Nitrite – Frequent urination may result in a false negative nitrite result. The test is dependent on the length of time urine is retained within the bladder. Excessive dilution of the urine and nocturia can be prevented by limiting fluid intake during the evening before the test. As nitrite 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. Urine that has been stored for long period of time (more than 4 hours) is likely to give a false negative or positive result. The latter could 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 bacteriema. Negative results may occur due to the following reasons:

1. when urinary tract infections are caused by organisms which do not contain reductase to convert nitrate to nitrite,
2. when urine has not been retained in the bladder long enough (4 hours or more) for reduction of nitrate to nitrite to occur,
3. when nitrate is absent, and
4. any combination of the above 3 factors.

Sensitivity of the test is reduced for urine with high specific gravity. Ascorbic acid at 30 mg/dl or greater may cause false negative results in urine containing nitrite less than or equal to 0.03 mg/dl.

Leukocytes – Glucose at > 500 mg/dl, protein > 500 mg/dl, high SG and cephalexin administered in high daily doses can diminish the intensity of the color reaction. High concentration of oxalic acid or trace of oxidizing agents may give false negative results. The result may not always be consistent with the leukocyte cell number obtained by microscopic examination.

PERFORMANCE CHARACTERISTIC

Specificity and Sensitivity

Glucose – The sensitivity is 75 – 125 mg/dl.

Bilirubin – This test reacts sensitively to direct bilirubin. The sensitivity is 0.8 – 1.0 mg/dl.

Ketones – The test sensitive to acetoacetic acid. Sensitivity at 5 – 10 mg/dl.

Specific Gravity – This test determines the range of specific gravity from 1.001 to 1.030.

Blood – The test is more sensitive to 10-15 RBC/uL of hemoglobin.

pH – This test measures pH values generally to within 1 unit in the range of 5 – 8.5.

Protein –The sensitivity is 15 – 30 mg/dl of albumin.

Urobilinogen – The test is sensitive to urobilinogen at 0.2 Ehrlich units/dl. For specificity see section under "Limitations" for possible interfering substances.

Nitrite – The test is specific for nitrite. However, color intensity does not correlate to the number of bacteria. The sensitivity is 0.05 – 0.1 mg/dl of nitrite ion.

Leukocytes – The test detects 20 – 25 cells/μl (intact and lyzsed WBC's).

REFERENCES

1. Tietz, N.W.: Clinical Guide to Laboratory Tests; W.B. Saunders Company, (1976).

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Urine Strips for Urinalysis

INTENDED USE

The Pulse Urine Strip is intended for the determination of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes in human urine.
This product is for *in vitro* diagnostic use only.
This product is not intended for use in emergency rooms or point of care facilities.[1]

SUMMARY & PRINCIPLES

Urinalysis by the "Dip & Read" Method is widely practiced as a rapid chemical analysis in the diagnosis of various diseases. These reagent strips consist of plastic strips affixed with reagent impregnated areas for Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes. Determination of the concentration level for each parameter can be made by visual comparison to the color chart provided or by use of the Pulse Urine Analyzer only. Uses of such reagent strips have provided an easy and convenient way to provide information on the status of carbohydrate metabolism, kidney and liver function, acid-base balance, and urinary tract infections.

MATERIALS SUPPLIED

Urine strips composed of the following chemicals applied at each specific reagent area:

Glucose	Glucose oxidase, Peroxidase, Potassium iodide.
Bilirubin	2,4-dichloroaniline diazonium salt, Sodium nitrite, Sulfosalicylic Acid
Ketone	Sodium nitroprusside.
Specific Gravity(SG)	Bromothymol blue
Blood	Cumene hydroperoxide (CHP),o-Tolidine.
pH	Methyl red, Bromothymol blue.
Protein	Tetrabromophenol blue.
Urobilinogen	4-Methoxybenzenediazonium
Nitrite	P. arsanilic acid
Leukocytes	Induced Indole amino acid ester

Additional Items Required: Clock or timer

STORAGE & STABILITY

Store urine strips at room temperature (15–30 Degree Celsius) in their original desiccated container. Avoid direct sunlight and moisture. When stored in their original container, the product is stable up to their expiry date. Once the container has been

[1] This Statement is made to comply with Health Canada Regulation regarding the Intended Use for Class II Medical Device.

opened, the remaining strips are stable only up to 6 months. Discoloration of the test pad may indicate deterioration.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. This product is not intended for use in emergency rooms or point of care facilities.[1]
3. Do not use test device after the expiration date.
4. Replace the cap immediately and tightly after removing the required number of urine strips. Do not remove desiccant.
5. Avoid touching the test pad on the strip.
6. It is preferred to use first morning urine for optimal nitrite, bilirubin and urobilinogen tests.
7. The effects of drugs or other metabolites on the individual tests are not known in all cases. As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result or method.
8. Good laboratory practice and universal precautions for handling biological specimens should be observed.
9. Specimens and waste materials should be properly disinfected before disposal.
10. All subsequent steps should be completed without interruptions and within the recommended time limits once a test has been started.

PROCEDURE

Correct operating procedures and measurement times are required to obtain accurate results.

1. Collect FRESH, well-mixed, UNCENTRIFUGED urine specimen in a clean dry container. DO NOT add preservatives. 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 reagent areas are discolored or darkened, do not use the strips.
3. Dip the test strip completely 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. If the Pulse Urine Analyzer is used, place strip onto the test tray and operate the instrument accordiing to instructions given in the operation manual.

QUALITY CONTROL

Commercial urine controls should be used periodically or when the urine strip deterioration is suspected.

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 – 80 mg.

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

Ketone – Normal urine specimens ordinarily yield negative results. However, fasting or over-exercise may cause a significant amount of ketones.

Specific Gravity – Normal SG is primarily influenced by the electrolytes and nitrogenous waste products, i.e. urea and creatinine dissolved in urine. The first morning specimen should have a specific gravity between 1.015 and 1.025. Normal adult specimens range from 1.005 – 1.030 (highest in the morning). Normal newborn specimens range from 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 judgment is required for individual assessment. The presence of blood may indicate kidney disease or a UTI. Blood is often, but not always, found in the urine of menstruating females. The test is highly sensitive to hemoglobin and is slightly less sensitive to intact red blood cells, and thus complements microscopic examination.

pH – Normal urine is about pH 6 but can vary from pH 4.5 to 8.5 with diet content.

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

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

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.

LIMITATIONS OF THE PROCEDURE

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

Bilirubin – Ascorbic acid at concentration of 30 mg/dl or greater may cause false negatives. Metabolites of drugs such as Pyridum and Selenium, which give a color at low pH, may cause false positives. Indican (indoxyl sulfate) can produce a yellow-orange to red color which may interfere with the interpretation of negative or positive results. Urobilinogen and other bilirubin-derived bile pigments give spurious results.

Ketones – Positive results (trace or less) may occur with highly pigmented urine specimens or those containing large amounts of phenylketones or L-dopa metabolites. Detectable levels of ketone may occur in urine during physiological stress conditions such as fasting, pregnancy, and frequent strenuous exercise in ketoacidosis, starvation or with other abnormalities of carbohydrate or lipid metabolism. Ketones may appear in urine in large amounts before serum ketone is elevated. Some urine specimens with high specific gravity and low pH may give trace reaction (5 mg/dl). Phenosulfonphthalein may cause false positive result.

Specific Gravity – Highly buffered and alkaline urine lower the value. Urine with low pH and proteinuria increases the value of specific gravity.

Blood – Elevated specific gravity or 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 false positive results. Ascorbic acid concentrations of 30 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 acidic 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 acidic 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 polyvinlypyrrolidone (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 by this product. The test area will react with interfering substances known to react with Ehrlich’s reagent, such as p-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.