UK Standards for Microbiology Investigations

Blood Borne Virus Testing in Dialysis Patients
Acknowledgments

UK Standards for Microbiology Investigations (SMIs) are developed under the auspices of the Health Protection Agency (HPA) 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.

For further information please contact us at:

Standards Unit
Microbiology Services Division
Health Protection Agency
61 Colindale Avenue
London NW9 5EQ
E-mail: standards@hpa.org.uk
Website: http://www.hpa.org.uk/SMI

The UK Standards for Microbiology Investigations are produced in association with:
UK Standards for Microbiology Investigations#: Status

**Users of SMIs**

Three groups of users have been identified for whom SMIs are especially relevant:

- SMIs are primarily intended as a general resource for practising professionals in the field operating in the field of laboratory medicine in the UK. Specialist advice should be obtained where necessary.

- SMIs provide clinicians with information about the standard of laboratory services they should expect for the investigation of infection in their patients and the documents provide information that aids the electronic ordering of appropriate tests from hospital wards.

- SMIs also provide commissioners of healthcare services with the 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 essential laboratory methodologies which underpin quality, for example assay validation, quality assurance, and understanding uncertainty of measurement.

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 interventions, surveillance, and research and development activities. SMIs align advice on testing strategies with the UK diagnostic and public health agendas.

**Involvement of Professional Organisations**

The development of SMIs is undertaken within the HPA in partnership with the NHS, Public Health Wales and with professional organisations.

The list of participating organisations may be found at [http://www.hpa.org.uk/SMI/Partnerships](http://www.hpa.org.uk/SMI/Partnerships). Inclusion of an organisation’s logo in an SMI implies support for the objectives and process of preparing SMIs. Representatives of professional organisations are members of the steering committee and working groups which develop SMIs, although the views of participants are not necessarily those of the entire organisation they represent.

---

 UK Standards for Microbiology Investigations were formerly known as National Standard Methods.

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.
SMIs are developed, reviewed and updated through a wide consultation process. The resulting documents reflect the majority view of contributors. SMIs are freely available to view at http://www.hpa.org.uk/SMI as controlled documents in Adobe PDF format.

Quality Assurance
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 well referenced 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. SMIs should be used in conjunction with other SMIs.

UK microbiology laboratories that do not use SMIs should be able to demonstrate at least equivalence in their testing methodologies.

The performance of SMIs depends on well trained staff and the quality of reagents and equipment used. 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.

Whilst every care has been taken in the preparation of SMIs, the HPA, its successor organisation(s) 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.

SMIs are the copyright of the HPA which should be acknowledged where appropriate.

Microbial taxonomy is up to date at the time of full review.

Equality and Information Governance
An Equality Impact Assessment on SMIs is available at http://www.hpa.org.uk/SMI.

The HPA 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.

Suggested citation for this document:
# Contents

ACKNOWLEDGMENTS............................................................................................................... 2

UK STANDARDS FOR MICROBIOLOGY INVESTIGATIONS: STATUS .................................................. 3

AMENDMENT TABLE ............................................................................................................... 6

BLOOD-BORNE VIRUS TESTING IN DIALYSIS PATIENTS FLOWCHART ............................................... 7

NOTIFICATION TO THE HPA ............................................................................................... 9

REFERENCES .......................................................................................................................... 10

---

The process for the development of SMIIs is certified to ISO 9001.

NHS Evidence has accredited the process used by the HPA to produce SMIIs. Accreditation is valid for three years from July 2011. The accreditation is applicable to all guidance produced since October 2009 using the processes described in the HPA’s Standard Operating Procedure SW3026 (2009) version 6. More information on accreditation can be viewed at [www.evidence.nhs.uk](http://www.evidence.nhs.uk)
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@hpa.org.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>1/02.11.11</th>
</tr>
</thead>
<tbody>
<tr>
<td>Issue no. discarded.</td>
<td>1</td>
</tr>
<tr>
<td>Insert Issue no.</td>
<td>1.1</td>
</tr>
<tr>
<td>Section(s) involved/ Page no.</td>
<td>Amendment.</td>
</tr>
<tr>
<td>References.</td>
<td>Some references updated.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Amendment No/Date.</th>
<th>-/20.02.08</th>
</tr>
</thead>
<tbody>
<tr>
<td>Issue no. discarded.</td>
<td>-</td>
</tr>
<tr>
<td>Insert Issue no.</td>
<td>1</td>
</tr>
<tr>
<td>Section(s) involved.</td>
<td>Amendment.</td>
</tr>
</tbody>
</table>
Blood Borne Virus Testing in Dialysis Patients Flowchart

[Flowchart diagram describing the process of blood borne virus testing in dialysis patients, including screening and follow-up tests for HBsAg, HIV, and HCV.]
Footnotes

a) If more than 1 month since negative tests for BBV.
b) Local risk assessment should be carried out based on the patient’s history including where and when dialysed if outside the UK.
c) Patients should be tested against HBsAg and anti-HBc to check for current/past infection; additional investigation and monitoring may need to be considered where anti-HBc alone is found, while absence of anti-HBc may indicate a need for vaccination against hepatitis B.
d) V 4 - Hepatitis B diagnostic serology in the immunocompetent (including Hepatitis B in pregnancy).
e) V 11 - Anti-HIV Screening.
f) V 5 - Investigation of Hepatitis C Infection.
g) Store blood samples for at least a year.
h) HBsAg may not be required if recent anti-HBs ≥ 100miu/mL.
i) If no risk factors as per the guidelines.
Notification to the HPA\textsuperscript{2,3}

The Health Protection (Notification) regulations 2010 require diagnostic laboratories to notify the Health Protection Agency (HPA) 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 HPA office. 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 the HPA. The vast majority of NHS laboratories voluntarily report a wide range of laboratory diagnoses of causative agents to the HPA and many HPA offices have agreements with local laboratories for urgent reporting of some infections. This should continue.

(Note: The Health Protection Legislation Guidance (2010) includes reporting of HIV & STIs, HCAIs and CJD under ‘Notification Duties of Registered Medical Practitioners’: it is not noted under ‘Notification Duties of Diagnostic Laboratories’).

Other arrangements exist in Scotland\textsuperscript{4} and Wales\textsuperscript{5}.

References


