### Summary of Significant Changes at this Revision
Add maintenance procedure and not doing dipstick from urine collected into boric acid

### Purpose and Scope
The purpose of this process is to offer a dipstick screening service testing for urinary tract infections and related abnormalities.

The dipstick analysis is NOT diagnostic and can only be used as a screening tool.

### Items Required

<table>
<thead>
<tr>
<th>Definitions and Abbreviations</th>
<th>Grade / Qualifications Required</th>
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</thead>
<tbody>
<tr>
<td>Applicable to grades Band 2 and above.</td>
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1. CLINICAL APPLICATION

The purpose of this process is to offer a dipstick screening service testing for urinary tract infections and related abnormalities.

The dipstick analysis is NOT diagnostic and can only be used as a screening tool.

The parameters that are tested for using the Medi-Test Combi 8 dipsticks include blood, protein, nitrites, ketones, glucose, pH, specific gravity and leucocytes.

The screening procedure for referral for culture will be based upon the presence of either leucocytes (leucocytes esterase) and/or nitrite or the presence of blood in male patients and the clinical findings.

Urine Dipstick can not be done on urine samples collected into boric aid collection pots a plain urine is required.
2. PROCEDURAL SUMMARY FLOW CHART

Specimens Collection

Samples are analysed using the dipsticks and reader

Negative dipstick
Positive for glucose and/or ketones and/or protein and/or *blood

Seek alternative aetiology

Positive for Leucocytes and/or Nitrites

All samples positive for Leucocytes and/or Nitrites are sent to the lab accompanied with an ICE request or a blue microbiology form.

Those samples where some or all of the other tests are positive may not be of a microbiological aetiology and may require further investigation.

* Those samples from male patients that show positive for blood may result from a microbiological aetiology and may require further investigation.

Following the Urinalysis flow chart the samples are either referred for culture or indicative of an alternative diagnosis

The specimens are taken by the patient on instruction from a Doctor

Taking note of the dipstick exceptions list samples are either tested or referred direct for culture.
3. THOSE SAMPLES THAT FALL INTO THE ‘MUST CULTURE’ CATEGORY:

Those patient and sample categories that are an exception to the use of screening via dipstick include:

- All urgent and on-call specimens which are referred to the urgent lab
- Children <10yrs old
- Pregnant women
- Neutropaenic patients
- Renal patients
- Pre-operative urology patients
- Pre-orthopaedic implant surgery
- Suprapubic aspirates
- Pyelonephritis
- Recurrent/persistent symptoms
- Patients undergoing planned catheter change with a history of infection
- Patients with heart valve lesion, septal defect, patent ductus, or prosthetic valve.
- Lower urinary tract infection.
- MRSA positive patients
- Self catheterisation
- Uro-sepsis
- Microscopic haematuria
- Catheter samples clinically suggestive of UTI eg pyrexia, abdo pain etc.
- Male patients with haematuria

4. PROCESSING PROCEDURE – Pre analytical overview

4.1 All samples for Urine M,C&S (Microscopy, Culture and Sensitivity) are sent to pathology using a relevant pathology request through ICE where available or on a microbiology form.

4.2 All sample will be reviewed and processed with reference to the must culture exceptions list (URGENT sample being processed in the “Hot Lab”).

5. PROCESSING PROCEDURE – Catheter Urine Samples

Those CSU samples that do not fall into the “must culture category” and do not show clinical details suggesting UTI will be requested and reported as below:

“Sample not processed for urine dipstick”
“Culture of Catheter urine is rarely indicated. No relevant clinical details given on request form so specimen NOT processed. Please discuss if clinical concerned.”

6. PROCESSING PROCEDURE – Old Samples

All urine samples should be processed on day of collection. Samples that fall outside this time frame will still be tested and a comment entered indicating that the sample was received more than two days after collection.

7. MAINTENANCE

Daily Maintenance.

1) The strip holder can be removed from its transport mechanism and cleaned with water. Make sure the instrument is turned off before removing the test slide.

2) Having removed the strip holder the two sensors require cleaning by wiping with a sterile cotton tipped applicator dampened with distilled water.

3) After cleaning the strip holder should be put back into its transport mechanism carefully. The rectangular notches of transport mechanism and stick retainer must be placed on top of each other.

4) Record on the QC/Maintenance log for the appropriate instrument.

Periodic maintenance.

1) Wipe off urine residues from the strip holder with a tissue after each measurement. This prevents crustification and drying of urine residues.

2) The instrument housing maybe wiped with a cloth using warm water with detergent or with a clini-wipe.

3) Record on the QC/Maintenance log for the appropriate instrument.

For further details refer to User manual
8. QC PROCEDURE

All URYXXON analysers must pass the QC prior to analysis.

There are two QC levels: QC 1 (Negative) & QC 2 (Positive).

Each level must be tested at the beginning of each day on all analysers and the results recorded on the relevant QC chart for each analyser.

If any of the QC fail the criteria as set down on the results sheet then the analyser must be taken out of action and the failure reported immediately to pathology on the numbers provided.

Acceptance Criteria – results for QC should fall within the limits as indicated on the QC results sheets provided as given by the manufacture.

9. PROCESSING PROCEDURE – Dipping and Analysis:

9.1 QC needs to be run on a daily basis. Remove QC from fridge and allow to warm for 15 minutes.
9.2 Record QC results on sheet provided.
9.3 Ensure the URYXXON is switched on. (in sleep mode the screen remains blank – to wake it up just touch the screen.
9.4 Invert the urine gently.
9.5 Remove lid and immerse the strip so that all the tests are covered.
9.6 Quickly remove the stick, blot off the excess urine and place on the strip holder.

N.B. As soon as the test strips come into contact with the urine the reaction starts. There should be as little delay in placing the strip on the strip holder as possible to avoid false results.

9.7 As soon as the strip is placed on the strip holder the URYXXON will detect it and begin the analysis.

A count down bar will display on screen to show the progress of the reaction.
9.8 After 30 seconds the strip holder will be drawn into the analyser for final analysis.
9.9 Once the analysis is complete the URYXXON will bleep and generate a print out of the results.
9.10 Wipe the strip holder with a tissue between tests.

10. PROCESSING PROCEDURE – Post Analytical

10.1 Once the results have printed out remove and discard the strip and wipe the strip holder with a tissue to remove excess urine.
10.2 IF the sample is NEGATIVE no further action is required.
10.3 IF the sample is POSITIVE for either Leucocytes or Nitrites follow the Urinalysis flow chart for advice on further action.
10.4 IF the patient is male and is POSITIVE for blood follow the Urinalysis flow chart for advice on further action.
10.5 IF the sample is POSITIVE for any of the other parameters refer to urinalysis interpretation sheet.
10.6 The URYXXON is now ready for the next test strip.

11. RESULTS

All samples referred to pathology will be reported on Ultra in the usual way. A note of the dipstick result must be entered in the patients notes.

12. TROUBLESHOOTING

Common errors:
If an error is encountered first repeat the test with a new dipstick.

If the error persists switch the analyser off then on again.

If the analyser does not detect the strip in the black holder wipe the sensors with a damp cotton bud.

Refer all problems to one of the contact names in pathology from the sheet provided.

13. URINALYSIS – USING DIPSTRIPS

13.1 NITRITES –

Detects a product of bacterial metabolism this test is specific for the presence of bacteria but not very sensitive – not all bacteria produce nitrites. Testing of old urine specimens may result in false positives due to the proliferation of scanty perineal flora with time.

13.2 Leucocyte Esterase (LE) –

Detects the presence of polymorphonuclear leucocytes involved in the inflammatory response. This test is sensitive but not very specific eg leucocytes may have been picked up from elsewhere in the genitourinary tract due to an infection, inflammation from other causes eg catheterisation or stones, or from other conditions such as analgesic nephropathy or tumours.

Used in combination, the nitrite and leucocyte esterase (N/LE) tests are helpful for the assessment of patients with suspected UTI and have been evaluated for predicting UTI in a variety of inpatient, outpatient and general practice populations where they have been found to have a sensitivity and specificity equivalent to microscopy. The performance of tests depends on the prevalence of the disease in the population tested and the N/LE tests are best interpreted after making an assessment of the likelihood of UTI in the patient to be tested (please refer to attached flow chart). In a typical population of patients presenting with symptoms where UTI enters the differential diagnosis, the prevalence of UTI is about 20%. In those with a high (>50%) clinical probability of UTI (symptoms or signs referable to the urinary tract such as frequency, dysuria, loin pain/tenderness, gross haematuria) and a positive N/LE test (either or both positive) the post-test probability of infection is in the region of 90%.
Those without these characteristics have a low clinical probability (<50%) of UTI and if the N/LE tests are both negative, the post-test probability of infection is <5%.

13.3 **Glucose** - Detects urine glucose >200 mg/L (= 1.1 mmol/L)

The test is not diagnostic for diabetes mellitus and should not be used for this purpose. A negative result does NOT exclude DM. A fasting blood glucose should be measured for diagnosing DM (refer to WHO guidelines).

*False negative:* may occur in a very old urine or if there is a lot of ascorbic acid (vitamin C) in the urine, e.g. patient is on supplements

13.4 **Protein** - Detects urine protein >300 mg/L

13.5 **pH**

Detects how acidic or alkaline the urine is. Usual pH value is 5-6 on a freshly passed sample.

A very alkaline urine (pH >9.0) may be associated with a urinary tract infection. However, a high pH value may also indicate that the sample is old or has not been stored properly and is therefore unsuitable for other tests on the dipstick. Some tests on the dipstick strip may give false results if the pH of the urine is too high (e.g. protein).

13.6 **Ketones** - Detects urine ketones >100 mg/L

Useful in rapid assessment of possible diabetic ketoacidosis – a positive result gives strong evidence that the patient has DKA. However, the test is NOT diagnostic and a laboratory blood glucose must be urgently performed as well.

*False positive:* may occur if urine has a very low pH

13.7 **Blood** - Detects haemoglobin or erythrocytes in urine (> 5 erythrocytes/ul)
A positive test is not specific for any particular cause of renal dysfunction. A positive test must be followed up with appropriate laboratory investigations (e.g. microscopy, renal function tests, etc.)

**False negative:** may occur if there is a lot of ascorbic acid (vitamin C) in the urine, e.g. patient on supplements

**False positive:** may occur as a result of contamination of the sample with menstrual blood flow or external injury to the urethral tract.
14. Other Sources of error using dipstrips

<table>
<thead>
<tr>
<th>Problem</th>
<th>May cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dipsticks out of date or inappropriately stored</td>
<td>False results due to altered reagent activity</td>
<td>Discard strips and repeat the test with a new vial of test strips.</td>
</tr>
<tr>
<td>Reading strip after too short or too long a time interval</td>
<td>False results</td>
<td>Repeat test, reading the results at the appropriate time, i.e. 60-120 seconds for leucocytes; 30-60 seconds for everything else. <strong>NB</strong> different makes of dipsticks will have different reaction times.</td>
</tr>
<tr>
<td>Inappropriate specimen pot and/or sampling vessel</td>
<td>False results due to residues of disinfectant and detergents.</td>
<td>Collect a fresh specimen using appropriate specimen pot and/or sampling vessel and re-test.</td>
</tr>
<tr>
<td>Old sample</td>
<td>False results</td>
<td>Collect a fresh urine sample and test within 2 hours of collection.</td>
</tr>
<tr>
<td>Test strip pot held the wrong way round when comparing test strip to reference colour fields</td>
<td>Wrong results</td>
<td>Ensure that the arrows on the test strip are aligned to those on the label before comparing to the colour scale.</td>
</tr>
<tr>
<td>Highly coloured urine (e.g. medical dyes or beetroot pigments)</td>
<td>May mask the colouration of test fields giving false positive or false negative results.</td>
<td>Be aware that test field colour changes may be affected when interpreting results.</td>
</tr>
<tr>
<td>Various drugs</td>
<td>Falsely high or low results</td>
<td>Be aware of any medications that the patient is taking and their effect on urine dipstick testing.</td>
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15. Urinalysis Flow Chart

See below:
Does this urine sample need to be sent to microbiology for culture?

Is the patient in the “complicated" group of patients?
- Children <10y old
- Neutropenic patients
- Suprapubic aspirates
- Recurrent/ persistent symptoms despite empiric therapy
- Pregnant women
- Renal patients
- Pyelonephritis
- Male with symptoms suggestive of a UTI
- Male with haematuria

Positive (either or both test positive)
Negative (both tests negative)

NITRITE OR LEUKOCYTE ESTERASE RESULT

Supports Diagnosis. Consider Empirical Therapy.
Consider Alternative Diagnosis: Send sample to microbiology and consider empirical therapy.
UTI Possible: Send sample to microbiology
Excludes UTI: No need to send a sample

Nitrite or Leukocyte Esterase Result

Is the patient catheterised?

Is the patient systemically unwell?

Do Not Send sample for culture unless patient due for re-catheterisation and has either a history of catheter-associated urinary tract infection following catheter change, or a heart valve lesion, septal defect, patent ductus, or prosthetic valve

Is the patient <10y old?

Children <10y old
Pregnant women
Male with symptoms suggestive of a UTI
Neutropenic patients
Renal patients
Pyelonephritis
Male with haematuria

Send sample for culture

Send sample for culture

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Send sample for culture

Send sample for culture
<table>
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<th>Copy number</th>
<th>Location held</th>
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<tbody>
<tr>
<td>1</td>
<td>GU Medicine</td>
</tr>
<tr>
<td>2</td>
<td>Children’s Ward</td>
</tr>
<tr>
<td>3</td>
<td>Children’s Outpatients</td>
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<tr>
<td>4</td>
<td>Diabetic Centre</td>
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<tr>
<td>5</td>
<td>ED Minors</td>
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<td>6</td>
<td>Urology</td>
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