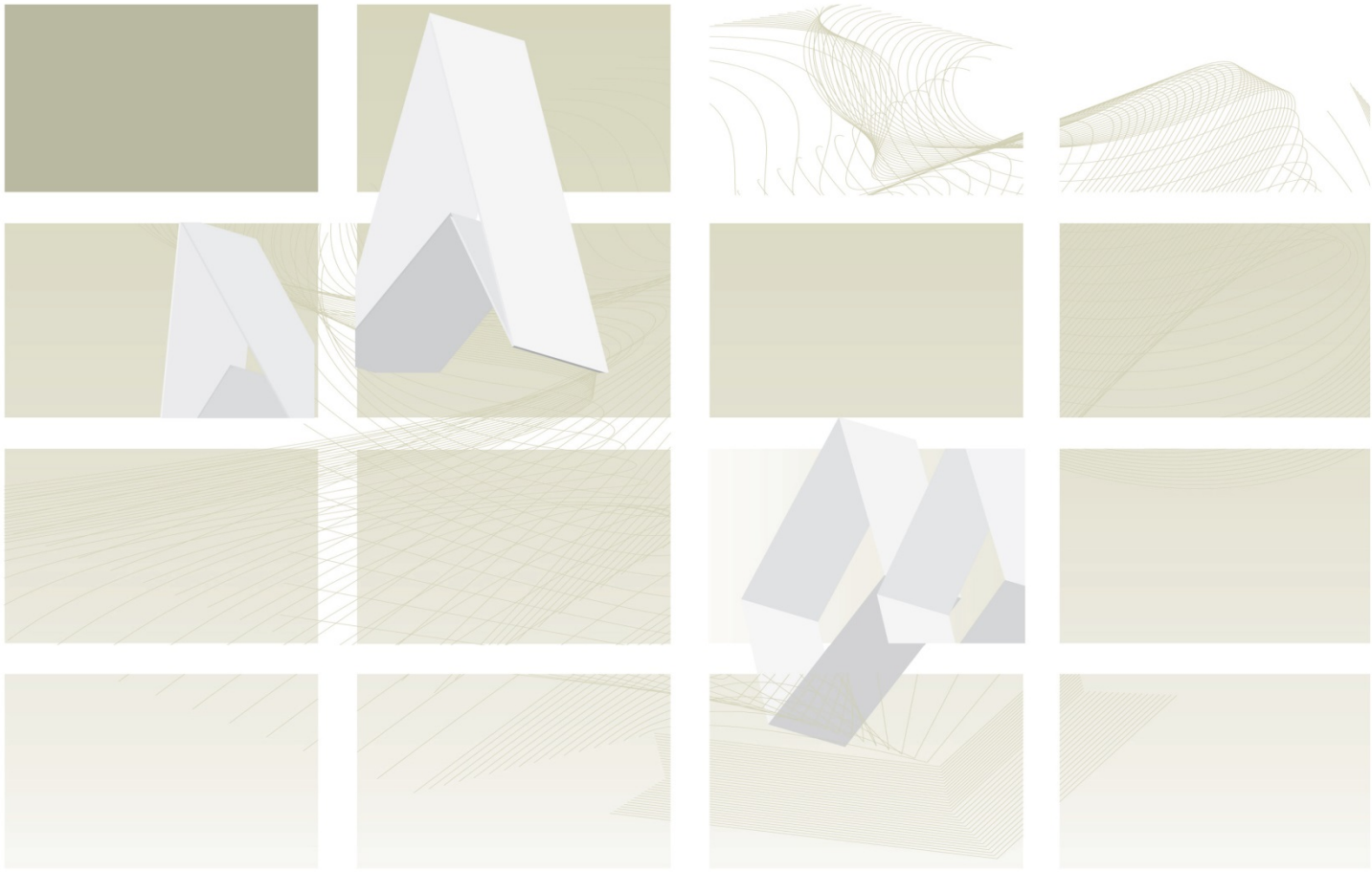
Public Health England

NHS

UK Standards for Microbiology Investigations

Review of users' comments received by
Joint working group for national user manual templates

U 3 National user manual worked example for urine tests



NICE accredited
www.nice.org.uk/accreditation

"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

First consultation: 24/10/2016 – 04/11/2016

Version of document consulted on: U a dc+

Proposal for changes

Comment number	1		
Date received	28/10/2016	**Lab name**	Microbiology Northern Health and Social Care Trust
Is the template populated with enough/right kind of information for the examples used?			
Seems okay.			
Do you think that there is too much information in the document?			
Seems reasonable for such a large part of a diagnostic microbiology laboratory workload.			
What advantages does the syndromic approach have over the sample type approach and vice versa?			
Syndromic approach more suited to clinical staff. Sample type more suited to laboratory staff.			
Overall, which approach would be most useful for your users?			
Syndromic.			
Does seeing a worked example help you know how best to use the User Manual Template?			
Yes.			
Would you prefer to see the syndrome/sample specific information as a separate section within individual UK SMIs (if this initiative is taken forward)?			
Yes and no, it makes sense however not sure if it will make UKAS inspections more burdensome.			
Financial barriers			
No.			
Health benefits			
No.			
Recommended action	**ACCEPT** The feedback is very useful for the document. Many thanks for the information.		

Comment number	2		
Date received	04/11/2016	**Lab name**	NHS England, seconded from PHE BRD

Is the template populated with enough/right kind of information for the examples used?

Not clearly - see comments below.

Do you think that there is too much information in the document?

Not comprehensive information seems confused as to target audience states it is for commissioners but does not include comprehensive evidence base.

What advantages does the syndromic approach have over the sample type approach and vice versa?

Syndromic follows reality for patient.

Overall, which approach would be most useful for your users?

Both.

Does seeing a worked example help you know how best to use the User Manual Template?

Would have to ask users.

Would you prefer to see the syndrome/sample specific information as a separate section within individual UK SMIs (if this initiative is taken forward)?

Probably both required for comprehensive care models.

Any other comments you wish to make

a. Users listed include - Commissioners of healthcare services use SMIs to find the standard of microbiology investigations they can seek as part of the clinical and public health care package for their population. Has consideration been given to including NHS England, NHS Improvement and NHS Wales as contributors, or additional relevant Royal Colleges such as the Royal College of Surgeons, Royal Pharmaceutical Society or NICE.
b. Evidence is not referenced.
c. Use of dipstick to guide treatment - ? evidence supporting this.
d. Treating >3 symptoms empirically without MSU collection how detect if antimicrobial resistant infections?
e. Cloudy vs non-cloudy urine treatment - ? evidence for not treating/testing if not cloudy.
f. Consider back up options for delayed treatment reference STMF and TARGET.
g. Blood on dipstick to follow up - evidence for using dipstick?
h. Differentials section
    i. Who is this guide for? Microbiologists as listed or primary care

physicians/carers/healthcare workers?

i. Indication of lab urine samples section
    i. MSU antenatal recommendation to take MSU only if failure to cure after empirical treatment alter to test and treat then review treatment depending on sensitivity and culture results.
    ii. Link to patient information sheet there is no link to consult on.
    iii. On the form - what form - please specify.
    iv. 48 h 4 degrees evidence this does not affect results?
    v. 4 h to lab evidence this time period or longer does not affect results? patients self-testing at home guidance to note time collection or evidence based information on how long sample can be taken prior to handing in at surgery/clinic etc.
    vi. Boric acid stability up to 48-96 hours listed - ? evidence for this detailed as 24 h by LaRocco et al., 2016.
    vii. Inhibition of dipstick/biomarker evidence correct please check evidence?
    viii. Urine volume listed min 1mL and standard 10mL (some micro lab user manuals state 15-20mL have the reduced volume been agreed widely?).
    ix. Urine catching method preferred method not highlighted as such, SPA not recommended for children (see DUTY study).
    x. Post mortem urine not included.
    xi. mL ml mls inconsistency in document.
    xii. Urine chlamydia and gon NOT screening what does this mean? NGNCU testing?
    xiii. Urine for schistosoma collection 1000-1400 h - post exercise not listed is it required?
    xiv. Legionella testing tests are designed against *L. pneumophila* serogroup 1, cross reaction/detection with other LPN serogroups can occur, other legionella species may not be detected. Perhaps clarify if legionella not LPN sg1 suspected LRT culture recommended or Lspp/Lpn spp PCR?
    xv. Significant pyuria level is not clear from guidance, 10^7 or 10^8.
    xvi. ? cross reference SMB1 urine?
j. Bacterial growths section
    i. States $>10^{-8}$, $>10^{-7}$ and $>10^{-5}$ depending on organism and patient group but does not specify which of either or reference evidence for difference.
    ii. Does not detail level of resistant strains to consider of importance or mention resistance.
    iii. States two specimens with same organism = increased probability of UTI does not state what organisms or based on what evidence this increases probability of UTI.
    iv. Does not mention antimicrobial resistance and sensitivity testing.
k. Children reference DUTY study and findings on recommendations for testing

methodologies. Main points: i. Evidence based not detailed. ii. Recommends dipstick testing and empirical treatment. iii. Level of infection considered important not consistent or clear per organism. iv. Antimicrobial resistance not detailed and mechanisms to reduce not considered.	
Financial barriers	
? How Links to SIGN and NICE urinary tract infection recommendations.	
Recommended action	**PARTIAL ACCEPT** Thanks for the strategic and technical comments. They have been updated accordingly. a. **ACCEPT** The document will be updated accordingly with other relevant bodies mentioned where necessary. b. **ACCEPT** References have been added to the evidence base in the document where relevant. Comments c to k has been updated with references where appropriate. UK SMI B 41: Investigation of Urine document has been referred to for further information.

Comment number	3		
Date received	04/11/2016	**Lab name**	Royal College of Nursing
Is the template populated with enough/right kind of information for the examples used?			
Yes.			
Do you think that there is too much information in the document?			
No.			
What advantages does the syndromic approach have over the sample type approach and vice versa?			
N/A			
Overall, which approach would be most useful for your users?			
Hybrid.			
Does seeing a worked example help you know how best to use the User Manual Template?			

Yes.
Would you prefer to see the syndrome/sample specific information as a separate section within individual UK SMIs (if this initiative is taken forward)?
A mixture of both or a hybrid is useful.
Any other comments you wish to make
There is no mention of the importance of healthcare workers undertaking standard precautions when collecting urine samples. I think this should be included as they mention infection prevention and the importance of sample collection but don't really tie the two together. There needs to be a link in with the AMR work primarily the target toolkit http://www.rcgp.org.uk/clinical-and-research/toolkits/target-antibiotics-toolkit.aspx and the CMO's five year forward work https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/244058/20130902_UK_5_year_AMR_strategy.pdf and the Start Smart then focus work by PHE.
Evidence
RCN (2012) Essential Practice for Infection Control https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/244058/20130902_UK_5_year_AMR_strategy.pdf Start Smart and Focus https://www.gov.uk/government/publications/antimicrobial-stewardship-start-smart-then-focus
Financial barriers
N/A
Health benefits
No.

Recommended action	**PARTIAL ACCEPT** Many thanks for the information. Adding the links suggested is outside the scope of this user manual as it does not discuss treatment.

Comments received outside of consultation

Comment number	1		
Date received	05/11/2016	**Lab name**	Royal Cornwall Hospitals Trust
Is the template populated with enough/right kind of information for the examples used?			

Good for the examples used.
Do you think that there is too much information in the document?
There is too much generic information at the start – would prefer that it was contents page, amendment table and then Introduction/scope of the specific syndrome/test. The acknowledgments, UK SMI: scope and purpose would be better as an Appendix – that is because we access these documents all the time.
What advantages does the syndromic approach have over the sample type approach and vice versa?
We think that the syndromic approach is good for requesting clinicians and trainees/explaining things to trainees. The sample type is great for a working diagnostic lab, making sure we cover all the different clinical conditions. However, I personally have used both and appreciate the knowledge and references that are provided.
Overall, which approach would be most useful for your users?
For our requesting users, probably syndromic.
Does seeing a worked example help you know how best to use the User Manual Template?
Not sure.
Would you prefer to see the syndrome/sample specific information as a separate section within individual UK SMIs (if this initiative is taken forward)?
Would need to see an example – one person said yes.
Any other comments you wish to make
These SMIs are fantastic for bacteriology, but do not work quite as well for virology. There were a few people who were unsure about who the expected audience is for these SMIs. Microbiology has to provide a user manual and it seems more appropriate to provide information such as location maps just the once, rather than with each SMI.

Recommended action	**ACCEPT** Thanks for the comment. The generic information at the start of the document is part of the UK SMI template and so will be kept in. The expected audience for whom this manual is aimed at will be reviewed before the second round of consultation.

Comment number	2		
Date received	08/12/2016	**Professional body**	GP Trainer and Partner
Any other comments you wish to make			
a. Overall comprehensive. I suspect in practice most of these recommendations are not carried out in practice b. Cather specimens to be taken aseptically from tubing or ports? Presume most are			

taken from the full bags. And samples to be received by the labs within 4 hours of collection? It may be an hour before patient brings to us and many more hours before labs receive. We don't fridge samples routinely. Maybe we should be using boric acid containers as standard? c. For diagnostics, Why are $10^{\geq 8}$ cfu/L used in the text when we learn 10^5 colonies/ml in med school (which they do mention in brackets). Only confuses things unless it's done for the sake of international standardisation. d. Finally recommendations are to treat women empirically if >=3 symptoms but how do they propose dealing with the worse outlook for women with bladder cancer who are diagnosed later because of empirical treatments and lack of urine dipsticks being carried out, particularly the older increased risk population?	
Recommended action	a. **NONE** Many thanks for your comments. b. **NONE** This comment is for local discussion and decision. c. **NONE** Although it is a good point, however it was decided that $10^{\geq 8}$ cfu/L is used to be in line with the UK SMI B 41: Investigation of urine document. d. **NONE** The diagnosis of cancer is out of scope for this UK SMI document.

Comment number	3		
Date received	08/12/2016	**Professional body**	GP Partner
Any other comments you wish to make			
UTI: a. I did not find the section on indications for dipstick / sending a sample was particularly clear. There is mention of indicative symptoms, but these are not included - perhaps a table of key symptoms should be included? The section on interpretation of results was good. However some obvious omissions which probably need mentioning – i. Risk of Staghorn calculus in urease-producing organisms (especially Proteus) - I am aware of at least two medical negligence cases related to this! ii. Management in response to MDR strains of bacteria (pseudomonas, ESBL E.coli) - perhaps with something about over-prescription of ABx?! iii. Advice for results where culture is positive but white cells not raised - personally I would usually assume that this is colonisation rather than infection unless patient is septic! Hope this is helpful.			

Would be interested to see the final versions when ready.....	
Recommended action	a. i. **ACCEPT** This has been updated accordingly in this document. ii. **NONE** This information is outside the scope of this document and would apply to various sections of user manual. iii. **ACCEPT** This has been updated accordingly in this document.

Comment number	4		
Date received	08/12/2016	**Professional body**	Community Clinical Tutor
Any other comments you wish to make			
I have had a look at the urine testing document. It looks good to me but I just wondered if on page 11 it could include the list of UTI symptoms it refers to for completeness. I appreciate we should all know these anyway, but as it is a supportive guide I wonder if it should be included?			
Recommended action	**NONE** This is outside the scope of this user manual. Refer to the Primary Care Guidance and the UK SMI B 41: Investigation of Urine document which is cross referenced in the document for more information on UTI symptoms.		

Comment number	5		
Date received	19/12/2016	**Professional body**	British Association of Urological Surgeons
Any other comments you wish to make			
This document provides detailed information which is useful for Urologists regarding standards for Microbiology laboratories. It outlines the process of urinary specimen collection and the correct and most efficient use of the laboratory to obtain results in simple UTI. We agree that it should be standard practice for laboratories to provide detailed information regarding their services including points of contact for obtaining results and facilitating clinical advice. We welcome the consistency with other UK UTI guidelines such as SIGN guideline 88. We would like to make the following comments regarding specific statements made in the document. a. Page 11 “Indications for lab urine samples” – we would recommend the addition of Patients with Recurrent UTI – they should be included as they are more likely to have resistant organisms as a result of previous antibiotic treatments or long			

term prophylaxis. b. Page 12 – which details the different types of urine specimens – post DRE specimens should be included such as those that form part of the Stamey-Mears test in men with suspected infective prostatitis c. Any urine specimens collected from nephrostomy tubes should also be labelled accordingly d. Cystoscopic samples should be sub-categorised to include those obtained post prostatic massage We hope this is helpful and look forward to being informed when the User Manual is published.	
Recommended action	a. **ACCEPT** This has been updated accordingly in this document. b. **ACCEPT** This will be updated accordingly in this document and during the next review of the UK SMI B 41 document. c. **ACCEPT** This has been updated accordingly in this document. d. **ACCEPT** This will be updated accordingly in this document and during the next review of the UK SMI B 41 document.

Comment number	6		
Date received	04/01/2017	**Professional body**	Primary Care Guidance
Any other comments you wish to make			
There are a few comments I would like to make: a. Reporting in children needs to be in line with NICE UTI in children guidance so that labs differentiate *E.coli* from non *E.coli* coliforms. I enclose an audit we undertook which shows that this is not routinely undertaken. b. Provision of on-call urine microscopy or culture in children needs to be considered. Again this is to be in line with NICE standards. c. Just for your information, the PCU will be reviewing the GP urine quick reference guide in the next 6 months so the section on collection of samples on page 10 and 11 may change. d. Please reference the section from the GP quick reference guide on page 10 and 11. e. I was very surprised there was only one reference. It would be very good to have the whole guidance referenced with the evidence base, or have a separate rationale. f. There is also updated UTI antibiotic guidance.			

Evidence	
McNulty CA et al, Do English NHS Microbiology laboratories offer adequate services for the diagnosis of UTI in children? Healthcare Quality Improvement Partnership (HQIP) Audit of Standard Operational Procedures. J Med Microbiol. 2015 Sep;64(9):1030-8; quiz 1038-9. doi: 10.1099/jmm.0.000114. Epub 2015 Jul 17.	
Recommended action	a. **PARTIAL ACCEPT** For identification, what is recommended in the UK SMI B 41 document needs to be followed. However information has been added on the use of NICE guidelines in the interpretation section. References have been added. b. **NONE** Many thanks for the information. This information is covered within the section on "*Locating and contacting the laboratory*". c. **NONE** Many thanks for the information. d. **ACCEPT** The GP urine quick reference guide has been referenced on the subsection heading "*Consent, collection and transport of specimens*" to cover for pages 10 and 11 of this document. e. **ACCEPT** More references have been added to the whole guidance. f. **ACCEPT** The UTI antibiotic guidance has been added to the document where appropriate.

Second consultation: 15/03/2017 – 29/03/2017

Version of document consulted on: U a dj+

Proposal for changes

Comment number	1		
Date received	15/03/2017	**Lab name**	Salisbury NHS Foundation Trust (Microbiology)
Section	Urine tests		
Comment			
One important issue has been completely missed. Need for clear clinical history/ signs/ symptoms. So often we get nurse generated urine samples, often before patient being seen or unknown to medical staff (once admitted) with nothing more than DIPSTICK test			

results in the clinical details. Often this will include MSU and CSU samples, despite repeated comments and discussions on the fact that dipsticks a) should NOT be used for CSU screening and b) the test result is only for the benefit of the screener, and is irrelevant to the Micro Lab and Clinical staff who need CLINICAL detail to interpret difficult cultures (eg, mixed growths). If clear urinary symptoms, selecting a predominant colony type OR requesting repeat samples could be more selective rather than blanket comments on all examples so that requesters become word-blind and ignore critical comments). It would be useful to include in the document key items of signs/ symptoms which medical and nursing staff need to ensure are noted on request forms both for MSU and CSU related requests. Leaving this out just means that MICROBIOLOGISTS don't care a damn about this, and so the requesters will not either.
Evidence
Just look at your lab request forms, you'll see plenty of examples of poorly completed clinical details for urine samples and dipsticks results (unless you have successfully had them removed from use!!). How many times have you looked at the list of urines to authorise out and wondered how many of them really need sending, eg, nursing homes, elderly care wards, etc. Samples sent as a primary response to non-specific symptoms is surely a waste of culture media and the decision making in labs which comes from them?
Financial barriers
How serious medical and non-medical requesters view this on their own scales of importance.
Health benefits
Perhaps better use of laboratory resources, better understanding on the use and limitations of laboratory tests, better defined investigation pathways and wider cost benefits for local health care and national health care costs.

Recommended action	**ACCEPT** The wording “relevant clinical information” has been included and updated to the subtitle *On the form* on page 11 of the document accordingly.

Comment number	2		
Date received	21/03/2017	**Lab name**	Microbiology Society Technical Advisory Group
Section			
Comment			
General comments: a. Discussion on whether it was the role of the laboratory to issue instructions on how to take a urine specimen-not all agreed this is appropriate. b. Whole document – there are two versions of mL or ml throughout the document,			

these should be reviewed and all changed to mL. None should appear as “mls”. c. The MSTAG are divided as to whether microscopy on urines is of value. d. There is no mention of clinical details which could be important. e. Page 11 should read children <3 months old with suspected UTI should be admitted to hospital. f. Page 11 Time to laboratory for boric acid containers keeps bacterial population steady for 48-96 hours (Is this referenced?) g. Page 11 states Urine not cloudy 97% predictive value. Is this referenced? h. Page 12 Under the heading “Ileal conduit or urostomy specimen collection” the text states “Use a plain container”. We think that this should be the same as for SPAs “Use a plain CE marked lead-proof container”. i. Page 13 discusses the use of plain universal containers or boric acid, there is no mention of primary urine tubes which are often used for automated systems. The text should be altered to reflect this. j. Page 14 mentions Schistosomiasis but does not mention 24 hr or terminal urine samples which are occasionally taken, this probably needs to be cross referenced with the parasite SMI. k. Page 16 It was discussed that many laboratories (especially with automated technology) now do not report the presence of casts, this parameter has been “turned off” on many of the automated systems.	
Recommended action	a. **NONE** The instructions for sample collection are down to local decision in the local hospital laboratories. b. **ACCEPT** This has been updated in the document accordingly. c. **NONE** Many thanks for the information. d. **ACCEPT** This has been updated in the document. e. **ACCEPT** This has been updated in the document accordingly. f. **ACCEPT** A reference has been added to this statement. g. **ACCEPT** A reference has been added to this statement. h. **ACCEPT** This has been updated in the document accordingly. i. **ACCEPT** This has been updated in the document accordingly.

	j. **ACCEPT** This has been updated in the document accordingly. k. **ACCEPT** The section on “Other lab reported findings” has been amended to note that not all laboratories report the presence of casts in their results.

Comment number	3		
Date received	22/03/2017	**Lab name**	PHE Public Health Laboratory Birmingham
Section	Interpreting laboratory results		
Comment			
I am a bit confused by the first bullet point on page 15. Pyuria without growth on routine culture media. Consider: lysis of the WBCs in alkaline urine The rest of the list are possible reasons for detecting sterile pyuria (ie detecting WBCs in urine but culture negative). If the WBCs are lysed then surely they would not be detected and you wouldn't have detected a high WBC count in the first place?			
Financial barriers			
Public Health England.			
Recommended action	**ACCEPT** This has been updated in the document accordingly.		

Comment number	4		
Date received	26/03/2017	**Professional body**	RCGP Clinical Advisor
Section	Consent, collection and transport of specimens		
Comment			
Indications for lab urine specimens: Routine MSU in antenatal booking, this asks for second specimen before treating. I would recommend also adding MSU also needs to be sent after treating asymptomatic UTI in pregnancy to check infection has cleared.			
Evidence			
Please see attached link from HPA and BIA quoted as: IS A FOLLOW-UP URINE SAMPLE NEEDED? Follow-up urine samples are not usually indicated, except when treating asymptomatic bacteriuria in pregnancy. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/323398/UTI_guidelines_with_RCGP_logo.pdf			

Financial barriers	
No.	
Health benefits	
No.	
Recommended action	**ACCEPT** This has been updated in the document accordingly. The above recommended reference has been added to this section.

Comment number	5		
Date received	26/03/2017	**Professional body**	RCGP
Section	Consent collection and transport		
Comment			
a. I agree with the requirements of transport - 4 hrs plain bottle/ boric 48 hrs + - but could you ensure that labs stick to this (some reject plain bottles even when produced according to guidance)? b. Blood in urine - an instruction is given to follow this finding up. I feel strongly that this needs careful thought bearing in mind primary care epidemiology. This is very common - and furthermore is a positive sign for UTI (according to your text) - thus the majority of patients diagnosed as having UTI will have follow up dipsticks - whilst sensitive this is very non-specific and burdensome (with great potential for over diagnosis and iatrogenic harm). You make no comment on how soon after the infection one needs to repeat the test and whether the microscopic haematuria during an infection counts as the first hit of two hits and a 2 week rule referral (NICE cancer guidance) - do you have any evidence related to restating for blood in specimens taken for acute UTI? c. CSU collection - there should be guidance (as with MSUs) on how to interpret symptoms/ signs.			
Financial barriers			
See comments in 1 and 2.			
Health benefits			
See comments.			
Recommended action	a. **NONE** Many thanks for your comments. b. **NONE** It is the view of the Working Group that no changes need to be made in this section. c. **PARTIAL ACCEPT** Many thanks for the information. Information has been		

	added to the section on *"Indications for laboratory urine samples"*.

Comment number	6		
Date received	29/03/2017	**Professional body**	Institute of Biomedical Science
Section	Page 11 under the consider differentials section		
Comment			
We recommend at this point the NICE guideline Suspected cancer: recognition and referral is referenced for its explicit guidance on the management of patients with visible and non-visible haematuria in section 1.6 Urological Cancers.			
Evidence			
Nice Guideline NG12 Suspected Cancer: recognition and referral (June 2015. Refer people using a suspected cancer pathway referral (for an appointment within 2 weeks) https://www.nice.org.uk/guidance/ng12			
Financial barriers			
Not aware.			
Recommended action	**ACCEPT** This reference has been added in the document.		

Respondents indicating they were happy with the contents of the document

Overall number of comments: 2			
Date received	20/03/2017	**Lab name**	Member of the public
Date received	22/03/2017	**Lab name**	Keith Shuttleworth and Associates Ltd