UK Standards for Microbiology Investigations

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

V 11 HIV screening and confirmation

Recommendations are listed as ACCEPT/ PARTIAL ACCEPT/DEFER/ NONE or PENDING
Consultation: 03/05/2016 – 16/05/2016
Version of document consulted on: V 11dzy+
Proposal for changes

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<tr>
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<td>11/05/2016</td>
</tr>
<tr>
<td>Lab name</td>
<td>Northern Ireland Public Health Agency</td>
</tr>
<tr>
<td>Section</td>
<td>Safety Considerations</td>
</tr>
<tr>
<td>Comment</td>
<td>Should there be a mention that it is a Hazard Group 3 pathogen and which laboratories can work with it, possible presence in routine specimens etc? Should there be something about care in handling in the laboratory with the avoidance of the use of sharps etc? I am not a virologist so cannot comment on the technical detail.</td>
</tr>
</tbody>
</table>

Evidence
A long time away from it now but the ACDP BBV Guidance might be useful.

Financial barriers
Coupled to the safety thing above, is there anything about Category 2 laboratories handling specimens from known HIV patients etc?

Health benefits
No.

Recommended action
NONE
This is not in line with the virology template.

<table>
<thead>
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<tr>
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<tr>
<td>Lab name</td>
<td>Cepheid</td>
</tr>
<tr>
<td>Section</td>
<td>a. Introduction window period of infection</td>
</tr>
<tr>
<td></td>
<td>b. Introduction types of HIV tests serological tests Fourth generation tests</td>
</tr>
<tr>
<td></td>
<td>c. Introduction types of HIV tests Nucleic Acid Amplification Tests (NAAT)</td>
</tr>
<tr>
<td></td>
<td>d. Footnotes relating to HIV screening</td>
</tr>
<tr>
<td></td>
<td>e. Appendix 2: HIV confirmation</td>
</tr>
<tr>
<td></td>
<td>f. Footnotes relating to HIV confirmation paragraph b</td>
</tr>
</tbody>
</table>
| Comment        | a. The text should clearly mention the window period for RNA detection that is
shown in the graphs.

b. Fourth generation tests are claimed to be 'better at detecting acute, established and very late HIV infection than other forms of testing'. The term Acute HIV Infection is used to describe the period when a patient is viremic and has detectable HIV RNA without diagnostic HIV antigens or antibodies. By definition therefore the best test for detecting acute infection is a NAAT. The BCN checkpoint study identified several acute cases that had viral loads in excess of 10 million copies / mL, so use of NAAT is critical in the containment of the infection spread and timely treatment in suspected acute cases.

c. NAATs are claimed as not recommended in initial HIV screening because they are not licensed for use and may give false positive results. There are qualitative NAATs that are regularly approved (CE-IVD marked) to aid in the diagnosis of HIV-1 infection in conjunction with clinical presentation and other laboratory markers. With respect to false positive results, there is no evidence to suggest false positive results in the selected references of the current document. We propose that the text include these assays as an option in specific situations where they may aid in HIV diagnosis (acute infections, Early Infant Diagnosis, confirmation of positive fourth generation tests 1,2,3,4)

d. HIV qualitative NAATs are not mentioned. We propose to insert a paragraph where qualitative NAATs are recommended for Early Infant Diagnosis (EID) and as an option for diagnosis of acute infections since they are able to detect the virus earlier than fourth generation tests 1,2 In addition immunoassays cannot be used for early infant diagnosis due to the passive transmission of antibodies during birth. Only NAAT can be used for diagnosis of early infant HIV infection.

e. To confirm a positive result, NAATs should be mentioned as an optional alternative to the confirmatory immunoassays and not only for the discordant results between fourth generation tests and confirmatory immunoassays.

f. To better qualify the role of HIV NAATs in confirmation, we propose to modify the claim as follow: 'HIV NAATs are helpful in confirming suspected infection and may be used as an optional alternative to confirmatory immunoassays or to resolve discordant results.'

Evidence

a. Acute infections

Graphs at page 9 of the current document are clearly illustrating that RNA is detectable at least 5 days earlier than p24 antigen.


- Rapid Confirmation and Early Detection of HIV Primary Infection in BCN Checkpoint, a Community Based Centre in Barcelona. Meulbroek M. - IAS 2015 Vancouver oral presentation - NAATs detection of acute infections not detected by fourth generation assays.

b. Early Infant Diagnosis

c. Confirmation of positive fourth generation tests
   - 2015 WHO consolidated guidelines on HIV testing services [http://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/] - NAATs can be used also as second-line confirmatory test (A2) with adaptations to the standard algorithm.

Financial barriers

No.

Health benefits

a. "Reduction in HIV-1 transmissions, especially in persons who have multiple concurrent sex partners or high rates of partner change. 1,2,3,4,5.

b. Patients with acute infection have very high viral loads and are about 26 times more infectious than they will be in the phase following acute HIV infection. 6,7,8,9

c. Early detection enables initiation of antiretroviral therapy that may have a number of beneficial outcomes, including improved immunologic function, significantly reduced time to viral suppression, reduced viremia and transmission of HIV to sexual partners by more than 96%. There is also the potential reduction in the emergence of viral mutations with the suppression of viral replication and the potential to reduce the severity and duration of illness during symptomatic acute HIV infection.10,11,12,13,14,15,16,17,18,19,20,21 - Not aware of side effects and risks that might affect the SMI.

Evidence:


d. Containment of HIV spread and possible better outcome of the long term treatment thanks to earlier detection of the acute infections, effective detection of mother to child transmission - Not aware of side effects and risks that might affect the SMI.

e. Effective and timely detection of mother to child transmission, containment of HIV spread and possible better outcome of the long term treatment thanks to earlier detection of the acute infections - Not aware of side effects and risks that might affect the SMI.

f. Correct and timely detection of mother to child transmission, containment of HIV spread and possible better outcome of the long term treatment thanks to earlier detection of the acute infections. Not aware of side effects and risks that might affect the SMI.

**Recommended action**

<p>| | |</p>
<table>
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| a. | **ACCEPT**  
This has been updated in the document accordingly. |
| b. | **NONE**  
The fourth generation tests are used for the initial screening as well as for detecting of acute, established and very late HIV infection as recommended by BHIVA /BASHH /BIS guidelines.  
NAATs are used as supplementary tests when a patient gives persistently indeterminate immunoblot/immunoassay results, or in suspected primary HIV infection. |
| c. | **NONE**  
This has already been mentioned in the document. See previous comment. |
| d. | **NONE** |
The scope of the document excludes the investigation of potential mother to child transmission of HIV in children under 18 months of age.

e. **NONE**
   This has already been mentioned in the document. See recommended action for comment b.

f. **ACCEPT**
   This has been updated and strengthened in the document accordingly.

**Health benefits**

Many thanks for the references. This was discussed at the VWG meeting and it was agreed that some information on health benefits should be mentioned in the introduction of the document and a few references from the list have been added.

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<td>Date received</td>
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<tr>
<td>Lab name</td>
<td>Regional Virus Laboratory, Belfast, Northern Ireland</td>
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**Section**

**Comment**

a. There is a discrepancy between BASHH/EAGA statement and EAGA statement i.e. 8 weeks versus 12 weeks. EAGA have been consulted in both. Is this the most recent occupational guidance? The reference is 2008? Can it be highlighted that the BASHH statement has changed

b. Appendix 1 - the footnotes are not in order in the algorithm e.g. abcdhkl, it would be easier to follow if they were.

c. Footnote b - should the use of separate antibody antigen assays be acceptable for screening? Why is there a need when combined tests are available? 4th generation tests are the standard of care in the UK.

d. Footnote c - The BASHH guidelines say POCT may be used this is not the same as recommending. Also in the BASHH guidelines 2008 it doesn't mention antenatal clinics. UKNSC standards state 4th generation screening assay should be used. The BASHH guidance is 2008, POCT tests have come a long way since then, are antibody only POCT still acceptable?

e. Footnote e this footnote seems inappropriate for this algorithm. In addition it is at odds with the text in the algorithm which states patient has no HIV related signs or symptoms.

f. Footnote f this isn't necessary.

g. Footnote g this doesn't seem practical to most high through put laboratories. It also needs to be more time specific as testing may be negative in both assays at
e.g. 12 days post exposure but not at 14 days post exposure. It is important to add a time point.

h. Footnote k should read 'If sample is negative on testing in a case of primary HIV infection, send a further sample for retesting within 14 days. Why 14 days? Also this footnote needs to be specific about the time period from exposure until testing. Footnote k in the wrong place on the algorithm.

i. Footnote l this is in the wrong place on the algorithm

j. Primary tube testing should be the standard rather than aliquoting and going back to clot if discrepant.

| Recommended action | 
|-------------------|---|
| **a. NONE** | The reference by DoH and EAGA is the most recent occupational guidance available. The two papers discussed here are both separate entities: the BASHH/EAGA statement November 2014 is on the HIV seroconversion window period while the reference from EAGA/DoH 2008 is for HIV post-exposure prophylaxis and this applies to healthcare workers. |
| **b. ACCEPT** | The footnotes have been updated accordingly. |
| **c. ACCEPT** | This footnote has been removed from the flowchart to avoid confusion amongst users. |
| **d. ACCEPT** | This has been updated accordingly. |
| **e. ACCEPT** | This has been removed and document has been updated accordingly. |
| **f. ACCEPT** | This has been removed and document has been updated accordingly. |
| **g. ACCEPT** | This has been removed and document has been updated accordingly. |
| **h. ACCEPT** | A footnote has been put in the right place within the algorithm to show the evidence base for sending a further sample for retesting. |
| **i. ACCEPT** | The footnote ‘l’ has been placed in the correct place in the algorithm and document has been updated accordingly. |
j. **NONE**

It is the view of the Working Group that going back to the clot is recommended but that this may be based on local decision.

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<td>Frimley Health &amp; PHE</td>
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<tr>
<td>Section</td>
<td>Types of HIV Tests</td>
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<tr>
<td>Comment</td>
<td>Whilst at PHE Colindale, I undertook a review of the use of p24 testing versus fourth generation EIA. This could inform the guidance of p24 testing though it is currently PHE data.</td>
</tr>
<tr>
<td>Evidence</td>
<td>I would suggest getting in contact with <a href="mailto:Jennifer.tosswill@phe.gov.uk">Jennifer.tosswill@phe.gov.uk</a> as this is PHE data and a PHE document. I'm happy to assist with this.</td>
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<tr>
<td>Recommended action</td>
<td><strong>NONE</strong></td>
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<td>The Virus Reference Department was consulted during the development of this document.</td>
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<tr>
<td>Professional body</td>
<td>British HIV Association (BHIVA)</td>
</tr>
<tr>
<td>Section</td>
<td>Whole document</td>
</tr>
<tr>
<td>Comment</td>
<td>Thank you for this timely update to the UK SMI for HIV screening and confirmation and for the opportunity for review. BHIVA has a few questions and comments relating to the draft and hopes these are helpful.</td>
</tr>
<tr>
<td></td>
<td>a. The descriptions of the window periods for the 3rd and 4th generation tests could be clearer. BHIVA appreciates that it is not known exactly but it should include the earliest reliable detection time to the earliest date at which a negative result confirms a lack of infection. BHIVA suggests that the window period for a 4th generation test is 14 days to 4 weeks. So-called 5th generation tests that can distinguish between HIV-1 antibody, HIV-2 antibody and p24 antigen are becoming available. It might be worth considering how these could fit into the testing algorithm as they may be used as a screening test. False positive results with the p24 assays can be a problem. Consideration should be given to performing a p24 neutralization test to improve specificity.</td>
</tr>
<tr>
<td></td>
<td>b. BHIVA agrees that saliva and dried blood spots are a very useful sample types in</td>
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certain circumstances. However, they have significant limitations due to variations in sample quality and volume. Saliva and dried blood spots should not be recommended if there has been a recent exposure due to the significant uncertainty of the window periods for these samples (as outlined in the document). It is very difficult to do a proper validation and verification for these samples types locally for the detection of recent infection due to the rarity of samples.

c. The algorithms given in appendix 1 and 2 are very clear and helpful. How would a screening test reactive result on a saliva or dried blood spots fit into these pathways?

d. BHIVA finds paragraph (d) on page 22 a bit confusing. Can a positive viral load result be used as a confirmation or not. The use of the word could lacks certainty. What is meant by the statement where viral load is lower or undetectable... - lower than what exactly?

e. In the section on NAAT testing the document states that NAAT tests are not recommended for screening as they are not licensed for use and may give false positive results. BHIVA thinks it would be better to state that NAAT tests offer very little advantage over 4th generation assays in terms of earlier detection of viraemia so are not cost effective. Any test can give a false positive result.

f. BHIVA thinks it would be helpful to tabulate what test or combination of tests would be acceptable to confirm a positive result on the second sample. It is not uncommon for patients to transfer their care between clinics. What would you advise as to what is sufficient confirmation testing on such patients to ensure they are positive? Should they be treated as a new diagnosis or can we reliably use fewer tests?

g. As the SMI should outline the standards of laboratory services, some comment about turnaround times would be appropriate. BHIVA thinks it would be helpful to provide some more detailed guidance on urgent HIV testing (such as for testing of women in labour with no previous antenatal care) and what are the minimum requirements for testing and interpretation.

<table>
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<tr>
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<th>a. PARTIAL ACCEPT</th>
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<td></td>
<td>The descriptions of the window periods for the 3rd and 4th generation tests are clear in the document under the types of HIV tests. Information has been added in the section on p24 tests.</td>
</tr>
<tr>
<td>b. NONE</td>
<td>Many thanks for the information.</td>
</tr>
<tr>
<td>c. NONE</td>
<td>The scope of document does not include testing of saliva and dried blood spots.</td>
</tr>
<tr>
<td>d. ACCEPT</td>
<td>This has been updated in the document accordingly.</td>
</tr>
<tr>
<td>e. ACCEPT</td>
<td>The advantage of using NAATs has been updated</td>
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</table>
f. **ACCEPT**
   
   This has been updated in the document accordingly.

g. **NONE**
   
   This is not within the scope of the document.

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<tbody>
<tr>
<td>Date received</td>
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<tr>
<td>Lab name</td>
<td>HIV/STI Department, Public Health England</td>
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</table>
| Section        | a. Introduction (pg 8, paragraph 4)  
    b. Introduction (pg 11, paragraph 2)  
    c. Introduction (pg 13) & Technical limitations/Information: Home testing/sampling kits (pg 15)  
    d. Public Health Management (pg 16, paragraph 2).  
    e. Appendix 2 (pg 22, paragraph C) |
| Comment        | a. A UK based document recommending expanded testing in healthcare settings can supplement citation 4.  
    b. Patients at ongoing risk of HIV infection should be advised to retest at regular intervals. This can be supplemented with citation(s) that recommend regular retesting of people with ongoing risk of infection.  
    c. Distinction between HIV home-sampling and self-testing needs to be made. Recommend that both should be clearly defined and described (possibly with own section for each). Furthermore, guidance for reactive home-sampling tests should also be given.  
    d. For information regarding notification to PHE Recommend consistent use of terminology (this paragraph refers to HIV reporting on pg 23). Suggest use of HIV reporting as not to confuse with mandatory notification.  
    e. Recommend addition of a hyperlink to the relevant reporting bodies (Public Health England, Health Protection Scotland). |
| Evidence       | Kindly see attached supporting references that recommend expanded testing in healthcare settings for this comment.  
    Kindly see attached documents for retesting guidance in reference to this comment.  
    Kindly see pg 20 HIV testing through self (home)-sampling or self (home)-testing on attached supporting reference for this comment. |
| Recommended    | a. **ACCEPT** |
The Royal College of Physicians (RCP) plays a leading role in the delivery of high quality patient care by setting standards of medical practice and promoting clinical excellence. We provide physicians in the United Kingdom and overseas with education, training and support throughout their careers. As an independent body representing over 32,000 Fellows and Members worldwide, we advise and work with government, the public, patients and other professions to improve health and healthcare. The RCP is grateful for the opportunity to respond to the above consultation. We have liaised with our Joint Specialty Committee for Genitourinary Medicine and would like to make the following comments.

General comments
Our experts believe there are two main area of concern:

1. The section on home testing/sampling is inaccurate and potentially misleading.
2. Saliva testing.
   a. The standards need to be clearer about the difference between home sampling and home testing. Currently the difference between the two is not made explicit. For example, HIV home test kits are not available through local authorities (LAs) – only home sampling kits are available from some LAs.
   b. Furthermore, our experts believe it is confusing to then mention test performance...
of saliva tests when this is not covered in the SMI. Both home sampling and home
test (BioSure is the only CE marked home test kit currently) have good test
performance (they are the same tests as used in clinical settings).

c. Regarding home sampling involving saliva, although Dr Thom offers a saliva
home-sample service (https://onlinedoctor.lloydspharmacy.com/uk/sexual-
health/hiv-saliva-test), OraSure home testing kit (saliva) is not yet CE marked.
Our experts note it might be worthwhile to redraft the saliva section as samples
that need work on validation to slightly future-proof.

Specific comments

Page 8
d. Our experts believe that the document should refer to the UK National Guidelines
for HIV testing 2008 BHIVA which are much more comprehensive than those
currently referenced and includes at risk groups eg GU attenders, MSM,
populations where the diagnosed HIV prevalence exceeds 2/1000, as well as
AIDS defining conditions.

e. The comment ‘conditions where not identifying the presence of HIV infection may
have significant adverse implications for the patient’s clinical management’ is
misleading. Failure to identify the presence of HIV will ultimately have adverse
implications for anyone with HIV. Our experts suggest that this may mean
conditions where other immunosuppressive agents such as biologics might be
used and which would be dangerous in undiagnosed HIV.

Page 9, for Fig. 1 (the different window periods of HIV tests).

f. Our experts suggest it would be beneficial if Fiebig stages were described with
durations. A table from Myron Cohen's paper in JID 2010 with ref. is attached.

Page 10
g. ‘A fourth generation HIV test on a venous blood sample performed in a laboratory
will detect the great majority of individuals who have been infected with HIV at 4
weeks after specific exposure’ our experts suggest providing a percentage here.

Page 11
h. ‘Patients at ongoing risk of HIV infection should be advised to retest at regular
intervals’ Our experts believe patients should also be advised on how to reduce
their risk of infection.

Page 12

Fourth generation point of care tests

These rapid tests are screening tests that can be performed on blood or from
other sample types. Testing of oral fluid/saliva is not covered in the SMIs. When
such samples are received, they should be referred to reference laboratories.
Those that use sample types other than blood may be subject to more sampling
variation which influences the sensitivity of the test which has to be taken into
consideration regarding their suitability as a screening test in a clinic setting. Like
fourth generation laboratory tests, these tests also detect HIV antibodies and P24
antigens. Their result output is rapid and comparable to laboratory antibody tests
17. According to the BASHH guidelines, these rapid point of care HIV blood tests
are generally satisfactory for detection of uncomplicated HIV infection and gives
results within minutes. They will detect most infections within 6 weeks of exposure.
to HIV. Results are available within 30 minutes of testing. Point-of-care HIV tests may also vary in their ability to discriminate between HIV-1 and HIV-2. The window period for these tests can be 11 days to 1 month. They are recommended only in certain settings, such as community outreach settings and some GUM attendees for screening high risk patients where referral to a phlebotomist is impractical.

i. Our experts believe that point-of-care tests offered should be overseen by local laboratories that have a robust quality assurance system and must be used under professional supervision with pre and post counselling. Further tests must be performed for all positive rapid test results.

j. The sentence below should go below the 4th gen POCT bit rather than above

Note: There are commercially available third and fourth generation points of care test kits and it should also be noted that their ability to detect antigens levels may be low.

Page 13

k. Our experts believe that the section on home-testing/home sampling is inaccurate and muddled. The distinction between the two systems should be spelt out ie one the person takes his or her own sample and does the test him/herself in the home, the second, the person takes his or her own sample and sends it off to a laboratory to be processed. A comment should be made on the pros and cons of both approaches eg support can be provided to someone with a positive result at the time of diagnosis in the latter system but not the former.

Our experts suggest the following rephrase:

HIV home test kits are now legalised and licensed in the UK and are available commercially. Only tests that meet the required standards of the Medicines and Healthcare products Regulatory Agency (MHRA) and have a CE mark to guarantee that they work properly and are safe can be used for home testing. Currently available self-tests are second generation antibody-only assays. These home kits should only be used according to the manufacturer’s instructions.

The disadvantages of using HIV self-tests are that they generally have low sensitivity and low specificity. For example, saliva (although not covered in SMIs) contains lower HIV screening and confirmation antibody/antigen levels and is less sensitive than blood (venous or capillary whole blood or dried blood spot) in detecting acute HIV infection (17).

Note: CE-marking guarantees that the essential health and safety requirements set out in the relevant European Directives are met. Our experts note that saying CE-marking ‘guarantees the test works properly’ may be interpreted as the test having good sensitivity/specificity, which CE-marking does not guarantee.


In addition to self-testing, our experts suggest that home sampling might be considered in efforts to improve patient access to HIV testing. Home-sampling kits are available from some local authorities in the UK via a PHE webpage (see link: https://www.gov.uk/government/news/free-hiv-home-sampling-launched-to-
increase HIV-testing) as well as through some NHS and third sector programmes. Dried blood spot and capillary blood collection devices are increasingly employed and they can be used only for HIV screening in conjunction with validated/CE marked 4th generation HIV EIAs that are locally verified and validated for the dried blood spot or capillary blood or saliva sample. Depending on the type of sample used, the window period even on the 4th generation assays may be extended. If saliva is used, the window period should be considered as 3 months and if using dried blood spot on validated 4th generation HIV EIAs, the window period may be a few weeks longer than the 4 weeks considered for venous or capillary blood samples.

Page 22

I. Our experts believe that further clarity required regarding HIV-2 DNA/RNA tests, as on Page 22 it says ‘There are currently no MHRA approved tests for HIV-2 RNA or DNA’ but on page 24 it says ‘Additional testing for HIV-1 RNA or HIV-2 RNA should be performed.’ Our experts note that these statements seem to contradict each other. On Page 13, where NAATs are introduced (‘Most assays are for HIV-1 RNA and specific HIV-2 RNA tests are available at a few centres in the UK on an individual patient basis’), it might be worth saying here that the HIV-2 RNA tests are not currently MHRA approved, and making explicit in which circumstances they can be used.

Page 26

m. ‘On notification to PHE or equivalent in the devolved administrations’, is very generic and sounds like the diagnostic laboratories in England do not have notification duties for HIV and it is the clinician who needs to notify, and in the devolved nations, other arrangements exist. It would be helpful if the section states specifically what needs to be done in England, in Scotland, in Wales and in Northern Ireland and reference to guidance on responsibilities for notification be cited.

Amendments

Page 13

n. ‘licenced’ should be ‘licensed’: ‘suspected primary HIV infection but should only be performed with specialist input18. NAAT are not recommended for use in initial HIV screening because they are not licenced for use and may give false positive results’.

Page 15

o. Missing apostrophe from “kits” (‘Therefore, patients should refer to the kit’s instructions to’).

Page 19

p. Footnote c): ‘gum’ should be capitalised

Page 19

q. Footnote j): ‘I’ should be ‘I’ after HIV Infection, and there’s an extra word before PHE, Colindale ‘In England, Wales and Northern Ireland, clinics and laboratories can have specimens tested for evidence of recent HIV Infection by antibody avidity testing through agreeing a memorandum of understanding between with PHE, Colindale.’
r. Change ‘There are a summary of the combinations’ to ‘Here is a summary’

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<tr>
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<th>General Comments</th>
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<tbody>
<tr>
<td></td>
<td>The two comments (1 and 2) raised in the general comments have been updated accordingly.</td>
</tr>
<tr>
<td>a. ACCEPT</td>
<td>This section has been updated accordingly in the document.</td>
</tr>
<tr>
<td>b. NONE</td>
<td>This is not within the scope of the document.</td>
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<tr>
<td>c. NONE</td>
<td>This is not within the scope of the document.</td>
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<td>e. ACCEPT</td>
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<tr>
<td>f. ACCEPT</td>
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<tr>
<td>g. NONE</td>
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<td>i. NONE</td>
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<tr>
<td>j. ACCEPT</td>
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<tr>
<td>k. ACCEPT</td>
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l. ACCEPT
   The pages/sections where indicated in the comment have been updated with appropriate wording accordingly.

m. NONE
   This is generic in all UK SMIs.

n. ACCEPT
   This has been updated accordingly in the document.

o. ACCEPT
   This has been updated accordingly in the document.

p. ACCEPT
   This has been updated accordingly in the document.

q. ACCEPT
   This has been updated accordingly in the document.

r. ACCEPT
   This has been updated accordingly in the document.

---

Comment number | 8
Date received   | 16/05/2016
Professional body | BASHH
Section
Comment
See comments in comment number 7 above.

Health benefits
No.

Recommended action
The comments from the RCP/BASHH are the same as the two bodies worked in collaboration on this document. See comments and recommended actions in comment number 7.

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Comment number | 9
Date received   | 16/05/2016
Lab name        | Newcastle
Section         | Several points
Comment
a. Appendix 1: The algorithm does not state that reactive samples should be sent for further confirmation. This is inferred, at least for concordant results, but should be stated in the algorithm for both concordant and repeatedly discordant samples.

b. Appendix 2: Lack of clarity regarding second line 4th generation assay. Is this...
algorithm meant to include only samples reactive in two assays or also those with discordant results from the first algorithm? This should be made clear in the first box.

c. Appendix 2: Laboratories performing full confirmation are unlikely to issue an interim report, and as currently written it is not clear that such laboratories still need to perform two 4th generation assays. This could be clarified by annotating the first box or a footnote.

d. Reporting table (general): This table is confusing in its current layout and it is difficult to relate it to the testing algorithms, which it sometimes appears to contradict. Reporting table (general): It is not clear if the 'notes' section is intended to be included in comments.

e. Reporting table (row 1): It should be highlighted that there is no need to issue a preliminary report when the typing assay can be performed immediately.

f. Reporting table (row 3): This part of the table cannot be followed and in some parts seems to contradict appendix 2 algorithm. E.g. the algorithm states that for a negative/indeterminate typing assay a negative result can be reported if P24/RNA is negative, while the table suggests further testing or referral.

Financial barriers

None.

<table>
<thead>
<tr>
<th>Recommended action</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. NONE</td>
<td>This is stated clearly in the lozenges underneath the concordant results and discordant results accordingly.</td>
</tr>
<tr>
<td>b. ACCEPT</td>
<td>This has been amended to read as “All preliminary reactive HIV screening results” in the first box.</td>
</tr>
<tr>
<td>c. ACCEPT</td>
<td>This has been updated accordingly in the document.</td>
</tr>
<tr>
<td>d. ACCEPT</td>
<td>This has been updated accordingly.</td>
</tr>
<tr>
<td>e. ACCEPT</td>
<td>This has been updated accordingly.</td>
</tr>
<tr>
<td>f. ACCEPT</td>
<td>The algorithm and the reporting table (row 3) have both been updated accordingly.</td>
</tr>
</tbody>
</table>

Respondents indicating they were happy with the contents of the document

| Overall number of comments: 3 |
|-------------------------------|-----------------|---------|
| Date received | 04/05/2016 | Lab name | IPS |
| Date received | 07/05/2016 | Lab name | University of Southampton |