# Lodestar DX

RAPID URINARY TRACT INFECTION DIAGNOSTICS

## Precision diagnostics.
## Precision management.

# 35 minutes

from sample to answer

Lodestar DX is a UKCA-marked molecular analyser for use by trained healthcare professionals in near-patient settings. It detects DNA from six common uropathogens in a 10 µL urine sample.

*Escherichia coli*

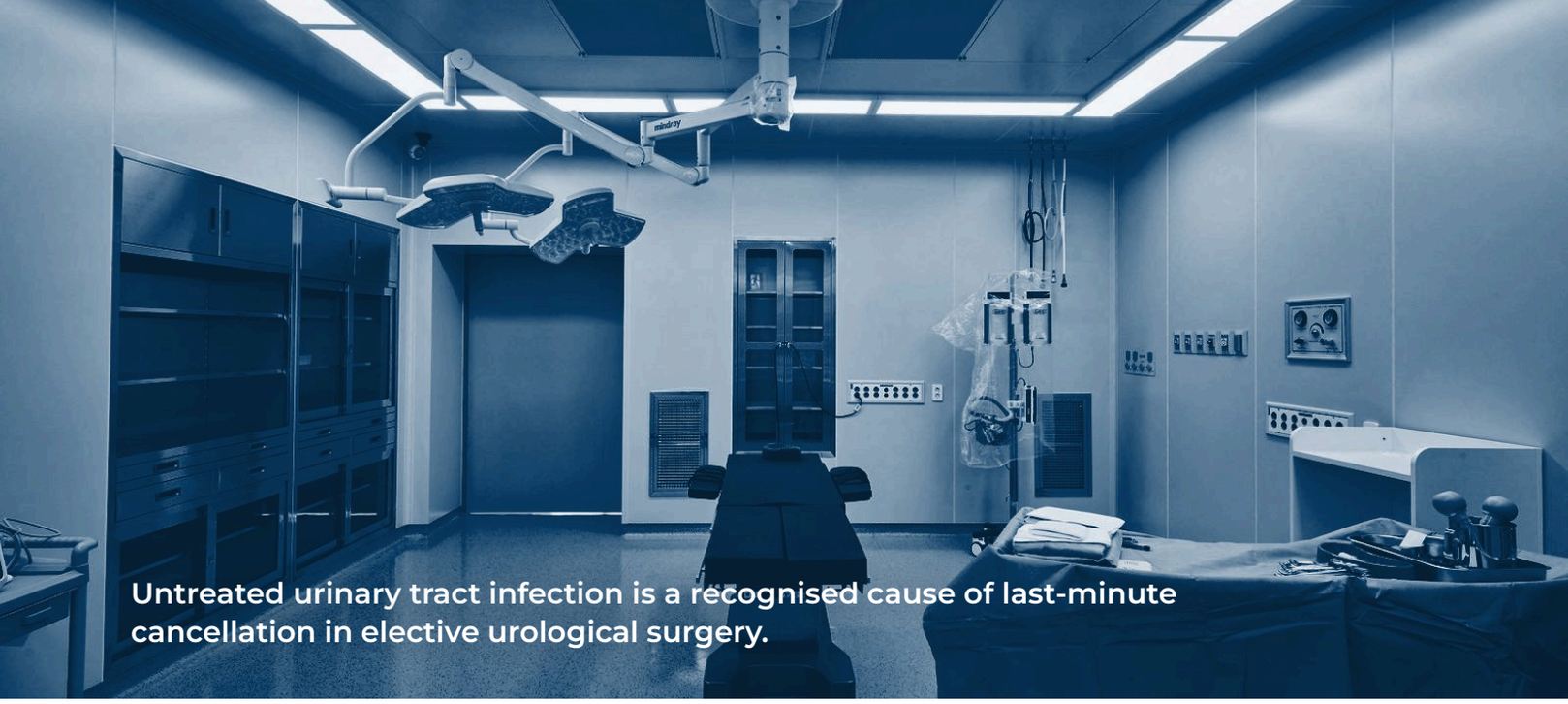
*Enterococcus species*

*Staphylococcus saprophyticus*

*Proteus mirabilis*

*Pseudomonas aeruginosa*

*Klebsiella pneumoniae*



Untreated urinary tract infection is a recognised cause of last-minute cancellation in elective urological surgery.

THE PROBLEM TODAY

# UTI diagnosis is running on empiricism

Most treatment decisions for urinary tract infection are made before the organism is known. The antibiotic is chosen on symptoms, against a background of rising pressure on every empirical option — and the burden of getting it wrong lands on patients, prescribers and theatre lists alike.

## 20%

Urinary tract infections account for 20% of all community antibiotic prescriptions — the second-largest driver of community antibiotic spend in primary care.

Dolk FCK, Pouwels KB, Smith DRM, et al. J Antimicrob Chemother 2018;73(suppl_2):ii2–ii10.

## 30.1%

National trimethoprim resistance in *E. coli* urinary isolates. An empirical first choice is made without knowing the organism — against resistance rates like these.

UK Health Security Agency. ESPAUR Report 2024–25.

## 189,756

UTI-related hospital admissions in England in 2023–24 — an increase of 9% year on year.

UK Health Security Agency. Hospital Episode Statistics data on UTI admissions in England, 2025 release.

## 50.8%

The share of UTI episodes in English general practice that receive a urine test of any kind — while 78.2% result in same-day antibiotic prescribing.

Ciaccio L, Fountain H, Beech E, et al. BMJ Open 2024;14(8):e084485. n=743,350 episodes.

**Organism identification is the missing piece of information, because it arrives days after the decision is needed.**

CLINICAL BACKGROUND

# Urine culture: where it works — and where it leaves patients without an answer

Culture is the reference standard, and Lodestar DX does not replace it. Both halves below are true at once — and the second half concentrates in recurrent and chronic patients.

| Reference standard | Route to susceptibility | No fixed panel | Quantified, viable growth | Surveillance substrate |
|---|---|---|---|---|
| Every UTI diagnostic is validated against it | Testing is performed on the cultured isolate | Grows whatever is present | cfu/mL — significance and test of cure | Antibiograms are built from its isolates |

## WHERE IT LEAVES PATIENTS WITHOUT AN ANSWER

*Design limits of any growth-based method — not failures of laboratory technique.*

| THE LIMIT | THE EVIDENCE | SO WHAT — FOR THE PATIENT |
|---|---|---|
| **After the decision** | Full report at 24–72 h from arrival — plus a mean 31 h in transit before testing begins. | **The first antibiotic is chosen blind; a wrong choice shows only after a failed course.** |
| **Mixed growth = no result** | 35% of symptomatic women's samples reported as contamination — yet 30–39% of UTIs are truly mixed. | **Roughly a third of symptomatic women leave with no answer.** |
| **"No growth" is not "no infection"** | 90.5% of culture-negative symptomatic women were *E. coli* PCR-positive (controls: 5.3%). | **A "clear" culture can wrongly close the case on an infected patient.** |
| **The culturability bias** | Compared with an enhanced culture protocol, standard culture detected just 33% of uropathogens — and only 12% of those other than *E. coli*. | **The infections culture is most likely to miss are the ones not caused by *E. coli*.** |
| **Never plated at all** | 16.6% of samples were screened out by flow cytometry and not cultured. | **Some symptomatic patients are ruled out by a screen, not a culture.** |
| **Suppressed or below threshold** | Recent antibiotics; organisms shed in cells; thresholds vary $10^3$–$10^5$ cfu/mL between laboratories. | **The recently treated patient — who re-presents most — is answered least well.** |

## One sample, two tests

Every arrow means the same thing: **the same sample carries on to the laboratory.** Culture is not the fallback — it is the second half of the answer.

| LODESTAR DX — IN 35 MINUTES | URINE CULTURE — AT 24 TO 72 HOURS |
|---|---|
| **AT THE CONSULTATION**<br>Identifies one or more of six common uropathogens, at clinically relevant levels, in 35 minutes — in time to inform the treatment decision in the consultation. | **THEN, AT THE LABORATORY**<br>Verifies the treatment decision. Susceptibility testing on the isolate either confirms the choice or refines it — and any organism outside the six is grown and named. |
| **WHEN GROWTH IS UNLIKELY**<br>Detection does not need the organism to grow. After recent antibiotics, or when organisms are shed inside cells, an identification is still possible — as in 19 of 70 samples that culture reported as mixed growth (Cardiff). | **THE SAME SAMPLE, CULTURED**<br>The same samples can defeat culture: the organisms are present but do not form colonies within 24–48 hours. That is a limit of any growth-based method. Culture still confirms the result once growth is possible. |
| **RECURRENT AND COMPLEX PATIENTS**<br>An organism named and recorded at every episode — even episodes that would otherwise be treated blind.<br>Over time, that record separates relapse (same organism) from reinfection (new organism) — the starting point of a longer-term plan. | **IN THESE PATIENTS, CULTURE STRUGGLES MOST**<br>• Recent antibiotics suppress growth<br>• Mixed growth is discarded — 35% of symptomatic samples; 30–39% of UTIs are truly mixed<br>• 50% of women not improving on culture-guided treatment had an organism only enhanced culture found<br>• Organisms in biofilm or intracellular reservoirs may not grow — or be shed — at all<br>*When growth does come, culture turns the record into susceptibilities — so every episode is still cultured.* |

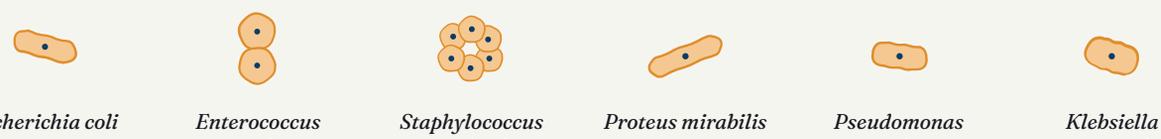
**THE SHARED BOUNDARY** Neither test reaches organisms sequestered in biofilm or intracellular reservoirs in the bladder wall, and neither diagnoses chronic UTI. A negative result from both does not exclude embedded infection.

Sources: Diggle 2024 (mixed growth 70/199; identification in 19/70 — clinical significance not established); Drazich-Taylor 2025 (31 h to testing; 57/344 not plated); Heytens 2017; Price 2016 (single centre, urogynaecology; enhanced protocol not routine); Nityadarshini 2022 — full references on page 5.

THE SYSTEM

# Where Lodestar DX fits

Lodestar DX does not replace urine culture. It answers a narrower question sooner: whether one of six common uropathogens is present at clinically relevant levels. The result is available in 35 minutes, at the bench or in the clinic room, from 10 µL of urine. Samples continue to the laboratory as normal.



*Escherichia coli* | *Enterococcus species* | *Staphylococcus saprophyticus* | *Proteus mirabilis* | *Pseudomonas aeruginosa* | *Klebsiella pneumoniae*

Each target is reported as detected or not detected at clinically relevant levels. The analytical limit of detection is between $10^4$ and $10^5$ cfu/mL across all six assays. The panel does not include Group B *Streptococcus*.

Llusern Scientific HUTI-10 IFU v4, March 2026 (Sections 5 and 14).

## Clinical performance against laboratory urine culture

| Patient population | Sensitivity | Specificity | PPV | NPV | Accuracy |
|---|---|---|---|---|---|
| Adults (18 years and over), n=468 | 87% | 72% | 85% | 75% | 82% |
| Paediatrics (0 to 17 years), n=189 | 77% | 97% | 90% | 93% | 92% |
| Overall (adults and paediatrics), n=657 | 86% | 84% | 86% | 84% | 85% |
| Pre-operative urology screening, n=189 | 78% | 92% | 78% | 92% | 88% |

Llusern Scientific HUTI-10 IFU v4, March 2026, Section 14. Overall sensitivity 85.8% (95% CI 82 to 89%) and specificity 83.7% (95% CI 79 to 88%), n=657 (455 female and 202 male urine samples). Reference standard: laboratory urine culture.

## 92% NPV

**Pre-operative urology screening**

Sensitivity 78%, specificity 92%, negative predictive value 92% (n=189), against laboratory urine culture.

Llusern Scientific. Clinical Performance of the Lodestar UTI Testing System for Preoperative Urology Screening, January 2026 (data on file). Reflected in HUTI-10 IFU v4, Section 14.

## 2–16%

**of patients each month started on antibiotics after pre-operative urine review**

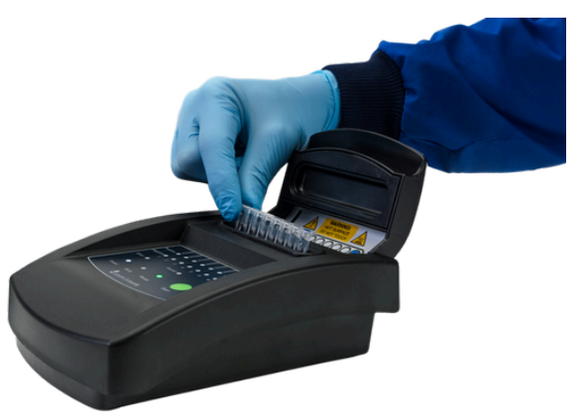
In a structured screening programme at Princess Royal University Hospital, urine results reviewed before the day of surgery meant infections were treated in time — and last-minute cancellations fell from 23.9% to 4.3%.

Spazzapan M, Javier P, Abu-Ghanem Y, et al. Int J Qual Health Care 2023;35(1):mzad008. A nurse-led screening programme, not a Lodestar DX study.

## The system

The Lodestar DX analyser and single-use test strip. One test, six pathogens, per 35-minute cycle — with a bench-top footprint roughly the size of an A5 sheet of paper.

Llusern Scientific HUTI-10 IFU v4, March 2026 (Sections 5 and 7).



IMPORTANT INFORMATION

Lodestar DX is for in vitro diagnostic use only and must be used in conjunction with the full clinical profile of the patient. A positive result does not guarantee that an infection is present; a negative result does not rule out the possibility of a UTI.

THE EVIDENCE

# Published UK evaluations

EVIDENCE BASE AS OF SEPTEMBER 2026

## Public Health Wales, Cardiff

**88.1%**
SENSITIVITY (95% CI 77.8–94.7%)

**83.9%**
SPECIFICITY (95% CI 72.3–92.0%)

**86.1%**
ACCURACY (n=129 EVALUABLE)

### STUDY DESIGN

199 fresh urine samples from symptomatic adult women — 96 from GP surgeries, 75 from outpatient clinics, 28 from inpatients — tested within four hours of receipt and before any culture result was available. Reference method: flow cytometry screening, chromogenic agar culture, MALDI-TOF identification where needed. Testing and result matching were performed by Public Health Wales, independently of Llusern Scientific.

### RESULTS IN FULL

PPV 85.5% (95% CI 76.9–91.3%); NPV 86.7% (95% CI 77.1–92.6%). For the *E. coli* assay: sensitivity 97.8%, specificity 90.4%, NPV 98.7%. Four culture-positive samples were organisms outside the six-target panel.

Diggle J, Van Der Goes Van Naters A, Roula MA, et al. JAC-Antimicrob Resist 2024;6(5):dlae148.

## Norfolk and Norwich University Hospital

**85.6%**
SENSITIVITY (95% CI 69.2–94.6%)

**92.0%**
SPECIFICITY (95% CI 88.1–94.9%)

**97.0%**
NPV (95% CI 94.0–98.6%)

### STUDY DESIGN

379 samples from non-pregnant adults, August to November 2024 — a routine Eastern Pathology Alliance workload: mean age 68, 58% female, 83% midstream and 17% catheter samples, 63% from general practice. 344 samples (91%) passed internal controls; 301 entered the primary analysis.

### RESULTS IN FULL

PPV 64.1%; NPV 97.0% (95% CI 94.0–98.6%). Overall accuracy against culture 91.2%.

### PER-ORGANISM SENSITIVITY

*E. coli* 87.9% (n=66) · *Enterococcus* 80% (n=20) · *S. saprophyticus* 92.3% (n=13) · *P. mirabilis* 93.8% (n=16) · *P. aeruginosa* 84.2% (n=19) · *K. pneumoniae* 100% (n=2). *S. aureus* was 27.3% (n=11); it is not a named target of the panel.

Drazich-Taylor S, Moore J, McCann B. JAC-Antimicrob Resist 2025;dlaf128.


**Published UK evaluations: Public Health Wales, Cardiff and the Eastern Pathology Alliance, Norwich**

**19 of 70**
MIXED-GROWTH SAMPLES

In the Cardiff evaluation, 70 samples were reported by culture as mixed growth with no clinical result. Lodestar DX returned a positive identification for one or more target pathogens in 19 of them. The clinical significance of those identifications was not established in the study.

Diggle J, et al. JAC-Antimicrob Resist 2024;6(5):dlae148, Table 4 and Discussion.


1. Ciaccio L, et al. Trends in urine sampling rates of general practice patients with suspected lower urinary tract infections in England, 2015–2022. BMJ Open 2024;14(8):e084485.
2. Diggle J, et al. Lodestar DX, an evaluation: LAMP for the diagnosis of urinary tract infection in symptomatic adult females. JAC-Antimicrob Resist 2024;6(5):dlae148.
3. Dolk FCK, et al. Antibiotics in primary care in England: which antibiotics are prescribed and for which conditions? J Antimicrob Chemother 2018;73(suppl_2):ii2–ii10.
4. Drazich-Taylor S, et al. Evaluation of the Lodestar DX: a comparison with traditional culture for the detection of bacteriuria. JAC-Antimicrob Resist 2025;dlaf128.
5. Heytens S, et al. Women with symptoms of a urinary tract infection but a negative urine culture: PCR-based quantification of Escherichia coli suggests infection in most cases. Clin Microbiol Infect 2017;23(9):647–652.
6. Kass EH. Asymptomatic infections of the urinary tract. Trans Assoc Am Physicians 1956;69:56–64.
7. Llusern Scientific Ltd. Lodestar DX UTI Test Kit (HUTI-10) Instructions For Use, Version 4, 25 March 2026.
8. Llusern Scientific Ltd. Clinical Performance of the Lodestar UTI Testing System for Preoperative Urology Screening. Summary report, 29 Jan 2026. Data on file.
9. Nityadarshini N, et al. Polymicrobial growth in standard urine culture: time to act or ignore? Trop Doct 2022;52:335–6.
10. Price TK, et al. The clinical urine culture: enhanced techniques improve detection of clinically relevant microorganisms. J Clin Microbiol 2016;54(5):1216–1222.
11. Spazzapan M, et al. Reducing last-minute cancellations of elective urological surgery. Int J Qual Health Care 2023;35(1):mzad008.
12. UK Health Security Agency. English Surveillance Programme for Antimicrobial Utilisation and Resistance (ESPAUR) Report 2024–25.
13. UK Standards for Microbiology Investigations. B 41: Investigation of urine. NHS / UKHSA.


### IMPORTANT INFORMATION

Lodestar DX is for in vitro diagnostic use only and must be used in conjunction with the full clinical profile of the patient. A positive result does not guarantee that an infection is present; a negative result does not rule out the possibility of a UTI.

IN PRACTICE

# Using Lodestar DX in your service

## Pre-operative urology

Bacteriuria found before urological surgery means either empirical treatment or a culture wait that puts the list at risk. A result at the pre-operative assessment appointment informs that decision on the day. A structured screening programme at Princess Royal University Hospital reduced last-minute urological cancellations from 23.9% to 4.3%.

Spazzapan M, et al. Int J Qual Health Care 2023;35(1):mzad008.

## Symptomatic presentation in clinic

A first, acute presentation: pathogen identification within the consultation, informing a targeted rather than empirical antibiotic choice for today's episode. Used alongside or in place of the dipstick at the clinician's discretion.

## From sample to answer — five steps

**01** Collect a urine sample. Process within 24 hours of collection.

**02** Transfer 10 µL of urine into the diluent tube and mix.

**03** Transfer 5 µL into each of tubes 1 to 7. Tube 8 is the negative control.

**04** Seal, mix, load the strip and start the run. 35 minutes.

**05** Read the display and record the result.

## The organism, and what usually works against it

Lodestar DX identifies the pathogen. It does not test susceptibility. An identified organism read against a current local antibiogram gives a firmer basis for a first-line choice than symptoms alone.

Below: the percentage of isolates **resistant** to each agent at one NHS trust. A darker cell means less of that organism remains susceptible.

| ANTIBIOTIC | *Escherichia coli* | *Enterococcus spp* | *Klebsiella spp* | *Proteus spp* | *Pseudomonas aeruginosa* | *Staphylococcus spp* |
|---|---|---|---|---|---|---|
| ISOLATES TESTED | **8,901** | **3,399** | **1,827** | **1,052** | **660** | **538** |
| Nitrofurantoin | 1.9 | 1.0 | 20.8 | 100.0 | – | 0.8 |
| Trimethoprim | 28.9 | – | 23.1 | 28.2 | – | 7.7 |
| Cephalexin | 13.7 | – | 18.4 | 10.9 | – | 2.7 |
| Co-Amoxiclav | 15.1 | 4.6 | 18.0 | 7.2 | – | 3.2 |
| Fosfomycin | 3.9 | – | – | – | – | – |
| Mecillinam | 9.7 | – | 17.3 | 53.0 | – | – |

ISOLATES RESISTANT: Under 5% | 5 to <10% | 10 to <20% | 20 to <50% | 50% or more | Not tested

Royal Berkshire Hospital urine antibiogram, 2025 column (17,171 isolates across eight organism groups; three-year dataset January 2023 – December 2025 supplied by Mr Bob Yang, Consultant Urologist, Royal Berkshire Hospital NHS Foundation Trust; reproduced with permission). Six Lodestar DX panel organism groups shown, and six oral agents used in urinary tract infection; the full antibiogram reports ten agents across eight organism groups. The laboratory groups several of these more broadly than the panel detects (for example *Staphylococcus* spp including MRSA, against the panel's *S. saprophyticus*). Blank cells: not tested. Values at or near 100% reflect intrinsic resistance. Resistance patterns vary by site and over time: prescribe against your own local antibiogram and current guidance.

## WHAT LODESTAR DX DOES NOT DO

- It does not test antibiotic susceptibility. Lodestar DX identifies the pathogen; the clinician selects the antibiotic on the basis of that organism and the local antibiogram.
- It does not detect organisms outside the six-target panel, including Group B *Streptococcus*. Cross-reactivity is documented in the IFU: the *E. coli* assay may also detect *Shigella* species; the *Enterococcus* assay may detect some strains of *Staphylococcus aureus* or *S. saprophyticus*; the *K. pneumoniae* assay may detect some strains of *K. variicola* or *K. oxytoca*.
- It does not replace urine culture. Culture remains the reference standard and the route to susceptibility testing.
- It is not currently indicated for use in pregnancy.

Llusern Scientific HUTI-10 IFU v4, March 2026 (Sections 4, 6 and 14). Practicalities: trained healthcare professionals, laboratory and near-patient settings; test kits supplied and stored cold chain; EPR integration via EKF Link subject to local IT; QC material QC-HUTI-10, monthly QC recommended; installation, training and support by Syner-Med.

## Request more information

Scan to request more information at your place of clinical practice, or visit lodestardx.co.uk