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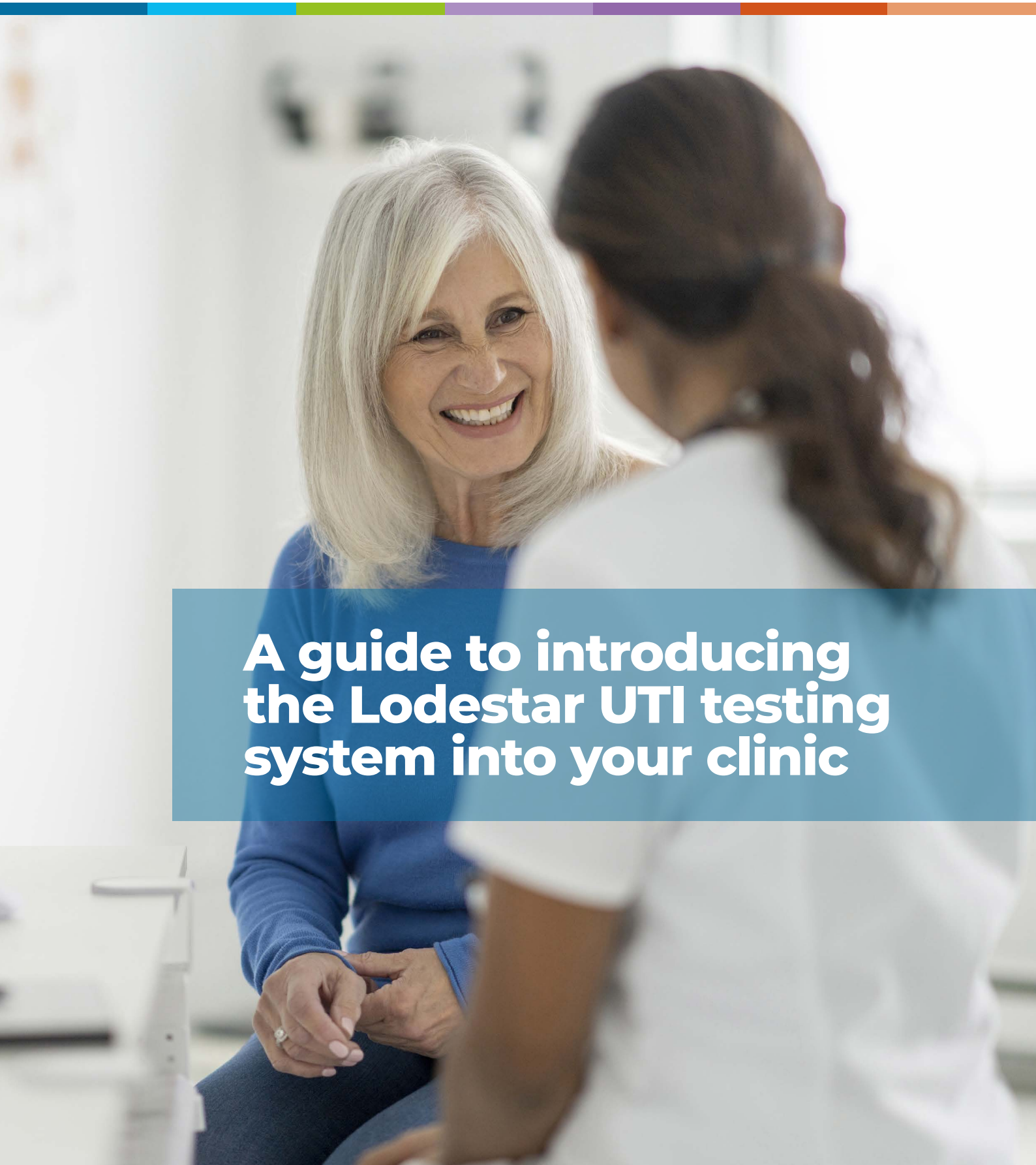
BRILLIANT MOLECULAR DIAGNOSTICS

Putting patients first

A new way to test and treat UTIs



A guide to introducing the Lodestar UTI testing system into your clinic

In this guide

Introducing the Lodestar UTI testing system

The standard method of diagnosing UTIs was developed in the 1950s. It was never intended to be used for this purpose and yet, more than 70 years on, little has changed.

Lab culture is an imperfect test. It fails many patients such as those with bacteria hiding in the bladder wall, or those with mixed infections. It also takes time, usually at least 48 hours and sometimes longer, especially if there are weekends and public holidays to account for.

Lodestar UTI

The Lodestar UTI testing system is a professional-use qualitative molecular diagnostic designed to detect DNA from six common uropathogens in 35 minutes.

Unlike lab culture Lodestar detects DNA targets and unlike PCR tests Lodestar does not require an extraction step or expensive laboratory equipment. This means that the system can easily be used in near patient settings.

The testing system consists of the Lodestar DX analyser and an eight-tube test panel comprised of six assays plus a negative and positive control.

Lodestar DX uses LAMP technology to detect DNA amplification through fluorescence. The analyser weighs less than a kilogram and has a footprint the size of an A5 sheet of paper. It can easily be moved from room to room without needing to be recalibrated and only requires a 12 amp power supply.

The Lodestar DX UTI panel tests for:

Escherichia coli (E. coli)

Enterococcus sp.

Staphylococcus saprophyticus

Proteus mirabilis

Pseudomonas aeruginosa

Klebsiella pneumoniae

Principle of the test

Detects 6 DNA targets

No DNA extraction step

Detects amplification by fluorescence

Amplification interpreted by algorithm

Results in 35 minutes

A new testing pathway for Urinary Tract Infections

Lodestar rules-out or confirms the presence of bacteria in a tiny urine sample in 35 minutes. If one or more of the main bacteria that cause UTI is present in the sample at or above a clinically relevant level then Lodestar will identify it. With this information, along with patient symptoms and medical history, a more informed diagnosis can be made.

Making big differences to patient treatment

A recent study conducted by a leading private urology clinic showed that Lodestar changed the treatment pathway for patients in 79% of cases. This means that the patient was either issued an antibiotic, changed antibiotic, were treated for inflammatory cystitis and not an infection or they were simply proceeded down a treatment pathway much quicker than they would otherwise have been.

The study also found that the average time to result from a laboratory culture test was three days (range 1-6 days). The time to action was five days (range 3-9 days).

Lab culture testing
Results in > 5 days

1 day
Patient samples batched and couriered to lab

2 days
Samples processed using flow cytometry or microscopy

Positive samples sent for culture

Samples incubated

3-4 days
Results transmitted to clinic

5-6 days
Prescription issued and collected

Lodestar UTI rapid test
Results in < 1 hr

1 min
Patient sample received

2 mins
Sample processed for testing

35 mins
Sample tested using Lodestar DX

40 mins
Results discussed with patient present

1 hour
Prescription issued based on result

Source: Kazi, Musabyimana, Alvarez, Yang 2025

One rapid test. Many applications

The Lodestar UTI testing system is appropriate for screening and for assisting with diagnosis across many different patient types and clinical settings.

A rapid result not only speeds up the treatment pathway for patients, it provides them with reassurance when they most need it – when they are in the consulting room. Perhaps they are going on holiday the next day and want to be sure they are UTI free.

Or it could be that they have had a procedure recently and need reassurance that there's no infection. Or maybe they want more insights into their diagnosis and by giving them a fast and accurate result they feel more confident in their diagnosis.

Patient	Application	Rationale
All adults	Repeat, underlying UTI	Ensure the patient is on the correct treatment pathway
Urological patients	Pre-operative screening	Rule-out UTI prior to invasive procedure
Urological patients	Post-operative screening	Rule-out UTI post-procedure
Adult male prostate cancer candidates	Pre-treatment	Rule-out UTI as cause of raised PSA levels
All adults	Point of care testing based on empiric symptoms	Rule-in/rule-out presence of a UTI to improve antibiotic stewardship
Pregnant women	Screening during pregnancy	Rule in/rule-out UTI to ensure informed prescribing decision made; improve patient conformance
Patients aged 65+	Screening for UTI where empiric symptoms are vague	Rule in/rule-out UTI to ensure informed prescribing decision made; reduce antibiotic use in a vulnerable population

> I had been on rounds and rounds of antibiotics and was still in pain, but the NHS tests kept coming back 'clear.' **The Lodestar was a game changer** - it actually picked up the infection despite the medication already in my system. **It's a huge relief to finally have proof.**

-Naomi

Real-world use in private practice

The reliability of Lodestar DX is validated by its integration into The Forbury Clinic, a premier private practice established in 2011.

Mr. Bob Yang, Consultant Urological Surgeon at the Royal Berkshire Hospital and The Forbury Clinic, utilises the system to drive data-led patient management.

The system was used across symptomatic patients, screening, and follow-up cases, demonstrating strong clinical utility and ease of integration.

Before integrating Lodestar into their clinic, Bob's team undertook a patient evaluation to examine Lodestar's benefits.

Key Clinical Findings

- **77% of cases** saw a change in treatment pathway based on Lodestar results
- **Superior sensitivity:** Traditional labs missed 52% of positive infections that Lodestar DX detected
- **Occult infections identified:** Pathogens such as Enterococcus and Proteus detected despite negative urine dipsticks
- **Rapid actionability:** Results available and actionable during the same visit, compared with several days for MSU culture
- **Targeted therapy enabled:** Uropathogens identified in 54% of cases, including E. coli, Enterococcus, Proteus, and Pseudomonas

Mr Bob Yang

Consultant Urologist FRCS (Urol), MBBS BSc (Hons), AICSM. Lecturer at University of Oxford

"From a private practice perspective, Lodestar DX fits seamlessly into our workflow and has made a significant impact on prescribing and patient management.

It enables us to confidently treat patients during the same visit, making informed treatment changes based on the diagnostic results. The system is intuitive and easy to use, which streamlines our processes and reduces delays.

Overall, Lodestar DX has become an invaluable tool, enhancing the quality of care we provide and contributing meaningfully to the success of our private practice."

The Forbury Clinic

A comparison of results from Lodestar UTI testing system and laboratory culture tests

Reference: The Forbury Clinic

44
lab culture results performed

Lodestar concordance with lab culture

89%

Assuming mixed growth significant

Of 44
lab culture results performed

24
positive Lodestar organisms NOT detected by lab culture

Lab culture failure to detect

54%

Assuming mixed growth is significant, though does not specify what organism

"The best part about the Lodestar was the speed. Usually, you send a sample and wait three or four days for a phone call. Here, I had my results and a treatment plan **before I even left the building.** It's a true one-stop service which was amazing, **I was very impressed.**"

-Liz

Antibiotic prescribing

First and second line antibiotics for the six bacteria tested by Lodestar.

Uropathogen	Antibiotic Options
Escherichia coli (E. coli) *E. coli* is a very common type of bacteria that normally lives in the intestines of people and animals. While most strains are harmless and part of a healthy gut, certain types can cause infections if they get into other parts of the body. *E Coli* is the number one cause of UTis and have special features, like tiny hair-like structures, which help it stick to the bladder walls, making it difficult for the body to flush out.	***Fosfomycin (3g 48-72 hrly)*** ***Nitrofurantoin (100mg BD MR)*** ***Pivmecillinam (400mg TDS)*** ***Cefalexin (500mg TDS)*** ***Ciprofloxacin (500mg BD)***
Enterococcus *Enterococcus* is a normal resident of human intestines. It is very hardy and can survive in a variety of environments. It is a common cause of UTis in hospital settings or in individuals with catheters. It is known for its natural resistance to many types of antibiotics.	***Amoxicillin/Co-amoxiclav (500/625mg TDS)*** ***Nitrofurantoin (100mg BD MR)***
Staphylococcus saprophyticus This type of *Staph* bacteria is a common cause of UTis, particularly in younger, sexually active women. This type is rarely found on the skin and is most associated with the urinary system. It is particularly good at attaching to the cells lining the urinary tract, allowing it to establish an infection after being introduced into the urethra.	***Amoxicillin/Co-amoxiclav| (500/625mg TDS)*** ***Levofloxacin (500mg OD)*** ***Nitrofurantoin (100mg BD MR)*** ***Trimethoprim/Co-Trimoxazole (200/960mg BD)***
Proteus mirabilis *Proteus* is found in the human gut and the environment (like soil and water). It can rapidly break down a substance called urea (found in urine). This process makes the urine less acidic and can lead to the formation of bladder or kidney stones.	***Cefalexin (500mg TDS)*** ***Ciprofloxacin (500mg BD)*** ***Co-amoxiclav (625mg TDS)***
Pseudomonas aeruginosa *Pseudomonas* is a widespread bacterium found in soil, water, and on plants. It is more common in patients who have been in the hospital for a long time, have a weakened immune system, or have a urinary catheter. *Pseudomonas* is known for being highly capable of forming biofilms and being resistant to many antibiotics, which is a key consideration in treatment.	***Ciprofloxacin (750mg BD)*** ***Moxifloxacin (400mg OD)*** ****HIGH local resistance rates****
Klebsiella pneumoniae *Klebsiella* are normally found in the human intestines and in the soil. They do not cause illness when they are in their normal place but can cause an infection if they travel to the urinary tract. These infections are more common in older individuals or in a hospital setting. *Klebsiella* have developed significant antibiotic resistance.	***Cefalexin (500mg TDS)*** ***Co-trimoxazole (960mg BD)*** ***Moxifloxacin (400mg OD)***

Reference: The Forbury Clinic

Resistance rate colour code: ***Very high >50%*** ***High 20% - 49.9%*** ***Medium 10% - 19.9%*** ***Low <10%***

Antibiograms versus AST

Antibiotic Sensitivity Testing (AST) is often requested when a culture test is ordered. However, AST profiles are rarely used in diagnosis because they are invariably received by clinicians long after a patient has been seen.

An alternative to AST is to use a clinical antibiogram in conjunction with the result from Lodestar. In the UK, resistance rates to first and second line antibiotics are well known and so, if the bacteria is identified, an appropriate decision can be made quickly and with confidence.

Antibiograms are freely available however we recommend checking with a local microbiologist before integrating the information into your practice.

Resistance rates for common antibiotics

Data shows percentage of urinary isolates likely to be sensitive to each antibiotic based on national or regional UK data.

	Nitrofurantoin	Trimethoprim	Fosfomycin	Pivmecillinam	Cefalexin	Co-amoxiclav	Ciprofoxacin*
E.coli	96.7% sensitive[1]	66.1% sensitive[1]	98.8% sensitive[1]	95.6% sensitive[1]	90.1%[2]	59.2% sensitive[1]	89.9% sensitive[4]
Enterococcus	95.1% sensitive[3]	Intrinsically resistant (0% sensitive)	Not recommended for Enterococcus infections	Intrinsically resistant (0% sensitive)	Intrinsically resistant (0% sensitive)	96.7% sensitive[4]	Not tested
Staphylococcus saprophyticus	99.3% sensitive[4]	96.3% sensitive[4]	High levels of resistance	28% UTIs don't respond clinically	99.4% sensitive	99.6% sensitive[4]	High levels of resistance[4]
Proteus mirabilis	Intrinsically resistant (0% sensitive)	72.6% sensitive[4]	High levels of resistance	84% sensitive[3]	90% sensitive[4]	96.2% sensitive[4]	95.9% sensitive[4]
Pseudomonas aeruginosa	Intrinsically resistant (0% sensitive)	Intrinsically resistant (0% sensitive)	High levels of resistance	Intrinsically resistant (0% sensitive)	Intrinsically resistant (0% sensitive)	Intrinsically resistant (0% sensitive)	51.3% sensitive[4]
Klebsiella pneumoniae	76.7% sensitive[4]	79.9% sensitive[4]	76.8% sensitive[4]	94.9% sensitive[3]	82.5% sensitive[4]	80.6% sensitive[4]	92.1% sensitive[4]

**This is for information only and should not be used to make treatment decisions. Treatment choice should be made with reference to UK guidance.*
1. Data taken from Public Heath Wales for outpatient urine samples, 2024. Available at: phw.nhs.wales/services-and-teams/antibiotics-and-infections/antimicrobial-surveillance/all-wales-reports/antimicrobial-resistance-in-urine-cultures-in-wales-2024-pdf/ 2. NICE 2018. UTI (lower): antimicrobial prescribing, choice of antibiotic. Available at: nice.org.uk/guidance/ng109/chapter/Summary-of-the-evidence 3. AST data from Public Health Wales. 4. 'Urinary Pathogen Antibiogram', Abstract 642 presented at ICS-EUS 2025. Available at ICS.org

Implementing Lodestar UTI into your clinic

The Lodestar DX analyser and UTI test kit is a mobile, simple to use diagnostic that can be used in a variety of settings.

By following a few simple steps you can ensure that Lodestar UTI is properly integrated into your practice and provides rapid results that will help guide patient treatment decisions and improve antibiotic stewardship.

Product training

Any professionally competent person in your clinic can use Lodestar. It is not necessary for the user to be a urologist, a lab technician or a senior member of staff. Training typically takes less than an hour and includes advice on storage and cleaning techniques. It is advisable for as many staff as possible to be trained so that they are aware of Lodestar and the UTI tests. It is also important to ensure that senior medical staff are aware of the system so they can request tests be undertaken.

Refrigeration

We recommend using a dedicated refrigerator to store boxes of test kits however any medical-grade fridge can be used provided that the temperature is kept between 0.5 ˚C and 6.5 ˚C at all times.
To do this the door should not be opened unless absolutely necessary and boxes of test kit should be stored away from the front of the refrigerator.
We also recommend that the refrigerator has a temperature logger that can alert a member of staff if the temperature rises above 6.5 ˚C or below 0.5 ˚C.

Clinical waste disposal

There is a possibility of contaminating the testing area if used test panels are not disposed of correctly. Use a dedicated waste container that has a lid and is not used for general waste. This will ensure the lids on the used test panels remain closed and no pathogen DNA will leak from the tubes. The pathogen DNA are harmless, however if they are circulating in the air or on surfaces around the testing area then they can inhibit the test results.

Quality control

We recommend undertaking a quality control check every month. If your site undertakes a lot of testing (around 20+ a week) then you may wish to undertake a QC check more regularly. Positive and negative QC kits are available for purchase from Llusern Scientific or your distributor.

Placing orders

Test panels have a shelf-life of 20 weeks from the date of manufacture. We recommend considering how many tests your clinic will use each month and ordering one to two months' supply at a time. This will ensure that tests are not stored for too long and the variations in refrigeration over a long period are limited.

Tell your customers

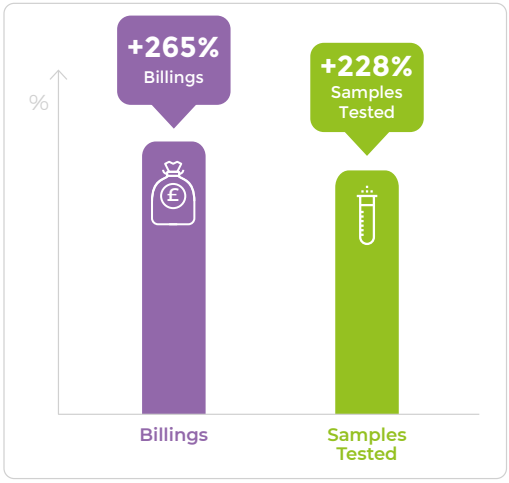
The Lodestar UTI testing system is a unique tool that allows clinics to change the way they test for infections. We know that patients benefit from having their test results during their appointment, so ask them to come in 30 minutes early so that their sample can be tested ahead of their consultation.

Integrating Lodestar into your business model

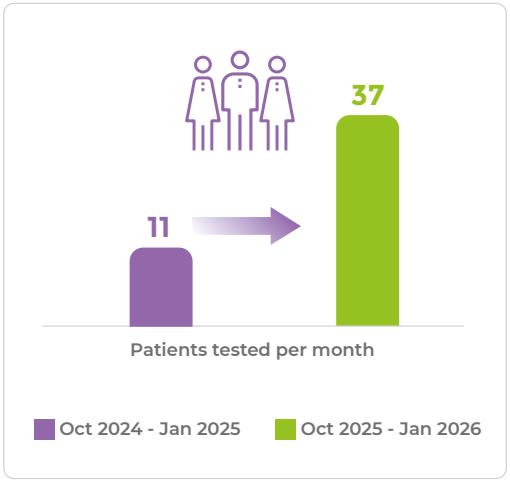
Reducing the number of outsourced urine samples tests undertaken not only improves the patient experience but improves a business' bottom line.

Instead of paying for a slow and often inaccurate culture result Lodestar allows a clinic to offer a premium in-house UTI testing service that offers the possibility of improving revenues and margins.

Increased revenues from UTI testing



Growth in patient UTI testing



Five simple steps to a result in 35 minutes

Once a sample has been provided it is mixed into a solution containing a blue dye and then pipetted into seven tubes The first six tubes test for a different bacteria. The seventh and eighth tubes are negative and positive controls that ensure the test has been run correctly.

Once the test panel has been placed into the Lodestar analyser, the user presses 'Start' and can then get on with other tasks until the result appears on the LED lights 35 minutes later.

01

Transfer 10µL of patient urine into the diluent tube.

02

Transfer 5µL of the mixed liquid from the diluent tube into the first reaction tube. Use the pipette tip to mix the liquids together until they turn blue.

03

Repeat the process for the five other tubes, plus the positive control.

04

Place the test panel into the Lodestar DX analyser and press 'Start'.

05

The test will run for 35 minutes. At the end of the run results will be displayed on the LED lights. The table opposite shows the bacterial identification for each tube.

> As a spinal injury patient, new symptoms feel overwhelming. Lodestar gave me instant peace of mind. I drove two hours to Reading just to avoid the usual three day wait for culture results. **It's brilliant.**
>
> **- Luke**

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