The Royal Liverpool and Broadgreen University Hospitals NHS Trust

Related Documents	
Hazard Data Sheets	Multistix 8 SG urine dipsticks_2826
Risk Assessments	Siemens Clinitek Status, Use of
Others	None

Significant changes from previous version:
Addition of result reporting responsibilities

Purpose

The Clinitek Status Urine Chemistry Analyser is a portable instrument used for the analysis of urine specimens. Bayer Multistix 8SG urine test strips are used for screening: Glucose, Ketones, Specific gravity, Blood, pH, Protein, Nitrite and Leukocytes.
The analyser can also report the colour and clarity of the urine sample and record operator and patient identification.
Urine dipsticks provide a simple and rapid semi quantitative analysis of 8 components in urine.
The reliability of urine analysis is dependant on the quality of the urine specimen

Only staff whose training and competence has been established and recorded should carry out urinalysis using the Clinitek Status Analyser and urine Multistix 8SG reagent test strips. Staff should attend initial training and annual update training of the Clinitek Status Analyser.

The results from these tests are NOT diagnostic. Any abnormal findings should be reported to the lead Physician or Nurse Consultant and the sample forwarded to the relevant Pathology laboratory for confirmation.

Further information on each section described below, can be found on the product insert sheet, included with the test strips.

Sample Collection

An **early morning, mid-stream sample** is preferred; as this sample is the most concentrated and will not contain normal bacteria usually found in the urinary tract.
The sample should be collected into a clean dry sterile container which is **clearly labelled.**
The sample should be **tested as soon as possible** after collection but may be refrigerated 4-8 degrees C for up to 2 hours. The sample should be allowed to return to room temperature before testing.
Contamination of the urine specimen with skin cleansers containing chlorhexidine may affect protein and to a lesser extent specific gravity and bilirubin test results. Work areas and specimen containers should always be free of detergents and other contaminating substances.

Preservatives

Thymol in amounts of 1g/l or greater, may give false positive reactions for albumin determinations**.**
Boric Acid is generally added for the preservation of bacteria in urine. However the concentration must not be excessive as this will prevent growth of bacteria during culture. The leucoyte reagent pad may be inhibited to varying degrees.

Storage and handling of reagent test strips

Remove only one test strip at a time and always replace the bottle cap in order to avoid exposure to moisture.
Always check that the reagent strips are in date and have not deteriorated. A quick check is inspection of the glucose pad. If it gives a positive reading before use, the reagent strips should be discarded.
Do not store the container in direct sunlight and do not remove the desiccant from the container.
Do not touch the test areas of the strip.
Reagent test strips should be stored at room temperature.

Method

1. Procedure for Visual Testing and recording results

Siemens Tests are scientifically designed to react progressively and produce colour changes in the case of positive reactions at the times specified.

Accurate timing is essential for reliable quantitative results

1. Always check the appearance of the urine sample as this may give useful information.
2. Dip reagent strip into fresh, well-mixed uncentrifuged urine so that all test pads are covered. Remove after 1-2 seconds to avoid dissolving out reagents.
3. Draw the edge of the reagent strip on the side of the urine container to remove excess urine.
4. Hold the reagent strip with the test areas upward to prevent possible mixing of chemicals from adjacent reagent areas or soiling of hands with urine.
5. After the appropriate time, compare the test areas closely with the corresponding colour chart on the bottle label.
6. Record results and insert in patient's file.

2. Procedure for Automated testing with Clinitek Status

Analyzer Set Up

Place the instrument on a level work surface where the temperature and humidity are fairly constant. The best temperature for using the instrument is between 22°C and26°C (72°F and 79°F). Do not place the analyzer outside or near windows, ovens, hot plates, or radiators.

Plugging Analyzer In

Plug the appropriate end of the power cord into the power inlet socket located on the rear of the Clinitek Status analyzer. Plug the other end of the power cord into a electrical wall socket.

Loading the Printer Paper or Label Roll

1. Open the printer cover by pulling up on the tab.
2. Open the paper roll compartment cover by pressing down on its tab and pulling out.
3. Lift the paper holding arm into the open, upright position.
4. Place the new paper roll into the printer paper compartment with the paper unrolling from underneath and toward the compartment wall.
5. Feed the paper up along wall and through the printer. Once you have approximately 4 inches (or10 cm) of paper through the printer then feed the edge of the paper through the printer cover.
6. Push the paper holding arm down in to the closed position.
7. Close the printer and paper roll covers by clicking them into position.

The analyzer is set up to automatically print the results

Turning off the Clinitek Status

1. Before turning the analyzer off, always ensure that there is no strip or cassette on the test table and that the table and insert are clean.
2. Press the on/off button for at least 2 seconds. The test table will retract into the analyzer. If there is no strip or cassette on the test table, the door will close and the analyzer will switch off.

If a strip or cassette is still on the test table, the test table will be pushed out and the analyzer will turn off. The test table will remain out. In order to retract the test table into the analyzer, turn the analyzer on, and then off (without a strip or cassette on the test table).

Do not push the test table fully into the analyzer as the test table may become jammed and prevent the use of the analyzer.

Cleaning and Maintenance of the Clinitek Status Analyser

The test table insert and the test table should be kept clean if the analyser is to operate properly. See Clinitek Status Urine Analyser Maintenance Checklist (which is kept near the analyser) for Daily, Weekly, and Periodic cleaning of the test table and cleaning the White Calibration Bar.

Clinitek Status daily Maintenance

Daily maintenance should be performed on the Clinitek Status analyser before testing patient specimens.

1. Check the test strip table is clean. If the table requires cleaning, remove it and wipe with a damp cloth before drying with a soft dry cloth.
2. Check the white calibration code strip at the top end of the test strip table for cracks, chips etc
3. Reinsert the table, pushing it half way into the body of the analyser.

Performing Patient Analysis

1. Make sure the machine is switched on and performs a self test.
2. Use only the strips displayed on the analyser. E.g Multistix 8SG
3. The patient sample should be fresh and well mixed and uncentrifuged. If the urine depth is less than 3inches or 7.6cm pour the sample into a narrow tube.
4. Select test strip on the touch screen.
5. Ensure the test table is correctly adjusted for the test strip.
6. Ensure you have the required test strip ready for use.
7. Press **"New Operator"** on the touch screen and enter your **User ID** using the alphanumeric touch screen then press **ENTER.**
8. Press **"Enter New Patient".**
9. Enter the Patient's name and then press **ENTER** and then Patient's unit number and press **ENTER** – using the touch screen.
10. Press the **START** button. You now have 8 seconds to dip the reagent strip and place it on the test table.
11. Dip the Bayer Multistix reagent test strip into the urine, making sure that all the test pads are wet.
12. Immediately remove the test strip from the urine, dragging the edge of the strip against the side o f the container.

13. Blot the reagent strip by touching the edge to a paper towel and then place the strip, with the pads face up, into the central trough of the test strip table. Slide the strip along the table until it touches the end of the trough.
14. The table is automatically pulled into the analyser for reading and the results are available in one minute.
15. When the results appear and the test strip table will be ejected from the analyser, remove the used reagent test strip and discard into a yellow waste bag for incineration.

Results
The analyser will show the results on the screen and will print out a copy.
The results print -out MUST be recorded immediately into the patient's notes.
The print out will record the unequivocal patient identity, the time and date of testing, the results and the identity of the user. The results printout must be inserted in the patient's file.
All patient results must be treated as confidential.

Calibration
No action is required to calibrate the analyser. The analyser performs a "self test" and calibration each time it is turned on. Then, each time a test is run, the analyser calibrates again using the whit plastic calibration bar located on the test strip table.

Analyser Support
A Clinitek Status "Users Guide" has been provided with the analyser as a source of information and guidance for the users.
Contact the Trust Point of Care Testing Coordinator on Tel ext 4166 for advice, support or trouble shooting issues.

Recording, calculation and reporting of results

For samples analysed on the Clinitek Status a print out of the results is available immediately after analysis. Additionally up to 200 patient results are stored on the analyser for review. Results are held on the analyser in chronological order.

Responsibilities of personnel in authorising reporting and monitoring reports:

(i) Users are responsible for ensuring results outside the expected range are communicated immediately to the relevant member of staff (Doctor or Senior nurse), as highlighted in training and in accordance with the Trust POCT Policy.

(ii) Users are also responsible for ensuring results are recorded in the patient notes, in accordance with the Trust POCT Policy.

(iii) Any therapeutic decision based on the POCT result is the responsibility of the Clinical Director, as highlighted in the Trust POCT Policy.

Health and Safety

Standard safety precautions should be followed for handling patient's urine samples. All patient samples and used reagent test strips should be disposed of as hazardous waste into a yellow bag for incineration.

All COSHH and risk assessment documents for urine dipstick analysis are available from POCT if required (see contacts).

Limitations/Interferences

Urine dipsticks are for qualitative and semi-qualitative testing and should be used in conjunction with other more definitive diagnostic testing.

Screening for Urinary Tract Infections

The urine sample should be visually inspected for clarity and colour. A clear sample is tested visually with a Multistix 8SG or read using the Clinitek Status Urine Analyser.
If **ALL** of the following are **NEGATIVE; Nitrite, Leucocytes, Blood or Protein** the sample can be discarded and reported as **'No evidence of infection'.**
If **ANY** of the following are **POSITIVE; Nitrite, Leucocytes, Blood or Protein** the sample should be sent to the Microbiology department for culture.
If on visual inspection the sample is obviously infected or blood stained the sample should be sent directly to the Microbiology department for culture.

Interpretation of results

Leucocytes

Normal result: Negative. Normal urine specimens generally yield NEGATIVE results.
A strip result of small or greater is a useful indicator of infection.

Chemical principles
This test is based on the principle that esterases found in granulocytic leucocytes catalyse the hydrolysis of a derivatised pyrrole amino acid ester to liberate 3-hydroxy-5-phenyl pyrrole. This pyrrole then reacts with a diazonium salt to produce a purple complex.

Sensitivity / Specificity
This test provides a semi-quantitative result for the presence of leucocytes. Trace indicating approximately 5 to 15 cells /ul, + + + indicating approximately 500 cells/ul.
The test for leucocytes is a specific enzymatic reaction which is able to detect lysed cells in addition to undamaged cells.

In clinical studies involving over 1000 specimens, the sensitivity was 91.4% when compared with the chamber count of numbers of 10 and more cells/ul.

Significance of positive results
Some of the leucocytes which have entered inflamed tissue from the blood are shed into the urine.

Commonest causes of positive results
Urinary tract infection: especially when acute inflammation of the urinary tract.
Note: Infection is by far the commonest cause of urinary tract inflammation.

Nitrite

Normal result; No nitrite is detectable in urine.

Chemical principles
This test is based on the conversion of nitrate to nitrite by the action of certain species of bacteria in the urine. Any degree of pink colour is considered 'positive'

Normal result: Negative.

Sensitivity/Specificity
The test is specific for nitite, with a sensitivity of 13 to 22 umol/l nitrite in urines of normal specific gravity.

Significance of Positive Results
Most of the organisms which infect the urinary tract contain an enzyme system which catalyses the conversion of nitrate, which is commonly present in urine, to nitrite, which is not usually found I urine in the absence of a urinary tract infection (UTI).

Commonest causes of positive results.
Urinary tract infection due to nitrite producing organisms.
False negatives will be obtained if the patient is on a low nitrate diet, antibiotic therapy or high doses of ascorbic acid.

A negative result does not exclude an infection of the urinary tract, because some organisms are unable to convert nitrate to nitrite.

Protein

Normal result: Negative. Less than 0.15g of total protein is normally excreted per day (24hrs). Clinical proteinuria is indicated at greater than 0.5g of protein per day. (strip result of 0.3g/l or 30mg/dl. Clinical judgement is needed to evaluate the significance of trace results.

Colour ranges from yellow for negative through to yellow – green, green to green-blue for positive reactions**.**

Sensitivity / Specificity
This is a quantitative test, with TRACE result indicating albumin concentration of between 0.15 to 0.30g/l.
These test strips should not be used to detect Bence Jones Proteins or other globulins. A sample should be sent to Immunology.

Significance of Positive Results
Strip tests will detect a range of proteins but are most sensitive to albumin. Excess albumin in urine is usually die to increased permeability of the basement membrane of the glomeruli.

Commonest causes of Positive Results

1. Acute and chronic glomerulonephritis
2. Glomerluar involvement in systemic lupus erythematosis.
3. Nephrotic syndrome.
4. Pre-eclampsia.
5. Fever.
6. Heart failure.

False positive results may be obtained if pH >9, after infusions with polyvinylpyrrolidone (blood substitute), after intake of medicines containing quinine and also by disinfectant residues in the urine sampling vessel.

pH

Normal result : The normal pH of urine can range from 4.6 to 8.0.
The pH test measures pH values from 5-8.5 visually and 5-9 instrumatically.

Chemical Principles
The test is based on the double indicator principle, which gives a broad range of colour covering the pH range 5 to 8.5. Colours change from orange through yellow to blue.

Sensitivity/Specificity
The test provides differentiation of urine pH in the range 5 to 8.5. Readings are not affected by urinary buffer variations, but pH may be changed by certain medications.

Normal result: the pH of uncontaminated urines varies between 4.5 and 8.0 depending on the rate of elimination of hydrogen ions.
PH < 7.0 = Acidic urine
PH > 7.0 = Alkaline urine

Significance of Positive Results
Urinary pH usually reflects the pH of body fluids, but may also be affected by the ability of the kidneys to eliminate hydrogen ions and by infection of the urinary tract.

Commonest causes of positive results:

Low values are found in acidaemia, e.g. diabetic ketoacidosis and lactic acidaemia, starvation or potassium depletion.

High values are found in alkalaemia (except when due to potassium depletion) e.g. due to vomiting and consumption of large amounts of antacids, renal tubular acidosis, and urinary tract infection with ammonia forming organisms.
A value greater than 7 may indicate a UTI.

Blood

Normal result = negative. Normally no haemoglobin is detectable in urine. The significance of the Trace reaction may vary among patients, and clinical judgement is required for assessment in an individual case. Blood is often, but not always found in the urine of menstruating females.

Chemical Principles
The test is based on the peroxidase like activity of haemoglobin, which catalyses the reaction of the reagent with the chromogen. The colour ranges from orange through green to dark blue.

Sensitivity / Specificity
The test is capable of detecting150 to 620ug/l free haemoglobin or 5 to 20 intact red blood cells per microlitre in urines with a Specific gravity (S.G) of 1.005
The test is less sensitive in a urine with high S.G.

Significance of Positive Results
Intact red cells in urine are found with diseases of the kidneys or urinary tract.

Commonest causes of Positive Results

1. Haematuria (intact red cells) due to kidney disorders, tumors, polycystic kidneys or glomerulonephritis.
2. Due to urinary tract disorders including stones, tumors, infection, benign prostatic enlargement.
3. Due to haemoglobinuria (free haemoglobin).
4. Severe haemolysis e.g. crises in sickle cell disease or red cell glucose-6-phosphate dehydrogenase deficiency.

A positive result will also be found if myoglobin (from muscle damage) is excreted.
If the test pad appears a uniform colour, red cells in the sample have been haemolysed.
A speckled appearance indicates haematuria with intact cells.
Normal concentrations of ascorbic acid (<400 mg/L) do not influence the test results.
A false positive result can be produced by a residue of peroxide containing cleansing agents (e.g. bleach) in the container.

Specific Gravity

Normal result: Specific Gravity (S.G) ranges from 1.001 to 1.035
If the SG of a random urine specimen is > 1.023 the concentrating ability of the kidneys can be considered normal.

Chemical Principles
This test is based on a pKa change of certain pre-treated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, colours range from deep blue-green through green and yellow-green in urines of increasing ionic concentration.

Sensitivity / Specificity
The test determines the S.G of urines in the range 1.000 to 1.030.
For increased accuracy add 0.005 to readings obtained from urines with pH values equal to or greater than 6.5

Significance of positive results
A measure of total solute concentration. This varies widely according to the need to excrete water and solutes.

Commonest causes of positive results
1. **High values** are found in dehydration.
2. In impaired kidney function as in chronic renal failure.
3. **Low values** are found in patients with intact renal function and high fluid intake; diabetes insipidus; chronic renal failure; hypercalcaemia and hypokalaemia.

Ketones

Normal result: Negative. Normally, no ketone is detectable in urine.

Chemical Principles
This test is based on the development of a pink or maroon colour by the reaction of acetoacetic acid with nitroprusside.

The test reacts with acetoacetic acid in urine, but does not react with acetone, beta-hydroxy butyric acid. The test detects as little as 0.5 mmol/l acetoacetic acid.

Significance of Positive Results
A positive result indicates accumulation of acetoacetate secondary to excessive breakdown of body fat. Acetone and beta-hydroxybutyrate are released at the same time.

Commonest causes of Positive Results
1. Positive results may be obtained if the patient has been starving or suffered prolonged diarrhoea and vomiting.
2. Diabetic ketoacidosis (grossly uncontrolled insulin-dependent diabetes).
3. Ketotic hypoglycaemia in young children.

Phenylketones in higher concentrations interfere with the test and will produce variable colours. Pthlaleins, contained in some laxatives, interfere by producing a red colouration.

Compounds that contain sulfhydryl groups, such as mesna and captopril, may cause false positives or an atypical colour reaction.

Glucose

Normal result : Negative. Small amounts of glucose are normaaly excreted by the kidney. These amounts are usually below the sensitivity level of this test but on occasion may produce a result between Negative and 5.5mmol/l that is interpreted as a positive result.

Chemical principles

This test is based on a double sequential enzyme reaction utilizing glucose oxidase and peroxidase with a potassium iodide chromogen. Colours range from green to brown**.**

Sensitivity / Specificity

The test is specific to glucose; no substance excreted in urine is known to give a positive result. Approximately 5.5mmol/l of glucose is detectable.

Significance of Positive Results

Glucose is found in urine when its concentration in plasma exceeds the renal threshold.

Commonest causes of Positive Results

In patients with raised blood glucose concentration.

- Diabetes mellitus
- Glucose infusion

1. In patients without raised blood glucose concentration.
   - Pregnancy
   - Renal glycosuria

High ketone levels (4mmol/l) may cause false negative for specimens containing small amounts of glucose (4-7mmol/l)

False positive results will be produced by a residue of peroxide containing cleansing agents (bleach) in the container.

Contacts

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