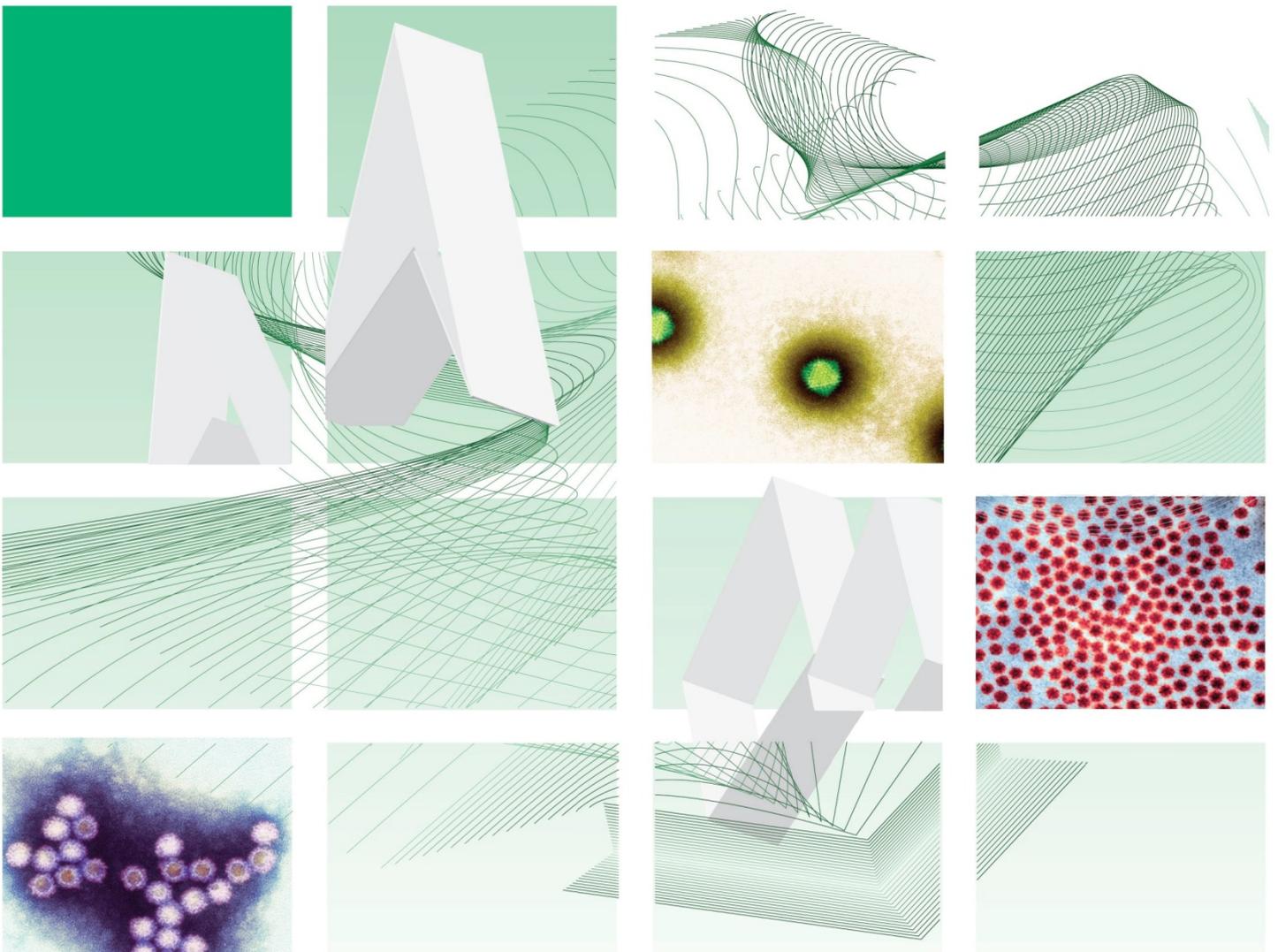




UK Standards for Microbiology Investigations

Anti-HIV Screening



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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society for general
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www.sgm.ac.uk



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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.	4/15.04.14
Issue no. discarded.	3.1
Insert Issue no.	3.2
Section(s) involved	Amendment
Whole document.	<p>Document has been transferred to a new template to reflect the Health Protection Agency's transition to Public Health England.</p> <p>Front page has been redesigned.</p> <p>Status page has been renamed as Scope and Purpose and updated as appropriate.</p> <p>Professional body logos have been reviewed and updated.</p> <p>Standard safety and notification references have been reviewed and updated.</p> <p>Scientific content remains unchanged.</p>

Amendment No/Date.	3/24.12.12
Issue no. discarded.	3
Insert Issue no.	3.1
Section(s) involved	Amendment
Contents.	NICE logo removed
References.	Hyperlink removed.

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 <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.

[#]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 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.

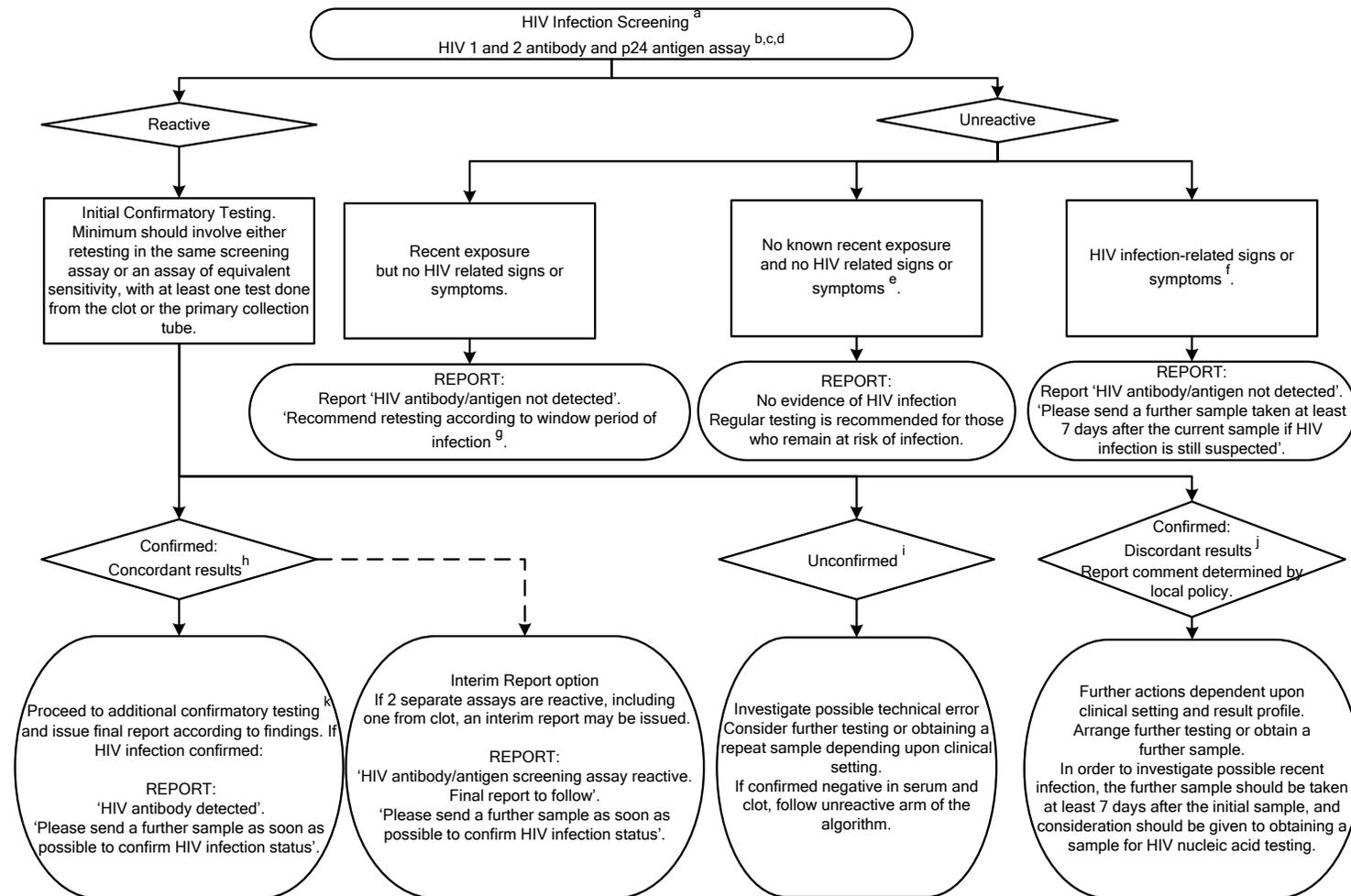
The evidence base and microbial taxonomy for the SMI is as complete as possible at the time of issue. Any omissions and new material will be considered at the next review. These standards can only be superseded by revisions of the standard, legislative action, or by NICE accredited guidance.

SMIs are Crown copyright which should be acknowledged where appropriate.

Suggested Citation for this Document

Public Health England. (2014). Anti-HIV Screening . UK Standards for Microbiology Investigations. V 11 Issue 3.2. <http://www.hpa.org.uk/SMI/pdf>.

Anti-HIV Screening¹⁻⁷



Footnotes

- a) This algorithm is not applicable to investigation of potential mother to child transmission of HIV in children under 18 months of age.
- b) It is anticipated that laboratories will typically use a combined antibody antigen assay, however, the use of separate antibody and p24 antigen assays would be acceptable. Tests should detect antibody to all major groups of HIV 1 and 2, including type 1 group O and should be performed on blood.
- c) BASHH UK national guidelines on HIV testing do not currently recommend point of care rapid tests; however, if local assessment indicates satisfactory performance, they could be used for screening. Such rapid tests (antibody only, or combined antibody/antigen) may be indicated in certain population groups where the overall benefit of increased testing outweighs any potential disadvantage of poorer test performance³.
- d) HIV RNA assays (viral load tests) are not recommended due to the potential for false positive and negative results and the marginal benefit in detecting recent infection¹.
- e) This patient category might include antenatal screening.
- f) Laboratories may opt to test such samples in two assays rather than rely on a single screening test. The routine screening test should be the most sensitive test available to the laboratory, however, dual testing may add an extra dimension of certainty regarding a negative result since inter assay performance varies and unrecognised laboratory process error is less likely.
- g) [BASHH statement](#) on HIV seroconversion window period. March 2010:
 “HIV testing using the latest (4th generation) tests are recommended in the BHIVA/BASHH/BIS UK guidelines for HIV testing (2008). These assays test for HIV antibodies and p24 antigen simultaneously. They will detect the great majority of individuals who have been infected with HIV at one month (4 weeks) after specific exposure.
 Patients attending for HIV testing who identify a specific risk occurring more than 4 weeks previously, should not be made to wait 3 months (12 weeks) before HIV testing. They should be offered a 4th generation laboratory HIV test and advised that a negative result at 4 weeks post exposure is very reassuring/highly likely to exclude an HIV infection. An additional HIV test should be offered to all persons at 3 months (12 weeks) to definitively exclude HIV infection. Patients at lower risk may opt to wait until 3 months to avoid the need for HIV testing twice.”
- h) Results are considered confirmed: concordant when either the initial screening test and the repeat test using the same assay are reactive, or when the initial screening test and the second test using an alternative assay are reactive.
- i) Results are considered unconfirmed when different results are obtained between the clot sample/ primary collection tube and the aliquot sample, or unrepeatability is obtained in any assay used in initial confirmatory testing.

- j) Results are considered confirmed: discordant when the screening assay is repeatedly reactive but the confirmatory assay is repeatedly unreactive.
- k) A sample has to be reactive in at least 3 HIV serology assays, the combination of which can distinguish antigen from antibody and type 1 from type 2. Ideally, tests should be of different formats and include different antigenic components. A Western Blot or immunoblot is preferred to provide a highly specific, reliable antibody positive status. A definitive positive diagnosis of HIV should not be reported unless a confirmatory laboratory has issued a report confirming tests on the first specimen are consistent with HIV infection and the results are confirmed by a second specimen.

This algorithm covers the serological diagnosis of HIV infection only. HIV NAAT may be helpful in confirming suspected infection, but local policies should be used to define their use and interpretation.

Laboratory reports of newly identified HIV antibody positive individuals should be reported to the HIV Reporting Section of Public Health England and to Health Protection Scotland.

Notification to PHE^{8,9} or Equivalent in the Devolved Administrations¹⁰⁻¹³

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 (HCAs) 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](#)^{10,11}, [Wales](#)¹² and [Northern Ireland](#)¹³.

References

1. IUSTI and WHO European STD Guidelines Editorial Board. European Guideline on HIV Testing. 21-8-2008.
2. WHO Pan-American Health Organisation. Guidelines for the implementation of reliable and efficient HIV testing. 2008.
3. British HIV Association. UK National Guidelines on HIV Testing. 2008.
4. European Centre for Disease Prevention and Control. HIV Testing: increasing uptake and effectiveness in the European Union. Stockholm. 2010.
5. World Health Organization. WHO recommendations on the diagnosis of HIV infection in infants and children. 2010.
6. Bell JE, Brettle RP, Chiswick A, Simmonds P. HIV encephalitis, proviral load and dementia in drug users and homosexuals with AIDS. Effect of neocortical involvement. *Brain* 1998;121:2043-52.
7. Parry JV, Mortimer PP, Perry KR, Pillay D, Zuckerman M. Towards error-free HIV diagnosis: guidelines on laboratory practice. *Commun Dis Public Health* 2003;6:334-50.
8. Public Health England. Laboratory Reporting to Public Health England: A Guide for Diagnostic Laboratories. 2013. p. 1-37.
9. Department of Health. Health Protection Legislation (England) Guidance. 2010. p. 1-112.
10. Scottish Government. Public Health (Scotland) Act. 2008 (as amended).
11. Scottish Government. Public Health etc. (Scotland) Act 2008. Implementation of Part 2: Notifiable Diseases, Organisms and Health Risk States. 2009.
12. The Welsh Assembly Government. Health Protection Legislation (Wales) Guidance. 2010.
13. Home Office. Public Health Act (Northern Ireland) 1967 Chapter 36. 1967 (as amended).