



ATLAS URINE REAGENT STRIPS

1 PARAMETER

Protein in urine.

For *In-Vitro* and professional use only
Store at 15-30°C

WARNING AND PRECAUTIONS:

ATLAS Urine Reagent Strips are for in vitro diagnostic use and are intended for professional use. The "universal precautions" recommended by the Centers for Disease control should be adhered to whenever blood or body fluids are handled.

These precautions include wearing gloves. ATLAS Urine Reagent test strips may contain either diazonium salt or nitroferrocyanide. Avoid contact with skin and mucous membranes; flush affected areas with copious amounts of water. Get immediate medical attention for eyes or if ingested. Exercise the normal precautions required for handling all laboratory reagents.

SUMMARY AND INTENDED USE:

ATLAS Urine reagent strip is a dip-and-read test strip and intended for use as an in vitro diagnostic and using urine specimens. The strip contains solid phase reagent areas affixed to a plastic support and is provided in a dry reagent format. This strip provides tests for, qualitatively and semi-quantitatively, **protein**, by the visual comparison with color charts of each concentration range. No additional reagents or laboratory equipment is required. The reagent strips are packaged in a plastic vial-containing desiccant. The test strips must be tightly capped in the plastic vial to assure reagent reactivity. The directions must be followed exactly, and it is necessary to use fresh, well-mixed and uncentrifuged urine for optimal results.

CHEMICAL PRINCIPLES OF THE PROCEDURE:

Protein: This test is based on the color change of the indicator, tetrabromophenol blue, in the presence of protein. A positive reaction is indicated by a color change from yellow through green and then to greenish-blue.

REAGENTS: (Based on dry weight at time of impregnation of 100strips)

Protein	Tetrabromophenol blue	0.3mg
	Citric acid	110.0mg
	Trisodium citrate	46.0mg

STORAGE:

Store at room temperature between 15°-30°(59°F-86°F). Do not store the strips in the refrigerator or freezer. Cap the bottle tightly.

Since the test strips are sensitive to specific environmental factors, such as moisture, heat and light, do not expose strips to these factors.

PROCEDURE FOR HANDLING THE STRIPS:

All unused strips must be stored in the original bottle. Do not remove desiccant from bottle. Transfer of the strips to another container may cause reagent strips to deteriorate and become unreactive. After taking out test strips, replace the cap, promptly and tightly. Do not touch test area of the strip. Do not use strips after expiration date. The work area should be clean and free of detergents and other contaminants.

SPECIMEN COLLECTION AND PREPARATION :

Use a clean, dry, unused vessel to collect the urine. Test the urine as soon as possible after collection. If testing cannot be done within an hour after voiding, refrigerate the specimen immediately and let it return to room temperature before testing.

PROCEDURE:

This procedure MUST BE FOLLOWED EXACTLY to achieve reliable test results.

1. Confirm that the product is within the expiration date shown on the label.
2. Remove the strip from the bottle and replace the cap immediately.
3. Inspect the strip. Discoloration or darkening of reagent areas may indicate deterioration. Do not use strip.
4. Dip the test strip completely for no more than 1 second in fresh, well-mixed, and uncentrifuged urine specimen. Excessive urine on the test strip may give

rise to a wrong result. Remove the excessive urine by touching the plastic film on the rim of vessel. At this time, do not allow the reagent areas to touch the rim of vessel. Excessive urine may be removed by gently blotting the lengthwise edge on absorbent paper.

5. Compare the test results carefully with the color chart on the bottle label in good light. Proper reading time (30-60 seconds) is critical for optimal results. While comparing, keep the strip in a horizontal position to avoid possible interaction of chemicals by excessive urine. Changes in color that appears only along the edges of the test areas or after the correct timing period has passed are of no diagnostic significance.

QUALITY CONTROL:

The strips must be properly stored and handled before and during the testing. Reaction of reagent strips should be confirmed by testing known positive and negative specimens or multiple analyte controls containing normal and abnormal amounts of each of the analytes being tested.

RESULTS:

The results are obtained by direct comparison of test strip with the color blocks printed on the bottle label. No calculations or laboratory instruments are necessary.

LIMITATIONS OF PROCEDURES:

Substances the cause abnormal urine color, such as drugs containing azo dyes, nitrofurantoin and riboflavin may affect the readability of reagent areas on urinalysis reagent strips. The color development on the reagent pad may be masked, or a color reaction may be produced on the pad that could be interpreted visually and instrumentally as a false positive. It is therefore recommended that in case of doubt, the test should be repeated after withdrawal of the medication.

Protein: The minimum sensitivity of this test is 10-20mg/dl of protein in urine. Highly buffered alkaline urines (pH 9) may give false negative results.² The interpretation of results is also difficult in turbid urine specimens.

EXPECTED VALUE:

Protein: Normal urine specimens ordinarily contain some protein (0-4mg/dl); therefore, only persistent elevated levels of urine protein indicate kidney or urinary tract disease. The persistent results of trace level or over indicate significant proteinuria, and thus

further clinical testing is needed to evaluate the significance of results. The concentrations given; "+"(30mg/dl); "++"(100mg/dl); "+++"(300mg/dl); "++++"(2000mg/dl or more); correlate well with the albumin concentrations in urine. Pathologic proteinuria generally gives values above 30mg/dl and is persistent.

PERFORMANCE CHARACTERISTICS:

Specific performance characteristics of the ATLAS Urine reagent strips are based both on clinical and laboratory studies. A study done at two clinical sites involving 94 patient samples compared ATLAS Urine reagent strips to a competitor's strip. 100% agreement within one color block was obtained for all analytes except protein. Protein gave a greater than 95% agreement. The lower agreement may be reflective of the technician's interpretation of the negative versus trace color block with both the Urine Reagent strips and the competitive strip. Parameters of importance to the user are sensitivity, limits of test, specificity, accuracy, precision and stability. Sensitivity and limits of tests are the generally detectable levels of each test described previously. The sensitivity depends upon several factors; the variability of color perception; the presence or absence of inhibitory factors typically found in urine, the specific gravity, ascorbic acid and pH; and lighting conditions when the product is read visually. The tests have been developed to be specific for the constituent to be measured with the exception of interferences listed previously. Exact agreement between visual results and instrumental results might not be found because of the inherent differences between the perception of the human eye and the optical system of the instruments. It is for this reason that each user is encouraged to develop his own standards for performance. The stability test has been developed by statistical procedure for various environmental conditions.

Protein: The test is more sensitive to albumins than to gamma-globulins. Bence-Jones proteins, and mucoproteins ; such proteins do not interfere with the reaction of albumin.

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