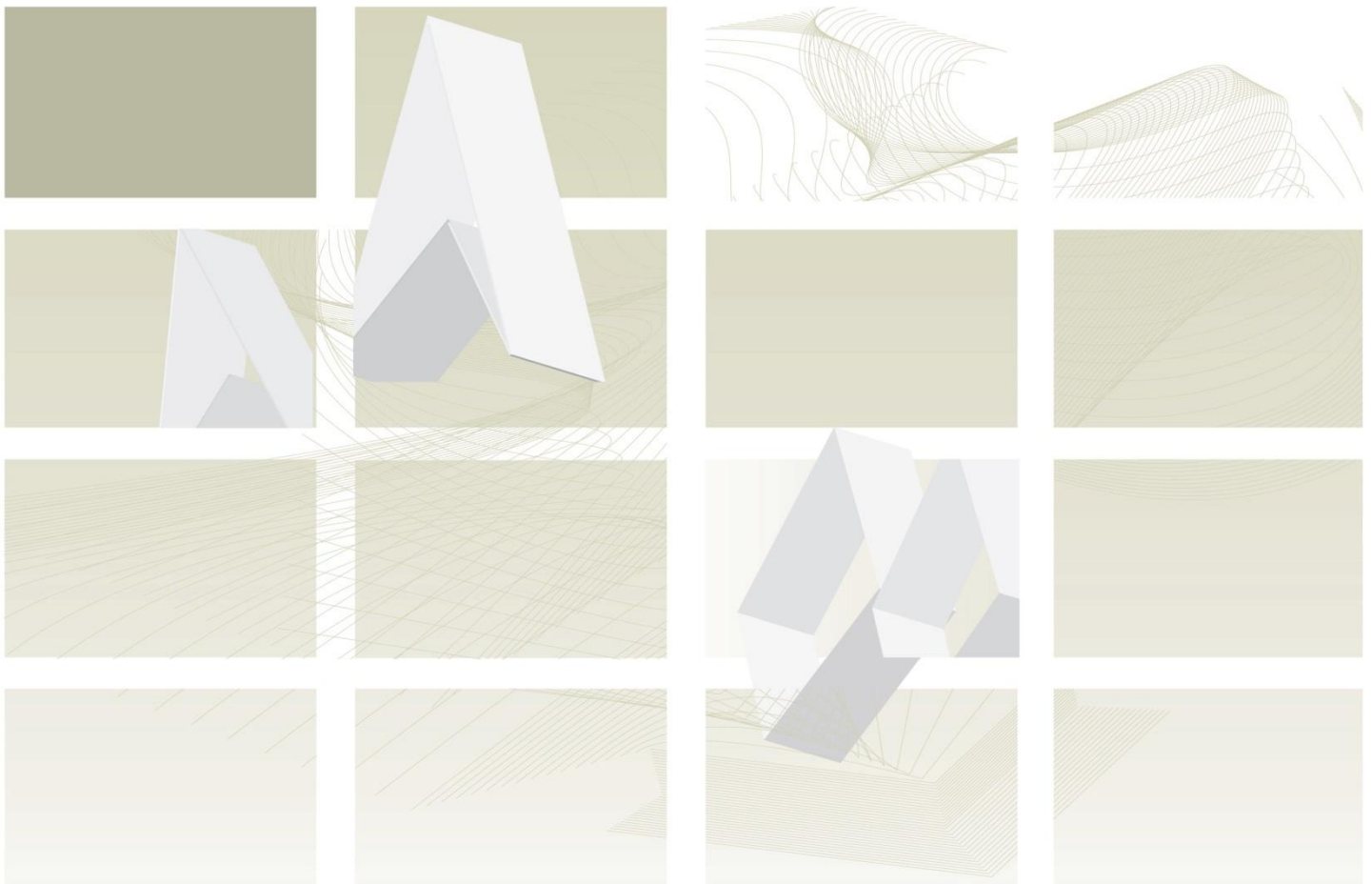




UK Standards for Microbiology Investigations

Review of users' comments received by
Working group for microbiology standards in clinical
virology/serology

V 8 Vertical and perinatal transmission of hepatitis C



"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**."

Recommendations are listed as ACCEPT/ PARTIAL ACCEPT/DEFER/ NONE or PENDING

Issued by the Standards Unit, National Infection Service, PHE

Page: 1 of 8

RUC | V 8 | Issue no: 2 | Issue date: 03.12.18

Consultation: 27/04/2018 – 11/05/2018

Version of document consulted on: V 8dq+

Proposal for changes

Comment number	1		
Date received	02/05/2018	Lab name/Professional body	Royal College of General Practitioners
Section	P9		
Comment			
It's a tiny thing but... when stating any risks of progressive fibrosis can it say any risks of progressive liver fibrosis, please? Fibrosis is culturally referred to in lung disease and liver fibrosis and fibroscans are relatively new so I think the clarity (it has been pasted without from the SIGN guideline) is helpful. Otherwise it's all really clear.			
Evidence			
<i>Not completed.</i>			
Financial barriers			
<i>Not completed.</i>			
Health benefits			
<i>Not completed.</i>			
Recommended action	ACCEPT This has been amended accordingly in the document.		

Comment number	2		
Date received	06/05/2018	Lab name/Professional body	Laboratory
Section	follow up of women found to be HCV +ve		
Comment			
Discovering a woman to be HCV positive, gives an opportunity not only to manage the risk of perinatal transmission of HCV, but to refer and investigate appropriately children from previous pregnancies. Even if current viraemia indicates a low risk to the baby in the current pregnancy, viraemia may have been more significant in previous pregnancies. Not sure about the title and how to separate the definition of vertical transmission from perinatal transmission?			
Evidence			
Reference No1 in the list attached to the document.			

Financial barriers	
<i>Not completed.</i>	
Health benefits	
Only benefits in clarifying process to all bodies involved.	
Recommended action	<p>NONE</p> <p>This is outside the remit of this document. However, a footnote has been added to say that “In current HCV positive patients, to consider previous pregnancies”.</p> <p>Both vertical transmission and perinatal transmission will be in the document as it is difficult to separate.</p>

Comment number	3		
Date received	08/05/2018	Lab name/Professional body	Public Health England, Bristol
Section	Multiple		
Comment			
<p>a. Footnote c - if the mother is unavailable for testing, consider consent issues of testing the baby.</p> <p>b. Footnote g - prioritises antibody over NAAT if insufficient for both, however, recommended test is NAAT. Please clarify. What if the baby was HCV antibody negative at 3 months of age? What would you report?</p> <p>c. Footnote h - is the intention that the specialist team will repeat the test immediately or wait for a further 3 months?</p> <p>d. Footnote i - seems out of place when advising antibody testing at 12-18 months, as the footnote is about comparative antigen and RNA assay sensitivity.</p> <p>e. Algorithm: HCV RNA positive at 3 months, repeat at 6 months negative arm should include antibody testing at 6 months also- if reactive that would support the possible clearance of infection.</p> <p>f. Algorithm - somewhere mention that it can be entered at any age. For example, what should be done if the child presents at 4 months of age, or 7 months?</p> <p>g. Page 14 - suggest remove headers 1st and 2nd assay. When I first read it I made the mistake of thinking it referred to a screen and confirmatory test set.</p> <p>h. Report comments 1- hepatitis A vaccine is not licensed under 1 year of age.</p> <p>Note - I ran out of time to finish going through the rest of the document.</p> <p>i. Ref 8 has an unusual 'electronic address pso' in it.</p>			
Evidence			
None; please only check logic of my suggestions.			

Financial barriers	
No.	
Health benefits	
Should benefit through identification of HCV infected infants.	
Recommended action	<p>a. ACCEPT The wording for footnote c has been rephrased accordingly.</p> <p>b. ACCEPT The NAATs has been updated to be test of priority over antibody test in the document accordingly.</p> <p>c. ACCEPT The further testing will be clarified in the document.</p> <p>d. ACCEPT The wording for footnote i) have been rephrased and clarified in the document.</p> <p>e. NONE Laboratories may wish to perform this test but it is down to local protocols.</p> <p>f. NONE This should be agreed on a case by case basis. Babies that present at any time before 11months will have NAATs only and not the antibody test which is not recommended for babies under 1 year of age. Babies that present at 12 months and above will have antibody testing.</p> <p>g. ACCEPT The headers have been removed and the Report Comments table amended accordingly.</p> <p>h. ACCEPT The report comment 1 notes have been updated as hepatitis A vaccine is not licensed under 1 year of age.</p> <p>i. ACCEPT This has been amended accordingly in the document.</p>

Comment number	4		
Date received	11/05/2018	Lab name/Professional body	Laboratory
Section	p11		
Comment			
<p>a. p11 Hepatitis C is a notifiable disease and laboratories should ensure that the Health Protection teams are notified of any new cases in line with national public health legislation - this is ambiguous, although perhaps technically correct. I would not inform HPTs of a patient who is HCV antibody positive, HCV RNA PCR negative. I would usually rely on SGSS to report chronic HCV cases to PHE. I probably would contact the local HPT about an acute HCV, which is a relatively infrequent event. I've just spoken to HPT colleagues about this point and this is our consensus.</p> <p>b. p9 Pregnant women who are at increased risk for hepatitis C infection should be screened at their prenatal visits by testing for anti-HCV antibodies. If the initial results are negative, this should be repeated later on in pregnancy in women with on-going risk factors for hepatitis C infection^{7,8}. Some more explicit guidance on which women are at increased risk would be helpful. In my experience, quite a few HCV patients are from developing countries with no obvious risk factor like history of IV drug use, MSM etc. Regions with high HCV prevalence include South Asia, Central Asia, North Africa, Central Africa etc. It is relatively rare to see HCV test requests in pregnancy, except when HCV infection or obvious risk is identified by patient self-declaration, or in the antenatal clinic consultation.</p> <p>c. p14, 15, 16, spelling: I do not support American English spellings in UK national guidelines i.e. it should be Paediatric, not Pediatric.</p>			
Evidence			
Note spelling of paediatrics https://www.rcpch.ac.uk/			
Financial barriers			
No.			
Health benefits			
No.			
Recommended action	<p>a. NONE This will remain in the document as it is standard in the UK SMI document template.</p> <p>b. NONE This is outside the remit of this UK SMI document. The scope of this document covers perinatal diagnosis and not antenatal diagnosis.</p> <p>c. ACCEPT This has been amended in the document accordingly.</p>		

Comment received outside of consultation

Comment number	1		
Date received	16/05/2018	Lab name/Professional body	IBMS
Section	Multiple		
Comment			
Definitions			
<p>a. The purpose of the terms “equivocal” and “inhibitory is not clear. Is the policy advocating the use of “equivocal” and “inhibitory” in reports regardless of the output from the analyser?</p>			
Introduction			
<p>b. The first sentence in the first paragraph should read “<i>Hepatitis C is a blood-borne viral infection transmitted through contact with infected blood and body fluids.</i>”</p> <p>c. Second sentence second paragraph <i>asymptomatic</i> would be a better choice of word than <i>silent</i>.</p> <p>d. Third paragraph and throughout the document the word <i>in utero</i> should be in italics.</p> <p>e. Third paragraph, it is suggested the second sentence should be split into two sentences to read “<i>Hepatitis C virus can be transmitted to the infant in utero or during the peripartum period. Infection during pregnancy is associated with ...</i>”</p> <p>f. Fourth paragraph second sentence. It is suggested that “<i>serology testing</i>” is replaced with <i>screening</i>.</p>			
Laboratory diagnosis			
<p>g. First paragraph second sentence. “<i>this should be repeated later on in pregnancy...</i>” Is there a recommended time interval or stage in pregnancy for repeat testing?</p>			
Safety Considerations			
Optimal transport and storage conditions			
<p>h. “<i>Specimen should be transported and processed...</i>” The type of acceptable samples should be noted here.</p>			
Public health management			
<p>i. Fourth paragraph replace <i>diagnosis</i> with the plural <i>diagnoses</i>.</p> <p>j. PHE Health Protection Teams – should a reference be made to the arrangements in the devolved UK countries?</p>			
Footnotes			
<p>k. Note a) First sentence “<i>... mother to baby occurs in 3-6%.</i>” Does this refer to live births?</p> <p>l. Note a) Second sentence “<i>...in up to one-third</i>” would be clearer and read better if <i>of infections</i> was added before the full-stop.</p> <p>m. Note i) “<i>If antigen negative ...</i>” Should this be <i>if antibody positive, but antigen</i></p>			

<i>negative?</i>	
Report comments	
n. 2 – RNA not detected at 6 months, third comment “Advise anti-HCV antibody testing at 12-18 months...” should read <i>If absence of RNA confirmed, advise anti-HCV...</i>	
Evidence	
<i>Not completed.</i>	
Financial barriers	
<i>Not completed.</i>	
Health benefits	
<i>Not completed.</i>	
Recommended action	<p>a. NONE This is standard in all UK SMI documents and dependent on the platforms used.</p> <p>b. ACCEPT The sentence has been rephrased in the document.</p> <p>c. ACCEPT This has been updated in the document.</p> <p>d. NONE This word is not italicised as it is a commonly used Latin loan word which has been used long enough and has become a naturalised citizen of the English language and printed like any other word. The UK SMIs also follow the PHE Editorial Style guide.</p> <p>e. ACCEPT This has been updated in the document.</p> <p>f. NONE The wording will remain as it is the document.</p> <p>g. NONE This is already in the document.</p> <p>h. NONE This has already been mentioned in the scope of the document and it is down to manufacturers’ recommendations.</p> <p>i. ACCEPT This has been updated in the document.</p> <p>j. NONE This has already been mentioned under the subheading</p>

	<p>“Notification to PHE, or equivalent in the devolved administrations” in the document.</p> <p>k. NONE</p> <p>The Virology Working Group members feel that the statement is clear enough and will remain as it is in the document.</p> <p>l. ACCEPT</p> <p>This has been updated in the document.</p> <p>m. NONE</p> <p>This has been updated in the document accordingly.</p> <p>n. NONE</p> <p>The report comment will remain as it is in the document.</p>
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Respondents indicating they were happy with the contents of the document

Overall number of comments: 2			
Date received	01/05/2018	Lab name/Professional body	Ipswich Hospital NHS Trust
Health benefits			
<i>Not completed.</i>			
Date received	11/05/2018	Lab name/Professional body	Laboratory
Health benefits			
<i>Not completed.</i>			