Scarborough, Hull and York Pathology Service

Urinalysis

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Changes from last version of this document

Amalgamation of PC-SOP-100 PRO, PC-SOP-USTICK

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1 Purpose and Principle

Urine test strips are an effective method for the preliminary screening of urine for Diabetes, Haemolytic disorders, Urogenital and kidney disease and metabolic disorders. The strips allow qualitative or semi quantitative analysis within one minute by measuring the colour change on each test pad.

Manual analysis should only take place in areas which do not have access to a Sterilab Urilyzer Pro 100 urinalysis meter.

Analyte	Chemical principle of the test strips	Commonest causes of positive test results
Ascorbic Acid	Detection is based on the decolouration of Tilmans reagent	Intake of Vitamin C supplements/fruit and vegetable. Positive test results may disturb other test results and all tests must be viewed with caution.
Blood	The detection is based on the pseudoperoxidative activity of haemoglobin and myoglobin which catalyzes the oxidation of an indicator producing a green colour	Haematuria due to kidney disorders, including glomerulonephritis, polycystic kidneys and kidney tumors.
Urobillinogen	The test area contains a diazonium salt which forms a reddish azo compound with urobilinogen	Inborn errors causing increase in production /excretion of urobilinogen Decreased uptake by the liver in cirrhosis/viral hepatitis Decreased excretion due to obstruction e.g. gallstones and carcinoma of the pancreas Certain antibiotics which prevent conversion of bilirubin to urobilinogen
Bilirubin	A red azo compound obtained in the presence of acid by combining bilirubin with a diazonium salt	Liver cell damage due to viral/drug induced hepatitis, paracetamol overdose or cirrhosis. Obstruction caused by gallstones, carcinoma of the pancreas, biliary atresia, and primary biliary cirrhosis.
Protein	The test area is buffered to a constant pH value and changes colour from yellow to greenish blue in the presence of albumin.	Chronic/acute glomerulonephritis, nephrotic syndrome, pre-eclampsia in pregnancy
Nitrite	Microorganisms, which can reduce nitrate to nitrite, are indicated indirectly by this test. The test area contains an	Urinary tract infection due to nitrite producing organisms

	amine and a coupling component. A red coloured azo compound is formed in the presence of nitrite.	
Ketones	Acetoacetic acid and acetone combined with sodium nitroprusside to give a violet coloured complex.	Fasting with fever/vomiting often seen in children. Diabetic ketoacidosis in uncontrolled insulin dependent diabetes. Ketotic hypoglycaemia in young children.
Glucose	The detection is based on the glucoseoxidase-peroxidase-chromogen reaction.	Patients with raised blood glucose i.e. Diabetes mellitus and glucose infusion. Patients without a raised blood glucose i.e. pregnancy and renal glycosuria.
pH	The test area contains indicators which change colour between pH 5 and pH9 (from orange-green-turquoise	Low values are found in Diabetic ketoacidosis, lactic acidosis, starvation, and potassium depletion. High values are found in vomiting, consumption of large amounts of antacids, urinary tract infections, and ammonia forming organisms.
Density	Determination of the concentration of ions. The colour changes from deep blue in low concentration of ions through green to yellow in the presence of high concentration of ions.	High values are found in dehydration. Low values are found in high fluid intake i.e. diabetes insipidus hypercalcaemia and hypokalaemia.
Leukocytes	The test is based on the esterase activity of granulocytes. The enzyme splits carboxylic acid esters. The alcohol constituent combines with a diazo salt to produce a violet colour	Urinary tract infection. The main cause of which is infection

2 Patient Preparation & Sample Requirements

A fresh un-centrifuged urine sample is required. **This should be collected into a plain container, with no additives**. Mix the sample well before use. If the sample is to be retained for further analysis it must be labeled with the patient's full name and DOB and transported to the laboratory in the appropriate container as soon as possible.

Collection of urine from a patient without a urinary catheter:

- Explain procedure and obtain informed consent from patient.
- Check whether any special considerations should be taken, e.g., mid-stream, early morning.
- Label the container using either a hospital sticker, or by handwriting the patient's name, date of birth, hospital number, and the date and time of collection. Check these details with the patient.

Collection of urine from a patient with a urinary catheter:

The urine sample should be collected from the sampling port using aseptic technique. The sampling port is usually located in the drainage tubing, proximal to the collection bag.

The sample should not be taken from the tap from the main collection chamber of the catheter bag as there may be stagnant urine around the tap, in which bacteria may have colonised and multiplied.

- If possible, obtain informed consent from the patient.
- If no urine is visible in the tubing, apply a non-traumatic clamp/gate clip a few centimetres distal to the sampling port.
- Once sufficient urine has collected in the tube, wipe the port with an alcohol wipe and allow to dry.
- Stabilising the tube below the port, insert the syringe tip into the port at an angle of 45°.
- Aspirate the required amount of urine. Refer to the Laboratory Medicine Handbook for further information, although 10 ml will usually be adequate.
- Remove the syringe and inject the urine sample into a white-topped urine container.
- Label the container using either a hospital sticker, or by handwriting the patient's name, date of birth, hospital number, and the date and time of collection. Check these details with the patient verbally or by checking the patient wristband.
- Wipe the sampling port with an alcohol wipe and allow to dry.
- Unclamp the catheter tubing as required.

3 Tasks, Responsibilities and Authorisations

These procedures must only be carried out by Staff who have received documented training on the use of the dipsticks and use of the Urilyzer 100pro by POCT Team members or by a certified link trainer.

Access is given to the Urilyzer 100PRO in Aegis POC middleware and paperwork is stored in the X-drive>Biochemistry>POCT>Training Logs.

Competency is recertified every 2 years.

Tasks	Responsible	Authorised
Analysis of patient sample and EQA samples	**Staff with documented training**	**POCT Team members**

4 Equipment

Equipment is supplied by Sterilab services.

The Depot, 18 Mornington Terrace, Harrogate

HG1 5DH. Tel: 01423 523300

Maintenance and training is undertaken by the Point of Care Team.

Please contact:

Bridlington Hospital 771 3321

Scarborough Hospital 771 2659

York Hospital 772 5890.

5 Chemicals and Reagents

The CombiScreen 11sys plus test strips are obtainable via **pharmacy**.

Store the container of strips below 30 C in a dry place. Avoid exposing the strips to direct sunlight and moisture.

The strips when stored correctly are stable to the date of expiry.

QC material cat no 1440-06

Quantimetrix Dropper Plus Level 1&2

QC material should be stored at 2-8 C in a dark place. After the initial use the control is stable for three months or 20 dips.

GENERAL FIRST AID

The following first aid guidelines may be applied to all the substances detailed in this SOP.

Eyes: Irrigate thoroughly with water. At least 10 minutes is the recommended duration. Sterile saline is also available at the eye wash stations.

Lungs: Remove from exposure, rest and keep warm.

Skin: Wash substance off skin thoroughly with water. Remove contaminated clothing and wash before re-use.

Mouth: Wash out mouth thoroughly with water and give plenty of water to drink.

Remember – If at all concerned about the nature or severity of the problem, SEEK MEDICAL ADVICE.

6 Risk Assessment (Environmental and Safety Controls)

For full risk assessment see PC/RA/YS-10 Risk Assessment for Urinalysis.

Staff carrying out this procedure should have read and understood the Local Rules or Health and Safety Manual applicable to their site which should be followed at all times during the procedure.

- All human samples must be treated as potentially BIO-HAZARDOUS.
- Approved Personal Protective Equipment (PPE) including laboratory coats, disposable gloves must be worn. Eye protection should also be considered and must be worn when directed within the procedure.

This SOP and the associated risk assessment(s) have considered all hazards and necessary precautions required to control any risks identified. Where appropriate this is detailed in the COSHH assessment and Risk Assessment. Any risk; where possible is mitigated and or monitored with health surveillance to ensure health and safety for all those affected by this procedure

7 Calibration

No manual calibration is required.

The Urilyzer 100Pro performs a system test each time it is turned on. Then, each time a test is run; the instrument automatically checks and corrects its performance through the independent internal sensor.

8 Quality Control

Each lot of urine dipsticks is quality controlled and validated by running on the Sterilab Urilyzer 100PRO.

Internal QC

The strips should be quality controlled weekly using Quantimetrix Dropper Plus level 1 and 2

This will usually be by a member of the Point of Care Team.

- The control should be allowed to reach room temperature before use.
- Select Enter ID
- Scan your barcode or manually enter your operator ID
- Enter your password.

- Select ‘QC’ from the Start screen.
- Invert the bottle gently squeeze the bottle and run the liquid over the strip until all the pads are wet.
- Select ‘Start Measure: Solution 1’.
- Scan the strip lot number (barcode on side of the pot of strips)
- Scan the QC lot number barcode.
- After the measurement has finished the start measure bar will turn green if the QC has passed.
- Repeat with the Positive Level 2 QC, selecting ‘Start Measure: Solution 2’.

If the QC fails, the Start Measure bar will turn red. Clean the strip test holder and repeat the control.

If the results are still incorrect, contact the Point of Care team.

Bridlington ext. 771 3321,

Scarborough ext. 771 2659

York ext. 772 5890.

9 External Quality Assurance (EQA)

External Quality Assurance samples are received every 2 months from WEQAS and should be run according to the test protocol for urinalysis. Results should then be returned to the Point of Care team as indicated within the enclosed letter.

10 Procedural Steps

Urine dipstick analysis may be requested verbally by qualified staff and clinicians or by documented protocols.

- Before any analysis, please check the expiry date of the strips in use. Remove only the required number of strips and reseal the container immediately. Do not touch the test areas on the strip.

Manual Dip

- Gloves should be worn at all times.
- Before any analysis, please check the expiry date of the strips in use. Remove only the required number of strips from the container and reseal the container immediately. Do not touch the test areas on the strip.
- Collect a fresh urine sample into a clean vessel **containing no additives**.
- Dip the test strip into the urine sample for approximately 2 seconds.
- Draw the strip along the edge of the container to remove excess urine

- Hold the strip in a horizontal position to prevent possible mixing of chemicals from adjacent reagent areas.
- Compare each test pad to the colour chart on the bottle. Read each pad at 60 seconds except Leukocytes which can be read up to 120 seconds) Colour changes at the rim of the test pad or after 2 minutes should be disregarded.
- Record all results in the patients' notes and/or the admission proforma
- Discard the used test strip as chemical waste as per local guidance. The urine may be retained for further tests or disposed of following local protocols.

Use of Urilyzer 100PRO

- Collect a fresh urine sample into a clean vessel **containing no additives**.
- Turn the reader on by pressing and holding the power button (rear left) firmly for 1 second. Once self-checks have finished the START screen will appear.
- Log in to the meter, scan your barcode and then enter your password
- Dip the test strip into the sample for approximately 1 second, ensuring all test pads are immersed.
- Draw the test strip along the edge of the container to remove excess urine and blot the edge of the strip on a clean paper towel.
- Place the strip onto the tray with the test pads facing upwards. Make sure the strip is inserted to the end of the channel on the strip holder tray. The following error will show if the strip is not correctly positioned; If the strip is not in the correct position, The Urilyzer will allow 10 seconds for you to re-position the strip, press retry, timing will be taken from the first attempt.

- Scan the strip barcode, to record lot number and expiry date of strips.
- While the meter begins its 60 second incubation enter the patient ID (NHS number) as prompted on screen and tick to confirm.
- The countdown screen will then appear indicating the time remaining until the strip will be read. Once the measurement has finished the tray will return to the start position and results will be displayed on the screen.
- Results will print automatically when the strip is removed from the strip holder tray.

The machine will automatically power down after a set period. To turn off manually, log off from the main screen. Do not remove the power cord or turn off the power socket while the machine is running.

Maintenance

The instrument does not require any specialist maintenance, only routine cleaning.

- Wipe the test strip holder using Clinell wipes after each sample.
- The exterior of the machine may be cleaned with Clinell wipes or any commercial cleaning product containing 70% alcohol. Take care not to let any liquids enter the instrument.
- The strip tray holder should be washed thoroughly with warm water daily.

11 Reporting of Results

The dipsticks should not be used for Patients over the age of 65 with the clinical details ?UTI

The results should always be recorded into the patients' notes. The following information should be recorded.

- Result as printed on the printout
- Date and time of analysis
- Identity of the person carrying out the test
- Results seen by clinician in charge of the patient

To establish a final diagnosis and / or therapy the results should always be verified by other means.

Results run on the Urilyzer 100PRO are found in the patient's electronic record providing the correct NHS number has been entered.

12 Reference Intervals

Non available.

Result interpretation

In order to avoid sending non-infected samples for microscopy and culture please use the following protocol.

Visual appearance of the urine sample	Results from the Urine dip stick analysis	Follow up Analysis
Clear	All results negative	Discard urine as there is no clinical

		evidence of infection
Clear	If any of the following are positive Nitrite, Leucocytes, Blood or protein	Send urine for culture and microscopy
Obviously infected or blood-stained urine		Send urine for culture and microscopy

13 Performance Characteristics

The following detection limits are quoted by the manufacturer.

Protein	0.15 g/L (15 mg/dL) of albumin
Blood	150-300 ug/L (0.015-0.03 mg/dL) haemoglobin
Leucocytes	10-20 leucocytes/uL
Nitrite	11 umol/L (0.05 mg/dL) nitrite ions
Glucose	2.2 mmol/L (40 mg/dL) glucose
Ketones	0.5 mmol/L (5 mg/dL) acetoacetic acid
Bilirubin	10 umol/L (0.6 mg/dL) bilirubin

14 Known Limitations

Interferences

Ascorbic Acid can cause interference with Bilirubin, Blood, Glucose and Nitrite

pH can cause interference with protein level estimation.

Foods that cause discoloration of the urine can case difficulty in interpreting colours. e.g Beetroot

15 Related Forms/Templates and Documents

PC/RA/YS-10 Risk Assessment for Urinalysis

PC/VV/YS-10 Verification of SteriLab Urilyzer 100PRO

16 References

- Urilyzer 100pro user manual
- Combiscreen 11sys PLUS strip insert.
- Evaluation carried out see PC/VV/YS-10 Verification of SteriLab Urilyzer 100PRO.