



# ATLAS URINE REAGENT STRIPS

## 2 PARAMETER

### Creatinine & pH 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 nitroferricyanide. 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 aid 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 test for, qualitative and semi quantitative determination of **Creatinine and pH** in urine samples 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 un-centrifuged urine for optimal results.

#### CHEMICAL PRINCIPLES OF THE PROCEDURE:

**Creatinine:** Testing for sample dilution. In this assay, creatinine reacts with a creatinine indicator in an alkaline condition to form a purplish-brown color complex. The concentration of creatinine is directly proportional to the color intensity of the test pad.

**pH:** Testing for the presence of acidic or alkaline adulterant. This test is based on the well-known double pH indicator method that gives distinguishable colors over wide pH range. The colors range from orange (low pH) to yellow and green to blue (high pH).

#### 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 the bottle. Transfer of the strips to another container may cause reagent strips to deteriorate and become not reactive. 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 un-centrifuged urine specimen. Excessive urine on the test strip may give rise to a wrong result. Remove the excess 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. Excess 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 excess 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:

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 standard of performance, and should question handling and testing procedures if these standards are not met.

#### 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 that 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.

**EXPECTED VALUES:**

**Creatinine:** Daily creatinine excretion, related to muscle mass of the human body, is usually constant. The DOT guideline states that urine specimens with creatinine levels of less than 20 mg/dl are indications of adulteration. Although these ranges are affected by age, sex, diet, muscle mass and local population distribution, sample with creatinine level of lower than 20 mg/dl should be considered adulterated

**pH:** Normal urine pH ranges from 4.5 to 8.0. Values below pH 4.0 or above pH 9.0 are indicative of adulteration.

**REFERENCES**

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