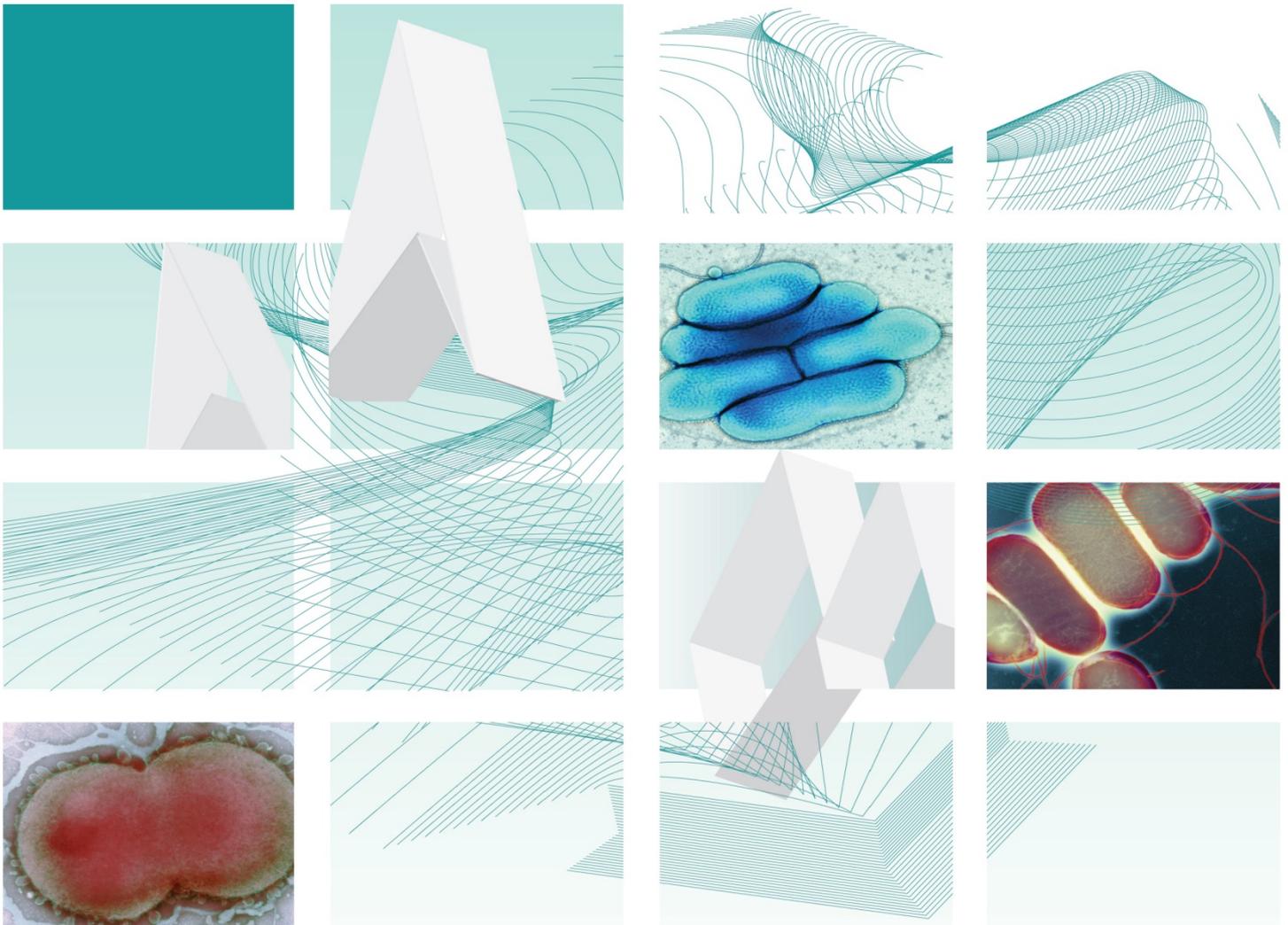




# UK Standards for Microbiology Investigations

Example reference strains for UK Standards for  
Microbiology Investigations test procedures



"NICE has renewed accreditation of the process used by **Public Health England (PHE)** to produce **UK Standards for Microbiology Investigations**. The renewed accreditation is valid until **30 June 2021** and applies to guidance produced using the processes described in **UK standards for microbiology investigations (UKSMIs) Development process, S9365', 2016**. The original accreditation term began in **July 2011**."

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Bacteriology – Test Procedures | TP 1 | Issue no: 3 | Issue date: 25.02.19 | Page: 1 of 18

## Acknowledgments

UK Standards for Microbiology Investigations (UK 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>. UK 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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Logos correct at time of publishing.

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## Amendment table

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Each UK 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](mailto:standards@phe.gov.uk).

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

Amendment number/date	4/25.02.19
Issue number discarded	2
Insert issue number	3
Anticipated next review date*	25.02.22
<b>Section(s) involved</b>	<b>Amendment</b>
Whole document.	<p>Document updated.</p> <p>UKSMI TP 39: staining procedures and TP 40: MALDI TOF MS have been added to the list of the test procedures added in the table.</p> <p>Technical limitations updated with subheadings.</p> <p>References updated and graded.</p> <p>Flowchart explaining the preparation and storage of reference strains created.</p> <p>TP 21: Nagler test removed from the list of Test Procedures as this document has been withdrawn.</p>
Quality control organisms.	<p>The NCTC 8540 strain for the X factor test only has been validated by NCTC.</p> <p>Alternative bacterial NCTC strains tested and validated for some phenotypic tests and EUCAST susceptibility tests.</p> <p>Fungal NCPF strains added to the document against the appropriate tests.</p>

\*Reviews can be extended up to five years subject to resources available.

## UK SMI<sup>#</sup>: scope and purpose

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### Users of UK SMIs

Primarily, UK SMIs are intended as a general resource for practising professionals operating in the field of laboratory medicine and infection specialties in the UK. 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 UK SMIs

UK 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. Quality guidance notes describe laboratory processes which underpin quality, for example assay validation.

Standardisation of the diagnostic process through the application of UK 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

UK 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 UK SMI indicates participation of the society in equal partnership and support for the objectives and process of preparing UK SMIs. Nominees of professional societies are members of the Steering Committee and working groups which develop UK 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. UK SMIs are developed, reviewed and updated through a wide consultation process.

### Quality assurance

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

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<sup>#</sup> 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.

accredited and represent neither minimum standards of practice nor the highest level of complex laboratory investigation possible. In using UK SMIs, laboratories should take account of local requirements and undertake additional investigations where appropriate. UK SMIs help laboratories to meet accreditation requirements by promoting high quality practices which are auditable. UK SMIs also provide a reference point for method development. The performance of UK 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 UK SMI working groups are committed to patient and public involvement in the development of UK SMIs. By involving the public, health professionals, scientists and voluntary organisations the resulting UK 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 UK SMIs is subject to PHE Equality objectives <https://www.gov.uk/government/organisations/public-health-england/about/equality-and-diversity>.

The UK 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

While every care has been taken in the preparation of UK SMIs, PHE and the partner organisations, 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 UK SMI or any information contained therein. If alterations are made by an end user to an UK SMI for local use, it must be made clear where in the document the alterations have been made and by whom such alterations have been made and also acknowledged that PHE and the partner organisations shall bear no liability for such alterations. For the further avoidance of doubt, as UK SMIs have been developed for application within the UK, any application outside the UK shall be at the user's risk.

The evidence base and microbial taxonomy for the UK SMI is as complete as possible at the date 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.

UK SMIs are Crown copyright which should be acknowledged where appropriate.

### Suggested citation for this document

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[standards-for-microbiology-investigations-smi-quality-and-consistency-in-clinical-laboratories](#)

## Scope of document

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This UK Standards for Microbiology Investigations (UK 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 SMIs. 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 webpages](#). In all cases the reference material should be an authenticated reference culture from a recognised 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. The reference strains listed in this document are commonly used and have been validated by NCTC for the tests shown otherwise where indicated.

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

## Introduction

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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

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### Viability of organisms

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

### Quality control

It is good practice to plate out reference controls weekly to maintain the organism's characteristics as well as record all subcultures on a record sheet. If any contamination is evident on the working cultures before the normal replacement time, fresh cultures 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.

### Repeated subculture of working stock culture<sup>1</sup>

The working stock culture should not be subcultured unless it is required and defined by a standard method or if laboratories can provide documentary evidence that there

has been no change in any relevant biological characteristics. However, it should be noted that working stocks should not be subcultured to replace the reference stocks.

## 1 Safety considerations<sup>2-19</sup>

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

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

It is recommended that all ampoules/vials are to be opened in a microbiological safety cabinet to avoid inhalation of aerosols/dust from the ampoule.

Where possible and if known, work with non-toxigenic strains for tests. However where the toxigenicity of organism strains is not known, extreme caution should be taken to avoid exposure to infection. A typical example is working with NCTC 6571 which is known to have the cytotoxin, Panton-Valentine Leukocidin gene that causes leucocyte destruction and tissue necrosis.

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

Compliance with postal and transport regulations is essential.

## 2 Reagents and equipment

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Different agar media or broths dependent on the test performed.

Incubator - both oxygen and carbon dioxide.

Anaerobic jars.

Diamond cutter/pen or glass file.

### 3 Quality control organisms

#### 3.1 Table of example reference NCTC strains

UK SMI	Example reference strain for both phenotypic and EUCAST disc susceptibility tests			
		Bacteria	Alternative bacteria	Fungi
<a href="#">TP 2 – Aesculin hydrolysis test</a>	Positive control Negative control	<i>Enterococcus faecalis</i> NCTC 12697 <i>Streptococcus agalactiae</i> NCTC 8181		
<a href="#">TP 3 – Agglutination test</a>	Positive control Negative control	N/A**		
<a href="#">TP 5 – Bile solubility test</a>	Positive control Negative control	<i>Streptococcus pneumoniae</i> NCTC 12977 <i>Streptococcus mitis</i> NCTC 10712		
<a href="#">TP 8 – Catalase test***</a>	Positive control Negative control	<i>Staphylococcus aureus</i> NCTC 6571 <i>Streptococcus mitis</i> NCTC 10712	<i>Staphylococcus aureus</i> NCTC 12973	<i>Cryptococcus neoformans</i> NCPF 3168 <i>Candida albicans</i> NCPF 3281
<a href="#">TP 10 – Coagulase test</a>	Positive control Negative control	<i>Staphylococcus aureus</i> NCTC 6571 <i>Staphylococcus haemolyticus</i> NCTC 11042	<i>Staphylococcus aureus</i> NCTC 12973	
<a href="#">TP 12 – Deoxyribonuclease test</a>	Positive control Negative control	<i>Staphylococcus aureus</i> NCTC 6571 <i>Staphylococcus haemolyticus</i> NCTC 11042	<i>Staphylococcus aureus</i> NCTC 12973	
<a href="#">TP 19 – Indole test</a>	Positive control Negative control	<i>Escherichia coli</i> NCTC 10418 <i>Proteus mirabilis</i> NCTC 10975	<i>Escherichia coli</i> NCTC 12241	
<a href="#">TP 21 – Motility test</a>	Positive control	<i>Proteus mirabilis</i> NCTC 10975		

Example reference strains for UK SMI test procedures

	<b>Negative control</b>	<i>Acinetobacter lwoffii</i> NCTC 5866		
<a href="#">TP 24 - ONPG (β-Galactosidase) test</a> (for Enterobacteriaceae)	<b>Positive control</b>	<i>Escherichia coli</i> NCTC 10418	<i>Escherichia coli</i> NCTC 12241	
	<b>Negative control</b>	<i>Proteus mirabilis</i> NCTC 10975		
<a href="#">TP 24 - ONPG (β-Galactosidase) test</a> (for <i>Neisseria</i> species)	<b>Positive control</b>	<i>Neisseria lactamica</i> NCTC 10617		
	<b>Negative control</b>	<i>Neisseria gonorrhoeae</i> NCTC 8375		
<a href="#">TP 25 – Optochin test</a>	<b>Positive control</b>	<i>Streptococcus pneumoniae</i> NCTC 12977		
	<b>Negative control</b>	<i>Streptococcus mitis</i> NCTC 10712		
<a href="#">TP 26 – Oxidase test</a> ***	<b>Positive control</b>	<i>Pseudomonas aeruginosa</i> NCTC 10662	<i>Pseudomonas aeruginosa</i> NCTC 12903	<i>Candida albicans</i> NCPF 3281
	<b>Negative control</b>	<i>Escherichia coli</i> NCTC 10418		
<a href="#">TP 27 – Oxidation/fermentation of glucose test</a> (Gram negative rods)	<b>Oxidation:</b>		<i>Pseudomonas aeruginosa</i> NCTC 12903	
	<b>Positive control</b>	<i>Pseudomonas aeruginosa</i> NCTC 10662		
	<b>Negative control</b>	<i>Acinetobacter lwoffii</i> NCTC 5866	<i>Escherichia coli</i> NCTC 12241	
	<b>Fermentation:</b>			
	<b>Positive control</b>	<i>Escherichia coli</i> NCTC 10418		
	<b>Negative control</b>	<i>Acinetobacter lwoffii</i> NCTC 5866		
<a href="#">TP 27 – Oxidation/fermentation of glucose test</a> (Gram positive cocci)	<b>Oxidation:</b>			
	<b>Positive control</b>	<i>Micrococcus luteus</i> NCTC 2665		
	<b>Negative control</b>	OF basal medium without carbohydrate	<i>Staphylococcus aureus</i> NCTC 12973	
	<b>Fermentation:</b>			
	<b>Positive control</b>	<i>Staphylococcus aureus</i> NCTC 6571		
	<b>Negative control</b>	OF basal medium without carbohydrate		

Example reference strains for UK SMI test procedures

<a href="#">TP 29 – Porphyrin synthesis (ALA) test</a>	<b>Positive control</b> <b>Negative control</b>	<i>Haemophilus parainfluenzae</i> NCTC 10665 <i>Haemophilus influenzae</i> NCTC 11931	<i>Haemophilus influenzae</i> NCTC 12975	
<a href="#">TP 30 - Potassium hydroxide test</a>	<b>Positive control</b> <b>Negative control</b>	<i>Escherichia coli</i> NCTC 10418 <i>Staphylococcus aureus</i> NCTC 6571	<i>Escherichia coli</i> NCTC 12241 <i>Staphylococcus aureus</i> NCTC 12973	
<a href="#">TP 32 - Changing the phase of <i>Salmonella</i></a>	<b>Positive control</b> <b>Negative control</b>	N/A**		
<a href="#">TP 34 – Thermonuclease test*</a>	<b>Positive control</b> <b>Negative control</b>	<i>Staphylococcus aureus</i> NCTC 6571 <i>Staphylococcus haemolyticus</i> NCTC 11042	<i>Staphylococcus aureus</i> NCTC 12973	
<a href="#">TP 36 – Urease test***</a>	<b>Positive control</b> <b>Negative control</b>	<i>Proteus mirabilis</i> NCTC 10975 <i>Escherichia coli</i> NCTC 10418	<i>Escherichia coli</i> NCTC 12241	<i>Cryptococcus neoformans</i> NCPF 3168 <i>Candida albicans</i> NCPF 3281
<a href="#">TP 38 – X and V factor test</a>	<b>X and V factor</b>	<i>Haemophilus influenzae</i> NCTC 11931	<i>Haemophilus influenzae</i> NCTC 12975	
	<b>V factor only</b>	<i>Haemophilus parainfluenzae</i> NCTC 10665		
	<b>X factor only</b>	<i>Haemophilus haemoglobinophilus</i> NCTC 8540		
<a href="#">TP39 – Staining procedures</a>	<b>Positive control</b> <b>Negative control</b>	Use the recommended controls within this document. However, if controls used are other than those recommended, laboratories should ensure that these are validated prior to use.		
<a href="#">TP40 - MALDI TOF MS test procedure</a>	<b>Positive control</b> <b>Negative control</b>	The quality control organisms used is dependent on what the manufacturer provides. Follow manufacturer’s instructions. Laboratories should include their own validated positive and negative controls		

## Example reference strains for UK SMI test procedures

		strains when performing MALDI-TOF MS runs.		
<p>*The reference bacterial strains have not been validated by NCTC for the test shown.</p> <p>**N/A – Not Applicable</p> <p>*** The reference fungal strains have not been validated by NCTC for the tests at the time of publication.</p> <p>There is validation data for all the strains tested.</p>				

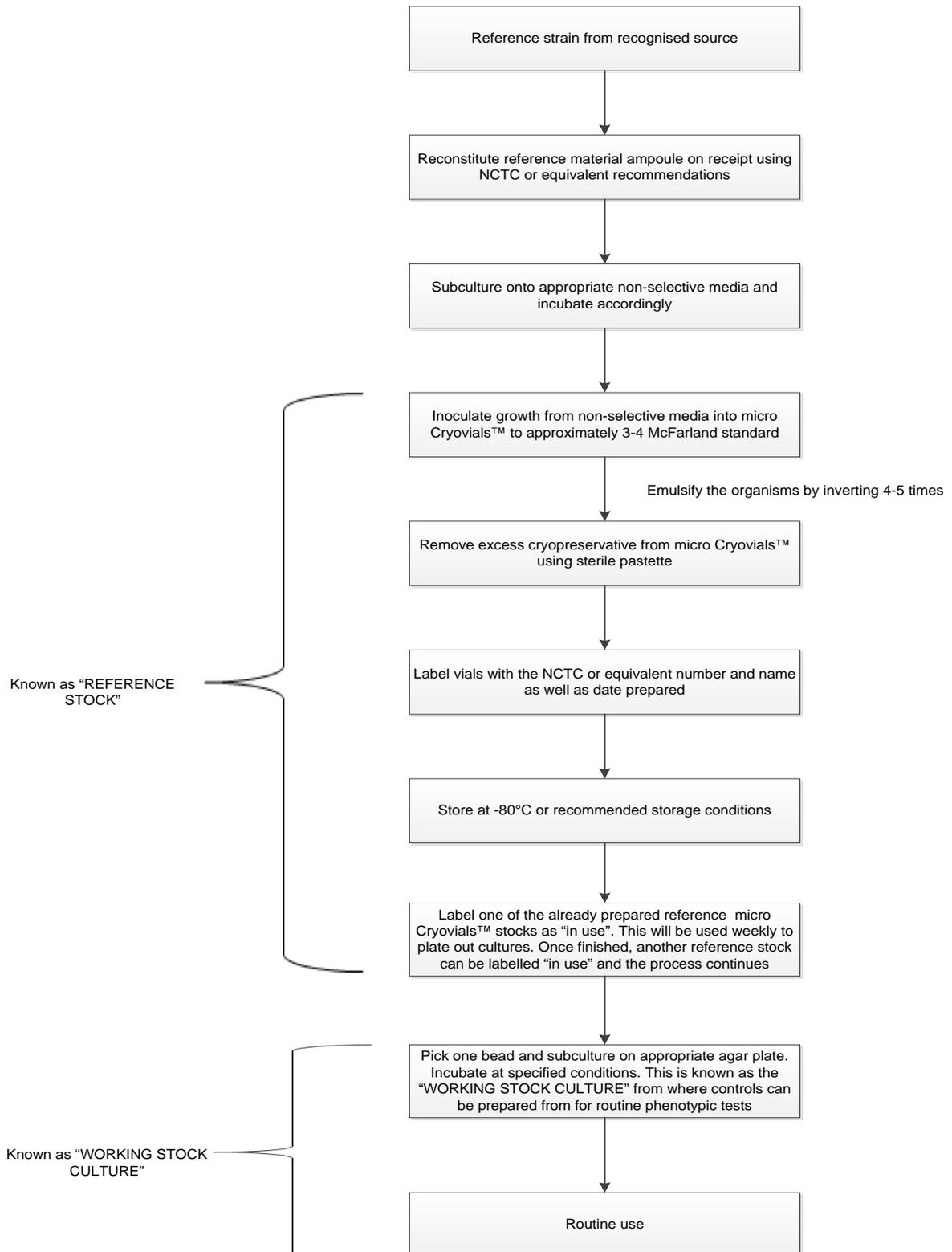
## 4 Procedure and results<sup>1</sup>

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- The reference material on receipt must be rehydrated in accordance with any [NCTC \(or equivalent\) recommendations](#). Laboratories should bear in mind that some reference materials may have specific manufacturers' instructions which may need to be considered.
- The reference material should be subcultured onto appropriate non-selective media and incubated using the correct atmosphere and temperature.
- If the culture (that is the direct first generation of the reference material) 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 micro Cryovials™ should be inoculated with young colonial growth (18-24hr old) from the subculture to approximately a 3-4 McFarland standard.  
**Note:** Laboratories may wish to produce bulk reference micro Cryovials™ stocks that they need for future routine use. This can however, be achieved by subculturing from the original inoculated plate/medium or from the first prepared reference micro Cryovial™.
- 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 stocks and are stored at -80°C.
- Every week, one bead from a reference stock (labelled "in use") should be subcultured to an appropriate non-selective medium to prepare plate culture. This freshly prepared plate is the "working stock culture". It should be noted that working stocks shall not be subcultured to replace reference stocks.
- 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 should be made weekly or every fortnightly to fresh plates from the Cryovial™ stock as above.

See relevant Test Procedures from [UK Standards for Microbiology Investigations](#).

## 5 Flowchart on preparation and storage of reference strains



The flowchart is for guidance only.

## References

### Modified GRADE table used by UK SMIs when assessing references

Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) is a systematic approach to assessing references. A modified GRADE method is used in UK SMIs for appraising references for inclusion. Each reference is assessed and allocated a grade for strength of recommendation (A-D) and quality of the underlying evidence (I-VIII). A summary table which defines the grade is listed below and should be used in conjunction with the reference list.

Quality/certainty of evidence	Types of evidence
A Strongly recommended	I Evidence from randomised controlled trials, meta-analysis and systematic reviews
B* Recommended but other alternatives may be acceptable	II Evidence from non-randomised studies
	III Evidence from documents describing techniques, methods or protocols
C* Weakly recommended: seek alternatives	IV Non-analytical studies, eg case reports, reviews, case series
D Never recommended	V Expert opinion and wide acceptance as good practice but with no study evidence
	VI Required by legislation, code of practice or national standard/ guideline
	VII Letter /short communication /editorials /conference communication
	VIII Electronic citation

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2. Advisory Committee on Dangerous Pathogens. Infections at work: Controlling the risks. Her Majesty's Stationery Office 2003. **A, VI**
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## Example reference strains for UK SMI test procedures

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6. British Standards Institution (BSI). BS EN12469 - Biotechnology - performance criteria for microbiological safety cabinets 2000. **A, VI**
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8. 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. **B, V**
9. Department for Transport. Transport of Infectious Substances, 2011 Revision 5. 2011. **A, VI**
10. Department of Health. Transport of Infectious Substances. Best Practice Guidance for Microbiology Laboratories. Department of Health. 1-13. 2007. **A, VI**
11. European Parliament. UK Standards for Microbiology Investigations (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". 1998. **A, VI**
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14. Health and Safety Executive. Safe use of pneumatic air tube transport systems for pathology specimens. 2009. **A, VI**
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17. Home Office. Anti-terrorism, Crime and Security Act. 2001. **A, VI**
18. 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 1998. 1-37. **A, VI**
19. World Health Organization. Guidance on regulations for the Transport of Infectious Substances 2017-2018. 2017. **A, VI**