Scarborough, Hull and York Pathology Service

Urinalysis by Dipstick

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Table of Contents

1 Purpose and Principle 3
2 Patient Preparation & Sample Requirements 4
3 Tasks, Responsibilities and Authorisations 5
4 Equipment 5
5 Chemicals and Reagents 5
6 Risk Assessment (Environmental and Safety Controls) 6
7 Calibration 6
8 Quality Control 6
9 External Quality Assurance (EQA) 6
10 Procedural Steps 6
11 Reporting of Results 7
12 Reference Intervals 8
13 Performance Characteristics 8
14 Known Limitations 8
15 Related Forms/Templates and Documents 8
16 References 8

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 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 amine and a coupling component. A red coloured azo	Urinary tract infection due to nitrite producing organisms

	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. Mix the sample well before use. If the sample is to be retained for further analysis it must be labeled with the patients full name and DOB and transported to the laboratory in the appropriate container as soon as possible.

- All human bodily fluids must be treated as potentially BIO-HAZARDOUS.
- Approved Personal Protective Equipment (PPE) including aprons, gloves and eye-protection must be worn when handling open samples or derivatives thereof.

	When performed according to the protocol detailed in this SOP, and in conjunction with adherence to Trust Policies and Good Laboratory Practice, the handling of patient samples represents minimal risk to staff.

Exposure to Bio-Hazardous Material

In the event of a needle stick injury or accidental blood splashes to eyes or mouth:

- If skin has been punctured encourage bleeding by gently squeezing. Wash with soap and running warm water then dry and dress the wound.
- Splashes to the eyes: irrigate eyes thoroughly with eye wash / saline
- Splashes to the mouth: gargle with drinking water (avoid swallowing)

Contact the Occupational Health Department / Emergency Department for guidance and report all adverse incidents to your line manager / complete a DATIX form.

Disposal of Patient Samples

Ensure compliance with the Laboratory Medicine Policy for the Retention, Storage and Disposal of Laboratory Samples: LM-POL-RSDS.

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.

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

4 Equipment

NA

5 Chemicals and Reagents

The CombiScreen 11sys plus test strips 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.

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)

Full Risk Assessment available on Q-Pulse PC-HSR-URINEDIP

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

None required.

8 Quality Control

Each lot of urine dipsticks is quality controlled and validated by running on the Sterilab Urilyzer Pro II

9 External Quality Assurance (EQA)

EQA (WEQAS)is run by all areas on a two monthly basis

10 Procedural Steps

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

- 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.
- 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 strip in a clinical waste bag. The urine may be retained for further tests or disposed of following local protocols.

11 Reporting of Results

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

The results should always be recorded into the patients' notes and /or the admission proforma . The following information should be recorded.

- Result with units
- Date and time of analysis
- Identity of the person carrying out the test
- Results given to patient
- Results given to the clinician

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

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

12 Reference Intervals

Semi Quantitative test no reference ranges are applicable.

13 Performance Characteristics

For evaluation see:.

PC-EVA-STERILAB

14 Known Limitations

The following detection limits are quoted by the manufacturer.

Protein	0.15 g/L (15 mg/dL) of albumin
Blood	150-300 µg/L (0.015-0.03 mg/dL) haemoglobin
Leucocytes	10-20 leucocytes/uL
Nitrite	11 µmol/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 µmol/L (0.6 mg/dL) bilirubin

Interferences

The only documented interferences on the strips is Ascorbic Acid and pH which will affect the following tests.

Ascorbic Acid-Bilirubin, Blood, Glucose and Nitrite

pH- Protein

15 Related Forms/Templates and Documents

PC-EVA-STERILAB

PC-HSR-URINEDIP

16 References

- Combi-screen strip insert.
- Evaluation carried out see PC-EVA-STERILAB. “See Kit insert for additional details and performance characteristics”.