UK standards for microbiology investigations

Urine tests



Acknowledgments

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

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 | New amendment number/dd.mm.yy <tab+enter> |
| Issue number discarded | xx |
| Insert issue number | #.# <tab+enter> |
| Anticipated next review date\* |  |
| **Section(s) involved** | **Amendment** |
|  |  |

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

UK SMI[[1]](#footnote-1)#: scope and purpose

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 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. (YYYY <tab+enter>). Urine tests. UK Standards for Microbiology Investigations. U a Issue #.# <tab+enter>. <https://www.gov.uk/uk-standards-for-microbiology-investigations-smi-quality-and-consistency-in-clinical-laboratories>

User manual template - background

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 template1. 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.

Introduction and scope

This guide outlines the process of urinary specimen collection and correct use of the lab 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 lab.

The guide further details other lab tests which are performed on urinary specimens.

Overview of services offered

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

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

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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.

Womenwith severe/or ≥ 3 symptoms can be treated empirically without collecting a MSU or dipstick testing.

In womenwithmild/or ≤ 2 symptoms AND

1. Urine not cloudy: 97% negative predictive value (NPV) - do not treat unless there are other risk factors for infection.
2. 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

1. Consider a back-up / delayed antibiotic option. Refer to [Managing common infections: guidance for primary care.](https://www.gov.uk/government/publications/managing-common-infections-guidance-for-primary-care)

**Consider differentials:**

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 lab urine samples:**

Indications for pre-treatment urinary lab samples are cystitis symptoms in men, pregnant women, children, complex cases eg the immunocompromised. Note children < 3 months old with suspected UTI should be admitted.

Patients with recurrent UTI or more complex symptoms eg possible pyelonephritis.

Routine MSU at ante-natal booking in pregnant women to detect asymptomatic bacteriuria is confirmed by a second MSU and then treated.

MSU should be obtained if there is failure to cure after empirical therapy.

* *Link to patient information sheet*

**On the form:** include details of 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**: 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 10mLis 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 10mLis 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 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 ofprostatitis

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.

Reporting results

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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  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 lab 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 [B 40: Investigation of specimens for *Mycobacterium* species](https://www.gov.uk/government/publications/smi-b-40-investigation-of-specimens-for-mycobacterium-species). | Plain container *250 or 500ml* |  | N/A |  | Early morning urine x3. Label as ‘high risk |
| Urine chlamydia and gonorrhoea detection  screening  RU clear screening sexually active under 25s annually or change of sexual partner. Note vaginal sample is preferred in women  https://www.ruclear.co.uk | First 20mls 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  Note vaginal sample is preferred in women | First 20mls catch into container with fluid |  |  |  | Urine sample obtained after not having passed urine for one hour  see genital infections |
| Urine for *Schistosoma haemotobium (Bilharzia)* microscopy | Plain container *250 or 500ml* |  | Collect all urine between 10am and 2pm |  | Parasitic cause of haematuria: eggs detected in urine |
| Urine bacterial antigen detection  (Legionella & Streptococcus pneumoniae) | Plain universal container (1-10 ml) |  |  |  | The test for legionella antigen only detects *L. pneumophila* serogroup 1 |
| Urine pregnancy test | Plain universal container (1-10 ml) |  | 24 hours |  | Any time of day from expected day of menses |

* For further information on urine testing, refer to UK Standards for Microbiology Investigations, [UK SMI B 41 - Investigation of urine](https://www.gov.uk/government/publications/smi-b-41-investigation-of-urine).

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 (eg 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 ≥107 WBC/L, although higher numbers of WBC (white blood cells) may be found in healthy, asymptomatic women. A level of >108 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.

Pyuria without growth on routine culture media. Consider:

* lysis of the WBCs in alkaline urine
* 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 growthsof ≥108 colony forming units (cfu)/L (105 cfu/mL) are consistent with infection and counts below this usually indicate contamination. A pure growth (single organism) with counts between 107 and 108 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 ≥105 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.

(NB. 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 107-108 cfu/L (104-105 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:**

**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

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)1
* 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

References

**Modified GRADE table used by UK SMIs 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 SMIs 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 |

1. European committee on Standardization. Medical laboratories - Requirements for quality and competence (ISO 15189:2012). British Standards Institution. 1-50. 2012. **A, V**

2. Hay AD, Birnie,K., Busby,J., Delaney, B.,Downing, H. et al on behalf of the DUTY team, . The Diagnosis of Urinary Tract infection in Young children (DUTY): a diagnostic prospective observational study to derive and validate a clinical algorithm for the diagnosis of urinary tract infection in children presenting to primary care with an acute illness. Research. NIfH 2016. **A, V**

3. National Institute for Health and Excellence. Urinary tract infection in under 16s: diagnosis and management 2007. 1 - 36. **A, V**

4. Public Health England. Management of infection guidance for primary care for consultation and local adaptation. Available at https://[www.gov.uk/government/publications/managing-common-infections-guidance-for-primary-care](http://www.gov.uk/government/publications/managing-common-infections-guidance-for-primary-care). PHE. 1 - 82. 2017. **A, V**

5. Public Health England. Urinary tract infections: quick reference guide. Available at https://[www.gov.uk/government/publications/urinary-tract-infection-diagnosis](http://www.gov.uk/government/publications/urinary-tract-infection-diagnosis). PHE. 1 - 8. 2011. **A, V**

6. Scottish Intercollegiate Guidelines Network. SIGN 88 - Management of suspected bacterial urinary tract infection in adults. Available at: <http://www.sign.ac.uk/guidelines/fulltext/88/index.html> Health Improvement Scotland. 1 - 45. 2012. **A, V**

1. # 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. [↑](#footnote-ref-1)