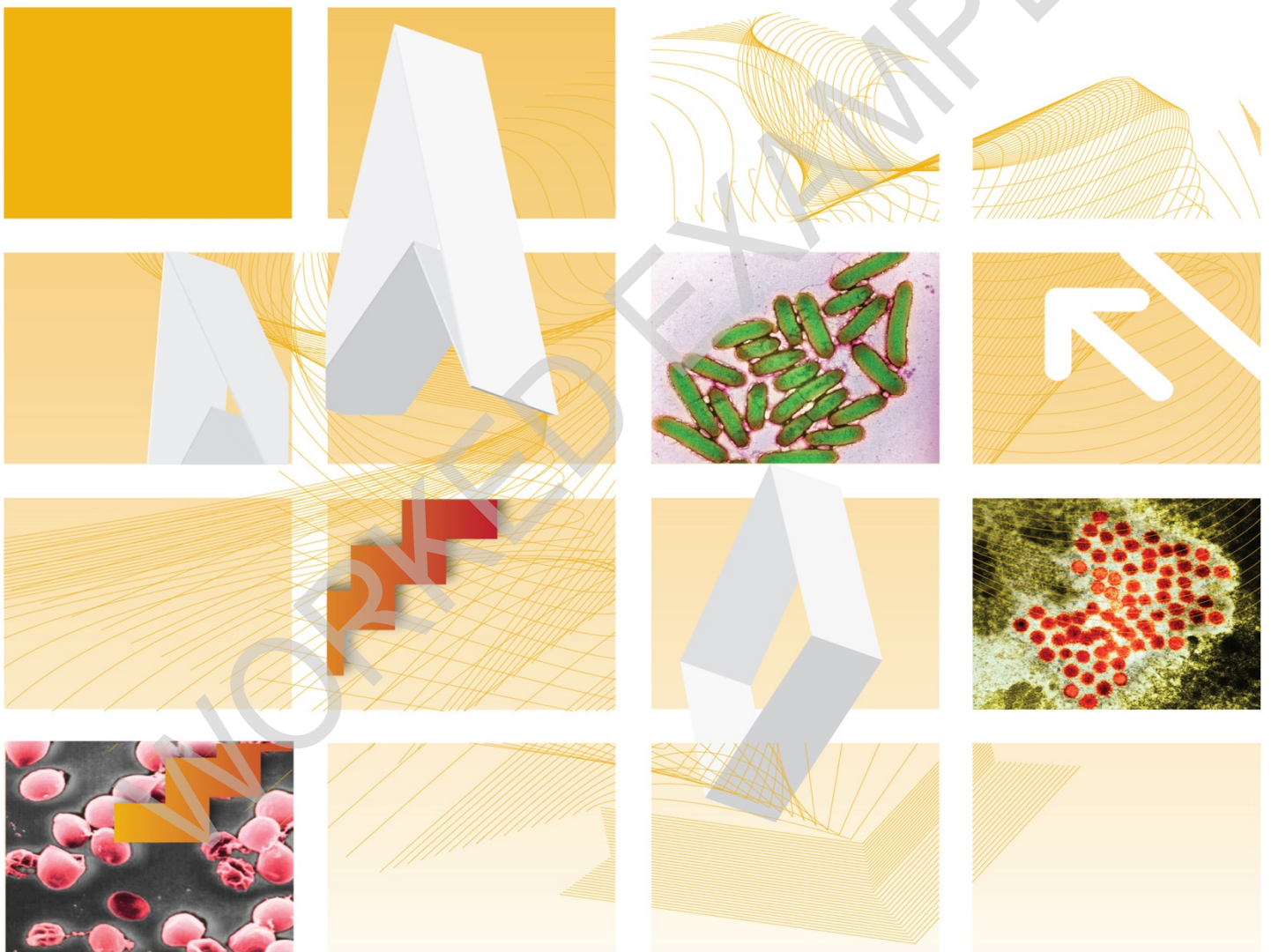




# UK standards for microbiology investigations

National user manual worked example for urine tests



"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**."

Issued by the Standards Unit, Microbiology Services, PHE

National user manual | U 3 | Issue no: 1 | Issue date: 07.08.17 | Page: 1 of 19

## Acknowledgments

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UK Standards for Microbiology Investigations (UK SMIs) are developed under the auspices of Public Health England (PHE) working in partnership with the National Health Service (NHS), Public Health Wales and with the professional organisations whose logos are displayed below and listed on the website <https://www.gov.uk/uk-standards-for-microbiology-investigations-smi-quality-and-consistency-in-clinical-laboratories>. UK SMIs are developed, reviewed and revised by various working groups which are overseen by a steering committee (see <https://www.gov.uk/government/groups/standards-for-microbiology-investigations-steering-committee>).

The contributions of many individuals in clinical, specialist and reference laboratories who have provided information and comments during the development of this document are acknowledged. We are grateful to the medical editors for editing the medical content.

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PHE publication gateway number: 2016401

UK Standards for Microbiology Investigations are produced in association with:



Logos correct at time of publishing.

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## Amendment table

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Each UK SMI method has an individual record of amendments. The current amendments are listed on this page. The amendment history is available from [standards@phe.gov.uk](mailto:standards@phe.gov.uk).

New or revised documents should be controlled within the laboratory in accordance with the local quality management system.

Amendment number/date	-/07.08.17
Issue number discarded	-
Insert issue number	1
Anticipated next review date*	07.08.20
<b>Section(s) involved</b>	<b>Amendment</b>

\*Reviews can be extended up to five years subject to resources available.

## UK SMI<sup>#</sup>: scope and purpose

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### Users of UK SMIs

Primarily, UK SMIs are intended as a general resource for practising professionals operating in the field of laboratory medicine and infection specialties in the UK. UK SMIs also provide clinicians with information about the available test repertoire and the standard of laboratory services they should expect for the investigation of infection in their patients, as well as providing information that aids the electronic ordering of appropriate tests. The documents also provide commissioners of healthcare services with the appropriateness and standard of microbiology investigations they should be seeking as part of the clinical and public health care package for their population.

### Background to UK SMIs

UK SMIs comprise a collection of recommended algorithms and procedures covering all stages of the investigative process in microbiology from the pre-analytical (clinical syndrome) stage to the analytical (laboratory testing) and post analytical (result interpretation and reporting) stages. Syndromic algorithms are supported by more detailed documents containing advice on the investigation of specific diseases and infections. Guidance notes cover the clinical background, differential diagnosis, and appropriate investigation of particular clinical conditions. Quality guidance notes describe laboratory processes which underpin quality, for example assay validation.

Standardisation of the diagnostic process through the application of UK SMIs helps to assure the equivalence of investigation strategies in different laboratories across the UK and is essential for public health surveillance, research and development activities.

### Equal partnership working

UK SMIs are developed in equal partnership with PHE, NHS, Royal College of Pathologists and professional societies. The list of participating societies may be found at <https://www.gov.uk/uk-standards-for-microbiology-investigations-smi-quality-and-consistency-in-clinical-laboratories>. Inclusion of a logo in an UK SMI indicates participation of the society in equal partnership and support for the objectives and process of preparing UK SMIs. Nominees of professional societies are members of the Steering Committee and working groups which develop UK SMIs. The views of nominees cannot be rigorously representative of the members of their nominating organisations nor the corporate views of their organisations. Nominees act as a conduit for two way reporting and dialogue. Representative views are sought through the consultation process. UK SMIs are developed, reviewed and updated through a wide consultation process.

### Quality assurance

NICE has accredited the process used by the UK SMI working groups to produce UK SMIs. The accreditation is applicable to all guidance produced since October 2009. The process for the development of UK SMIs is certified to ISO 9001:2008. UK SMIs represent a good standard of practice to which all clinical and public health microbiology laboratories in the UK are expected to work. UK SMIs are NICE

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<sup>#</sup> Microbiology is used as a generic term to include the two GMC-recognised specialties of Medical Microbiology (which includes Bacteriology, Mycology and Parasitology) and Medical Virology.

accredited and represent neither minimum standards of practice nor the highest level of complex laboratory investigation possible. In using UK SMIs, laboratories should take account of local requirements and undertake additional investigations where appropriate. UK SMIs help laboratories to meet accreditation requirements by promoting high quality practices which are auditable. UK SMIs also provide a reference point for method development. The performance of UK SMIs depends on competent staff and appropriate quality reagents and equipment. Laboratories should ensure that all commercial and in-house tests have been validated and shown to be fit for purpose. Laboratories should participate in external quality assessment schemes and undertake relevant internal quality control procedures.

## **Patient and public involvement**

The UK SMI working groups are committed to patient and public involvement in the development of UK SMIs. By involving the public, health professionals, scientists and voluntary organisations the resulting UK SMI will be robust and meet the needs of the user. An opportunity is given to members of the public to contribute to consultations through our open access website.

## **Information governance and equality**

PHE is a Caldicott compliant organisation. It seeks to take every possible precaution to prevent unauthorised disclosure of patient details and to ensure that patient-related records are kept under secure conditions. The development of UK SMIs is subject to PHE Equality objectives <https://www.gov.uk/government/organisations/public-health-england/about/equality-and-diversity>.

The UK SMI working groups are committed to achieving the equality objectives by effective consultation with members of the public, partners, stakeholders and specialist interest groups.

## **Legal statement**

While every care has been taken in the preparation of UK SMIs, PHE and the partner organisations, shall, to the greatest extent possible under any applicable law, exclude liability for all losses, costs, claims, damages or expenses arising out of or connected with the use of an UK SMI or any information contained therein. If alterations are made by an end user to an UK SMI for local use, it must be made clear where in the document the alterations have been made and by whom such alterations have been made and also acknowledged that PHE and the partner organisations shall bear no liability for such alterations. For the further avoidance of doubt, as UK SMIs have been developed for application within the UK, any application outside the UK shall be at the user's risk.

The evidence base and microbial taxonomy for the UK SMI is as complete as possible at the date of issue. Any omissions and new material will be considered at the next review. These standards can only be superseded by revisions of the standard, legislative action, or by NICE accredited guidance.

UK SMIs are Crown copyright which should be acknowledged where appropriate.

### **Suggested citation for this document**

Public Health England. (2017). National user manual worked example for urine tests. UK Standards for Microbiology Investigations. U 3 Issue 1. <https://www.gov.uk/uk-standards-for-microbiology-investigations-smi-quality-and-consistency-in-clinical-laboratories>

WORKED EXAMPLE



## User manual template - background

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The user manual template has been developed by a UK SMI joint working group of microbiologists. The document aims to help microbiology service providers produce a comprehensive user manual meeting the current ISO standards. The ISO standards should be used in conjunction with this template<sup>1</sup>. Duplications within the document are intended to emphasise key points. The document should be considered a template, with suggested headings providing the basis on which individual labs or services can develop their own user manual.

The suggested ordering and content of this user manual can be changed but we recommend all suggested content remains included, for example, it may be possible to encompass many elements in a single hyperlinked table of services and tests offered.

The microbiology service provider's user manual is intended as a general resource for practising healthcare professionals.

It is recommended that user manuals are made available to general practitioners through their local Clinical Commissioning Group (CCG). Although not intended for public and patient groups, they may find the user manual a useful source of information.

The use of plain English is recommended.

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## Introduction and scope

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This guide outlines the process of urinary specimen collection and correct use of the laboratory to obtain results in simple UTI; it does not cover uncommon presentations and pathologies in any detail. It is not a clinical guideline but a short practical guide to the best use of your microbiology laboratory.

Women with severe/or  $\geq 3$  symptoms can be treated empirically without collecting a MSU or dipstick testing.

In women with mild/or  $\leq 2$  symptoms AND

- a. Urine not cloudy: 97% negative predictive value (NPV) - do not treat unless there are other risk factors for infection<sup>2</sup>.
- b. Urine is cloudy: use dipstick to guide treatment.  
Nitrite plus blood or leucocytes has a 92% positive predictive value (PPV);  
Nitrite, leucocytes, blood all negative has a 76% NPV of UTI
- c. Consider a back-up / delayed antibiotic option. Refer to [Managing common infections: guidance for primary care](#).

### Consider differentials<sup>3</sup>:

Infective differentials: sepsis, acute and chronic pyelonephritis, perinephric abscess, cystitis, urethritis, prostatitis, epididymitis, genital infections.

Non-infective or pathologies coexisting with UTI: bladder cancer, ovarian cancer and chronic bladder pain syndrome.

Blood in urine on dipstick or MSU requires follow up even if thought to be due to UTI to ensure it has cleared.

### Indications for laboratory urine samples:

Indications for pre-treatment urinary laboratory samples are cystitis symptoms in men, pregnant women, children, complex cases for example the immunocompromised.

**Note:** children  $< 3$  months old with suspected UTI should be admitted to hospital.

Patients with recurrent UTI or more complex symptoms for example possible pyelonephritis.

Routine MSU at ante-natal booking in pregnant women to detect asymptomatic bacteriuria is confirmed by a second MSU and then treated. Follow-up urine samples should be requested after treating asymptomatic bacteriuria in pregnancy to ensure that infection has cleared.

MSU should be obtained if there is failure to cure after empirical therapy. Send catheterised samples if there is systemic infection.

The guide gives further details of other laboratory tests which are performed on urinary specimens.

## Overview of services offered

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You should include:

- detail of basic services (diagnostic testing, clinical advice, infection control, infectious diseases, outbreak management, antibiotic stewardship, etc)
- listing of specialist areas, for example, regional or national reference facilities and provision of immunoglobulins and vaccines

## Locating and contacting the laboratory

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You should include:

- location maps for both outside and inside the hospital (or links to the relevant source)
- specimen reception opening times and out of hours contact instructions
- instructions on making enquiries for results and requests for additional tests on existing samples
- availability of clinical advice on ordering of examinations and interpretation of examination results
- details of any out-of-hours service or shift system at the laboratory. Outline which services will always be provided and which will only be provided after consultation
- contact details for key members of staff including availability times, email addresses of key members of staff, how to obtain results and clinical advice for out of hours service
- whether the public has access to the laboratory or not and where phlebotomy (and paediatric phlebotomy) services are located
- clear advice to patients on how to obtain results; explain whether patients should or should not call the laboratory directly for results – indicating consideration of data security and clinical risk

## Consent, collection and transport of specimens<sup>2,4-7</sup>

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Urinary Infections – when and how to collect a urinary sample

In primary care most UTIs occur in women and are limited to the lower urinary tract.

- *link to patient information sheet*

**On the form:** include details of relevant clinical information, current, just finished or intended antibiotic therapy in the clinical details space.

**Urine minimum volume:** of 1mL for specimens is required in a plain CE marked leak-proof container for bacterial pathogens.

**Time to laboratory for plain containers:** The specimen should reach the laboratory within 4 hours of collection. Where delays in processing are unavoidable, refrigerate at 4°C (maximum delay 48 hours if refrigerated) or use boric acid containers.

**Time to laboratory for Boric acid containers<sup>8-12</sup>:** Boric acid 1–2% holds the bacterial population steady for 48–96 hours, and other cellular components remain intact. Boric acid may be inhibitory to some organisms and may inhibit dipstick tests

for leucocyte esterase. If boric acid preservative is used, ensure that the container is filled up to the line and the contents mixed well.

- *picture of collection container(s)*

### **MSU (midstream specimen of urine) collection**

The first part of voided urine is discarded and, without interrupting the flow, approximately 10mL is collected into a CE marked leak proof container (plain or boric acid).

### **Clean catch urine collection**

Periurethral cleaning is recommended. The whole specimen is collected and then an aliquot sent for examination in a CE marked leak proof container (plain or boric acid).

### **CSU (catheter sample of urine) collection**

The sample may be obtained either from a transient ('in and out') catheterisation or from an indwelling catheter. In the latter case, the specimen is obtained aseptically from a sample port in the catheter tubing or by aseptic aspiration of the tubing. The specimen should not be obtained from the collection bag. Approximately 10mL is collected into a CE marked leak proof container (plain or boric acid).

Please ensure that any urine samples obtained from 'in and out' catheterisation are notified clearly as this may affect how the sample is processed and reported in the laboratory.

### **Ileal conduit or urostomy specimen collection**

Use a plain CE marked leak-proof container. Urine is obtained via a catheter passed aseptically into the stomal opening after removal of the external appliance. Results from this type of specimen may be difficult to interpret.

### **Pad collection**

After washing the nappy area thoroughly, a pad is placed inside the nappy. As soon as the pad is wet with urine (but no faecal soiling), push the tip of a syringe into the pad and draw urine into the syringe. Transfer specimen to a CE marked leak-proof container. If difficulty is experienced in withdrawing urine, the wet fibres may be inserted into the syringe barrel and the urine squeezed directly into the container with the syringe plunger. In young children, diagnostic accuracy has been shown to be greater for clean-catch than nappy pad samples: primary care clinicians should prioritise the use of clean-catch sampling wherever possible.

### **SPA (suprapubic aspirate), cystoscopic, nephrostomy, expressed prostatic secretions or ureteric collection**

Use a plain CE marked leak-proof container.

**Note:** Urine catheters, bag urines, catheter tips and ureteric stents are not acceptable sample types.

### **Meares and Stamey localisation culture method for diagnosis of prostatitis**

The following specimens are collected in a plain CE marked leak-proof container:

- the initial 5–8mL voided urine (urethral urine)
- MSU (bladder urine)
- expressed prostatic secretions following prostatic massage

- the first 2–3mL voided urine following prostatic massage

## Test repertoire

You should include the following:

- examinations offered by the laboratory. Include logical listings or tables of tests and turnaround times), primary sample volumes, specific specimen containers, special precautions, and procedures for medico-legal samples
- details of relevant clinical algorithms, with links to local or national policies
- lists of referred tests, including the names, addresses and accreditation status of laboratories to which work is routinely referred
- a table to state the duration of storage for samples that may need re-testing, with information on disease incubation periods, testing interval and time limits for requesting additional tests

You may also wish to include information on the costs of tests.

Investigation	Container (sample volume)	Laboratory Turnaround time	Time limit for requesting additional investigations	Cost of test	Further info
Urine culture • MSU • Clean catch • CSU	Plain universal container (1-10 mL) OR Primary urine tubes (often used for automated systems) OR Boric acid container (fill to line)	16-72 hours	24 hours		See notes above
Urine culture • Cystoscopic • SPA • Ureteric • Ileal conduit • Urostomy • Pad Expressed prostatic secretions	Plain universal container (1-10 mL)	16-72 hours	24 hours		See notes above

## Table summary of other laboratory urinary tests

Investigation	Container (sample volume)	Laboratory Turnaround time	Time limit for requesting additional investigations	Cost of test	Further info
Urine TB culture Refer to UK SMI <a href="#">B 40: Investigation of specimens for <i>Mycobacterium</i> species.</a>	Plain container 250 or 500mL		N/A		Early morning urine x3. Label as 'high risk'

Urine chlamydia and gonorrhoea detection screening Screening sexually active under 25s annually or change of sexual partner. <b>Note:</b> vaginal sample is preferred in women	First 20mL catch into container with fluid				Urine sample obtained after not having passed urine for one hour see genital infections
Urine chlamydia and gonorrhoea not screening <b>Note:</b> vaginal sample is preferred in women	First 20mL catch into container with fluid				Urine sample obtained after not having passed urine for one hour see genital infections
Urine for <i>Schistosoma haematobium</i> ( <i>Bilharzia</i> ) microscopy Refer to UK SMI <a href="#">B 31: Investigation of specimens other than blood for parasites</a>	Plain container 250 or 500mL		Collect all urine between 10am and 2pm Alternatively, 24hr collection of terminal urine samples are occasionally taken which may be helpful		Parasitic cause of haematuria: eggs detected in urine
Urine bacterial antigen detection ( <i>Legionella</i> & <i>Streptococcus pneumoniae</i> )	Plain universal container (1-10 mL)				The test for legionella antigen only detects <i>L. pneumophila</i> serogroup 1

- For further information on urine testing, refer to UK Standards for Microbiology Investigations, [UK SMI B 41 - Investigation of urine](#).

## Reporting results

You should include the following:

- provide instructions for making result enquiries
- advice to review electronic reporting systems before phoning for results
- explanation of different report status categories (interim, final, amended)

## Interpreting laboratory results

### Adverse factors affecting the interpretation of urine culture results:

- contamination of the sample at the point of collection
- delay >4 hours in arrival at laboratory
- excessive temperature
- incorrect sample type (for example bag urine)
- incorrect sample volume (if boric acid containers are used)

- incomplete clinical details on request form

**Note:** rapid transport to the laboratory is the best way to minimise uncertainty of results.

**Significant pyuria:**

The occurrence of  $\geq 10^7$  WBC/L is significant, although higher numbers of WBC (white blood cells) may be found in healthy, asymptomatic women. A level of  $>10^8$  WBC/L may be more appropriate in discriminating infection. Where a significant growth is present, absence of pyuria in adult patients makes a diagnosis of UTI less likely, but does not exclude it. For interpretation of microscopy (and culture) results, appropriate guidance should be followed.

Diagnosis of prostatitis may be achieved by comparing the levels of pyuria in sequential specimens taken in association with prostatic massage. If the level of pyuria after prostatic massage is 10 times that of the initial urine, then bacterial prostatitis is likely. More than 15 WBCs per high power field in expressed prostatic secretions is considered abnormal, even if the WBCs in the urethral and bladder urine are within the normal range.

**Sterile pyuria (with no growth on routine culture media and persistent presence of WBCs in urine). Consider:**

- prior treatment with antimicrobial agents
- catheterisation
- nephritis
- calculi (stones)
- bladder neoplasms
- sexually transmitted diseases
- or other infection with a difficult to grow organism
- renal tuberculosis

**Bacterial growths:**

Bacterial growths of  $\geq 10^8$  colony forming units (cfu)/L ( $10^5$  cfu/mL) are consistent with infection and counts below this usually indicate contamination. A pure growth (single organism) with counts between  $10^7$  and  $10^8$  cfu/L should be evaluated based on clinical information or confirmed by repeat culture. The probability of UTI is increased by the isolation of the same organism from two specimens. However, in some patient groups counts  $\geq 10^5$  cfu/L may be significant. Interpretation of culture results must be made with care and take into account adverse factors in specimen collection and transport.

**Common causes are:**

*E. coli* and *Proteus* species, then *Klebsiella* species and *Enterobacter* species.

(**Note:** Urease-producing organisms such as *Proteus mirabilis* may be associated with renal stone formation).

In pregnancy, organisms are as above plus *Staphylococcus saprophyticus*.

In CSU, organisms are as above plus *Pseudomonas* species, *Enterococcus* species, *S. aureus* and *Candida* species.

*S. aureus* is unusual except in CSU or perineum contamination in women. In men a secondary source is likely.

### **Children MSUs and bacterial growths:**

A pure growth of between  $10^7$ - $10^8$  cfu/L ( $10^4$ - $10^5$  cfu/mL) is consistent with UTI in a carefully taken specimen from a child but it can be difficult to get clean samples.

### **CSU and bacterial growths:**

May not accurately reflect the true bladder pathogen and often contains several bacterial species. Urine cultures may not reflect bladder bacteriuria because sampled organisms may have arisen from biofilms on the inner surface of the catheter. Quality of specimen collection and clinical circumstances in the individual patient are critical in the interpretation of bacterial counts. In specimens from long term-catheterised patients, interpretation of significance on the basis of bacterial counts alone may be impossible. Catheterisation is occasionally used to collect a contamination free sample ('in and out') when any bacterial growth is significant: these results should be interpreted in the same way as MSUs.

### **Other lab reported findings:**

Note: It should be noted that the other laboratory reported findings below should be adopted locally as not all laboratories report these now.

**Squamous epithelial cells** – may be due to skin contamination of sample

**Red blood cells** – requires follow up to exclude serious pathology

**Hyaline casts** - Large numbers of hyaline casts are associated with renal disease, but may also be found in patients with fever or following strenuous exercise

**Granular and cellular casts** - indicate pyelonephritis or glomerulonephritis

**RBC casts** - RBC casts usually indicate glomerular bleeding and are excreted in large numbers in the acute phase of glomerulonephritis

## **Quality assurance and governance**

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You should include details of:

- the quality assurance and governance structure for the laboratory
- the complaints procedure
- the laboratory's policy on protection of personal information; and the fax and email policy
- ensure that the manual is consistent with ISO15189 guidance (reference the ISO guidance in this section)<sup>1</sup>
- a statement on the accreditation status, link to the accreditation body, and list of which (if any) tests are excluded from the accredited scope of practice (accreditation status of test repertoire)
- how to obtain validation/verification data



- compliance with Human Tissue Act

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## References

### Modified GRADE table used by UK SMI's when assessing references

Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) is a systematic approach to assessing references. A modified GRADE method is used in UK SMI's for appraising references for inclusion. Each reference is assessed and allocated a grade for strength of recommendation (A-D) and quality of the underlying evidence (I-VI). A summary table which defines the grade is listed below and should be used in conjunction with the reference list.

Strength of recommendation	Quality of evidence
A Strongly recommended	I Evidence from randomised controlled trials, meta-analysis and systematic reviews
B Recommended but other alternatives may be acceptable	II Evidence from non-randomised studies
C Weakly recommended: seek alternatives	III Non-analytical studies, for example, case reports, reviews, case series
D Never recommended	IV Expert opinion and wide acceptance as good practice but with no study evidence
	V Required by legislation, code of practice or national standard
	VI Letter or other

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2. Public Health England. Urinary tract infections: quick reference guide. Available at <https://www.gov.uk/government/publications/urinary-tract-infection-diagnosis>. PHE. 1 - 8. 2011. **A, V**
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8. Porter IA, Brodie J. Boric acid preservation of urine samples. Br Med J 1969;2:353-5. **B, II**
9. Johnston HH MM, Guthrie GA., The use of boric acid for the preservation of clinical urine specimens. In: Meers PD, editor. The bacteriological examination of urine: Report of a workshop on needs and methods. Public Health Laboratory Service Monograph Series No. 10 ed. London: HMSO; ; 1978. **B, III**
10. Watson PG, Duerden BI. Laboratory assessment of physical and chemical methods of preserving urine specimens. J Clin Pathol 1977;30:532-6. **B, II**
11. Nickander KK, Shanholtzer CJ, Peterson LR. Urine culture transport tubes: effect of sample volume on bacterial toxicity of the preservative. J Clin Microbiol 1982;15:593-5. **B, II**
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