



UK standards for microbiology investigations

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**."

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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>).

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NICE has accredited the process used by Public Health England to produce Standards for Microbiology Investigations. Accreditation is valid for 5 years from July 2011. More information on accreditation can be viewed at www.nice.org.uk/accreditation.

For full details on our accreditation visit: www.nice.org.uk/accreditation.

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.

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.

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UK SMI[#]: 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/government/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 or 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

DNICE 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 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.

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.

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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.

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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

Consent, collection and transport of specimens

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.

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

In women with mild/or ≤ 2 symptoms AND

- a. Urine NOT cloudy: 97% negative predictive value (NPV)- do not treat unless other risk factors for infection.
- 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 from <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 and the immunocompromised. Note children < 3 months old with suspected UTI should be admitted.

Patients with more complex symptoms eg possible pyelonephritis.

Routine MSU at ante-natal booking in pregnant women to detect asymptomatic bacteriuria 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 lab 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).

Time to lab for Boric acid containers: Boric acid 1–2% holds the bacterial population steady for 48–96 hours, and other cellular components remain intact. Ensure that the container is filled to the mark and where delays in processing are unavoidable, store at room temperature (maximum delay 96 hours if refrigerated). Boric acid may be inhibitory to some organisms and may inhibit dipstick tests for leucocyte esterase.

- *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). If boric acid preservative is used, the container is filled up to the line.

Clean catch urine collection

Periurethral cleaning is recommended. The whole specimen is collected and then approximately 10mL is collected in a CE marked leak-proof container (plain or boric acid). If boric acid preservative is used, the container is filled up to the line. Hold infants over a suitable clean container to obtain the specimen.

CSU (catheter sample of urine) collection

The sample may be obtained either from a transient ('in and out') catheterisation or from an indwelling catheter, 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). If boric acid preservative is used, the container is filled up to the line.

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

SPA (suprapubic aspirate), cystoscopic or ureteric collection

Use a plain container.

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

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	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	Plain container 250 or 500ml		N/A		Early morning urine x3. Label as 'high risk'
Urine chlamydia and gonorrhoea detection screening RUclear 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 <i>Schistosoma haematobium</i> (<i>Bilharzia</i>) 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 <i>L. pneumophila</i> 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 investigation of urine refer to UK Standards for Microbiology Investigations.

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 uric 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, 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.

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 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* sp. Then *Klebsiella* sp and *Enterobacter* sp.

In pregnancy as mentioned plus *Staphylococci saprophyticus*.

In CSU as mentioned plus *Pseudomonas* sp., *Enterococcus* sp., *S. aureus*, *Candida* sp.

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:

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

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References

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

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