FOR MICROBIOLOGY AND INFECTION SERVICES

Lodestar DX does not replace urine culture. It answers a narrower question sooner.

This note sets out where culture works and where it leaves patients without an answer, how the two tests run on the same sample, and the boundary both share. It is written for the people who will be asked to govern the test, not to buy it.

Samples continue to the laboratory as normal.

A Lodestar DX result is only useful if the clinician can read the organism against a **current local antibiogram**. That antibiogram is built from cultured isolates. If culture volumes fall, the value of a rapid identification falls with them — and so does the surveillance the whole service depends on. **The two tests are not alternatives, and our own case for the technology collapses without yours.**

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
Every UTI diagnostic is validated against it

Route to susceptibility
Testing is performed on the cultured isolate

No fixed panel
Grows whatever is present

Quantified, viable growth
cfu/mL — significance and test of cure

Surveillance substrate
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.**

Cohorts: 24–72 h and 31 h in transit, 16.6% not plated — Drazich-Taylor 2025, n=379 non-pregnant adults, Eastern Pathology Alliance, Norwich.[2] 35% mixed growth — Diggle 2024, n=199 symptomatic adult women, Public Health Wales, Cardiff.[1] 30–39% true mixed infection — Nityadarshini 2022.[5] 90.5% *E. coli* PCR-positive among culture-negative symptomatic women (controls 5.3%) — Heytens 2017, n=220, Belgian general practice.[3] 33% and 12% — Price 2016, n=150 urogynaecology patients, single US centre; the enhanced protocol is not routine practice.[4] Significance thresholds — UK SMI B 41.[7]

ON THE SAME SAMPLE

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 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** 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 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** 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 An organism named and recorded at every episode — even episodes that would otherwise be treated blind. 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** • Recent antibiotics suppress growth • Mixed growth is discarded — 35% of symptomatic samples; 30–39% of UTIs are truly mixed • 50% of women not improving on culture-guided treatment had an organism only enhanced culture found • Organisms in biofilm or intracellular reservoirs may not grow — or be shed — at all *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.

Also outside both tests: the cause of haematuria; the distinction between asymptomatic bacteriuria and infection; and fastidious or atypical organisms, which need specific requests and methods. Lodestar DX detects DNA and is not validated as a test of cure. Intracellular reservoirs: Rosen 2007.[6]

How it runs alongside the laboratory

Sample flow
The sample continues to the laboratory as normal. The Lodestar DX result informs the interval before the culture report; it does not replace or pre-empt it.

Operators and setting
Trained healthcare professionals, in laboratory or near-patient settings. Training is required before first use and is provided by Syner-Med.

Controls and quality control
Every test strip carries a positive and a negative control, and both are read on every run. QC material (QC-HUTI-10) is available; monthly QC is recommended, or on starting a new lot.

Recording the result
Results are not stored on the analyser and must be recorded in the patient record. Integration with common EPR systems is possible via EKF Link, subject to local IT configuration.

Governance ownership
Near-patient testing sits under local laboratory or POCT governance. We ask that the service names the responsible lead, and agrees the standard operating procedure, before installation — not after.

Storage and consumables
Test kits are supplied and stored cold chain. One test strip, one patient, per 35-minute cycle.

Two things we would rather raise ourselves

Interpretation burden, and the risk of more calls to you

In the Norfolk and Norwich evaluation, positive predictive value was 64.1% and 28% of samples returned more than one positive channel. The authors note this may represent a contaminated sample rather than polymicrobial infection, and raise the concern that it could lead to increased antimicrobial prescribing, or to more consultations with microbiology for interpretation.[2] We would rather agree with you what a multi-target result means locally, and who is called, before go-live than after.

What NICE has and has not said

NICE's early value assessment of point-of-care tests for UTI (HTE7, 4 May 2023) covered **primary and community care**. Lodestar DX was identified among the rapid tests considered but was not the subject of a recommendation: at that time it did not hold regulatory approval.[9] The tests NICE did not recommend for early routine use were the Astrego PA-100 and Uriscreen; NICE recommended further research on accuracy and on the effect on prescribing. Lodestar DX is now UKCA-marked, two UK evaluations are published,[1,2] and it is among the platforms being compared with conventional methods in the NIHR-funded TOUCAN primary-care study.[2]

1. Diggle J, Van Der Goes Van Naters A, Roula MA, 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.
2. Drazich-Taylor S, Moore J, McCann B. Evaluation of the Lodestar DX: a comparison with traditional culture for the detection of bacteriuria. JAC-Antimicrob Resist 2025;dlaf128.
3. Heytens S, De Sutter A, Coorevits L, 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.
4. Price TK, Dune T, Hilt EE, et al. The clinical urine culture: enhanced techniques improve detection of clinically relevant microorganisms. J Clin Microbiol 2016;54(5):1216–1222.
5. Nityadarshini N, Mohapatra S, Gautam H, et al. Polymicrobial growth in standard urine culture: time to act or ignore? Trop Doct 2022;52:335–6.
6. Rosen DA, Hooton TM, Stamm WE, Humphrey PA, Hultgren SJ. Detection of intracellular bacterial communities in human urinary tract infection. PLoS Med 2007;4(12):e329.
7. UK Standards for Microbiology Investigations. B 41: Investigation of urine. NHS / UKHSA.
8. Llusern Scientific Ltd. Lodestar DX UTI Test Kit (HUTI-10) Instructions For Use, Version 4, 25 March 2026.
9. National Institute for Health and Care Excellence. Point-of-care tests for urinary tract infections to improve antimicrobial prescribing: early value assessment. HTE7, 4 May 2023.