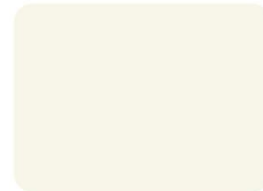
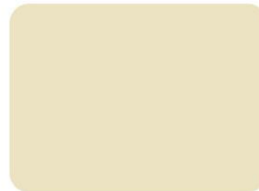
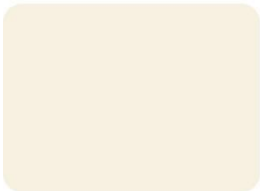
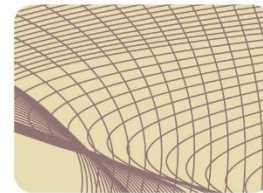
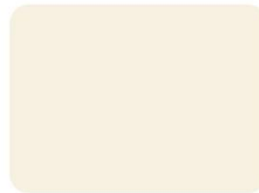
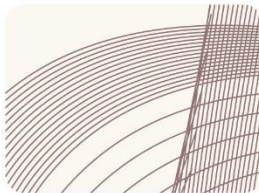
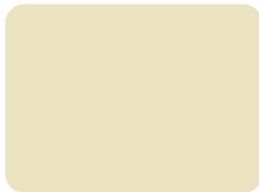
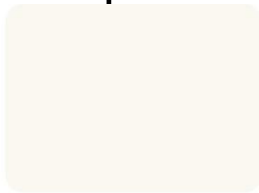
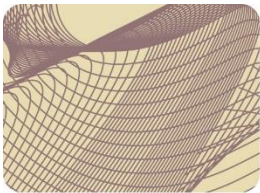




# UK Standards for Microbiology Investigations

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

## V 37 Chlamydia and Gonorrhoea infection – testing by Nucleic Acid Amplification Tests (NAATs)



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

### 3 Scope of document

#### Comment number: 1

Date received: 24/07/2024

Laboratory or organisation name: UKHSA regional SW (Bristol)

Suggest specifically also exclude gonococcal eye infection- this will also help with the statement on p6 about how it is spread (vagina, anus, oral).

#### Recommended action

1. Accept

#### Comment number: 2

Date received: 24/07/2024

Laboratory or organisation name: UKHSA South West Regional Laboratory

2nd paragraph states that ocular trachoma and neonatal infections are out-of-scope. However it is not immediately clear if testing of ocular samples from patients with suspected chlamydial or gonococcal conjunctivitis are in or out of scope (these samples are not mentioned in 7.1), and it is not immediately clear if oropharyngeal samples are in scope (this sample type is included in 7.1). It would be useful if testing of out-of-scope samples could be cross-referenced to another SMI.

#### Recommended action

1. Accept: Link to [UK SMI S 11 red or painful eye](#) has been added.

#### Comment number: 3

Date received: 28/07/2024

Laboratory or organisation name: Synnovis Infection Sciences, GSTT

You could specifically state it does not include gonococcal arthritis.

#### Recommended action

1. Accept

## Comment number: 4

Date received: 12/08/2024

Laboratory or organisation name: UKHSA STIRL

Definitions section, in pooled samples remove or blood, as not tested for *C. trachomatis* or *N. gonorrhoeae*.

### Recommended action

1. Accept

## 4 Introduction

## Comment number: 5

Date received: 24/07/2024

Laboratory or organisation name: UKHSA South West Regional Laboratory

1. LGV, the first paragraph ends with the sentence "These are usually less frequently reported." It is not clear what "these" is referring to.
2. 2nd paragraph: Suggest: "reflex LGV testing of *C. trachomatis* positive rectal swabs is recommended for patients with proctitis and GBMSM with or without symptoms. However there are limited options for commercial LGV-specific NAAT, and limited capacity for reference laboratory testing.

### Recommended action

1. Accept: Sentence removed.
2. None: Removed the paragraph and add "For LGV testing refer to BASHH guidance".

## Comment number: 6

Date received: 28/07/2024

Laboratory or organisation name: Synnovis Infection Sciences, GSTT

1. Suggest to use genovar rather than serovar, although there is not a clear agreement on this ([https://www.clinicalmicrobiologyandinfection.com/article/S1198-743X\(22\)00087-8/fulltext](https://www.clinicalmicrobiologyandinfection.com/article/S1198-743X(22)00087-8/fulltext))
2. Last sentence - it is not clear what the last sentence is referring to when saying 'these are usually less frequently reported'

### Recommended action

1. Accept: Serovar changed to genovar.

2. Accept: Last sentence removed.

### Comment number: 7

Date received: 31/07/2024

Laboratory or organisation name: London School of Hygiene & Tropical Medicine

1. Second paragraph of gonorrhoea: Specify what year diagnoses have increased to. It may be obvious now but a few years down the line it won't.
2. Treatment for gonorrhoea is 1 g ceftriaxone, dose should be mentioned.

### Recommended action

1. Accept: Year and treatment added.
2. Accept: Year and treatment added.

### Comment number: 8

Date received: 06/08/2024

Laboratory or organisation name: Virology Dept, Royal Preston Hospital

"Pregnancy outside the womb" is a redundant term, it is reasonable to assume users of the UK SMI will understand the term ectopic pregnancy.

### Recommended action

1. Accept

### Comment number: 9

Date received: 15/08/2024

Laboratory or organisation name: UKHSA STIRL

Chlamydia section- Change to "Most sexually-acquired cases are asymptomatic; however the patient can have the following signs and symptoms".

### Recommended action

1. Accept

### Comment number: 10

Date received: 15/08/2024

Laboratory or organisation name: UKHSA STIRL

Change LGV section to "Lymphogranuloma venereum (LGV) is a sexually transmitted infection caused by 3 genovars of the bacterium *C. trachomatis*: L1, L2 and L3. LGV is almost exclusively detected in GBMSM in the UK. Symptoms can be complex, severe and may involve multiple sites in the body such as the genitals, the anus, rectum and

lymph nodes. The incubation period can range from 3 – 30 days from the time of contact with an infected individual. Patients typically present with proctitis however asymptomatic infection may occur”.

#### Recommended action

1. Accept

#### Comment number: 11

Date received: 15/08/2024

Laboratory or organisation name: UKHSA STIRL

LGV section- Note in the algorithm it says only for those HIV positive. I think this is still being decided in the BASHH LGV guideline update. For this reason I would just say refer for LGV as per BASHH guidance

#### Recommended action

1. Accept: Paragraph changed to “For LGV testing refer to BASHH guidance”.

#### Comment number: 12

Date received: 02/08/2024

Laboratory or organisation name: Chester and Wirral Microbiology Service

1. "extra genital" should be "extragenital" or "extra-genital" (you used the hyphenated form elsewhere in the document)
2. delete "other" in "other complications" - no complications have been mentioned before this

#### Recommended action

1. Accept: Changed to "extra-genital".
2. Accept

#### Comment number: 13

Date received: 02/08/2024

Laboratory or organisation name: Chester and Wirral Microbiology Service

missing date: "... to 85,223 diagnoses in England (3)" should be "...to 85,223 diagnoses in England in 2023 (3)"

#### Recommended action

1. Accept

## 4.1 Screening

Comment number: 14

Date received: 24/07/2024

Laboratory or organisation name: UKHSA South West Regional Laboratory

At the end of the third paragraph: Where chlamydia testing or screening is taking place, gonorrhoea testing often takes place simultaneously due to the widespread use of dual chlamydia/gonorrhoea NAAT.

### Recommended action

1. Accept: Sentence added.

Comment number: 15

Date received: 15/08/2024

Laboratory or organisation name: UKHSA STIRL

The NCSP recommends that they are offered a chlamydia test. State when and the frequency

### Recommended action

1. Accept: Added "The NCSP recommends that they are offered a chlamydia test after sexual intercourse with a new partner. Persons under the age of 25 should be tested annually".

## 6 Public health management

Comment number: 16

Date received: 08/08/2024

Laboratory or organisation name: UKHSA STIRL

Delete the following as these infections are not notifiable

For information regarding notification refer to:

<https://www.gov.uk/government/collections/notifications-of-infectious-diseases-noids>

### Recommended action

1. Accept

## 7.1 Specimen type

### Comment number: 17

Date received: 24/07/2024

Laboratory or organisation name: UKHSA regional SW (Bristol)

'Note: Urine in women should be avoided.'

Akin to washing detergent pods, 'always keep away from children'.

Suggest better as 'urine from women (or equivalent inclusive meaning) is not a recommended sample type.'

### Recommended action

1. Accept: Sentence changed to "Urine in women/persons with a vagina is not a suitable sample type".

### Comment number: 18

Date received: 28/07/2024

Laboratory or organisation name: Synnovis Infection Sciences, GSTT

I suggest recommending to test ulcer swabs (for LGV).

### Recommended action

1. None: BASHH guidance is currently being updated. So therefore, it is stated to refer to guidance.

### Comment number: 19

Date received: 02/08/2024

Laboratory or organisation name: Chester and Wirral Microbiology Service

Note: Urine in women should be avoided. Suggest rewrite as "Urine is not the optimal specimen type in women". (Should everywhere say 'women/persons with vagina'??) Suggest adding some referenced data to the document on the differences between urine and swabs in women. While recognising that urine is less sensitive than vulvovaginal swab, in practice urine is a very commonly used sample type in women, and with a detection rate of >80% it is hard to say that that (convenient) sample type should be avoided. Negative reports should have a caveat where urine has been used.

### Recommended action

1. None: If we add data for urine and swabs then we would also need to add for other sample types.

## 7.1.1 Laboratory diagnosis

### Comment number: 20

Date received: 08/08/2024

Laboratory or organisation name: UKHSA STIRL

'Endocervical swabs have been shown to be less sensitive than vulvovaginal swabs when self-collected and must be taken by a healthcare worker (1).'

Suggest clearer as 'Endocervical swabs must be taken by a healthcare worker have been shown to be less sensitive than self-collected vulvovaginal swabs (1).'

#### Recommended action

1. Accept

### Comment number: 21

Date received: 24/07/2024

Laboratory or organisation name: UKHSA South West Regional Laboratory

3rd paragraph; Suggest: .... not available, for example when testing vulnerable patients (1,33). Female urine samples are of suboptimal sensitivity compared to other female genital sample types.

#### Recommended action

1. Accept

### Comment number: 22

Date received: 06/08/2024

Laboratory or organisation name: Italian Group

"The recommended sample type for persons with a vagina is a vulvovaginal swab (VVS) which may be self-collected."

Although the literature confirms the effectiveness of self-collection, we would not consider the vaginal swab as the first choice, but the cervical one. Which does not mean excluding this method, but neither considering it the gold standard. It is clear that the "microbiological" point of view is not exactly the epidemiological or public health one...

We would like to underline that the most suitable sample is the cervical swab. The vaginal swab can be proposed for self-collection.

#### Recommended action

1. None: The text is in line with BASHH guidance.



## 7.1.1 Table 1

Comment number: 23

Date received: 24/07/2024

Laboratory or organisation name: UKHSA regional SW (Bristol)

Table 1, italicise gonorrhoeae.

### Recommended action

1. None: The table has been removed.

Comment number: 24

Date received: 24/07/2024

Laboratory or organisation name: UKHSA South West Regional Laboratory

Footnote: In GBMSM it may be standard practice to obtain individual or pooled rectal swabs, oropharyngeal swabs and 1st void urine samples from all patients.

### Recommended action

1. None: The table has been removed.

Comment number: 25

Date received: 08/08/2024

Laboratory or organisation name: UKHSA STIRL

New guidance for pharyngeal testing is currently being updated in BASHH GC guideline. Recommend referring to BASHH guidelines.

### Recommended action

1. Accept

## 7.2 Specimen transport and storage conditions

Comment number: 26

Date received: 28/07/2024

Laboratory or organisation name: Synnovis Infection Sciences, GSTT

Grammar correction, sentence is singular context, media is for plural. 'stored in an appropriate transport medium' (not media)

#### Recommended action

1. Accept

#### Comment number: 27

Date received: 06/08/2024

Laboratory or organisation name: Virology Dept, Royal Preston Hospital

"Samples should be stored in an appropriate transport media and transported to the laboratory within 24 hours of collection." : Samples in dedicated collection devices for CT/NG NAAT are much more stable than 24 hours.

#### Recommended action

1. Accept: Sentence rephrased to "Samples should be stored in an appropriate transport medium and transported to the laboratory within 24 hours of collection or within the timescales detailed in the manufacturers' instructions".

#### Comment number: 28

Date received: 15/08/2024

Laboratory or organisation name: UKHSA STIRL

Add or within the timescales detailed in the manufacturers' instructions.

#### Recommended action

1. Accept

## 8 Investigation

#### Comment number: 29

Date received: 24/07/2024

Laboratory or organisation name: UKHSA regional SW (Bristol)

'NAATs should be performed on all sites where penetration has occurred (1).'  
Does ref 1 describe penetration by what? Seems penis and sex toys are relevant.

#### Recommended action

1. None: Sentence removed.

## 8.1 Laboratory tests

### Comment number: 30

Date received: 31/07/2024

Laboratory or organisation name: London School of Hygiene & Tropical Medicine

1. Page 11, 3rd line after *Neisserias gonorrhoeae*: should be persons with a penis.
2. A lot of sections need referencing

### Recommended action

1. Accept
2. Accept

### Comment number: 31

Date received: 06/08/2024

Laboratory or organisation name: Italian group

We would be less drastic (and perhaps less "historical") in recommending – for gonococcus - direct plating during the sampling phase. We would be more "accommodating" allowing up to few hours (2-3 hours) the delivery time.

### Recommended action

1. None: Once the sample arrives to the laboratory it should be plated as soon as possible as per local procedures.

### Comment number: 32

Date received: 12/08/2024

Laboratory or organisation name: UKHSA STIRL

Reword the sentence “NAATs have varying sensitivities and specificities for diagnostic tests in urogenital specimens have been demonstrated in clinical trial data, manufacturers’ validation data and published papers”.

### Recommended action

1. Accept: Changed to “NAATs are the assays of choice for both genital and extra-genital samples, though the sensitivities are variable”.

## Comment number: 33

Date received: 08/08/2024

Laboratory or organisation name: UKHSA STIRL

Add reference:

[https://assets.publishing.service.gov.uk/media/605a11d7d3bf7f2f1608d12b/Guidance\\_for\\_the\\_detection\\_of\\_gonorrhoea\\_in\\_England\\_2021.pdf](https://assets.publishing.service.gov.uk/media/605a11d7d3bf7f2f1608d12b/Guidance_for_the_detection_of_gonorrhoea_in_England_2021.pdf)

### Recommended action

1. Accept

## 8.2 Window period and test of cure

### Comment number: 34

Date received: 24/07/2024

Laboratory or organisation name: UKHSA regional SW (Bristol)

'Patients should be offered testing when they first present. If there has been possible sexual exposure within the previous two weeks, patients should return for a repeat test two weeks following exposure (1).'

Suggest repeat test only if one or both of the CT or GC NAAT is negative.

### Recommended action

1. None: as it may over complicate the matter.

### Comment number: 35

Date received: 31/07/2024

Laboratory or organisation name: London School of Hygiene & Tropical Medicine

Section is titled window period and test of cure. This section needs to be more specific as it seems to conflate window periods with TOC.

Window period should be 1 week, relevant to any exposure including re-exposure post treatment

TOC depends on the method of testing, for NAAT testing should be approximately 2 weeks and should be offered to all treated patients but particularly patients with pharyngeal infection.

### Recommended action

1. Accept: This section has been updated and reflects on BASHH guidance.

## 8.3 Medico-legal cases

Comment number: 36

Date received: 06/08/2024

Laboratory or organisation name: Virology Dept, Royal Preston Hospital

Broken hyperlink for "BASHH National Guidelines..." now available at [https://www.bashh.org/resources/42/sti\\_and\\_related\\_conditions\\_in\\_children\\_and\\_young\\_people\\_2021](https://www.bashh.org/resources/42/sti_and_related_conditions_in_children_and_young_people_2021)

Recommended action

1. Accept

## 9 Algorithm 1

Comment number: 37

Date received: 24/07/2024

Laboratory or organisation name: UKHSA regional SW (Bristol)

Algorithm-footnote f is absent.

Recommended action

1. Accept: Removed from algorithm.

Comment number: 38

Date received: 28/07/2024

Laboratory or organisation name: Synnovis Infection Sciences, GSTT

1. "Invalid" branch of the algorithm - 'manufactures' needs to be 'manufacturer's'
2. Also again I would add in ulcer swab in the footnote

Recommended action

1. Accept
2. Added refer to BASHH guidance

Comment number: 39

Date received: 02/08/2024

Laboratory or organisation name: Chester and Wirral Microbiology Service

Middle box: Report C.Trachomatis not detected - should be lower case t ie C.trachomatis

#### Recommended action

1. Accept: Changed.

## 9 Algorithm 2

### Comment number: 40

Date received: 24/07/2024

Laboratory or organisation name: UKHSA regional SW (Bristol)

1. Algorithm- suggest add option to test all by confirmatory given the difficulty in truly knowing the PPV and balance of operational ease.
2. Also sensitives should be sensitivities, although I like the idea of taking account of one's feelings.

#### Recommended action

1. Accept: Footnote added \* Routine diagnostic laboratories may not operationally be able to manage high and low PPV patient populations differently. An option in which all NG reactive samples are reflex tested with a second NAAT is likely to reflect usual practice.
2. Accept: Sensitives changed to antimicrobial susceptibility testing.

### Comment number: 41

Date received: 24/07/2024

Laboratory or organisation name: UKHSA South West Regional Laboratory

It is unlikely that routine diagnostic laboratories would be in a position to manage high and low PPV patient populations differently as suggested here. An option in which all NG reactive samples are reflex tested with a second NAAT is likely to reflect usual practice.

#### Recommended action

1. Accept: Footnote added. See comment 39. PPV has been removed from the algorithm.

### Comment number: 42

Date received: 28/07/2024

Laboratory or organisation name: Synnovis Infection Sciences, GSTT

Same typo of "manufactures" should be "manufacturer's" in all boxes.

#### Recommended action

1. Accept

#### Comment number: 43

Date received: 31/07/2024

Laboratory or organisation name: London School of Hygiene & Tropical Medicine

Not sure what is meant by 'sensitives' on the reporting box. Is this susceptibility testing? If so, describe it as antimicrobial susceptibility testing (AST).

#### Recommended action

1. Accept

#### Comment number: 44

Date received: 06/08/2024

Laboratory or organisation name: Italian group

We agree on the 2-step operation for gonococcus, leaving the culture only for PCR positive cases. It remains to be understood whether the original sample can be used (theoretically possible if the time for plating is extended to 3 hours). Of course, it is better to do the culture after a positive NAAT test.

#### Recommended action

1. None.

#### Comment number: 45

Date received: 08/08/2024

Laboratory or organisation name: UKHSA STIRL

Should say request sample for 'antimicrobial susceptibility testing' not 'sensitivities'.

#### Recommended action

1. Accept: Changed.

#### Comment number: 46

Date received: 15/08/2024

Laboratory or organisation name: UKHSA STIRL

I think confirmation is not always required with rectal samples in populations with >90% PPV. Suggest: 'confirm with a different target' as some tests have the two targets detected at the same time

#### Recommended action

1. Accept: Changed to “alternative”.

## 9 Algorithm 3

### Comment number: 47

Date received: 24/07/2024

Laboratory or organisation name: UKHSA regional SW (Bristol)

I don't think the medico-legal algorithm is necessary. The recommendation to use dual target has been mentioned in text, it is a niche issue, and there is no mention of accreditation to forensic standard etc.

#### Recommended action

1. None: Agreed to keep.

### Comment number: 48

Date received: 28/07/2024

Laboratory or organisation name: Synnovis Infection Sciences, GSTT

Middle column, missing arrow from Rectal swabs box to the box below.

#### Recommended action

1. Accept

### Comment number: 49

Date received: 06/08/2024

Laboratory or organisation name: Italian Group

For tests with medico-legal value: We think it is useful to specify whether all validated diagnostic kits can be used or only those that explicitly state that they are authorised for the specific use.

#### Recommended action

1. Accept: Added to section 8.3 “Refer to manufacturer’s instruction when using testing kits”.



### Comment number: 50

Date received: 15/08/2024

Laboratory or organisation name: UKHSA STIRL

I think algorithm not required.

#### Recommended action

1. None: Agreed to keep.

### Comment number: 51

Date received: 12/08/2024

Laboratory or organisation name: UKHSA STIRL

1. Missing an arrow from rectal swabs to LGV.
2. Also, would only be tested for LGV if referral criteria met e.g. symptomatic

#### Recommended action

1. Accept: Arrow added.
2. None: We don't know who is symptomatic and who is not. Therefore agreed to leave as it is.

### Comment number: 52

Date received: 02/08/2024

Laboratory or organisation name: Chester and Wirral Microbiology Service

There is a missing arrow below "Rectal swabs" middle boxes, and an upper case Trachomatis as previously noted which should be corrected.

#### Recommended action

1. Accept

## 10 Interpreting and reporting laboratory results

### Comment number: 53

Date received: 24/07/2024

Laboratory or organisation name: UKHSA regional SW (Bristol)

The interpretative comment doesn't seem particularly interpretative or therefore useful, more of a simple statement. Also, it isn't technically correct, as at least one NAAT detects rRNA. If trying to imply the detection of nucleic acid doesn't mean active infection, there must be another way of doing that. E.g Consistent with chlamydia trachomatis infection.

#### Recommended action

1. Accept: Changed to Consistent with *C. trachomatis* infection.

#### Comment number: 54

Date received: 06/08/2024

Laboratory or organisation name: Virology Dept, Royal Preston Hospital

"*C. trachomatis* DNA detected in sample" - whilst this is a factually correct comment a more user-friendly comment might be "*C. trachomatis* NOT detected by [insert NAAT method]. Emphasis on "NOT" or "DETECTED" in capitals as the standout message to users.

#### Recommended action

1. This has been reworded. Refer to comment 53

#### Comment number: 55

Date received: 06/08/2024

Laboratory or organisation name: Virology Dept, Royal Preston Hospital

We suggest that users are more likely to understand the term "indeterminate" rather than "Initial reactivity has not confirmed". Comments need to be mindful that users do not know that the laboratory diagnosis involve confirmatory assays.

#### Recommended action

1. None: The reported result is indeterminate and initial reactivity is just an interpretative comment.

#### Comment number: 56

Date received: 06/08/2024

Laboratory or organisation name: Italian Group

We think the terms used are homogeneous with those used in the UK. In Italy there is a discussion, so far without homogeneity, between Positive vs Reactive and Indeterminate vs Invalid. Perhaps Indeterminate and Invalid could be grouped together and specified in a note the interpretation of the meaning and indication of the continuation.

### Recommended action

1. None: The terms have already been discussed at previous working group meetings. They will remain as they are.

## Financial barriers

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

None noted by respondents

## 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: 57

Date received: 24/07/2024

Laboratory or organisation name: UKHSA regional SW (Bristol)

All UKSMIs are conceived with the concept of delivering health benefits through good practice diagnosis and appropriate use of public funds, aren't they?

### Recommended action

None

### Comment number: 58

Date received: 02/08/2024

Laboratory or organisation name: Unit of Microbiology - The Great Romagna Hub  
Laboratory DIMEC University of Bologna

I would suggest more detail about the possibility to test self collected specimens

### Recommended action

None. There is reference of published guidance.

### Comment number: 59

Date received: 06/08/2024

Laboratory or organisation name: Virology Dept, Royal Preston Hospital

No differences compared to previous version

### Recommended action

None: Not sure which previous version reference is made to.

## Interested parties

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

### Comment number: 60

Date received: 24/07/2024

Laboratory or organisation name: UKHSA regional SW (Bristol)

sexual health, fertility professional groups.

### Recommended action

None

### Comment number: 61

Date received: 06/08/2024

Laboratory or organisation name: Virology Dept, Royal Preston Hospital

Internal review of this draft SMI was performed by Dr David Orr, Consultant Microbiologist, Mr Callum Goolden, Trainee Clinical Scientist, Mr Paul Wilkinson, Clinical Scientist / Lead BMS.

### Recommended action

None

# Respondents indicating they were happy with the contents of the document

<b>Overall number of comments: 2</b>			
<b>Date received</b>	31/07/2024	<b>Lab name/Professional body (delete as applicable)</b>	Bedfordshire
<b>Date received</b>	02/08/2024	<b>Lab name/Professional body (delete as applicable)</b>	Unit of Microbiology - The Great Romagna Hub Laboratory DIMEC University of Bologna
<b>Health benefits</b>			
I would suggest more detail about the possibility to test self-collected specimens			