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 http://www.hpa.org.uk/SMI/Partnerships. SMIs are developed, reviewed and revised by various working groups which are overseen by a steering committee (see http://www.hpa.org.uk/SMI/WorkingGroups).

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

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Website: http://www.hpa.org.uk/SMI

UK Standards for Microbiology Investigations are produced in association with:
**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.

<table>
<thead>
<tr>
<th>Amendment No/Date.</th>
<th>9/02.04.14</th>
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**Section(s) involved**

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<tbody>
<tr>
<td>Whole document.</td>
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<tr>
<td>Document has been transferred to a new template to reflect the Health Protection Agency’s transition to Public Health England.</td>
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<tr>
<td>Front page has been redesigned.</td>
</tr>
<tr>
<td>Status page has been renamed as Scope and Purpose and updated as appropriate.</td>
</tr>
<tr>
<td>Professional body logos have been reviewed and updated.</td>
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<tr>
<td>Standard safety and notification references have been reviewed and updated.</td>
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<td>Scientific content remains unchanged.</td>
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**Section(s) involved**

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<tr>
<td>Whole document.</td>
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<td>Document presented in a new format.</td>
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<tr>
<td>The term “CE marked leak proof container” replaces “sterile leak proof container” (where appropriate) and is referenced to specific text in the EU in vitro Diagnostic Medical Devices Directive (98/79/EC Annex 1 B 2.1) and to Directive itself EC1,2.</td>
</tr>
<tr>
<td>Minor textual changes.</td>
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<tr>
<td>Sections on specimen collection, transport, storage</td>
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<td>and processing.</td>
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<tr>
<td>References.</td>
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</table>
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 http://www.hpa.org.uk/SMI/Partnerships. Inclusion of a logo in an SMI indicates participation of the society in equal partnership and support for the objectives and process of preparing SMIs. Nominees of professional societies are members of the Steering Committee and Working Groups which develop SMIs. The views of nominees cannot be rigorously representative of the members of their nominating organisations nor the corporate views of their organisations. Nominees act as a conduit for two way reporting and dialogue. Representative views are sought through the consultation process. SMIs are developed, reviewed and updated through a wide consultation process.

Quality Assurance

NICE has accredited the process used by the SMI Working Groups to produce SMIs. The accreditation is applicable to all guidance produced since October 2009. The process for the development of SMIs is certified to ISO 9001:2008. SMIs represent a good standard of practice to which all clinical and public health microbiology laboratories in the UK are expected to work. SMIs are NICE accredited and represent

Microbiology is used as a generic term to include the two GMC-recognised specialties of Medical Microbiology (which includes Bacteriology, Mycology and Parasitology) and Medical Virology.
neither minimum standards of practice nor the highest level of complex laboratory investigation possible. In using SMIs, laboratories should take account of local requirements and undertake additional investigations where appropriate. SMIs help laboratories to meet accreditation requirements by promoting high quality practices which are auditable. SMIs also provide a reference point for method development. The performance of SMIs depends on competent staff and appropriate quality reagents and equipment. Laboratories should ensure that all commercial and in-house tests have been validated and shown to be fit for purpose. Laboratories should participate in external quality assessment schemes and undertake relevant internal quality control procedures.

**Patient and Public Involvement**

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

**Information Governance and Equality**

PHE is a Caldicott compliant organisation. It seeks to take every possible precaution to prevent unauthorised disclosure of patient details and to ensure that patient-related records are kept under secure conditions. The development of SMIs are subject to PHE Equality objectives [http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1317133470313](http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1317133470313).

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

**Legal Statement**

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

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

SMIs are Crown copyright which should be acknowledged where appropriate.

**Suggested Citation for this Document**

Scope of Document

Type of Specimen
Mouth swab

Scope

This SMI describes the processing and bacteriological investigation of mouth swabs.
This SMI should be used in conjunction with other SMIs.

Introduction

Candidosis
Candidosis is the most frequent type of oral infection. Infection of the buccal mucosa, tongue or oropharynx is usually due to Candida albicans. Species of yeast other than C. albicans, such as Candida krusei and Candida glabrata, can also occasionally colonise the mouth but are rarely associated with infection. However, they are becoming increasingly important, particularly in patients who are immunocompromised.

Cancrum oris (Noma or Gangrenous Stomatitis)
Cancrum oris (noma or gangrenous stomatitis) is a necrotising polymicrobial infection, rarely seen in the UK, arising in the severely debilitated and malnourished, with children most often affected particularly in Africa. It is usually preceded by ulcerative (Vincent’s) gingivitis. Vincent’s gingivitis is diagnosed by microscopy, and the appearance of a fusospirochetal complex is pathognomonic for the disease.

Sialadenitis
Sialadenitis, or infections of the salivary glands (parotid, submandibular, sublingual and accessory parotid), include suppurative, chronic bacterial and viral parotitis.

Parotitis
Parotitis may result in pus exuding from the parotid glands, which is sampled via the mouth. The predominant organisms causing suppurative parotitis are staphylococci, but members of the enterobacteriaceae and other Gram negative bacilli, viridans streptococci and anaerobes have been isolated. Chronic bacterial parotitis is due to staphylococci, or mixed oral aerobes and anaerobes. Mumps, influenza and enteroviruses are the usual viral agents of parotitis.

Other infective causes of oral ulceration include syphilis, herpes simplex virus and Mycobacterium species. Fungi may attack the sinuses and encroach on the palate, eg Aspergillus species. Infection with Histoplasma can lead to ulceration of oral mucosa.

Specimens which may be submitted for the investigation of dental abscesses include pus (refer to B 14 - Investigation of Abscesses and Deep-Seated Wound Infections).
Technical Information/Limitations

Limitations of UK SMIs
The recommendations made in UK SMIs are based on evidence (e.g., 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.

Specimen Containers¹,²
SMIs use the term, “CE marked leak proof container,” to describe containers bearing the CE marking used for the collection and transport of clinical specimens. The requirements for specimen containers are given in the EU in vitro Diagnostic Medical Devices Directive (98/79/EC Annex 1 B 2.1) which states: “The design must allow easy handling and, where necessary, reduce as far as possible contamination of, and leakage from, the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen. The manufacturing processes must be appropriate for these purposes.”
1 Safety Considerations

1.1 Specimen Collection, Transport and Storage

Use aseptic technique.
Collect swabs into appropriate transport medium and transport in sealed plastic bags.
Compliance with postal and transport regulations is essential.

1.2 Specimen Processing

Containment Level 2.
Laboratory procedures that give rise to infectious aerosols must be conducted in a microbiological safety cabinet.
Refer to current guidance on the safe handling of all organisms documented in this SMI.
The above guidance should be supplemented with local COSHH and risk assessments.

2 Specimen Collection

2.1 Type of Specimens

Mouth swab
Sample pus if present, otherwise sample any lesions or inflamed areas. A tongue depressor or spatula may be helpful to aid vision and avoid contamination from other parts of the mouth.

2.2 Optimal Time and Method of Collection

For safety considerations refer to Section 1.1.
Collect specimens before antimicrobial therapy where possible.
Unless otherwise stated, swabs for bacterial and fungal culture should be placed in appropriate transport medium.

2.3 Adequate Quantity and Appropriate Number of Specimens

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

3 Specimen Transport and Storage

3.1 Optimal Transport and Storage Conditions

For safety considerations refer to Section 1.1.
Specimens should be transported and processed as soon as possible.
If processing is delayed, refrigeration is preferable to storage at ambient temperature.
4 Specimen Processing\textsuperscript{1,2}

4.1 Test Selection
N/A

4.2 Appearance
N/A

4.3 Sample Preparation
For safety considerations refer to Section 1.2.

4.4 Microscopy

4.4.1 Standard
(Refer to TP 39 – Staining Procedures).
Stain for Vincent's organisms if clinically indicated.

4.4.2 Supplementary
N/A

4.5 Culture and Investigation

4.5.1 Pre-treatment
N/A

4.5.2 Specimen processing
Inoculate each agar plate with swab (refer to Q 5 - Inoculation of Culture Media for Bacteriology).
For the isolation of individual colonies, spread inoculum with a sterile loop.

4.5.3 Culture media, conditions and organisms for all specimens:

<table>
<thead>
<tr>
<th>Clinical details/ conditions</th>
<th>Specimen</th>
<th>Standard media</th>
<th>Incubation</th>
<th>Cultures read</th>
<th>Target organism(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Standard media</td>
<td>Temp °C</td>
<td>Atmos</td>
<td>Time</td>
</tr>
<tr>
<td>Oral candidosis Fungal infection</td>
<td>Mouth swabs</td>
<td>Sabouraud agar</td>
<td>35-37</td>
<td>air</td>
<td>40-48hr</td>
</tr>
</tbody>
</table>

For this situation, add the following:

<table>
<thead>
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<th>Clinical details/ conditions</th>
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<th>Supplementary media</th>
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<th>Cultures read</th>
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<td></td>
<td></td>
<td></td>
<td>Temp °C</td>
<td>Atmos</td>
<td>Time</td>
</tr>
<tr>
<td>Mouth ulcer</td>
<td>Mouth swabs</td>
<td>Blood agar</td>
<td>35-37</td>
<td>5-10% CO2</td>
<td>16-24hr</td>
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</tbody>
</table>
4.6 Identification
Refer to individual SMIs for organism identification.

4.6.1 Minimum level in the laboratory

<table>
<thead>
<tr>
<th>Lancefield group A streptococcus</th>
<th>Lancefield group level</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>S. aureus</em></td>
<td>species level</td>
</tr>
<tr>
<td>Yeasts</td>
<td>&quot;yeasts&quot; level</td>
</tr>
</tbody>
</table>

4.7 Antimicrobial Susceptibility Testing
Refer to British Society for Antimicrobial Chemotherapy (BSAC) and/or EUCAST guidelines.

4.8 Referral for Outbreak Investigations
N/A

4.9 Referral to Reference Laboratories
For information on the tests offered, 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

Scotland

Northern Ireland
http://www.publichealth.hscni.net/directorate-public-health/health-protection

5 Reporting Procedure

5.1 Microscopy

5.1.1 Microscopy reporting time
Urgent microscopy results to be telephoned or sent electronically.
Written report, 16–72hr for Vincent's organisms.

5.2 Culture

Report clinically significant organisms isolated or
Report other growth, eg: “Mixed upper respiratory tract flora,” or
Report absence of growth.

5.2.1 Culture reporting time

Clinically urgent culture results to be telephoned or sent electronically.
Written report, 16–72hr stating, if appropriate, that a further report will be issued.

5.3 Antimicrobial Susceptibility Testing

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

6 Notification to PHE\textsuperscript{31,32} or Equivalent in the Devolved Administrations\textsuperscript{33-36}

The Health Protection (Notification) regulations 2010 require diagnostic laboratories to notify Public Health England (PHE) when they identify the causative agents that are listed in Schedule 2 of the Regulations. Notifications must be provided in writing, on paper or electronically, within seven days. Urgent cases should be notified orally and as soon as possible, recommended within 24 hours. These should be followed up by written notification within seven days.

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

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

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

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

Other arrangements exist in Scotland\textsuperscript{33,34}, Wales\textsuperscript{35} and Northern Ireland\textsuperscript{36}. 
Appendix: Investigation of Mouth Swabs

Prepare all specimens

All specimens from Oral candidosis Fungal Infection

Sabouraud agar

Incubate at 35-37°C Air
40-48hr
Read ≥ 40hr*

Yeast Fungi

All specimens from Mouth ulcer

Blood agar

Incubate at 35-37°C 5-10% CO₂
16-24hr
Read ≥ 16hr*

Lancefield group A streptococcus refer to ID 4
S.aureus refer to ID 7

*Fungal culture may need to be prolonged if clinically indicated; in such cases plates should be read at ≥ 40hr and then left in the incubator/cabinet until required.
References

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


