SIEMENS

IVD

Note: Package insert for use with the products listed below.

Multistix® 10 SG • Multistix® SG • Combistix® SG • Uristix® • Reagent Strips

Tests for Protein, Blood, Leukocytes, Nitrite, Glucose, Ketone (Acetoacetic Acid), pH, Specific Gravity, Bilirubin and Urobilinogen in Urine.

INTENDED USE:

Siemens Healthcare Diagnostics Reagent Strips for Urinalysis include test pads for protein, blood, leukocytes, nitrite, glucose, ketone (acetoacetic acid), pH, specific gravity, bilirubin and urobilinogen. Please refer to the carton or bottle label to see which tests are included on the product you are using.

Siemens Reagent Strips are for professional *in vitro* diagnostic use in near-patient (point of care) and centralized laboratory locations. The strips are intended for use in at-risk patient groups to assist diagnosis in the following areas:[1-3]

- kidney function
- urinary tract infections
- carbohydrate metabolism (e.g., diabetes mellitus)
- liver function

The strips also measure physical characteristics, including acid-base balance and urine concentration. Test results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed.[1,4]

SUMMARY AND EXPLANATION:

Siemens Reagent Strips are ready to use upon removal from the bottle and the reagent strip is disposable. The strips may be read visually, requiring no additional laboratory equipment for testing. The strips can also be read instrumentally, using the CLINITEK® family of Urine Chemistry Analyzers and the appropriate software; contact your product representative for further information. Siemens Reagent Strips with ID bands provide Auto-Checks when read on select CLINITEK instruments. Auto-Checks include automatic strip identification and quality checks. Siemens Reagent Strips have been determined to be nonhazardous under the guidelines issued by NOHSC:2011 (2003).

SPECIMEN COLLECTION AND PREPARATION:

Collect freshly-voided urine in a clean container and test it as soon as possible. The container should allow for complete dipping of all reagent trip areas. A first-morning specimen is preferred but random collections ire acceptable. Test the urine within two hours after voiding. If unable o test within the recommended time, refrigerate the specimen immediately and let it return to room temperature, between 15–30°C (59–86°F), before testing. The use of urine preservatives is not recommended.

CAUTION: Ensure that work areas and specimen containers are always free of detergents and other contaminants. Some substances can interfere with patient results. Contamination of the urine specimen with skin cleansers containing chlorhexidine may affect protein test results. The user should determine whether the use of such cleansers is warranted.

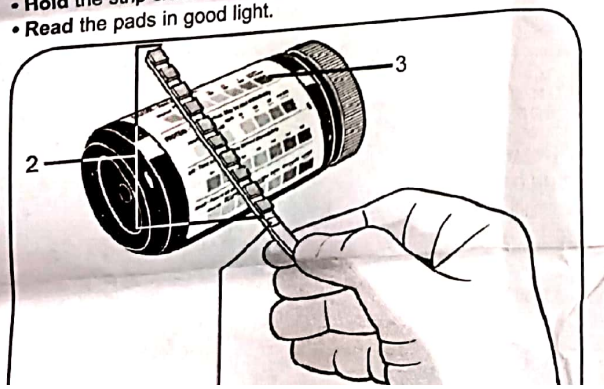
PROCEDURE:

1. Collect a fresh urine specimen in a clean, dry container.
2. Mix well just before testing, but do not centrifuge.
3. Check the expiration date on the Reagent Strip bottle. If the date has passed, discard and get a new bottle. Record the opening date on the label.

   Use of Reagent Strips beyond the expiration date may yield inaccurate results.
4. Remove a strip from the bottle and replace the cap.

   NOTE: Do not touch the test pads on the strip.
5. Dip all the test pads of the strip into the urine and immediately remove the strip. If reading the strip visually, start timing.

   NOTE: *The ID band can be dipped into urine and control solutions.*
6. Drag the edge of the strip against the container rim to remove excess urine and blot the edge on a paper towel or tissue if using the CLINITEK 50 or CLINITEK Status Analyzers. It is not necessary to blot if reading visually or using the CLINITEK Advantus Analyzer.
7. **If reading visually:**
   - **Compare** each test pad to the corresponding row of color blocks on the bottle label.
   - **Read** each pad at the time shown on the label, starting with the shortest time.
   - **Hold** the strip close to the color blocks and match carefully.
   - **Read** the pads in good light.



of the analytes in contrived urines; however, because of the inherent variability of clinical urines, lesser concentrations may be detected under certain conditions. The percentage of clinical specimens correctly detected as positive increases with analyte concentration.

Performance characteristics are based on clinical and analytical studies and depend upon several factors: the variability of color perception; the presence or absence of inhibitory and matrix factors typically found in urine; and the laboratory conditions in which the product is used (e.g., lighting, temperature, and humidity). The strips should be read in good light, such as fluorescent; do not read in direct sunlight.

Each color block or instrumental result 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 will usually be within one level of the true concentration. 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 systems of the instruments.

Limitations given for the reagents include specific substances and conditions that may affect the test results. **As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result or method.**

Substances that cause abnormal urine color may affect the readability of test pads on urinalysis reagent strips. These substances include visible levels of blood or bilirubin and drugs containing dyes (e.g., Pyridium®, Azo Gantrisin®, Azo Gantanol®), nitrofurantoin (Macrodantin®, Furadantin®), or riboflavin. Levels of ascorbic acid normally found in urine do not interfere with these tests.

PROTEIN PRO :

Expected values: Protein in urine can be the result of urological and nephrological disorders. In normal urine, less than 150 mg of total protein is excreted per day (24 hour period) (< 15 mg/dL). Clinical proteinuria is indicated at greater than 500 mg of protein per day (strip result of ≥ 30 mg/dL). Positive results may also indicate tubular or overflow proteinuria in the *absence of any glomerular abnormality or proteins of renal origin that may be excreted during infection. Urinary protein excretions can be temporarily elevated in the absence of renal abnormality by strenuous exercise, orthostatic proteinuria, dehydration, urinary tract infections, and acute illness with fever.*[1,6-7] *Clinical judgment is needed to evaluate the significance of Trace results.*

Sensitivity: *15–30 mg/dL albumin*

Performance characteristics: *The protein test pad is not specific for a particular protein, and proteins other than albumin can cause a positive response. The test is less sensitive to mucoproteins and globulins, which are generally detected at levels of 60 mg/dL or higher.*[8]

Limitations: A visibly bloody urine may cause falsely elevated results.[8]

BLOOD BLO :

Expected values: Normally, no hemoglobin *is detectable in urine (< 0.010 mg/dL or 3 RBC/µL). Occult blood occurs in urine as intact erythrocytes and hemoglobin, which can occur during urological, nephrological* and bleeding disorders. Small amounts of blood *(0.030–0.065 mg/dL or a* strip result of Small) are sufficiently abnormal to require further investiga tion. The significance of the Trace reaction may vary among patients, and clinical judgment is required for assessment in an individual case. Blood is often, but not always, found in the urine of menstruating females![1,9]

Sensitivity: *0.015–0.062 mg/dL hemoglobin*

Performance characteristics: The appearance of green spots on the reacted test pad indicates the presence of intact erythrocytes, while green color across the entire test pad indicates free hemoglobin. The test is equally sensitive to myoglobin as to hemoglobin. This test complements the microscopic examination; a hemoglobin concentration of 0.015–0.062 mg/dL is approximately equivalent to 5–20 intact red blood cells per microliter.

Limitations: Capoten® (captopril) may reduce the sensitivity. Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbial peroxidase associated with urinary tract infection may cause a false positive reaction.

LEUKOCYTES LEU :

Expected values: Normal urine specimens generally yield negative results. An increase in leukocytes (≥ 10 leukocytes/µL) is an indication of pyuria and is found in nearly all diseases of the kidney and urinary tract; however, pyuria may often be present in non-infective conditions! A strip result of Small or greater is a useful indicator of infection. Trace results may be of questionable clinical significance; however, Trace results ob-served repeatedly may be clinically significant.

Sensitivity: 5–15 white blood cells/hpf in clinical urine.

Performance characteristics: Leukocyte esterase is a reliable indicator of leukocytes in urine.[1] A positive reaction (Small or greater) at less than the 2 minute reading time may be regarded as a positive indication of leukocytes in urine.

Limitations: Elevated glucose concentrations (≥ 3 g/dL) may cause decreased test results. The presence of cephalexin (Keflex®),cephalothin, or high concentrations of oxalic acid may also cause decreased test results. Tetracycline may cause decreased reactivity, and high levels of the drug may cause a false negative reaction. Positive results may occasionally be due to contamination of the specimen by vaginal discharge.