Urisys 1100 Test Strip Meter

VERSION	1.5
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COPY	1
LOCATION OF COPIES	1. Room PA2 2. Q-PULSE

CONTENTS

1 SCOPE AND PURPOSE

Roche Combur 7 urine strips provide screening tests for glucose, ketones, blood, pH, protein, nitrite and leucocytes. The reagent test areas on the strips are ready to use upon removal from container and may be read visually or on the Urisys 1100 analyser.
The following procedures must be followed to protect the welfare of the patient. Failure to adhere to the procedures may be detrimental to operators and nurse managers in the event of litigation.

2 RESPONSIBILITY

The PoCT team is responsible for the maintenance of the Urisys meters in use in the Northern Devon Healthcare Trust. The manufacturer and the PoCT team provide training and the PoCT team supply the test strips on request. The PoCT team holds a stock of meters, log books and ward manuals.

2.1 Ward/Location managers

Are responsible for ensuring meters are used in accordance with Trust Policies and are consequently fit for purpose.

Where meters are found to be or suspected of being faulty they are responsible for removing them from service and ensuring that the PoCT team are informed so the appropriate remedial action can be taken.

2.2 Meter Users

Complying with Board ratified policies and procedures.

Participation in medical device education and training, and ensuring individual training matrix and Personal Development Portfolios are updated.

Acceptance of individual or team responsibility and accountability for maintaining a safe environment and only operate devices for which the user is competent and this competence can be demonstrated.

Adhering to incident reporting procedures.

3 REFERENCES

- Urisys 1100 Operator's manual - Q-PULSE
- Investigation of Urine. Health Protection Agency, National Standard Method BSOP41.

- Diagnosis of UTI, Quick Reference Guide, Health Protection Agency and Association of Medical Microbiologists.

3.1 Definitions

PoCT Point of Care Testing, pathology investigations performed outside the laboratory setting.

QC Quality Control, materials or processes used to check system performance.

EQA External Quality Assurance, materials/processes used to check system performance that are supplied by an external source.

UTI Urinary Tract Infection.

3.2 Related documents

Medical Devices Policy – Accessed via Trust Intranet
Infection Control Policy- Accessed via Trust Intranet
Urisys 1100 instruction manual – Q-PULSE POC-EXT-31
Urisys 1100 Quick Guide - Q-PULSE POC-OTHER-6

4 ACTIONS AND METHODS

4.1 Principle of test

pH. The test pad contains the indicators methyl red, phenolphthalein and bromothymol blue which react with the hydrogen ions present in the sample and the resultant colour indicates the concentration which is expressed as a negative common log.
Glucose. The glucose concentration is determined by the specific glucose-oxidase and peroxidase reaction. The test is independent of the pH and specific gravity of the urine and is not affected by ketone bodies. The effect of vitamin C (ascorbic acid) has been reduced but there is a risk of false negative results with glucose values below 5.5 mmol/L and very high vitamin C.
Ketones. The Legal's nitroprusside test uses nitroferricyanide in an alkaline medium to react with the ketones and produce a violet colour. The test is more sensitive to acetoacetic acid than acetone. Phenylketones and phthalein produce a red colour which is obviously different from the violet produced by ketones. Substances containing sulfhydryl groups may produce false positive results; these include Captopril and mesna (2-mercaptoethanesulfonic acid sodium salt).
Leukocytes. The esterase enzymes present in whole or lysed granulocytes cleave indoxyl ester which reacts with diazonium salt to produce a violet dye. The reaction is not affected by bacteria, trichomonads or erythrocytes. Formaldehyde and medication containing imipenem, meropenem or clavulanic acid may cause false positive results. Strong colouration e.g. due to bilirubin or nitrofurantoin may mask the reaction colour. High protein levels, high glucose levels, cephalexin and gentamicin may diminish the intensity of the reaction colour.

Nitrite. The conversion of nitrate to nitrite by many common urinary pathogens is detected by the Griess reaction giving a pink colouration to the test area. The test is reliant on the urine having sufficient incubation time with the nitrite forming organisms so is best performed on early morning urine. The test is not reliable if antibiotics or chemotherapeutics have been administered in the previous three days.
Protein. The test is based on the protein error of indicators and is particularly sensitive to albumin. High pH, quinine, quinidine, chloroquine and tolbutamide do not affect the test. False positive results may be obtained after infusion of polyvinylpyrrolidone or if the urine specimen collection vessel contains residues of disinfectants based on quaternary ammonium compounds or chlorhexidine.
Blood. Haemoglobin and myoglobin catalyse the oxidation of the indicator by an organic hydroperoxide contained in the test pad. The result from the meter refers to intact erythrocytes so the haemoglobin detected either from intact or lysed cells is related back to intact cells assuming a normal chromic state.

4.2 Personnel to do the task / level of training required

Staff should only undertake the procedure if they have had the relevant training.

4.3 Specimen requirements

Fresh (less than two hours old) urine of sufficient volume to allow simultaneous immersion of all test pads on the strip. Early morning samples are preferable particularly for the nitrite.

4.4 Equipment

Roche Combur 7 urine strips (available from PoCT)

Urisys 1100 analyser

Collecting vessel – must be fit for purpose. Containers from patient homes eg jam jars etc, should be avoided.

Paper towel

4.5 Materials/Reagents

Store strips only in original bottle

Do not remove strips from bottle until immediately before it is to be used for testing

Store at temperatures 15 - 30’C

Do not use after expiry date

Do not touch test areas of reagent strips

4.6 Calibration

The analyser performs a self-check calibration each time it is switched on. If the analyser is kept on continuously, it needs to be calibrated weekly by switching off then on.

4.7 Quality Control

Internal QC should be run weekly where available.

External QA should be performed according to the scheme schedule.

All QC results and instrument events e.g. start of new strips must be recorded in the instrument log book.
If a QC is outside of the limits it should be repeated once. If it is still outside limits then use a different pot of strips and QC that. If the error still occurs then contact the PoCT team and do not use the strips or meter.

4.8 Specimen Collection

Collect freshly voided urine in a clean, dry container. Mix the sample before testing and test it within 2 hours after voiding. Contamination of the urine specimen with skin cleansers containing chlorhexidine may affect results. Specimen containers should always be free of detergents and other contaminating substances.

NB: DO NOT COLLECT INTO CONTAINER THAT CONTAINS PRESERVATIVES e.g. red topped universal used for Microbiology.

4.9 Method/Procedure

1. The patient's urine sample should be fresh, well mixed and uncentrifuged.
2. If the urine depth is less than 3 inches (7.6cm) pour the specimen into a narrow tube / vessel.
3. Switch on Analyser using switch at back. Analyser will perform a calibration self-check and print a report.
4. Input operator ID by using bar-code scanner or keyboard. If using keyboard enter number followed by "enter".
5. When "INSERT STRIP" message appears input patient ID (hosp. number) by using bar-code reader or keyboard followed by "enter" key. The message bar will now flash.
6. Immerse all reagent strip areas in the specimen and remove the strip immediately.
7. Run the edge of the strip against the rim of the container to remove excess urine and blot the edge of the strip on a paper towel. **Excess urine on the strip may cause false positive results.**
8. Place the strip, with the pads facing upward, on the test strip tray. The end of the strip **must be pushed below the clip as far as it will go**.
9. Press the blue start button. The retaining bar will close. It is important the strip is correctly positioned so manually adjust the strip if necessary.
10. Measurement will now automatically take place and results will be printed.
11. Discard the used strip into waste container and gently wipe the tray with moist towel.

12. Note: After 5 minutes without use the analyser will go into sleep-mode. Press the blue button to activate.

5 RESULT REPORTING

Results must be entered clearly into the notes as positive or negative and the date, time and person performing the test must also be recorded. As stated in the pack insert the result must not be read after 10mins.

5.1 Reference Ranges

See below.

5.2 Guide to interpretation

Please note this information is not exhaustive and users should also refer to product insert for more information. All point of care testing devices have limitations and this should be remembered at all times. Definitive diagnostic or therapeutic decisions should not be based on any single result or method. Substances that cause abnormal urine colour may affect the readability of test pads e.g. blood, bilirubin and drugs containing dyes, nitrofurantoin and riboflavin.

pH	The normal pH can range from 4.6 – 8.0. The test measures pH between 5 – 9 (analyser) and 5 – 8.5 visually. Bacterial growth by certain organisms may cause a marked alkaline shift (> 8.0), usually because of urea being converted to ammonia.
Glucose	Small amounts are often excreted by the kidney and are usually below the sensitivity of this test. However a result of between Negative and 5.5mmol/l is indicated as Positive. The test is specific for Glucose, and false positives do not occur. False negatives may occur with high levels of ketones combined with low levels of glucose (4 -7 mmol/l). Glycosuria is indicative, but not diagnostic, of diabetes mellitus. Glycosuria in known diabetics can indicate poor control.
Ketone	Normally no ketone is detectable in urine. Substances containing sulfhydryl groups may produce false positive results; these include Captopril and mesna (2-mercaptoethanesulfonic acid sodium salt). The presence of ketones, in the urine of a diabetic patient, is potentially serious and must be brought to the attention of a doctor.
Leucocytes	Normal urine is generally negative. A strip result of 100 or greater is a good indicator of infection. Trace results are of questionable clinical significance unless observed repeatedly. Contamination may give false positives.

Nitrite — Normally, no nitrite is present in urine. High numbers of enteric gram negative bacteria will give a positive result. A negative result does not rule out significant bacteruria. False negatives may occur with shortened bladder incubation of urine (<4hrs), absence of dietary nitrates, or the presence of non-reductive pathological microbes.

Protein — Normal protein excretion is < 0.15 g/L. A strip result of 0.3 g/L or above is indicative of clinical proteinuria. Clinical judgement is required to evaluate the significance of results but proteinuria in hypertensive/diabetic patients suggests renal disease. The test is less sensitive to mucoproteins and globulins, so a negative result does not rule out the presence of other proteins.

Blood — Normally, no haemoglobin is detectable in urine. Haematuria is often found in the presence of urinary tract infections and disappears with its resolution however urinalysis dip sticks are very sensitive so evaluation of trace results needs clinical judgment. Where no infection is apparent positive results merit further investigation. Blood is often, but not always, found in menstruating females. Contaminates e.g. hypochlorite may give false positives. Microbial peroxidise associated with UTI may also cause a false positive reaction. **Myoglobin will produce positive results**.

6 MAINTENANCE

1. Switch off analyser
2. Gently pull the test tray out of the analyser.
3. Rinse with running tap water and remove any crystalline deposits.
4. Wipe tray with medi-wipe or other suitable disinfectant and dry.
5. Gently re-install the test tray.
6. Switch on instrument.

If the instrument errors/fails please contact the PoCT team and **do not** use the meter.

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6.1 To Load Paper Roll

Press structured area below the cover to release printer paper cover. Lift cover backwards. Place paper roll in the compartment. Pull out first few centimetres of paper to just beyond the edge of the compartment with outer surface of the paper roll (thermosensitive side) facing downwards. Close cover until it locks into position.

7 CODE CHIP UPGRADE

To enter a new code chip into the Urisys first switch the device on and perform a self check to make sure it is in working order.

Switch the device off and press the raised area below the paper roll to open the flap.
The code chip is situated to the right hand side of the paper roll – take it out.
Place the new chip in its place and close the flap.
Turn the device back on and perform a self test – it will produce a message which says 'wrong tray' or ask for parameters to be set.
Press the blue enter button and change to C7 or press Menu.
Having pressed Menu follow the procedure for Set Up 1 as follows:
>Set Up 1
>Modes
>Printer
>On (1 copy)
>Press the blue enter button after every entry

Menu
>Set Up 1
> Modes
> Measure
> Normal
> As above

Menu
>Set Up 1
> Modes
> Interf
> Unidir
> As above

Menu
>Set Up 1
>Strip
> Type
> C7
As above

Menu
>Set Up 1
>Strip
>Units
>Combined
>SI/Arb
As above

Menu
>Set Up 1
>Strip
>Limits
>Default
>As above

Set Up 2 is as follows:

Menu
>Set Up 2
>Date/time – 24hr
>Set time +/-

Menu
>Set Up 2
>Parameters
>Default

Set Up 3 is as follows:

Menu
>Set Up 3
>Language
>Device ID
>OP ID – ON

Once all steps have been completed switch the meter off and on again to perform a self check.

8 HEALTH AND SAFETY/COSHH

Follow Universal Precautions when handling patient specimens as detailed by the Infection Control Manual. Handle all components and all patient samples as recommended for any potentially infectious human serum or blood specimen in the HHS Publication No. (CDC) 93-8395, Biosafety in Microbiological and Biomedical Laboratories, U.S. Government Printing Office; Washington, DC. Use supplied personal protective equipment. Wipe up spills promptly and decontaminate affected surfaces. Avoid generation of aerosols. Follow appropriate waste handling regulations applicable to your area.
See associated COSHH sheets for details of individual reagents and link below.

MSDS Combur 7 POC-EXT-32

http://physchem.ox.ac.uk/MSDS/