SIEMENS

Albustix® Reagent Strips for Urinalysis

Test for Protein in Urine.

INTENDED USE:

ALBUSTIX® are intended for *in vitro* diagnostic use by healthcare professionals to detect the presence of protein in urine.[1–3]

SUMMARY AND INTRODUCTION:

ALBUSTIX are firm, plastic Reagent Strips to which is affixed a chemically treated area, the test pad, that tests for protein in urine.

It is also important to read the entire ALBUSTIX insert carefully before you begin testing.

ALBUSTIX are ready to use upon removal from the bottle and the Reagent Strip is disposable. No additional laboratory equipment is necessary for testing. ALBUSTIX Reagent Strips have been determined to be nonhazardous under the guidelines issued by OSHA in 29CFR 1910.1200(d).

SPECIMEN COLLECTION AND PREPARATION:

Wash and rinse your hands with an appropriate cleanser. Collect urine in a clean container and test it as soon as possible. If testing cannot be done within an hour after voiding, refrigerate the specimen immediately. Let it return to room temperature before testing. Do not let the urine stand at room temperature for an extended period of time before testing or microbial growth could occur and cause false ALBUSTIX results.

⚠ **CAUTION: Ensure that work areas and specimen containers are always free of detergents and other contaminating substances. Some substances can interfere with patient results.**

Do not centrifuge. The use of urine perservatives is not recommended.

ALBUSTIX STORAGE AND HANDLING:

- Do not use ALBUSTIX after expiration date. Record the opening date on the bottle label.
- Store at room temperature between 15–30°C (59–86°F).
- Do not store the bottle in direct sunlight.

  IMPORTANT: Protection against ambient moisture, light and heat is essential to guard against altered reagent reactivity.
- The Reagent Strips must be kept in the bottle with the cap tightly closed. Do not remove desiccant from bottle. Replace cap immediately and tightly after removing Reagent Strip. Do not touch test pad on the Reagent Strip.

⚠ **WARNING: ALBUSTIX Reagent Strips are for *in vitro* diagnostic use only. DO NOT SWALLOW.**

DIRECTIONS FOR TESTING:

Materials needed:

- ALBUSTIX Reagent Strips
- Clean, dry container

Step 1. Check the Expiration Date. If the date has passed, discard and test with strips from a new bottle. Record the opening date on the label. **Use of Reagent Strips beyond the expiration date may yield inaccurate results.**

Remove the Reagent Strip from the bottle. Replace the cap immediately and tightly. *Do not* touch the pad on the Reagent Strip.

Step 2. Dip the test end of the Reagent Strip into a fresh, well-mixed, uncentrifuged urine sample and remove it immediately, drawing the edge of the Reagent Strip against the rim of the urine container to remove excess urine (or pass the end of the Reagent Strip through a stream of urine.)

Step 3. Wait 60 seconds after removing from the urine, and then match the test pad to the color chart on the bottle. Do not read the test pad after 2 minutes. Color changes that occur after this time are of no diagnostic value.

Step 4. Record the results.

RESULTS:

Results with ALBUSTIX Reagent Strips are obtained in clinically meaningful units directly from the Color Chart comparison. The color blocks represent nominal values; actual values will vary around the nominal values.

It is important to dip test pad in urine completely, but briefly, to avoid dissolving out reagents. Read the results carefully within the specified time, in a good light and with the test pad held near the Color Chart on the bottle label.

EXPECTED VALUES FOR PROTEIN PRO :

Normally, no protein is detectable in urine, although the normal kidney will excrete a small amount. Color matching any block greater than “Trace” indicates significant protein in urine. For urine of high specific gravity (or very cloudy urine), the test pad may most closely match the “Trace” color block even though only normal concentrations of protein are present.

IF TEST RESULTS SEEM QUESTIONABLE:

Do not use if pad appears discolored or darkened. If this is evident, if test results are questionable, or if they are inconsistent with expected findings, the following steps are recommended:

1. Check the EXPIRATION DATE printed on the bottle label. If the date has passed, discard and retest with Reagent Strips from a new bottle.
2. Test the urine again with a Reagent Strip from a new bottle and compare the results.
3. Whenever test results are questionable or whenever a new bottle is first opened, run a Control Test to check performance of the whole system (reagent, strip and technique). CHEK-STIX® Positive and Negative Control

Strips, with positive, negative or defined results, provide a convenient basis for a urinalysis quality control program. Negative and positive specimens or controls may also be randomly hidden in each batch of specimens tested. Each laboratory should establish its own goals for adequate standards of performance.

If a problem cannot be identified or corrected, call your authorized Siemens Healthcare Diagnostics Representative or contact your healthcare professional.

LIMITATIONS:

Substances that cause abnormal urine color, such as drugs containing azo dyes (e.g., Pyridium, Azo Gantrisin, Azo Gantanol), nitrofurantoin (Macrodantin, Furadantin), and riboflavin, may affect the readability of the protein reagent pad on urinalysis 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 as a false positive.

False positive results may be obtained with highly buffered or alkaline urines. Contamination of the urine specimen with quaternary ammonium compounds (e.g., from some antiseptics and detergents) or with skin cleansers containing chlorhexidine may also produce false positive results.

SPECIFIC PERFORMANCE CHARACTERISTICS:

Specific performance characteristics are based on clinical and analytical studies. In clinical specimens, 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, and the pH; and the lighting conditions under which the product is read.

Each color block represents a range of values. Because of specimen and reading variability, specimens with analyte concentrations that fall between nominal levels may give results at either level. Results at levels greater than the second positive level will usually be within one level of the true concentration.

The test generally detects 15–30 mg/dL of albumin as a Trace result; however, because of the inherent variability of clinical urines, lesser concentrations may be detected under certain conditions. The test area is more sensitive to albumin than to globulin, hemoglobin, Bence-Jones Protein and mucoprotein; a negative result does not rule out the presence of these other proteins.

CHEMICAL PRINCIPLES OF THE PROCEDURE:

The test is based on the protein-error-of-indicators principle. At a constant buffered pH, the development of any green color is due to the presence of protein. Colors range from yellow for “Negative” through yellow-green and green to green-blue for “Positive” reactions.

REAGENTS:

(Based on dry weight at time of impregnation): 0.3% w/w tetrabromphenol blue; 97.3% w/w buffer; 2.4% w/w non-reactive ingredients.

AVAILABILITY:

ALBUSTIX is available in bottles of 100 strips (#2191).

BIBLIOGRAPHY:

1. Free, A. H., Rupe, C. O., and Metzler, I.: Studies with a simple colorimetric test for urine protein. *Abstracts of Papers, American Chemical Society Division of Biological Chemistry;* Miami, Florida; 1957.
2. Giordano, A. S. *et al.:* A new colorimetric test for albuminuria. *Amer. J. Med. Tech. 216;* 1957.
3. Longfield, G. M. *et al.:* Comparison studies of simplified tests for glucosuria and proteinuria. Tech. *Bull. Reg. Med. Technol. 30:76;* 1960.

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TECHNICAL ASSISTANCE:

For customer support, contact your local technical support provider.

In the US, call 877-229-3711.

www.siemens.com/diagnostics

SIEMENS

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