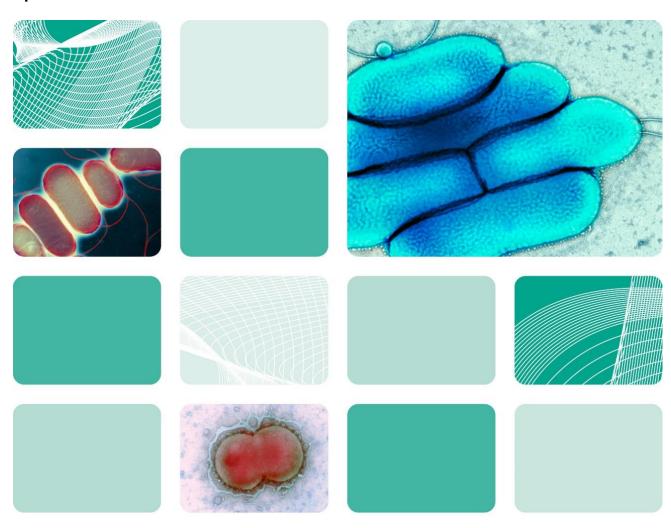


UK Standards for Microbiology Investigations



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:













































Displayed logos correct as of December 2024

Contents

| ACK | nowleagments | 2 |
|------|--|----|
| Cont | tents | 3 |
| Ame | endment table | 4 |
| 1 | General information | 6 |
| 2 | Scientific information | 6 |
| 3 | Scope of document | 6 |
| 4 | Introduction | 6 |
| 5 | Technical information/limitations | 10 |
| 6 | Safety considerations | 11 |
| 7 | Specimen collection | 11 |
| 8 | Specimen transport and storage | 12 |
| 9 | Specimen processing/procedure | 13 |
| 10 | Reporting procedure | 16 |
| 11 | Notification to UKHSA, or equivalent in the devolved administrations | 17 |
| 12 | Referral to reference laboratories | 18 |
| 13 | Public health responsibilities of diagnostic laboratories | 19 |
| Algo | orithm: Investigation of intravascular cannulae and associated specimens | 20 |
| Refe | erences | 21 |

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 | 11/17.10.25 | | | | |
|------------------------|--|--|--|--|--|
| Issue number discarded | 6.1 | | | | |
| Insert issue number | 6.2 | | | | |
| 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 27/06/2017. | | | | |
| | 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. | | | | |

| Section(s) involved | Amendment |
|----------------------|-------------|
| Insert issue no. | 6.1 |
| Issue no. discarded. | 6 |
| Amendment no/date. | 10/27.06.17 |

| Introduction. | Minor textual additions. |
|---------------|--------------------------|
| Section 2.2.1 | Edited for clarity. |

| Amendment no/date. | 9/30.11.15 | | | | |
|----------------------|---|--|--|--|--|
| Issue no. discarded. | 5.2 | | | | |
| Insert issue no. | 6 | | | | |
| Section(s) involved | Amendment | | | | |
| | Document presented in a new format. | | | | |
| | Hyperlinks updated to gov.uk. | | | | |
| | Reorganisation of some text. | | | | |
| Whole document. | Edited for clarity. | | | | |
| | Minor textual changes. | | | | |
| | All hyperlinked documents updated with the correct address. | | | | |
| Page 2. | Updated logos added. | | | | |
| Scope of document. | This document has been updated to exclude the investigation of specimens such as pacing wires and ventricular assist devices. | | | | |
| References. | References updated. | | | | |
| Appendix. | The flowchart has been updated for easy guidance. | | | | |

1 General information

View general information related to UK SMIs.

2 Scientific information

View scientific information related to UK SMIs.

3 Scope of document

Type of specimen

Line tips eg CVP or Hickman lines, swabs of cannula insertion sites

Note: Peripheral lines are not suitable specimens for cultures and should not normally be sent to the laboratory for testing.

This UK SMI describes the processing and bacteriological investigation of intravascular cannulae and associated specimens. This document does not include the investigation of specimens such as pacing wires and ventricular assist devices. It should also be noted that the words "cannulae" and "catheters" are widely used interchangeably and in this document, the same applies to the two terms.

Occasionally blood may be used and for more information, refer to <u>UK SMI S 12 – Sepsis and systemic or disseminated infections.</u>

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

4 Introduction

The use of indwelling cannulae for reliable intravascular access is an essential feature of modern health care for both monitoring and intervention. Insertion of intravascular cannulae allows continuous and painless access to the circulation for administration of fluids and electrolytes, medications, blood products and nutritional support. In addition the intravascular access can be used for blood sampling, haemodynamic monitoring, haemodialysis and haemofiltration. Each year, millions of intravascular devices are used in acutely or chronically ill hospitalised patients around the world. These devices come in various lengths to suit peripheral or central insertion and can have single or multiple lumens. Although the vast majority of these devices are cannulae for peripheral use, central venous or arterial catheters are also used especially in patients with difficult peripheral access or when haemodynamic monitoring is indicated.

Cannula-related infections are amongst the most important nosocomial infections. Skin colonisation (which is often asymptomatic) acts as a precursor of systemic or localised infection. The overall incidence of infection related to the use of intravascular cannulas is about 1%, however this figure may be as high as 4-8% for central venous cannulas used for total parenteral nutrition. In high risk patients, central venous line infections carry a significant mortality rate and a high cost¹.

Intravascular device related blood stream infection is a significant clinical problem. Evidence Based Practice for Infection Control (EPIC) guidelines have been issued by the Department of Health for the prevention of hospital acquired infections associated with the use of central venous catheters². Catheter-related blood stream infections (CR-BSI) can be defined as the isolation of the same organism ie identical species from the colonised catheter and peripheral blood in a patient with accompanying clinical signs and symptoms of bloodstream infection (BSI) and no other apparent source of BSI^{3,4}. The guidelines recommend several practices and strategies for reducing the risk of CR-BSI, including catheter type, site of insertion, optimum aseptic technique, good catheter care, and the appropriate use of antimicrobial coated or impregnated central venous catheters (CVCs).

4.1 Types of cannulae

Specific examples of descriptions of cannulae (or catheters), defining their siting, use or design, include:

- peripheral lines these lines are usually inserted into the veins of the forearm or the hand to administer medication, fluids or nutrition eg Venflons, Abbocaths and Parenteral nutrition catheters. They can be used either short term or long term
- **midline catheters** these are inserted via the antecubital fossa into the proximal basilic or cephalic veins. They do not enter the central veins and are for short-term use to sample blood or administer fluids intravenously
- central lines these are inserted into central veins (such as triple lumen, subclavian lines, jugular lines or less commonly femoral lines) with the tip residing in the vena cava. This permits intermittent or continuous infusion of irritant, vesicant or hyper-osmolar drugs/fluids and/or access into the venous system and can be used short term or long term eg peripherally inserted central catheter (PICC). There are various subtypes of central lines and their uses. They are as follows:
 - monitoring lines, eg central venous pressure lines, Swan Ganz lines, arterial lines
 - long term access such as chemotherapy, antibiotics, blood sampling, continuous renal replacement therapy (CRRT), haemodialysis eg Hickman lines, Broviac lines, Groshong lines, Hickman-like catheters such as Lifecath, RedoTPN, etc
 - miscellaneous eg dialysis lines (Vascath used for haemofiltration), and umbilical cannulae for exchange transfusions in neonates
 - implantable ports eg TIVAD, Portacath. These are subcutaneous ports or reservoirs with self-sealing septum which are tunnelled beneath the skin and accessed by a needle through intact skin. They are implanted in subclavian or internal jugular veins. It is associated with low rates of infection
 - antimicrobial coated or impregnated CVCs: recent studies have demonstrated that antimicrobial coated or impregnated CVC can reduce the incidence of catheter colonisation and CR-BSI in appropriate situations²

 catheter hubs, stopcocks and needle-free connectors are used to reduce the risk of accidental needle puncture or biological contamination in clinical settings. Manufacturer's recommendations should be adhered when using these devices⁵

Cannula-related bacteraemia or cannula-related fungaemia

The cannula may be the source of a bacteraemia or fungaemia. This is likely to be so if it is infected with the same organism as that isolated from a blood culture, usually in the absence of an identifiable alternative focus of infection, and when cultures from infusions are negative⁶. Infection of intravenous cannulae may lead to widespread dissemination of infection. More usually the patient develops a fever and may become generally unwell.

Cannula-related sepsis

This is defined as the presence of clinical sepsis when two or more of the following occur; such as fever, leucocytosis, or hypotension, documentation of a catheter isolate (irrespective of quantitative count), and negative blood cultures obtained within 48hr before and 24hr after catheter removal. There is usually no other source of sepsis demonstrated, and this resolves following catheter removal⁷.

Localised infection

This can occur at the insertion site and subcutaneous track of the device⁸. Clinical signs of infection include erythema, exudate formation, oedema and thrombophlebitis. The patient may complain of pain or irritation at the insertion site, and may become pyrexial. This infection is caused by pyogenic bacteria such as *Staphylococcus aureus*.

4.2 Cannula removal and culture

According to the Centres for Disease Control and Prevention - Infectious Diseases Society of America (CDC-IDSA) guidelines, it recommends that culture of tips should only be done when CRBSIs are suspected. Cannula tip culture gives valuable information but necessitates the removal of the cannula. This can sometimes result in the loss of venous access that can interfere seriously with the medical management of the patient, although sometimes catheter removal is necessary to gain control of a catheter-related infection, especially with certain organisms, such as *Candida* species^{9,10}.

Cannula associated swabs (eg swabs of catheter insertion sites) may be employed as alternative specimens. However, routine investigation of cannula associated swabs from asymptomatic patients is of dubious value.

When skin and blood culture results concur, removal of the cannula is usually recommended (depending on clinical settings and organism identified), although this may not happen in practice unless clinical sepsis unresponsive to antibiotics is present. Quantitative and semi-quantitative culture methods have been described for these sites, but are not recommended in this SMI¹¹⁻¹⁴.

An alternative method of investigating cannula-associated infection that preserves central venous access is to take samples of blood simultaneously through the cannula and from a peripheral vein¹⁵. For added specificity, both samples are cultured

quantitatively. If the concentration of organisms in the blood from the central line is equal to or greater than 10 times the concentration of organisms in blood from the peripheral vein, then central venous cannula infection is diagnosed¹⁶. The latter methodology has not been widely adopted because of its complexity, cost and limited added value.

4.3 Infections and organisms

The incidence of infection is related to the length of time the cannula remains *in situ*. The catheter tip may be infected secondarily by organisms already infecting the hub or insertion site which track down the catheter lumen or tunnel; but it may also acquire organisms from fluids passing through it or from the bloodstream itself. Colonisation of cannulae is a far commoner source of CR-BSI than contaminated infusate. Organisms causing cannula-related infections may be acquired from^{17,18}:

- patients' microflora
- hands of staff
- contaminated disinfectants
- contaminated hub
- bacteraemia due to other causes
- contaminated intravenous fluids
- ward air

Most central venous line-associated infections are caused by organisms from the skin near the exit site which gains access to the intravascular segment of the cannula.

Organisms isolated from cannula tips and swabs commonly associated with cannula sites in descending order of frequency include 19,20:

- coagulase negative staphylococci (CoNS)
- Staphylococcus aureus including MRSA
- enterobacteriaceae
- enterococci
- pseudomonads
- Corynebacterium species
- streptococci
- Bacillus species

Fungi may be isolated including:

- Candida albicans and other yeasts
- Aspergillus species
- Fusarium species
- Malassezia furfur (in patients receiving intralipid infusions)

Coagulase negative staphylococci

Coagulase negative staphylococci (CoNS) are the most frequent causes of cannularelated infections. It should also be noted that intraluminal colonisation of the common skin flora from repeated puncture through the septum may account for the high percentage of CoNS²¹. They can produce extracellular slime that facilitates adherence and may limit the access of antibiotics, and may reduce the host's inflammatory response. If a patient has a central venous cannula and coagulase negative staphylococci are isolated from multiple sets of blood cultures, infection with the organism must be considered seriously. However, there may be difficulty in interpretation of the significance of these isolates, as coagulase negative staphylococci are commonly isolated from contaminated blood cultures.

Any organism isolated in significant numbers should be considered as of potential significance when using methods of quantitative culture^{1,22}.

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^{23,24}

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".

Matrix-assisted laser desorption/ionisation - time of flight mass spectrometry (MALDI-TOF MS)

Direct identification of bacteria and yeast from blood culture bottle broth by MALDI-TOF MS methods is promising and it has the potential to speed the identification process in the laboratory thereby reducing turnaround times as well as resulting in significant improvements to patient care. Rapid identification of blood culture

Bacteriology | B 20 | Issue no: 6.2 | Issue date: 17.10.25 | Page: 10 of 26

contaminants may also allow more rapid discontinuation of unnecessary antimicrobial therapy. Different protocol types have been reported by several studies to accurately identify the microorganisms present in positive blood culture broth; however, a lack of standardised protocols and the use of different software for mass analysis and different blood culture bottles make it difficult to compare the performances of the different methods²⁵⁻²⁸.

6 Safety considerations^{23,24,29-43}

6.1 Specimen collection, transport and storage^{23,24,29-32}

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 in sealed plastic bags⁴⁴.

Compliance with postal, transport and storage regulations is essential.

6.2 Specimen processing^{23,24,29-43}

Containment Level 2 organisms.

Laboratory procedures that give rise to infectious aerosols must be conducted in a microbiological safety cabinet³⁵.

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

Line tips eg CVP or Hickman lines, swabs of cannula insertion sites

7.2 Optimal time and method of collection⁴⁵

For safety considerations refer to Section 6.1.

Collect specimens before starting antimicrobial therapy where possible⁴⁵.

Cannulae should be collected in appropriate CE marked leak proof containers and transported and processed as soon as possible.

Unless otherwise stated, swabs for bacterial and fungal culture should be placed in appropriate transport medium^{44,46-49}.

7.2.1 Correct specimen type and method of collection

Cannulae

Bacteriology | B 20 | Issue no: 6.2 | Issue date: 17.10.25 | Page: 11 of 26

Disinfect the skin around the cannula entry site, remove cannula using aseptic technique, and ideally cut off 4cm of the tip into an appropriate CE marked leak proof container using sterile scissors⁸. Place in sealed plastic bags for transport.

Note 1: skin disinfection procedures depend on local protocols and may vary.

Note 2: cannulae should only be sent if there is evidence of infection.

Swabs

Sample the inflamed area / exudate around the catheter insertion site using an appropriate swab.

Blood

At least two blood cultures should be obtained when catheter infection is suspected by peripheral venepuncture²⁰. For more information on blood cultures, refer to UK SMI S 12 – Sepsis and systemic or disseminated infections. but microscopy, subculturing and further testing should be handled in accordance with the methods outlined in this UK SMI.

7.3 Adequate quantity and appropriate number of specimens⁴⁵

Numbers and frequency of specimens collected are dependent on clinical condition of patient.

8 Specimen transport and storage^{23,24}

8.1 Optimal transport and storage conditions

For safety considerations refer to Section 6.1.

Specimens should be transported and processed as soon as possible⁴⁵.

If processing is delayed, refrigeration is preferable to storage at ambient temperature⁴⁵.

Note: Refrigerated storage of intravascular line tips does not significantly decrease the yield of culture⁵⁰.

9 Specimen processing/procedure^{23,24}

9.1 Test selection

Culture techniques

Diagnosis of CR-BSI may be difficult due to the lack of clear clinical definitions. Definitive diagnosis can only be achieved if both the removed catheter tip / cannula cultured and blood cultures yield potentially pathogenic organisms in sufficient quantity¹⁹. Techniques that have been used to diagnose local or systemic infection associated with cannulae include⁵¹:

- semiquantitative and quantitative culture of cannula segments
- broth culture of cannula segments, particularly the tip
- staining of cannulae
- culture of blood aspirated through an intravascular cannula
- · culture of the cannula hub
- · culture of the cannula insertion site
- ultrasonication of cannulae

Semiquantitative method

Culture of the cannula surface is used to predict which are truly infected and likely to cause bloodstream infections. The terminal 4-5cm segment of the cannula (or as provided) is rolled over the entire surface of the agar plate back and forth several times (4-5 times). The inoculated agar plate is incubated and the number of colonies on the plate is counted after incubation^{7,52}.

When culturing the external surface of the cannula tip, a threshold of >15 colonies of any organism is commonly accepted to predict cannula-related sepsis and is associated with bacteraemia in 10-14% of cases^{7,53}. This threshold is based on the culture of a 4cm length. In practice, varying lengths of line are often received and interpretation should be made with care, and in conjunction with blood culture results. However, in practice this threshold may be too low where stringent removal precautions are not taken or there is a delay before processing. A threshold of >100 colonies may be more appropriate⁵².

Multiple isolates present at >15 cfu are counted individually and their significance related to any blood culture isolate⁷.

Quantitative method⁵⁴

This method provides information on both the inner and outer surfaces of the cannula. A cut-off of 1000 cfu/mL is used as indicating sepsis^{22,52}. The lumen result is reported to be a more reliable predictor of systemic infection where there is no evidence of localised exit site infection⁵². This method is labour intensive and is not recommended for routine use in this UK SMI. Both quantitative and semi-quantitative methods are equally effective in predicting absence of infection.

Enrichment method

The distal segment of the cannula is placed in enrichment broth, incubated for about 48hr and then organisms isolated on appropriate agar media. However, this does not distinguish among colonisation, infection or contamination of the cannula. It should be noted that the use of enrichment broth is not recommended except in certain settings eg such as if a source of candida fungaemia is suspected. However, its use is not recommended in this SMI.

Endoluminal brush

This has been reported as an accurate method of detecting catheter related sepsis without the need for catheter removal⁵⁵.

Rapid diagnostic methods

Staining the cannula (or an impression smear of the cannula) with Gram stain or acridine orange have been described and these provide information without the 24-48hr delay required for isolation of organisms^{56,57}.

9.2 Appearance

N/A

9.3 Sample preparation

For safety considerations refer to Section 6.2.

9.4 Microscopy

9.4.1 Standard

Stain an impression smear of the cannula or the isolate if clinically indicated either by Gram stain or Acridine Orange stain (refer to <u>UK SMI TP 39 – Staining procedures</u>).

Note: Refer to manufacturers' instructions with respect to preparing smears from blood culture bottles.

9.5 Culture and investigation

Cannulae

Roll specimen across the agar surface several times (semiquantitative technique) to cover as much of the agar surface and external cannula surface as possible⁵².

If >4cm is received, the distal end should be reduced to a 4cm length, prior to culture, by cutting with sterile scissors or scalpel.

Swabs

Inoculate agar plate with swab (refer to <u>UK SMI Q 5 – Inoculation of culture media in bacteriology</u>). 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 organism(s)‡ |
|--|--|---|------------|--------------------------|------------------|--------------------|--|
| conditions | | | Temp °C | Atmos | Time | rouu | |
| Cannula- related bacteraemia Cannula- related infection | Cannulae | Blood agar | 35-37 | 5-10% CO ₂ | 24-48hr | Daily | ≥15 cfu per plate of any bacteria |
| Local cannula site infection | Swabs | Blood agar | 35-37 | 5-10% CO ₂ | 24-48hr | Daily | Coagulase negative staphylococci S. aureus including MRSA* Corynebacterium species Enterobacteriaceae Enterococci Pseudomonads Streptococci Bacillus species Yeasts# |
| For these situation | ns, add the follo | ving: | | | | | |
| Clinical details/ | Specimen | | Incubation | | Cultures read | Target organism(s) | |
| conditions | | Optional media | Temp °C | Atmos | Time | | |
| Cannula- related fungaemia | Blood (after flagging positive on blood culture automated systems) Cannulae | Sabouraud agar supplemented with chloramphenicol and gentamicin or chromogenic agar ^{58,59} | 28-30 | Air | Up to 7d | 2d and at 5d | Yeasts** |
| Cannula- related bacteraemia Cannula- related infection | Peripheral IV line tips (after there is a positive blood culture in the 7 days before or after the day the line tip is sent) ^{10,60} | Blood agar | 35-37 | 5-10% CO ₂ | 24-48hr | Daily | Coagulase negative staphylococci S. aureus including MRSA* Corynebacterium species Enterobacteriaceae Enterococci Pseudomonads Streptococci Bacillus species |

** Some yeasts can grow at much higher temperatures such as *Malassezia* species which grow strictly at 30-35°C and not outside this range⁶¹.

Any cfu growth of yeasts is considered significant and should be reported.

‡ For appearance of relevant target organisms, refer to individual SMIs for organism identification.

Note: If automated monitoring systems are used, refer to local protocols and manufacturer's recommendations. These should be checked continuously for bottles that flag positive. A blood agar plate should be set up for all bottles that are flagged positive to check for contamination.

Rapid test methods such as MALDI-TOF MS and NAATs should be performed according to manufacturers' instructions^{26-28,62,63}.

9.6 Identification

Refer to individual UK SMIs for organism identification.

9.6.1 Minimum level of identification in the laboratory

| <u>α-haemolytic streptococci</u> | "α-haemolytic" level |
|----------------------------------|----------------------------|
| <u>β-haemolytic streptococci</u> | Lancefield group level |
| Coagulase negative staphylococci | "coagulase negative" level |
| Coryneforms | "diphtheroids" level |
| Enterobacteriaceae | "coliforms" level |
| <u>Enterococcus</u> | genus level |
| <u>Pseudomonads</u> | "pseudomonads" level |
| S. aureus | species level |
| Yeasts | "yeasts" level |

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.

9.8 Referral for outbreak investigations

N/A

10 Reporting procedure

10.1 Microscopy

Report organism seen.

10.1.1 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.

Bacteriology | B 20 | Issue no: 6.2 | Issue date: 17.10.25 | Page: 16 of 26

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

10.2 Culture

10.2.1 Cannulae

Report the number of cfu of organism(s) isolated with an interpretative comment, eg ≥15 cfu may be associated with systemic cannula-related infection, or may represent superficial colonisation or contamination - refer to blood culture results

OR

Report absence of growth.

10.2.2 Swabs

Report the amount (eg heavy, moderate or scanty) of growth isolated with an interpretative comment relating to the presence of local infection

OR

Report the absence of growth.

10.2.3 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.

10.3 Antimicrobial susceptibility testing

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

11 Notification to UKHSA ^{64,65}, or equivalent in the devolved administrations ⁶⁶⁻⁶⁹

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/ourgovernance#health-protection-regulations-2010

Other arrangements exist in Scotland^{66,67}, Wales⁶⁸ and Northern Ireland⁶⁹.

12 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

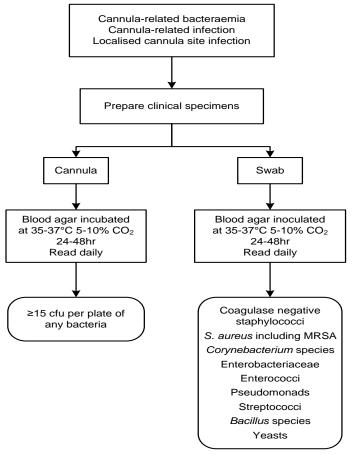
Note: In case of sending away to laboratories for processing, ensure that specimen is placed in appropriate package and transported accordingly.

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.



This flowchart is for guidance only.

References

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

- 1. Garrison RN, Wilson MA. Intravenous and central catheter infections. Surg Clin North Am 1994;74:557-70.
- 2. Loveday HP, Wilson JA, Pratt RJ, Golsorkhi M, Tingle A, Bak A, et al. epic3: national evidence-based guidelines for preventing healthcare-associated infections in NHS hospitals in England. J Hosp Infect 2014;86 Suppl 1:S1-70.
- 3. Moretti EW, Ofstead CL, Kristy RM, Wetzler HP. Impact of central venous catheter type and methods on catheter-related colonization and bacteraemia. J Hosp Infect 2005;61:139-45.
- 4. Bion J, Richardson A, Hibbert P, Beer J, Abrusci T, McCutcheon M, et al. 'Matching Michigan': a 2-year stepped interventional programme to minimise central venous catheter-blood stream infections in intensive care units in England. BMJ Qual Saf 2013;22:110-23.
- 5. Pittiruti M, Hamilton H, Biffi R, MacFie J, Pertkiewicz M. ESPEN Guidelines on Parenteral Nutrition: central venous catheters (access, care, diagnosis and therapy of complications). Clin Nutr 2009;28:365-77.
- 6. Gutierrez J, de la Higuera A, Piedrola G. Microbiological techniques for the diagnosis of intravascular catheter associated infections. Med Microbiol Lett 1992;1:243-50.
- 7. Dooley DP, Garcia A, Kelly JW, Longfield RN, Harrison L. Validation of catheter semiquantitative culture technique for non-staphylococcal organisms. J Clin Microbiol 1996;34:409-12.
- 8. Elliott TSJ, Faroqui MH, Armstrong RF, Hanson GC. Guidelines for good practice in central venous catheterization. J Hosp Infect 1994;28:163-76.
- 9. Mermel LA, Allon M, Bouza E, Craven DE, Flynn P, O'Grady NP, et al. Clinical practice guidelines for the diagnosis and management of intravascular catheter-related infection: 2009 Update by the Infectious Diseases Society of America. Clin Infect Dis 2009;49:1-45.
- Perez-Parra A, Guembe M, Martin-Rabadan P, Munoz P, Fernandez-Cruz A, Bouza E. Prospective, randomised study of selective versus routine culture of vascular catheter tips: patient outcome, antibiotic use and laboratory workload. J Hosp Infect 2011;77:309-15.
- Fan ST, Teoh-Chan CH, Lau KF, Chu KW, Kwan AK, Wong KK. Predictive value of surveillance skin and hub cultures in central venous catheters sepsis. J Hosp Infect 1988;12:191-8.

- 12. Elliott TS. Line-associated bacteraemias. Commun Dis Rep CDR Rev 1993;3:R91-R96.
- 13. Keri Hall, Barry Farr. Diagnosis and Management of Long-term Central Venous Catheter Infections. J Vasc Interv Radiol 2004;15:327-34.
- 14. Raad I, Hanna H, Maki D. Intravascular catheter-related infections:advances in diagnosis, prevention, and management. Lancet Infect Dis 2007;7:645-57.
- 15. Raad I, Hanna HA, Alakech B, Chatzinikolaou I, Johnson MM, Tarrand J. Differential time to positivity: a useful method for diagnosing catheter-related bloodstream infections. Ann Intern Med 2004;140:18-25.
- 16. Armstrong CW, Mayhall CG, Miller KB, Newsome HH, Jr., Sugerman HJ, Dalton HP, et al. Clinical predictors of infection of central venous catheters used for total parenteral nutrition. Infect Control Hosp Epidemiol 1990;11:71-8.
- 17. Goldmann DA, Pier GB. Pathogenesis of infections related to intravascular catheterization. Clin Microbiol Rev 1993;6:176-92.
- 18. Linnemann B. Management of complications related to central venous catheters in cancer patients: an update. Semin Thromb Hemost 2014;40:382-94.
- 19. Pratt RJ, Pellowe C, Loveday HP, Robinson N, Smith GW, Barrett S, et al. The epic project: developing national evidence-based guidelines for preventing healthcare associated infections. Phase I: Guidelines for preventing hospital-acquired infections. Department of Health (England). J Hosp Infect 2001;47 Suppl:S3-82.
- 20. Shah H, Bosch W, Thompson KM, Hellinger WC. Intravascular catheter-related bloodstream infection. Neurohospitalist 2013;3:144-51.
- 21. Tsai HC, Huang LM, Chang LY, Lee PI, Chen JM, Shao PL, et al. Central venous catheter-associated bloodstream infections in pediatric hematology-oncology patients and effectiveness of antimicrobial lock therapy. J Microbiol Immunol Infect 2014;1-8.
- 22. Brun-Buisson C, Abrouk F, Legrand P, Huet Y, Larabi S, Rapin M. Diagnosis of central venous catheter-related sepsis. Critical level of quantitative tip cultures. Arch Intern Med 1987;147:873-7.
- 23. European Parliament. UK Standards for Microbiology Investigations (SMIs) use the term "CE marked leak proof container" to describe containers bearing the CE marking used for the collection and transport of clinical specimens. The requirements for specimen containers are given in the EU in vitro Diagnostic Medical Devices Directive (98/79/EC Annex 1 B 2.1) which states: "The design must allow easy handling and, where necessary, reduce as far as possible contamination of, and leakage from, the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen. The manufacturing processes must be appropriate for these purposes".

- 24. Official Journal of the European Communities. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices. 7-12-1998. p. 1-37.
- 25. Clark AE, Kaleta EJ, Arora A, Wolk DM. Matrix-assisted laser desorption ionization-time of flight mass spectrometry: a fundamental shift in the routine practice of clinical microbiology. Clin Microbiol Rev 2013;26:547-603.
- 26. Christner M, Rohde H, Wolters M, Sobottka I, Wegscheider K, Aepfelbacher M. Rapid identification of bacteria from positive blood culture bottles by use of matrix-assisted laser desorption-ionization time of flight mass spectrometry fingerprinting. J Clin Microbiol 2010;48:1584-91.
- 27. La Scola B, Raoult D. Direct identification of bacteria in positive blood culture bottles by matrix-assisted laser desorption ionisation time-of-flight mass spectrometry. PLoS One 2009;4:e8041.
- 28. Fothergill A, Kasinathan V, Hyman J, Walsh J, Drake T, Wang YF. Rapid identification of bacteria and yeasts from positive-blood-culture bottles by using a lysis-filtration method and matrix-assisted laser desorption ionization-time of flight mass spectrum analysis with the SARAMIS database. J Clin Microbiol 2013;51:805-9.
- 29. Health and Safety Executive. Safe use of pneumatic air tube transport systems for pathology specimens. 9/99.
- 30. Department for transport. Transport of Infectious Substances, 2011 Revision 5. 2011.
- 31. World Health Organization. Guidance on regulations for the Transport of Infectious Substances 2013-2014. 2012.
- 32. Home Office. Anti-terrorism, Crime and Security Act. 2001 (as amended).
- 33. Advisory Committee on Dangerous Pathogens. The Approved List of Biological Agents. Health and Safety Executive. 2013. p. 1-32
- 34. Advisory Committee on Dangerous Pathogens. Infections at work: Controlling the risks. Her Majesty's Stationery Office. 2003.
- 35. Advisory Committee on Dangerous Pathogens. Biological agents: Managing the risks in laboratories and healthcare premises. Health and Safety Executive. 2005.
- 36. Advisory Committee on Dangerous Pathogens. Biological Agents: Managing the Risks in Laboratories and Healthcare Premises. Appendix 1.2 Transport of Infectious Substances Revision. Health and Safety Executive. 2008.
- 37. Centers for Disease Control and Prevention. Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories. MMWR Surveill Summ 2012;61:1-102.

- 38. Health and Safety Executive. Control of Substances Hazardous to Health Regulations. The Control of Substances Hazardous to Health Regulations 2002. 5th ed. HSE Books; 2002.
- 39. Health and Safety Executive. Five Steps to Risk Assessment: A Step by Step Guide to a Safer and Healthier Workplace. HSE Books. 2002.
- 40. Health and Safety Executive. A Guide to Risk Assessment Requirements: Common Provisions in Health and Safety Law. HSE Books. 2002.
- 41. Health Services Advisory Committee. Safe Working and the Prevention of Infection in Clinical Laboratories and Similar Facilities. HSE Books. 2003.
- 42. British Standards Institution (BSI). BS EN12469 Biotechnology performance criteria for microbiological safety cabinets. 2000.
- 43. British Standards Institution (BSI). BS 5726:2005 Microbiological safety cabinets. Information to be supplied by the purchaser and to the vendor and to the installer, and siting and use of cabinets. Recommendations and guidance. 24-3-2005. p. 1-14
- 44. Barber S, Lawson PJ, Grove DI. Evaluation of bacteriological transport swabs. Pathology 1998;30:179-82.
- 45. Baron EJ, Miller JM, Weinstein MP, Richter SS, Gilligan PH, Thomson RB, Jr., et al. A Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2013 Recommendations by the Infectious Diseases Society of America (IDSA) and the American Society for Microbiology (ASM). Clin Infect Dis 2013;57:e22-e121.
- 46. Rishmawi N, Ghneim R, Kattan R, Ghneim R, Zoughbi M, Abu-Diab A, et al. Survival of fastidious and nonfastidious aerobic bacteria in three bacterial transport swab systems. J Clin Microbiol 2007;45:1278-83.
- 47. Van Horn KG, Audette CD, Sebeck D, Tucker KA. Comparison of the Copan ESwab system with two Amies agar swab transport systems for maintenance of microorganism viability. J Clin Microbiol 2008;46:1655-8.
- 48. Nys S, Vijgen S, Magerman K, Cartuyvels R. Comparison of Copan eSwab with the Copan Venturi Transystem for the quantitative survival of *Escherichia coli, Streptococcus agalactiae* and *Candida albicans*. Eur J Clin Microbiol Infect Dis 2010;29:453-6.
- 49. Tano E, Melhus A. Evaluation of three swab transport systems for the maintenance of clinically important bacteria in simulated mono- and polymicrobial samples. APMIS 2011;119:198-203.
- 50. Bouza E, Guembe M, Gomez H, Martin-Rabadan P, Rivera M, Alcala L. Are central venous catheter tip cultures reliable after 6-day refrigeration? Diagn Microbiol Infect Dis 2009;64:241-6.

- 51. Collignon PJ, Munro R. Laboratory diagnosis of intravascular catheter associated sepsis. Eur J Clin Microbiol Infect Dis 1989;8:807-14.
- 52. Kristinsson KG, Burnett IA, Spencer RC. Evaluation of three methods for culturing long intravascular catheters. J Hosp Infect 1989;14:183-91.
- 53. Maki DG, Weise CE, Sarafin HW. A semiquantitative culture method for identifying intravenous-catheter-related infection. N Engl J Med 1977;296:1305-9.
- 54. Cleri DJ, Corrado ML, Seligman SJ. Quantitative culture of intravenous catheters and other intravascular inserts. J Infect Dis 1980;141:781-6.
- 55. Tighe MJ, Kite P, Fawley WN, Thomas D, McMahon MJ. An endoluminal brush to detect the infected central venous catheter in situ: a pilot study. BMJ 1996;313:1528-9.
- 56. Cooper GL, Hopkins CC. Rapid diagnosis of intravascular catheter-associated infection by direct Gram staining of catheter segments. N Engl J Med 1985;312:1142-7.
- 57. Zufferey J, Rime B, Francioli P, Bille J. Simple method for rapid diagnosis of catheter-associated infection by direct acridine orange staining of catheter tips. J Clin Microbiol 1988;26:175-7.
- 58. Murray CK, Beckius ML, Green JA, Hospenthal DR. Use of chromogenic medium in the isolation of yeasts from clinical specimens. J Med Microbiol 2005;54:981-5.
- 59. Bouchara JP, Declerck P, Cimon B, Planchenault C, de GL, Chabasse D. Routine use of CHROMagar Candida medium for presumptive identification of Candida yeast species and detection of mixed fungal populations. Clin Microbiol Infect 1996;2:202-8.
- 60. Colston J, Batchelor B, Bowler IC. Cost savings and clinical acceptability of an intravascular line tip culture triage policy. J Hosp Infect 2013;84:77-80.
- 61. Kurtzman CP, Fell JW, Boekout T, Robert V. Methods for isolation, phenotypic characterization and maintenance of yeasts. The yeasts, a taxonomic study. 5 ed. Elsevier, Amsterdam; 2011. p. 87-110.
- 62. Warwick S, Wilks M, Hennessy E, Powell-Tuck J, Small M, Sharp J, et al. Use of quantitative 16S ribosomal DNA detection for diagnosis of central vascular catheter-associated bacterial infection. J Clin Microbiol 2004;42:1402-8.
- 63. Cattoir V, Merabet L, Djibo N, Rioux C, Legrand P, Girou E, et al. Clinical impact of a real-time PCR assay for rapid identification of Staphylococcus aureus and determination of methicillin resistance from positive blood cultures. Clin Microbiol Infect 2011;17:425-31.
- 64. Public Health England. Laboratory Reporting to Public Health England: A Guide for Diagnostic Laboratories. 2013. p. 1-37.
- 65. Department of Health. Health Protection Legislation (England) Guidance. 2010. p. 1-112.

Bacteriology | B 20 | Issue no: 6.2 | Issue date: 17.10.25 | Page: 25 of 26

- 66. Scottish Government. Public Health (Scotland) Act. 2008 (as amended).
- 67. Scottish Government. Public Health etc. (Scotland) Act 2008. Implementation of Part 2: Notifiable Diseases, Organisms and Health Risk States. 2009.
- 68. The Welsh Assembly Government. Health Protection Legislation (Wales) Guidance. 2010.
- 69. Home Office. Public Health Act (Northern Ireland) 1967 Chapter 36. 1967 (as amended).