**Multistix® 10 SG • Multistix® 9 • Multistix® 9 SG • Multistix® 8 SG • Multistix® 7 • N-Multistix® SG • N-Multistix® • Multistix® SG • Multistix® • Bili-Labstix® Reagent Strips**

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

**SUMMARY AND EXPLANATION / INTENDED USE:** Bayer 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.

Bayer Reagent Strips are for professional 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:

- 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.

Bayer Reagent Strips are ready to use upon removal from the bottle and the entire 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.

**INFORMATION REGARDING CLIA WAIVER:**

- The CLINITEK STATUS and CLINITEK 50 Analyzers are CLIA waived only when used with Bayer Reagent Strips, manufactured by Bayer HealthCare LLC.
- These tests are CLIA waived when read visually and when run on the CLINITEK STATUS and CLINITEK 50 Analyzers. A certificate of CLIA waiver is required to perform these tests in a waived setting. To obtain a Certificate of Waiver, contact your state department of health or visit the CMS web site for an application, Form CMS-116.
- Failure to adhere to the instructions for use, including instructions for limitations, intended use, and performing quality control testing, is off-label use, resulting in these tests being categorized as high complexity and subject to all CLIA regulations.

**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 strip areas. A first-morning specimen is preferred but random collections are acceptable. Test the urine within two hours after voiding, sooner if testing for bilirubin or urobilinogen. If unable to test within the recommended time, refrigerate the specimen immediately and let it return to room temperature before testing. Work areas and specimen containers should always be free of detergents and other contaminating substances.

**Procedure**

1. Collect a fresh urine specimen in a clean, dry container.
   - Mix well just before testing.
   - Remove one strip from the bottle.
   - Replace the cap.
2. Dip all the test pads of the strip into the urine.
   - Immediately remove the strip.
   - If reading the strip visually, start timing.

3. Drag the edge of the strip against the container rim to remove excess urine.
4. a. 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.

   b. If using a CLINITEK instrument, carefully follow the directions given in the appropriate instrument operating manual. The instrument will automatically read each test pad at a specified time.

5. Report the results to the lab supervisor or physician.

**RESULTS: With visual use, results are obtained in clinically meaningful units directly from the Color Chart comparison. With CLINITEK instruments, the test pads are “read” by the instrument and the results are displayed or printed as soon as they are available.**

**QUALITY CONTROL:** Test known negative and positive specimens or controls whenever a new bottle is first opened. Water should NOT be used as a negative control. Each laboratory should establish its own goals for adequate standards of performance. CHEK-STIX® Positive and Negative Control Strips provide a convenient basis for a quality control program.
Acute illness with fever. Clinical judgment is needed to evaluate temporarily elevated in the absence of renal abnormality by strenuous that may be excreted during infection. Urinary protein excretions can be in the absence of any glomerular abnormality or proteins of renal origin (≥0.15 mg/dL). Positive results may also indicate tubular or overflow proteinuria of test pads on urinalysis reagent strips. These substances include visibly bloody urine may cause falsely elevated results.

**Expected values:**

- 0.015–0.062 mg/dL hemoglobin
- 15–30 mg/dL albumin
- ≥0.10 mg/dL nitrite
- ≥0.015 mg/dL creatinine
- ≥0.001 mg/dL ketones
- ≥0.003 mg/dL glucose
- ≥0.015 mg/dL bilirubin
- ≥0.015 mg/dL myoglobin
- ≥0.015 mg/dL hemoglobin

**Expected values:**

- 0.015–0.062 mg/dL hemoglobin
- 75–125 mg/dL glucose
- 1.4–3.3 g/dL creatinine

**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:**

Expected values: Normal urine specimens generally yield negative results. An increase in leukocytes (≥10 leukocytes/μL) is an indication of pus and is found in nearly all diseases of the kidney levels are elevated; 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 observed 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. 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 cephalixin (Kellex), cephalothin (Keflin), 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.

**NITRITE:**

Expected values: Normally no nitrite is detectable in urine. Many enteric gram-negative organisms give positive results when their number is greater than 10³/mL (0.075 mg/dL nitrite ion or greater).

**Sensitivity:** 0.06–0.1 mg/dL nitrite ion.

**Performance characteristics:** The test is specific for nitrite and will not react with any other substance normally excreted in urine. Nitrite concentration during infection increases with the length of time the urine specimen is retained in the bladder prior to collection. A minimum of four hours of bladder incubation significantly increases the likelihood of obtaining a positive result.

**Limitations:** Pink spots or pink edges should not be interpreted as a positive result. A negative result does not rule out significant bacteruria. False negative results may occur with shortened bladder incubation of the urine, absence of dietary nitrate, or the presence of nonreductive pathological microbes.

**GLUCOSE:**

Expected values: Small amounts of glucose (<15 mg/dL or 50 mg/day) are normally excreted by the kidney. These amounts are usually below the sensitivity level of this test but on occasion may produce a result between Negative and 100 mg/dL that is interpreted as a positive result. Results at the first positive level may be significantly abnormal if found consistently.

**Sensitivity:** 75–125 mg/dL glucose

**Performance characteristics:** The test is specific for glucose; no substance excreted in urine other than glucose is known to give a positive result. This test may be used to determine whether the reducing substance found in urine is glucose. If the color appears somewhat modified at the higher glucose concentrations, match the darkest color to the color blocks.

**Limitations:** Ketone bodies reduce the sensitivity of the test; moderately high ketone levels (40 mg/dL) may cause false negatives for specimens containing small amounts of glucose (75–125 mg/dL) but the combination of such ketone levels and low glucose levels is metabolically improbable in screening.

**KETONE:**

Expected values: Normally, no ketone is detectable in urine (up to 2 mg/dL acetoacetic acid). In ketoacidosis, starvation or with other abnormalities of carbohydrate or lipid metabolism, ketones may appear in urine at levels of 10 mg/dL or higher before serum ketone levels are elevated. Clinical judgment is needed to determine the significance of Trace results, which may occur during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise.

**Sensitivity:** 5–10 mg/dL acetoacetic acid

**Performance characteristics:** The test reacts with acetoacetic acid in urine. It does not react with acetone or β-hydroxybutyric acid.

**Limitations:** False Trace results may occur with highly pigmented urine specimens or those containing large amounts of levodopa metabolites. Compounds such as mesna (2-mercaptopethane sulfonic acid) that contain sulfhydryl groups may cause false positive results or an atypical color reaction.
TRACE AMOUNTS OF BILIRUBIN ARE SUFFICIENTLY ABNORMAL TO REQUIRE FURTHER INVESTIGATION, WHICH IS NOT DETECTABLE BY EVEN THE MOST SENSITIVE METHODS. EVEN NORMAL ADULT URINE CONTAINS ABOUT 0.02 MG/DL OF BILIRUBIN.

BILIRUBIN:

- Expected values: Normal SG of urine ranges from 1.001–1.035. If the specific gravity of a random urine is 1.023 or greater, the concentrating ability of the kidneys can be considered normal.

- Performance characteristics: This test permits determination of urine specific gravity between 1,000 and 1,030. In general, it correlates within 0.005 with values obtained with the refractive index method. For increased accuracy, 0.005 may be added to readings from urines with pH ≥6.5. Strips read instrumentally are automatically adjusted for pH by the instrument. The Bayer SG test is not affected by the presence of radiopaque dyes as are the refractive index, urinometer, and osmosality methods.

SPECIFIC GRAVITY:

- Expected values: Normal adult urine contains about 0.02 mg/dL of bilirubin, which is not detectable by even the most sensitive methods. Even trace amounts of bilirubin are sufficiently abnormal to require further investigation. Since very small amounts of bilirubin (0.1 mg/dL or greater) may be found in the earliest phases of liver disease, the user must consider whether the sensitivity of Bayer Reagent Strips to bilirubin is sufficient for the intended use. When very small amounts of bilirubin in urine are sought (e.g., in the earliest phase of viral hepatitis), ICTOTEST® Reagent Tablets should be the method of choice.

Sensitivity: 0.4–0.8 mg/dL bilirubin

Performance characteristics: The test is specific for bilirubin and will not react with any other substance normally excreted in urine.

Limitations: Indican (indoxyl sulfate) can produce a yellow-orange to red color which may affect protein (and to a lesser extent specific gravity and bilirubin) test results. The user should determine whether the use of such skin cleansers is warranted.

It is especially important to use fresh urine to obtain optimal results with the tests for bilirubin and urobilinogen, as these compounds are very unstable when exposed to room temperature and light.

CHEMICAL PRINCIPLES OF PROCEDURES AND INGREDIENTS:

- Expected values: Normal SG of urine ranges from 1.001–1.035. If the specific gravity of a random urine is 1.023 or greater, the concentrating ability of the kidneys can be considered normal.1

- Performance characteristics: The pH test area measures pH values from 5–8.5 visually and 5–9 instrumentally, generally to within one unit of the expected result. pH readings are not affected by variations in the urinary buffer concentration.

Limitations: Bacterial growth by certain organisms in a specimen may cause a marked alkaline shift (pH >8.0), usually because of urea conversion to ammonia.

SPECIFIC GRAVITY:

- Expected values: The normal pH of urine can range from 4.6 to 8.0. Certain dietary conditions can produce acid or alkaline urines, which can be useful in the treatment of some calculi.1

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AVAILABILITY: Bayer Reagent Strips for Urinalysis are available in bottles of 100 strips: MULTISTIX® 10 SG (#2161); MULTISTIX® 9 (#2162); MULTISTIX® 9 SG (#2163); MULTISTIX® 8 SG (#2164); MULTISTIX® 7 (#2165); N-MULTISTIX® 9 SG (#2176); MULTISTIX® 8 SG (#2177); N-MULTISTIX® (#2178); MULTISTIX® (#2179); and BILI-LABSTIX® (#2180).

U.S. PATENT NUMBERS: Refer to the carton of the product you are using for applicable patent numbers.

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BIBLIOGRAPHY: