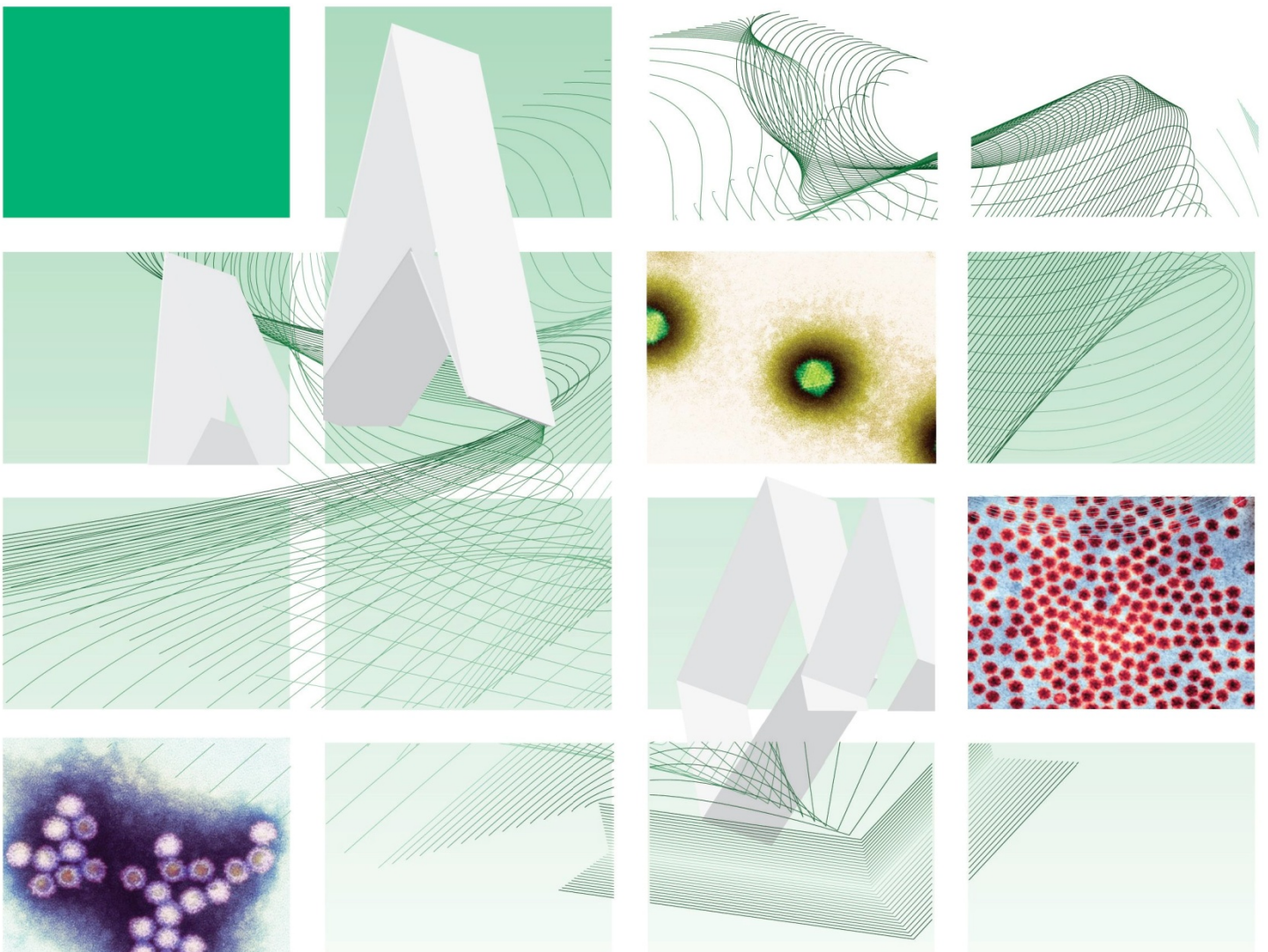




UK Standards for Microbiology Investigations

Hepatitis A Virus Acute Infection Serology



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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Contents

ACKNOWLEDGMENTS	2
AMENDMENT TABLE	4
UK STANDARDS FOR MICROBIOLOGY INVESTIGATIONS: SCOPE AND PURPOSE.....	6
SCOPE OF DOCUMENT	9
HEPATITIS A VIRUS ACUTE INFECTION SEROLOGY.....	10
NOTIFICATION TO PHE OR EQUIVALENT IN THE DEVOLVED ADMINISTRATIONS	12
REFERENCES	13



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.	3/12.05.14
Issue no. discarded.	2.5
Insert Issue no.	3
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>
Scope.	Scope including type of specimen and definitions for all antigen, antibody and NAAT results added.
Algorithm.	<p>Algorithm updated to include results as defined in the scope.</p> <p>Addition of boxes to flowchart for differentiation between acute infection and non-specific IgM reactivity.</p> <p>'Refer to Reference Laboratory' added to the reactive - consistent with acute infection arm of the algorithm.</p> <p>Footnotes updated (see below).</p>
Footnotes.	<p>Footnotes updated:</p> <p>Reporting of negative HAV IgM assay strengthened.</p> <p>Testing for HAV IgG - HAV IgG results can be helpful in interpretation.</p> <p>Other assay results updated to include examples,</p>

	<p>clinical picture and risk factors.</p> <p>Interpretation in the elderly. HAV IgM can be long lived (>200 days).</p> <p>Footnotes added:</p> <p>Immunocompromised - consider referring for PCR.</p> <p>IgM may be reactive after recent infection.</p> <p>Serology index interpretation footnote added.</p> <p>Reactive samples consistent with acute infection should be sent to a reference laboratory.</p>
References.	Updated.

Amendment No/Date.	2/02.11.11
Issue no. discarded.	2.4
Insert Issue no.	2.5
Section(s) involved	Amendment
Whole document.	Document presented in new format.
References.	Some references updated.

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). Hepatitis A Virus Acute Infection Serology. UK Standards for Microbiology Investigations. V 27 Issue 3.
<http://www.hpa.org.uk/SMI/pdf>.

Scope of Document

Type of specimen

Blood

Scope

This virology algorithm outlines laboratory testing for hepatitis A virus (HAV) IgM (anti-HAV IgM) for diagnosis of acute infection. Other tests should be considered in patients who are immunocompromised^{1,2}.

A reactive anti-HAV IgM is consistent with recent HAV infection. However, interpretation should take into consideration results of other assays and the clinical picture. Negative results should be interpreted in light of the anti-HAV IgG result and the onset date of illness.

Positive IgM results consistent with recent HAV should be reported to the local Public Health England Centre, or equivalent in the devolved administrations.

Refer to [S 1 - Acute Infective Hepatitis](#) for further information regarding clinical presentations of acute infective hepatitis, and associated tests.

This SMI should be used in conjunction with other SMIs.

Definitions

For all antigen, antibody and NAAT results the following definitions apply:

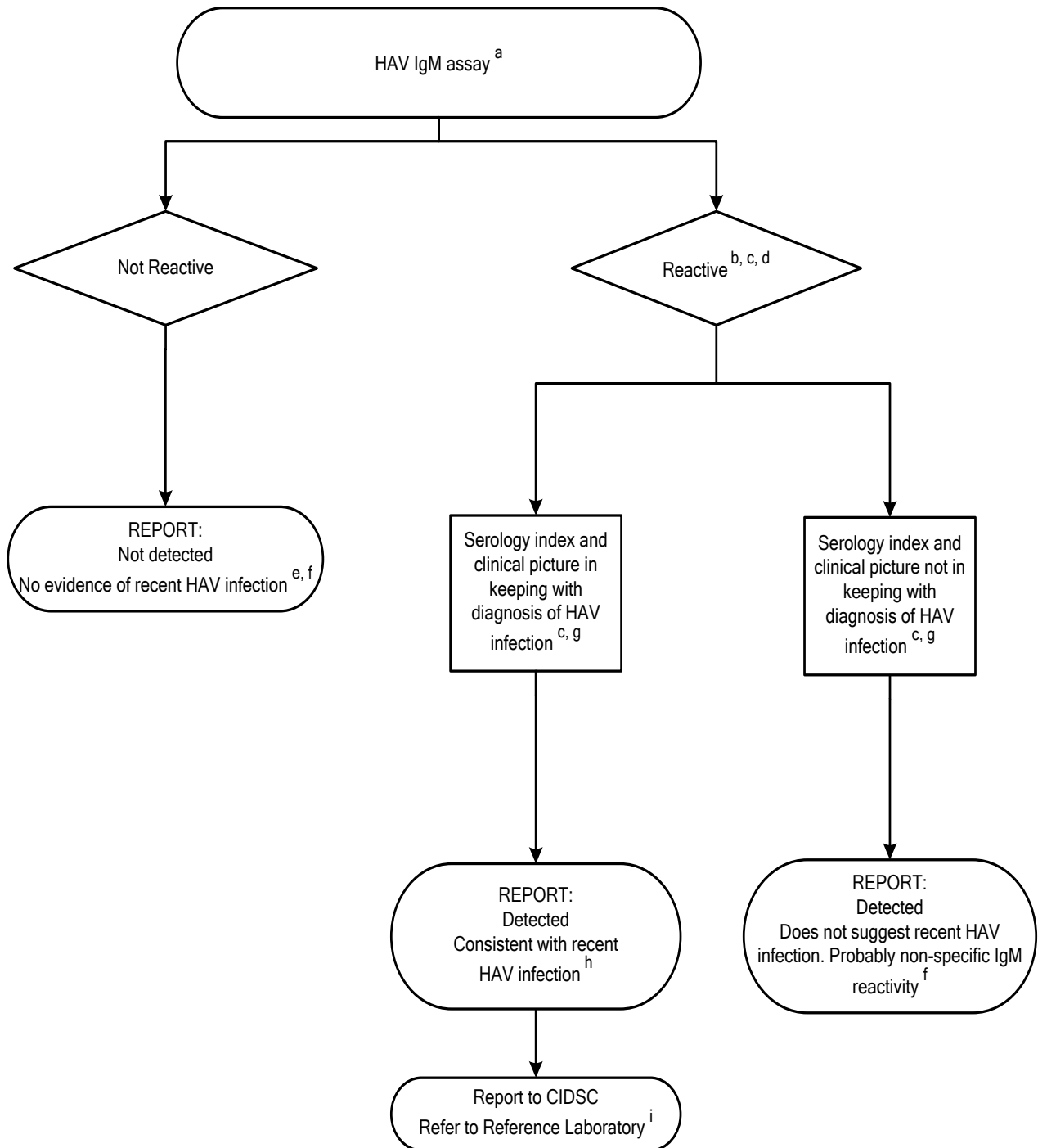
Reactive – Initial internal-stage positive result pending confirmation.

Not reactive – Initial internal-stage negative result.

Detected – Report-stage confirmed reactive result.

Not detected – Report-stage not reactive result.

Hepatitis A Virus Acute Infection Serology¹



Footnotes

- a) HAV IgM serology may not be reliable in patients who are significantly immunocompromised. Consider referring for HAV PCR².
- b) In accordance with manufacturer's instructions.
- c) Specificity of HAV IgM assays is often poor. HAV IgM results should be interpreted in light of results of other assays (eg HAV IgG, EBV VCA IgM), rheumatoid factor (RF), liver function test (LFT), the clinical picture (eg symptoms and onset date), other risk factors (eg contact with case, MSM) and age¹. False IgM results are more common in older adults, or those from developing countries, as they are more likely to have had hepatitis A in childhood³.
- d) IgM may be reactive after recent vaccination⁴.
- e) Report no evidence of recent HAV infection if sample taken ≥ 5 days after the onset of symptoms. A negative result on a sample taken < 5 days after onset of symptoms may not exclude hepatitis A, as it may be too soon for the production of HAV IgM antibodies, so a second blood sample should be requested¹.
- f) Test for HAV IgG if indicated or when immune status is requested. HAV IgG results can be helpful for interpretation of some negative or suspected falsely reactive HAV IgM results. Testing of a previous or later sample may also be considered.
- g) Serology index interpretation should be based upon local assay performance data in conjunction with clinical likelihood.
- h) Interpret reactive result with caution in the elderly and note also that hepatitis A IgM can be long lived (> 200 days)⁵.
- i) Send serum, blood or stool samples (if available) to a Reference Laboratory for confirmation by alternative serological assay or PCR and genotyping for surveillance.

Notification to PHE^{6,7} or Equivalent in the Devolved Administrations⁸⁻¹¹

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](#)^{8,9}, [Wales](#)¹⁰ and [Northern Ireland](#)¹¹.

References

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