COPY

Summary of Significant Changes at this Revision

Updated for new RANDOX quality control sample processes.
Small changes to result handling related to the paperless inpatient project.
Add Gynae OPD Location

Purpose and Scope

This procedure describes the selection and subsequent testing of RUH inpatient urines for dipstick screening. Specimens are tested using the Medi-test URYXXON® urine analyser. Results are transcribed into the EPR allowing hospital users and clinical teams to make decisions about patient management.

Items covered are:

- Handling
- Processing the specimen and loading onto the Medi-test URYXXON® urine analyser.
- Test results and reporting
- Repeat testing
- Specimen referral after testing

Items Required

Medi-test URYXXON® urine analyser
Medi-Test Combi 8 Urine test strips
RANDOX urinalysis control solutions
PPE (gloves)

Definitions and Abbreviations

IQC - Internal Quality Control
CSU - Catheter stream urine
EMU - Early morning urine
MSU - Mid-stream urine

Grade / Qualifications

Only applicable to healthcare personnel who have been suitably trained to perform dipstick screening using Medi-test Urine strips.

Competencies Required:

General user: current Version of FM/POCT/COMP/14
or
Advanced user: current version of FM/POCT/COMP/2

Risk Assessment:

Current Version of RA/POCT/6 – Can be found on the POCT intranet page

Contents

1.0 Scope

This SOP describes the use of the Medi-test URYXXON® urine analyser for urine dipstick screening of related abnormalities. These include midstream urine (MSU), early morning urine (EMU) and clean catch urines (CU).

- Handling
- Processing the specimen and loading onto the Medi-test URYXXON® urine analyser
- Test results and reporting
- Repeat testing
- Specimen referral after testing

2.0 Introduction and background

Urine test strips are used as a screening method for early detection of possible diseases such as metabolic disorders, renal, urogenital, liver and haemolytic disorders. Medi-test Combi 8 urine test strips measure glucose, protein, blood, ketone, nitrite, specific density, leukocyte levels and pH. Dipstick analysis is NOT diagnostic and can only be used as a screening tool. Test strips are read using the Medi-test URYXXON® urine analyser. The analyser allows the reader to minimise subjectivity compared to visual reading. The URYXXON® relax analyser is a semi-automated system using reflectance photometry. The test strip moves below a fixed measuring head on a sled with an embedded reference pad. The strip is illuminated with an LED and a detector registers the intensity of light reflected by the test strip at three different wavelengths. The test pads are reflectrophotometrically evaluated using an internal calibration. Whenever samples are strongly alkaline, a density correction is automatically conducted. The analyser can carry out 50 tests per hour. The results obtained with the Medi-test URYXXON® urine analyser correspond to the concentration ranges indicated on the colour chart for visual evaluation.

3.0 Safety

3.1 Specimen, processing and disposal

For urine dipstick analysis, samples must be collected in a white top universal container or yellow top Vacuette tube. The sample must be labelled with a minimum of three patient identifiers. Lids must be screwed on tight to be carried to the urinalysis meter.
Specimens should be discarded into appropriate waste stream in department sluices. All used containers must be disposed into clinical waste bins. See RA/POCT/6.

3.2 PPE

All patient samples are a potential infection risk. Disposable non-latex gloves must be worn at all times when handling specimens. Cover cuts and abrasions with plasters. If hands do become contaminated with urine, wash immediately with soap and water.

3.3 COSHH and Risk Assessments

All specimens should be considered infectious and handled appropriately. Before commencing work, all staff should check the COSHH assessment and Materials Safety Data Sheet if supplied.
Risk Assessment: see RA/POCT/6
Material Safety Data Sheet and COSHH: see EXT/POCT/11

3.4 Other Safety information

Bench areas should be cleaned with Clinell wipes after all procedures are completed.

3.5 Safety Spillage procedures

All spillages should be cleaned according to departmental spill policy. Contain the spill with absorbent material and discard in relevant waste streams. Do not use chorine-releasing agents or hypochlorite solutions directly on spills of urine as it can cause the release of chlorine gas.

4.0 Specimen Collection

4.1 Specimen collection and preparation

Urine Dipstick **cannot** be performed on urine collected into **boric acid** containers. A fresh early morning urine, mid-stream urine or clean catch urine should be collected into a white top universal container or a yellow top Vacuette tube for testing.

4.2 Unsatisfactory Specimens (including query UTI)

- Specimens collected in Boric acid containers are unsuitable for testing.
- Samples should be processed on the day of collection.
- Samples in query of UTI should **not** be processed for Urine Dipstick. If UTI clinically indicated samples should be sent to the laboratory for MC&S with an electronic millennium/ICE request.

5.0 Equipment and Reagents

5.1 Equipment

- Medi-test URYXXON® urine analyser
- Medi-Test Urine Combi 8 test strips
- PPE (gloves)
- RANDOX urinalysis control solutions – level 1 (negative) and level 2 (positive)

5.2 Reagent Storage

- Store the Medi-Test Urine Combi 8 test strips at 4 - 30 °C in a dry place. When stored properly, the strips are stable up to the expiry date.
- Do not touch the test pads
- Do not use strips past the expiry date.
- Avoid exposing strips to sunlight and moisture.

6.0 Method

6.1 Preparation of analysis

1. Switch on the Medi-test URYXXON® Relax urine analyser or touch the display screen if in sleep mode.
2. Allow the sample to reach room temperature (18 - 25°C) before processing - around 15 minutes.
3. Check the expiry date of the test strips in use.
4. Gently invert the sample 4 times to mix.

6.2 Analysis

1. The patient MRN or NHS number should be entered by pressing ID.
2. Manually enter number using keypad and select ✓ to confirm.
3. Remove the lid from the sample and take a test strip from the container. Hold the white end of the test strip, do not touch the pads.
4. Immerse the test strip so that all tests pads are covered for 1 second.
5. Draw the strip across the rim of the sample container to remove any excess urine.
6. Touch the side of the strip on a dry tissue briefly to remove excess urine.
7. Place the test strip on the strip holder ensuring the end of the strip is touching the top of the frame.
8. The URYXXON® Relax meter will detect the strip and begin the analysis countdown. The strip will automatically be drawn into the analyser. The results become available after 30 seconds.
9. Discard the test strip into a clinical waste bin.
10. Wipe the strip holder with lint-free tissue after each use to prevent carryover and drying of urine residues.

Note: Once the test strip comes into contact with the urine sample the reaction begins. There should be little delay in placing the strip on the holder to avoid false results.

6.3 Viewing and Recording Results

1. Results will be displayed on the screen and automatically printed out.
2. All results must be transcribed into the patient record on the EPR using the appropriate result form, along with the name of the person performing the test, the date and time of analysis and the analyser used. Any action or comments should also be recorded (e.g. sent to the lab, no abnormalities found).
3. If results are normal, no further action is required.
4. If any result is abnormal, refer to document "Interpretation of urine dipstick screening" (FM/POCT/95). All abnormal results will be displayed with a *****

7.0 Interpretation of results

See document “Interpretation of urine dipstick screening” (FM/POCT/95).

8.0 Quality Assurance

8.1 Internal Quality Control (IQC)

Third party RANDOX urinalysis control solutions level 1 and 2 are used to perform batch acceptance testing of all new lots of Medi-Test Combi 8 strips and following any breakdown and/or maintenance for acceptance into use.

The third party controls are also run daily, on an alternating basis, to ensure precision, quality of performance and reproducibility. The IQC samples are provided to the relevant departments by the POCT team. Control samples should be stored between 2 - 8°C in a temperature monitored fridge. Once opened, the IQC samples are stable for 30 days if stored appropriately. IQC should not be used past expiry dates. IQC should be discarded if there is evidence of microbial contamination or turbidity.

The analyser cannot be used if IQC has not been performed on that day, or if the control values fall outside of the ranges below. In the event of an IQC failure, the POCT team should be contacted on extension 6044.

	Level 1 (Negative)	**Level 2 (Positive)**
Nitrite	NEGATIVE	POSITIVE
Leukocytes	NEGATIVE	25 - 500
Ketones	NEGATIVE	2.5 - 30
Glucose	NEGATIVE – NORMAL	8.3 - 56
Blood	NEGATIVE	10 - 250
Total Protein	NEGATIVE	0.3 - 5.0
pH	5.0 - 7.0	7.0 - 9.0
Specific Gravity	1.005 - 1.030	1.000 - 1.015

The quality control record sheet (FM/POCT/96) should be completed each time IQC is performed. Strip lot numbers and expiry dates should also be recorded on this form. Once a month, the POCT team retrieves all previous month’s record sheets which are then reviewed, scanned and stored in the QMS against the equipment.

IQC analysis instructions

1. Switch on the Medi-test URYXXON® Relax urine analyser or touch the display screen if in sleep mode.
2. Allow the IQC sample to reach room temperature (18 - 25°C) before processing - around 15 minutes.
3. Check the expiry date of the test strips in use.
4. Gently invert the sample 4 times to mix.
5. Select the ▼ button at the bottom of the screen.
6. Select check mode – measurement – negative or positive (according to the IQC sample being analysed)

7. Remove the lid from the IQC sample and take a test strip from the container. Hold the white end of the test strip, do not touch the pads.
8. Immerse the test strip so that all test pads are covered for 1 second.
9. Draw the strip across the rim of the sample container to remove any excess urine.
10. Touch the side of the strip on a dry tissue briefly to remove excess urine.
11. Place the test strip on the strip holder ensuring the end of the strip is touching the top of the frame.
12. The URYXXON® Relax meter will detect the strip and begin the analysis countdown. The strip will automatically be drawn into the analyser. After 30 seconds, the IQC results will be displayed.
13. Compare the results with the ranges provided in the quality control record sheet.
14. Select the ✓/ × button on the top right corner.
15. If all results are within range, select passed followed by ✓.
16. If any result is outside range, select failed followed by ✓ and repeat the analysis of the IQC sample.
17. The analyser must not be used in the event of an IQC failure.
18. All IQC failures should be reported to the POCT team.
19. Transcribe the IQC results from the printout to the quality control record sheet.
20. The printout and test strip can now be discarded appropriately.
21. Wipe the strip holder with lint-free tissue.

8.2 External Quality Assurance (EQA)

The Trust is enrolled in the UKNEQAS Urine Dipstick scheme. Every month, the POCT team distributes 2 EQA samples to the relevant departments for analysis by ward staff. The POCT team will contact the departments in advance to let staff know that EQA samples will be arriving soon. EQA samples are analysed by the same method as patient samples.

The sample ID must be used as the patient MRN/NHS number.

The result forms should be returned to the POCT department to be reviewed and submitted to NEQAS.

Performing EQA ensures accuracy and comparability of unknown results between centres using the same methods. Every month, NEQAS issues a report for review by the POCT Coordinator who will contact the relevant department in case of discrepancies with the intended results.

Note for POCT staff only: refer to SOP/POCT/77 for further details.

9.0 Maintenance and Errors

9.1 Maintenance

Daily Maintenance

- Switch the instrument off.
- The instrument housing may be wiped with Clinell wipes.
- Grip the sides of the strip holder and carefully pull from the metal sled **(picture 1)**.
- Disinfect it with Clinell wipes. If necessary, rinse it with warm water. Make sure to remove any urine crystallization deposits. Dry with a lint free tissue.
- Clean the sensors (visible in the metal sled's window) with a sterile cotton swab and warm water. Dry with a lint free tissue.
- Re-insert the strip holder onto the metal sled **(picture 2)**. Use reasonable force to push the strip holder completely back onto the metal sled (until the holder is completely inside the analyser).
- Switch the instrument back on.
- Check that the window in the strip holder is aligned with the window in the metal sled **(picture 3)**.

Picture 1: strip holder and metal sled (bottom view)

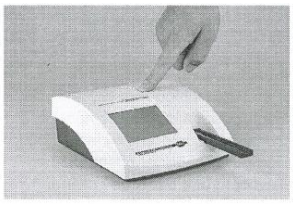
Picture 2: re-insertion of strip holder

Picture 3: check alignment of sensor windows

The daily clean box on the quality control sheet (FM/POCT/96) should be ticked when maintenance is complete.

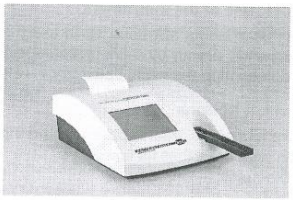
Periodic Maintenance

- Switch the instrument off.
- Wipe the strip holder with lint-free tissue after each use to prevent carryover and drying of urine residues.
- Changing printer paper: open printer cover by pressing the rectangular button next to the paper slot **(picture 1)**. Remove old roll. Unroll approximately 10 cm of the new paper roll and insert it in the paper compartment with the end on the lower side **(picture 2)**. Close the printer cover **(picture 3)**.



Picture 1: open cover

Picture 2: replace paper roll



Picture 3: close cover

9.2 Errors

If an error is encountered repeat the test where possible, if the error continues refer to the table below. Contact the POCT team on extension 6044 further troubleshooting.

Error Message	Cause	Solution
Dry Strip	The test strip wasn't dipped properly	Repeat measurement with a new strip
Wrong Strip	A wrong test strip has been detected	Use correct test strips
Wrong Position	The strip wasn't placed properly on the strip holder	Repeat measurement with new strip; ensure the end of the strip is touching the edge of the frame.
Printer out of paper	Empty paper roll or printer cover open	Replace paper roll and close printer cover
Instrument doesn't start	Power supply not installed or defective	Check if all connections are plugged in and if the power socket is functioning
Communication error E - O	Network connection issues	Turn off both plugs attached to the analyser. If the error persists after turning them back on, contact POCT on 6044.

10.0 Performance Characteristics

See Medi - Test Combi 9 Package Insert – EXT/POCT/11

11.0 Validation and Verification

11.1 Validation

Validation was performed by the manufacturer. All products are CE marked and used within expiry dates. For laboratory validation see – VAL/POCT/20

11.2 Verification

Continuous Verification is performed using EQA. Results are reviewed by the POCT Coordinator. Any non-conformities are actioned and reviewed at Quality, POCT and Departmental Meetings.

12.0 Limitations and interferences

- Blood:
    - Normal concentrations of ascorbic acid (vitamin C) < 40 mg/dL do not interfere with this test.
    - A false positive may occur as a result of sample contamination with menstrual blood or from an external injury to the urethral tract. Sample contamination with peroxide containing detergents can also cause false positives.

- Protein:
    - A negative dipstick result does NOT exclude proteinuria. Some proteins do not react with the dipstick (e.g. immunoglobulin light chains or Bence Jones protein).
    - False positives may occur in alkaline samples (pH > 9), patients on polyvinylpyrrolidone (blood substitute) infusion and patients on quinine medications. False positives may also be caused by sample contamination with residues of disinfectant. The presence of medical dyes (e.g. methylene blue) or beetroot pigments in the sample may mask the colour of the reaction pad.

- Nitrite:
    - Any pink colour indicates a bacterial infection of the urinary tract. The colour intensity depends only on the nitrite concentration and it does not provide information about the extent of the infection. A negative result does not exclude an infection of the urinary tract – non-nitrite producing bacteria may be present.
    - False negatives may be caused by high concentrations of ascorbic acid (vitamin C) or antibiotic therapy.
    - False positives may be caused by the presence of medical dyes in the sample.

- Ketones:
    - β-hydroxybutyrate is not detected by this test. Phthalein compounds interfere by producing a red colouration.

- Glucose:
    - False positives may occur if the sample is contaminated with residues of peroxide containing detergents. This test is not affected by the presence of ascorbic acid (vitamin C).
    -
- Density:
    - An increase is the sample density due to glucose > 1000 mg/dL is not detected by the test.
    - Elevated density results may be caused the moderate proteinuria.
    - Low alkaline urines may cause low readings.

- Leucocytes:
    - False positives may occur if the sample is contaminated with formaldehyde or vaginal discharge.
    - False negatives may occur in samples with protein > 500 mg/dL and glucose > 2 g/dL as well as in patients on cephalexin and gentamicin.
    - Excretion of bilirubin and nitrofurantoin may mask the colour of the reaction pad.

13.0 Special considerations

Samples from catheterized patients should not be used for urine dipstick testing.
Samples from patients > 65 years old should also not be analysed by this method as it becomes more unreliable with increasing age.
Most patients in these categories will have bacteria present in the bladder/urine without infection (known as asymptomatic bacteriuria).

Urine dipstick testing is not recommended for patients under 3 months with suspected UTI – these patients should be referred to paediatric specialist care and have a urine sample sent to the lab for urgent MC&S.

Urine dipstick testing is not recommended for patients with signs/symptoms of sepsis or pyelonephritis – these patients should have a urine sample sent to the lab for MC&S before antibiotics are started.

Samples for MC&S should be collected directly into a boric acid container. Paediatric sample should be transferred to a boric acid container. Small samples < 10 mL can be sent in white top universal containers. MC&S samples should be labelled with a Millennium or ICE request label and sent to the lab in a sealed leak-proof bag.

14.0 References

1. PHE; *Diagnosis of urinary tract infections: quick reference tool for primary care*, 2020
2. NICE guideline, *Urinary tract infection in under 16s: diagnosis and management [NG224]*, 2022
3. NICE quality standard, *Urinary tract infections in adults [QS90]*, 2015
4. Macherey-nagel, *URYXXON® Relax User manual*, 2019
5. Macherey-nagel, *Medi-Test urine analysis brochure*, 2019
6. Macherey-nagel, *Medi-Test urine test strips – instructions for use* (kit insert), 2022
7. RANDOX *Urinalysis Control Levels 1 and 2* (kit insert), 2024

Copy number	Location held In Urinalysis SOP Folder
1	Laboratory POCT bench – Shelf
2	ED Minors – Sluice room
3	Children's OP – Sluice room
4	Children's Ward – Sluice room
5	Urology – Sluice room
6	Parry Ward – Sluice room
7	Riverside Gum Clinic – Laboratory
8	BBC – Sluice room
9	DAU – Centrifuge bench
10	Mary Ward – Sluice room
11	Frome Maternity
12	Chippenham Maternity
13	Paulton Maternity
14	Trowbridge Maternity
15	Gynae Outpatients