Atlas Medical CE

Urine Reagent Strips
(14 Parameters)

For rapid detection of multiple analytes in human urine.

IVD *For in vitro diagnostic use only.*

Store at 2-30℃

INTENDED USE

Urine Reagent Strips are firm plastic strips onto which several separate reagent areas are affixed. The test is for the qualitative and semi-quantitative detection of one or more of the following analytes in urine: Leukocytes, Urobilinogen, Albumin at low concentrations also known as Microalbumin, Protein, Bilirubin, Glucose, Ascorbic Acid, Specific Gravity, Ketone, Nitrite, Creatinine, pH, Blood, Calcium.

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 that affect kidney function, endocrine disorders and diseases or disorders of the urinary tract.

PRINCIPLE AND EXPECTED VALUES

Calcium: The test is based on color reaction of metal ions with chelators. The complexone of calcium ion with o-cresolphthalein produce a purple color proportional to calcium concentration in urine. 8-Hydroxy-5-quinolinesulfonic is used to reduce the interference of Magnesium present in urine.

Blood: This test is based on the peroxidase-like activity of hemoglobin which catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine. The resulting color ranges from orange to green to dark blue. Any green spots or green color development on the reagent area within 60 seconds is significant and the urine specimen should be examined further. Blood is often, but not invariably, found in the urine of menstruating females. The significance of a trace reading varies among patients and clinical judgment is required in these specimens.

PH: This test is based on a double indicator system which gives a broad range of colors covering the entire urinary pH range. Colors range from orange to yellow and green to blue. The expected range for normal urine specimens from newborns is pH 5-7. The expected range for other normal urine specimens is pH 4.5-8, with an average result of pH 6.

Creatinine: The peroxidase-like activity of a copper creatinine complex catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine to produce a resulting color range from orange through green to blue. Creatinine concentrations of 10-300 mg/dL are normally present in urine.

Nitrite: This test depends upon the conversion of nitrate to nitrite by the action of Gram negative bacteria in the urine. In an acidic medium, nitrite in the urine reacts with p-arsanilic acid to form a diazonium compound. The diazonium compound in turn couples with 1N-(1-naphthyl) ethylenediamine to produce a pink color. Nitrite is not detectable in normal Urine. The nitrite area will be positive in some cases of infection, depending on how long the urine specimens were retained in the bladder prior to collection. Retrieval of positive cases with the nitrite test ranges from as low as 40% in cases where little bladder incubation occurred, to as high as approximately 80% in cases where bladder incubation took place for at least 4 hours.

Ketone: Ketone is normally not present in urine. Detectable Ketone levels may occur in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise. In starvation diets, or in other abnormal carbohydrate metabolism situations, Ketones appear in the urine in excessively high concentration before serum Ketones are elevated. Legal's test principle is the test basis.

Specific Gravity: This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, colors range from deep blue-green in urine of low ionic concentration to green and yellow-green in urine of increasing ionic concentration. Randomly collected urine may vary in specific gravity from 1.003-1.035. Twenty-four hour urine from healthy adults with normal diets and fluid intake will have a specific gravity of 1.016-1.022. In cases of severe renal damage, the specific gravity is fixed at 1.010, the value of the glomerular filtrate.

Ascorbic acid: This test involves decolorization of Tillmann's reagent. The presence of ascorbic acid causes the color of the test field to change from blue-green to orange. Patients with adequate diet may excrete 2-10 mg/dL daily. After ingesting large amounts of ascorbic acid, levels can be around 200 mg/dL.

Glucose: This test is not affected by the presence of Ketones, or the pH of the urine. This test is a specific glucose-oxidase/peroxidase (GOD/POD) reaction based method.

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.

Protein: This reaction is based on the phenomenon known as the "protein error" of pH indicators where an indicator that is highly buffered will change color in the presence of proteins (anions) as the indicator releases hydrogen ions to the protein. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow to yellow-green for negative results and green to green-blue for positive results. 1-14 mg/dL of protein may be excreted by a normal kidney. A color matching any block greater than trace indicates significant proteinuria. Clinical judgment is required to evaluate the significance of trace results.

Albumin: The basis for the test is a high affinity sulfonephthalein dye, using the dye binding method to produce any blue color if albumin is present at a constant pH. Results range in color from pale green to aqua blue. Normally, albumin is present in urine at concentrations <20 mg/L. Results of 20-200 mg/L may indicate micralbuminuria. It is associated with early-stage kidney disease when a small amount of Albumin, also called Microalbumin is consistently present in urine. Clinical albuminuria is indicated by results of >200 mg/L. These levels can be predictive of albumin excretion rates of 30-300 mg/24hours and >300 mg/24hours, respectively. Exercise, acute illness and fever, and urinary tract infections may temporarily elevate urinary albumin excretions.

Urobilinogen: This test is based on the azo-coupling reaction of a stable diazonium salt with Urobilinogen in a strongly acidic medium to produce a red azo 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 is 0.2-1.0 mg/dL (3.5-17 µmol/L). A result of more than 1.0 mg/dL(17µmol/L) should be examined further.

Leukocytes: This test reveals the presence of granulocyte esterases. The esterases cleave a derivatized pyrazole amino acid ester to liberate derivatized hydroxy pyrazole. This pyrazole then reacts with a diazonium salt to produce a beige-pink to purple color. Normal urine specimens generally yield negative results. Trace results may be of questionable clinical significance. When trace results occur, it is recommended to retest using a fresh specimen from the same patient. Repeated trace and positive results are of clinical significance.

Albumin-to-Creatinine Ratio: It is also called Microalbumin-to-Creatinine ratio which is the most accurate and easiest test available to assess microalbuminuria. Albumin is normally present in urine at concentrations of <30 mg albumin/g creatinine. Microalbuminuria is indicated at a ratio result of 30-300 mg/g (Abnormal) and clinical albuminuria at a ratio of >300 mg/g (High Abnormal).

REAGREAGENTS 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	Composition	Description
Calcium (Ca)	60 seconds	o-cresolphthalein complexone	Detects calcium between 4-40 mg/dL (1.0-10 mmol/L)
Blood (BLO)	60 seconds	3,3',5,5'-tetramethylbenzidine (TMB); diisopropylbenzene dihydroperoxide; buffer and non-reactive ingredients	Detects free hemoglobin as low as 0.018-0.060 mg/dL or 5-10 Ery/µL in urine specimens with ascorbic acid content of < 50 mg/dL.
pH	60 seconds	methyl red sodium salt; bromthymol blue; non-reactive ingredients	Permits the quantitative differentiation of pH values within the range of 5-9.
Creatinine (CRE)	60 seconds	Copper acetate; diisopropylbenzene dihydroperoxide; 3,3',5,5'-tetramethylbenzidine; buffer; nonreactive ingredients	Detects creatinine between 10-300 mg/Dl (0.9 and 26.5 mmol/L)
Nitrite (NIT)	60 seconds	p-arsanilic acid; N-(1-naphthyl) ethylenediamine; non-reactive ingredients	Detects sodium nitrite as low as 0.05-0.1 mg/dL in urine with a low specific gravity and less than 30 mg/dL ascorbic acid.
Ketone (KET)	60 seconds	sodium nitroprusside; buffer	Detects acetoacetic acid as low as 2.5-5 mg/dL (0.25-0.5 mmol/L).
Specific Gravity	60 seconds	bromthymol blue indicator; buffer and non-reactive	Determines urine specific gravity between 1.000 and

(SG)		ingredients; poly (methyl vinyl ether/maleic anhydride); sodium hydroxide	1.030. Results correlate with values obtained by refractive index method within ± 0.005.
Ascorbic Acid (ASC)	60 seconds	2,6-dichlorophenolindophenol; buffer and non-reactive ingredients	Detects ascorbic acid as low as 5-10 mg/dL (0.28-0.56 mmol/L).
Glucose (GLU)	60 seconds	glucose oxidase; peroxidase; 3,3',5,5'-tetramethylbenzidine (TMB); buffer; non-reactive ingredients	Detects glucose as low as 25-40 mg/dL (1.25-2 mmol/L).
Bilirubin (BIL)	60 seconds	2, 6-dichloroaniline; buffer and non-reactive ingredients	Detects bilirubin as low as 0.4-1.0 mg/dL (6.8-17 µmol/L).
Protein (PRO)	60 seconds	tetrabromophenol blue; buffer and non-reactive ingredients	Detects albumin as low as 7.5-15 mg/dL (0.075-0.15 g/L).
Albumin (ALB)	60 seconds	bis(3',3"-diiodo-4',4"-dihydroxy-5',5"-dinitrophenyl)-3,4,5,6-tetrabromosulfonephthalein; buffer; non-reactive ingredients	Detects albumin between 10-150 mg/L
Urobilinogen (URO)	60 seconds	4-methoxybenzene diazonium tetrafluoroborate; buffer and non-reactive ingredients	Detects urobilinogen as low as 0.8-1.0 mg/dL (13.6-17 µmol/L).
Leukocytes (LEU)	120 seconds	derivatized pyrrole amino acid ester; diazonium salt; buffer; non-reactive ingredients	Detects leukocytes as low as 9-15 white blood cells Leu/ L in clinical urine.

The performance characteristics of the Urinalysis Reagent Strips (Urine) 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.
- Use fresh urine specimens for optimal results.

STORAGE AND STABILITY

Store as packaged in a cool, dry at temperature (2-30°C).Store away from moisture and light. 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 3 months. Stability may be reduced in high humidity conditions.

SPECIMEN COLLECTION AND PREPARATION

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

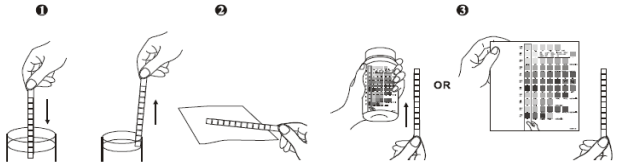
1. Strips
2. Package insert

Materials Required But Not Provided

1. Specimen collection container
2. Timer

PROCEDURE

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. 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. Dip the test strip into the urine specimen slowly to avoid bubbles on the reagent area. If there is a bubble present, repeat the test by dipping the strip more slowly into the urine specimen.

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.

Note: Water should not be used as negative control. If the problem persists, discontinue using the strip immediately and contact your local distributor.

If desired, refer to following table to determine the albumin-to-creatinine ratio.

Albumin (mg/L)	**Creatinine (mg/dL)**				
	10	**50**	**100**	**200**	**300**
10	Recollect Specimen*				
30					
80					
150					

Normal**
Abnormal
High Abnormal

*If specimen is too dilute to accurately determine ratio result. Repeat test on new specimen, preferably a first-morning collection.

**Both Albumin and A: C ratio results should be taken under consideration to determine clinical diagnosis decision or the need for confirmatory testing.

Note: Within several seconds after dipping, there may be a quick change in color on the albumin pad. Make sure to wait until the color stabilizes and until the 60 second reading time, before making a final reading.

Visually interpreted test result compared to urine analyzer interpreted result may provide different results because the urine analyzer determines the intermediate correlation value and uses a specific software calculation to determine the approximate albumin to creatinine ratio.

Variations in visual results may be due to visual interpretation limitations for each parameter result.

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: The Reagent Strips (Urine) may be affected by substances that cause abnormal urine color such as drugs containing azo dyes (e.g. Pyridium®, Azo Gantrisin®, Azo Gantanol®), nitrofurantoin (Microdantin®, Furadantin®), and riboflavin. The color development on the test pad may be masked or a color reaction may be produced that could be interpreted as false results.

Calcium: Magnesium higher than 20 mg/dL may cause elevated results.

Blood: A uniform blue color indicates the presence of myoglobin, hemoglobin or hemolyzed erythrocytes. Scattered or compacted blue spots indicate intact erythrocytes. To enhance accuracy, separate color scales are provided for hemoglobin and for erythrocytes. Positive results with this test are often seen with urine from menstruating females. It has been reported that urine of high pH reduces sensitivity, while moderate to high concentration of ascorbic acid may inhibit color formation. Microbial peroxidase, associated with urinary tract infection, may cause a false positive reaction. The test is slightly more sensitive to free hemoglobin and myoglobin than to intact erythrocytes.

pH: If the procedure is not followed and excess urine remains on the strip, a phenomenon known as "runover" may occur, in which the acid buffer from the protein reagent will run onto the pH area, causing the pH result to appear

artificially low. pH readings are not affected by variations in urinary buffer concentration.

Creatinine: This test detects urinary creatinine in concentrations as low as 10 mg/dl; the absence of creatinine in a specimen can not be determined. A new specimen such as a first-morning collection should be tested. Falsely elevated results with the creatinine tests can occur in the presence of hemoglobin or myoglobin (≥5 mg/dL or visible bloody urine).

Nitrite: The test is specific for nitrite and will not react with any other substance normally excreted in urine. Any degree of uniform pink to red color should be interpreted as a positive result, suggesting the presence of nitrite. Color intensity is not proportional to the number of bacteria present in the urine specimen. Pink spots or pink edges should not be interpreted as a positive result. Comparing the reacted reagent area on a white background may aid in the detection of low nitrite levels, which might otherwise be missed. Ascorbic acid above 30 mg/dL may cause false negatives in urine containing less than 0.05 mg/dL nitrite ions. The sensitivity of this test is reduced for urine specimens with highly buffered alkaline urine or with high specific gravity. A negative result does not at any time preclude the possibility of bacteruria. Negative results may occur in urinary tract infections from organisms that do not contain reductase to convert nitrate to nitrite; when urine has not been retained in the bladder for a sufficient length of time (at least 4 hours) for reduction of nitrate to nitrite to occur; when receiving antibiotic therapy or when dietary nitrate is absent.

Ketone: The test is more sensitive to acetoacetic acid than to acetone. Urine specimens of high pigment, captopril, mesna, and other substances containing sulfhydryl groups occasionally react may give false positive results.8 Phenylketone and phthalein compounds can produce red coloration on the edges of the reagent area, but are different than the violet colors caused by the presence of Ketone bodies and should be considered negative.

Specific Gravity: Ketoacidosis or protein higher than 300 mg/dL may cause elevated results.

Results are not affected by non-ionic urine components such as glucose. If the urine has a pH of 7 or greater, add 0.005 to the specific gravity reading indicated on the color chart.

Ascorbic acid: No interference is known.

Glucose: The reagent area does not react with lactose, galactose, fructose or other metabolic substances, nor with reducing metabolites of drugs (e.g. salicylates and nalidixic acid). Effects of Ascorbic Acid on Glucose have been greatly reduced. Glucose concentrations of 100 mg/dL and above are not effected by Ascorbic Acid concentrations, and high Ascorbic Acid concentrations will unlikely produce false negative results. The reactivity of the test decreases as the Specific Gravity of urine increase.

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.

Protein: Any green color indicates the presence of protein in the urine. This test is highly sensitive for albumin, and less sensitive to hemoglobin, globulin and mucoprotein. A negative result does not rule out the presence of these other proteins. False positive results may be obtained with highly buffered or alkaline urine. Contamination of urine specimens with quaternary ammonium compounds or skin cleansers containing chlorhexidine may produce false positive results. The urine specimens with high specific gravity may give false negative results.

Albumin: All positive results for albumin including low concentrations of Albumin also known as Microalbumin should be confirmed with quantitative test methods. Falsely elevated results with the albumin tests can occur in the presence of hemoglobin or myoglobin (≥5 mg/dL or visible bloody urine). The albumin test in contrived urine detects albumin at a concentration of 20-40 mg/L. Because of clinical urines' inherent variability, lesser concentrations may be detected under certain conditions. Both albumin and albumin-to-creatinine ratio should be considered during decision making regarding clinical diagnosis or need for confirmatory testing. This test is specific for albumin and is not affected by the following proteins when tested at concentrations at least nine times greater than the excretion rate considered to be abnormal:13 lysozyme, Bence-Jones protein, α1-acid glycoprotein, prealbumin, Tamm Horsfall glycoprotein, α1-microglobulin, immunoglobulins, β2-microglobulin, α1-antitrypsin, haptoglobin, β2-glycoprotein, retinal binding protein, transferrin. High specific gravity urine and/or high alkali urine may cause falsely elevated results with the microalbumin test.

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 will not react with interfering substances known to react with Ehrlich's reagent. False negative results may be obtained if formalin is present. The test cannot be used to detect porphobilinogen.

Leukocytes: The result should be read between 60-120 seconds to allow for complete color development. The intensity of the color that develops is proportional to the number of leukocytes present in the urine specimen. High specific gravity or elevated glucose concentrations (≥ 2,000 mg/dL) may cause test results to be artificially low. The presence of cephalexin, cephalothin, or high concentrations of oxalic acid may also cause test results to be artificially low. Tetracycline may cause decreased reactivity, and high levels of the drug may cause a false negative reaction. High urinary protein may diminish the intensity of the reaction color. This test will not react with erythrocytes or bacteria common in urine.

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ATLAS MEDICAL
Ludwig-Erhard Ring 3
15827 Blankenfelde-Mahlow
Germany
Tel: +49 - 33708 – 3550 30
Email: Info@atlas-medical.com

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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