PROCEDURE
Corewell Health East - Laboratory Manual Urinalysis Dipstick Testing - Dearborn, Taylor, Trenton, Wayne

This Procedure is Applicable to the following Corewell Health sites:
Corewell Health Dearborn Hospital, Corewell Health Taylor Hospital, Corewell Health Trenton Hospital, Corewell Health Wayne Hospital

Applicability Limited to: N/A

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Functional Area: Clinical Operations, Laboratory

Lab Department Area: Lab - Urinalysis

1. Principle

To provide guidance on performing a manual urinalysis dipstick, using Siemens Multistix® 10 SG Reagent Strips, for Urinalysis when automated testing methods are not available or for confirmation of automated Urinalysis results. Results will be used to determine if microscopic analysis Is needed. Siemens Multistix® 10 SG Reagent Strips are intended for use in at-risk patient groups to assist in diagnosis in kidney function, urinary tract infections, carbohydrate metabolism (e.g. diabetes mellitus) and liver function.

A. **pH**: Certain dietary conditions can produce acid or alkaline urines, which can be useful in the treatment of some calculi.
B. **Protein**: Protein in urine can be the result of urological and nephrological disorders. Positive results may also indicate tubular or overflow proteinuria in the absence of any glomerular abnormality or proteins of renal origin that may be excreted during infection. Urinary protein excretions can be temporarily elevated in the absence of renal abnormality by strenuous exercise, orthostatic proteinuria, dehydration, urinary tract infections and acute illness with fever.
C. **Glucose**: Small amounts of glucose are normally excreted by the kidneys which are usually below the sensitivity level of the test. Results at the first positive level may be significantly abnormal if found consistently.
D. **Ketone**: In ketoacidosis, starvation, or with other abnormalities or carbohydrate or lipid metabolism, ketones may appear in urine before serum ketone levels are detected. Clinical judgement is needed to determine the significance of trace results which may occur during physiological stress conditions such as fasting, pregnancy, and frequent strenuous exercise.
E. **Bilirubin**: Trace amounts of bilirubin are sufficiently abnormal to require further investigation for the presence of liver disease.
F. **Blood**: Occult blood occurs in urine as intact erythrocytes and hemoglobin, which can occur during urological, nephrological and bleeding disorders. Small amounts of blood are sufficiently abnormal to require further investigation. Blood is often, but not always, found in

the urine of menstruating females.

G. **Nitrite:** Many enteric Gram-negative organisms give positive results when their number is greater than 10^5 mL.
H. **Leukocytes**: An increase in leukocytes is an indication of pyuria and is found in nearly all diseases of the kidney and urinary tract. However, pyuria may often be present in non-infective conditions. A strip result of Small or greater is a useful indicator of infection.
I. **Urobilinogen:** Elevation of both the bilirubin and urobilinogen results help in the differential diagnosis of jaundice, as well as other liver and biliary disorders.
J. **Specific Gravity:** If the specific gravity of a random urine is 1.023 or greater, the concentrating ability of the kidneys can be considered normal.

2. Responsibility

Personnel who have completed the competency requirements will perform this testing.

3. Specimen

See Lab Test Directory for Urinalysis specimen requirements.

4. Reagent/Equipment Needed

A. Multistix 10 SG Reagent Strips for Urinalysis
   1. See Siemens Multistix® 10 SG Package insert for each test pad's performance characteristics, sensitivity, chemical principles, and ingredients.
   2. Protection from exposure to light, heat and ambient moisture is mandatory to guard against altered reagent activity.
   3. All unused strips must remain in the original bottle with the cap tightly sealed.
   4. Do not remove the desiccant from the bottle.
   5. Store at 15-30ºC.
   6. Do not use strips past the expiration date on the bottle.
B. Timing Device
C. As Needed Supplies
   1. 16 X 100 Plastic tube
   2. Transfer pipette
   3. Kimwipe®, paper towel, or gauze

5. Quality Control (QC)

A. Negative and positive controls should be tested whenever a new bottle of strips is first opened.
B. Taylor, Trenton, Wayne and Canton
   1. KOVA-Trol™ I and KOVA-Trol™ III are run daily when patient testing is performed.
      a. KOVA-Trol™ controls are stable until the expiration date on the label until reconstituted, when stored between 2° and 8°C.
      b. KOVA-Trol™ controls are stable for 7 days once reconstituted.
      c. Do not freeze.
      d. KOVA-Trol™ controls are prepared weekly by reconstituting with clinical laboratory reagent water (deionized water) using a graduated cylinder. See package insert for more details based on the bottle size.
         1) Gently rotate the bottle until completely dissolved (approximately 15 minutes).
   2. Allow quality control materials to come to room temperature before performing testing.
   3. Gently mix the control material and transfer an aliquot to a clean 16 X 100 plastic tube.
C. Dearborn
   1. KOVA Liqua-Trol™ Liquid Controls Level I and II are run daily when patient testing is performed.
      a. Liqua-Trol™ controls are ready to use.
      b. Liqua-Trol™ controls are stable until the expiration date stated on the label, when stored between 2° and 8°C.
      c. Liqua-Trol™ controls can be stored at room temperature (20° to 25°C) for up to 30 days.

d. Do not freeze.
2. Allow quality control materials to come to room temperature before performing testing.
3. Gently mix the control material and transfer an aliquot to a clean 16 X 100 plastic tube.

D. See below for testing procedure.
E. Record results on the Manual Urine Dipstick QC/Patient Log.
F. All quality control results will be reviewed for acceptability prior to reporting patient results.

6. New Lot / New Shipment Reagent Strip Verification

A. Each new lot number and/or shipment of test strips are tested in parallel with the current test strips in use.
1. Two previously run patients (one “negative” and one “positive”) are pulled and tested in parallel with each new lot or shipment of testing strips.
2. Results are recorded on the Urinalysis Testing Strip Verification Worksheet.
3. Qualitative results must agree within one grade and specific gravity must agree within ±0.005.
4. Completed Urinalysis Testing Strip Verification Worksheets are given to the Lead Technologist or designee for approval.

B. Any new lot or shipment of strips that do not correlate with the previous lot or shipment will not be used for patient testing.

7. Procedure

A. QC and Patient Testing
1. If the QC or patient samples have been refrigerated, allow samples to come to room temperature before performing testing.
2. Gently mix the QC or patient sample.
a. Samples may be aliquoted into a clean 16 x 100 plastic tube.
3. Remove a Reagent Strip from the bottle and replace cap.
a. Do not remove the strip from the bottle until immediately before it is to be used for testing.
b. Do not remove the desiccant from the bottle.
c. Replace the cap immediately and tightly after removing the reagent strip.
4. Do not touch the test areas of the strip.
5. Dip the Reagent Strip into the well mixed patient or QC sample.
a. Thoroughly saturate all of the reagent pads on the test strip. Excess sample may be removed by slowly running the edge of the entire length of the strip against the side of the urine container or plastic tube or by gently blotting the edge of the entire length of the strip against a paper towel, Kimwipe®, or a piece of gauze. Do not blot the reagent pads directly.
b. For small volumes of urine, a transfer pipette may be used to saturate each of the reagent pads on the test strip. Excess sample may be removed by gently blotting the edge of the entire length of the strip against a paper towel, Kimwipe®, or a piece of gauze. Do not blot the reagent pads directly.
6. Immediately start timing.
7. Visually read the Reagent Strip. Read each pad at the time shown on the bottle label, starting with Glucose at 30 seconds.
a. Compare each test pad to the corresponding row of color blocks on the bottle label.
b. Hold the Reagent Strip close to the color blocks and match carefully.
c. Read each pad at the time shown on the bottle label.
d. Read the pads in good lighting.
e. Do not read any test pad after 2 minutes of being dipped in urine.

B. Record results on the Manual Urine Dipstick QC/Patient Log.
C. Evaluate the results for any confirmation testing that is needed:
1. Specific Gravity: Confirm >1.030 results on the refractometer. See site-specific refractometer procedures for more details.
2. Nitrites: Per the package insert, pink spots or pink edges should not be interpreted as a

positive result. If the microscopic results do not correlate with a positive Nitrite result, repeat the testing procedure to verify the positive Nitrite result.

D. Evaluate the results for the requirements of a microscopic exam. Any positive macroscopic result (except urobilinogen) reflexes a microscopic exam. Please refer to the Corewell Health East - Laboratory Examination of Urinary Sediment - Dearborn, Taylor, Trenton, Wayne or Corewell Health East – Sysmex UN Series (UN-9000, UN-3000, and UN-2000) Comprehensive Automated Urinalysis System Operation procedures for more information.

E. Procedural Notes
   1. Verification of unusual results is accomplished by comparing reagent strip to the color chart on the Multistix bottle and/or repeating the analysis from start to finish.
   2. Discoloration or darkening of the test pads may indicate deterioration. If this is evident, check the performance with positive and negative controls.
   3. Nitrite test results are optimized by using a first morning urine specimen or one that has incubated in the bladder for 4 hours or more.
   4. Bilirubin and urobilinogen must be done on fresh urine to achieve optimal results as these substances are very unstable when exposed to room temperature and light.
   5. Prolonged exposure of unpreserved urine to room temperature may result in microbial proliferation with a resultant change in pH. A shift to alkaline pH may cause false positives in the protein test area.
   6. Bacterial growth from contaminating organisms may cause false positive blood reactions due to production of peroxidases.

8. Results / Interpretations

A. In order to have the correct reporting options available in the Laboratory Information System (LIS):
   1. In the result entry field, choose the [Method] tab (bottom of the screen).
   2. Click on the search icon and choose one of the automated instruments.
   3. Click [Apply].

B. Add the smart phrase ".MANDIP' (Testing performed by Manual Dipstick method) to the Urine Comment section to document the proper testing method.

Parameter	Reference Range	LIS Reportable Range
Color	NA	Amber, Blue, Brown, Colorless, Dark Yellow, Green, Orange, Pink, Red, Straw, Yellow, Other
Clarity	Clear	Clear, Cloudy, Turbid
Urine Glucose	Negative	Negative, 100, 250, 500, ≥1000, Color Interference
Urine Bilirubin	Negative	Negative, Positive, Color Interference
Urine Ketone	Negative	Negative, 5, 15, 40, 80, ≥160, Color Interference
Urine Specific Gravity	1.005 – 1.030	1.000 – 1.030 (>1.030 will be confirmed using a refractometer and report out up to 1.045)
Urine Blood	Negative	Negative, Trace, 1+, 2+, 3+, Color Interference

Urine pH	5.0 – 8.0	5.0 – 8.5, Color Interference
Urine Protein	Negative	Negative, Trace, 30, 100, 300, ≥1000, Color Interference
Urine Urobilinogen	0.2 – 1.0 mg/dL	0.2, 1.0, 2.0, 4.0, ≥8.0, Color Interference
Urine Nitrites	Negative	Negative, Positive, Color Interference
Urine Leukocytes	Negative	Negative, Trace, 1+, 2+, 3+, Color Interference

C. Critical Results: Urine Ketones >=80 mg/dL
Note: Critical call notification is waived for patients in the Emergency Center (EC).

9. Limitations

A. Because of specimen and reading variability, specimens with analyte concentrations that fall between nominal levels may give results at either level. Results 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 systems of the instruments.

B. Color Interference:
Abnormally colored or very dark urine may interfere with or obscure reagent strip test results. Substances that cause abnormal urine color include visible levels of blood or bilirubin, drugs containing azo dyes (e.g. Pyridium®), nitrofurantoin, or riboflavin. The color development on the reagent pad may be masked or a color reaction may be produced on the pad that could be interpreted visually and/or instrumentally as a false positive.

1. If such a specimen is submitted,
   a. All results (except color, clarity and Specific Gravity) should not be reported and should be resulted as COLOR INTERFERENCE in the LIS.
   b. Color and Clarity should be determined visually and manually entered into the LIS.
   c. Specific Gravity testing should be performed on the refractometer. These results should be manually entered into the LIS and performed according to site-specific refractometer procedures.
   d. A microscopic exam should be performed.
   e. See the Corewell Health East - Guideline for Handling Suboptimal Urinalysis Samples - Dearborn, Taylor, Trenton, Wayne procedure for additional information..

C. Bloody Urine: See the Corewell Health East - Urinalysis Procedure for Analyzing Bloody Specimens - All Beaumont Hospitals procedure.

1. Enter the smart phrase comment ". bldyua**"** (**Bloody specimen. Urine chemistry testing was performed on the supernatant of a centrifuged specimen. Interpret results cautiously)** in the white Urine Comment box in the LIS.
   a. Note: Canton adds an additional comment ". BLDCOLOR" (Color is reported on the supernatant of the bloody urine specimen. Interpret results cautiously) to the Color result as requested by the emergency room physicians.
2. Spin the urine and process the chemistry portion of the urinalysis manually using the supernatant on a stand alone instrument.
   a. If the supernatant remains red, DO NOT perform the chemistry portion of the urinalysis.
      1) Manually result the color and clarity of the supernatant.
      2) Perform and report the Specific Gravity by refractometer.
      3) Report "color interference" for Glucose, Bilirubin, Ketone, Blood, pH, Urobilinogen, Nitrite, and Leukocytes.
3. Interfering Substances

a. See Color Interference section above for abnormally colored urines.
b. pH: Bacterial growth by certain organisms in a specimen may cause a marked alkaline shift (pH >8.0), usually because of urea conversion to ammonia.
c. Protein: A visibly bloody urine may cause falsely elevated result. Contamination of the urine specimen with skin cleansers containing chlorhexidine may affect protein results.
d. Glucose: Ketone bodies reduce the sensitivity of the test; moderately high ketone levels may cause false negatives for specimens containing small amounts of glucose, but the combination of such ketone levels and low glucose levels is metabolically improbable in screening.
e. Ketone: False trace results may occur with highly pigmented urine specimens or those containing large amounts of levodopa metabolites. Compounds such as mesna (2-mercaptoethane sulfonic acid) that contain sulfhydryl groups may cause false positives or an atypical color reaction.
f. Bilirubin: Indican (indoxyl sulfate) can produce a yellow-orange to red color response which may interfere with the interpretation of a negative or a positive bilirubin reading. Metabolites of etodolac may cause false positive or atypical results. Atypical colors (colors that are unlike the negative or positive color blocks shown on the Color Chart) may indicate that bilirubin-derived bile pigments are present in the urine sample and may be masking the bilirubin reaction. These colors may indicate bile pigment abnormalities. The comment “Positive bilirubin by dipstick. Unable to exclude color interference. Suggest clinical correlation” is automatically attached to all positive Bilirubin results in the LIS. Contamination of the urine specimen with skin cleansers containing chlorhexidine may affect Bilirubin results.
g. Blood: Captopril may reduce sensitivity. Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbial peroxidase associated with urinary tract infection may cause a false positive reaction.
h. Nitrite: Pink spots or pink edges should not be interpreted as a positive result. A negative result does not rule out significant bacteriuria. False negative results may occur with shortened bladder incubation of the urine, absence of dietary nitrate, or the presence of nonreductive pathological microbes.
i. Leukocytes: Elevated glucose concentrations may cause decreased test results. The presence of cephalexin, cephalothin, or high concentrations of oxalic acid may cause decreased test results. Tetracycline may cause decreased reactivity, and high levels of the drug may cause a false negative reaction. Positive results may occasionally be due to contamination of the specimen by vaginal discharge.
j. Urobilinogen: The test pad may react with interfering substances known to react with the Ehlich’s reagent, such as p-amino salicylic acid and sulfonamides. Atypical color reactions 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 22-26ºC. The test is not a reliable method for detection of porphobilinogen.
k. Specific Gravity (SG): The Siemens SG test is dependent on ions in urine and results may differ from those obtained with other specific gravity methods when certain nonionic urine constituents, such as glucose, are present. Highly buffered alkaline urines may cause low readings, while the presence of moderate quantities of protein may cause elevated readings. Contamination of the urine specimen with skin cleansers containing chlorhexidine may affect Specific Gravity results. All Specific Gravities ≥1.030 should be verified using a refractometer.

10. Revisions

Corewell Health reserves the right to alter, amend, modify or eliminate this document at any time without prior written notice.

11. References

A. Multistix® 10 SG package insert, Siemens Healthcare Diagnostics Inc, Tarrytown, NY 07-2017

12. Procedure Development and Approval

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13. Keywords

Not Set