



UK Standards for Microbiology Investigations

Investigation of Ear Infections and Associated Specimens



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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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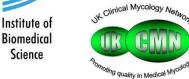






























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NICE has accredited the process used by Public Health England to produce Standards for Microbiology Investigations. Accreditation is valid for 5 years from July 2011. More information on accreditation can be viewed at www.nice.org.uk/accreditation.

For full details on our accreditation visit: www.nice.org.uk/accreditation.

Amendment Table

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

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

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

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

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.

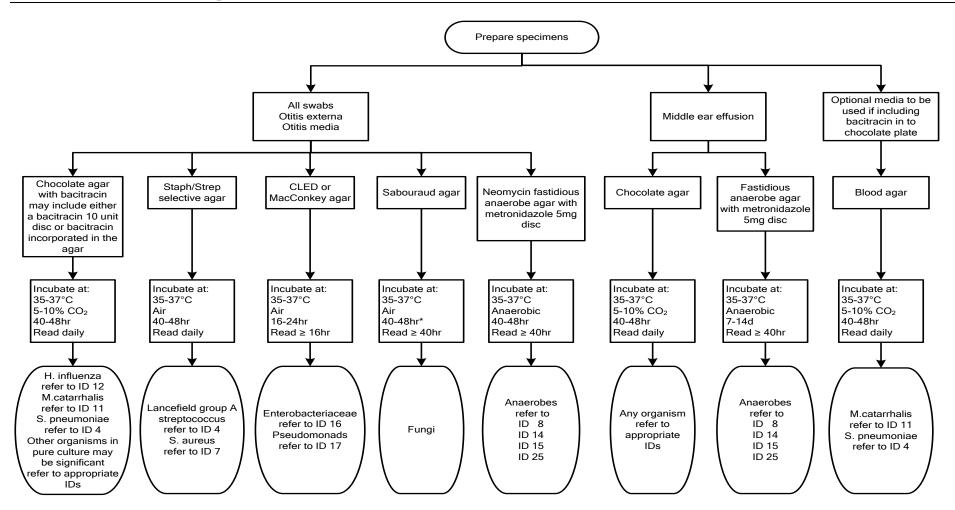
Investigation of Ear Infections and Associated Specimens

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 <u>Scotland</u>^{33,34}, <u>Wales</u>³⁵ and <u>Northern Ireland</u>³⁶.

Appendix: Investigation of Ear Swabs and Associated Specimens



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

References

- Geyer M, Howell-Jones R, Cunningham R, McNulty C. Consensus of microbiology reporting of ear swab results to primary care clinicians in patients with otitis externa. Br J Biomed Sci 2011;68:174-80
- 2. Narayan S, Swift A. Otitis externa: a clinical review. Br J Hosp Med (Lond) 2011;72:554-8.
- 3. Gould JM, Matz PS. Otitis media. Pediatr Rev 2010;31:102-16.
- 4. Cunningham M, Guardiani E, Kim HJ, Brook I. Otitis media. Future Microbiol 2012;7:733-53.
- Wald ER. Acute otitis media and acute bacterial sinusitis. Clin Infect Dis 2011;52 Suppl 4:S277-S283.
- 6. 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".
- 7. 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.
- 8. Health and Safety Executive. Safe use of pneumatic air tube transport systems for pathology specimens. 9/99.
- 9. Department for transport. Transport of Infectious Substances, 2011 Revision 5. 2011.
- 10. World Health Organization. Guidance on regulations for the Transport of Infectious Substances 2013-2014. 2012.
- 11. Home Office. Anti-terrorism, Crime and Security Act. 2001 (as amended).
- 12. Advisory Committee on Dangerous Pathogens. The Approved List of Biological Agents. Health and Safety Executive. 2013. p. 1-32
- 13. Advisory Committee on Dangerous Pathogens. Infections at work: Controlling the risks. Her Majesty's Stationery Office. 2003.
- 14. Advisory Committee on Dangerous Pathogens. Biological agents: Managing the risks in laboratories and healthcare premises. Health and Safety Executive. 2005.
- 15. 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.
- 16. 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.
- 17. 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.

- 18. Health and Safety Executive. Five Steps to Risk Assessment: A Step by Step Guide to a Safer and Healthier Workplace. HSE Books. 2002.
- 19. Health and Safety Executive. A Guide to Risk Assessment Requirements: Common Provisions in Health and Safety Law. HSE Books. 2002.
- 20. Health Services Advisory Committee. Safe Working and the Prevention of Infection in Clinical Laboratories and Similar Facilities. HSE Books. 2003.
- 21. British Standards Institution (BSI). BS EN12469 Biotechnology performance criteria for microbiological safety cabinets. 2000.
- 22. 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
- 23. 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.
- 24. Barber S, Lawson PJ, Grove DI. Evaluation of bacteriological transport swabs. Pathology 1998;30:179-82.
- 25. 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.
- 26. 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.
- 27. 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.
- 28. 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.
- 29. Jousimies-Somer H, Summanen P, Citron D. Advanced Identification Methods. Anaerobic Bacteriology Manual. 6th ed. Star Publishing Company; 2002. p. 104.
- 30. Nye KJ, Fallon D, Gee B, Howe S, Messer S, Turner T, et al. A comparison of the performance of bacitracin-incorporated chocolate blood agar with chocolate blood agar plus a bacitracin disk in the isolation of Haemophilus influenzae from sputum. J Med Microbiol 2001;50:472-5.
- 31. Public Health England. Laboratory Reporting to Public Health England: A Guide for Diagnostic Laboratories. 2013. p. 1-37.
- 32. Department of Health. Health Protection Legislation (England) Guidance. 2010. p. 1-112.
- 33. Scottish Government. Public Health (Scotland) Act. 2008 (as amended).
- 34. Scottish Government. Public Health etc. (Scotland) Act 2008. Implementation of Part 2: Notifiable Diseases, Organisms and Health Risk States. 2009.
- 35. The Welsh Assembly Government. Health Protection Legislation (Wales) Guidance. 2010.
- 36. Home Office. Public Health Act (Northern Ireland) 1967 Chapter 36. 1967 (as amended).