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URS - OBGYN

SUMMARY
Teco Urine Reagent Strips (URS) for Urinalysis are firm plastic strips to which several different reagent areas are affixed. Teco URS-OBGYN strips provide tests for Leukocytes, Nitrite, Blood, Protein, and Glucose in Urine. Test results may provide information regarding the status of urinary tract infection (UTI), toxemia, and gestational diabetes.

Teco URS-OBGYN strips are packaged along with a drying agent in a plastic bottle with a twist-off cap. Each strip is stable and ready to use upon removal from the bottle. The entire reagent strip is disposable. Results are obtained by direct comparison of the test strip with the color blocks printed on the bottle label. No calculations or laboratory instruments are required.

TEST PRINCIPLE
Leukocytes: This test is based on the action of esterase present in leukocytes, which catalyzes the hydrolysis of an indoxyl ester derivative. The indoxyl ester liberated reacts with a diazonium salt to produce a beige-pink to purple color.

Nitrite: This test depends on the conversion of nitrate to nitrite by the action of gram-negative bacteria in the urine. The nitrite reacts with *p*-arsanilic acid to from a diazonium compound in an acid medium. The diazonium compound in turn couples with 1,2,3,4-tetrahydrobenzo(h) quinolin to produce a pink color.

Blood: This test is based on the pseudoperoxidase action of hemoglobin and erythrocytes which catalyzes the reaction of 3, 3', 5, 5'-tetramethyl-benzidine and buffered organic peroxide. The resulting colors range from orange to yellow-green and dark green. Very high blood concentration may cause the color development to continue to dark blue.

Protein: This test is based on the protein error-of-indicator principle. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow for a "Negative" reaction to yellow-green and green to blue-green for a "Positive" reaction.

Glucose: This test is based on a double sequential enzyme reaction. One enzyme, glucose oxidase, catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. A second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with potassium iodide chromogen to oxidize the chromogen to colors ranging from blue-green to greenish-brown through brown and dark brown.

REAGENTS (Based on dried weight at time of impregnation)
Leukocytes: 0.4% w/w indoxyl ester derivative; 0.2%w/w diazonium salt; 99.4% w/w buffer and nonreactive ingredients.

Nitrite: 1.4% w/w *p*-arsanilic acid, balanced with buffer and nonreactive ingredients.

Blood: 6.6% w/w cumene hydroperoxide; 4.0% w/w 3, 3', 5, 5'-tetramethylbenzidine; 89.4% w/w buffer and nonreactive ingredients.

Protein: 0.3% w/w tetrabromophenol blue; 99.7% w/w buffer and nonreactive ingredients.

Glucose: 16.3%w/w glucose oxidase (Aspergillus niger, 1.3IU); 0.6%w/w peroxidase (horseradish, 3300 IU); 7.0% w/w potassium iodide; 76.1% w/w buffer and non-reactive ingredients.

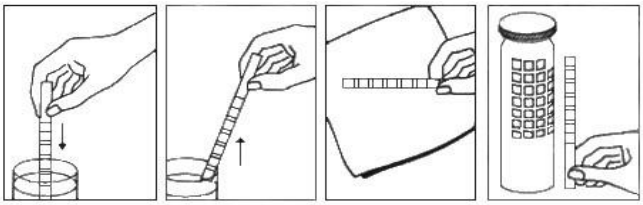
WARNINGS AND PRECAUTIONS
URS-OBGYN strips are for *in vitro* diagnostic use. Do not touch test areas of the strips.

STORAGE
Store at room temperature between 15°-30°C (59°-86°F) and out of direct sunlight. Do not use after expiration date.

RECOMMENDED HANDLING PROCEDURES
All unused strips must remain in the original bottle. Transfer to any container may cause reagent strips to deteriorate and become nonreactive. Do not remove desiccant from bottle. Do not open container until ready to use. Opened bottles should be used within 3 months after first opening.

SPECIMEN COLLECTION AND PREPARATION
Collect urine in a clean container and test as soon as possible. Do not centrifuge. The use of urine preservatives is not recommended. If testing cannot be performed within one hour after voiding, refrigerate the specimen immediately. Allow refrigerated specimen to return to room temperature before testing.

TEST PROCEDURE
1. Remove from the bottle only enough strips for immediate use and replace cap tightly.
2. Completely immerse reagent areas of the strip in fresh, well-mixed urine. Remove the strip immediately to avoid dissolving out the reagent areas.
3. While removing, touch the side of the strip against the rim of the urine container to remove excess urine. Blot the lengthwise edge of the strip on an absorbent paper towel to further remove excess urine and avoid running over (contamination from adjacent reagent pads.)
4. Compare each reagent area to its corresponding color blocks on the color chart and read at the times specified. Proper read time is critical for optimal results.
5. Obtain results by direct color chart comparison.



Note: All reagent areas except Leukocytes may be read between 1-2 minutes for screening positive urine from negative urine. Changes in color after 2 minutes are of no diagnostic value.

QUALITY CONTROL
For best results, performance of reagent strips should be confirmed by testing known negative and positive specimens or controls whenever a new bottle is first opened. Each laboratory should establish its own goals for adequate standards of performance, and should question handling and testing procedures if these standards are not met.

RESULTS
Results are obtained by direct comparison of the color blocks printed on the bottle label. The color blocks represent nominal values; actual values will vary around the nominal values.

LIMITATIONS OF PROCEDURE
Comparison to the color chart is dependent on the interpretation of the individual. It is therefore, recommended that all laboratory personnel interpreting the results of these strips be tested for color blindness.

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

Leukocytes: Highly colored urine and the presence of the drugs cephalexin (Keflex®) and gentamicin have been found to interfere with this test. High urinary protein of 500 mg/dl or above diminishes the intensity of the reaction color. Elevated glucose concentration or high specific gravity may cause decreased results.

Nitrite: The pink color is not quantitative in relation to the number of bacteria present. Any degree of pink coloration should be interpreted as a positive nitrite test suggestive of 10^5 or more organisms/ml. There are occasional urinary tract infections from organisms, which do not contain reductase to convert nitrate to nitrite.

Blood: The sensitivity of the blood test is reduced in urine with high specific gravity and/or high ascorbic acid content. False negative and weak reaction of the blood test may be observed if more than 10 mg/dl ascorbic acid in the sample. Microbial peroxidase, associated with urinary tract infection may cause false positive reactions.

Protein: False positive results may be obtained with highly alkaline urine. Contamination of the urine specimen with quarternary ammonium compounds may also produce false positive results.[4]

Glucose: Moderate amounts of ketone bodies (40mg/dL or greater) may decrease color development in urine containing small amounts of glucose (75-125 mg/dl). However, such concentration of ketone simultaneously with such glucose concentration is metabolically improbable in screening. The reactivity of the glucose test decreases as the SG of the urine sample increases and/or as the ascorbic acid in the urine sample increases. False negative and weak reaction of the glucose test may be observed if more than 50 mg/dl ascorbic acid in the sample. Reactivity may also vary with temperature.[3]

EXPECTED VALUES

Leukocytes: Normal urine specimens generally yield negative results with this test. A trace result may be of questionable clinical significance and it is recommended that the test be repeated using a fresh sample from the same patient. Repeated trace and positive results are of clinical significance.

Nitrite: Normally no detectable amount of nitrite is present in urine.[3] The nitrite area will be positive in a proportion of cases of significant infection, depending on how long the urine specimens were retained in the bladder prior to collection. Retrieval of positive cases with the nitrite test ranges from as low as 40%, in instances where little bladder incubation occurred, to as high as 80%, in instances where a minimum of 4 hours incubation occurred.

Blood: Any green spots or green color developing on the reagent area within 40 seconds is significant and the urine should be examined further. Blood is frequently, but not invariably found in the urine of menstruating females.

Protein: In 24-hour urine, 1-14 mg/dl of protein may be excreted by the normal kidney.[4] A color matching any color block greater than trace indicates significant proteinuria. For urine with high specific gravity, the test area may most closely match the trace color block even though only normal concentrations of protein are present. Clinical judgment is needed to evaluate the significance of trace results.

Glucose: Small amounts of glucose are normally excreted by the kidney.[5] Concentrations as little as 0.1 g/dl glucose, read either at 10 or 30 seconds, may be significantly abnormal if found consistently. At 10 seconds, results should be interpreted qualitatively; for semi-quantitative results, read at 30 seconds only.

SPECIFIC PERFORMANCE CHARACTERISTICS

The performance characteristics of Teco Urine Reagent Strips (URS-OBGYN) have been determined both in the laboratory and in clinical tests. Parameters of importance to the user are sensitivity, specificity, accuracy, and precision. Generally, the strips have been developed to be specific for the constituent to be measured with the exception of interferences listed above. (See LIMITATIONS OF PROCEDURE)

For visually read strips, accuracy is a function of the manner in which the color blocks on the bottle label are determined and the discrimination of the human eye in reading the test. Precision is difficult to assess in a test of this type because of the variability of the human eye. It is for this reason that users are encouraged to develop their own standards of performance.

Leukocytes: This test can detect as low as 10-15 WBC/μL. This test will not react with erythrocytes or bacteria common in urine.

Nitrite: At the time of reagent manufacture, this test has sensitivity to sodium nitrite of 0.075 mg/dl. Comparison of the reacted reagent area on a white background may aid in the detection of low levels of nitrite ion, which may otherwise be missed. This test is specific for nitrite and will not react with substances normally excreted in the urine.

Blood: At the time of reagent manufacture, this test when read as instructed has sensitivity to free hemoglobin of 0.015 mg/dl or 5-10 intact red blood cells/μL urine. This test is slightly more sensitive to free hemoglobin and myoglobin than to intact erythrocytes.

Protein: The test area is more sensitive to albumin than to globulin, hemoglobin, Bence-Jones proteins, and mucoprotein; a negative result does not rule out the presence of these other proteins. The test area is sensitive to 15 mg/dl albumin. Depending on the inherent variability in clinical urine lesser concentration may be detected under certain conditions.

Glucose: This test is specific for glucose; no substances 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 substances found in urine is glucose. Approximately 100 mg/dl glucose in urine is detectable.

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URS-OBGYN: 03/2012

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