Urine Reagent Strips (3 Parameters)

IVD For *in vitro* diagnostic and professional use only

Store at 15-30 °C CE

INTENDED USE

Urine Reagent Strips are firm plastic strips onto which several separate reagent areas are affixed. The test is for the detection of one or more of the following analyses in urine: Glucose, Protein, and Ketone.

SUMMARY

Urine undergoes many changes during states of disease or body dysfunction before blood composition is altered to a significant extent. Urinalysis is a useful procedure as an indicator of health or disease, and as such, is a part of routine health screening. Urine Reagent Strips can be used in general evaluation of health, and aids in the diagnosis and monitoring of metabolic or systemic diseases that affect kidney function, endocrine disorders and diseases or disorders of the urinary tract.

PRINCIPLE AND EXPECTED VALUES

Glucose: This test is based on the enzymatic reaction that occurs between glucose oxidase, peroxidase and chromogen. Glucose is first oxidized to produce gluconic acid and hydrogen peroxide in the presence of glucose oxidase. The hydrogen peroxide reacts with potassium iodide chromogen in the presence of peroxidase. The extent to which the chromogen is oxidized determines the color which is produced, ranging from green to brown. Low amounts of glucose are normally excreted in urine.[3] Glucose concentrations as low as 100 mg/dL, read at 30 seconds, may be considered abnormal if results are consistent.

Ketone: This test is based on ketones reacting with nitroprusside and acetoacetic acid to produce a color change ranging from light pink for negative results to a darker pink or purple color for positive results. Ketones are normally not present in urine. Detectable ketone levels may occur in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise. In starvation diets, or in other abnormal carbohydrate metabolism situations, ketones appear in the urine in excessively high concentration before serum ketones are elevated.

Protein: This reaction is based on the phenomenon known as the "protein error" of pH indicators where an indicator that is highly buffered will change color in the presence of proteins (anions) as the indicator releases hydrogen ions to the protein. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow to yellow-green for negative results and green to green-blue for positive results. 1-14 mg/dL of protein may be excreted by a normal kidney. A color matching any 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 required to evaluate the significance of trace results.

MATERIALS

MATERIALS PROVIDED

- Strips Bottle.
- Package insert.

MATERIALS NEEDED BUT NOT PROVIDED

- Specimen collection container.
- Timer.

REAGENTS AND PERFORMANCE CHARACTERISTICS

Based on the dry weight at the time of impregnation, the concentrations given may vary within manufacturing tolerances. The following table below indicates read times and performance characteristics for each parameter.

Reagent	Read Time	Composition	Description
Glucose (GLU)	30 seconds	1.5% w/w glucose oxidase; 0.5% w/w peroxidase; 10.0% w/w potassium iodide; 75.0% w/w buffer; 13.0% w/w non-reactive ingredients	Detects glucose as low as 50-100 mg/dL (2.5-5 mmol/L).
Protein (PRO)	60 seconds	0.3% w/w tetrabromophenol blue; 99.7% w/w buffer and non-reactive ingredients	Detects albumin as low as 7.5-15 mg/dL (0.075-0.15 g/L).
Ketone (KET)	40 seconds	5% w/w sodium nitroprusside; 95% w/w buffer	Detects acetoacetic acid as low as 2.5-5 mg/dL (0.25-0.5 mmol/L).

The performance characteristics of the Urine Reagent Strips have been determined in both laboratory and clinical tests. Parameters of importance to the user are sensitivity, specificity, accuracy and precision. Generally, this test has been developed to be specific for the parameters to be measured with the exceptions of the interferences listed. Please refer to the Limitations section in this package insert.

Interpretation of visual results is dependent on several factors: the variability of color perception, the presence or absence of inhibitory factors, and the lighting conditions when the strip is read.

Each color block on the chart corresponds to a range of analyte concentrations.

PRECAUTIONS

- For *in vitro* diagnostic and professional use only.
- Do not use after the expiration date.
- The strip should remain in the closed bottle until use.
- Do not touch the reagent areas of the strip.
- Discard any discolored strips that may have deteriorated.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used strip should be discarded according to local regulations after testing.
- Never smoke, drink, or eat in the assay laboratory.
- Wear protective clothing and disposable gloves when dealing with samples and reagents. Wash hands after performing the test.
- Handle specimens as though they contain infectious agents.
- Humidity and temperature can adversely affect results.
- Do not use the test if printing is unclear and/or expiry date is missing.

STORAGE AND STABILITY

- Store as packaged in the closed bottle at room temperature (15-30°C).
- Keep out of direct sunlight. The strip is stable through the expiration date printed on the bottle label.
- Do not remove the desiccant. Remove only enough strips for immediate use. Replace cap immediately and tightly.
- **DO NOT FREEZE**.
- Do not use beyond the expiration date.
- Once the bottle has been opened, the remaining strips are stable for up to 3 months. Stability may be reduced in high humidity conditions.

SPECIMEN COLLECTION AND PREPARATION

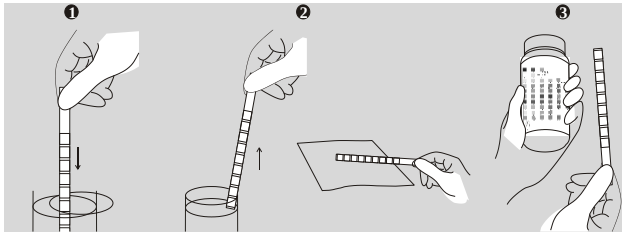
- A urine specimen must be collected in a clean and dry container and tested as soon as possible.
- Do not centrifuge.
- The use of urine preservatives is not recommended.
- If testing cannot be done within an hour after voiding, refrigerate the specimen immediately and let it return to room temperature before testing.
- Prolonged storage of unpreserved urine at room temperature may result in microbial proliferation with resultant changes in PH. A shift to alkaline pH may cause false positive results with the protein test area.
- Urine containing glucose may decrease in pH as organisms metabolize the glucose.
- Contamination of the urine specimen with skin cleansers containing chlorhexidine may affect protein (and to a lesser extent, specific gravity and bilirubin) test results.

DIRECTION FOR USE

1. Remove the strip from the closed bottle and use it as soon as possible. Immediately close the bottle tightly after removing the required number of strip(s). Completely immerse the reagent areas of the strip in fresh, well-mixed urine and immediately remove the strip to avoid dissolving the reagents. See illustration 1 below.
2. While removing the strip from the urine, run the edge of the strip against the rim of the urine container to remove excess urine. Hold the strip in a horizontal position and bring the edge of the strip into contact with an absorbent material (e.g. a paper towel) to avoid soiling hands with urine. See illustration 2 below.
3. Compare the reagent areas to the corresponding color blocks on the bottle label at the specified times. Hold the strip close to the color blocks and match carefully. See illustration 3 below.

Note:

Results may be read up to 2 minutes after the specified times.



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 close to the nominal values. In the event of unexpected or questionable results, the following steps are recommended; confirm that the specimens have been tested within the expiration date printed on the bottle label, compare results with known positive and negative controls and repeat the test using a new strip. If the problem persists, discontinue using the strip immediately and contact your local distributor.

QUALITY CONTROL

For best results, performance of reagent strips should be confirmed by testing known positive and negative specimens/controls whenever a new test is performed, or whenever a new bottle is first opened. Each laboratory should establish its own goals for adequate standards of performance.

LIMITATIONS

Note: The Urinalysis Reagent Strips (Urine) may be affected by substances that cause abnormal urine color such as drugs containing azo dyes (e.g. Pyridium®, Azo Gantrisin®, Azo Gantanol®), nitrofurantoin (Microdantin®, Furadantin®), and riboflavin.[8] The color development on the test pad may be masked or a color reaction may be produced that could be interpreted as false results.

As with all diagnostic and therapeutic tests, all results must be considered with other clinical information available to the physician.

Glucose: This test is highly specific for glucose. No substance excreted in urine other than glucose is known to give a positive result. The reagent area does not react with ketones, lactose, galactose, fructose or other metabolic substances, nor with reducing metabolites of drugs (e.g. salicylates and nalidixic acid). Sensitivity may be decreased in specimens with high specific gravity (>1.025) and with ascorbic acid concentrations of ≥ 25 mg/dL. High ketone levels ≥ 100 mg/dL may cause false negative results for specimens containing a small amount of glucose (50-100 mg/dL).

Protein: Any green color indicates the presence of protein in the urine. This test is highly sensitive for albumin, and less sensitive to hemoglobin, globulin and mucoprotein. A negative result does not rule out the presence of these other proteins. False positive results may be obtained with highly buffered or alkaline urine. Contamination of urine specimens with quaternary ammonium compounds or skin cleansers containing chlorhexidine produce false positive results. The urine specimens with high specific gravity may give false negative results.

Ketone: The test does not react with acetone or β-hydroxybutyrate.[8] Urine specimens of high pigment and other substances containing sulfhydryl groups may occasionally give reactions up to and including trace (±).

REFERENCES

- Free AH, Free HM. *Urinalysis, Critical Discipline of Clinical Science*. CRC Crit. Rev. Clin. Lab. Sci. 3(4): 481-531, 1972.
- Yoder J, Adams EC, Free, AH. Simultaneous Screening for Urinary Occult Blood, Protein, Glucose, and pH. Amer. J. Med Tech. 31:285, 1965.
- Shchersten B, Fritz H. Subnormal Levels of Glucose in Urine. JAMA 201:129-132, 1967.
- McGarry JD, Lilly. Lecture, 1978: New Perspectives in the Regulation of Ketogenesis. Diabetes 28: 517-523 May, 1978.
- Williamson DH. Physiological Ketoses, or Why Ketone Bodies? Postgrad. Med. J. (June Suppl.): 372-375, 1971.
- Paterson P, et al. Maternal and Fetal Ketone Concentrations in Plasma and Urine. Lancet: 862-865; April 22, 1967.
- Fraser J, et al. Studies with a Simplified Nitroprusside Test for Ketone Bodies in Urine, Serum, Plasma and Milk. Clin. Chem. Acta II: 372-378, 1965.
- Henry JB, et al. Clinical Diagnosis and Management by Laboratory Methods, 18th Ed. Philadelphia. Saunders. 396-397, 415, 1991.
- Burtis CA, Ashwood ER. Tietz Textbook of Clinical Chemistry 2nd Ed. 2205, 1994.
- Tietz NW. Clinical Guide to Laboratory Tests. W.B. Saunders Company. 1976.

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size.		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry