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Supersedes 2/6/08 –name change from Bayer to Siemens

TITLE: URINALYSIS TESTING USING Siemens MULTISTIX 10 SG REAGENT STRIPS

Principle:

Siemens Multistix 10 SG reagent strips are firm plastic strips to which are affixed several separate reagent areas. Multistix 10 SG strips provide tests for glucose, bilirubin, ketones, specific gravity, blood, pH, protein, urobilinogen, nitrite, and leukocytes in urine. Test results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance, and urinary tract infection.

The reagent test areas on the Multistix 10 SG strips are ready to use upon removal from the bottle and the entire reagent strip is disposable. The strips are read visually.

The directions must be followed exactly. Accurate timing is essential to provide optimal results. The reagent strips must be kept in the bottle with the cap tightly closed to maintain reagent reactivity. To obtain optimal results, it is necessary to use FRESH, WELL-MIXED, uncentrifuged urine. For the chemical principles of each test area, please refer to the product insert found in the box with each bottle of Multistix 10 SG.

Specimen Requirement:

Collect urine in a clean container and test it as soon as possible. Do not centrifuge. The use of urine preservatives is not recommended. If testing cannot be done within an hour after voiding, refrigerate the specimen immediately and let it return to room temperature before testing.

Reagents and Equipment:

Multistix 10 SG reagent strips (see product insert for a complete list of reagents). Store at room temperature between 15-30 degrees C (59-86 degrees F). Do not use after expiration date. Do not store the bottle in direct sunlight.

Clean, dry urine collection container
Stopwatch or clock with a second hand

Controls (positive and negative) for quality assessment-located in central laboratory
Note: See central lab UA procedure for QC. Read strips visually.

Quality Control

Each bottle of Multistix 10 SG reagent strips will have QC performed using known positive and negative controls. This function will be carried out by testing personnel. Please notify the central laboratory when opening a new bottle. Records of quality control will be kept in the central laboratory. If a bottle of strips fails to give the expected results, central lab personnel will notify Occupational Health.

Procedure:

MUST BE FOLLOWED EXACTLY TO ACHIEVE RELIABLE RESULTS

1. Collect fresh urine specimen in a clean, dry container. If specimen has been refrigerated, let it come to room temperature before testing. Mix well immediately before testing.
2. Remove one strip from the bottle of strips and replace the cap. Completely immerse reagent areas of the strip in the urine and remove immediately to avoid dissolving out reagents.
3. While removing, run the edge of the strip against the rim of the urine container to remove excess urine. Hold the strip in a horizontal position to prevent possible mixing of chemicals from adjacent reagent areas and/or contaminating the hands with urine.
4. Compare reagent areas to corresponding color chart on the bottle label at the time specified. Hold strip close to color blocks and match carefully. Avoid laying the strip directly on the color chart, as this will result in the urine soiling the chart. **PROPER READ TIME IS CRITICAL FOR OPTIMAL RESULTS.** Read the glucose and bilirubin test at 30 seconds after dipping. Read the ketone test at 40 seconds; the specific gravity at 45 seconds; pH, protein, urobilinogen, blood, and nitrite at 60 seconds; and leukocytes at 2 minutes. The pH and protein areas may also be read immediately or at any time up to 2 minutes after dipping. After dipping the strip, check the pH area. If the color on the pad is not uniform, read the reagent area immediately, comparing the darkest color to the appropriate color chart. All reagent areas except leukocytes may be read between 1 and 2 minutes for identifying negative specimens and for determination of the pH and specific gravity. A positive reaction (small or greater) at less than 2 minutes on the leukocyte test may be regarded as a positive indication of leukocytes in urine. Color changes that occur after 2 minutes are of no diagnostic value.

Reporting Results

Results are reported directly back to the patient in the amounts expressed on the charts on the bottle label.

Expected Values:

Glucose: small amounts of glucose are normally excreted by the kidney, usually below the sensitivity of this test, but may, on occasion, produce a color between negative and 100 mg/dl that may be interpreted as positive. Results at the first positive level may be significantly abnormal if found consistently.

Bilirubin: normally no bilirubin is detectable in urine by even the most sensitive methods. Even trace amounts of bilirubin are sufficiently abnormal to require further investigation.

Ketone: normal urine specimens ordinarily yield negative results. Detectable levels of ketone may occur in urine during physiological stress conditions such as fasting, pregnancy, and frequent strenuous exercise. In ketoacidosis, starvation, or other abnormalities of carbohydrate or lipid metabolism, ketones may appear in urine in large amounts before serum ketone is elevated.

Specific Gravity: random urines may vary in specific gravity from 1.001-1.035.

Blood: the significance of the trace reaction may vary among patients and clinical judgement is required for assessment in an individual case. Development of green spots or green color on the reagent area within 60 seconds indicates the need for further investigation. Blood is often, but not always, found in the urine of menstruating females.

Urine pH: Both the normal and abnormal urinary pH range is from 5 to 9.

Protein: normally no protein is detectable in urine, although a minute amount is excreted by the normal kidney. A color matching any block greater than trace indicates significant proteinuria. For urine with a high specific gravity, the test area may most closely match the trace color block even though only normal concentrations of protein are present. Clinical judgement is needed to evaluate the significance of trace results.

Urobilinogen: normal urobilinogen range obtained with this test is 0.2 to 1.0 mg/dl. A result of 2.0 represents transition from normal to abnormal, and the patient and/or urine specimen should be evaluated further.

Nitrite: normally no nitrite is detectable in urine.

Leukocytes: normal urine specimens generally yield negative results. Positive results (small or greater) are clinically significant. Trace results observed individually may be of questionable clinical significance. 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.

Procedure Notes:

1. All unused reagent strips must remain in their original bottle. Do not remove the dessicant.
2. Do not remove the reagent strip from the bottle until immediately before testing. Replace the cap immediately and tightly.
3. Do not touch areas of the reagent strip and keep work areas and specimen containers free of detergents and other contaminating substances.
4. Dip test areas in urine completely, but briefly, to avoid dissolving out the reagents.
5. Read test results carefully at specified times in good light (avoid sunlight).
6. Protection against ambient moisture, light, and heat is essential to guard against altered reagent reactivity. Do not use strips if there is any discoloration or darkening of reagent areas.

Limitations of Procedure:

As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result or method.

Substances that cause abnormal urine color (e.g. pyridium) may affect the readability of the reagent areas by masking color development or producing a color reaction that could be interpreted as a false positive.

The following may cause false positive or false negative or falsely low or high results:

Glucose:

False negative: Ascorbic acid (vitamin C)
Ketone bodies
High specific gravity

Bilirubin:

False positive: Iodine

False negative: Ascorbic acid

Note: Indican can produce a yellow-orange to red color response that may interfere with the interpretation of a negative or a positive bilirubin reading

Ketone:

False positive: Highly pigmented urine
Levodopa metabolites
Compounds such as mesna that contain sulfhydryl groups

Specific gravity:

Falsely elevated: Moderate quantities of protein

Falsely low: Highly buffered alkaline urines

Blood:

False positive: Hypochlorite
Microbial peroxidase

Falsely low: High specific gravity
Capoten

Urine pH:

Excess urine on the strip may cause “runover” in which the acid buffer from the protein reagent will run onto the pH area, causing a false lowering of the pH.

Protein:

False positive: Highly buffered or alkaline urines
Contamination of urine with antiseptic and detergents containing ammonium compounds
Skin cleansers containing chlorhexidine

Urobilinogen:

False positive: Substances known to interfere with Ehrlich's reagent (*p*-aminosalicylic acid and sulfonamides) may react with the reagent area

Atypical color reactions with *p*-aminobenzoic acid

Increased temperature of reagent strip

False negative: Formalin

Nitrite:

False negative: Ascorbic acid

Reduced sensitivity: High specific gravity

Note: A negative result does not in itself prove that there is no significant bacteriuria

Leukocytes:

Decreased reactivity: Elevated glucose concentrations

High specific gravity

Presence of cephalexin, cephalothin

High concentrations of oxalic acid

Tetracycline

References:

Siemens Multistix 10 SG product inserts