



**TRITECH**

Sefydliad | Institute

**Hywel Dda University Health Board**

## **Evaluation Report**

**A new point of care (POC) test for Urinary  
tract infections (UTI)**

**This evaluation was undertaken as part of the Bevan  
Commission Planned Care Innovation Programme**

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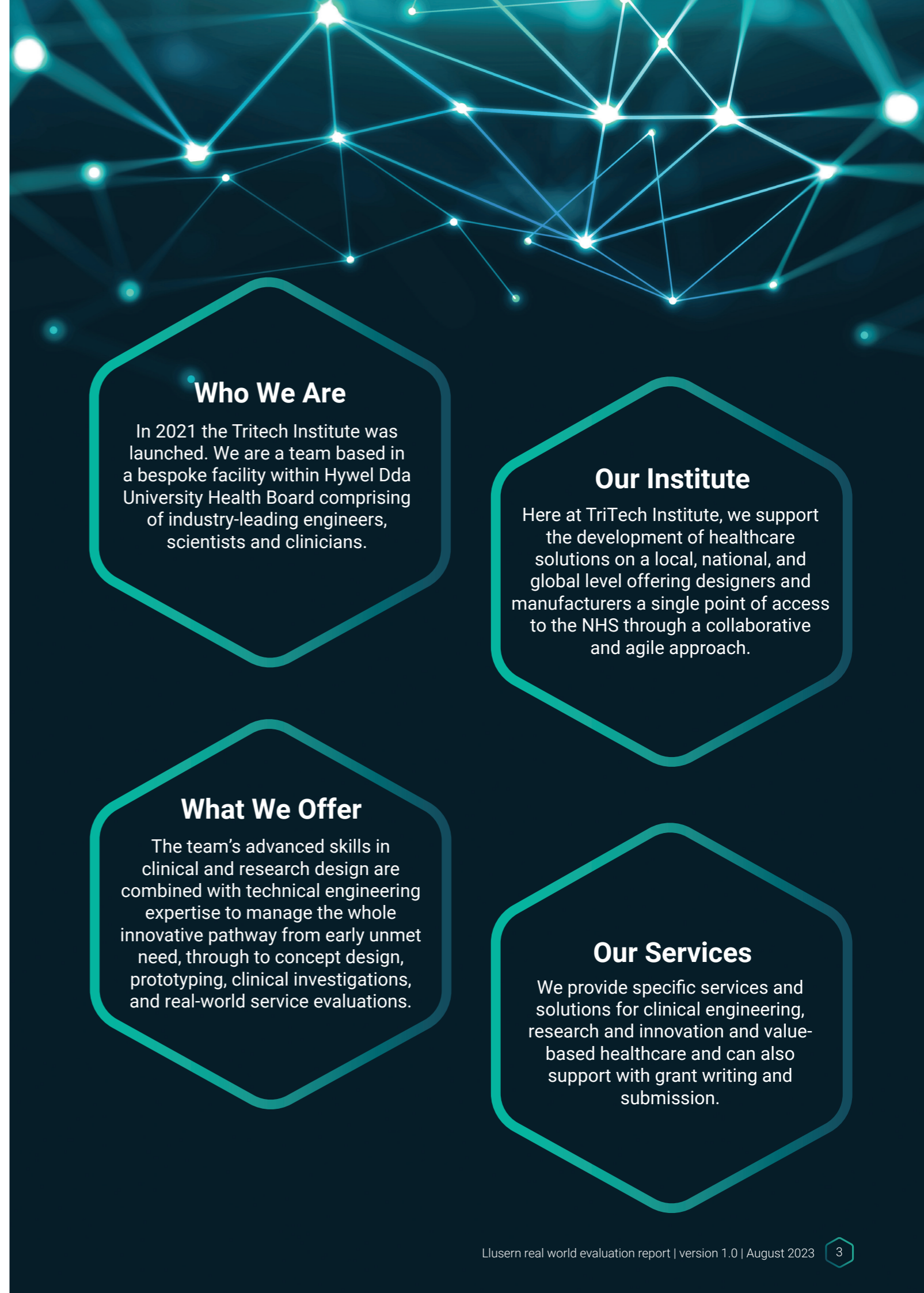
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### Who We Are

In 2021 the Trittech Institute was launched. We are a team based in a bespoke facility within Hywel Dda University Health Board comprising of industry-leading engineers, scientists and clinicians.

### Our Institute

Here at TriTech Institute, we support the development of healthcare solutions on a local, national, and global level offering designers and manufacturers a single point of access to the NHS through a collaborative and agile approach.

### What We Offer

The team's advanced skills in clinical and research design are combined with technical engineering expertise to manage the whole innovative pathway from early unmet need, through to concept design, prototyping, clinical investigations, and real-world service evaluations.

### Our Services

We provide specific services and solutions for clinical engineering, research and innovation and value-based healthcare and can also support with grant writing and submission.

# Executive summary

This report covers the period of 01/09/2022 to 30/04/2023.

## Background

A urinary tract infection (UTI) is caused by microorganisms in the urinary tract[1]. The high prevalence of UTIs across the UK has led to it being identified as a priority area by the NHS. The cause of the majority of UTIs is through microorganism *E. coli* exacerbated by its antibiotic resistance. The clinical burden of UTIs is high across all areas of healthcare, due to the high number of resources to test and treat the high volume of patients affected[4].

In Primary and community care the dipstick test is the most widely and convenient test used at point of care. Whilst the dipstick method is easy to use it is known to have several significant drawbacks, foremost of which are the inaccuracies of its results. Despite these drawbacks other more accurate methods such as laboratory testing also have drawbacks such as significant time delays and costs associated with sending the samples away for testing. Additionally, due to the inaccuracies of the dipstick test and the cost and time constraints of laboratory testing, diagnosis of UTIs in the community and GP practices is primarily done using a symptoms-based approach as per national guideline recommendations.

## Situation

Llusern Scientific, a company based in Pontypridd, Wales, have developed a molecular testing platform and assay for the purpose of diagnosing UTIs at the point of care (POC). The Llusern test was designed for use in primary and community care. This test is portable and returns a result within 40 minutes. Llusern Scientific in partnership with Cwm Taf Morgannwg University Health Board (CTMUHB), Public Health Wales (PHW) and other collaborators have conducted clinical evaluations of their innovation as part of the Bevan Commission Planned Care Innovation Programme.

The TriTech Institute were commissioned to evaluate the potential clinical impact of the Llusern test with primary and community care clinicians. This evaluation used a mixture of questionnaires and clinical focus groups. This report presents

the findings of the evaluation which covers the period of 01/09/2022 to 30/04/2023.

## Findings

30 participants were included in the evaluation, who comprised of a mixture of GPs, Pharmacists, and nurse practitioners. All participants were sent a questionnaire in which they were asked to score the importance of a list of user needs in relation to devices that could be used at the Point of Care (POC) of UTI testing. All participants were also recruited to take part in focus groups, conducted out of hours. Participants were asked to discuss a range of topics relating to current practice for UTI management and how a new test or device at the point of care could influence and support clinical activity. The final stage of the evaluation involved demonstrations of the Llusern test for 10 of the participants who had completed questionnaires and gave feedback relating to its practical use within a clinical environment. The conclusions from this evaluation across these activities have been divided into four main themes; Infrastructure, Technology, Staff and Patient, and are summarised below.

## Conclusions

### Infrastructure

Current guidelines and clinical practice for suspected UTIs are focussed more on a symptoms-based approach to testing. The Covid-19 pandemic has negatively affected the testing frequency of UTIs as more clinics are conducted virtually. This has led to less testing at the POC. Clinicians involved in the focus groups reported concerns with inappropriate prescribing relating to POC testing, when staff do not also incorporate a symptom-based approach to the testing. Any new POC test would need to demonstrate clinical or economic benefits before it would find acceptability clinically and hence could be considered for current guidelines and practice.

There are financial implications of any new POC tests (including Llusern). The primary concern being an initial upfront cost or investment needed for the devices or tests themselves, where GP practices and high street pharmacies may struggle to pay if it is more expensive than a dipstick test. Understanding the potential financial support or investment from health boards, or government need to be considered. Being able to demonstrate cost savings in other areas could help to offset the financial concerns that were voiced during the focus groups. Staff feedback highlighted the potential clinical case for the Llusern POC test, particularly in remote community care settings where Hospitals and testing locations for urine samples are not close enough for routine drop offs. Weekend and out of hours testing where a mid-stream urine (MSU) request would be impractical could also be an opportunity case for the Llusern test.

### Technology

Consultation times and contact frequency with patients are a limiting factor for GPs and Pharmacists. The Llusern test could take up to 40 minutes to return a result which could cause complications, expecting patients to wait. Furthermore, the number of transferal steps required for the Llusern test could increase contamination risk, particularly in a busy community setting or GP practice. Feedback from clinicians suggests that any new test or device for UTI testing would need to either provide the sensitivity and specificity results of an MSU test in a reduced time or offer clear benefits over existing POC methods.

Being able to show a negative result for a number of pathogens was identified as another potential use for the Llusern test. Feedback from clinicians indicated that some patients insist on antibiotics or know which symptoms to mention on a proforma to get a prescription they think they need, for a particular condition. Being able to present a negative result for a range of pathogens without the need for an MSU test could provide additional reassurance for clinicians and patients.

### Staff

Clinical guidelines encourage attaching a proforma of symptoms against the MSU test requests, but microbial pharmacists report that not all clinicians follow this. More

research to identify how frequently guidelines are ignored may help to understand how new tests or devices could help with compliance.

### Patients

Contaminated urine samples from patients is a known problem that all clinicians who took part in the evaluation reported. This increases false positive detection rates and over prescribing of antibiotics. It is not always obvious to the clinician if a sample is contaminated or not mid urine flow (instructions are given to patients to reduce contamination). During the focus groups, it was identified that the Llusern test may demonstrate reduced 'false-positive' rates with contaminated samples when compared to dipsticks, but this would need validating prior to clinical use.

## Recommendation 1: Engagement with policy makers to understand how new UTI tests might be implemented

There is a range of guidance including SIGN, NICE, and Public Health Wales microbiology guidelines, all of which have a focus on the symptoms, with clear steps and advice on how to treat. More work is required to understand how the results from a new test could support these guidelines. Any new UTI test on the market will face challenges with wide scale adoption as the clinical guidelines would not offer guidance on how to interpret the results. Engagement with Public Health Wales, and policy makers in the health boards would be required to understand what would be required for any potential adoption. This would be a good first step, as it could influence next steps in the innovation pathway and further research and evaluation projects. This work would identify the key barriers to adoption and acceptance of any new POC device and what evidence policy makers would require prior to adoption.

## Recommendation 2: Real-world evaluation in clinical environments

Feedback in relation to the Llusern test indicated that there were some concerns with transferal steps for the urine and potential for contamination. Real-world testing in a range of clinical environments will provide insights on the practicality of the test in primary and community care. As part of this real-world evaluation, data could also be collected on the



potential clinical application of having a negative result for a range of pathogens which was identified as a use case for the Llusern test.

### Recommendation 3: Direct comparison against dipstick tests to show improvements

Dipsticks are reported to have ambiguity in results and low-quality urine samples from patients can negatively affect all UTI tests. A head-to-head direct comparison between the Llusern test and dipstick test may show an improvement in reliability and/or a reduced false positive rate for contaminated samples. Evidence of these improvements could support the adoption of the Llusern test, this would require paired testing of a range of samples to quantify any improvements.

### Recommendation 4: Evaluation in a community care setting

Community care was identified as a potential use case for the Llusern test because of its portability. Nurse practitioners working across sites and in care homes may have less restrictions on time in some cases, unlike GPs or pharmacists who have a limited window per patient. An evaluation in a community care setting, such as a residential care home or with nurses who visit them may provide evidence for a use case for the Llusern test.

### Recommendation 5: Exploring other uses of the test

Feedback from clinicians involved in this evaluation indicated that the test may be useful for other clinical scenarios such as throat cultures for Strep A and STIs. This may be a lower priority focus for Llusern, but the portable nature of the test and range of pathogens that it can predict at one time could provide other beneficial use cases.

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## Abbreviations

AST	Antimicrobial Susceptibility Testing
ANP	Advanced Nurse Practitioner
CTMUHB	Cwm Taf Morgannwg University Health Board
GP	General Practitioner
HCA	Health care assistant
HDUHB	Hywel Dda University Health Board
MS	Microsoft
MSU	Mid-stream urine
NHS	National Health Service
NICE	National Institute for health and Care Excellence
PHW	Public Health Wales
POC	Point of care
SIGN	Scottish International Guidelines Network
STI	Sexually transmitted infection
UTI	Urinary tract infection



## Background

### Urinary tract infections (UTIs)

A urinary tract infection (UTI) is caused by the presence and multiplication of microorganisms in the urinary tract, which is comprised of the urethra, bladder, ureter, and kidneys[1]. Several clinical syndromes can result from a UTI including acute and chronic pyelonephritis (infection of kidney and renal pelvis), cystitis (infection of bladder), urethritis (infection of urethra), epididymitis (infection of epididymis) and prostatitis (infection of prostate gland). Bacteriuria is the occurrence of bacteria in the urine and can be symptomatic or asymptomatic[1].

Treatment for UTIs typically involves a course of antibiotics to eradicate the bacterial infection[2]. If left untreated UTIs can lead to various complications, such as the infection spreading to the kidneys where it can cause damage, and potentially lead to sepsis, a life-threatening condition[3]. Recurrent UTIs require more aggressive treatment which can increase the risk of antibiotic resistance within the patient[3].

UTI is considered an NHS priority area due to the antibiotic resistance associated with E. coli infection, which is responsible for a majority of UTI cases. The clinical burden of UTIs is high in both primary care and acute care, due to the large number of patients and the resources needed to test, treat, and prescribe for the high number of patients affected[4].

One third of all the women in the UK will have had at least one UTI by the age of 24 and about 50 percent of women will be treated for a symptomatic UTI during their lifetime[5]. UTI in men is generally uncommon, but incidence rates are higher in elderly men and those who have risk factors such as being at risk of benign prostatic hypertrophy, catheterisation. Being immunocompromised or having undergone previous urinary tract surgery are also risk factors for UTI[4].

Asymptomatic bacteriuria is estimated to occur in one to five percent of healthy pre-menopausal women. This rate increases to between 4 and 19 percent in otherwise healthy older women and men[6]. Clinical audits conducted in English care homes in 2013 identified that residents

were frequently prescribed antibiotics for the treatment of UTIs from dipstick results. The same audits showed that 19 to 48 percent of residents in these care homes were prescribed antibiotics on a positive dip stick instead of from clinical symptoms. Using dip stick results only and not utilising clinical signs and symptoms causes inappropriate prescribing of antibiotics and can put those residents at risk of harm[7].

### Testing methods in primary and community care

Dipstick urinalysis is a widely used initial screening test in primary and community care for UTIs. It involves testing urine samples for the presence of leukocytes, nitrites, and blood[1]. The presence of leukocytes suggests inflammation, while the detection of nitrites indicates the presence of bacteria[5]. This method is quick & easy to perform and can be used in a wide range of clinical scenarios. Despite its advantages around ease of use, there are drawbacks to dipstick urinalysis chief of which is its low accuracy, and the results are susceptible to poor sample quality from patients. Despite these negatives dipstick testing remains a commonly used tool for the initial assessment of UTIs, due to their low cost and ease of access[5].

Other types of testing for UTIs include culture-based identification and antimicrobial susceptibility testing (AST). This is usually done as a mid-stream urine (MSU) test. The MSU involves testing the urine after the first parts of urine have exited the urethra. This part of the urine is tested because the early stages of a urine stream can contain bacteria and skin cells which may cause a false positive for bacteriuria. An MSU test requires the sample being processed at a testing laboratory [5]. The advantage of an MSU test is that the results can give an indication of sensitivity and specificity of the bacteria's resistance to various antibiotics. This is crucial information for a clinician when deciding which antibiotics to prescribe (if any) as they may not work. For this reason an MSU is considered the 'gold standard' for UTI testing but the results can take up to 48 hours to return, which in some cases may be too long for a treatment decision and are



costly compared to the dipstick testing[7]. Due to the issues with the different currently used tests there is an opportunity for innovation around new UTI testing techniques or technologies, to improve the appropriate management of UTIs while minimizing unnecessary antibiotic use[7].

## Situation

### Planned care innovation programme

The Bevan Commission set up a Planned Care Innovation Programme to fund a diverse range of projects that had an aim to innovate and transform planned care services across Wales. The Welsh government has identified a need to transform services across many planned care services and the 18 projects that have been funded by the Planned Care Innovation Programme were successful in demonstrating how they could help with this transformation [8].

Llusern Scientific, along with other partners including EKF Diagnostics, Cwm Taf Morgannwg University Health Board (CTMUHB), Chronic UTI Campaign, PRIME Centre Wales, Trittech, Rhondda Urgent Primary Care Centre and the University of South Wales were successful

in securing funding to clinically evaluate the Llusern Scientific test. CTMUHB were the overall clinical lead for this project. The TriTech Institute were commissioned to investigate the potential clinical impact as part of this project.

### Llusern Scientific UTI test

Llusern Scientific, is a company based in Wales, who have developed a molecular testing platform and assay for the purpose of diagnosing UTIs at the point of care. The Llusern test was designed for use in primary and community care: anywhere that may benefit from point of care testing such as GP practices, high street pharmacies or care homes. This test is portable, can be used at the point of care and returns a result within 40 minutes.

The Llusern test consists of six molecular assays, which has been validated for the detection of specific uropathogens that relate to UTIs. The user is given a 'positive' or 'negative' result for each of the six pathogens tested for after the 40-minute test has completed. Llusern Scientific are currently going through the regulatory approval process for this test. Figure 1 shows the Llusern test, and appendix 1 shows the test procedure step-by-step.

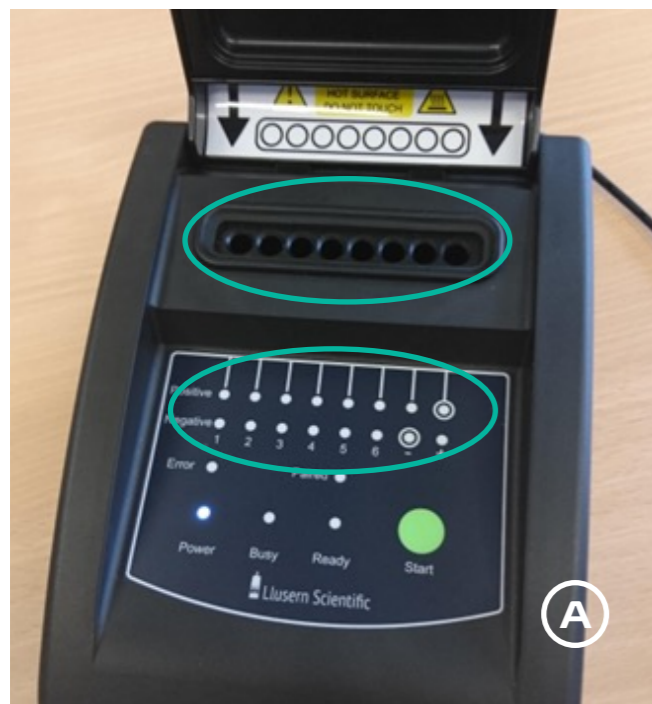


Figure A shows the Llusern test, with assay insertion area at the top and the 'positive' and 'negative' result display below it



Figure B shows the assay test tubes that hold a small amount of urine

## Methodology

### Evaluation Introduction

The TriTech Institute was commissioned to explore the potential clinical impact of the Llusern Scientific UTI test with primary, secondary and community care clinicians. The evaluation was carried out to understand the user needs and explore any potential barriers to adoption for clinicians relating to point of care devices for UTI testing.

The evaluation, used a mixture of questionnaires, focus groups and device demonstrations to explore the evaluation objectives (see below). Primary, secondary and community care clinicians were contacted through the health board and using the NHS Wales Global email system. A clinician invitation letter (Appendix 2) was sent out to interested participants, which detailed what they would be asked to do by being part of the evaluation. As part of the funding through the Bevan Commission's planned care innovation programme a £300 incentive was made available to participants who could attend the online focus groups.

### Recruitment

30 participants were recruited for the evaluation. All focus groups were conducted over Microsoft (MS) Teams outside of clinical hours. This report covers the evaluation period between 01/09/2022 and 30/04/2023.

### Evaluation Objectives

- 1. User device needs assessment** – To understand the key needs for clinicians who would foreseeably use a new point of care device for the purpose of UTI testing.
- 2. Clinical impact focus groups** – Explore the potential clinical impact of the Llusern test and a new point of care UTI test in general.
- 3. Device user feedback** – Obtain device focussed feedback from relevant clinicians about the Llusern test and its practical use for UTI testing.

### User device needs assessment (initial Questionnaire)

To understand the priority of needs for potential users of a new point of care UTI test, an online questionnaire was sent out to all 30 participants. This questionnaire can be seen in Appendix 3. Participants were also asked to state a job description and there was a free text box at the end of the questionnaire for feedback. The questionnaire in Appendix 3 was sent electronically to the participants in the first instance before receiving any information about the Llusern test, to keep the responses more specific to all point of care testing. This questionnaire had a range of questions relating to clinical accuracy and relevance, cost of procurement, ease of use and storage, maintenance, and safety of a device.

The data privacy teams at Hywel Dda University Health Board (HDUHB) were consulted about the participant recruitment process, no issues were found. Participants were informed in the clinician invite letter that all responses to the questionnaires and focus groups would be kept anonymous. Consent for data collection during the evaluation was also confirmed verbally at the start of each focus group.

### Clinical impact focus groups (Focus Group)

Focus groups with between 3 and 7 participants for each group were conducted for all 30 participants. The focus groups were structured around a list of guided topics (Appendix 4). For each of the questions asked, the participants were given time to provide answers and also to raise questions and have a discussion amongst themselves. These focus groups were recorded on MS Teams for transcription purposes. After the focus groups had taken place, the focus group recordings were reviewed to extract key themes and responses for each of the discussion topics. A proposed clinical pathway was provided by Llusern Scientific that could allow clinicians to consider the results of the test in a clinical context, this was used during the focus groups for feedback and can be seen in appendix 5.

## Device user feedback (Device Demonstration Questionnaire)

Two of the focus groups that took place during February 2023 also had an extended section at the end for a Lusern test demonstration. The test procedure outlined in Appendix 1 was demonstrated to the two focus who were able to view the procedure on screen and to ask questions during the demonstration.

For the device feedback from these two focus groups, the participants were requested to complete a questionnaire relating to the Lusern test demonstration (Appendix 6). The device user feedback included 7 statements with a Likert scale response (Strongly disagree to Strongly agree) with space to add comments against each of the statements and a space to include more general comments about the device.

## Results

### User device needs assessment

The 30 participants had a variety of different roles (Appendix 7) within healthcare but could be categorised into General Practitioner (GP), Pharmacist and Advanced Nurse Practitioner (ANP). The split for these roles can be seen in table 1.

Clinical profession	Number involved in evaluation
General Practitioner (GP)	13
Pharmacist	12
Advanced Nurse Practitioner (ANP)	5

Table 1 shows the split of clinical professions across the 30 participants

Appendix 8 shows a number of pie charts for the responses to the 16 user needs by all 30 participants. These pie charts are used as a visual representation of the responses and indicate that all the user needs presented were deemed important, very few needs were

labelled as 'not important' by the participants. Appendix 9 shows the user needs scores for the whole group and the additional feedback they provided can also be seen in appendix 10.

Using the scoring system, it was possible to rank these needs to understand which ones had a higher overall priority. Appendices 11, 12 and 13 show the scores for the user needs in relation to the GPs, Pharmacists and ANPs respectively. The order from most (1st) to least (16th) importance for these user needs can be seen in table 2. The user needs in table 2 have been arranged by scores from the whole group, but the importance is also ranked for the three professions in the same table for comparison.

Each of the 16 questions asked for the user needs assessment (Initial Questionnaire) (Appendix 3) were scored between 1 (Not important at all) to 5 (Very important). Using these scores, it was possible to count a total for each question across all participants in order to rank the needs from highest (1st place, most cumulative points across all participants) to least (16th place, least cumulative points) importance as seen in table 2. The scores per question and overall placement can be seen in Appendix 9.

There were some small differences between clinical professions in terms of priority of user needs for potential new point of care devices for UTI testing. However, there was an overall consensus that reliability, performance, and relevance of the test results were the most important factors, with ease of storage, portability and environmental considerations being seen as generally less important. The ease of procurement was rated higher by the Pharmacists and GPs compared to the ANPs. This may be due to practices and high street pharmacies needing to purchase these devices whereas a nurse may be utilising existing health board equipment, or the nurses not being as involved in the overall procurement process.

All of the user needs were scored as important to most participants, the ranking of these may prove useful for future design and development considerations of the device.

User need	Whole group	GPs	Pharmacists	Nurses
Confidence in the results over time (reliability of test)	1st	2nd	1st	1st
Clinical performance (accuracy of results)	2nd	1st	4th	1st
Relevance of the result to treatment or prescription decisions	3rd	4th	2nd	3rd
Can be used outside of the laboratory environment (being able to use in your usual place of work)	4th	6th	2nd	3rd
Safety of the user whilst operating the test	5th	3rd	5th	6th
How quickly the result is obtained	6th	7th	5th	3rd
Affordability	7th	7th	8th	6th
How easy the test is to use	8th	4th	10th	8th
Ease of procurement on the NHS	8th	7th	5th	12th
Easy to clean and disinfect	10th	12th	9th	8th
Easy to maintain (Low maintenance requirements)	10th	11th	10th	8th
How easy the results are to interpret (If the user needs additional knowledge to interpret)	12th	10th	12th	8th
Environmentally considerate in production and use (Green initiatives)	13th	13th	16th	12th
Connectivity of the test to digital systems (existing infrastructure or systems within your practice)	14th	14th	12th	14th
Portability of the test	15th	15th	12th	15th
How easy it is to store	16th	15th	15th	16th

Table 2 shows the order of importance for the user needs for the whole group, GPs, Pharmacists and ANPs

The final section of this questionnaire (Appendix 3) was a free text box for comments, the clinical responses to this section can be seen in Appendix 10. The comments written in this free text section can be summarised as:

- Questions about training requirements for staff to use the device or test.
- Any new test would need to be better than existing methods (faster than requesting MSU, or more accurate than the dipstick).
- The storage space and cost requirements would be a factor in adoption and use of a new device or test.
- Ease of procurement for a new test or device.

### Clinical impact focus groups

The questions listed in appendix 4 were used for each of the six focus groups conducted. The responses and discussion points for each of the questions were pooled together across focus groups due to common themes displayed

in each. The common themes from the focus group discussions can be found in appendices 14 for section 1 (current practice), 15 for section 2 (guidelines) and 16 for section 3 (POC tests). The themes in this appendix are an amalgamation of responses and not direct quotes from participants. Appendix 17 also contains themes that formed part of the additional comments and closing of each of the focus groups.

Due to large amount of feedback for each of the questions asked during the focus groups (including the additional comments), the response themes were grouped together into key challenges and opportunities for point of care UTI tests. These challenges and opportunities have been divided into areas of focus and whether they relate to the Lusern device specifically or all potential POC tests. The results from the focus groups were divided into challenges and opportunities and focused on the 4 topics of: Infrastructure, Technology, Staff and Patients.



## Challenges

Key challenges	Area of focus	Device specific or all POC?
Suspected UTIs are treated primarily on symptoms, testing is usually done only when there is a particular need and an MSU is typically preferred where possible because of the value of the sensitivity and specificity results.	Infrastructure	All POC
Covid-19 has changed clinical practice in community and primary care, less face-to-face clinics for UTIs are conducted, so a bigger focus is currently on empirical treatment of presenting symptoms and less on testing.	Infrastructure	All POC
Current guidelines for suspected UTIs are followed closely by most clinicians, any device or test would need to be included in these guidelines for successful adoption. Although, little evidence currently exists to show how compliant primary and community care providers are with these guidelines.	Technology	Llusern
There are concerns about adopting new testing technologies and methods, more information is required in terms of how it would fit into daily clinical practice. This how new results should be interpreted in reference to clinical decision making.	Technology	All POC
There are cost considerations for any new test, currently GPs and Pharmacists can claim back costs for certain tests. Surgeries and high street pharmacists would be hesitant to pay for a new device or test without support or knowing there would be cost savings in other areas.	Technology	Llusern
There are a large number of patients that need testing and there is a time limit for GP and pharmacist consultations. The 40-minute time to test for Llusern may cause additional complications and require follow ups.	Technology	Llusern
E. coli is commonly tested for, but this does not always give a good indication of antibiotic requirements for the patient. The pathogens that are tested for would need to be carefully selected to ensure validity of results.	Technology	All POC
The patient history and presenting symptoms are very important to treatment decisions, any new device would still need to be interpreted by someone with clinical knowledge to avoid inappropriate antibiotic prescription.	Staff	All POC
Antimicrobial pharmacists report that some primary care clinicians request an MSU test for UTI without attaching a proforma of symptoms. This kind of request is sent back because there is a risk of inappropriate prescribing.	Staff	All POC
Contamination of urine samples negatively affect dip stick and MSU results, this is currently difficult to assess before testing. This includes contaminated samples and not having a 'mid-stream' sample.	Patient	All POC

Table 3 shows the key challenges that relate to adoption of point of care tests for UTI, based on feedback from the clinical impact focus groups

## Challenges summary

### Infrastructure

A number of potential challenges were identified for any new device or technology in UTI testing during the focus group discussions. These challenges would be faced by any new test on the market and not just Llusern specifically. One significant barrier is adherence to already established clinical guidelines by clinicians who treat UTI, any acceptance or use of a new device would require amendment to the current

guidelines to include these devices. Any device or test placed onto the market would need to be incorporated into the procedures so that a clinician using it knows how to interpret the result in relation to any relevant national guidelines. An example guideline document was presented to participants (Appendix 5) during the clinical focus groups, which proposed a way to incorporate the Llusern test. The feedback to this proposed

guideline was that it could potentially create extra steps in the patient pathway and an MSU may still be requested, with no resources saved.

Other key challenges for any new UTI test relate to the current shift away from testing entirely. Covid-19 had an impact on services that resulted in more virtual clinics being conducted over the phone and remotely. Symptoms are now routinely used for treatment decisions, rather than UTI testing. The Welsh Microguide and other national guidelines recommended empirical treatment on symptoms themselves instead of dipstick testing. Any new device or test for use with UTI would need to show added value in the clinical decision-making process.

### Technology

There are some concerns regarding the cost of any new device and its consumables. GP practices and pharmacies are able to claim reimbursement from local health boards for certain tests and procedures they carry out. Any new test that is available for UTIs would need to be either financially supported by the

health board in some way or have evidence of cost savings in other areas to make it appealing to high street pharmacies and GP practices.

The only challenge that the Llusern test (specifically) may face is the time taken to produce a result, which is currently 40 minutes. GPs and Pharmacists only have small time windows to meet with patients and make clinical decisions, with pharmacists typically having 20-minute consultation windows and GPs getting as little as 5 minutes with a patient. The tests could be done by a HCA or other staff member, but a knowledgeable clinician may still need to review the result. More information would be needed in order to understand how to best overcome this challenge.

### Staff

Clinical knowledge would still be required for the test, as even if conducted by a health care assistant (HCA) the results would need to be considered against presenting symptoms and other risk factors.

## Opportunities

Key challenges	Area of focus	Device specific or all POC?
Health board Pharmacists report that a high amount of dipstick overuse is with in-patients on Hospital wards, there may be an opportunity for a new POC test in these areas. More exploration is required.	Infrastructure	All POC
The Llusern test may be beneficial for care providers who have to travel across multiple community care sites where dropping urine samples off for testing is not feasible, this could also include care homes.	Infrastructure	All POC
Being able to get a definitive negative results for a range of pathogens could be very reassuring for both clinicians and patients. This would require further validation, but the Llusern test may be useful for ruling out the need for an antibiotic prescription or requesting an MSU test.	Technology	Llusern
It is suggested that there is an element of subjectivity for dipstick testing, the Llusern device may reduce this subjectivity. Evaluation of new test against dipstick results may show added value.	Technology	All POC
Dipstick urine tests may show a positive response to a pathogen if the sample is contaminated, if Llusern was shown to reduce this error it would show added value over dipstick testing.	Technology	Llusern
The Llusern test may have value with detecting other pathogens or biomarkers, such as throat cultures for strep A, or sexually transmitted infections. But this would require further testing and validation.	Technology	Llusern

Table 4 shows the key opportunities that relate to adoption of point of care tests for UTI, based on feedback from the clinical impact focus groups



## Opportunities summary

### Infrastructure

There were some suggestions of other areas the Llusern Test could be evaluated in, such as within care homes or patient areas that are rural in nature and far away from Hospitals or lab-based testing facilities. The ANPs who were involved in community work reported that they regularly need UTI testing for care home residents where an MSU would not be able to provide a result for many days. The community based ANPs also reported having to travel distances between care homes and that it would be unfeasible to drop urine samples off at suitable locations for the MSU, indicating the Llusern test may be beneficial for use in community care.

### Technology

The potential for the Llusern test to provide a negative result for a number of pathogens was seen as a strong use case. GPs and Pharmacists discussed the fact that many patients will request antibiotics when asymptomatic and it was not uncommon to have repeat requests from some patients. Being able to use the Llusern test to rule out pathogens and provide patients with

feedback to alleviate anxieties would be very beneficial. This type of use case for the test may prevent the need for an MSU test in some cases. This would need validation in a real-world context because there remains the potential for false positives in poor quality urine samples.

Other suggestions for the Llusern technology from the focus groups, was for the adaption of the technology for detecting other biomarkers, such as throat cultures for Strep A or as a screening tool for sexually transmitted infections (STIs). These suggestions for using the test for other conditions would require more clinical testing so may not be suitable for a short-term goal.

Dipsticks are also reported to have subjectivity and ambiguity, so the Llusern test could also be evaluated to explore any increased reliability of results when compared to the dipstick test. Contamination of urine samples is a key challenge for all UTI tests, including MSU. If the Llusern test was able to show an improvement over other methods like the dipstick test, such as a reduced false positive rate, then this would show added value.

## Device user feedback

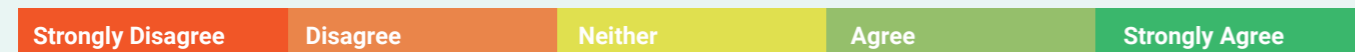


Figure 2) shows the Likert scale response key for the device user feedback questions

### Question 1 - The test is easy to use

Participants generally agreed that the test seemed easy to use, although concerns were raised about the potential for sample contamination whilst performing all the sample preparation steps for the test. One participant commented that they would require hands on testing with live samples to get a clearer understanding of the ease of use with the test before they could give proper feedback. Two participants commented that they thought this was too complicated.



Figure 3) shows the Likert scale response frequency for user feedback question 1

### Question 2 - The test is portable enough for non-laboratory use

All participants agreed or strongly agreed that the Llusern test would be portable enough for use outside of a laboratory. No other feedback given for this question.



Figure 4) shows the Likert scale response frequency for user feedback question 2

### Question 3 - The results are easy to interpret

The participants commented that more information would be required to understand if the results would be easy to interpret. Factors such as pathogens tested, labelling of the device and relevance of positive and negative result per pathogen tested would impact on the interpretation. Hands on testing with live samples in a 'real-world' context would help participants answer this question in future.

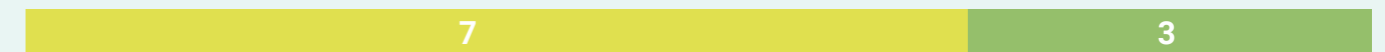


Figure 5) shows the Likert scale response frequency for user feedback question 3

### Question 4 - The costs of the test are a concern for me

All participants, (except for one) agreed that costs of the Llusern test and the associated consumables would be a concern for them. GPs and Pharmacists can claim reimbursement from the health boards for some tests and procedures. If the Llusern test was incorporated into the health board with some financial support, then using the test would be more feasible. Smaller high street pharmacies and GP practices may struggle to pay for a new device and consumables without clear evidence of cost savings in other areas. There was one question regarding the amount of clinical waste that might accumulate across many tests if the plastic parts are hard to clean.



Figure 6) shows the Likert scale response frequency for user feedback question 4

### Question 5 - The test samples are easy to set up

Only two participants thought the samples would be easy to set up. Similar to comments received during question 1, participants focused on the number of steps required to transfer the urine from a sample into the test assays, and that it could be difficult to set up. It was mentioned that a pipette may be easier to use for the transferal steps, but there was a high degree of worry around contamination of the sample with the steps suggested. There was one concern from a participant that the grey 3D printed plastic parts might break easily but that it would require some hands-on testing with live urine samples.

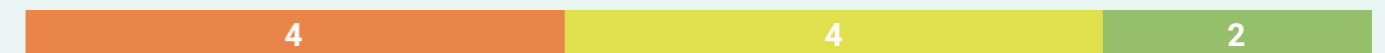


Figure 7) shows the Likert scale response frequency for user feedback question 5

### Question 6 - The consumables would be easy for me to store

Six participants agreed that the consumables would be easy to store, commenting that they seemed small enough not to be a concern. The one participant who disagreed with this statement worked in a high street pharmacy and said that storage space for consumables and clean sterile desk space for such a test would be at a premium. Smaller GP practices and pharmacies might struggle more to store the consumables. One participant commented again on the potential clinical waste in plastic parts cannot be cleaned effectively.



Figure 8) shows the Likert scale response frequency for user feedback question 6

### Question 7 - The results would have clinical value to me

All participants indicated an uncertainty about the clinical value of the results. Not enough is known at this stage about how the results would be interpreted and how it might fit into current clinical guidelines. GPs, Pharmacist and ANPs all follow the guidelines and recommendations for UTI testing. Any new test method would need a consensus on how it would fit into the patient pathway most effectively. This is an issue that all new devices and test methods for UTI will likely face.

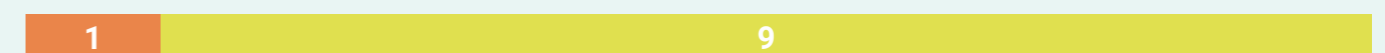


Figure 8) shows the Likert scale response frequency for user feedback question 6

# Conclusions

## Infrastructure

Current guidelines and clinical practice for suspected UTIs are focussed on empirical treatment of presenting symptoms. Microbiology labs in Wales will not test for UTI with samples that do not include a proforma of presenting symptoms, and the Micro guide Wales guidance also describes a symptoms-based approach to testing. The Covid-19 pandemic also had an effect on testing frequency as more clinics were conducted virtually using a symptom-based approach.

Treatments with a focus on symptoms rather than testing is undertaken to avoid unnecessary prescriptions, any new POC test would need to demonstrate clinical or health economic benefits to support adoption. The Llusern test would produce results that current POC methods do not, so further validation is required to understand how it would fit into the current guidelines and practice.

There are also financial implications of the Llusern test (or any new POC); the test might not be financially viable for GP practices and high street pharmacies if it is more expensive than a dipstick test. Understanding potential financial support from the health boards or being able to demonstrate cost savings in other areas will be priority research areas for any new POC UTI test.

Feedback from staff involved in this evaluation suggests that the Llusern test could be beneficial in community care settings where Hospitals and testing locations for urine samples are not close enough for routine drop offs. Weekend and out of hours testing where an MSU request would be impractical could also present opportunities for the Llusern test.

## Technology

Consultation times and contact frequency with patients are a limiting factor for GPs and Pharmacists. The Llusern test could take up to 40 minutes to return a result which means patients will either be waiting or need to return for a prescription if one is required. The number of transferal steps required between the urine sample and the Llusern test device could increase contamination risk, and this was an additional

concern for participants. Real-world testing would be required to assess how practical the test would be in a range of clinical scenarios.

Feedback from clinicians suggests that any new test or device for UTI testing would need to either provide the sensitivity and specificity results of an MSU test in a reduced time or offer clear benefits over existing POC methods. The dipstick test is shown to be unreliable, have a high false positive rate and can have ambiguity in the results, these are areas the Llusern test could improve upon in clinical practice.

Being able to show a negative result for a number of pathogens was identified as a potential use for the Llusern test. Feedback from clinicians indicate that some patients insist on antibiotics or know which symptoms to mention on a proforma to get a prescription they think they need. Being able to present a negative result for a range of pathogens without the need for an MSU test could provide additional reassurance for clinicians and patients.

## Staff

The Llusern test may prove to reduce ambiguity in results when compared to standard urine tests, but feedback from the focus groups suggest that clinical expertise would still be required to avoid inappropriate prescriptions for antibiotics. Clinical guidelines require the inclusion of a proforma of symptoms to be included with the MSU test requests, but microbial pharmacists report that not all clinicians follow this requirement. More research to identify how frequently guidelines are overlooked may help understand how new tests or devices could help with compliance.

## Patient

All clinicians involved in this evaluation reported a high rate of poor sample quality from patients. This includes contaminated or inappropriate containers, which if tested are more likely to show a false positive for infection. Patients are requested to provide new samples if contamination is obvious, but some patients may not understand how to collect a urine sample that is 'mid-stream' which can also affect the results. There is an opportunity for the Llusern test to demonstrate improvements over standard dipstick tests when considering poor quality samples.

# Recommendations

As a result of this evaluation, several recommendations relating to potential next steps for the Llusern test have been identified. These recommendations relate to the feedback from all clinicians who participated in the questionnaires and focus groups.

## Recommendation 1: Engagement with policy makers to understand how new UTI tests might be implemented

There is a range of guidance including SIGN, NICE, and Public Health Wales microbiology guidelines, all of which have a focus on the symptoms, with clear steps and advice on how to treat. More work is required to understand how the results from a new test could support these guidelines. Any new UTI test on the market will face challenges with wide scale adoption as the clinical guidelines would not offer guidance on how to interpret the results. Engagement with Public Health Wales, and policy makers in the health boards would be required to understand what would be required for any potential adoption. This would be a good first step, as it could influence next steps in the innovation pathway and further research and evaluation projects. This work would identify the key barriers to adoption and acceptance of any new POC device and what evidence policy makers would require prior to adoption.

## Recommendation 2: Real-world evaluation in clinical environments

Feedback in relation to the Llusern test indicated that there were some concerns with transferal steps for the urine and potential for contamination. Real-world testing in a range of clinical environments will provide insights on the practicality of the test in primary and community care. As part of this real-world evaluation, data could also be collected on the potential clinical application of having a negative result for a range of pathogens which was identified as a use case for the Llusern test.

## Recommendation 3: Direct comparison against dipstick tests to show improvements

Dipsticks are reported to have ambiguity in results and low-quality urine samples from patients can negatively affect all UTI tests. A head-to-head direct comparison between the Llusern test and dipstick test may show an improvement in reliability and/or a reduced false positive rate for contaminated samples. Evidence of these improvements could support the adoption of the Llusern test, this would require paired testing of a range of samples to quantify any improvements.

## Recommendation 4: Evaluation in a community care setting

Community care was identified as a potential use case for the Llusern test because of its portability. Nurse practitioners working across sites and in care homes may have less restrictions on time in some cases, unlike GPs or pharmacists who have a limited window per patient. An evaluation in a community care setting, such as a residential care home or with nurses who visit them may provide evidence for a use case for the Llusern test.

## Recommendation 5: Exploring other uses of the test

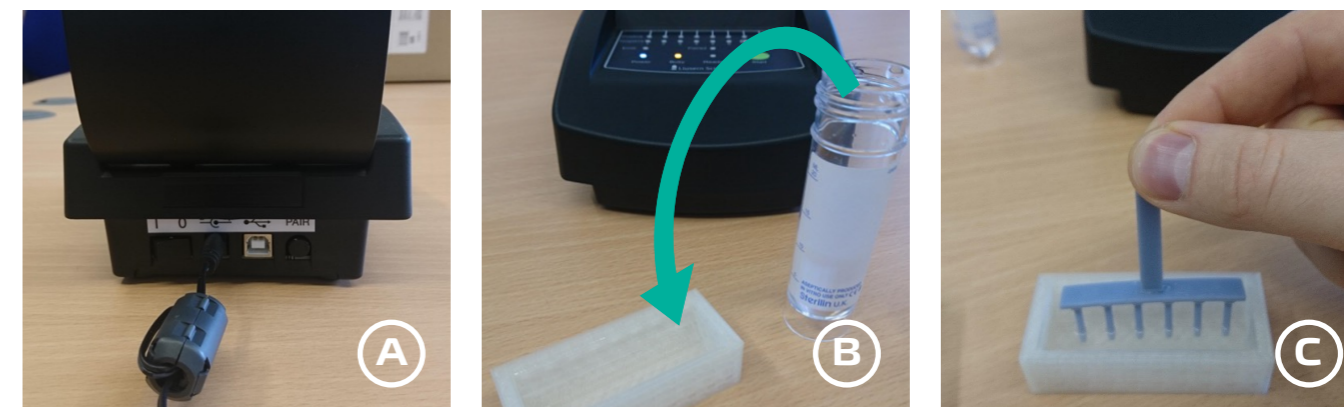
Feedback from clinicians involved in this evaluation indicated that the test may be useful for other clinical scenarios such as throat cultures for Strep A and STIs. This may be a lower priority focus for Llusern, but the portable nature of the test and range of pathogens that it can predict at one time could provide other beneficial use cases.



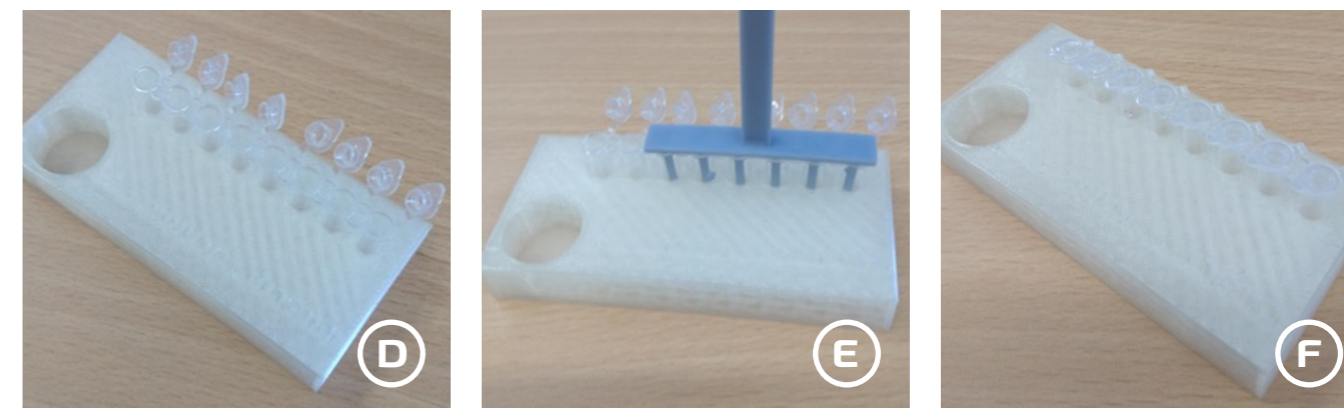
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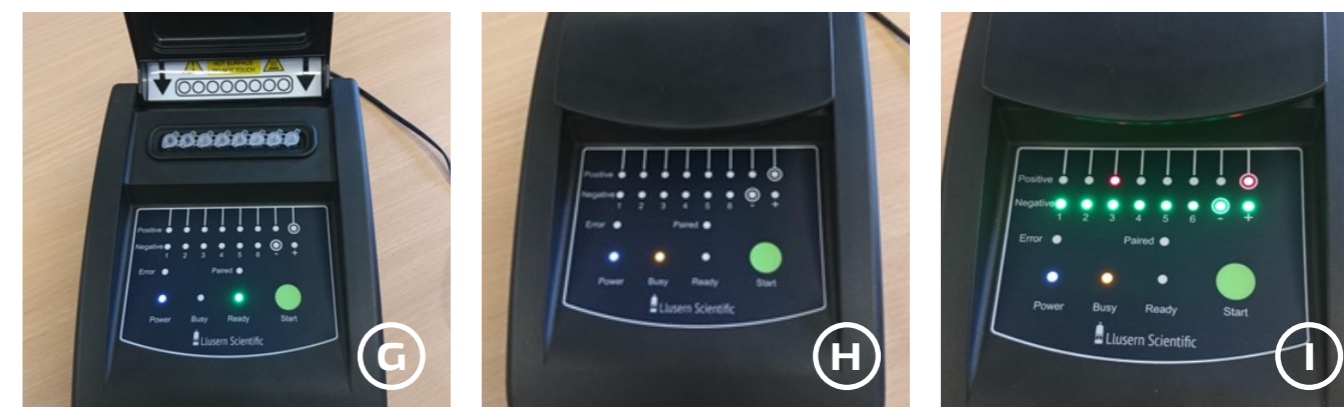
## Appendix 1 – Llusern test procedure



Ⓐ shows the Llusern test, with power cable going into the back of the device. The On/Off switch is also at the back. Once the device is turned on it needs time to warm up to a temperature ready for testing. Ⓑ shows a urine sample pot, for this testing procedure, some of the urine is poured into a container. Ⓒ shows a dipstick array used to collect a specific amount of the urine.



Ⓓ shows the test assay in a holder, with each of the lids open. Ⓔ shows the dipstick array with the prongs in the test assay tubes, not two are left empty as a control check in the Llusern test device. Ⓕ after a small amount of urine has been transferred to the test assay the lids need closing so it is ready for the Llusern test.



Ⓖ shows the Llusern test with the assay inserted. Ⓗ with the assay inserted the lid of the Llusern test is closed and the device will analyse over a 40-minute period. Ⓘ once that time has passed a result is seen on the display, there will be a green (negative for pathogen) or red (positive for pathogen) for each of the six assays with urine inside, there will be 1 green and 1 red on the right of this display for control checks.





## Appendix 2 – Clinician invitation letter



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### UTI Focus group invitation letter

We would like to invite you to take part in a 90-minute focus group which will be conducted out of office hours. This focus group will relate to current practice for urinary tract infections (UTIs) in primary care.

The TriTech Institute which is a part of Hywel Dda University Health (HDUHB) board are conducting a qualitative analysis of a device which can test for UTIs at the point of care (POC). The focus group aims to get clinician feedback about the current practice for UTI testing and how such a POC test would impact the patient pathway.

The device, which is currently undergoing its MHRA regulatory approval, is in no way endorsed by TriTech or HDUHB at this stage and all feedback provided regarding such a device will be anonymous. We are looking for honest feedback from those with relevant experience as part of a wider clinical evaluation for this device's regulatory approval.

There are incentive payments of £300 for participants that are able to attend one of the focus groups. These incentive payments will be transferred from Hywel Dda finances to your practice directly for including into your wages. Before you attend the focus group you will also be sent a short questionnaire regarding user needs for point of care tests.

**If you would like to participate and want to know when the focus groups will be, or if you have any questions, please contact us:**

Name: Billy Woods  
Role: Clinical Scientist  
Site: TriTech Institute  
Email: [billy.wood@wales.nhs.uk](mailto:billy.wood@wales.nhs.uk)

Name: Michelle Jones  
Role: Administrative Assistant TriTech Institute  
Site: TriTech Institute  
Email: [michelle.jones43@wales.nhs.uk](mailto:michelle.jones43@wales.nhs.uk)

## Appendix 3 – User needs assessment



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Hywel Dda  
University Health Board



Name..... Job Description.....

### User needs assessment for POC UTI Device

Considering a device that could test for urinary tract infections (UTI) at the point of care (POC), could you please score each of the following device categories with regards to how important they would be to you. Think about it in the context of you considering buying such a device for use in your practice.

#### 1. How quickly the result is obtained

Not important at all					Very important
1	2	3	4	5	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

#### 2. Ease of use

Not important at all					Very important
1	2	3	4	5	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

#### 3. Portability of device

Not important at all					Very important
1	2	3	4	5	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

#### 4. How easy the results are to interpret (if the user needs additional knowledge to interpret)

Not important at all					Very important
1	2	3	4	5	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

#### 5. Connectivity of the device to digital systems

Not important at all					Very important
1	2	3	4	5	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

#### 6. Affordability

Not important at all					Very important
1	2	3	4	5	
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**7. Clinical performance (accuracy of results)**

Not important at all				Very important
1	2	3	4	5
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**8. Safety of device**

Not important at all				Very important
1	2	3	4	5
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**9. Confidence in the result (reliability)**

Not important at all				Very important
1	2	3	4	5
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**10. Can be used outside of the laboratory environment**

Not important at all				Very important
1	2	3	4	5
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**11. Environmentally considerate in production and use (Green initiatives)**

Not important at all				Very important
1	2	3	4	5
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**12. Easy to clean/disinfect**

Not important at all				Very important
1	2	3	4	5
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**13. Easy to maintain**

Not important at all				Very important
1	2	3	4	5
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**14. How easy it is to store**

Not important at all				Very important
1	2	3	4	5
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**15. Relevance to treatment decisions**

Not important at all				Very important
1	2	3	4	5
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**16. Availability of purchase (ease of procurement)**

Not important at all				Very important
1	2	3	4	5
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you have any comments for any of the above device properties, please write below:

**This questionnaire can be scanned and sent to the following contact. And if you have any questions or comments, please contact:**

Name: Billy Woods  
 Role: Clinical Scientist  
 Site: TriTech Institute  
 Email: [billy.wood@wales.nhs.uk](mailto:billy.wood@wales.nhs.uk)

## Appendix 4 – Focus group questions

### Introductions and current roles of participants

- Can you introduce yourself and briefly explain where you work?

### Current practice and experience with UTI testing in your clinical practice

- What can you tell me about current best practice with suspected UTIs in primary care?
- What typically happens with patients in your practice when they present with UTI symptoms?
- How do you currently decide if a patient requires either a urine test or antibiotics for a suspected UTI?
- What are your thoughts on existing diagnostic options for UTIs?

### Current guidelines and other regulations for UTI tests

- What guidelines do you currently follow for UTI tests in your practice? What are your thoughts on those guidelines?
- Do these differ at all between health boards / practices?

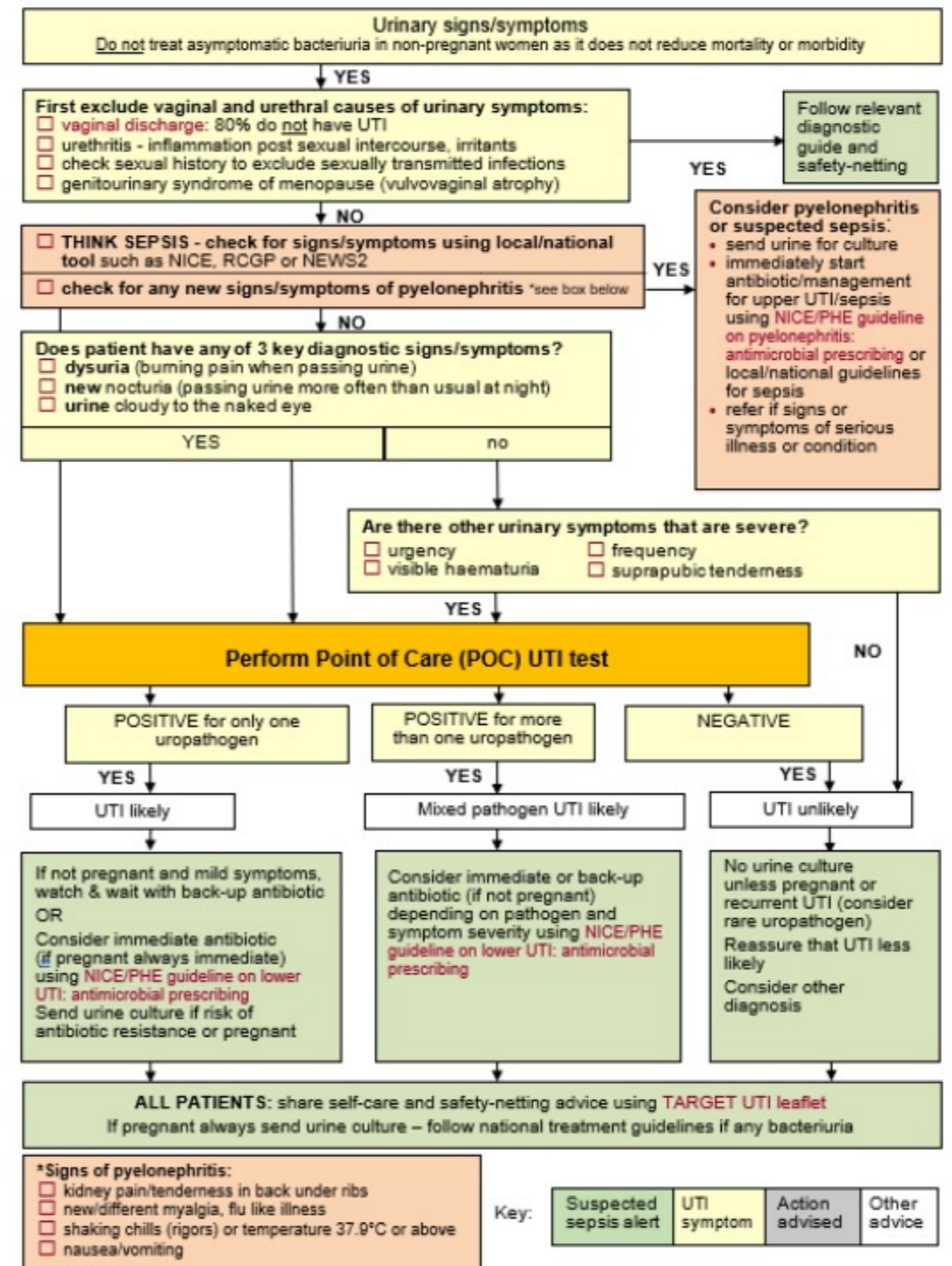
### POC testing implications for UTIs

- What are your opinions around the potential use of POC tests for UTIs?
- If there was a POC test for UTI on the market that could tell you the causative pathogen in 30 minutes and didn't need to go to a lab, in which circumstances would you use it? (eg for all UTI suspected patients, for recurrent UTI patients etc etc)
- Page 2 shows current PHE guidelines for the diagnosis of uncomplicated UTIs in women under the age of 65 and Page 3 shows the same guidelines with the insertion of a new test to guide treatment decisions at POC without needing to first wait for lab results. Would such a POC test for UTI have any impact on your current clinical practice?
- What might you be able to change in your practice with such a test?
- What kind of costs would be acceptable for this?
- Anyone interested in hands on testing with the device?

### Any other comments?



## Appendix 5 – Focus group UTI flow chart





# Appendix 6 – Device user feedback questionnaire



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## Llusern Scientific UTI Test – User feedback

For this questionnaire could you please rate the Llusern Scientific UTI test against each of the following statements. There is a box below each category for any additional comments you may have.

### 1. The device is easy to use

Strongly disagree    Disagree    Neither agree nor disagree    Agree    Strongly agree

Additional comments here

### 2. The test is portable enough to be used outside of a laboratory setting

Strongly disagree    Disagree    Neither agree nor disagree    Agree    Strongly agree

Additional comments here

### 3. Test results are easy to interpret

Strongly disagree    Disagree    Neither agree nor disagree    Agree    Strongly agree

Additional comments here

Ver 1

26/08/2022



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University Health Board



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SERBUOD I'N FECTO

### 4. The cost of the device and/or consumables is a concern for me in primary/community care

Strongly disagree    Disagree    Neither agree nor disagree    Agree    Strongly agree

Additional comments here

### 5. The test samples are easy to set up

Strongly disagree    Disagree    Neither agree nor disagree    Agree    Strongly agree

Additional comments here

### 6. The test consumables are easy to store in a primary care setting

Strongly disagree    Disagree    Neither agree nor disagree    Agree    Strongly agree

Additional comments here

Ver 1

26/08/2022



**7. The results from the test would be valuable to my service/practice**

Strongly disagree   Disagree   Neither agree nor disagree   Agree   Strongly agree

Additional comments here

If you have any additional comments about the Llusern Scientific UTI test or how it could or should be used in primary care, please input below. Thank you.

**This questionnaire can be scanned and sent to the following contact. And if you have any questions or comments, please contact:**

Name: Billy Woods  
 Role: Clinical Scientist  
 Site: TriTech Institute  
 Email: [billy.wood@wales.nhs.uk](mailto:billy.wood@wales.nhs.uk)

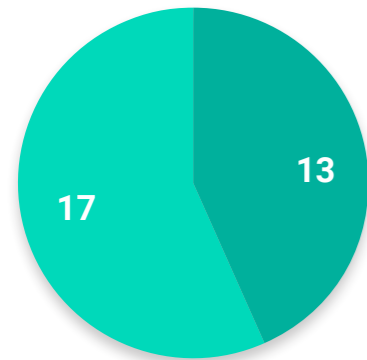
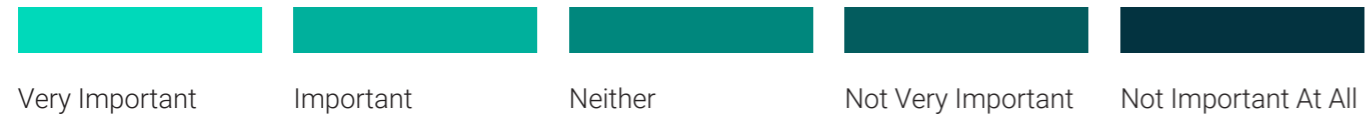
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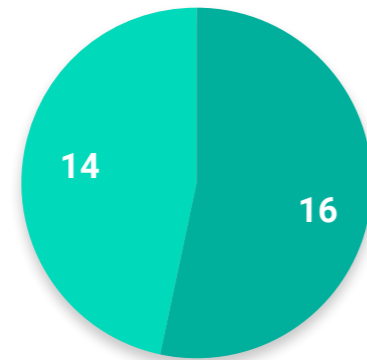
## Appendix 7 – Participant job titles

ID	Please state your job title
1	GP
2	GP
3	GP
4	GP
5	GP
6	GP
7	GP
8	Trainee independent prescribing pharmacist
9	Advanced Pharmacist - Community & Practice development
10	Independent Pharmacist Prescriber
11	GP
12	GP
13	Advance Nurse Practitioner
14	Pharmacist (community)
15	Antimicrobial pharmacist
16	Pharmacist
17	GP trainee
18	Pharmacist
19	GP
20	Prescribing Advisor Pharmacist / Practice Pharmacist
21	Community Pharmacist Manager
22	Prescribing Advisor pharmacist
23	Advanced Nurse Practitioner
24	Pharmacist Prescriber, Community pharmacy based
25	Senior Nurse Infection Prevention Community
26	GP
27	Lead Advanced Nurse Practitioner for Primary Care
28	Pharmacist
29	Advanced Nurse Practitioner
30	SGP

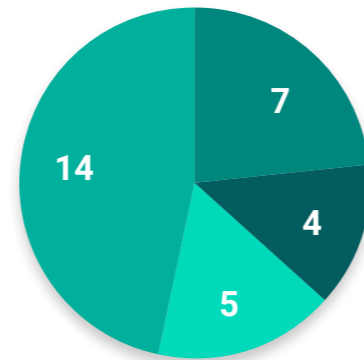
## Appendix 8 – User needs feedback (Whole group, pie charts)



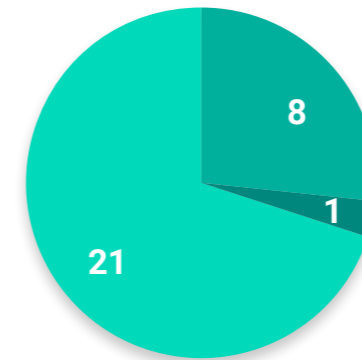
How quickly the result is obtained



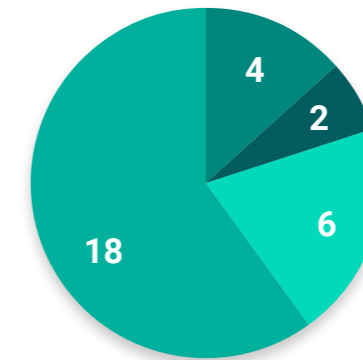
How easy the test is to use



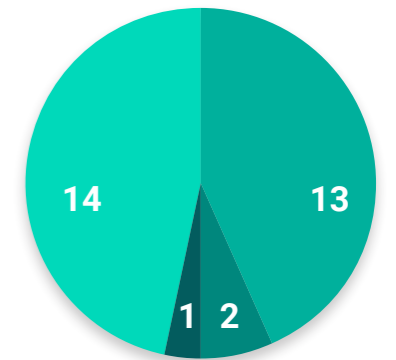
Portability of the test



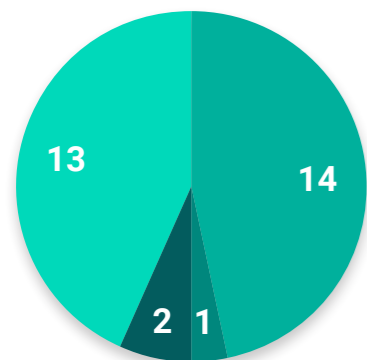
Can be used outside of the laboratory environment



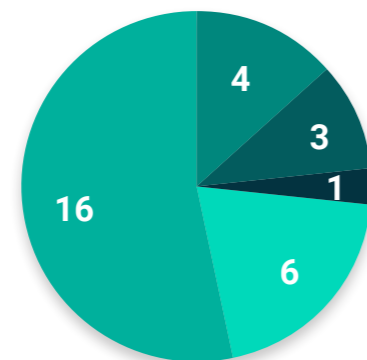
Environmentally considerate in production and use



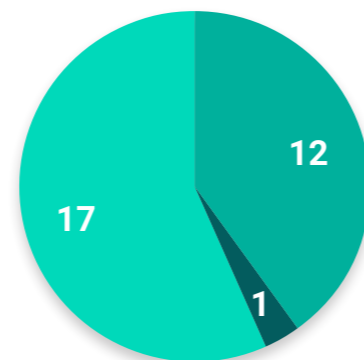
Easy to clean and disinfect



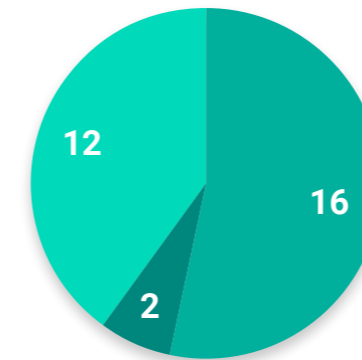
How easy the results are to interpret



Test connectivity to digital systems



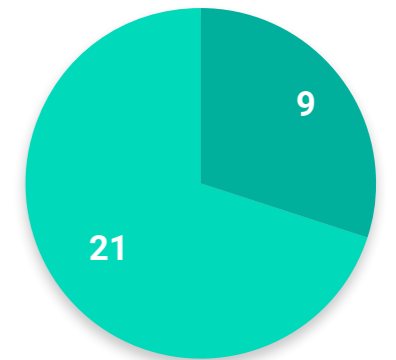
Affordability



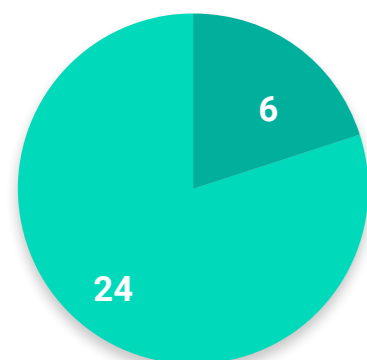
Easy to maintain



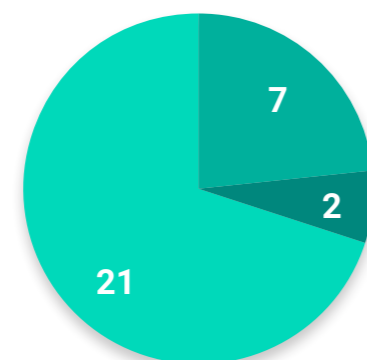
How easy it is to store



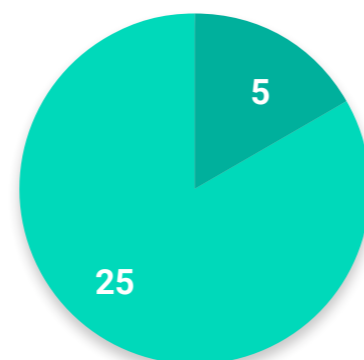
Relevance of the result to treatment or prescription decisions



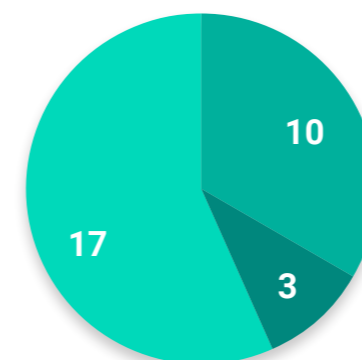
Clinical performance



Safety of the user whilst operating the test



Confidence in the results over time



Ease of procurement on the NHS



## Appendix 9 – User needs feedback (Whole group scores, 30)

How quickly the result is obtained	How easy the test is to use	Portability of the test	How easy the results are to interpret (If the user needs additional knowledge to interpret)	Connectivity of the test to digital systems (existing infrastructure or systems within your practice)	Affordability	Clinical performance (accuracy of results)	Safety of the user whilst operating the test
137	134	110	128	113	135	144	139
6th	8th	15th	12th	14th	7th	2nd	5th

Confidence in the results over time (reliability of test)	Can be used outside of the laboratory environment (being able to use in your usual place of work)	Environmentally considerate in production and use (Green initiatives)	Easy to clean and disinfect	Easy to maintain (Low maintenance requirements)	How easy it is store	Relevance of the result to treatment or prescription decisions	Ease of procurement on the NHS
145	40	118	130	130	106	141	134
1st	4th	13th	10th	10th	16th	3rd	8th

## Appendix 10 – User needs feedback (Whole group, comments)

- Ideally the test that is being discussed should be "better" than the existing system used. In this case, "better" means that a result is obtained more quickly than sending an MSU to the lab or is more reliable / provides more information than a urine dipstick. It should be able to do these things in a manner that is cost-effective for the NHS and should be relatively easy to use so that negligible additional labour or skills are required.
- Ideally would need to be suitable for operation by an HCA/Nurse with ease of interpretation for a wide variety of doctors/trainees from F2 level to GP principles. Ability to consistently interpret by all.
- Currently run Uncomplicated UTI enhanced service, rely on symptoms to determine decision and urinalysis if needed. New test introduction to aid decision making would be welcome.
- I would assume the test would not be stored away but placed somewhere where there was easy access for all clinicians to use. The size of the test would also be a consideration as finding a place for it to be placed would be difficult if it was a large, bulky item.
- Q5 - I would expect that staff would be trained in the interpretation of results and management of those results.
- Being over half an hour from either hospital with only one collection a day (lunch time) for samples, the ability to get a result in the same day would be very beneficial.
- I think the most 4 points are, that the test is easy to get/order (and is not too expensive), that it is not complicated to work , that cleaning is easy and environmentally acceptable (sustainable and biodegradable material should be used for the test and its attachments) - and that the results are accurate and reproducible e.g. the device reliably tests what it is supposed to test.

## Appendix 11 – User needs feedback (GP scores, 13)

How quickly the result is obtained	How easy the test is to use	Portability of the test	How easy the results are to interpret (If the user needs additional knowledge to interpret)	Connectivity of the test to digital systems (existing infrastructure or systems within your practice)	Affordability	Clinical performance (accuracy of results)	Safety of the user whilst operating the test
59	61	45	59	47	59	64	62
7th	4th	15th	10th	14th	7th	1st	3rd

Confidence in the results over time (reliability of test)	Can be used outside of the laboratory environment (being able to use in your usual place of work)	Environmentally considerate in production and use (Green initiatives)	Easy to clean and disinfect	Easy to maintain (Low maintenance requirements)	How easy it is store	Relevance of the result to treatment or prescription decisions	Ease of procurement on the NHS
63	60	54	56	57	45	61	59
2nd	6th	13th	12th	11th	15th	4th	7th

## Appendix 12 – User needs feedback (Pharmacist scores, 12)

How quickly the result is obtained	How easy the test is to use	Portability of the test	How easy the results are to interpret (If the user needs additional knowledge to interpret)	Connectivity of the test to digital systems (existing infrastructure or systems within your practice)	Affordability	Clinical performance (accuracy of results)	Safety of the user whilst operating the test
54	51	47	47	47	53	55	54
5th	10th	12th	12th	12th	8th	4th	5th

Confidence in the results over time (reliability of test)	Can be used outside of the laboratory environment (being able to use in your usual place of work)	Environmentally considerate in production and use (Green initiatives)	Easy to clean and disinfect	Easy to maintain (Low maintenance requirements)	How easy it is store	Relevance of the result to treatment or prescription decisions	Ease of procurement on the NHS
57	56	43	52	51	45	56	54
1st	2nd	16th	9th	10th	15th	2nd	5th

## Appendix 13 – User needs feedback (Nurse practitioner scores, 5)

How quickly the result is obtained	How easy the test is to use	Portability of the test	How easy the results are to interpret (If the user needs additional knowledge to interpret)	Connectivity of the test to digital systems (existing infrastructure or systems within your practice)	Affordability	Clinical performance (accuracy of results)	Safety of the user whilst operating the test
24	22	18	22	19	23	25	23
3rd	8th	15th	8th	14th	6th	1st	6th

Confidence in the results over time (reliability of test)	Can be used outside of the laboratory environment (being able to use in your usual place of work)	Environmentally considerate in production and use (Green initiatives)	Easy to clean and disinfect	Easy to maintain (Low maintenance requirements)	How easy it is store	Relevance of the result to treatment or prescription decisions	Ease of procurement on the NHS
25	24	21	22	22	16	24	21
1st	3rd	12th	8th	8th	16th	3rd	12th

## Appendix 14 – Focus group feedback (Section 1)

Section 1 - Current practice and experience with UTI care
Q1 - Current best practice for suspected UTIs
Clinicians treat suspected UTIs with symptoms that are presenting, whilst following current protocols and guidelines
If a patient is well with only minor symptoms an MSU test might be requested if there is a particular need. But MSU tests are only typically requested for symptomatic patients
No dip stick testing is done for patients over the age of 65, regardless of symptoms
Antibiotics that are issued typically follow a 3-day course
Community care usually involves a large number of patient that need testing, and not enough of them are referred to the pharmacists
Urine samples get dropped off by other staff and patients at practices. It is difficult to know the quality and cleanliness of samples
There are large numbers of patients across primary and community care who require assistance with suspected UTIs, there is not enough time to test them all
For GPs - majority of patients are encouraged to bring a sample in, a proforma is done for the symptoms, this is then looked at and a dip stick carried out if needed. Urine sent off for MSU later in the day if required. Dip stick tests are done in addition to the MSU in some cases.

Section 1 - Current practice and experience with UTI care
Q2 - Patient factors for suspected UTI
The patient experience will vary between patient, but in community settings the patient will typically have brought in a urine sample to hand over to one of the nurses in a GP practice or to the pharmacist
There is an online system that can be used for young and healthy patients, so that treatment can be prescribed over the phone
Dip sticks are used for higher risk patients that also have symptoms
Community pharmacists can do outreach work to collect samples from patients
Community pharmacists usually require a consultation session to help patients with suspected UTIs. This consultation includes a form and patient history. Pharmacists will sometimes prescribe antibiotics on symptoms alone if there is clinical justification
Patients are often asked to bring urine samples in to primary or community care, but patients often do not know how to correctly do a mid-stream urine sample which can affect results
Current practices changed during and after the COVID pandemic, patients are not attending as many face to face clinics. So empirical treatment and treatment of symptoms is more common
Patients sometimes drop a urine sample off without any documentation or notes as to why it should be tested

Section 1 - Current practice and experience with UTI care
Q3 - How do they choose between a urine test or antibiotics
There are many factors for deciding whether or not do a urine test or to treat empirically on symptoms alone
Age and comorbidities also factor into the decision between the test selected or if to treat immediately
The clinical expertise of the prescriber is key here, some patients know what symptoms to mention if they think they need antibiotics, and it is common for a urine sample to be 'contaminated'
Patient history with previous UTIs or other clinical risk factors will influence if an MSU is requested or if a 3-day course is prescribed straight away
Advanced Nurse Practitioners will hold telephone triage sessions with patients to help with clinical decision making
GPs are not always able to hold telephone consultations and only get a limited time window to decide on prescription options.
Dip stick tests are used when a presenting patients' symptoms are typical of a UTI and a quick decision is required
Empirical treatment of suspected pathogens in high-risk patients is sometimes used, with no MSU requested or dip stick used
Antibiotics can sometimes be the low risk (and easiest/fastest) option if there are potential clinical complications that might result from no treatment (Sepsis, Nephritis)
Descriptive prescribing process: out of three symptoms, 1 symptom (17%), 2 (70%), 3 (90%+) [3 symptoms in all guidelines; Fever, Increased frequency, burning/stinging whilst peeing, Public Health Wales and Scottish SIGN]

Section 1 - Current practice and experience with UTI care
Q4 - Thoughts on existing diagnostic options for UTI
The dip stick urine tests can show positive results for pathogens, but this may not mean infection. Urine samples that are dipped may be contaminated
Ambulance and paramedic staff are no longer allowed to carry dip stick tests
Patients over 60 commonly have bacteria in the urine but are asymptomatic for UTI
The high rate of contamination on urine samples negatively affects the usefulness of dip stick tests
MSU test results can take between 24 hours and 3 days to come back.
MSU results are the most useful in a clinical context because they give the sensitivity and specificity results which can aid antibiotic selection. But the process can take too long in some cases
Community and primary care staff are unsure of other technologies that can help, other than dip sticks and MSU lab tests
Both dipstick testing and MSU results can be negatively affected by poor quality urine samples
Dipstick tests are not very helpful clinically as the sensitivity/specificity information is needed. But MSU tests can take too long
HCA's sometimes conduct the dip stick tests; this might be driving prescribing higher. This needs to be avoided where possible
Not device related but may clinicians mentioned the descriptive prescribing guidelines that have been produced by Public Health Wales for determining antibiotic prescriptions for UTI, and that they are frequently used across many practices/surgeries
Dipstick tests can be overused, and more training is required for some staff. There can be a subjectivity element to the reading of the dipstick tests
The majority of overuse of dip stick tests in Hospitals for the over 65's (note from HDUHB based pharmacist)
E. Coli is commonly tested for, but this doesn't give a good indication of antibiotic requirements
Microbiology will send MSU urine samples back if the symptoms and patient notes are not present. The labs are trying to reduce wasted time as some primary care clinicians will send samples with 'test for UTI' and no other information. Sensitivities/specificities only released by microbiology if there are not concerned that antibiotics will be incorrectly prescribed
Dipsticks can show a positive result that is then disproved by an MSU

## Appendix 15 – Focus group feedback (Section 2)

Section 2 - Guidelines and regulations for UTIs
Q1 - What guidelines are currently followed for UTIs in practice
NICE guidelines
PHE Guidelines
Public Health Wales microbiology guidelines
National patient group direction (PGD) guidance NHS Scotland
Microguide Global ( <a href="https://viewer.microguide.global/guide/1000000198">https://viewer.microguide.global/guide/1000000198</a> ) This is an app that clinicians can use on a PC browser or phone and is heavily supported and used by younger clinicians. Not all were aware of this tool
SIGN - Health Improvement Scotland
Clinical Knowledge summary from NICE guidelines

Section 2 - Guidelines and regulations for UTIs
Q2 - Are there differences between health boards or practice etc.
All the guidelines are not enforced by law, so there is a little interpretation and deviation in some practices. But this is usually done with previous clinical experience in mind. These differences are small and, on a case-by-case basis
Guidelines are always being updated with new evidence, GPs and community care clinicians don't always have enough time to train on updated guidance. So there may be a skills gap between some practices/areas of clinical work
Practice nurses and HCAs need more training in the UTI guidelines
Guidelines are in place, but it is currently difficult to quantify compliance between primary and community care settings

## Appendix 16 – Focus group feedback (Section 3)

Section 3 - Clinical implications of POC test
Q1 - Opinions on potential of POC tests for UTIs
New POC devices would potentially be very helpful, but it depends on what the device would offer and how it would compare with existing options
If a POC device could offer similar results to an MSU but with a quicker turnaround time, this would benefit a lot of services
New POC tests could be helpful, but the patient history is still very important to the results. So a new device still needs to be interpreted by someone with relevant clinical knowledge
A POC test could be done by a health care assistant (HCA) or other less trained person. But this would need testing with the device
Validation of any new POC test is essential to understand how it fits into practice
Less potential for use in the community by ANP, as they often have to be referred anyway if they require clinical support
Would a POC test bring more patients into practice/clinic? If so, there needs to be guidance in place for managing additional workflow
Some concerns/worries about new POC tests being used incorrectly. More data and testing would be required
One potential use case for new POC tests was for ANPs who needs to drive long distances between Hospitals (Lampeter, 45-minute drive between sites). POC test could provide more information that dipstick without complication of MSU send off
Care homes may also be another use case as over prescribing of antibiotics is common

Section 3 - Clinical implications of POC test
Q2 - Thoughts on the Llusern test concept
The concept seems very helpful, but if the new device would not indicate the specificity and sensitivity to antibiotics, the use cases would be limited.
Does the device only indicate the pathogens present, or would this indicate the amount present in the sample?
Current guidelines for antibiotic prescription currently require the information received from lab based MSU tests. More information is required regarding the data it can return
Could the data it generates be downloaded digitally to microbiology to supplement trend data?
Staff are stating that 85% of UTIs are related to E. Coli but evidence shows that 2/3rds of these are resistant to common antibiotics. So the sensitivity and specificity information is needed
There is potential use for the Llusern test for patients with recurring infections to identify the presence of specific pathogens
Having a negative result for a range of pathogens would be useful for ruling out infections quickly
Being able to test for presence of a range of pathogens quickly to reassure patients or to avoid unnecessary prescription is a potential use case. But this will require validation
Time taken for test to complete may cause an issue. Consultations in pharmacy take no longer than 20 minutes. GPs only get a 5-minute window typically. 40 minutes for test result will mean that a patient will have to return later the same day, this could affect other consultations/appointments
Decision fatigue is a big factor, waiting for additional results may negatively affect this
More information is required about how the test would fit into current practice and link with UTI guidelines and decision trees
There were some concerns about this test complicating the prescribing process
If given to HCAs or other less skilled clinical workers, could it increase inappropriate prescribing?



How many times can the device be used in an hour? Or over the course of the day?  
Would several devices be necessary to keep up with demand?

How robust is the test device? Could it break whilst being moved around and being cleaned often

Concerns about the quality of the urine test still being an issue with the Llusern test.  
Could this be something Llusern does better than dipstick testing?

### Section 3 - Clinical implications of POC test

#### Q3 - Feedback related to adapted PHE guidelines

This proposed protocol appears 'busy' and a little difficult to follow for some

This proposed guidelines requires a lot of clinical expertise or medical history checking. This would prevent the process from being used by all staff and would preclude an HCA for example.

This new proposed flow chart is lacking in non-antibiotic treatment options

This new proposed guidance may not add anything new to existing guidance

There were concerns around the use of terms such as 'likely' and 'unlikely'. Even though the device is testing for multiple pathogens the is no certainty about the presence of an actual UTI and not just the presence of bacteria from contamination

This proposal with the device results still requires a lot of input from clinical expertise and may not advance the guidelines or speed up the process

The process may be quite a lot longer than that what is currently followed

If the Llusern test returns a 'likely' result, then an MSU may still be requested anyway. This will not improve current processes

Changing of existing guidelines would require a lot of evidence and validation data

### Section 3 - Clinical implications of POC test

#### Q4 - What might change with the introduction of the Llusern test

It would depend on the practicality behind the test, how many tests could be done per hour or each day.  
If only a small number of tests can be done each day, it might limit the impact of the new test

If the new test does not give the sensitivity and specificity data, then this might not offer more utility than current dip stick tests

Dip sticks are very quick and cheap, MSU lab test offer vital clinical information. The Llusern test sits in between these two

Having a negative result available for some patients may prove useful, but this would require testing and evaluating in clinics

Less prescribing by showing negative results for a number of pathogens. But this would also need validation. Patient deterrent would be useful.

Changes with the Llusern test would depend on current guidelines and how it is adopted

Care homes were mentioned as a good use case for the Llusern test. Often the visiting ANP are being given urine samples at the end of play on a Friday, no way to get MSU tests done over the weekend

More data/information is required to accurately answer this question

### Section 3 - Clinical implications of POC test

#### Q5 - What cost implications would there be

The main consideration would be who pays for the tests and consumables. Currently GP and Pharmacists who do dip sticks, can either claim money back from the health boards or can buy the tests for a very low cost (£10 for 50 dipsticks)

There seems to be some reimbursement from the health board for some MSU and dip stick testing. The Llusern test may need to fit into a similar model with the Welsh health boards to be an attractive option for primary and community care

Cost considerations would also be impacted by any potential time saved elsewhere in the patient pathway

More information and discussion regarding pricing models would be required

Some clinicians discussed C-Reactive Protein tests and how they rarely get used due to cost of the consumables

More information and data is required, such as follow up rates (inconclusive tests, or low-quality sample), time saved versus existing methods and any effect on MSU request rates

For better or worse primary and community care providers sometimes have to consider the cost of an antibiotic prescription against the cost of test consumables and clinic/staff time

More information would be needed on maintenance, frequency of deep cleaning and replacement parts, accessories etc.

## Appendix 17 – Focus group feedback (Additional comments)

### Additional comments

Could a test such as this be used to detect early prostate cancer biomarkers?

Multi-drug resistant UTIs require the information offered by MSU tests

Staff are trying to move away from urine dip stick tests where possible, but they still offer useful results

There were questions about other tests on the market that could offer similar results

Dip stick tests are apparently used very frequently in secondary care to test for sepsis. Could the Llusern test find a use case in this area?

Some patients may be filling out proformas in a certain way because they think they need the antibiotics anyway

Could the Llusern test be used for throat cultures/swabs? Strep A POC testing could be a valuable clinical tool

Storage of the device and its consumables was mentioned as a concern from several pharmacists. The device is small, but it would need a surface that needs to be away from other equipment and medicines (like a clean room). High street pharmacists are usually short of counter and storage space

Could a test like this be used for inpatients, on admission to the wards?

Nitrates and nitrites were mentioned during one of the focus groups, could the Llusern test check for these? Would this be relevant?

Dip stick checks for sugar and ketones, and only used in high-risk patients.

Could the Llusern test be used to test for Chlamydia and other STIs?

## Appendix 18 – Device feedback

Job title	The test is easy to use	Comments
GP	Agree	
GP	Agree	Transfer of urine may be fiddly
Nurse specialist	Agree	There are some concerns around spillage during transfer
Nurse specialist	Neither	
Nurse specialist	Disagree	Potential for contamination across several steps is high
Pharmacist	Agree	A pipette may be easier to use
Pharmacist	Neither	Hard to tell from the example, would need some hands on testing with live samples. But it appears to be fiddly and time consuming
Pharmacist	Strongly agree	
Pharmacist	Agree	Seems easy to use, but there might be an easier way to transfer the urine into the test tubes
Primary care manager	Agree	

Job title	Portable enough for non-laboratory use	Comments
GP	Agree	
GP	Agree	
Nurse specialist	Agree	
Nurse specialist	Agree	
Nurse specialist	Agree	
Pharmacist	Strongly Agree	
Pharmacist	Strongly Agree	
Pharmacist	Strongly agree	
Pharmacist	Agree	
Primary care manager	Agree	

Job title	Results are easy to interpret	Comments
GP	Neither	May be open to user error
GP	Neither	Easy to indicate, but need more information on the interpretation of results
Nurse specialist	Neither	Could the test be changed between practice? Could Nitrites, blood and leukocytes be tested?
Nurse specialist	Neither	
Nurse specialist	Neither	
Pharmacist	Neither	This will depend on the labelling of the test, and what pathogens are tested. A digital display may be easier to read
Pharmacist	Neither	Would require some hands on testing with live samples, but it seems like it might be easy to interpret
Pharmacist	Agree	
Pharmacist	Agree	
Primary care manager	Agree	

Job title	Costs are a concern	Comments
GP	Strongly agree	Need to know more about the costing model and if reimbursement would be available from health boards etc.
GP	Agree	
Nurse specialist	Agree	Clinical waste implications of the contaminated parts?
Nurse specialist	Agree	Need more information about use cases as this may potentially be a very expensive dip stick alternative
Nurse specialist	Agree	
Pharmacist	Neither	This would depend on who is funding the it
Pharmacist	Agree	Use of this test would very much depend on the associated costs
Pharmacist	Agree	
Pharmacist	Strongly agree	
Primary care manager	Agree	

Job title	Test samples are easy to set up	Comments
GP	Neither	
GP	Disagree	Too many transferring steps
Nurse specialist	Neither	Would require hands on testing with live samples
Nurse specialist	Neither	
Nurse specialist	Disagree	Potential for contamination
Pharmacist	Agree	But a pipette would make this even easier
Pharmacist	Disagree	The process appears to be fiddly and the consumables (grey dips) seem flimsy
Pharmacist	Agree	
Pharmacist	Neither	
Primary care manager	Disagree	The process seems 'fiddly' a pipette might be easier

Job title	Ease of storing consumables	Comments
GP	Neither	
GP	Neither	Potentially a lot of waste with the 3D parts and not being able to clean easily
Nurse specialist	Agree	
Nurse specialist	Agree	
Nurse specialist	Agree	
Pharmacist	Agree	The consumables would be easy to store
Pharmacist	Agree	Consumables seem small so no issues with storage
Pharmacist	Disagree	Storage space is at a premium in high street pharmacy, there might be a struggle to store the consumables
Pharmacist	Neither	There would need to be counter space or a separate room for this, may not be possible in some practices
Primary care manager	Agree	

## Appendix 19 – Device feedback (Question 7)

Job title	Value of results	Comments
GP	Neither	Guidelines would need to be updated to include the test results, support and training would be required
GP	Neither	There is a chance that an MSU is required anyway, in which case nothing has been gained
Nurse specialist	Disagree	Guidelines is the main restriction at the moment, the test results do not currently fit into the clinical decision making
Nurse specialist	Neither	Treating empiracally is still the best practice in most cases, this test may not show what an MSU does
Nurse specialist	Neither	
Pharmacist	Neither	This would depend on a number of factors, further validation would be needed
Pharmacist	Neither	Don't think this would be beneficial to community pharmacy, but could help with GP practices for complex elderly patients
Pharmacist	Neither	
Pharmacist	Neither	
Primary care manager	Neither	

## Appendix 20 – Device feedback (Additional comments)

Job title	Other comments
GP	Need to understand more about the value added, would a positive result from this test lead to additional treatments, or treatments avoided? Open to being involved in further evaluation work when the time is right
GP	What does the green light indicate? How significant is the detection?
Nurse specialist	There could be a use for this test, but more work may be required to understand how it could be implemented
Nurse specialist	The test needs validation in a clinical setting
Nurse specialist	Great concept, good to see this kind of test being developed. If this would be able to show data regarding specificities and sensitivities it would be a massive increase in value
Pharmacist	Does the test need programming between practice? Could it be customised? Could this test also be used for throat swabs?
Pharmacist	
Pharmacist	Could this be used with throat cultures or for step A testing?
Pharmacist	Sterility of the testing area would be a concern
Primary care manager	Would the result give an indication of the levels (amount) of each bacteria present?





**TRITECH**

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