

Intended Use

For the qualitative or semiquantitative determination of various analytes in human urine.

Principle

The presence of specific compounds in urine is used to determine the approximate values of the various analytes. Reactions between chemicals on the pads and said compounds in urine, combined with certain color indicators, produce colors that correlate with the presence and concentration of the relevant analyte.

See package inserts for detailed principles for each analyte.

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Teco Diagnostics

Test:

Urine Reagent Strip-OBGYN (URS-OBGYN) Leukocytes/Nitrite/Protein/Blood/Glucose

Format:

Strip

Method:

Color Indicator

Testing Procedure:

Manual

Storage Temperature:

15-30°C

Expected Values/Sensitivity:

<u>Glucose</u>: Concentrations as little 0.1g/dL may be significantly abnormal if found consistently (100mg/dL sensitivity)

Blood: No blood in normal urine (0.015mg/dL sensitivity)

Protein: 1-14mg/dL may be excreted by the normal kidney (15mg/dL sensitivity)

Nitrite: No nitrite in normal urine (0.075mg/dL sensitivity)

 $\underline{\text{Leukocytes}} : \text{Normal urine specimens generally yield negative results (10-15 WBC/} \mu \text{L}$

sensitivity)

Limitations of Procedure:

<u>Glucose</u>: Moderate amounts of ketone bodies (40mg/dL or greater) may decrease color development in urine containing small amounts of glucose (75-125mg/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 specific gravity and/or ascorbic acid of the urine increases. Reactivity may also vary with temperature.

<u>Blood</u>: The sensitivity of the blood test is reduced in urine with high specific gravity and/or high ascorbic acid content. Microbial peroxidase, associated with urinary tract infection may cause false positive reactions.

<u>Protein</u>: 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.

<u>Nitrite</u>: 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 into nitrite.

<u>Leukocytes</u>: 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 500mg/dL or above diminishes the intensity of the reaction color. Elevated glucose concentration or high specific gravity may cause decreased results.

Expected Shelf Life:

90 days at 15-30°C once opened 18 months at 15-30°C unopened