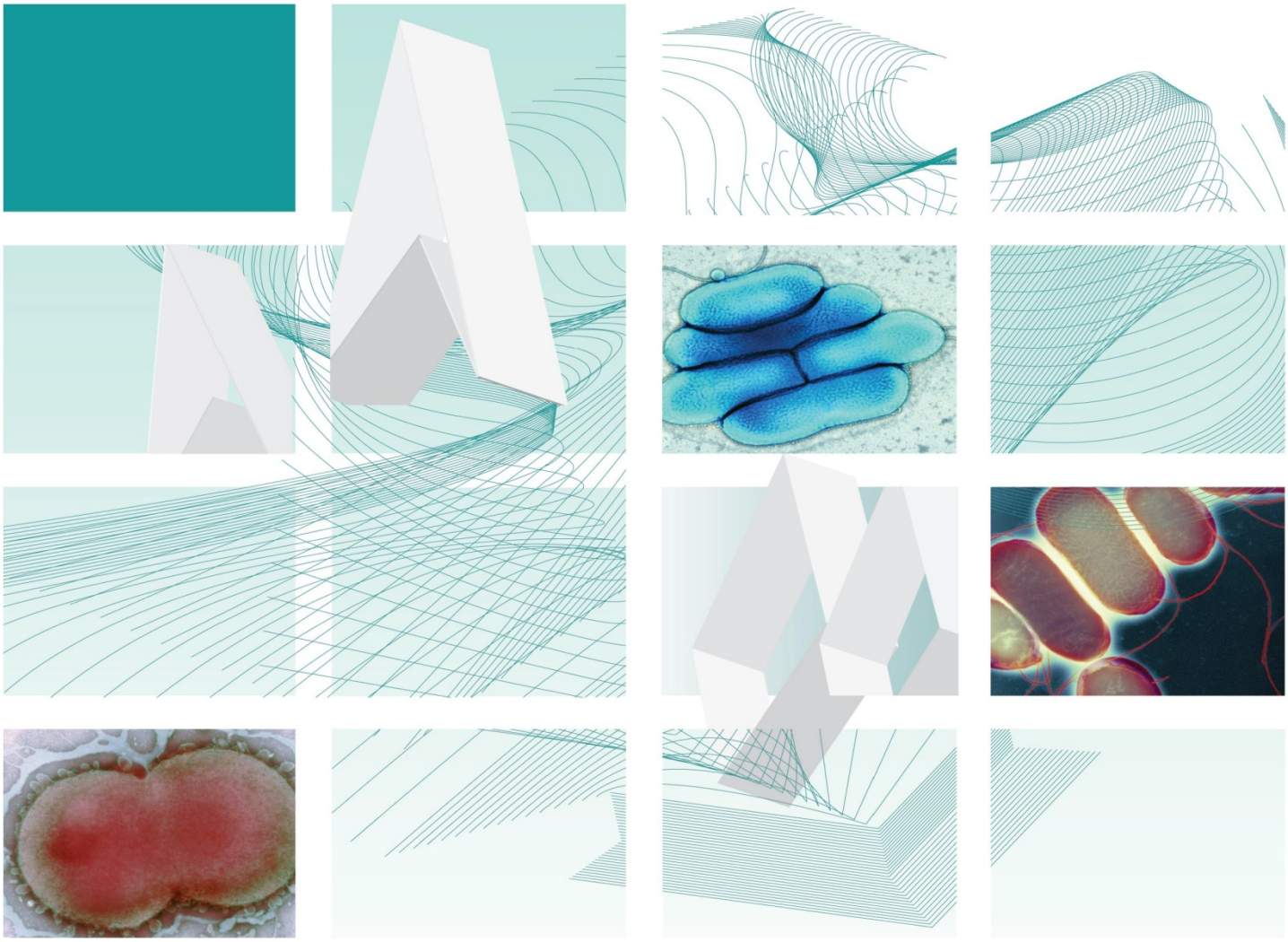
Public Health England

NHS

UK Standards for Microbiology Investigations

Example Reference Strains For UK Standards for Microbiology Investigations Test Procedures



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Bacteriology – Test Procedures | TP 1 | Issue no: 2 | Issue date: 05.01.15 | Page: 1 of 13

Acknowledgments

UK Standards for Microbiology Investigations (SMIs) are developed under the auspices of Public Health England (PHE) working in partnership with the National Health Service (NHS), Public Health Wales and with the professional organisations whose logos are displayed below and listed on the website https://www.gov.uk/uk-standards-for-microbiology-investigations-smi-quality-and-consistency-in-clinical-laboratories. SMIs are developed, reviewed and revised by various working groups which are overseen by a steering committee (see https://www.gov.uk/government/groups/standards-for-microbiology-investigations-steering-committee).

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

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UK Standards for Microbiology Investigations are produced in association with:

Logos correct at time of publishing.

Contents

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.	3/05.01.15
Issue no. discarded.	1.2
Insert Issue no.	2
Section(s) involved	**Amendment**
Whole document.	Hyperlinks updated to gov.uk.
Page 2.	Updated logos added.
Quality Control Organisms.	This section has been updated with the NCTC strains that are currently used. All tests have been validated apart from the Nagler test.

UK Standards for Microbiology Investigations[#]: Scope and Purpose

Users of SMIs

- SMIs are primarily intended as a general resource for practising professionals operating in the field of laboratory medicine and infection specialties in the UK.
- SMIs 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.
- SMIs provide commissioners of healthcare services with the appropriateness and standard of microbiology investigations they should be seeking as part of the clinical and public health care package for their population.

Background to SMIs

SMIs comprise a collection of recommended algorithms and procedures covering all stages of the investigative process in microbiology from the pre-analytical (clinical syndrome) stage to the analytical (laboratory testing) and post analytical (result interpretation and reporting) stages.

Syndromic algorithms are supported by more detailed documents containing advice on the investigation of specific diseases and infections. Guidance notes cover the clinical background, differential diagnosis, and appropriate investigation of particular clinical conditions. Quality guidance notes describe laboratory processes which underpin quality, for example assay validation.

Standardisation of the diagnostic process through the application of SMIs helps to assure the equivalence of investigation strategies in different laboratories across the UK and is essential for public health surveillance, research and development activities.

Equal Partnership Working

SMIs are developed in equal partnership with PHE, NHS, Royal College of Pathologists and professional societies.

The list of participating societies may be found at https://www.gov.uk/uk-standards-for-microbiology-investigations-smi-quality-and-consistency-in-clinical-laboratories. Inclusion of a logo in an SMI indicates participation of the society in equal partnership and support for the objectives and process of preparing SMIs. Nominees of professional societies are members of the Steering Committee and Working Groups which develop SMIs. The views of nominees cannot be rigorously representative of the members of their nominating organisations nor the corporate views of their organisations. Nominees act as a conduit for two way reporting and dialogue. Representative views are sought through the consultation process.

SMIs are developed, reviewed and updated through a wide consultation process.

[#]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.

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 neither minimum standards of practice nor the highest level of complex laboratory investigation possible. In using SMIs, laboratories should take account of local requirements and undertake additional investigations where appropriate. SMIs help laboratories to meet accreditation requirements by promoting high quality practices which are auditable. SMIs also provide a reference point for method development.

The performance of SMIs depends on competent staff and appropriate quality reagents and equipment. Laboratories should ensure that all commercial and in-house tests have been validated and shown to be fit for purpose. Laboratories should participate in external quality assessment schemes and undertake relevant internal quality control procedures.

Patient and Public Involvement

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

Information Governance and Equality

PHE is a Caldicott compliant organisation. It seeks to take every possible precaution to prevent unauthorised disclosure of patient details and to ensure that patient-related records are kept under secure conditions.

The development of SMIs are subject to PHE Equality objectives https://www.gov.uk/government/organisations/public-health-england/about/equality-and-diversity. The SMI Working Groups are committed to achieving the equality objectives by effective consultation with members of the public, partners, stakeholders and specialist interest groups.

Legal Statement

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

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

SMIs are Crown copyright which should be acknowledged where appropriate.

Suggested Citation for this Document

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Scope of Document

This SMI is designed as a stand-alone document giving information on example reference material that can be used as control strains for the range of test procedures covered in the UK Standards for Microbiology Investigations (SMI) Test Procedures. This document contains information on the reference material and does not include information on how to carry out the test procedure which can be found in the individual Test Procedures available through the UK Standards for Microbiology Investigations Website. In all cases the reference material should be an authenticated reference culture from a recognised national culture collection.

Note: the organisms are not all necessarily type strains.

Reference materials can be provided by the Public Health England Culture Collections, National Collection of Type Cultures (NCTC) (http://www.phe-culturecollections.org.uk/) or from equivalent organisations including the American Type Culture Collection. The reference strains listed in this document are commonly used and have been validated by NCTC for the tests shown otherwise where indicated.

This SMI should be used in conjunction with other SMIs.

Introduction

Use of appropriate reference material alongside the test procedure is crucial to ensure reliability of results. Appropriate controls are needed to ensure that the test is working within defined limits. If the reference material fails to give a positive or negative result (as appropriate) for the test it is used in and it is the appropriate control then the validity of the results is questionable. If this is the case the reason for failure should be fully investigated and where necessary the test should be repeated and a review of the process performed. The use of controls is recognised as good laboratory practice and a recognised part of any accreditation process.

Technical Information/Limitations

Cryovials™ should be returned to -80°C as quickly as possible as excessive changes in temperature reduce the viability of the organisms.

It is good practice to record all subcultures on a record sheet. If any contamination is evident on the working cultures before the normal replacement time, fresh ones should be prepared from the reference bead stock.

It is important to check and ensure that the control organisms give the correct results before routine use. Any inconsistent results need investigation.

1 Safety Considerations[1-17]

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

All work likely to generate aerosols must be performed in a microbiological safety cabinet.

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

2 Reagents and Equipment

Incubator - both oxygen and carbon dioxide.

Anaerobic jars.

3 Quality Control Organisms

3.1 Table of Example Reference NCTC Strains

UK SMI	Example Reference Strain		
TP 2 – Aesculin Hydrolysis Test	**Positive control** **Negative control**	*Enterococcus faecalis* *Streptococcus agalactiae*	NCTC 12697 NCTC 8181
TP 3 – Agglutination Test	**Positive control** **Negative control**	N/A	
TP 5 – Bile Solubility Test	**Positive control** **Negative control**	*Streptococcus pneumoniae* *Streptococcus mitis*	NCTC 12977 NCTC 10712
TP 8 – Catalase Test	**Positive control** **Negative control**	*Staphylococcus aureus* *Streptococcus mitis*	NCTC 6571 NCTC 10712
TP 10 – Coagulase Test	**Positive control** **Negative control**	*Staphylococcus aureus* *Staphylococcus haemolyticus*	NCTC 6571 NCTC 11042
TP 12 – Deoxyribonuclease Test	**Positive control** **Negative control**	*Staphylococcus aureus* *Staphylococcus haemolyticus*	NCTC 6571 NCTC 11042
TP 19 – Indole Test	**Positive control** **Negative control**	*Escherichia coli* *Proteus mirabilis*	NCTC 10418 NCTC 10975
TP 21 – Motility Test	**Positive control** **Negative control**	*Proteus mirabilis* *Acinetobacter lwoffii*	NCTC 10975 NCTC 5866
TP 22 – Nagler Test	**Positive control** **Negative control**	*Clostridium perfringens* *Clostridium difficile*	NCTC 8359* NCTC 11204*
TP 24 - ONPG (ß-Galactosidase) Test (for	**Positive control**	*Escherichia coli*	NCTC 10418

Enterobacteriaceae)	**Negative control**	*Proteus mirabilis*	NCTC 10975
TP 24 - ONPG (ß-Galactosidase) Test (for *Neisseria* species	**Positive control** **Negative control**	*Neisseria lactamica* *Neisseria gonorrhoeae*	NCTC 10617 NCTC 8375
TP 25 – Optochin Test	**Positive control** **Negative control**	*Streptococcus pneumoniae* *Streptococcus mitis*	NCTC 12977 NCTC 10712
TP 26 – Oxidase Test	**Positive control** **Negative control**	*Pseudomonas aeruginosa* *Escherichia coli*	NCTC 10662 NCTC 10418
TP 27 – Oxidation/Fermentation of Glucose Test (Gram negative rods)	**Oxidation:** **Positive control** **Negative control**	*Pseudomonas aeruginosa* *Acinetobacter Iwoffii*	NCTC 10662 NCTC 5866
	Fermentation: **Positive control** **Negative control**	*Escherichia coli* *Acinetobacter Iwoffii*	NCTC 10418 NCTC 5866
TP 27 – Oxidation/Fermentation of Glucose Test (Gram positive cocci)	**Oxidation:** **Positive control** **Negative control**	*Micrococcus luteus* OF basal medium without carbohydrate	NCTC 2665
	Fermentation: **Positive control** **Negative control**	*Staphylococcus aureus* OF basal medium without carbohydrate	NCTC 6571
TP 29 – Porphyrin synthesis (ALA) Test	**Positive control** **Negative control**	*Haemophilus parainfluenzae* *Haemophilus influenzae*	NCTC 10665 NCTC 11931
TP 30 - Potassium Hydroxide Test	**Positive control** **Negative control**	*Escherichia coli* *Staphylococcus aureus*	NCTC 10418 NCTC 6571
TP 32 - Changing the Phase of *Salmonella*	**Positive control** **Negative control**	N/A	
TP 34 – Thermonuclease Test	**Positive control** **Negative control**	*Staphylococcus aureus* *Staphylococcus haemolyticus*	NCTC 6571 NCTC 11042
TP 36 – Urease Test	**Positive control** **Negative control**	*Proteus mirabilis* *Escherichia coli*	NCTC 10975 NCTC 10418
TP 38 – X and V factor Test	**X and V factor**	*Haemophilus influenzae*	NCTC 11931
	V factor only	*Haemophilus parainfluenzae*	NCTC 10665
	X factor only	*Haemophilus haemoglobinophilus*	NCTC 8540*

*The reference strains have not been validated by NCTC for the tests shown.

There is validation data for all the strains tested.

4 Procedure and Results

The reference material on receipt must be rehydrated in accordance with any NCTC (or equivalent) guidelines. The reference material should be sub-cultured to appropriate non-selective media and incubated using the correct atmosphere and temperature. If the culture is to be stored for future use, this should be done in such a way as to ensure optimum recovery. It is suggested that micro Cryovials™, which contain a cryopreservative, are used. These should be inoculated with young colonial growth (18-24hr old) from the subculture to approximately a 3-4 McFarland standard. The vial should be closed tightly and inverted 4-5 times to emulsify the organisms. Do not vortex. The organisms are then bound to the porous beads. The excess cryopreservative should be aspirated with a sterile pastette leaving the beads as free of liquid as possible. Re-close the vial finger tight. Label the vial with the corresponding storage number, NCTC (or equivalent) number, name and date. These beads constitute the reference bead stock and are stored at -80°C. A second set of beads should be made which constitutes the working stock culture.

One bead from each working stock should be sub-cultured to an appropriate non-selective medium monthly, to prepare plate cultures. Under aseptic conditions, open the Cryovial™ and with a sterile needle or forceps, remove one bead. The inoculated bead may be directly streaked on the appropriate plate culture medium. The plates must be clearly labelled with name of organism, date of subculture and NCTC number (or equivalent). The plate cultures may be sub-cultured weekly to fresh plates, and every 4th week plates should be made from the Cryovial™ stock as above.

See relevant Test Procedure from UK Standards for Microbiology Investigations Website.

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".

2. 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.

3. Health and Safety Executive. Safe use of pneumatic air tube transport systems for pathology specimens. 9/99.

4. Department for transport. Transport of Infectious Substances, 2011 Revision 5. 2011.

5. World Health Organization. Guidance on regulations for the Transport of Infectious Substances 2013-2014. 2012.

6. Home Office. Anti-terrorism, Crime and Security Act. 2001 (as amended).

7. Advisory Committee on Dangerous Pathogens. The Approved List of Biological Agents. Health and Safety Executive. 2013. p. 1-32

8. Advisory Committee on Dangerous Pathogens. Infections at work: Controlling the risks. Her Majesty's Stationery Office. 2003.

9. Advisory Committee on Dangerous Pathogens. Biological agents: Managing the risks in laboratories and healthcare premises. Health and Safety Executive. 2005.

10. 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.

11. 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.

12. 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.

13. Health and Safety Executive. Five Steps to Risk Assessment: A Step by Step Guide to a Safer and Healthier Workplace. HSE Books. 2002.

14. Health and Safety Executive. A Guide to Risk Assessment Requirements: Common Provisions in Health and Safety Law. HSE Books. 2002.

15. Health Services Advisory Committee. Safe Working and the Prevention of Infection in Clinical Laboratories and Similar Facilities. HSE Books. 2003.

16. British Standards Institution (BSI). BS EN12469 - Biotechnology - performance criteria for microbiological safety cabinets. 2000.

17. 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