Atlas Medical

Urine Reagent Strips
(2 Parameters)

For rapid detection of multiple analytes in human urine.

IVD For *in vitro* diagnostic and professional use only

15°C 30°C Store at 15-30°C CE

INTENDED USE

Urine Reagent Strips are firm plastic strips onto which several separate reagent areas are affixed. The test is for the detection of one or more of the following analytes in urine: Bilirubin, Urobilinogen.

SUMMARY

Urine undergoes many changes during states of disease or body dysfunction before blood composition is altered to a significant extent. Urinalysis is a useful procedure as an indicator of health or disease, and as such, is a part of routine health screening. Urine Reagent Strips can be used in general evaluation of health, and aids in the diagnosis and monitoring of metabolic or systemic diseases.

PRINCIPLE AND EXPECTED VALUES

Bilirubin: This test is based on azo-coupling reaction of bilirubin with diazotized dichloroaniline in a strongly acidic medium. Varying bilirubin levels will produce a pinkish-tan color proportional to its concentration in urine. In normal urine, no bilirubin is detectable by even the most sensitive methods. Even trace amounts of bilirubin require further investigation. Atypical results (colors different from the negative or positive color blocks shown on the color chart) may indicate that bilirubin-derived bile pigments are present in the urine specimen, and are possibly masking the bilirubin reaction.

Urobilinogen: This test is based on a modified Ehrlich reaction between p-diethylaminobenzaldehyde and urobobilinogen acid in strongly acidic medium to produce a pink color. Urobilinogen is one of the major compounds produced in heme synthesis and is a normal substance in urine. The expected range for normal urine with this test is 0.2-1.0 mg/dL (3.5-17 µmol/L). A result of 2.0 mg/dL (35 µmol/L) may be of clinical significance, and the patient specimen should be further evaluated.

REAGENTS AND PERFORMANCE CHARACTERISTICS

Based on the dry weight at the time of impregnation, the concentrations given may vary within manufacturing tolerances. The following table below indicates read times and performance characteristics for each parameter.

Reagent	Read Time	Compos-ition	Description
Bilirubin (BIL)	30 sec	0.5 % w/w 2, 4-dichloroaniline diazonium salt; 99.5% w/w buffer and non-reactive ingredients	Detects bilirubin as low as 0.4-1.0 mg/dL (6.8-17.0 µmol/L).
Urobilinogen (URO)	60 sec	2.5% w/w p-diethylaminobenzaldehyde; 97.5% w/w buffer and non-reactive ingredients	Detects urobilinogen as low as 0.2-1.0 mg/dL (3.5-17 µmol/L).

The performance characteristics of the Urine Reagent Strips have been determined in both laboratory and clinical tests. Parameters of importance to the user are sensitivity, specificity, accuracy and precision. Generally, this test has been developed to be specific for the parameters to be measured with the exceptions of the interferences listed. Please refer to the Limitations section in this package insert.

Interpretation of visual results is dependent on several factors: the variability of color perception, the presence or absence of inhibitory factors, and the lighting conditions when the strip is read. Each color block on the chart corresponds to a range of analyte concentrations.

PRECAUTIONS

- For *in vitro* diagnostic use only. Do not use after the expiration date.
- The strip should remain in the closed canister until use.
- Do not touch the reagent areas of the strip.
- Discard any discolored strips that may have deteriorated.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used strip should be discarded according to local regulations after testing.

STORAGE AND STABILITY

Store as packaged in the closed canister either at room temperature (15-30°C). Keep out of direct sunlight. The strip is stable through the expiration date printed on the canister label. Do not remove the desiccant. Remove only enough strips for immediate use. Replace cap immediately and tightly. **DO NOT FREEZE.** Do not use beyond the expiration date.

Note: Once the canister has been opened, the remaining strips are stable for up to 3months. Stability may be reduced in high humidity conditions.

SPECIMEN

A urine specimen must be collected in a clean and dry container and tested as soon as possible. Do not centrifuge. The use of urine preservatives is not recommended. If testing cannot be done within an hour after voiding, refrigerate the specimen immediately and let it return to room temperature before testing.

Prolonged storage of unpreserved urine at room temperature may result in microbial proliferation with resultant changes in pH. A shift to alkaline pH may cause false positive results with the protein test area. Urine containing glucose may decrease in pH as organisms metabolize the glucose.

Contamination of the urine specimen with skin cleansers containing chlorhexidine may affect protein (and to a lesser extent, specific gravity and bilirubin) test results.

MATERIALS

Materials Provided

1. Strips
2. Package Insert

Materials Required But Not Provided

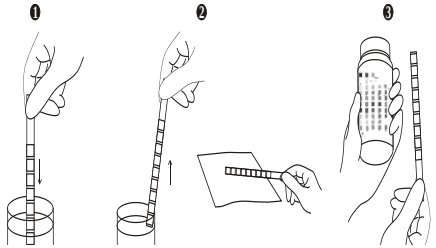
1. Specimen collection container
2. Timer

DIRECTIONS FOR USE

1. Remove the strip from the closed canister and use it as soon as possible. Immediately close the canister tightly after removing the required number of strip(s). Completely immerse the reagent areas of the strip in fresh, well-mixed urine and immediately remove the strip to avoid dissolving the reagents. See illustration 1 below.
2. While removing the strip from the urine, run the edge of the strip against the rim of the urine container to remove excess urine. Hold the strip in a horizontal position and bring the edge of the strip into contact with an absorbent material (e.g. a paper towel) to avoid mixing chemicals from adjacent reagent areas and/or soiling hands with urine. See illustration 2 below.

3. Compare the reagent areas to the corresponding color blocks on the canister label at the specified times. Hold the strip close to the color blocks and match carefully. See illustration 3 below.

Note: Results may be read up to 2 minutes after the specified times.



INTERPRETATION OF RESULTS

Results are obtained by direct comparison of the color blocks printed on the canister label. The color blocks represent nominal values; actual values will vary close to the nominal values. In the event of unexpected or questionable results, the following steps are recommended; confirm that the specimens have been tested within the expiration date printed on the canister label, compare results with known positive and negative controls and repeat the test using a new strip. If the problem persists, discontinue using the strip immediately and contact your local distributor.

QUALITY CONTROL

For best results, performance of reagent strips should be confirmed by testing known positive and negative specimens/controls whenever a new test is performed, or whenever a new canister is first opened. Each laboratory should establish its own goals for adequate standards of performance.

LIMITATIONS

Note: As with all diagnostic and therapeutic tests, all results must be considered with other clinical information available to the physician.

Bilirubin: Bilirubin is absent in normal urine, so any positive result, including a trace positive, indicates an underlying pathological condition and requires further investigation. Reactions may occur with urine containing large doses of chlorpromazine or rifampen that might be mistaken for positive bilirubin. The presence of bilirubin-derived bile pigments may mask the bilirubin reaction. This phenomenon is characterized by color development on the test patch that does not correlate with the colors on the color chart. Large concentrations of ascorbic acid may decrease sensitivity.

Urobilinogen: All results lower than 1 mg/dL urobilinogen should be interpreted as normal. A negative result does not at any time preclude the absence of urobilinogen. The reagent area may react with interfering substances known to react with Ehrlich's reagent, such as p-aminosalicylic acid and sulfonamides.[10] false negative results may be obtained if formalin is present. The test cannot be used to detect porphobilinogen.

Calibration (CAL): The calibration area is free of any chemicals and is solely used as a reference for internal evaluation.

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry