URINALYSIS REAGENT STRIPS

This Package Insert to be used with 1~5 parameter urinalysis Reagent Strips

MAIN PERFORMANCE CHARCTERISTICS

Glucose: This test is specific for glucose; no substances excreted in urine other than glucose is known to give a positive result. This test may be used to determine whether the reducing substances found in urine is glucose. Moderate amounts of ketone (0.28mmol/L or greater) may decrease color development in urine containing small amounts of glucose (more than 2.2mmol/L). The reactivity of the glucose test decreases as the SG of the urine increases. Reactivity may also vary with temperature. Small amounts of glucose are normally excreted by the kidney,and the strip is not sensitive to the amount.

Ketone: The ketone test area provides semi-quantitative results and reacts with acetoacetic acid in urine. This test does not react with beta hydroxybutyric acid or acetone. Normally, no ketones are present in urine. Detectable levels of ketone may occur in urine during physiological stress conditions such as fasting, pregnancy, and frequent strenuous exercise. In starvation diet, or in other abnormal carbohydrate metabolism situation, ketones appear in the urine excessively large amounts before serum ketones are elevated.

Occult Blood: This test is slightly more sensitive to free hemoglobin and myoglobin than to intact erythrocytes. The sensitivity of the Occult 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. Occult Blood is frequently, but not invariably found in the urine of menstruating females.

pH: The pH test area permits quantitative differentiation of pH values to one unit within the range of 5-9. pH reading are not affected by variation in the urinary buffer concentration. 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 area run onto the pH area, causing a false lowering in the pH result.

Protein: The test area is more sensitive to albumin than to globulin, hemoglobin, Bence-Jones proteins and mucoprotein; a negative result does not rule out the presence of these other proteins. 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 judgement is needed to evaluate the significance of trace results. False positive result may be obtained with highly alkaline urine. Contamination of the urine specimen with quaternary ammonium compounds may also produce false positive results.

REAGENTS:

1.REAGENTS COMPOSITION:

Glucose: 16.3%w/w glucose oxidase;0.6%w/w peroxidase;7.0%w/w potassium iodide;76.1%w/w buffer and nonreactive ingredients.

Occult Blood: 6.6%w/w cumene hydroperoxide;4.0%w/w 3,3',5,5'-tetramethylbenzidine;89.4%w/w buffer and nonreactive ingredients.

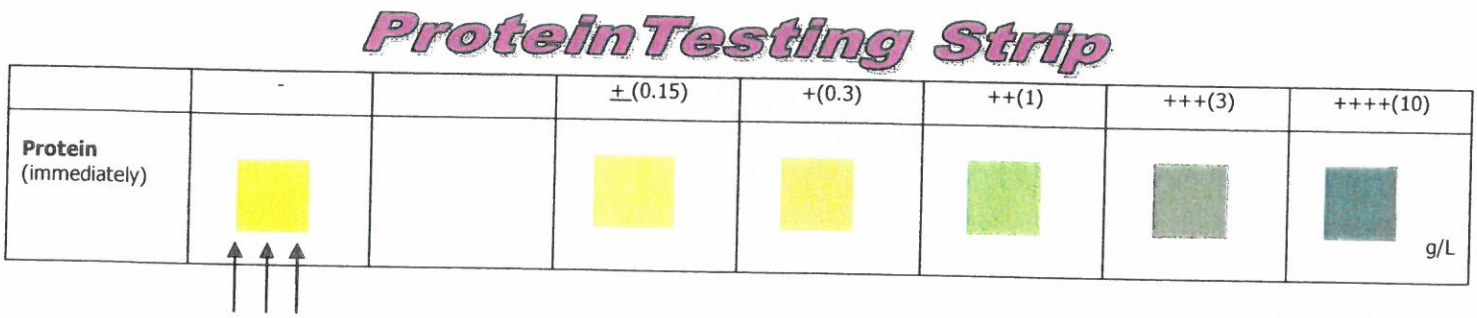
pH: 0.2%w/w methyl red;2.8%w/w bromothymol blue;97%w/w nonreactive ingredients.

Protein: 0.3%w/w tetrabromophenol blue;99.7%w/w buffer and nonreactive ingredients.

Ketone: 7.7%w/w sodium nitroprusside;92.3%w/w buffer and nonreactive ingredients.

2.SENSITIVITY AND RANGE OF TEST

Reagent region	Sensitivity	Range of instrumental	Range of visual method
Glucose	2.8-5.5mmol/L	0-110mmol/L	0-110mmol/L
Ketone	0.5-1.0mmol/L	0-7.8mmol/L	0-16mmol/L
Occult Blood (Hemoglobin)	150-450ug/L	0-6000ug/L	0-6000ug/L
(Erythrocyte)	5-15cells/uL	0-200cells/uL	0-200cells/uL
Protein	0.15-0.3g/L	0-3.0g/L	0-20.0g/L
pH		5.0-9.0	5.0-8.5



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SUMMARY

Urinalysis Reagent Strips for Urinalysis provide tests for Glucose, Ketone (Acetoacetic acid), Occult Blood, pH, Protein in urine. Test results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance and bacteriurea. Please refer to the outside box and bottle label for the specific test parameters of the product you are using. If necessary, please contact with our company.

STORAGE

1) Store at room temperature between 2-30℃(35.6℉-86℉).
2) Leave away form direct sunlight and moisture.
3) Do not use after expiration date.

NOTICE

1) Do not remove desiccant form the bottle.
2) Do not touch test areas of Urinalysis Reagent Strips.
3) Do not open container until ready to use.
4) The use of urine preservatives can prevent the decomposition of ketone, bilirubin and urobilinogen in the urine.
5) Do not store the sample long time (one hour or longer) before testing.

SPECIMEN COLLECTION AND PREPARATION

Collect fresh urine in a clean container and test as soon as possible. Do not centrifuge. If testing cannot be performed within one hour after voiding, refrigerate the specimen immediately. Allow refrigerated specimen to return to room temperature before testing.

VISUAL TEST PROCEDURE

1. Remove from the bottle only enough strips for immediate use and replace cap tightly.
2.Completely immerse reagent areas of the strip in fresh, well-mixed urine. Remove the strip immediately to avoid dissolving out the reagent areas.
3.While removing, touch the side of the strip against the rim of the urine container to remove excess urine.
4.Compare each reagent area to its corresponding color blocks on the color chart and read at the times specified. Proper read time is critical for optimal results.
5.Obtain results by direct color chart comparison.

Note: All reagent areas may be read between 1-2minutes for screening positive urine from negative urine. Changes in color after 2 minutes are of no diagnostic value. **Please read the result of analysis according to the given time which is noted on the color chart of the bottle.**

INSTRUMENT TEST PROCEDURE

Please follow the manual of the instrument.

QUALITY CONTROL

For best results, performance of reagent strips should be confirmed by testing known negative and positive specimens or 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, and should question handling and testing procedures if these standards are not met.

RESULTS

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 around the nominal values.

LIMITATIONS OF PROCEDURE

Comparison to the color chart is dependent on the interpretation of the individual. It is therefore, recommended that all laboratory personnel interpreting the results of these strips be tested for color blindness. As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single test or method.