Scarborough, Hull and York Pathology Service

Use of the Sterilab Urilyzer 100 Pro for Urinalysis

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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.

In conjunction with the Combi-Screen 11 SYS PLUS urine strips, the Urilyzer 100 Pro allows the colour change to be measured by a photometric reader. The intensity of the light reflected from the test pad gives an indication of the result in clinically meaningful units.

Analyte	**Chemical principle of the test strips**	**Commonest causes of positive test results**
Ascorbic Acid	Detection is based on the decolouration of Tillman's 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.
Urobilinogen	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 bilrubin 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 amine and a coupling component. A red-coloured azo compound is formed in the presence of nitrite.	Urinary tract infection due to nitrite producing organisms
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, uncentrifuged urine sample is required in a plain container. Mix the sample well before use. Sample should be analysed within 4 hours.
If the sample is to be retained for further analysis it must be labelled with the patient's full name and DOB and transported to the laboratory as soon as possible.

3 Tasks, Responsibilities and Authorisations

These procedures must only be carried out by staff members who have received face-to-face Urilyzer 100 Pro training with POCT or with a link trainer and completed competency paperwork.

Access is given 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
Urinalysis using Sterilab urilyzer	**Trained personel**	**SBMS**

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 or York Hospital 772 5890.

5 Chemicals and Reagents

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.

6 Risk Assessment (Environmental and Safety Controls)

- PC-HSR-URILYZER

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.
- Include reference to table in 'chemicals and reagents' section for specific COSHH assessment.

Risk assessment must also evaluate the impact of work processes and potential failures on examination results as they affect patient safety, the procedure should incorporate any modifications taken to reduce or eliminate identified risks. The overall intention is to be able to leave the following text box in the SOP.

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 instrument 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

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. 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. Observe universal precautions and appropriate hand hygiene.

- 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.
- Collect a fresh urine sample into a clean vessel.
- 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 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.

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 References

- Urilyzer 100pro user manual
- Combiscreen 11sys PLUS strip insert