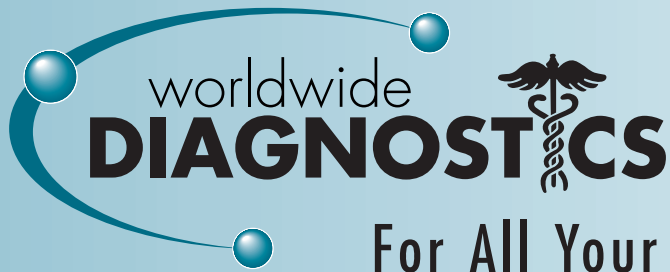


worldwide
DIAGNOSTICS



For All Your Clinical Diagnostic Needs

INTENDED USE

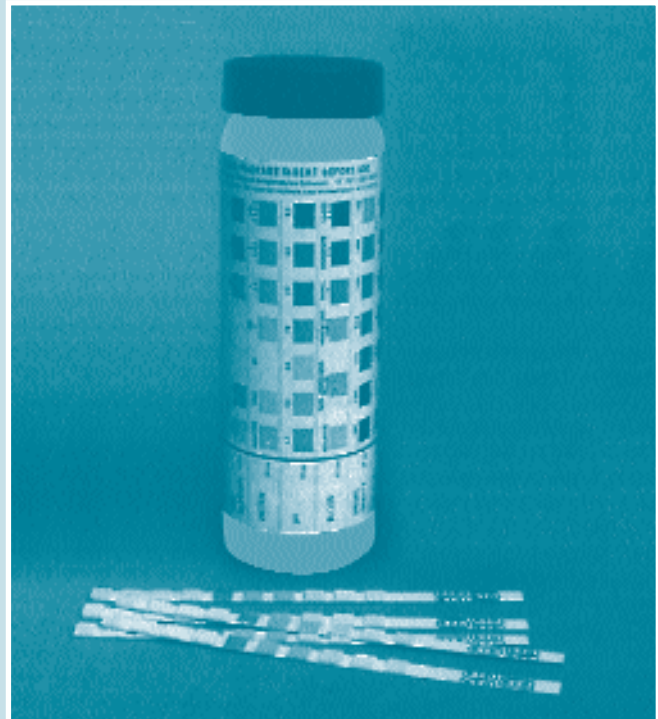
The intended use of the reagent strips are for the in-vitro determination of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, and Leukocytes in Urine.

SUMMARY

Urinalysis by the "Dip & Read" Method is widely practiced as a rapid chemical analysis in the diagnosis of various diseases. These reagent strips consists of plastic strips affixed with reagent impregnated areas for Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, and Leukocytes. Determination of relative quantities can be made by visual comparison to a color chart provided or by use of a reflectance meter. Use of such reagent strips has made measurement of multiple urine constituents and use for routine diagnosis and group examinations all the more easier.

STORAGE CONDITIONS & GENERAL PRECAUTIONS AND WARNINGS

For in-vitro use only. As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result or method. The effects of drugs or metabolites on the individual test are not known in all cases. Reagent strips should be stored in their original con-



tainer, which has a desiccant. It should be kept at room temperature (between 5-25 degrees centigrade), and away from direct sunlight. Do not use after the expiration date shown. Good laboratory practice and Universal precautions for handling biological specimens should be observed. Specimens and waste materials should be properly disinfected before disposal. Once a test has been started all subsequent steps should be completed without interruptions and within the recommended time limits.

10 PARAMETER REAGENT STRIPS FOR URINALYSIS

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Composition (for 100 strips)

Glucose

Glucose Oxidase	1.00mg
Peroxidase	0.54mg
Potassium iodide	5mg

Bilirubin

2,4 dichloroaniline diazonium salt	1.12mg
Sodium nitrite	1.52mg

Ketone

Sodium nitroprusside	43mg
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Specific Gravity

Bromothymol blue	1 mg
Poly (methyl, vinyl ether maleic acid Sodium salt)	18mg

Blood

Cumene hydroperoxide (CHP)	10.1 mg
3,3',5,5'-Tetramethylbenzidine (TMB)	6.5mg

pH

Methyl red	0.045 mg
Bromothymol blue	0.45 mg

Protein

Tetrabromophenol blue	0.31 mg
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Urobilinogen

p-dimethylaminobenzaldehyde	1.02mg
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Nitrite

N-1-Naphthyl-ethylenediamine dihydrochloride	0.6mg
Arsenic Acid	3.2 mg

Leukocytes

3-(N-Toluenesulfonyl-L-alanyloxy)-indols	0.6mg
1-diazo-2-naphthol-4-sulfonic acid	0.3mg

Testing Procedures

Correct operating procedures and measurement time is required to obtain accurate results.

1. Collect FRESH, WELL-MIXED, UNCENTRIFUGED urine specimen in a clean dry container. Mix well immediately before testing.
2. Remove only as many strips as necessary from the container and reseal the closure immediately after removing the strips. It is important to keep the remaining strips dry. Do not touch the test areas of the strip. Inspect the strips. If the reagent areas are discolored or darkened do not use the strips.
3. Dip the test strip into the urine for no more than 1 second, making sure all the reagent areas have contacted the urine specimen.
4. Remove the strip and gently remove excess urine by running the edge of the strip against the rim of the urine container.
5. Hold the strip in a horizontal position to prevent mixing of chemical from adjacent reagent areas and/or contaminating the hands with urine.
6. Properly orient the strip near the appropriate color chart on the container label. At the times specified, read the results carefully under good lighting or with the appropriate instrument compatible with the strips.

Expected Values

Glucose- A small amount of Glucose may be detected in normal urine. The concentration is 2-20 mg/dl and the daily amount of excretion is 40-80mg.

Bilirubin- Even a small amount of bilirubin detected in urine should be considered as significant.

Ketones- Normal urine specimens ordinarily yield negative results. However, fasting or overexercise may cause a significant amount of Ketones.

Specific Gravity- Normal specific gravity is primarily influenced by the electrolytes and nitrogenous waste products, e.g. Urea and creatinine dissolved in urine. The first morning specimen should have a specific gravity between 1.015 and 1.025. Adults random specimen, 1.005-1.030 (highest in the morning). Newborns random specimen, 1.002-1.004. In severe renal damage the specific gravity is fixed at 1.010, the value of the glomerular filtrate.

Blood- The significance of trace reaction may vary among patients, and clinical judgement is required for individual assessment. Development of green spots (Intact erythrocytes) or green color (free hemoglobin/myoglobin) 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. The test is highly sensitive to hemoglobin and is slightly less so to intact red blood cells, and thus complements microscopic examination.

pH – Normal urine is around pH 6 and acidic. It varies from pH 4.5 to 8.5 depending on diet content.

Protein – Normally no protein is detectable in urine, although a minute amount is excreted by the normal kidney. Pathogenic proteinuria generally gives values above 30mg/dl and is persistent.

Urobilinogen – The normal urobilinogen range is 0.1 to 1.0 Ehrlich units per 100ml.

Nitrite – Normally no nitrite is detectable in urine. (A false negative may occur due to fasting, since there is insufficient dietary nitrate to convert to nitrite by Gram negative bacteria.)

Leukocytes – Normal urine specimens ordinarily yield negative results.

PLEASE CONTACT:

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Peroxidase	0.54mg	Bromothymol blue	0.45 mg
Potassium iodide	5mg		
Bilirubin		Protein	
2,4 dichloroaniline diazonium salt	1.12mg	Tetrabromophenol blue	0.31 mg
Sodium nitrite	1.52mg		
Ketone		Urobilinogen	
Sodium nitroprusside	43mg	p-dimethylaminobenzaldehyde	1.02mg
Specific Gravity		Nitrite	
Bromothymol blue	1mg	N-1-Naphthyl-ethylenediamine	0.6mg
Poly (methyl, vinyl ether maleic acid Sodium salt)	18mg	dihydrochloride Arsenic Acid	3.2 mg
Blood		Leukocytes	
Cumene hydroperoxide (CHP)	10.1mg	3-(N-Toluenesulfonyl-L-alanyloxy)-indols	0.6mg
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LIMITATIONS

Glucose

Specific gravity greater than 1.020, particularly in combination with high pH, may reduce sensitivity of the test. Ascorbic acid at concentrations of 50-75 mg/dl or higher may also cause false negatives for specimens containing small amounts of glucose.

Bilirubin

Ascorbic acid at concentrations of 25mg/dl or greater may cause false negatives. Uric acid and nitrite may also cause false negatives. Metabolites of drugs such as Pyridium and Selenium, which give a color at low pH, may cause false positives. Urobilinogen and other bilirubin-derived bile pigments may give spurious results.

Ketones

Positive results (trace or less) may occur with highly pigmented urine specimens or those containing large amounts of levodops metabolites. Detectable levels of ketone may occur in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise in ketoscidosis, starvation or with other abnormalities of carbohydrate or lipid metabolism, ketones may appear in urine in large amounts before serum ketone is elevated. Some high specific gravity-low pH urines may give reactions up to and including trace (5mg/dl). Clinical judgement is needed to determine the significance of reactions up to and including trace.

Specific Gravity

Highly buffered and alkaline urine lowers the value. Urine with lower pH, and proteinuria increases the value of specific gravity. X-ray contrast media and urine preservatives also increase specific gravity.

Blood

Elevated specific gravity or elevated protein may reduce the reactivity of the blood test. Certain oxidizing contaminants, such as hypochlorite or chlorine, may produce false positive results. Microbial peroxidase associated with urinary tract infection may cause a false positive result. Ascorbic acid concentrations of 40 mg/dl and higher may cause false negatives at the trace levels.

pH

If proper procedure is not followed and a drop of urine remains on the strip, it may wash the acid buffer from the neighboring protein reagent onto the pH area and change the pH reading to an acid pH if the urine being tested is originally neutral or alkaline. This is called the "run-over" phenomenon.

Protein

Urine with elevated specific gravity and acid urine with a pH less than 3 will cause false negative results. False positive results may be found in strongly basic urine (pH 9), during therapy with quinine, quinidine, chlorquine, trimethoprim, or phenazopyridine, when infusion of polyvinylpyrrolidone (blood substitutes) are administered, or when residues of disinfectants containing quaternary ammonium compounds or chlorhexidine are present in the urine vessel.

Urobilinogen

The absence of urobilinogen in the specimen cannot be determined. The test will react with interfering substances known to react with Ehrlich's reagent, such as para-aminosalicylic acid. The test is not a reliable method for the detection of porphobilinogen. Drugs containing azo-Gantrisin may give a masking golden color. Urine with a high level of bilirubin causes the development of green color.

Nitrite

Increased diuresis with attendant frequent micturition can lead to a negative nitrite finding because the urine does not remain in the bladder long enough. Excessive dilution of the urine and nocturia can be prevented by limiting fluid intake during the evening before the test. As nitrate can be absorbed only from the food ingested and subsequently passed into the urine, false negative results for the nitrite test may be found particularly during starvation or fasting period, when the patient is being fed intravenously or when the diet contains no vegetables. The urine specimen should be as fresh as possible; midstream urine is not necessary. Urine that has been stored for long periods of time (more than 4 hours) is likely to give a false negative or positive result. The latter can be shown to be due to bacterial contamination. Pink spots or edges should not be interpreted as a positive result. Any degree of uniform pink to red color development should be interpreted as a positive nitrite test suggesting the presence of 100,000 or more organisms per ml, but color development is not proportional to the number of bacteria present. A negative result does not in itself prove that there is no significant bacteria. Negative results may occur when urinary tract infections are caused by organisms which do not contain reductase to convert nitrate to nitrite, when urine has not been retained in the bladder long enough (4 hours or more) for reduction of nitrate to nitrite to occur, or when nitrate is absent, even if organisms containing reductase are present and bladder incubation is ample. Sensitivity of the test is reduced for urines with high specific gravity. Ascorbic acid at 25mg/dl or greater may cause false negative results in urine containing nitrate at 0.03 mg/dl or less.

Leukocytes

Glucose at more than 500 mg/dl and protein in excess of 500mg/dl diminish the intensity of the color reaction, as can cephalixin if administered in high daily doses. Formaldehyde can give false positive results.

SPECIFICITY AND SENSITIVITY OF EACH TEST

Glucose- This test reacts with beta-D-glucose only and should not be affected by other reducing sugars (sucrose, lactose, and fructose). The sensitivity is at 75-125mg/dl. **Bilirubin** – This test reacts sensitively to direct bilirubin. The sensitivity is 0.4-0.8 mg/dl. **Ketones** – The test is more sensitive to acetoacetic acid than to acetone, but should not react with beta-hydroxybutyric acid. The reaction to acetone is 1/10 of that to acetoacetic acid. The sensitivity is at 5-10 mg/dl. **Specific Gravity** – This test allows determination of specific gravity between 1.0 and 1.03. **Blood** – The test is more sensitive to hemoglobin and myoglobin than erythrocytes. It is sensitive at 0.05-0.06 mg/dl of hemoglobin. **pH** – This test measures pH values generally to within 1 unit in the range of 5-6.5. **Protein** – This test area is particularly sensitive to albumin but less sensitive to globulin, Bence-Jones proteins and mucoproteins. The sensitivity is 15-30 mg/dl of albumin. **Urobilinogen** – The test is sensitive to urobilinogen at 0.1 Ehrlich units/dl. For specificity, see section under "limitations" for possible interfering substances. **Nitrite** – The test is specific for nitrite. Color intensity does not correlate to number of bacteria however. The sensitivity is 0.06-0.1 mg/dl of nitrite ion. **Leukocytes** – The test reacts with esterase found in urine leukocytes. The sensitivity is equivalent to 5-15 cells/microliter.



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