

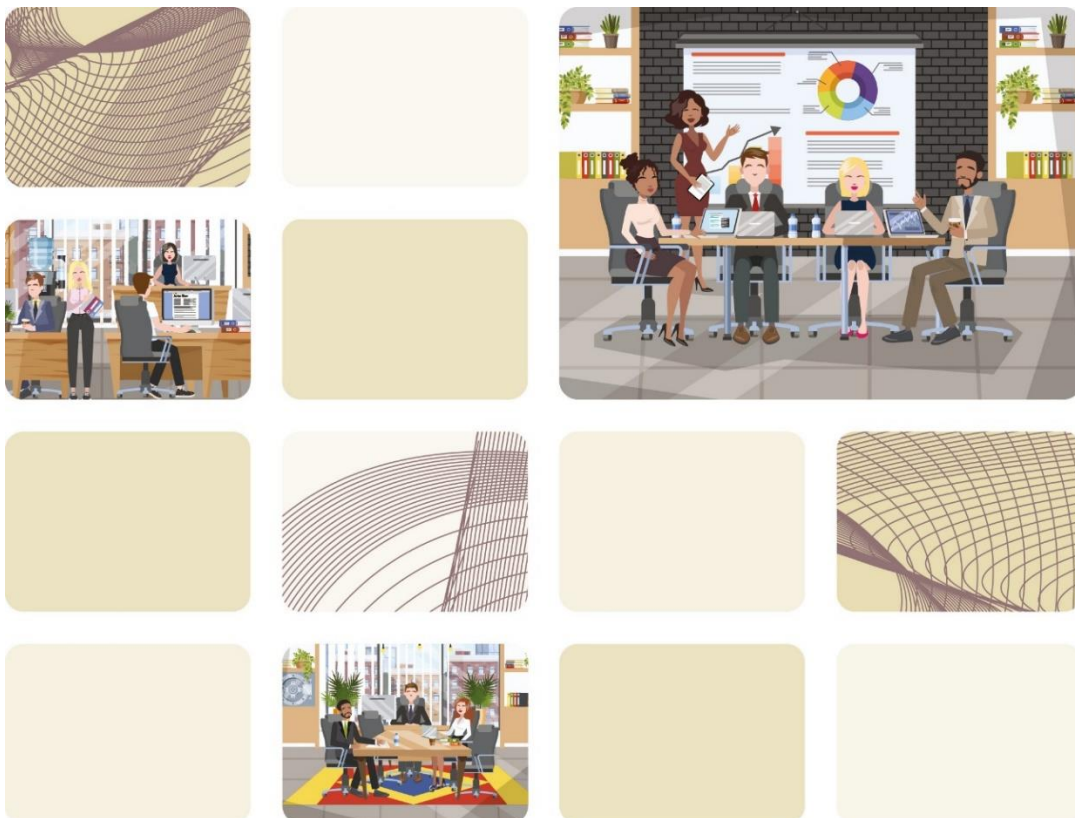


UK Health
Security
Agency

UK Standards for Microbiology Investigations

Review of users' comments received by
Working group for microbiology standards in clinical
bacteriology

UK SMI ID 22 Identification of Shiga toxin-producing
Escherichia coli (STEC) using conventional methods
including Escherichia coli O157



National Institute for Health and Care Excellence (NICE) has renewed accreditation of the process used by the UK Health Security Agency to produce UK Standards for Microbiology Investigations (UK SMIs). The renewed accreditation is valid until 30 June 2026 and applies to guidance produced using the processes described in 'UK Standards for Microbiology Investigations Development Process' (2021). The original accreditation term began on 1 July 2011.

This publication was created by UK Health Security Agency (UKHSA) in partnership with the partner organisations.

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

Issued by the Standards Unit, Specialised Microbiology and Laboratories, UKHSA

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3 Scope of document

Comment number: 1

Date received: 20/09/2022

Laboratory or organisation name: Southwest Pathology Services

Scope of document should be ALL STEC producing E. coli NOT just O157.

Recommended action

Accept. The sentence has been reworded to 'identification of presumptive Shiga toxin-producing *Escherichia coli* (STEC) isolated from faeces'

Comment number: 2

Date received: 03/10/2022

Laboratory or organisation name: Public Health Scotland and Scottish E coli
Reference laboratory

The way this section is written it seems only O157 in scope and not other STEC?

Recommended action

Accept. The information on O157 has reduced and included information about non O157 STEC.

Comment number: 3

Date received: 04/10/2022

Laboratory or organisation name: IBMS

Some biochemical tests may not be done routinely in laboratory except in... Replace done with performed and laboratory with laboratories.

Recommended action

Accept. Sentence reworded to 'Some biochemical tests may not be performed routinely in laboratories.'

4 Introduction

Comment number: 4

Date received: 20/09/2022

Laboratory or organisation name: Southwest Pathology Services

Lots on O157 but what about other serotypes - absolutely nothing!

Recommended action

Accept. Included non O157 STEC.

Comment number: 5

Date received: 30/09/2022

Laboratory or organisation name: Wirral and Chester Microbiology Services

'haemolytic uraemic syndrome' would be more common usage than '...uraemia....'

Recommended action

Accept. Sentence changed to 'haemolytic uraemic syndrome'.

Comment number: 6

Date received: 30/09/2022

Laboratory or organisation name: Wirral and Chester Microbiology Services

'children living in endemicity' - could this be clearer ?'endemic areas'

Recommended action

Accept. Sentence changed to 'endemic areas'.

Comment number: 7

Date received: 30/09/2022

Laboratory or organisation name: Wirral and Chester Microbiology Services

'In 2010 STEC O157 PT8 phage type reported' - should this be '.....type infections were reported'?

Recommended action

None. Section removed to reduce information on STEC O157.

Comment number: 8

Date received: 03/10/2022

Laboratory or organisation name: Public Health Scotland and Scottish E coli
Reference laboratory

- 1) Non-O157 STEC mentioned here but nothing about their clinical severity in comparison to O157 (although briefly mentioned in section 7) might be good to have it all in the same place
- 2) Suggest remove inclusion of Phage typing here.

Recommended action

1. None. O157 STEC section has reduced.
2. Accept. Phage typing removed.

Comment number: 9

Date received: 04/10/2022

Laboratory or organisation name: IBMS

In 2010 STEC O157 PT8 phage type reported. Should read 'In 2010 STEC O157 PT8 phage type was reported'

Recommended action

None. Sentence removed.

Comment number: 10

Date received: 21/09/2022

Laboratory or organisation name: Manchester Foundation Trust

Current text: In 2019, 768 culture-positive non-O157 STEC cases (655 in England, 113 in Wales) were reported compared to 89 cases reported between 2009 and 2013.

Is this sentence correct? Or is it describing an increase in the reporting of PCR positive non-O157-STECS cases? This should be clearer

Recommended action

Accept. Sentence rephrased "In 2019, 768 culture-positive non-O157 STEC cases were reported (655 in England, 113 in Wales). Between 2009 and 2013, only 89 cases reported prior to PCR being implemented".

5 Technical information and limitations

Comment number: 11

Date received: 03/10/2022

Laboratory or organisation name: Public Health Scotland and Scottish E coli
Reference laboratory

This should include a small sentence on the danger of misclassification of *E. albertii* as *E. coli* using certain commercial systems (API20E)

Recommended action

None. The sentence "Hence, all presumptive *E. coli* O157 from human and non-human sources should be referred to the appropriate specialist laboratories for confirmation" covers this.

Comment number: 12

Date received: 20/09/2022

Laboratory or organisation name: UKHSA

Any chance we can expand on how SMAC/CT-SMAC reduces the likelihood of *E. hermannii* being mis-identified?

Recommended action

None The issue of *E. hermannii* cross-reaction with *E. coli* O157 antiserum would be mitigated by confirmation with other methods. Laboratories should report "presumptive *E. coli* O157" and get confirmation via molecular methods either locally or from the reference laboratory

Comment number: 13

Date received: 21/09/2022

Laboratory or organisation name: Manchester Foundation Trust

Current text describes false positive identification of *E. hermannii* as *E. coli* O157 as it is a non-sorbitol fermenter that agglutinates with O157 antiserum. Then describes the same 2 tests as 'useful for rapid detection of *E. coli* O157'

This seems contradictory - it is useful to know that you can get false positives, but it doesn't offer any alternative tests to mitigate for this

Recommended action

Accept. Section reworded.

Comment number: 14

Date received: 30/09/2022

Laboratory or organisation name: Wirral and Chester Microbiology Services

MALDI caveats - shouldn't this be linked somehow with the generic section on MALDI 8.4.4?

Recommended action

None

Comment number: 15

Date received: 21/09/2022

Laboratory or organisation name: Manchester Foundation Trust

'...to reliably distinguish pathogenic from non-pathogenic E. coli isolates.'
- MALDI is used (in this context) to identify organisms and not differentiate between different pathotypes of E. coli, so the aim of this sentence is not very clear

Recommended action

None. To remain as a limitation.

Comment number: 16

Date received: 20/09/2022

Laboratory or organisation name: Southwest Pathology Services

Why bother mentioning the green book when this is a non-vaccine preventable disease. Remove this sentence – irrelevant.

Recommended action

Accept. Sentence removed.

7 Target Organisms

Comment number: 17

Date received: 04/10/2022

Laboratory or organisation name: IBMS

Other E. coli serotypes like O145 can act like O157:H7. Replace like with such as.

Recommended action

Accept. Like has been replaced with such as.

Comment number: 18

Date received: 20/09/2022

Laboratory or organisation name: UKHSA

1. Final sentence = 'This procedure...' = which procedure? we haven't really started talking about specific procedures - do you mean the whole process regardless of which method? In that case can we say something like 'Methods may for the detection of STEC may result in the identification of isolates of presumptive E. coli O157 that do not produce Shiga toxin and some organisms that give equivocal results'.
2. Then I think it would be useful to expand what to do with equivocal or non-shiga toxin O157 even if that is to refer the reader to the relevant section.

Recommended action

1. Accept. Sentence has been reworded as suggested.
2. None.

8.1 Microscopic appearance

Comment number: 19

Date received: 20/09/2022

Laboratory or organisation name: Southwest Pathology Services

1. Do you really want staff to be performing gram stains on potential STEC!!!!!!
2. Also mention subculture to lactose containing media but then go on to say not all O157 strains are lactose fermenters - contradictory - remove subculture to lactose containing media.

Recommended action

1. None. Gram Staining if required has been included as part of the template
2. Accept. Removed to subculture to lactose containing media.

Comment number: 20

Date received: 03/10/2022

Laboratory or organisation name: Public Health Scotland and Scottish E coli Reference laboratory

1. Under chromogenic selective agar – Use O for O111 (not 0111).
2. In Scotland we advocate the use of TBS – not MTSB – for enrichment. The modifications in the modified TSB can inhibit the growth of some non-O157 STEC.

Recommended action

1. Accept
2. Accept. Reworded to say enrichment culture without naming specific media.

Comment number: 21

Date received: 20/09/2022

Laboratory or organisation name: UKHSA

This sentence 'Culture methods to detect STEC O157 by its inability to ferment sorbitol on selective media (MacConkey agar)' is not a full sentence. I wonder if the word 'to' should be removed to become 'Culture methods detect STEC O157 by its inability to ferment sorbitol on selective media (MacConkey agar)'.

Recommended action

Accept. Removed 'to'.

Comment number: 22

Date received: 21/09/2022

Laboratory or organisation name: Manchester Foundation Trust

Culture methods to detect STEC O157 by its inability to ferment sorbitol on selective media (MacConkey agar). However, non-O157 STEC ferment sorbitol and there is no culture method to differentiate non-O157 STEC from non-pathogenic E.coli in frontline laboratories (45).

This paragraph doesn't make sense - remove 'to' from the first sentence?

Recommended action

Accept.

Comment number: 23

Date received: 20/09/2022

Laboratory or organisation name: UKHSA

Are you suggesting that clinical labs start using TBX on stool samples?? I am not sure of the implications of this message. If you are suggesting it to be used as part of colony identification then that should be made clear, because putting it as primary isolation media suggests that faeces should be inoculated onto TBX. TBX is used in food labs at 44 degrees to maintain specificity - but most clinical labs do not have a 44 degree incubator.

Recommended action

Accept. Removed TBX.

8.3 Colonial appearance

Comment number 24:

Date received: 03/10/2022

Laboratory or organisation name: Public Health Scotland and Scottish E coli
Reference laboratory

Would make sense to add E.coli O157 colony morphology to the table too

Recommended action

Accept. *E. coli* (non-O157) added to the table.

8.4.5 Molecular Testing

Comment number 25:

Date received: 03/10/2022

Laboratory or organisation name: Public Health Scotland and Scottish E coli
Reference laboratory

States that positive PCR should be cultured, which puts responsibility on local labs?
(8.6. says cultures/isolates should be sent to ref lab)

Recommended action

None. Sentence removed.

8.5.2 Whole genome sequencing

Comment number 26:

Date received: 03/10/2022

Laboratory or organisation name: Public Health Scotland and Scottish E coli
Reference laboratory

Its pulsed-field gel electrophoresis

Recommended action

None. Section amended.

Comment number 27:

Date received: 21/09/2022

Laboratory or organisation name: UKHSA Bristol

The document is about UK standard so the items in the document should be precise and accurate. In the section of WGS there is only general information about the

technique not particular application details.

The WGS has achieved some on identifying bacterial pathogen transmission pathways in the past. it is accurate and comprehensive but seems not quite rapid and not low cost.

Because of uncertainty of: 1. which bacterial pathogen would be in concern; 2. how many cases would in need to sequencing; 3. varied laboratory staff training, skills and experience might cause discrepancies of the sequencing results; 4. the IT infrastructure is not unified set up yet; etc, also because of: 1. sequencing equipment capacity usually larger than the bacterial pathogen's genomes' size so the batch test would be only choice; 2. the sequencing equipment is not yet standardised by anyway near to a unified protocols (although COVID WGS seemed performed by a universal guiding document but the quality control depended on individual laboratory operation); 3. data extraction and report generation will be hard to standardise in near future as the databases are expanding and developing; etc., so the rapid and low cost of WGS on bacterial pathogen work need longer time to achieve.

Recommended action

1. None

8.6 Storage and referral

Comment number 28:

Date received: 03/10/2022

Laboratory or organisation name: Public Health Scotland and Scottish E coli

Reference laboratory

1) Mentions Phage typing, Scottish E coli ref lab and UKHSA moving towards stopping this

2) Please add "appropriate National" text in section as below:

'Cultures should be referred promptly to the appropriate National Reference Laboratory for confirmation of identification, biochemical confirmation, detection of stx genes, serotyping and phage typing.'

3) This doesn't include WGS, and you don't serotype (?) so suggest the following additional rewrite for this section:

'Cultures should be referred promptly to the appropriate National Reference Laboratory for confirmation of identification, detection of stx genes and further typing, including WGS.'

Recommended action

1. Accept. Phage typing removed.
2. None. Added 'appropriate reference laboratory'.
3. Accept

9.1 Infection Specialist

Comment number 29:

Date received: 04/10/2022

Laboratory or organisation name: IBMS

Consider adding Food Handler to the list

Recommended action

Accept. Food Handler added to the list

Comment number 30:

Date received: 03/10/2022

Laboratory or organisation name: Public Health Scotland and Scottish E coli
Reference laboratory

Doesn't really distinguish what to do should GI PCR be first line in local lab

Recommended action

Accept. The flowchart has a bullet point 'For molecular testing, follow local procedure'.

9.2 Confirmation of identification

Comment number 31:

Date received: 03/10/2022

Laboratory or organisation name: Public Health Scotland and Scottish E coli
Reference laboratory

The link should also include the Scottish E coli Ref lab (SERL) User Manual and request form

Recommended action

None. The second paragraph mentions to contact appropriate reference laboratory for information on the tests available, including Scotland.

9.3 UK Health Security Agency

Comment number: 32

Date received: 03/10/2022

Laboratory or organisation name: Public Health Scotland and Scottish E coli
Reference laboratory

Doesn't cover Scottish/DA position -suggestion for addition- "In Scotland, local diagnostic laboratories report presumptive cases of STEC to their local Health Protection Teams (HPTs), PHS via ECOSS and then refer samples to the reference laboratory for confirmation and further testing."

Recommended action

None. Discussed at the Bacteriology Working Group to keep the paragraph generic. In England, local diagnostic laboratories report presumptive cases of STEC to their local Health Protection Teams (HPTs) and then refer samples to the appropriate reference laboratory for confirmation and further testing. The title of this section changed from UK Health Security Agency to Health Protection Teams.

Algorithm

Comment number: 33

Date received: 21/09/2022

Laboratory or organisation name: Manchester Foundation Trust

What is the process for following up PCR positive-culture negative samples? I think it would be useful to include information on this scenario

Recommended action

Accept. Included as a bullet point 'a sample is PCR positive-culture negative, consider repeating the test or send the sample to appropriate reference laboratory'.

Comment number: 34

Date received: 03/10/2022

Laboratory or organisation name: Public Health Scotland and Scottish E coli
Reference laboratory

This is really just for the ID of E. coli O157 and not STEC?
You no longer provide this service (?):

Recommended action

None. Non O157 is included in the document.

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Comment number: 35

Date received: 20/09/2022

Laboratory or organisation name: Southwest Pathology Services

Need to include use of chromogenic agar at the start of the process – this flowchart concentrates solely on O157 even though chromogenic agar and other serotypes mentioned throughout the document.

Recommended action

Accept. The box on the right at the top has been changed to identification by conventional methods.

Comment number: 36

Date received: 20/09/2022

Laboratory or organisation name: UKHSA

On the HTML version there are paragraphs about what to do with sorbitol-fermenting and non-sorbitol fermenting colonies - this comes just before the references but after the algorithm. This is not seen in the pdf version.

Also, in this section, the last sentence is: 'If the patient presents with diarrhoea, only then the sample can be discarded.' Is the comma in the right place? I am not sure if it is supposed to say 'if the patient presents with diarrhoea only, then the sample can be discarded'.

Recommended action

Accept. The text has been added to describe the algorithm for accessible readers following the web publishing guidance. The suggested sentence is correct and will be added to the text description. However the text description is no longer required.

General Comments

Comment number 37:

Date received: 04/10/2022

Laboratory or organisation name: Infection Sciences laboratory, North Bristol NHS Trust/Public Health England

No further feedback

Recommended action

NA

Financial barriers

Respondents were asked: 'Are there any potential organisational and financial barriers in applying the recommendations or conflict of interest?'

Comment number: 38

Date received: 20/09/2022

Laboratory or organisation name: Southwest Pathology Services

None

Comment number: 39

Date received: 20/09/2022

Laboratory or organisation name: UKHSA

no

Comment number: 40

Date received: 21/09/2022

Laboratory or organisation name: UKHSA Bristol

no

Comment number: 41

Date received: 21/09/2022

Laboratory or organisation name: Manchester Foundation Trust

No

Comment number: 42

Date received: 30/09/2022

Laboratory or organisation name: Wirral and Chester Microbiology Services

no

Comment number: 43

Date received: 03/10/2022

Laboratory or organisation name: Public Health Scotland and Scottish E coli
Reference laboratory

No

Health benefits

Respondents were asked: 'Are you aware of any health benefits, side effects and risks that might affect the development of this UK SMI?'

Comment number: 44

Date received: 20/09/2022

Laboratory or organisation name: Southwest Pathology Services

No

Comment number: 45

Date received: 20/09/2022

Laboratory or organisation name: UKHSA

no

Comment number: 46

Date received: 21/09/2022

Laboratory or organisation name: UKHSA Bristol

The WGS approach has been beneficial towards clinical bacteriology in the past years. To standardise the work may be too early. A lot of work need to be done such as: updating staff training; recruiting and train more bioinformaticians; UKHSA network improvement on sharing not only data but skills and experience; etc.

Comment number: 47

Date received: 21/09/2022

Laboratory or organisation name: Manchester Foundation Trust

No

Comment number: 48

Date received: 30/09/2022

Laboratory or organisation name: Wirral and Chester Microbiology Services

no

Comment number: 49

Date received: 03/10/2022

Laboratory or organisation name: Public Health Scotland and Scottish E coli
Reference laboratory

No

Interested parties

Respondents were asked: 'Are you aware of any interested parties we should consider consulting with on the development of this document?'

Recommended action

Comment number: 50

Date received: 20/09/2022

Laboratory or organisation name: Southwest Pathology Services

UKAS. Inform UKAS that these are guidance ONLY documents and that the processes and methods described within can be altered if good clinical reasons provided.

Comment number: 51

Date received: 20/09/2022

Laboratory or organisation name: UKHSA

no

Comment number: 52

Date received: 21/09/2022

Laboratory or organisation name: Manchester Foundation Trust

Local HPTs

Comment number: 53

Date received: 30/09/2022

Laboratory or organisation name: Wirral and Chester Microbiology Services

no

Comment number: 54

Date received: 03/10/2022

Laboratory or organisation name: Public Health Scotland and Scottish E coli

Reference laboratory

Scottish e coli Ref lab (SERL)

Respondents indicating they were happy with the contents of the document

Overall number of comments: None			
Date received		Lab name/Professional body (delete as applicable)	
Health benefits			