

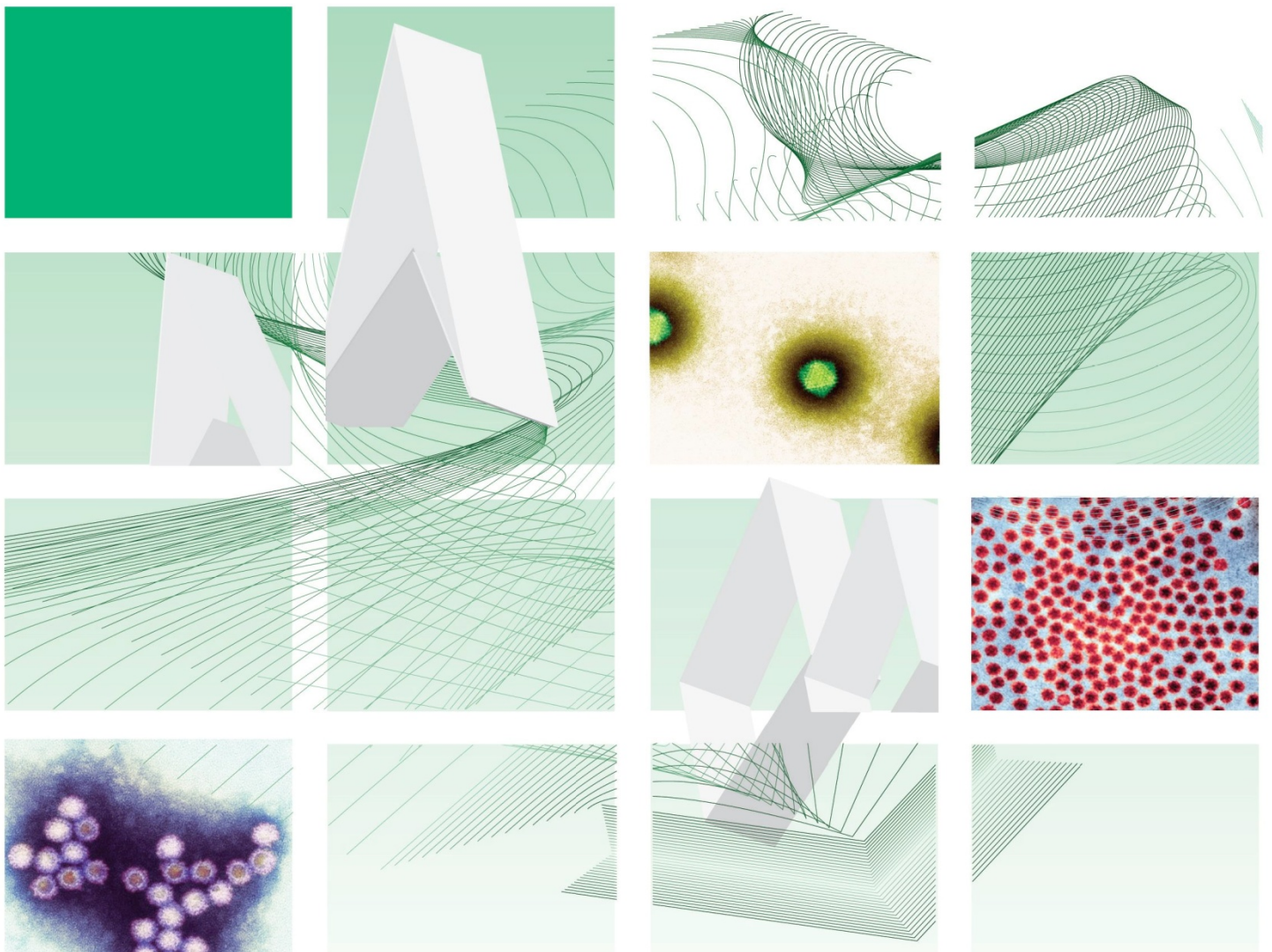


Public Health
England



UK Standards for Microbiology Investigations

Vertical and Perinatal Transmission of Hepatitis C



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Acknowledgments

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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.	3/03.11.14
Issue no. discarded.	1.2
Insert Issue no.	2
Section(s) involved	Amendment
Whole document.	Hyperlinks updated to gov.uk.
Page 2.	Updated logos added.
Title.	Title of document and flowchart changed to 'Vertical and perinatal transmission of Hepatitis C'.
Scope.	<p>'Scope' section added to the document.</p> <p>Links to UK SMI documents added and definitions of test results (for example reactive, non-reactive) included.</p> <p>Clarification of when testing should be carried out: 'Only babies born from mothers who are HCV RNA positive require routine testing, however babies born from mothers who are HCV RNA negative, anti HCV antibody positive may be tested dependent on local policy.'</p>
Flowchart.	<p>Flowchart updated in line with definitions in the scope.</p> <p>Report comments updated.</p> <p>Order of tests updated.</p> <p>Time frames for testing updated.</p>
Footnotes.	Footnotes expanded to include information on perinatal transmission, when/who to test, and sensitivity of tests.
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 <https://www.gov.uk/uk-standards-for-microbiology-investigations-smi-quality-and-consistency-in-clinical-laboratories>.

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 <https://www.gov.uk/government/organisations/public-health-england/about/equality-and-diversity>. 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.

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Suggested Citation for this Document

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Scope of Document

Type of specimen

Blood

Scope

This virology algorithm outlines the laboratory screening for HCV infection in babies born to hepatitis C virus (HCV) infected mothers¹. Infection may be acquired through vertical or perinatal transmission^{2,3}. Only babies born from mothers who are HCV RNA positive require routine testing, however babies born from mothers who are HCV RNA negative, anti-HCV antibody positive may be tested dependent on local policy. Transmission from HCV RNA negative mothers is rare, but has been documented in some studies⁴⁻⁶.

CE marked assays should be evaluated and verified prior to use. If assays are to be used outside of the scope of their CE marking they should be validated, and shown to be fit for purpose.

Refer to [S 1 - Acute Infective Hepatitis](#) and [G 5 – Investigation of Hepatitis](#) for further information regarding clinical presentations of acute infective hepatitis, treatment and associated tests.

This SMI should be used in conjunction with other SMIs.

Definitions

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

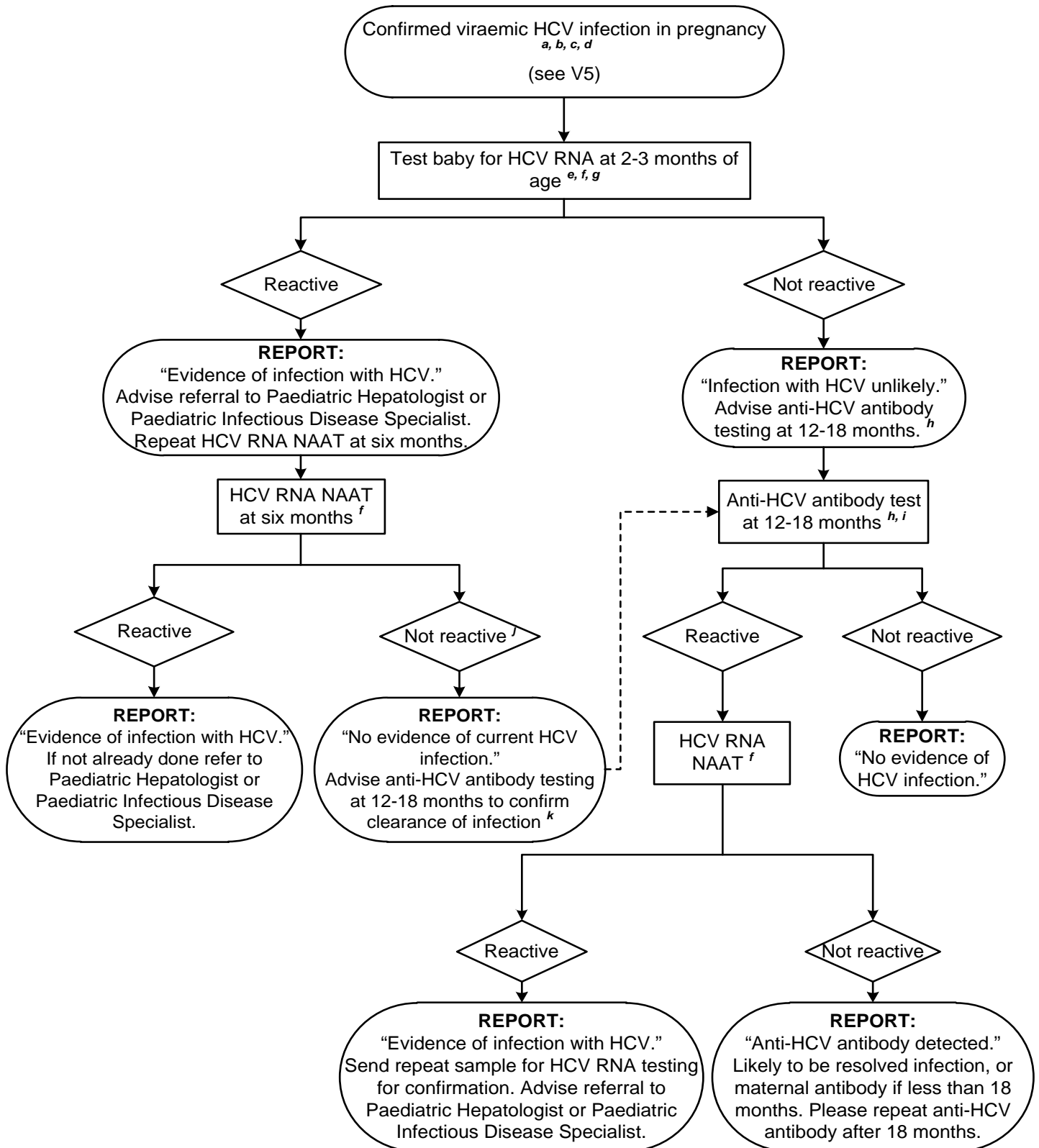
Reactive – Initial internal-stage positive result pending confirmation.

Not reactive – Initial internal-stage negative result.

Detected – Report-stage confirmed reactive result.

Not detected – Report-stage not reactive result.

Vertical and Perinatal Transmission of Hepatitis C^{1,7,8}



Footnotes

- a) Transmission of hepatitis C from HCV RNA positive mother to baby occurs in 3-6%. Most cases occur as a result of perinatal transmission, usually during birth, although in utero transmission has been suggested in up to one-third⁹. The transmission rate is increased 3 to 4 fold in HIV-HCV co-infection and with prolonged rupture of membranes¹⁰. Transmission via breastfeeding is rare^{11,12}. For women with on-going risk factors for HCV who have a negative RNA test, consideration should be given to a further confirmatory NAAT test in the third trimester.
- b) For women who have acquired infection during pregnancy, but have cleared viraemia, the baby should be followed up as described in this algorithm.
- c) For babies born to a woman who has injected drugs, when the mother is unavailable for testing, test the baby for HCV antibody and follow the algorithm if the baby is HCV antibody positive. If the baby is HCV antibody negative then this is highly predictive of absence of infection providing the exposure risk is more than 6 months ago⁵.
- d) Mothers with evidence of hepatitis C antibodies who are stably HCV RNA negative are highly unlikely to transmit HCV to the baby⁴⁻⁶. Babies born from HCV RNA PCR negative, anti-HCV antibody positive mothers do not require routine testing, however testing may be considered dependent on local policy³.
- e) It should be noted that other guidelines do not always advocate early NAAT testing in children³.
- f) HCV RNA assay target sensitivity level of 50 IU/mL or lower².
- g) Sufficient sample should be taken to do both the antibody and NAAT test; this should be included in the local user manual. If there is insufficient sample for both, the antibody test should be done rather than NAAT.
- h) Combined HCV antigen/antibody or HCV antigen only assays can also be used^{13,14}. These assays generally have a sensitivity of ~1000-5000 IU/mL and may therefore miss about 3% of viraemia cases¹⁵⁻¹⁹. Precise analytical sensitivity and clinical sensitivity varies from assay to assay, and should be carefully assessed before the assay is put into service²⁰⁻²⁵. If antigen negative, ensure that NAAT test is performed.
- i) A negative HCV RNA NAAT result may be observed in infected children with fluctuations in viraemia, thus an anti-HCV antibody test should be carried out between 12–18 months^{26,27}.
- j) Might reflect resolution of infection (>25% resolve), fluctuating RNA level or a laboratory error.
- k) Request repeat sample. Laboratories may wish to repeat discordant results.

Notification to PHE^{28,29} or Equivalent in the Devolved Administrations³⁰⁻³³

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’.

<https://www.gov.uk/government/organisations/public-health-england/about/our-governance#health-protection-regulations-2010>

Other arrangements exist in [Scotland](#)^{30,31}, [Wales](#)³² and [Northern Ireland](#)³³.

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