

OREGON HEALTH & SCIENCE UNIVERSITY
Hospitals and Clinics
Point of Care

Urine Dipstick by Clinitek Status+

Principle

Urine undergoes many changes during states of disease or body dysfunction before blood composition is altered to a significant extent. It is a useful procedure as an indicator of health or disease, especially in the areas of metabolic and renal disorders.

Urine dipstick testing is a screening test performed on fresh urine. A chemically impregnated reagent strip is dipped in fresh urine to determine glucose, bilirubin, ketones, specific gravity, blood, pH, protein, urobilinogen, nitrites, and leukocyte esterase.

Specimen Requirements

1. A random fresh urine sample.
2. Perform test as soon as possible.
3. Urine sample is stable at room temperature for 1 hour and refrigerated for 4 hours. If sample is refrigerated, allow it to come to room temperature before testing.
4. Minimum volume is 1 mL.

Interferences

Note: Abnormal urine color may affect the readability of the reagent areas on the urinalysis reagent test strips and these urine specimens should be sent to the Core Laboratory for analysis.

False Positives

Analyte	Specific Cause	Course of Action to Take
Glucose	Oxidized cleaning agents in urine container.	Recollect urine in a clean plastic container.
Bilirubin	Metabolites from drugs that lower pH.	Send to Core Lab.
Ketones	Highly pigmented urine, large amounts of levodopa metabolites, and compounds with sulfhydryl groups.	Send to Core Lab.
Specific Gravity	Protein (100-750 mg/dL).	Send to Core Lab.
Blood	Menstruating females.	Test after menstruation cycle has ended.

Blood	Oxidized cleaning agents in urine container.	Recollect urine in a clean plastic container.
Blood	Microbial peroxidase.	Send to Core Lab.
Protein	pH > 9.	Send to Core Lab.
Protein	Residues of disinfectants.	Recollect urine in a clean plastic container.
Urobilinogen	Increased temperature of strip.	Maintain test strips at room temperature; keep away from heat source.
Urobilinogen	Substances known to react with Ehrlich's reagent (p-aminosalicylic acid and sulfonamides).	Send to Core Lab.
Leukocytes	Fecal contamination.	Recollect urine sample. Do not test sample contaminated with feces.
Leukocytes	Vaginal discharge.	Recollect specimen.

False Negatives

Analyte	Specific Cause	Course of Action to Take
Glucose	Ascorbic acid \geq 50 mg/dL.	Wait for 10 hours after ingestion to perform urine test.
Glucose	Increased Specific Gravity.	Send to Core Lab.
Bilirubin	Ascorbic acid \geq 25 mg/dL.	Send to Core Lab.
Specific Gravity	Highly buffered alkaline urine.	Send to Core Lab.
Blood	Ascorbic acid.	Send to Core Lab.
Blood	Increased Specific Gravity.	Send to Core Lab.
Blood	Presence of captopril.	Send to Core Lab.
pH	Excess urine remains on strip resulting in reagent "runover" from protein test pad.	Repeat test.
Urobilinogen	Formalin.	Collect urine in a clean catch container.
Nitrite	Ascorbic acid \geq 25 mg/dL.	Wait 10 hours after ingestion to perform urine test.
Leukocytes	Glucose \geq 3000 mg/dL, or increased Specific Gravity.	Send to Core Lab.
Leukocytes	High levels of Tetracycline.	Send to Core Lab.
Leukocytes	Cephalexin, cephalothin, or high concentrations of oxalic acid.	Send to Core Lab.

Sensitivity

The following table lists the generally detectable levels of analytes in contrived urine.

Reagent Area	Sensitivity
Glucose	75 - 125 mg/dL glucose
Bilirubin	0.4 - 0.8 mg/dL bilirubin
Ketone	5 - 10 mg/dL acetoacetic acid
Blood	0.015 - 0.062 mg/dL hemoglobin (~1-3 RBC/HPF)
Protein	15 - 30 mg/dL albumin
Nitrite	0.06 - 0.1 mg/dL nitrite ion
Leukocytes	5 - 15 cells/HPF in clinical urine

Reference Range

Analyte	Normal
Glucose	Negative to Trace
Bilirubin	Negative
Ketone	Negative
Specific Gravity	1.005 to 1.030
Blood	Negative
pH	5.0 to 8.0
Protein	Negative to Trace
Urobilinogen	0.2 to 1.0 mg/dL
Nitrite	Negative
Leukocytes	Negative

Critical Values

1. Urine glucose values greater than or equal to 1000 mg/dL on patients from the ED or L&D.

Action Values

The following Values are not considered Critical Values, but are abnormal enough that it is recommended a sample be sent to Core Lab for confirmation.

1. Specific Gravity is less than 1.005 or greater than 1.030.
2. Any Positive Bilirubin.
3. Urine pH greater than or equal to 9.0 with a positive protein.
4. Orange, red, brown, or other heavily colored urines that produce positive dipstick values should be sent to Core Lab for confirmation (if nothing is positive - especially nitrite and leukocyte esterase - then there is no concern for false positives from color interference). Nitrite and leukocyte esterase tend to be the most sensitive to false

positives from color interferences since the color change from negative to positive is fairly subtle.

Quality Control Procedure

1. Two levels of QC will be run once every day of patient testing and with every new bottle of strips.
2. Remove QC bottle from the refrigerator and allow it to come to room temperature (18-25°C) before using.
3. Invert the bottle several times to mix.
4. Run controls on Clinitex:
RUN LEVEL 1 CONTROL FIRST, THEN LEVEL 2 SECOND. The controls must always be run in this order for QC to pass.
 - a. Touch 'QC Test Due' on the main screen
 - b. Touch 'QC Strip Test Required' on screen
 - c. Touch 'Enter New Operator Name'; Scan your employee barcode or enter your 5 digit ID; then touch enter
 - d. Touch 'Enter lot and expiration date'; enter lot number of LEVEL 1 control, hit enter. Enter expiration date of LEVEL 1 control, hit enter.
 - e. Touch 'Enter new lot and expiration date'; then enter lot and expiration date of Multistix 10SG. Touch 'ABC' in the upper right of the screen to change from numeric to letters.
 - f. Touch the start pad on the main screen. You have **8 seconds** to:
 - i. Dose the test strip by squeezing bottle, touching the tip of the dropper to the dipstick reagent pads. Draw the tip along the dipstick such that all pads are saturated. **Note:** Do not aspirate excess liquid back into the bottle.
 - ii. Place the reagent strip in the channel with test pads facing up.
 - iii. The test strip will be pulled into the analyzer at the end of the 8 seconds.
 - iv. Wipe the test strip channel dry with a KIMWIPE after each test procedure.
5. Print the results. If the controls pass, a 'P' will appear next to each analyte. Tear off the printer paper, place initials by results and tape onto appropriate page in QC manual.
6. If QC fails, repeat using same vial of dipsticks and QC solution, making sure that level 1 was run first, then level 2.
7. If QC fails again, repeat using new vial of QC solution.
8. If second repeat QC fails using new vial of QC solution, repeat using new vial of dipsticks.

9. If third repeat QC fails using new vial of dipsticks and QC solution, do not perform patient testing until problem is resolved. Document all results and action taken in QC Logbook. Send patient samples to the Core Laboratory and contact POCT staff at 4-5497 for assistance.

Patient Testing Procedure

1. On the main screen on the Clinitek Status touch "Strip Test".
2. Touch "Operator ID". Scan your employee barcode or enter your 5 digit employee ID. Touch "Enter".
3. Touch "Enter New Patient". Touch 'ABC' in upper left corner of screen and enter the patient's last name. Touch enter.
4. Enter Patient's ID#. Touch enter.
5. Touch the "Start" button. The user has **8 seconds** to:
 - a. Dip the reagent strip into the urine sample, wetting all pads. Immediately remove strip from the urine.
 - b. Drag the edge of the strip against the side of the sample container as it is removed.
 - c. Blot by touching the edge of the strip to a paper towel.
 - d. Place the reagent strip in the channel with test pads facing up. Slide the strip to the end of the channel
 - e. The test strip will be pulled into the analyzer at the end of the 8 seconds.
 - f. Wipe the test strip channel with a KIMWIPE after each test procedure.
5. While the strip is being analyzed, a "Select Appearance" screen will appear.
 - a. Observe and note color of urine. Colorless, straw, yellow, amber, orange, red, brown, green, blood tinged, or bloody.
 - b. Observe and note appearance of urine. Clear, hazy, slightly cloudy, moderately cloudy, or turbid.
6. If the urine sample is Yellow and Clear touch the "Yellow and Clear" button.
7. If the urine is not yellow and clear touch the "Other" button for more choices.
8. The analyzer will automatically print the results
9. Results will print on the printer tape. Abnormal results will appear with a *.
10. Remove test strip from test table. Wipe test table clean with a Kimwipe.

Results Reporting

1. Report the biochemical results using the following:
 - a. Urine color as: colorless, straw, yellow, amber, or bloody.
 - b. Urine appearance as: clear, hazy, slightly cloudy, moderately cloudy, or turbid.
 - c. Glucose as: negative, 100, 250, 500, >1000 mg/dL.
 - d. Bilirubin as: negative, small, moderate, or large.
 - e. Ketone as: negative, 5, 15, 40, 80, or >160.
 - f. Specific gravity as: 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, or 1.030.
 - g. Blood as: negative, trace, small, moderate, or large.
 - h. pH as: 5.0, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5 or >9.0.
 - i. Protein as: negative, trace, 30, 100, >300 mg/dL
 - j. Urobilinogen as: 0.2, 1, 2, 4, or 8.
 - k. Nitrites as: negative or positive.
 - l. Leukocytes as: negative, trace, small, moderate, or large.
2. Record results in patient's chart.

Interpretation

COLOR: affected by components such as: concentration, food pigments, dyes, and blood. The intensity of the color of normal urine is dependent on the concentration of the urine. The yellow or amber color of a normal urine is due to the presence of a yellow pigment, urochrome.

Color changes in disease states because of the presence of pigments that do not normally appear. Bile pigments: yellow to yellow-brown or greenish; porphyrins: dark brown-red upon standing; hemoglobin: reddish-brown; melanins: brown-black upon standing; alkaptonuria: dark brown or black upon standing. Dark amber usually represents normal concentrated urine, but may indicate the presence of urobilin or conjugated bilirubin. Bright orange urine is seen when azo dye compounds are given therapeutically and bright yellow with riboflavin.

APPEARANCE: cloudy urine, due to phosphates (alkaline) or urates (acid) is usually normal. Occasionally, cloudiness is due to blood (pink, red or brown), leukocytes, bacteria, or mucous.

GLUCOSE: Reagent strip tests are specific for glucose. Although glucose appears in urine in diabetes mellitus, it is not a sensitive test for detection of diabetes mellitus. In renal glucosuria, in which there is a low renal threshold, glucose loss is most communally due to an inherited, isolated proximal tubular defect and is harmless, or it may be associated with diseases of the proximal tubule. Glucosuria is occasionally seen with rapid intestinal absorption and massive glucose intake.

The glucose oxidase enzyme test may be inhibited or delayed by large amounts of ascorbic acid. The same ascorbic acid will give a positive copper reduction test.

Reducing sugars other than glucose may be present when copper reduction test is positive and the glucose oxidase is negative, e.g. with galactosemia or lactosuria. The glucose oxidase test is more sensitive to glucose than the reduction test.

BILIRUBIN: The urine may be dark with yellow foam if much bilirubin is present. Bilirubin in urine is in the conjugated form and is seen when there is obstruction to the outflow of bile, either extra hepatic or intrahepatic. It may stain sediment elements.

KETONE: Ketonuria is associated with starvation, weight reducing diets, and often in febrile children not eating. It is also found with diabetes mellitus.

SPECIFIC GRAVITY: This test is based on the pKa change of certain pretreated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, colors range from deep blue-green in urine of low ionic concentration through green and yellow-green in urines of increasing ionic concentration. The specific gravity test permits determination of urine specific gravity between 1.005 and 1.030. The Clinitek internally adjusts the SG results for urinary pH. Results will generally be within one display level of the corresponding nearest 0.005 increment of the Refractometer results. The SG test is not affected by certain non-ionic urine constituents such as glucose or by the presence of radio-opaque dye. The chemical nature of the SG test may cause different results from those obtained with other specific gravity methods when elevated amounts of certain urine constituents are present. Highly buffered alkaline urines may cause low readings relative to other methods. Elevated specific gravity readings may be obtained in the presence of moderate (100-750mg/dl) quantities of protein.

Concentrated urine is seen with dehydration. High specific gravity is recorded with x-ray dye (greater than 1.035) and with high concentrations of glucose or protein and is not necessarily indicative of normal renal function. Polyuria (excretion of too much urine, >2.5L/day) occurs with diabetes mellitus; the urine is pale, but has a high specific gravity when too much glucose is excreted (osmotic diuresis).

Dilute urine is present with high fluid intake. In decreased renal function, specific gravity is <1.020. As renal impairment becomes more severe, specific gravity approaches 1.010. Very dilute urine may negate findings of proteinuria or lower the bacterial count on culture, i.e., produce false negative results.

BLOOD: Hematuria is relatively common, hemoglobinuria uncommon, and myoglobinuria rare. Any pink, red, or brown urine is bloody until proven otherwise. When casts are present with significant proteinuria, the red cells are probably emanating from the kidney and associated with diseases such as acute glomerulonephritis or lupus nephritis. Red cells and smaller amounts of protein are seen with lower urinary tract bleeding and inflammation.

Glomerulitis associated with several renal diseases (lupus erythematosus, poly-arthritis nodosa, malignant hypertension, subacute bacterial endocarditis, glomerulonephritis) may result in hematuria of renal rather than lower urinary tract origin. Hemoglobinuria reflects intravascular hemolysis. Urine specific gravity of 1.010 or higher is necessary

to preclude lysis of erythrocytes in hematuria, which might otherwise be misinterpreted as hemoglobinuria.

The reagent strip is inhibited by ascorbic acid, so that a test for blood may be negative while the sediment reveals many red cells.

pH: The pH of the urine indicates the acid-base status: acidosis (starvation diets, severe diarrhea, diabetes mellitus, and respiratory disease) and alkalosis (excess alkali ingestion, severe vomiting, and respiratory hyperventilation). A urinary tract infection associated with urea-splitting organisms, (Proteus or Pseudomonas), may also cause alkaline urine. Paradoxical aciduria (<7.0) occurs in potassium depleted, chloride depleted alkalosis. The pH is very helpful in identifying crystals in urine.

PROTEIN: Proteinuria is indicative of renal disease. It is probably the single most sensitive indicator of renal disease, and quantitative measurement often correlates with severity of renal disease. Large amounts are lost in urine in the nephrotic syndrome. Small amounts accompany hematuria and acute urinary tract infection. With chronic renal disease, proteinuria may be intermittent. More urine protein is excreted by ambulatory persons than those in bed.

UROBILINOGEN: This test will detect urobilinogen in concentrations as low as 0.2 mg/dl (0.2 Eu/dl). The absence of urobilinogen cannot be determined. In patients with elevated urobilinogen excretion, urobilinogen test results correlate closely with Watson-Schwartz spectrophotometric procedures. This test is based on the Ehrlich reaction in which para-dimethylaminobenzaldehyde reacts with urobilinogen in a strongly acid medium to produce a brown-orange color.

NITRITE: Normally no nitrite is detectable in urine. The proportion of positive nitrite results in cases of significant infection depends on how long the urine was retained in the bladder prior to collection. Identification of known positive cases with the nitrite test ranges from as low as 40% when little bladder incubation occurred to as high as approximately 80% when a minimum of four hours of bladder incubation occurred. The test is specific for nitrite and will not react with any other substance normally excreted in the urine. This test depends upon the conversion of nitrate (derived from the diet) to nitrite by the action of Gram negative bacteria in the urine. At the acid pH of the strip, nitrite from the urine reacts with para-arsanilic acid to form a diazonium compound. This diazonium compound in turn couples with 1,2,3,4-tetrahydrobenzo(h)quinolin-3-ol to produce a pink color.

LEUKOCYTE ESTERASE: Normal urine specimens generally yield negative results; positive results (small or greater) are clinically significant. Individually observed trace results may be of questionable clinical significance; however, trace results observed repeatedly may be clinically significant. Positive and repeated trace results indicate the need for further testing of the patient and/or urine specimen, according to medically accepted procedures for pyuria. Positive results may occasionally be found with random specimens from females due to contamination of the specimen by vaginal discharge.

Granulocytic leukocytes contain esterases that catalyze the hydrolysis of the derivatized pyrrole amino acid ester to liberate 3-hydroxy-5-phenyl pyrrole. This pyrrole then reacts with a diazonium salt to produce a purple product.

Calibration

The Clinitek Status+ optics are calibrated automatically by the analyzer.

Maintenance:

1. Daily:
 - a. Wipe the outside of the Clinitek once/day with a sani-wipe or 70% alcohol.
2. Weekly:
 - a. Remove the 'test table arm' by pulling it slowly out of the analyzer. Clean the test table and arm by holding it under warm running water. Dry thoroughly by blotting with a paper towel, taking care to not scratch the white strip. Re-insert the 'test table arm' by gently pushing back into the analyzer only as far as the edge of the analyzer. Turn off the analyzer by holding down the power button until the screen goes blank. Wait 30 seconds then push the power button to turn the analyzer on. The meter will recalibrate and send the tray back out.

Reagents:

1. Siemens Urine Reagent Strips:
 - a. **Unopened** - Stable at room temperature (15°-30°C) until the expiration date on the vial. **Opened** - Stable at room temperature (15°-30°C) until the expiration date on the vial as long as recommended QC was performed.
 - b. Do not store bottle in direct sunlight or near heat source.
 - c. Keep bottle cap tightly closed to protect against moisture.
 - d. Do not touch test pads on the test strip.
 - e. Mark bottle with open date.
2. Quantimetrix Dropper Plus Urine QC Solutions, Level 1 and Level 2:
 - a. Unopened/Opened- Stable refrigerated (2°-8°C) until expiration date on the vial.
 - b. Allow urine control to sit at room temperature (20°-25°C) for 15 minutes before testing.
 - c. Discard if turbid or any evidence of microbial contamination is present.
 - d. Mark vials with open date.
 - e. Save QC inserts for 2 years.

References

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