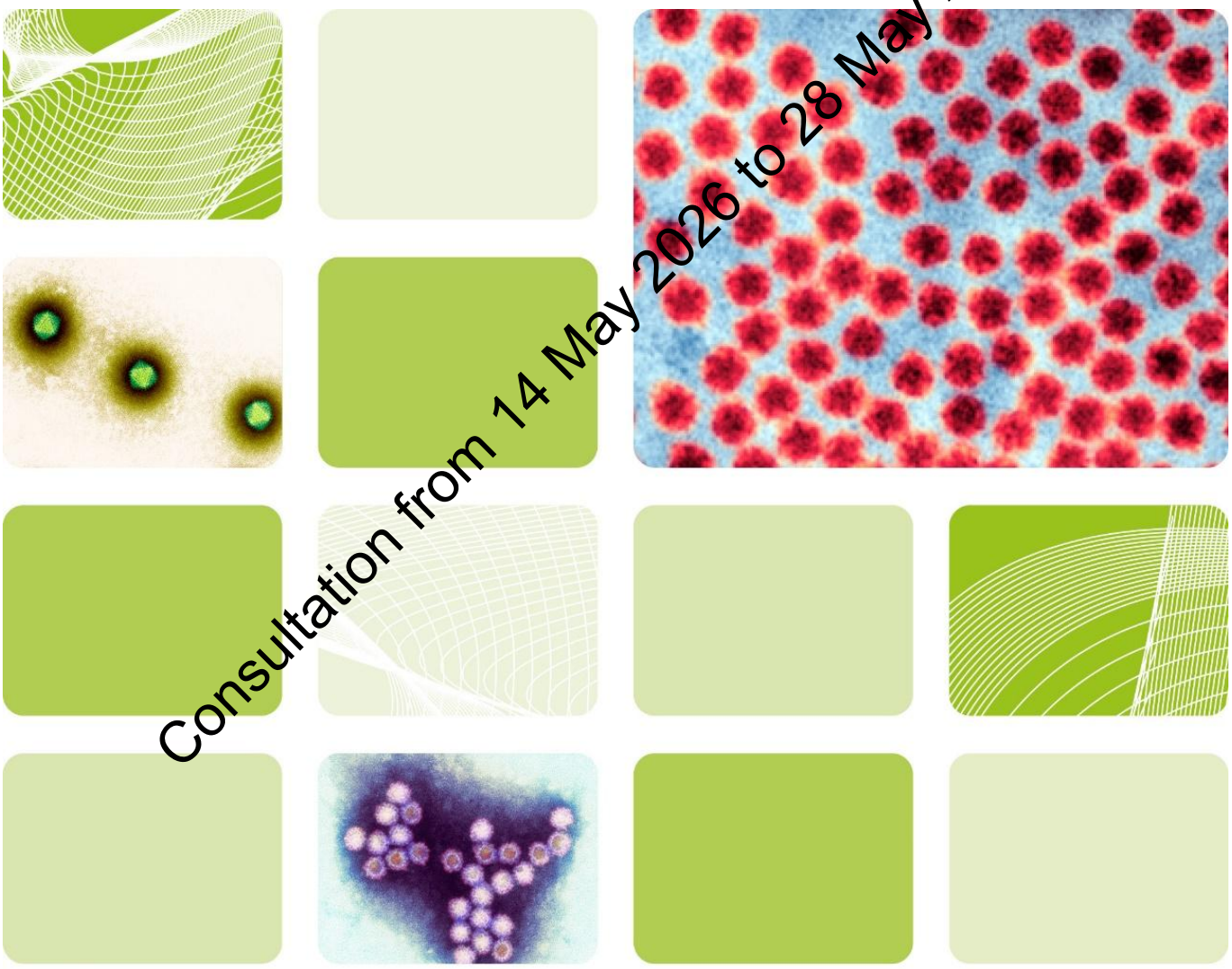
UK Health Security Agency

UK Standards for Microbiology Investigations

Laboratory diagnosis of hepatitis C virus



Acknowledgments

UK Standards for Microbiology Investigations (UK SMIs) are developed under the auspices of UKHSA working in partnership with the partner organisations whose logos are displayed below and listed on the UK SMI website. UK SMIs are developed, reviewed and revised by various working groups which are overseen by the UK SMI steering committee.

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UK SMIs are produced in association with:

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Contents

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Amendment table

The amendments since the previous version of this UK SMI document are listed in the amendments table below.

Any alterations to this document should be controlled in accordance with the local document control process.

Amendment number/date	x/dd.mm.yy
Issue number discarded	
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Anticipated next review date*	dd.mm.yy
Section(s) involved	Amendment

*Reviews can be extended up to 5 years where appropriate

1 General information

View general information related to UK SMIs.

2 Scientific information

View scientific information related to UK SMIs.

3 Scope of document

This UK Standards for Microbiology Investigation (UK SMI) document provides a detailed review of initial and supplemental laboratory-based serological and Nucleic Acid Amplification Tests (NAAT) for the detection and exclusion of hepatitis C virus (HCV). Refer to UK SMI S 1: Acute infective hepatitis for further information regarding clinical presentations of acute infective hepatitis and associated tests.

This document covers the different types of samples - whole blood, plasma and serum and the various methods of collection including venous and capillary blood sampling and dried blood spot (DBS) collection. It also addresses testing in specific patient groups. In addition, the algorithm aims to assist clinicians and laboratories in their decision making, by providing a framework for testing. Reporting and interpretation of the test results are provided in section 7.3 Table 1.

All assays should be verified prior to use. If assays are to be used outside the scope for which the manufacturer has designated for its use, these should be validated and shown to be fit for purpose by the laboratory to suit its needs. For more information, refer to UK SMI Quality-related guidance

This UK SMI is intended for use in the laboratory diagnosis of HCV infection within healthcare settings. It is not intended to cover:

- testing of blood prior to organ or blood donation (refer to the SaBTO Guidance on the microbiological safety of human organs, tissues and cells used in transplantation).
- testing methods or strategies commonly used in community testing such as POCT testing, self-sampling, or self-testing excluding DBST and finger-prick capillary testing.
- testing of specimens other than blood, plasma and serum obtained by venepuncture, such as oral fluid and saliva.
- monitoring of HCV RNA viral load and sustained virological response (SVR) for those undergoing treatment.

For the investigation and management of occupational exposure, refer to UKHSA (formerly PHE) and HSE guidelines (1-4).

For blood-borne virus (BBV) testing following dialysis away from base (DAFB), refer to DHSC guidelines (5,6).

For HCV testing and management in infants, refer to national or local paediatric HCV guidelines.

For the management and treatment of hepatitis C virus, refer to the EASL recommendations on treatment of hepatitis C virus and BHIVA guidelines for the management of hepatitis viruses in adults infected with HIV (7,8).

UK SMIs should be used in conjunction with other relevant UK SMIs.

Abbreviations

Abbreviation	Definition
HCV	hepatitis C virus
BBV	Blood-borne virus
DBS	Dried blood spot
POCT	Point of care testing
PWID	People who inject drugs
NAAT	Nucleic acid amplification test
DAAs	Direct-acting antivirals

Definitions

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

Reporting stage for serology

These terms are used for final or preliminary reports.

Positive – Report-stage for reactive result.

Negative – Report-stage for a non-reactive result.

Indeterminate – Manufacturer's or locally validated, evidence-based equivocal range.

Reporting stage for molecular assays

These terms are used for final or preliminary reports.

Scenarios	Qualitative result	Quantitative actual value	Quantitative Log_{10} of actual value
1	Detected	Actual value	Calculated log from actual value of the assay

Scenarios	Qualitative result	Quantitative actual value	Quantitative Log_{10} of actual value
2	Detected	Below the lower limit of quantitation of the assay	Calculated to the lower limit of the assay value
3	Detected	Above the upper limit of quantitation of the assay	Calculated to the upper limit of the assay value
4	Not detected	Not applicable	Not applicable
5	Inhibitory	Not applicable	Not applicable
6	Insufficient	Not applicable	Not applicable
7	Invalid	Not applicable	Not applicable

For reporting terminologies please refer to section 8: Post-laboratory processes.

4 Introduction

In the UK, hepatitis C virus infections remain a significant public health concern. The UK government has aligned its national efforts with the WHO's goal of eliminating HCV (and HBV) globally as a public health threat by 2030. In 2016 the UK government committed to the WHO's Global Health Sector Strategy on Viral Hepatitis (GHSS) and in May 2022 adopted the updated 2022-2030 strategy.

Significant progress has been made towards the elimination of HCV across the UK (9-12). Improvements in testing, including the use of point-of-care testing (POCT) in hard-to-reach areas, and opt-out testing programmes in emergency departments along with accessible treatments such as direct-acting antivirals (DAAs) are key drivers in hepatitis C elimination efforts (13-17). These advancements, if continued at the current rate, are predicted to achieve an 80% reduction in chronic HCV by 2030 compared to 2015 as the baseline (18,19).

4.1 Hepatitis C Virus (HCV)

Hepatitis C virus (HCV) is a blood-borne virus currently classified within the family *Hepaciviridae*, genus *Orthohepacivirus* (formerly *Hepacivirus* within the family *Flaviviridae*) (20-22). It is a single-stranded, positive-sense enveloped RNA virus with a genome of approximately 9600 bases (20). There are eight known genotypes of HCV (1 to 8) to date, each with multiple subtypes that are distributed worldwide (23-26). The most common genotypes in the UK are HCV genotypes 1 and 3 (27,28).

4.2 Stages of HCV infection

New acute HCV infections are usually asymptomatic (85 - 90% cases) and therefore acute infection is rarely diagnosed. Around 30% (15 - 45%) of infected persons spontaneously clear the virus within 6 months of infection without any treatment (21,29-31). Spontaneous viral clearance is rare beyond 4 to 6 months of infection, therefore HCV RNA detectable for longer than 6 months is defined as chronic HCV infection (21,29-31). Levels of HCV RNA remain relatively stable over time in chronically infected patients.

Sustained viral clearance, also referred to as a sustained virological response (SVR), is defined as the absence of detectable HCV RNA in blood at least 12 weeks after completion of antiviral therapy, confirmed using a sensitive nucleic acid amplification test. Achievement of SVR is considered equivalent to virological cure(32-34).

HCV reinfection is defined as the reappearance of HCV RNA at least 6 months after a SVR with a different HCV genotype or strain (7).

4.3 HCV diagnostic approaches

WHO recommends that all adults have access to and be offered HCV testing with linkage to prevention, care and treatment services (21). WHO also recommends testing in settings with high HCV antibody seroprevalence of ≥ 2% or ≥ 5% in the

general population (21). In addition, it recommends blood donor screening, as well as focused or targeted testing of specific high-risk groups, including migrants from endemic regions, health-care workers, people who inject drugs (PWID), people in prisons and custody, men who have sex with men (MSM), sex workers and HIV-infected persons (21).

Targeted and more frequent hepatitis C virus screening in people who are at increased risk of infection is also strongly recommended by UK bodies such as UKHSA, British HIV Association, British Association of Sexual Health and HIV, and National Institute for Health and Care Excellence to address the need to improve rates of earlier diagnosis (8,18,21,35).

Specific groups are usually screened for HCV by specialist service providers. These include blood, organ or tissue donors, end-stage kidney disease patients, new healthcare workers who will perform exposure-prone procedures (EPPs) and healthcare workers following occupational exposure.

It should be noted that while routine testing of pregnant women for HCV infection is recommended by the National Strategy Group for Viral Hepatitis and NHS England, this is not currently endorsed by the UK National Screening Committee. However, pregnant women at increased risk of infection should be tested (36,37).

Routine laboratory diagnosis of established infection is commonly based upon the detection of antibodies for the virus using serological methods, followed by the detection of the virus using HCV RNA NAAT on the same sample to confirm viraemia (20,35,38-42).

The approach to HCV infection diagnosis and monitoring is tailored to individual patient circumstances, considering factors such as immune status, and risk behaviours. In the UK, since the introduction of screening of blood and blood-derived products, HCV is most common in PWID, with 10% and 70% antibody prevalence for those injecting for 2 years and 15 years respectively (18,19,43). This is especially the case within PWID populations in prison or those experiencing homelessness.

Antibodies to HCV are detected using Enzyme Linked Immunosorbent Assays (ELISA), Enzyme Immunoassays (EIA), Chemiluminescent Immunoassays (CLIA) (44). Confirmatory serology tests, including recombinant Immunoblot Assay (RIBA) and other second-line antibody tests are no longer commonly used. However, laboratory protocols may differ based on local practice and resource availability. Assays have been developed to detect antibodies to an increasing range of viral proteins from second generation (core proteins and non-structural proteins 3 and 4), third generation (also with non-structural protein 5) and now fourth generation (combine antibody detection with direct detection of HCV capsid antigen) (41,45).

The diagnosis of recently acquired or chronic HCV infection is based on the detection of HCV RNA by qualitative or quantitative molecular methods (7). An HCV RNA assay with target sensitivity level of 15 IU/mL or lower is recommended (7). Reflex NAAT

testing on existing antibody positive or indeterminate samples is recommended to streamline the HCV care pathway (46-48). Molecular methods are recommended over HCV core antigen testing for confirmation as they have higher sensitivity. Therefore, we do not recommend hepatitis C core antigen testing (49-51). For this reason, hepatitis C core antigen testing will not be discussed further within this document.

4.4 Types of HCV diagnostic tests and markers of infection

- **HCV RNA** is a marker of replicating virus in peripheral blood. HCV RNA may be detected as early as 1 to 3 weeks after initial infection, approximately 1 month before the appearance of total HCV antibodies.
- **Immunoglobulin G (IgG) antibodies** emerge after IgM antibodies and persist lifelong beyond the clearance of HCV RNA. Most assays are designed to detect IgG which become detectable at approximately 8 to 12 weeks following exposure (52).

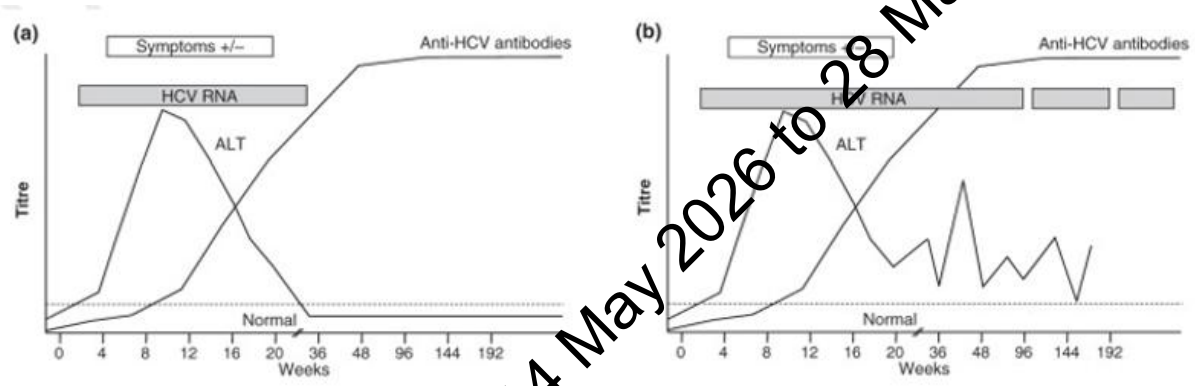


Figure 1. Kinetics of virological markers during acute (a) and chronic (b) hepatitis C virus (HCV) infection (53). HCV antibodies appear following the acute phase of infection (Fig 1a and 1b). HCV RNA persists beyond 6 months in chronic HCV infection (Fig 1b).

5 Safety considerations

The section covers specific safety considerations related to this UK SMI and should be read in conjunction with the general safety considerations (54-72).

Hepatitis C virus is classified as a Hazard Group 3 agent; however full containment level 3 measures may be derogated based on local risk assessment.

5.1 Specimen collection, transport, and storage

Use aseptic technique to collect blood.

Collect adequate and appropriate specimens in appropriate leak-proof containers that meet the required regulatory standards for safety and quality, and transport in sealed plastic bags.

Compliance with postal, transport and storage regulations is essential.

This 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.

5.2 Specimen handling and processing

Laboratory procedures that give rise to infectious aerosols must be conducted in a microbiological safety cabinet.

Refer to current guidance on the safe handling of all organisms documented in this UK SMI.

The above guidance should be supplemented with local COSHH and risk assessments.

6 Pre-laboratory processes

6.1 Specimen type

Whole blood, serum or plasma DBS or finger capillary

Note: Venous blood is the preferred specimen for hepatitis C virus testing. However, alternative sample types can also be used. DBS or finger capillary samples are increasingly employed in hard-to-access populations such as in prisons, homeless and in people who inject drugs (PWID) and can be used in HCV serology and qualitative NAAT for HCV diagnosis (14,73).

Use of specific sample types in individual assays is subject to local verification and validation requirements, alongside the manufacturer's instructions.

6.2 Specimen collection and handling

Collect specimens as soon as possible after onset of symptoms.

For safety considerations refer to Section 5.

Specimens collected in EDTA, or serum separator tubes are generally acceptable for testing. Please refer to manufacturer instructions for specimen acceptability.

Providing adequate sample volume is essential for maintaining test sensitivity and accuracy. If dilution of a sample is performed by the laboratory, it is recommended to report on the dilution factor with the results.

Refer to local laboratory protocols or the manufacturer's instructions for specific requirements on serum or plasma separation for NAAT.

Refer to current guidance on the safe handling of all organisms documented in the UK SMI general safety document.

6.3 Specimen transport and storage

This section covers specimen transport and storage consideration related to this UK SMI, and should be read in conjunction with the scientific information on our webpages.

For safety considerations refer to Section 5.

Specimens should be transported and processed as soon as possible (74). If processing is delayed, refrigeration is preferable to storage at ambient temperature (74).

Note: Specimens for NAAT can be stored long-term at - 20° or - 70°C to minimise RNA loss (75).

Samples should be retained in accordance with The Royal College of Pathologists guidelines 'The retention and storage of pathological records and specimens' (71).

6.4 Technical limitations

6.4.1 Sample types and collection methods

The standard sample types are whole blood, serum and plasma. Dried Blood Spots (DBS) and capillary blood samples have been adapted for use in HCV serology and qualitative NAAT for HCV diagnosis (76-79). These samples are useful in identifying individuals with HCV but may be limited by lower sensitivity for HCV RNA quantification, particularly for monitoring purposes and by potential inhibition due to the nature of the samples (80-82). Therefore, appropriate local validation and/or verification is required prior to their use to ensure accuracy and effectiveness in both diagnostic and monitoring context.

For more information on managing inhibition and contamination in molecular methods, refer to UK SMI Q 4: Good practices when performing molecular amplification assays.

6.4.2 Immunoassays

HCV antibody tests:

The limitations of HCV antibody tests are most evident when they are used in isolation, particularly in low-risk populations and in immunocompromised individuals (e.g., patients receiving renal dialysis). In these groups, results may be unreliable, and individuals with recent exposure, suspected acute hepatitis C, or that are immunocompromise should undergo HCV RNA testing using NAAT. In low-prevalence settings, weakly positive antibody results may represent false positive results (83).

Antibody production is delayed following infection, typically becoming detectable after 8-12 weeks in immunocompetent individuals and potentially much later, or not at all, in immunocompromised patients (83,84). This delay reduces the clinical utility of antibody testing during the window period and in patients with impaired immune responses.

Additionally, antibody tests cannot differentiate between:

- Past resolved infection
- Chronic infection or
- reinfection with a different HCV genotype.

For these reasons, individuals who are immunocompromised or have risk factors for recent acquisition for HCV infection should be assessed using HCV RNA detection by NAAT (83-85).

6.4.3 Molecular methods

HCV RNA is a marker of active viral replication, but low-level results in EDTA blood and serum should be interpreted with caution particularly near the assay's limit of detection. Such results may reflect assay variability or occur during antiviral therapy; a single low-level result cannot determine virological responses. Laboratories should therefore provide detailed quantification for more informed clinical interpretation. Careful evaluation, including repeat testing or clinical correlation, may be required. In addition, if dilution is performed it is recommended to report the dilution factor with the HCV RNA results to ensure accurate interpretation of viral load and support clinical decision-making.

Follow manufacturer's instructions for assay thresholds and recommended dilutions.

Some assays may require non-standard dilutions (e.g., 1:2.5 or 1:5.0), and local laboratory practice may also determine when dilution is performed. When reporting diluted samples, the adjusted threshold or corrected result should be clearly stated. All results must be interpreted in conjunction with clinical information.

For examples on how to report on the dilution factor, please see below with a result comment and a dilution factor comment.

- For a "not detected" result after dilution, a suitable combined comment is: *"HCV RNA was not detected following a 1:x dilution. After applying the dilution factor, the adjusted threshold is [value] IU/mL. Results should be interpreted within the clinical context."*
- For a "detected" result after dilution, a suitable combined comment is: *"HCV RNA detected. After applying the 1:x dilution factor, the final viral load is [value] IU/mL. Results should be interpreted within the clinical context."*
- Example calculation (if needed): an analyzer readout of 200,000 IU/mL with a 1:2 dilution produces a final reported value of 400,000 IU/mL.

6.5 Test selection

The choice of test can be influenced by risk factors.

Please note that HCV RNA NAAT is recommended as the initial test in certain patient populations or situations to avoid missing cases of HCV infection. This ensures early detection and appropriate management.

6.5.1 Immunocompetent people

The initial screening assay should be a 3rd or 4th generation antibody assay which if positive should be followed by an HCV RNA NAAT to determine whether the patient is currently infected with HCV. People at risk of acute HCV infection or HCV reinfection should be screened using HCV RNA NAAT. There is no need for a second antibody assay because it is of very little clinical utility.

6.5.2 Immunocompromised people

Screen using HCV RNA NAAT.

For immunosuppression definitions, refer to UKHSA Immunisation against infectious disease.

6.5.3 Pregnant women and infected babies

Pregnant women who are at increased risk for hepatitis C virus infection should be tested at their prenatal visits by testing for HCV antibodies. If the initial results in pregnant women with on-going risk factors for hepatitis C virus infection are negative, the test should be repeated later, in the third trimester of pregnancy (36,86). It should be noted that routine testing of pregnant women for HCV infection is currently not recommended (87).

Routine testing of babies born to mothers with evidence of hepatitis C virus antibodies who are HCV RNA negative is not required but may be considered where there is clinical or historical evidence of recent maternal infection (88).

For women who have acquired infection during pregnancy, but have cleared viraemia, the baby should be followed up. Consider testing children from previous pregnancies or partners of current HCV positive mother. Please refer to local or national guidelines for paediatric HCV testing and management.

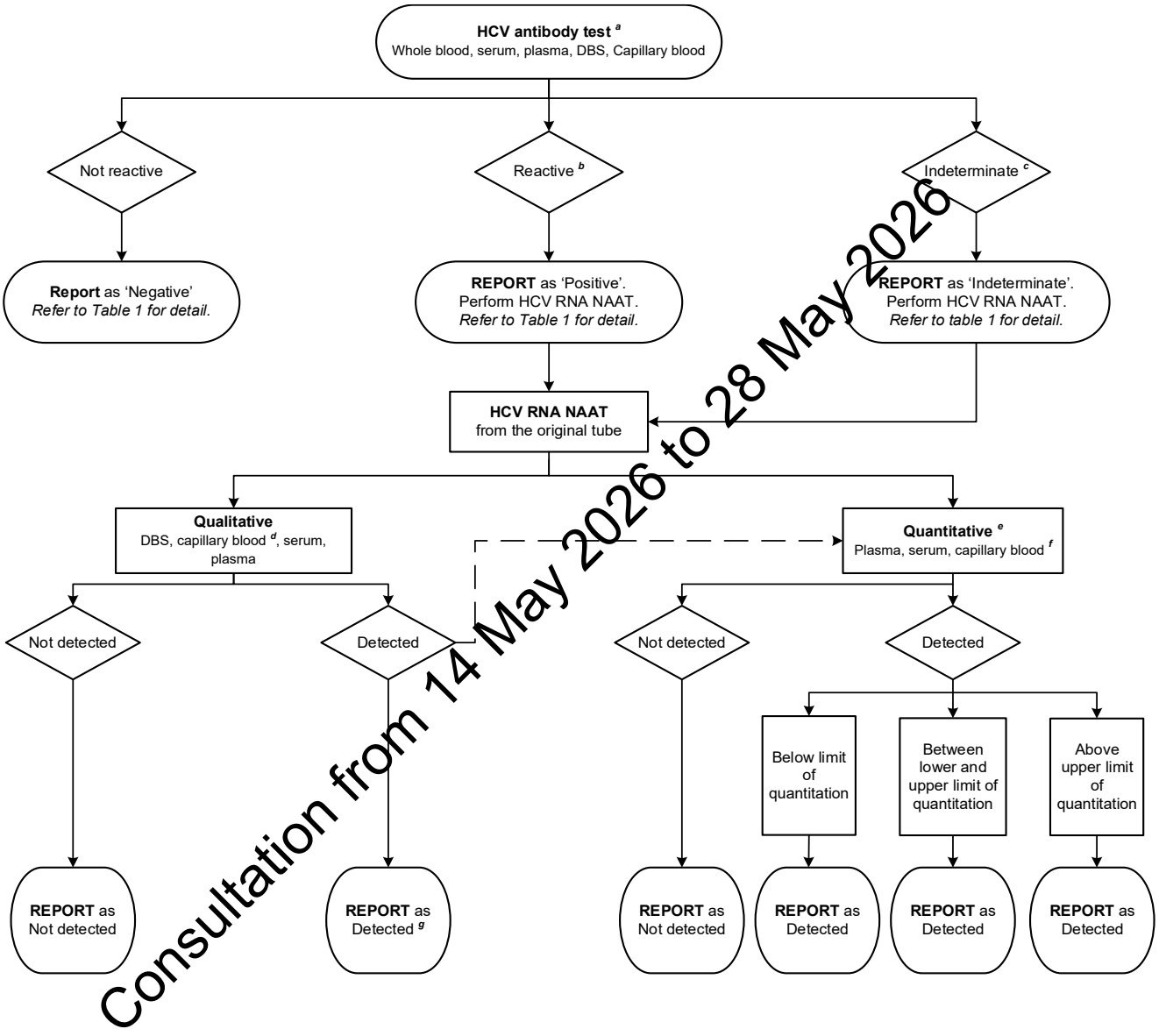
For babies born to a PWID, if the mother is unavailable to consent for testing and there is evidence of suspected HCV infection, test the baby for HCV antibody and follow up if the baby is HCV antibody positive. If the baby is HCV antibody negative, then this is highly predictive of absence of infection providing the exposure risk is more than 6 months ago (89).

A negative HCV RNA NAAT result in babies may reflect resolution of infection (>25% resolved), fluctuating RNA level or a lab error. Therefore, an antibody test should be performed between 12 to 18 months (90,91). Please note that other guidelines do not always advocate early NAAT testing in children (88).

Infants infected with HCV should be monitored and assessed clinically every 6 - 12 months to identify any risks of progressive liver fibrosis during childhood (88,92).

7 Laboratory processes

7.1 Investigation of hepatitis C infection by HCV antibody testing confirmed by HCV RNA NAAT (7,39,42,93)



Footnotes:

a Screening directly with HCV RNA NAAT is required for certain patient groups, particularly those who are immunocompromised or when the risk of recent or ongoing infection is high, as NAAT is more reliable in these cases than HCV antibody testing.

b Report at this stage as an interim report if additional testing will be delayed and the result may have immediate significance for patient management; suggested wording "Initial HCV antibody reactive. Hepatitis C RNA result to follow".

c Some HCV antibody kits do not provide an indeterminate range. Indeterminate ranges may be established using local data.

d Follow up with quantitative HCV RNA NAAT is recommended for both DBS and capillary blood samples to assess viral load and guide treatment decision.

e For detected results, quantitative HCV RNA NAAT reports include three fields: 'Detected', Actual value in IU/mL and Log of actual value. Report according to manufacturer's instructions for assay limits. For non-detected results, only 'Not detected' is reported.

f Capillary blood may be used for quantitative reporting if validated according to local protocols and manufacturer guidance.

g For samples with very low-level detection near the assay's sensitivity threshold, consider an interpretive comment indicating that the result is close to the assay limit and may require clinical correlation or repeat testing.

8 Post-laboratory processes

8.1 Interpretation and reporting of results

Reporting terminology should be determined through local laboratory clinical governance, ensuring results are communicated in a way that optimises patient safety and supports accurate clinical interpretation. Laboratories should use clear, consistent terminology appropriate to their users, reflecting local clinical pathways and risk management processes. While UK Standards for Microbiology Investigations (UK SMIs) provide guiding principles, the final choice of wording remains a matter of local professional judgement, informed by local disease population and accountability.

The final result should be able to distinguish active HCV infection from resolved infection using a combination of antibody and NAAT tests.

It is recommended that when HCV test results are obtained from diluted samples, the diluted factor is included in the report to aid in the interpretation of low-positive results and support clinical decision-making.

Following an initial (first sample) positive result, it is best practice to request a repeat sample.

Table 1. Investigation of hepatitis C virus infection by HCV antibody testing confirmed by NAAT.

	1st Assay	2nd Assay	Interpretative comments	Notes
	HCV Ab	**HCV NAAT**		
1	Negative	Not tested	HCV antibody not detected.	In the case of suspected acute hepatitis C or in immunocompromised patients, HCV RNA testing should be part of the initial evaluation.
2	Negative	RNA Detected [quantitative value as appropriate]	Evidence of active HCV infection. Advise referral to an appropriate specialist for further assessment/treatment. Hepatitis A and B vaccine recommended if appropriate.	For a first detected HCV RNA sample: Indicates either acute HCV infection or possibly a chronic infection in an immunocompromised patient. Please ensure hepatitis A and B vaccination status is known and vaccination given if needed. Reflex genotyping may be considered for HCV RNA detected samples to support surveillance, treatment decisions, or local policy requirements. BBV testing should also be considered unless already performed. For a second and subsequent HCV RNA detected sample: Known active HCV infection
3	Positive	RNA detected [quantitative value as appropriate]	Evidence of active HCV infection.	For a first detected HCV RNA sample: HCV antibody detected in the presence of HCV RNA allows one to infer with confidence that the HCV antibody reaction is a true positive.

	1st Assay	2nd Assay	Interpretative comments	Notes
	HCV Ab	HCV NAAT		
			Advise referral to an appropriate specialist for further assessment/treatment. Hepatitis A and B vaccine recommended if appropriate.	Please ensure hepatitis A and B status is known and vaccination given if needed. Reflex genotyping may be considered for HCV RNA detected samples to support surveillance, treatment decisions, or local policy requirements. BBV testing should also be considered unless already performed. For a second and subsequent HCV RNA detected sample: Known active HCV infection
4	Indeterminate	RNA detected [quantitative value as appropriate]	Evidence of active HCV infection. Advise referral to an appropriate specialist for further assessment/treatment. Hepatitis A and B vaccine recommended if appropriate.	For a first detected HCV RNA sample: If HCV antibody assay is indeterminate and RNA detected, this may be recent infection. Consider review of clinical and results history, that is, can seroconversion to HCV antibodies be documented. Please ensure hepatitis A and B status is known and vaccination given if needed. Consider requesting HCV genotyping and other BBV testing unless already performed. For a second and subsequent HCV RNA detected sample: Known active HCV infection

	1st Assay	2nd Assay	Interpretative comments	Notes
	HCV Ab	**HCV NAAT**		
5	Positive	RNA not detected	No evidence of active HCV infection.	HCV antibody positive result may indicate past HCV infection. EASL 2020 recommend that “Anti-HCV antibody-positive, HCV RNA-negative or HCV core antigen-negative patients with suspected *de novo* recently acquired HCV infection should be retested for HCV RNA 12 and 24 weeks later to confirm definitive clearance” (7).
6	Indeterminate	RNA not detected	No evidence of active HCV infection.	If HCV antibody assay is equivocal and HCV RNA is not detected this may represent false reactivity or waning of antibody (94-96).

8.2 Public health management

All confirmed cases of HCV infections should be reported to local public health authorities.

For information regarding notification refer to:

https://www.gov.uk/government/collections/notifications-of-infectious-diseases-noids

For further information on public health management refer to:
https://www.gov.uk/government/collections/hepatitis-c-guidance-data-and-analysis

In addition to reporting new positive diagnosis to UKHSA Health Protection Teams, participating laboratories should also report into sentinel surveillance programmes for HCV.

In the UK, guidance for hepatitis C infected health care workers (HCW) is available. See link: https://www.gov.uk/guidance/bloodborne-viruses-in-healthcare-workers-report-exposures-and-reduce-risks

For the final report published on the Infected Blood Inquiry in May 2024 refer to the following link: Reports | Infected Blood Inquiry

9 Referral to reference or specialist testing laboratories

When sending away isolates to reference or specialist testing laboratories for processing, ensure that the specimen is placed in the appropriate package and transported accordingly. Follow local regulations and instructions provided by the reference or specialist testing laboratories for sending isolates.

Contact the appropriate reference laboratory (refer to the links provided below) for information on the tests available, turnaround times, transport procedure and any other requirements for sample submission.

England

Wales

Scotland

Northern Ireland

10 Public Health Responsibilities of diagnostic laboratories

Diagnostic laboratories have public health responsibility as part of their duties. Amongst these are additional local testing, or referral to further characterise the organism as required, primarily for public health purposes e.g., routine cryptosporidium detection; serotyping or microbial subtyping; and a duty to refer appropriate specimens and isolates of public health importance to a reference laboratory.

Diagnostic laboratory outputs inform public health intervention, and surveillance data is required to develop policy and guidance forming an essential component of healthcare. It is recognised that additional testing and referral of samples may entail some costs that has to be borne by the laboratory but in certain jurisdictions these costs are covered centrally.

Diagnostic laboratories should be mindful of the impact of laboratory investigations on public health and consider requests from the reference laboratories for specimen referral or enhanced information.

References

An explanation of the reference assessment used is available in the scientific information section on the UK SMI website.

For suggested citation of UK SMIs, refer to UK SMI Development.

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