Teco Diagnostics

Intended Use

For the qualitative or semi-quantitative 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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Test:
Urine Reagent Strip-10 (URS-10)
Leukocytes/Nitrite/Urobilinogen/Protein/pH/Blood/SG/Ketone/Bilirubin/Glucose

Format:
Strip

Method:
Color Indicator

Testing Procedure:
Manual

Storage Temperature:
15-30°C

Expected Values/Sensitivity:
Glucose: Concentrations as little 0.1g/dL may be significantly abnormal if found consistently (100mg/dL sensitivity)
Bilirubin: No bilirubin in normal urine (0.4-0.8mg/dL sensitivity)
Ketone: No ketones in normal urine (5-10mg/dL sensitivity)
Specific Gravity: Random urine varies in specific gravity from 1.003-1.040+ (correlates within 0.005 with values obtained with the refractive index method)
Blood: No blood in normal urine (0.015mg/dL sensitivity)
pH: Newborn: 5.0-7.0; Thereafter: 4.5-8.0 ; Average: 6.0 (quantitative differentiation of values to one unit)
Protein: 1-14mg/dL may be excreted by the normal kidney (15mg/dL sensitivity)
Urobilinogen: 0.2-1.0 EU/dL in healthy urine (0.2 EU/dL sensitivity)
Nitrite: No nitrite in normal urine (0.075mg/dL sensitivity)
Leukocytes: Normal urine specimens generally yield negative results (10-15 WBC/µL sensitivity)

Limitations of Procedure:
Glucose: 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.
Bilirubin: Reactions may occur with urine containing large doses of chlorpromazine or rafampen that might be mistaken for positive bilirubin. Indican (indoxyl sulfate) and metabolites of Lodine® may cause false positive or atypical color; ascorbic acid (25mg/dL or greater) may cause false negative results.
Ketone: Color reaction that could be interpreted as “positive” may be obtained with urine specimens containing MESNA or large amounts of phenylketones or L-dopa metabolites.
Specific Gravity: The chemical nature of the specific gravity test may cause slightly different results from those obtained with the specific gravity methods when elevated amounts of certain urine constituents are present. Highly buffered alkaline urine may cause low readings relative to other methods. Elevated specific gravity readings may be obtained in the presence of moderate quantities (100-750mg/dL) of protein.

Blood: 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.
pH: If proper procedure is not followed and excess urine remains on the strip, a phenomenon known as "running over" may occur, in which the acid buffer from the protein reagent are runs onto the pH area, causing a false lowering in the pH result.
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.
Urobilinogen: The test area will react with interfering substances known to react with Ehrlich's reagent, such as porphobilinogen and *p*-aminosalicyclic acid. This test is not a reliable method for the detection of porphobilinogen. Drugs containing azo-dyes (e.g. Azo Gantrisin) may give a masking golden color. The absence of urobilinogen cannot be determined with this test.
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 into nitrite.
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 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