Performance of a novel molecular test designed for Point-of-Care UTI diagnosis

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Introduction

The current 'gold standard' method for UTI diagnosis is the culture method. However, it is time consuming (24-72 hours), requires expensive equipment, a high volume of consumables and highly skilled laboratory staff to interpret and report results.

Clinical decisions are often made on the basis of a urine dipstick test and patient symptoms at the point of care. The inaccuracies of these methods and the slow return of culture results means infections are often missed, or antibiotics are given out inappropriately or unnecessarily. This increases the risk of resistant, chronic/recurrent or severe infections developing, with negative impacts on patient outcomes[1].

We have developed a rapid molecular test, Lodestar DX (**Figure One**) which could provide accurate results in 40 minutes at the point of care. This is a Loop-Mediated Isothermal AMPlification (LAMP) based test, able to detect clinically relevant levels of pathogens direct from urine.

Study Objective

To evaluate the clinical performance of one of the Lodestar DX LAMP assays - for *Escherichia coli,* the most common uropathogen.

Methods

149 randomly selected fresh urines were tested using Lodestar DX (LAMP) technology, alongside laboratory culture method at UHW, Cardiff Microbiology.

Urine samples (1 µL) were added directly to the *E.coli* assay

Results were shown and recorded after 40 minutes as 'positive' or 'negative' according to the decision of Lodestar's algorithm

Lodestar DX results were compared to standard culture results and sensitivity and specificity calculated.

Figure One. A. Lodestar DX analyser. **B**. UTI test panel. Each tube is specific for a different uropathogen.

Results

Overall sensitivity of the *E.coli* LAMP test was 86.2%. Specificity was 88.3% (**Table One).**

Of the 14 samples positive in the LAMP test for *E.coli* but not recorded as *E.coli* using culture, 11 were from 'mixed growth' samples (**Table Two**).

Table One. Sensitivity and specificity of the Lodestar DX *E.coli* LAMP test.

	LAMP Positive	LAMP Negative	Total
Culture Positive	**25** (True Positives)	**4** (False Negatives)	**29**
Culture Negative	**14** (False Positives)	**106** (True Negatives)	**120**
Total	**39**	**110**	**149**
Overall sensitivity	((25/29)*100) = **86.2%**		
Overall specificity	((106/120)*100) = **88.3%**		

Table Two. Results of Lodestar DX *E.coli* LAMP test compared to culture results.

Culture Result	*E.coli* Lodestar LAMP result			
		Positive	Inconclusive	Negative
E.coli positive	29	25	0	4
Other pathogen positive	12	1	0	11
Mixed growth	61	11	0	50
No growth	47	2	0	45
Total	149	39	0	110

Discussion and Conclusion

Sensitivity and specificity for *E.coli* was high and the test system may be better at diagnosing mixed infections which represent a high proportion of all culture results.

The test system is easy to use with no sample processing and minimal training requirements. Test results are available in 40 minutes, compared to 24-72 hours for culture results.

The performance of the test system for the detection of other uropathogens (*Klebsiella, Enterococcus*, *Pseudomonas, Proteus* and *S. saprophyticus*) is ongoing. Sensitivity can be further improved by refining the test method.

The Llusern Scientific Lodestar DX UTI test system shows great promise as a point-of-care diagnostic tool.

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References

1 NICE. Point-of-care tests for urinary tract infections to improve antimicrobial prescribing: early value assessment. Available at: https://www.nice.org.uk/guidance/hte7/resources/pointofcare-tests-for-urinary-tract-infections-to-improve-antimicrobial-prescribing-early-value-assessment-pdf-1396175715781

Conflict of interest statement: EH, JN and AR are co-founders and directors of Llusern Scientific, a company who hope to commercialise the Lodestar DX test system