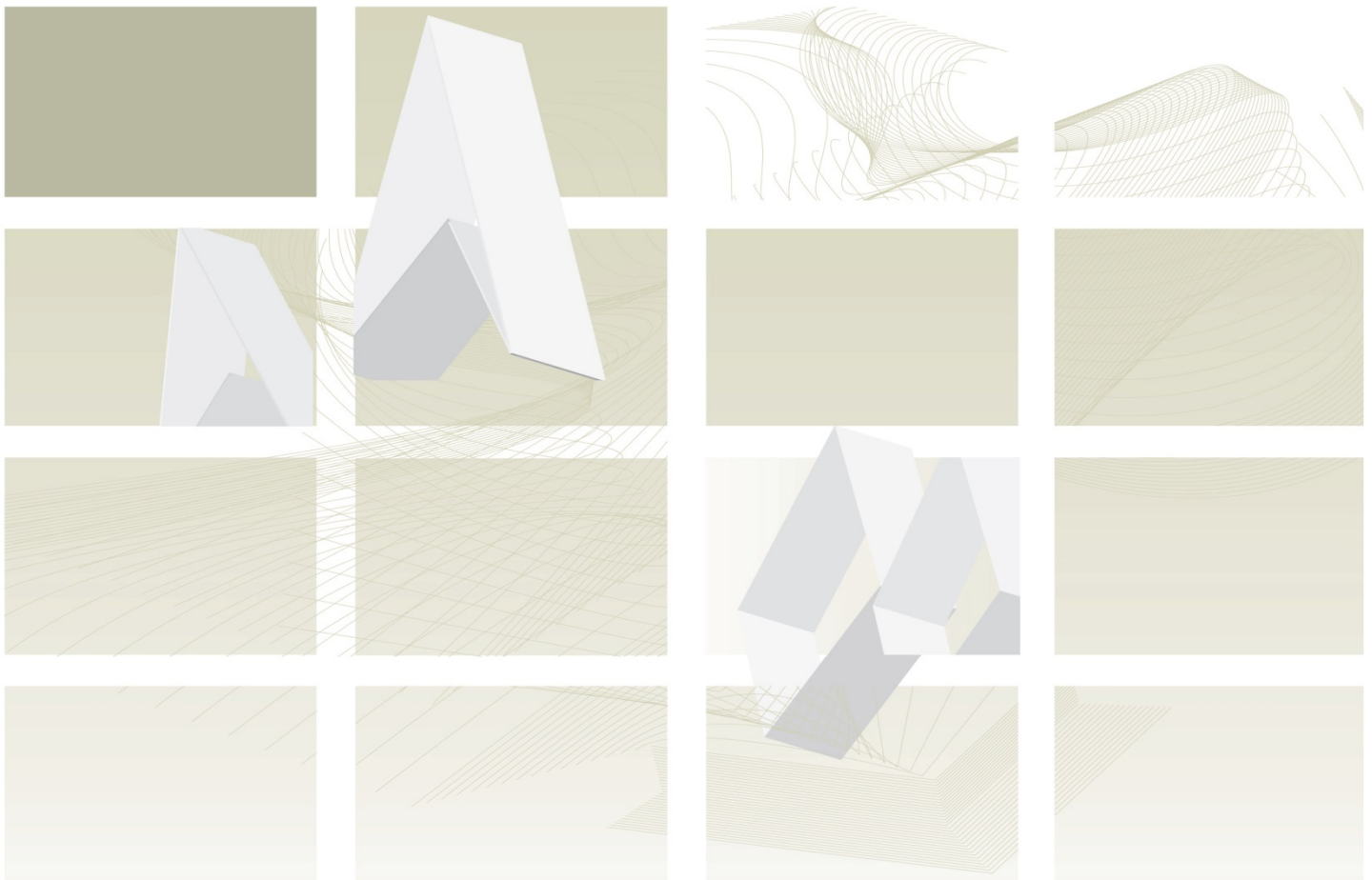




UK Standards for Microbiology Investigations

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



"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

1st Consultation: 05/10/2015 – 07/11/2015

Version of document consulted on: dk+

Proposal for changes

Comment number	1		
Date received	08/10/2015	Lab name	Aberdeen Royal Infirmary, Virology Lab
Section	Various		
Is the proposed layout of headings appropriate, could this be organised in a more user-friendly way?			
Yes.			
Do the scope and suggestions for each heading cover all user requirements, are there any gaps?			
Yes.			
Health benefits			
No.			
Recommended action	NONE Many thanks for the information.		

Comment number	2		
Date received	08/10/2015	Professional body	British Society for Microbial Technology
Section			
Comment			
I have consulted widely within my Network and I have received no comments suggesting we change anything, add or take away. Most seem very happy with our proposal.			
Recommended action	NONE Many thanks for the information.		

Comment number	3		
Date received	28/10/2015	Lab name	PHE Public Health Laboratory Birmingham
Section	Main section of template		

Comment	
<p>Collection and transport of specimens, types of services offered and how to use the laboratory, and test turnaround times and parameters of performance should all be combined for test specific information. I imagine most users will want to look up a particular test and see everything they need to know about that test in one place rather than flitting around the document.</p> <p>I'd want to know how to collect, patient information sheets, sample volume requirements, sample pot type, specific information needed on the form, costs, TATs and limitations all in one place.</p>	
Evidence	
Experience.	
Do the scope and suggestions for each heading cover all user requirements, are there any gaps?	
Who to call for clinical advice.	
Recommended action	ACCEPT Clinical advice has been updated in the document.

Comment number	4		
Date received	28/10/2015	Lab name	Health and Social Care trust, Northern Ireland
Section	General		
Comment			
<p>Although I have been out of the laboratory for a long time, I thought that this template was excellent. It will provide standardisation for the difficult task of preparing these Manuals and be a guide for accreditors.</p> <p>The key question is in the 'scope' section and is 'who is the Manual for?' as several different manuals each with slightly different nuances and structure may be required for Trusts, GPs, patients etc.</p>			
Is the proposed layout of headings appropriate, could this be organised in a more user-friendly way?			
Seems fine.			
Financial barriers			
No.			
Health benefits			
A reduction in stress for those who have to write the Manual(s)!			
Recommended	ACCEPT		

action	Many thanks for the information. Those individuals for whom the manual are produced for will be made clear in the scope of the document.
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Comment number	5		
Date received	29/10/2015	Lab name	GP
Section	Various		
Do the scope and suggestions for each heading cover all user requirements, are there any gaps?			
The scope covered within each heading seems very thorough. In the reporting section it may be helpful to advise on how and who to contact for advice on results.			
Recommended action	ACCEPT Many thanks for the information. This will be updated in the document accordingly.		

Comment number	6		
Date received	04/11/2015	Lab name	GP and undergraduate educator
Section	Various		
Comment			
This template is really well laid out and useful I am not a lab scientist but as a GP I am desperate for information about which sample, how to take it and when. If you decide to open out that area do let me run with it with you.			
Is the proposed layout of headings appropriate, could this be organised in a more user-friendly way?			
Yes.			
Do the scope and suggestions for each heading cover all user requirements, are there any gaps?			
Yes.			
Financial barriers			
For GPs' education.			
Health benefits			
None.			
Recommended action	ACCEPT		

	Many thanks for the information.
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Comment number	7		
Date received	06/11/2015	Professional body	The Institute of Biomedical Science (IBMS)
Section	General		
Comment			
The IBMS broadly supports the concept of the UK SMI National User Manual Template and believes it would be particularly useful for laboratories when reviewing user manuals for ISO 15189 compliance. To this end it is suggested that where appropriate the corresponding ISO standard is quoted under each heading. In addition to this it is recommended that the document needs to make clear that it is a recommendation template that laboratories can choose to use and not a mandate.			
Recommended action	PARTIAL ACCEPT Many thanks for the information. The importance of the ISO guidance will be mentioned in this template but it is up to the users to add this in relevant sections that are of importance to them.		

2nd Consultation: 25/01/2016 – 22/02/2016

Version of document consulted on: User manual template dt+

Proposal for changes

Comment number	1		
Date received	28/01/2016	Lab name	Public Health Agency, Northern Ireland
Section	All		
Comment			
I thought it looked good and was easy to follow.			
Is the proposed layout of headings appropriate – could this be organised in a more user-friendly way?			
Yes. The order flows well. A minor point: <ol style="list-style-type: none"> a. I wondered if the section on 'Locating and Accessing the Laboratory' should become before 'Contacting the Laboratory'. b. Also, should the Locating part be separate; and accessing and contacting the Laboratory be combined? 			
Do the scope and suggestions for each heading cover all user requirements – are			

there any gaps?	
Couldn't see any.	
Financial barriers	
No.	
Health benefits	
No.	
Recommended action	<p>a. NONE Individual laboratories are free to change headings for their local use.</p> <p>b. NONE Individual laboratories are free to change headings for their local use.</p>

Comment number	2		
Date received	18/02/2016	Lab name	GP and undergraduate educator University of Liverpool School of Medicine
Section	See below.		
Comment			
<p>a. This is excellent and I wish I had this at the start of my GP career or as a medical student.</p> <p>b. The cover is too busy and confusing - we all just want a microbe pic to tell us that's what it is!</p> <p>c. P7. overview of services: I want this strengthened to "must include" not "wish to include" as this part makes it a very useable primary care manual.</p> <p>d. Contacting the lab: same point not wish but must include please.</p> <p>e. The booklet gets split up now but surely better to combine collection, transport and test repertoires.</p> <p>f. Add incubation periods for testing.</p> <p>g. Pictures are an excellent idea for testing.</p> <p>h. Results great with pitfalls - excellent.</p> <p>I think you are doing really well with this, it's exciting. Thanks.</p>			
Is the proposed layout of headings appropriate – could this be organised in a more user-friendly way?			

See above. Combine areas by condition/test so it's all in one read when in clinic.

Do the scope and suggestions for each heading cover all user requirements – are there any gaps?

Incubation was the only one I noticed you may want to add link to the HPE primary care antibiotic guidelines but they also have regional variances.

Financial barriers

None.

Health benefits

Benefits: GPs do not have up to date guidance for microbiological or virology testing. This would enhance our skills and make testing more rational.

DOWNSIDE or maybe an UPSIDE: but may increase testing rates. Just recently my chlamydia swabs have changed yet again after 20 years of certainty and none of us are sure about them. I rang the lab and got through eventually. I have a yellow top urine screening one for under 25s with fluid in the bottle. I have a purple dry one for the first time and another purple one with a fluid still. The instructions to the primary care staff when these are rolled out are pretty much nil and causes confusion. If you can prevent this I am very pleased.

Recommended action

- a. **NONE**
Many thanks for the information.
- b. **ACCEPT**
New images will be added and updated accordingly.
- c. **PARTIAL ACCEPT**
It was agreed by the Joint working group that the word 'should' will be used to strengthen the document. The word 'must' if used, makes it mandatory and appear like a legal obligation which is not within the remit of the UK SMIs.
- d. **PARTIAL ACCEPT**
See comment c.
- e. **NONE**
The test repertoire subheading will be kept separate from the collection and transport subheading as agreed by the group members.
- f. **ACCEPT**
It was agreed by the group that users should be reminded of disease-specific incubation periods, where relevant, to inform optimum time points for testing.
- g. **ACCEPT**
This has been updated in the user manual template accordingly that pictures should be added to show for

	<p>example the different collection tubes/bottles that can be used in different clinical situations eg in the case of Chlamydia.</p> <p>h. ACCEPT</p> <p>This will be updated accordingly.</p>
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Comment number	3		
Date received	18/02/2016	Lab name	Not stated
Section	Various		
Comment			
What is the government doing about the out breaks of Alabama rot, including research and control?			
Recommended action	<p>NONE</p> <p>This is outside the scope of the work of the UK SMIs.</p>		

Comments received outside of consultation

Comment number	1		
Date received	19/03/2016	Lab name	Microbiology Society Technical Advisory Group
Section	Various		
Comment			
<p>Comments from the MSTAG were very favourable with regards to this document:</p> <ol style="list-style-type: none"> The SMI provided a well-defined template for a User manual clearly in line with UKAS requirements. The SMI should give details as to the format for the electronic version that should be used on the website as most are available electronically this should be clearly linked directly for the user. The SMI should add a statement that validation and verification data for specific tests/assays are available upon request. 			
Recommended action	<ol style="list-style-type: none"> NONE Many thanks for the information. NONE At the current time, this should be agreed with the user's local team but this is something we can consider further into the project's development. ACCEPT 		

	<p>It was agreed by the group that validation and verification data is important in the National user manual template and this will be strengthened in the document. Information that users should communicate with laboratories for information/suggestions on test assays will also be added.</p>
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