerobic Actinomycetes species Yeasts
					28d	4 days	Moulds

		Sabouraud agar slope + chloramphenicol	28-30	Air			
Nocardiosis	Tissue Biopsy (bronchoal veolar lavage)	Blood agar	35-37	5-10% CO ₂	16- 48hr	daily	Nocardia species**
Suspected Legionellosis	Tissue Biopsy	BMPA or BCYEA or alternative Legionella agar	35-37	Moist Atmos*	Up to 10d	3d, 7d and 10d	Legionella species
	Optional me	dia:					
When clinical details or when microscopy suggestive of mixed infection or dependent on local policy	Tissue Biopsy	Staphylococci/ Streptococci selective agar or Mannitol Salt Agar (not for Streptococcus)	35-37	Air	40- 48hr	daily	S. aureus Streptococci

Other organisms for consideration – Fungi (<u>UK SMI B 39 - Investigation of dermatological specimens for superficial mycoses</u>), *H. pylori* (<u>UK SMI B 55 - Investigation of infectious causes of dyspepsia</u>), *Listeria* species, *Mycobacterium* species (<u>UK SMI B 40 - Investigation of specimens for Mycobacterium species</u>) and parasites (<u>UK SMI B 31 - Investigation of specimens other than blood for parasites</u>).

9.6 Identification

Refer to individual UK SMIs for organism identification.

9.6.1 Minimum level of identification in the laboratory

Actinomycetes	genus level
	UK SMI ID 10 – Identification of aerobic Actinomycetes species
	UK SMI ID 15 – Identification of anaerobic Actinomycetes species
Anaerobes	"anaerobes" level
	UK SMI ID 8 - Identification of Clostridium species
<u>β-haemolytic streptococci</u>	species level
Coagulase negative staphylococci	"coagulase negative" level
Enterobacteriaceae	species level

^{*}Agents of exotic imported mycoses eg *Histoplasma capsulatum* and some *Cryptococcus* isolates may take up to 8 weeks to grow; adequate humidification of incubators will be necessary^{36,37}.

^{*}It should be noted that incubation in 2-5% CO₂ can enhance growth of some *Legionella* species such as *L. sainthelensi* and *L. oakridgensis*³⁸. This low level of CO₂ will not affect the growth of *L. pneumophila*, but CO₂ levels higher than 5% may inhibit growth.

^{**} If laboratories choose to use *Legionella* selective agar plates such as BCYE agar as supplementary media for isolation of *Nocardia* species, its inclusion should be subject to the results of local validation. The document, <u>UK SMI ID 10: Identification of aerobic actinomycetes</u> recommends that if selective agar plates are used, they should be incubated for 2 to 3 weeks.

<u>Pseudomonads</u>	species level
S. aureus	species level (consider Panton-Valentine leukocidin (PVL) and toxin testing if appropriate clinical details) (consider toxin testing on samples from post mortems)
S. anginosus group	S. anginosus group level
Yeast	species level
Mould	species level
<u>Legionella species</u>	species level
Mycobacterium species	species level <u>UK SMI B 40 - Investigation of specimens for Mycobacterium species</u>
<u>Parasites</u>	species level UK SMI B 31 - Investigation of specimens other than blood for parasites

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

9.7 Antimicrobial susceptibility testing

Refer to <u>British Society for Antimicrobial Chemotherapy (BSAC)</u> and/or <u>EUCAST</u> guidelines.

CLSI breakpoints are available for Candida species and moulds.

9.8 Referral for outbreak investigations

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

10 Referral to reference laboratories

For information on the tests offered, turnaround times, transport procedure and the other requirements of the reference laboratory see user manuals and request forms

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

England

Wales

Scotland

Northern Ireland

Note: In case of sending away to laboratories for processing, ensure that specimen is placed in appropriate package and transported accordingly.

11 Reporting procedure

11.1 Microscopy

Gram stain

Report on WBCs and organisms detected.

Legionella immunofluorescence

Legionella pneumophila detected by immunofluorescence or

Legionella pneumophila not detected by immunofluorescence

Fungal fluorescent stain

Report on type of fungal element seen.

11.1.1 Microscopy reporting time

All results should be issued to the requesting clinician as soon as they become available, unless specific alternative arrangements have been made with the requestors.

Urgent results should be telephoned or transmitted electronically in accordance with local policies.

11.2 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.

11.2.1 Culture reporting time

Interim or preliminary results should be issued on detection of potentially clinically significant isolates as soon as growth is detected, unless specific alternative arrangements have been made with the requestors.

Urgent results should be telephoned or transmitted electronically in accordance with local policies.

Final written or computer generated reports should follow preliminary and verbal reports as soon as possible.

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.

11.3 Antimicrobial susceptibility testing

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

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12 Notification to UKHSA^{39,40}, or equivalent in the devolved administrations⁴¹⁻⁴⁴

The Health Protection (Notification) regulations 2010 require diagnostic laboratories to notify UK Health Security Agency (UKHSA) 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 UKHSA 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 UKHSA. The vast majority of NHS laboratories voluntarily report a wide range of laboratory diagnoses of causative agents to UKHSA and many UKHSA 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 (HCAIs) 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^{41,42}, Wales⁴³ and Northern Ireland⁴⁴.

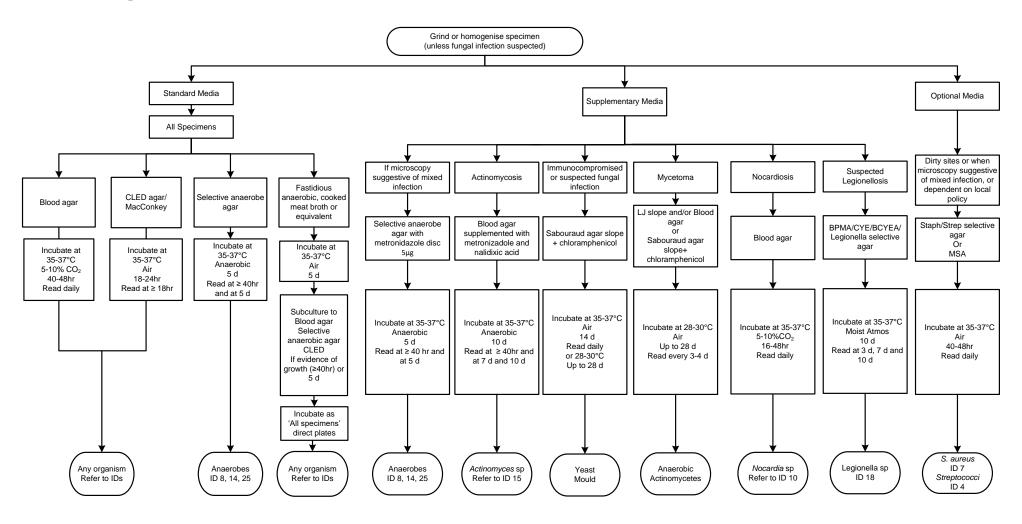
13 Public health responsibilities of diagnostic laboratories

Diagnostic laboratories have public health responsibility as part of their duties. Amongst these are additional local testing, or referral to further characterise the organism as required, primarily for public health purposes e.g. routine cryptosporidium detection; serotyping or microbial subtyping; and a duty to refer appropriate specimens and isolates of public health importance to a reference laboratory.

Diagnostic laboratory outputs inform public health intervention, and surveillance data is required to develop policy and guidance forming an essential component of healthcare. It is recognised that additional testing and referral of samples may entail some costs that has to be borne by the laboratory but in certain jurisdictions these costs are covered centrally.

Diagnostic laboratories should be mindful of the impact of laboratory investigations on public health and consider requests from the reference laboratories for specimen referral or enhanced information.

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An explanation of the reference assessment used is available in the <u>scientific</u> information section on the UK SMI website.

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