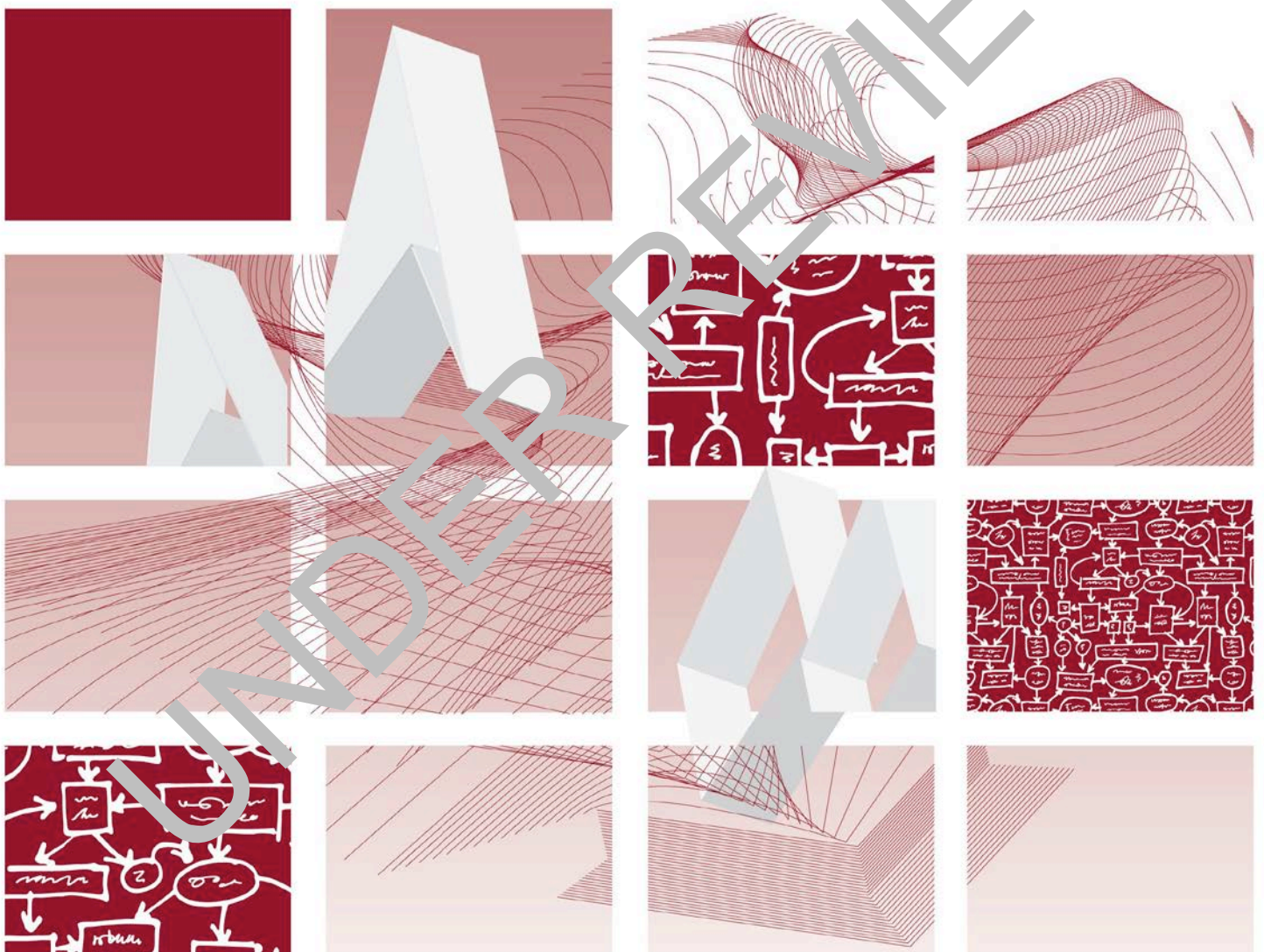




UK Standards for Microbiology Investigations

Acute Infective Hepatitis



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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UNDER REVIEW



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.

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|----------------------------|--|
| Amendment No/Date. | 3/13.02.14 |
| Issue no. discarded. | 1.2 |
| Insert Issue no. | 1.3 |
| 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> <p>Scientific content remains unchanged.</p> |

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| Amendment No/Date. | 2/25.06.12 |
| Issue no. discarded. | 1.1 |
| Insert Issue no. | 1.2 |
| Section(s) involved | Amendment |
| Whole document. | Minor formatting amendments. |

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/web/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.

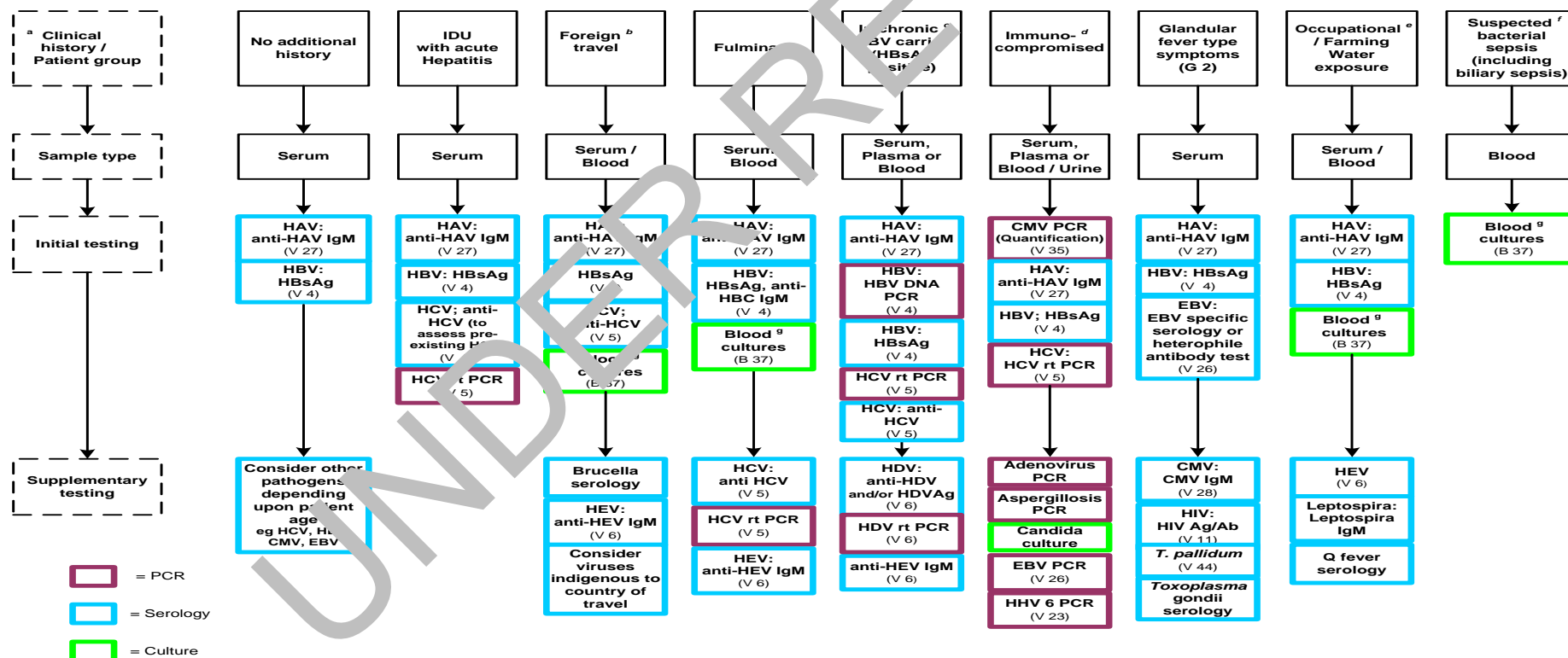
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UNDER REVIEW

Acute Infective Hepatitis (Except Asymptomatic and Neonates)

Clinical features of hepatitis include malaise, fever, jaundice and serum chemical tests revealing evidence of abnormal liver function. An inflammation of the liver can be caused by a number of aetiological agents, including viruses, bacteria, fungi, parasites, drugs and chemicals. Testing is recommended in all patients in whom abnormal liver function tests (LFTs) have been recorded. Abnormal LFTs can be defined as test results that indicate an increase of two times above the upper limit of the locally defined "normal" range of values for liver function tests (LFTs). The most common infectious hepatitis is of viral aetiology. All types of hepatitis are characterised by distortion of the normal hepatic lobular architecture due to varying degrees of necrosis of individual liver cells or groups of liver cells, acute and chronic inflammation, and Kupffer cell enlargement and proliferation. There is usually some degree of disruption of normal bile flow, which contributes to jaundice. The severity of the disease is highly variable and often unpredictable, and it should be noted that acute hepatitis can vary from being asymptomatic to fulminant.

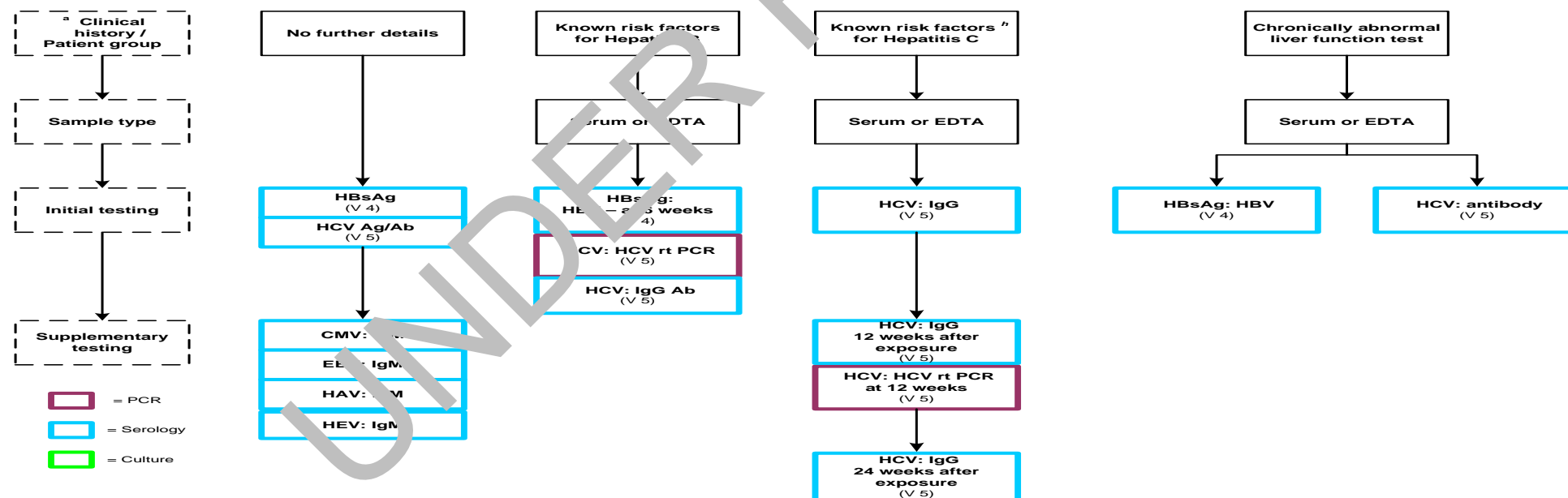


Asymptomatic Hepatitis

Liver function tests (LFTs) are often performed as part of a routine set of tests in patients who have no signs or symptoms of liver disease; either as health screening, drug monitoring, or to establish baseline values prior to starting potentially hepatotoxic medications. This can result in the detection of abnormal values in otherwise well patients, and subsequent requests for investigation of possible infective causes. The pattern of abnormalities can indicate the likely cause; however, such information is often unavailable to the microbiology/virology laboratory receiving such requests. The majority of UK patients with persistently abnormal LFTs do have liver disease, most of which is not related to infection.

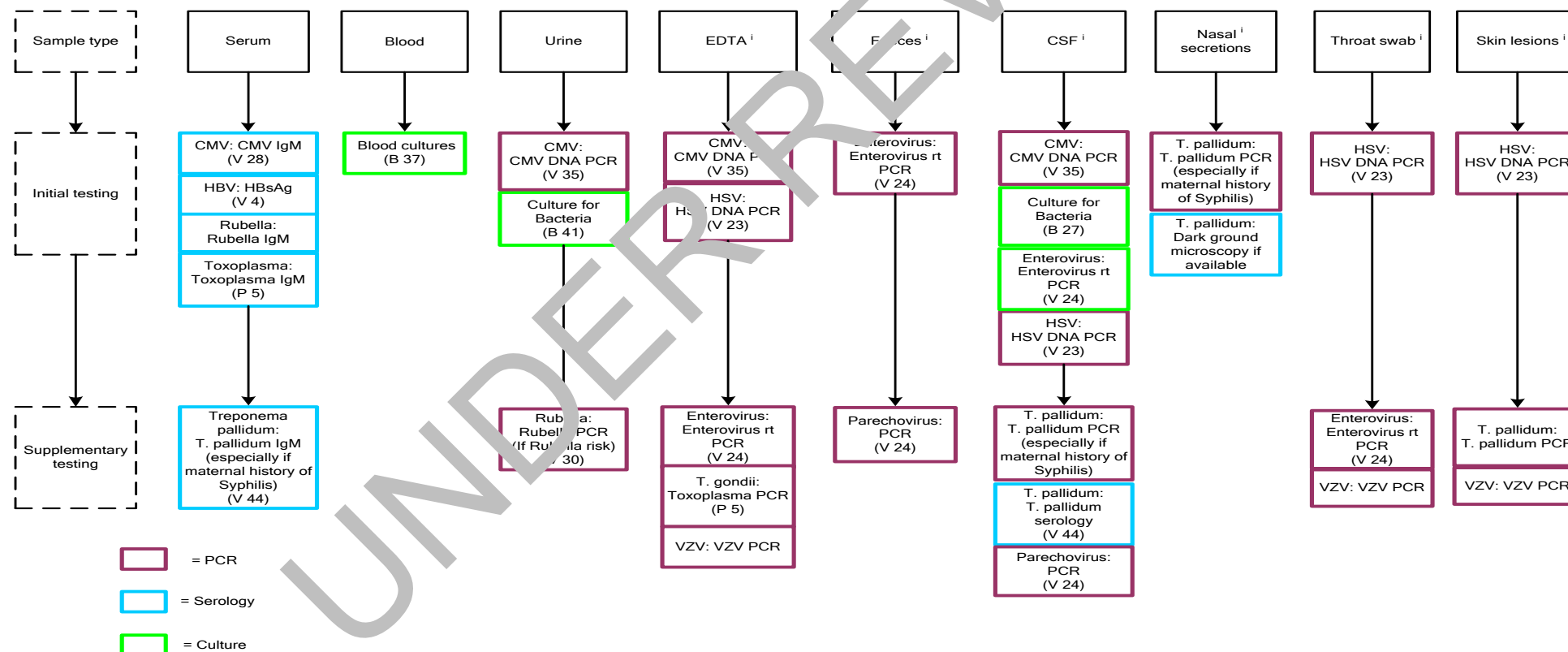
Chronic hepatitis B and hepatitis C may be present for many years without resulting in symptomatic disease, and detection of these infections could lead to successful treatment along with protection of relevant contacts from transmission. The minimum testing required in the setting of clinical details simply stating abnormal LFTs (when it is impractical to gain further information) should therefore be HBsAg and HCV antibody. Testing for other potential infective causes (for example, CMV, EBV, HAV, and HEV) should be based upon local decision.

Note: This algorithm investigates the causes of LFTs above the normal range at the particular time of testing / presentation.



Hepatitis in Neonates

Neonatal hepatitis is the term given to non-specific hepatic inflammation which may develop due to many different causes. The pathognomonic signs for this syndrome include conjugated hyperbilirubinaemia, dark urine and pale stools. These signs when presented should be investigated immediately by the liver unit even if awaiting the results of first line investigations. In some cases direct referral to a supra regional liver unit is appropriate to exclude the diagnosis of biliary atresia as quickly as possible. Early discussion with the supra regional liver unit is necessary for infants presenting with neonatal liver failure or possible obstruction. Discussion should not be delayed whilst waiting for results of first line investigations. In some cases paediatric gastroenterologists will perform some of the second line investigations depending upon radiological and histopathological expertise. There are also cases when the testing of maternal samples can act as surrogate testing for neonates and/or provide additional information.



Footnotes

- a) In all cases testing for hepatitis C should be considered (HCV rtPCR) although it may not be the primary cause of acute hepatitis.
- b) Information received must include country, length of stay, date of return, when symptoms manifested and immunisation details.
- c) When presented with a patient who is a chronic HBV carrier tests for all viruses should be carried out including the HIV antibody.
- d) Must consider underlying conditions, duration and severity.
- e) If pig farming then it should be noted that these are recognised reservoirs of Hepatitis E, however, farming is not considered to be of risk.
- f) Bacterial sepsis may present as positive cholestatic jaundice, increase in alkaline phosphatase, bilirubin and aminotransferases.
- g) With blood cultures consider *Brucella* and other organisms.
- h) For known exposure to Hepatitis C then PCR should be carried out at 6, 12 and 24 weeks after exposure.
- i) These samples should be taken based upon presenting symptoms and results from previous serology tests.

1 Notification to PHE^{1,2} or Equivalent in the Devolved Administrations³⁻⁶

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 (HCIs) and Creutzfeldt-Jakob disease (CJD) under 'Notification Duties of Registered Medical Practitioners': it is not noted under 'Notification Duties of Diagnostic Laboratories'.

Other arrangements exist in Scotland^{3,4} Wales⁵ and Northern Ireland⁶.

References

1. Public Health England. Laboratory Reporting to Public Health England: A Guide for Diagnostic Laboratories. 2013. p. 1-37
2. Department of Health. Health Protection Legislation (England) Guidance. 2010. p. 1-112.
3. Scottish Government. Public Health (Scotland) Act. 2008 (as amended).
4. Scottish Government. Public Health etc. (Scotland) Act 2008. Implementation of Part 2: Notifiable Diseases, Organisms and Health Risk States. 2009.
5. The Welsh Assembly Government. Health Protection Legislation (Wales) Guidance. 2010.
6. Home Office. Public Health Act (Northern Ireland) 1967 Chapter 36. 1967 (as amended).

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