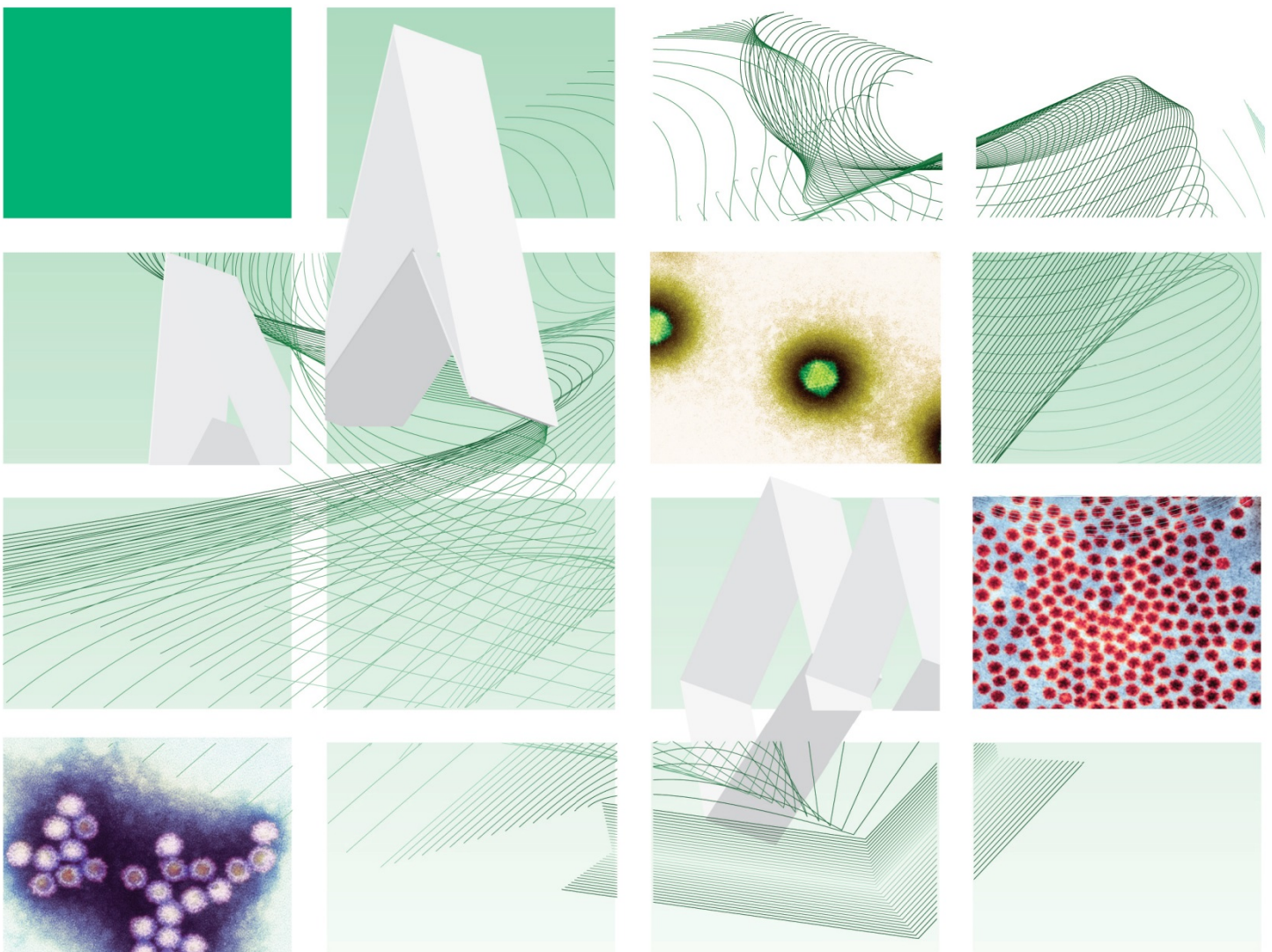




# UK Standards for Microbiology Investigations

## Hepatitis A virus acute infection serology



"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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## Amendment table

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	4/18.01.19
Issue number discarded	3
Insert issue number	4
Anticipated next review date*	18.01.22
<b>Section(s) involved</b>	<b>Amendment</b>
Whole document.	<p>The whole document has been reformatted to a new more interactive and comprehensive template.</p> <p>All the background, technical, scientific and legal information has been moved to two separate documents: General information and Scientific information that can be accessed from this document via hyperlink.</p> <p>Included a new interpreting and reporting table.</p>
Footnote.	<p>Footnote d: the sentence “test for IgG when immune status requested” has been removed as it is not relevant to the context.</p> <p>Added a new footnote (f).</p>

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

## 1. General information

[View](#) general information related to UK SMIs.

## 2. Scientific information

[View](#) scientific information related to UK SMIs.

## 3. Scope of document

The 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<sup>1,2</sup>.

Further information:

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

Refer to [Laboratory reports of hepatitis A and C: 2016](#), for annual and quarterly laboratory-confirmed hepatitis A virus and hepatitis C reports in England and Wales in 2016.

Refer to [Immunisation against infectious disease: the green book](#) for the latest information on vaccines and vaccination procedures.

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

## 4. Safety considerations

The guidance should be supplemented with local COSHH and risk assessments. Refer to current guidance on the safe handling of all organisms documented in this UK SMI.

## 5. Specimen processing and procedure

### 5.1 Specimen type

Blood or refer to manufacturer's guidelines.

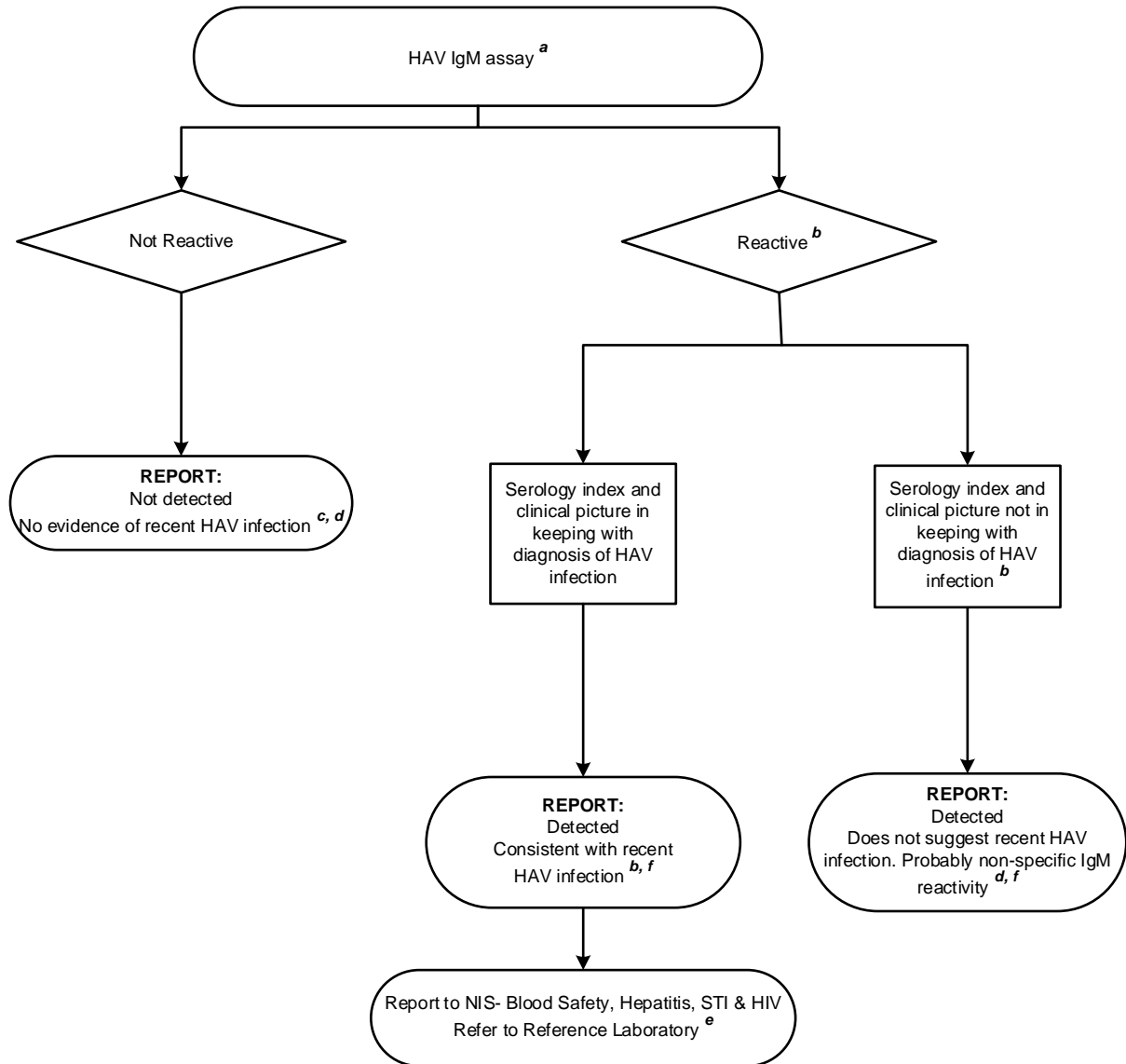
### 5.2 Specimen transport and storage conditions

Specimens should be collected in appropriate CE marked leak proof containers and transport in sealed plastic bag<sup>3</sup>.

Specimens should be transported and processed according to manufacturer's instructions or locally validation data<sup>4</sup>.

Samples should be retained in accordance with The Royal College of Pathologists guidelines 'The retention and storage of pathological records and specimens'<sup>5</sup>.

## 6. Investigation: Hepatitis A virus acute infection serology



## Footnotes

- a) HAV IgM serology may not be reliable in patients who are significantly immunocompromised. Consider referring for HAV PCR<sup>2</sup>.
- b) Specificity of HAV IgM assays is often poor. HAV IgM results should be interpreted in light of results of other assays (for example HAV IgG, EBV VCA IgM), rheumatoid factor (RF), liver function test (LFT), the clinical picture (for example symptoms and onset date), other risk factors (for example contact with case, MSM) and age<sup>1</sup>. 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 childhood<sup>6</sup>. Interpret reactive results with caution in the elderly and note also that hepatitis A IgM can be long lived (>200 days)<sup>7</sup>. IgM may be reactive after recent vaccination<sup>8</sup>. Serology index interpretation should be based upon local assay performance data in conjunction with clinical likelihood<sup>7</sup>.
- c) Report no evidence of recent HAV infection if sample taken  $\geq 5$  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 requested<sup>1</sup>.
- d) 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.
- e) Consider sending serum, blood or stool samples (if available) to a Reference Laboratory for confirmation by alternative serological assay or PCR and genotyping for surveillance.
- f) In case of a false IgM positive result and uncertain diagnosis, further confirmatory testing is indicated and clarity could be sought with public health team.

## 7. Interpreting and reporting laboratory results

A positive result indicates acute or recent (<6 months) hepatitis A 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.

	HAV IgM	Others	Suggested wording of report comment	Notes
1	Not Reactive		Not detected No evidence of recent HAV infection	
2	Reactive	Serology index and clinical picture in keeping with diagnosis of HAV infection	Detected Consistent with recent HAV infection	Report to NIS – Blood Safety, Hepatitis, STI & HIV Refer to reference laboratory
3	Reactive	Serology index and clinical picture not in keeping with diagnosis of HAV infection	Detected Does not suggest recent HAV infection. Probably non-specific IgM reactivity	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 childhood.

## References

1. Thomas L and the Hepatitis A Guidelines Group. Guidance for the prevention and control of hepatitis A infection Health Protection Agency. 2009. **A, VI**
2. Chakvetadze C, Mallet V, Gaussec L, Hannoun L, Pol S. Acute hepatitis A virus infection without IgM antibodies to hepatitis A virus. *AnnInternMed* 2011;154:507-8. **B, II**
3. 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, V**
4. Baron EJ, Miller JM, Weinstein MP, Richter SS, Gilligan PH, Thomson RB, Jr. et al. A Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2013 Recommendations by the Infectious Diseases Society of America (IDSA) and the American Society for Microbiology (ASM). *ClinInfectDis* 2013;57:e22-e121. **B, V**
5. The Royal College of Pathologists. The retention and storage of pathological records and specimens (5th edition). 1-59. 2015. **A, V**
6. Centre for Disease Control and Prevention. Positive test results for acute hepatitis A virus infection among persons with no recent history of acute hepatitis, United States, 2002-2004. *MMWR MorbMortalWklyRep* 2005;54:453-6. **B, II**
7. Kao HW, Ashcavai M, Redeker AG. The persistence of hepatitis A IgM antibody after acute clinical hepatitis A. *Hepatology* 1984;4:933-6. **B, II**
8. Advisory Committee on Immunization Practices. Prevention of hepatitis A through active or passive immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR RecommRep* 2006;55:1-23. **A, VI**