

Urobilinogen: This test is based on a modified Ehrlich reaction, in which p-diethylaminobenzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strongly acid medium to produce a pink-red color.

Nitrite: 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 acid pH of the reagent area, nitrite in the urine reacts with p-arsanilic acid to form a diazonium compound. This diazonium compound couples with 1,2,3,4-tetrahydro-benzo(h) quinolin-3-ol to produce a pink color.

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

III. POLICY:

A. GENERAL

- 1. Staff who have documented evidence of training and competency may perform Bayer Multistix 10 SG urine dipstick testing. All personnel performing the test must be tested to certify no difficulty with visual color discrimination.**
- 2. New personnel will be oriented to the procedures for Bayer Multistix 10 SG urine dipstick testing during orientation.**
- 3. Skill validation in testing procedure will occur on nursing units during orientation. Thereafter, all personnel will be validated annually. Individual records will be maintained on the unit documenting current satisfactory performance.**
- 4. A freshly voided specimen should be used.**
- 5. Urine for testing ordered a.c. and h.s. should be obtained ½ hour prior to meals and at bedtimes.**

B. SPECIMEN

- 1. Bayer Multistix 10 SG test strips may be used on any freshly voided urine specimen or on urine collected under special conditions, such as first-morning specimens and post-prandial specimens.**
- 2. The urine must be collected in a clean container and should be tested as soon as possible after collection (do not centrifuge or use preservatives). All containers must be labeled with the patient's name and medical record # (or other patient-specific identifier) to ensure proper patient identification.**
- 3. If testing cannot be performed within one hour after collection, the specimen should be refrigerated at 2-8 C immediately and returned to room temperature before testing.**

C. URINE TEST STRIPS

Bayer Multistix® SG 10 (Catalog #2161)

- 1. Urine test strips will be current (stable until the expiration date stamped on vial label by manufacturer). Vials should be labeled with the date first opened.**

2. Urine test strips will be tightly capped and stored at room temperature in their original container. Do not freeze. In order to avoid exposure to moisture, the vial must be closed immediately after removal of a strip and the cap should be tightly closed.
3. The urine test strip will not be cut or altered in any way prior to performing the test.
4. Remove only the number of strips needed for testing and immediately close the container; unused strips should not be returned to the container.
5. Avoid touching chemical test sites on the reagent strips.
6. Urine test strips may be obtained from the manufacturer (Bayer Corporation).

D. QUALITY ASSESSMENT

1. Urinalysis Control Solutions – Normal and Abnormal Levels (Quantimetrix Urine Dipstick Control Catalog # 1440-04)
 - a. Quality control solutions will be current and labeled with the date opened; quality control solutions are stable for 1 month if maintained at room temperature and until the manufacturer's expiration date if maintained refrigerated.
 - b. Quality control solutions will be stored at room temperature or refrigerated.
 - c. Acceptable ranges for control solutions can be found on the package insert (contact Point-of-Care Supervisor at 8-6767 ext.334) and on the Bayer Multistix® 10 SG Urinalysis Log.
 - d. Quality control solutions may be contained from the MCVH Pharmacy.
2. Quality control testing, using both Normal and Abnormal levels, will be performed:
 - a. Daily (Note: In areas where patient testing is not performed daily, quality control testing will be performed each day of patient testing);
 - b. Each time a new vial of Bayer Multistix® 10 SG Urine Test Strips is opened;
 - c. When a vial of Bayer Multistix® 10 SG Urine Test Strips has been left open;
 - d. In the event that patient test results contraindicate patient symptoms.
3. If a quality control result exceeds the acceptable range, the appropriate corrective action will be taken before proceeding with patient testing.
4. Any corrective action will be documented on the Bayer Multistix® 10 SG Quality Control Log.
5. Internal proficiency testing (UPT No.#) to verify test accuracy and operator competency will be performed quarterly for all units performing urine dipsticks.(DISCONTINUED)
6. Problems related to performance of test that cannot be resolved will be reported to the charge/resource nurse or Point-of-Care Testing Supervisor.

E. RESULT REPORTING AND REVIEWING

1. The reporting format for each test is as follows:

Specific Gravity 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030

pH	5.0, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5
Leukocytes	Neg, trace, small, moderate, large
Nitrite	Neg, Pos
Protein	Neg, trace, 30, 100, 300, 2000 mg/dl
Glucose	Normal, 100, 250, 500, 1000, 2000 mg/dl
Ketones	Neg, trace, 5, 15, 40, 80, 160 mg/dl
Urobilinogen	0.2, 1, 2, 4, 8 mg/dl
Bilirubin	Neg, small, moderate, large
Blood	Neg, trace non-hemolyzed, moderate non-hemolyzed, hemolyzed trace, small, moderate, large

2. This reporting format is consistent with the MCVH Clinical Hematology Laboratory. Due to the nature of the test, results of tests performed by licensed professionals (persons who qualify as supervisors according to CLIA 88 guidelines) are reviewed at the time of test performance and then transferred to the patient chart. Once the result is transferred to the chart, the person transcribing the result should reconfirm the result. If a patient test is performed by anyone other than a licensed professional, a licensed professional must initial the test result when it is transferred to the patient chart.
3. If the testing supervisor upon review of the test result detects an error, corrective actions must be initiated immediately. The corrective action involves making the correction to the patient chart and initialing it.
4. Point-of-Care testing results that do not correlate with patient condition should be followed up with confirmatory testing in the main laboratory.
5. Bayer Multistix® 10 SG Quality Control Logs will be reviewed weekly by the Nurse Manager or designee and monthly by laboratory personnel. Weekly/Monthly review is documented on the Bayer Multistix® 10 SG Quality Control Log.

IV. PROCEDURES:

PROCEDURE A: SPECIMEN COLLECTION

For detailed specimen collection instructions, see *Perry & Potter – Specimen Collection (Skill 45-1, Skill 45-2, Skill 45-3, Skill 45-4)* available in this manual.

PROCEDURE B: PATIENT TESTING

Requisites:

Multistix Urine Test Strip
Urine specimen in a clean specimen collection container
Timing device
Gloves

Procedure:

1. Check that quality control is acceptable.
2. Wash hands and put on gloves.
3. Remove a Multistix® 10 SG urine test strip from the vial and recap the vial.

4. Completely immerse reagent area of the strip in fresh urine and remove immediately to avoid dissolving out reagent. Ensure that the chemically impregnated patches on the test strip are totally saturated.
5. Draw the edge of the strip along the rim of the specimen container to remove excess urine.
6. Turn the test strip on its side and tap once on a piece of absorbent paper to remove any remaining urine and to prevent the possible mixing of chemicals between reagent pads. Do not directly blot the reagent pads on the test strip with the absorbent paper.
7. Hold the strip close to the color blocks and match carefully, ensuring that the strip is properly oriented to the color chart on the vial label. After the appropriate time, as indicated below, read the test. The reagent pads are in order according to time for interpretation starting with the glucose. Timing is critical for optimum results.

Glucose	30 seconds
Bilirubin	30 seconds
Ketone.....	40 seconds
Specific gravity	45 seconds
Blood.....	60 seconds
pH	60 seconds
Protein	60 seconds
Urobilinogen	60 seconds
Nitrite	60 seconds
Leukocytes	2 minutes

For convenience, all reagent areas on the strip, except leukocytes, may be read between 1 and 2 minutes after immersion in the urine. The colors are stable up to 120 seconds after immersion. Color changes that occur only along the edge of the test area should be ignored. Careful removal of excess urine should eliminate this effect.

8. Document results on the patient chart and initial all results.

PROCEDURE C: QUALITY CONTROL

Requisites:

Multistix Urine Test Strips
Normal and Abnormal Control Solutions
Timing Device
Gloves

Procedure:

1. Wash hands and put on gloves.
2. Remove a Multistix® 10 SG urine test strip from the vial and recap the vial.
3. Briefly (no longer than 1 second) dip test strip into the Quantimetrix Normal Urine Dipstick control solution. Ensure that the chemically impregnated patches on the test strip are totally immersed.
4. Draw the edge of the strip along the rim of the specimen container to remove excess urine.

5. Turn the test strip on its side once on a piece of absorbent paper to remove any residual urine and to prevent the possible mixing of chemicals. Do not directly blot the reagent pads on the test strip with absorbent paper.
6. Hold the strip close to the color blocks and match carefully, ensuring that the strip is properly oriented to the color chart on the vial label. After the appropriate time read the test as follows:

Glucose 30 seconds
Bilirubin 30 seconds
Ketones 40 seconds
Specific gravity 45 seconds
Blood..... 60 seconds
pH 60 seconds
Protein 60 seconds
Urobilinogen 60 seconds
Nitrite 60 seconds
Leukocytes 2 minutes

For convenience, all values on the strip may be read between 1 and 2 minutes after immersion in the urine. The colors are stable up to 120 seconds after immersion. Color changes that occur after 2 minutes from immersion are not of clinical value. Color changes that occur only along the edge of the test area should be ignored. Careful removal of excess urine should eliminate this effect.

7. Document results on the Multistix® 10 SG Quality Control Log. Verify that the control results for each test are within the acceptable limits as stated on the quality control package insert and the Bayer Multistix® 10 SG Urinalysis Log.
8. Repeat steps 2 – 7 using the Quantimetrix Abnormal Urine Dipstick control solution.

Quality Control Corrective Actions:

If quality control results exceed the acceptable limits, the following steps will be taken:

1. Check the expiration dates printed on the Multistix® SG vial label and on the quality control vial labels and repeat the test. If either level is unacceptable, proceed with step 2.
2. To verify stability of quality control solutions, open new solutions and repeat the test. If either level is unacceptable, proceed with step 3.
3. To verify that the Multistix® SG urine test strip has not been exposed to heat extremes or moisture, open a new vial of test strips and repeat the test. If either level is unacceptable, proceed with step 4.
4. Seek supervisory assistance. Consult the Charge Nurse, Clinical Coordinator, Nurse Manager or Point-of-Care Testing Supervisor in the laboratory.

V. APPENDIX:

APPENDIX A: ABOUT THE TEST

Reference Ranges (Manufacturer provided):

Specific Gravity 1.001 – 1.035 (Random urine)
 1.016 – 1.022 (24 hr. urine with normal diet and fluid intake)

PH	5 – 8
Leukocytes	Negative
Nitrite	Negative
Protein	Negative
Glucose	Negative
Ketones	Negative
Urobilinogen	Up to 1 mg/dl
Bilirubin	Negative
Blood	Negative

Panic Values:

Urine Ketones **Greater than 80 mg/dl: The urine specimen should be sent to the main lab for repeat testing and the primary care giver should be notified.**

Procedural Limitations Provided by Manufacturer:

Glucose: Ascorbic acid concentrations of 50 mg/dl or greater may cause false negatives for specimens containing small amounts of glucose (75-125 mg/dl). Ketone bodies reduce the sensitivity of the test; moderately high ketone levels (40 mg/dl) may cause false negatives for specimens containing small amounts of glucose (75-125 mg/dl) but the combination of such ketone levels and low glucose levels is metabolically improbable in screening. The reactivity of the glucose test decreases as the SG of the urine increases. Reactivity may also vary with temperature.

Bilirubin: Indican (indoxyl sulfate) can produce a yellow-orange to red color response that may interfere with the interpretation of a negative or positive bilirubin reading. Metabolites of Lodine® (etodolac) may cause false positive or atypical results; ascorbic acid concentrations may cause false positive or atypical results; ascorbic acid concentrations of 25 mg/dl or greater may cause false negatives. Since very small amounts of bilirubin may be found in the earliest phases of liver disease, the user must consider whether the sensitivity of the Bayer Diagnostic Reagent Strips is sufficient for intended use. When very small amounts of bilirubin in urine are sought (e.g., earliest phase of viral hepatitis), ICTOTEST® Reagent Tablets should be the method of choice. No known interferences when handled according to instructions.

Ketones: False positive results (Trace or less) may occur with highly pigmented urine specimens or those containing large amounts of levodopa metabolites. Compounds such as mesna (2-mercapoethane sulfonic acid) that contain sulfhydryl groups may cause false positive results or an atypical color reaction.

Specific gravity: The chemical nature of the Bayer Diagnostics SG test may cause slightly different results from those obtained from other specific gravity methods when elevated amounts certain urine constituents are present. Highly buffered alkaline urines may cause low reading relative to other methods. Elevated specific gravity readings may be obtained in the presence of moderate quantities (100-750 mg/dl) of protein.

Blood: Elevated specific gravity may reduce the reactivity of the blood test. Capoten® (Captopril) may also cause decreased reactivity. Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbial peroxidase associated with urinary tract infections may cause a false positive reaction. Levels of ascorbic acid normally found in urine do not interfere with this test.

pH: If proper procedure is not followed and excess urine remains on the strip, a phenomenon known as “runover” may occur, in which the acid buffer from the protein reagent will run into the pH area causing a false lowering of the pH result.

Protein: False positive results may be obtained with highly buffered or alkaline urines. Contamination of the urine specimen with quaternary ammonium compounds (e.g., from some antiseptics and detergents) or with skin cleansers containing chlorhexidine may also produce false positive results.

Urobilinogen: The reagent area may react with substances known to interfere with Erlich's reagent, such as p-aminosalicylic acid and sulfonamides. Atypical color changes may be obtained in the presence of high concentrations of p-aminobenzoic acid. False negative results may be obtained if formalin is present. Strip reactivity increases with temperature; the optimum temperature is 22 – 26 C. This test is not a reliable method for the detection of porphobilinogen. The absence of urobilinogen cannot be determined with this test.

Nitrite: Pink spots or pink edges should not be interpreted as a positive result. Any degree of uniform pink color development should be interpreted as a positive nitrite test suggesting the presence of 10^5 or more organisms per mL, but color development is not proportional to the number of bacteria present. A negative result may occur when urinary tract infections are caused by organisms that do not contain reductase to convert nitrate to nitrite; when urine has not been retained in the bladder long enough (4 hours or more) for reduction of nitrite to occur; or when dietary nitrate is absent, even if organisms containing reductase are present and bladder incubation is ample. Sensitivity of the nitrite test is reduced for urines with high specific gravity. Ascorbic acid concentrations of 25 mg/dl or greater may cause false negative results with specimens containing small amounts of nitrite ion (0.06 mg/dl or less).

Leukocytes: Elevated glucose concentrations (≥ 3 g/dl) or high specific gravity may cause decreased test results. The presence of cephalexin (Keflex®), cephalothin (Keflin®), or high concentrations of oxalic acid may also cause decreased test results. Tetracycline may cause decreased reactivity, and high levels of the drug may cause a false negative reaction.

Specific Performance Characteristics Provided By the Manufacturer

Each color block or instrument display value represents a range of values. Because of specimen and reading variability, specimens with analyte concentrations that fall between the nominal levels may give results at either level. Results at levels greater than the second positive level for glucose, ketone, protein, and urobilinogen tests will usually be within one level of the true concentration. Exact agreement between visual results and instrumental results might not be found because of the inherent differences between the perception of the human eye and the optical system of the instruments.

Glucose: The test is specific for glucose; no substance excreted in urine other than glucose is known to give a positive result. The reagent area does not react with lactose, galactose, fructose or reducing metabolites of drugs (e.g. salicylates and nalidixic acid). This test may be used to determine whether the reducing substance found in urine is glucose. Reactivity may be influenced by urine specific gravity and temperature. In dilute urines containing less than 5 mg/dl ascorbic acid, as little as 40 mg/dl glucose may produce a color change that might be interpreted as positive. The test is more sensitive than the copper reduction test (e.g., CLINITEST® Reagent Tablets). If the color appears somewhat mottled at the higher glucose concentrations, match the darkest color to the color blocks.

Bilirubin: The test is less sensitive than ICTOTEST® Reagent Tablets.

Ketone: The test reacts with acetoacetic acid in urine. It does not react with acetone or B-hydroxybutyric acid. Some high specific gravity/low pH urines may give reactions up to and including Trace. Clinical judgement is needed to determine the significance of reactions up to and including Trace.

Specific gravity: The specific gravity test permits determination of urine specific gravity between 1.000 and 1.030. In general, it correlates within 0.005 with values obtained with the refractive index

method. For increased accuracy, 0.005 may be added to readings with pH equal to or greater than 6.5. Strips read instrumentally are automatically adjusted for pH by the instrument. The Bayer Diagnostics SG test is not affected by certain nonionic urine constituents such as glucose nor by the presence of radiopaque dye.

Blood: The sensitivity of this test may be reduced in urines with high specific gravity. The test is equally sensitive to myoglobin as to hemoglobin. The appearance of green spots on the reacted reagent area indicates the presence of intact red cells in the urine. The color chart includes examples of trace and moderate nonhemolyzed color blocks. Reactions ranging from trace to large with proportionally more numerous spots, may be observed. (Hemoglobin concentrations of 0.015 to 0.062 mg/dl is approximately equivalent to 5-20 intact red cells per microliter.) Because of the optical systems of urine chemistry instruments, the sensitivity to intact erythrocytes is lower than that perceived visually.

pH: The pH test area measures pH values generally to within 1 unit range of 5-8.5 visually and 5-9 instrumentally. PH readings are not affected by variations in the urinary bladder concentration.

Protein: The reagent area is more sensitive to albumin than to globulins, hemoglobin, Bence-Jones protein and mucoprotein; a negative result does not rule out presence of these proteins.

Urobilinogen: This test area will detect urobilinogen in concentrations as low as 0.2 mg/dL (approximately 0.2 EU/dL) in urine. The absence of urobilinogen in the specimen being tested cannot be determined.

Nitrite: Comparison of the reacted reagent area against a white background may aid in the detection of low levels of nitrite ion, which may be otherwise missed. The test is specific for nitrite and will not react with any other substance normally excreted in the urine.

Leukocytes: The sensitivity claim has been verified by clinical evaluations at a number of clinical sites.

VI. REFERENCES:

Bayer Multistix® 10 SG Urine Test Strips Package Insert. Bayer Corporation, Diagnostic Division, Elkhart, IN, 1995.
Nursing Policy: Diagnostic Testing of Urine, File Section: U, 1993.
Perry & Potter, Specimen Collection

VII. RESOURCES:

Procedure Committee
Department of Clinical Pathology