



Urine Strip

10, 10 AA, 11, 11 AA

Test strips for the determination of urobilinogen, glucose, ketones, bilirubin, proteins, nitrite, pH, blood, specific gravity, leukocytes and ascorbic acid in urine

PRINCIPLE

The sample reacts with solid phase dry reagent areas attached to a plastic holder. Reagents for the detection of urobilinogen, glucose, ketones, bilirubin, proteins, nitrite, pH, blood, specific gravity, leukocytes and ascorbic acid are provided. The chemical principles of each test are as follows:

Urobilinogen: based on the diazotization reaction of a diazonium salt and urinary urobilinogen in a strong acid medium. The color changes range from light-pink to dark-reddish-pink.

Glucose: based on a sequential enzyme reaction. First, glucose oxidase catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. Then, peroxidase catalyzes the reaction of hydrogen peroxide with potassium iodide to colors ranging from greenish light-blue through greenish-brown and then to brown.

Ketones: based on the reaction of acetoacetic acid in urine with nitroprusside. The resulting color ranges from tan, when no reaction takes place, to different purple shades for positive reactions.

Bilirubin: based on the coupling of bilirubin with 2,4-dichlorophenyl diazonium salt in a strong acid medium. The color changes from light tan to dark-tan.

Proteins: based on the color change of the indicator, tetrabromophenol blue, in the presence of proteins. A positive reaction is indicated by a color change from greenish-yellow to green and then to dark-green.

Nitrite: based on the reaction of the p-arsanilic acid and nitrite, derived from a dietary nitrate in the presence of bacteria in urine, to form a diazonium compound. This compound reacts with N-(1-naphthyl)-ethylenediamine in an acidic medium. The resulting color is pink. Any degree of pink color is considered positive.

pH: based on double indicators (methyl red and bromothymol blue), which give a broad range of colors, covering the entire urinary pH range. Colors range from orange to greenish-yellow and then to bluish-green.

Blood: based on the pseudoperoxidase activity of hemoglobin, which catalyzes the reaction of 3,3',5,5'-tetramethyl-benzidine with buffered organic hydroperoxide. The resulting color ranges from greenish-yellow to greenish-blue and then to dark blue.

Specific gravity: based on the pKa change. In the presence of urinary cations, protons are released from a polyelectrolyte producing a color change in the bromothymol blue indicator from blue to yellow.

Leukocytes: reveals the presence of granulocyte esterases. The esterases cleave a derivatized pyrazol ester to release derivatized hydroxy pyrazol. This reacts with diazonium salt

to produce a purple product.

Ascorbic acid: based on the reducing process of ascorbic acid. The composition comprises certain aromatic compound which is colored in its oxidized state but which becomes colorless when reduced by ascorbic acid. The color changes from dark-green to greenish-yellow.

PROVIDED REAGENTS

Strips for individual determinations containing dry reagents to test the following parameters in urine, depending on the kit size (10, 10 AA, 11, 11 AA): urobilinogen, glucose, ketones (acetoacetic acid), bilirubin, proteins, nitrite, pH, blood, specific gravity, leukocytes and ascorbic acid. The composition of each reagent area is detailed for 100 strips:

Urobilinogen	4-Metoxybenzenodiazonium	2.5 mg
URO	Citric acid	30.0 mg
Glucose	Glucose oxidase	4.51 units
GLU	Peroxidase	1.86 units
	Potassium iodide	10.0 mg
Ketones	Sodium nitroprusside	20.0 mg
KET	Magnesium sulfate	246.5 mg
Bilirubin	2,4-Dichlorophenyldiazonium	3.0 mg
BIL	Oxalic acid	30.0 mg
Proteins	Tetrabromophenol blue	0.3 mg
PRO	Citric acid	110.0 mg
	Trisodium citrate	46.0 mg
Nitrite	p-Arsanilic acid	5.0 mg
NIT	N-(naphthyl)-ethylenediamine	0.6 mg
pH	Methyl red	0.04 mg
	Bromothymol blue	0.5 mg
Blood	Hydroperoxide	4.0 mg
BLO	3,3',5,5'-Tetramethylbenzidine	3.7 mg
Specific gravity	Bromothymol blue	1.2 mg
SG	Polyelectrolyte	12.0 mg
Leukocytes	Derivative	
LEU	Pyrazol amino acid ester	1.0 mg
	Diazonium salt	0.7 mg
Ascorbic acid	2,6-Dichlorophenol	1.6 mg
AA	indophenol	

INSTRUCTIONS FOR USE

The test strips are ready to use.

WARNINGS

Urine strip test strips are for "in vitro" diagnostic use and

are intended for professional use. The universal precautions recommended by the Centers for Disease Control should always be followed whenever blood or biological fluids are handled. These precautions include wearing gloves. All reagents and samples should be discarded according to the local regulations in force.

STABILITY AND STORAGE INSTRUCTIONS

Provided Reagents are stable at room temperature (< 30°C) until the expiration date stated on the box. The test strips are provided in a container with desiccant pouch. Since strips are sensitive to specific environmental factors such as moisture, heat and light, do not expose strips to these factors. After taking out one strip, replace the cap to avoid moistening of the reagent. Do not remove desiccant from the container. Transferring the strips to another container may deteriorate them or turn them non-reactive.

INSTABILITY OR DETERIORATION OF REAGENTS

Discoloration or darkening of reactive areas may indicate deterioration. Discard in such case.

SAMPLE

Urine

Collection: obtain in the usual way. Perform the test shortly after collection. If it cannot be performed within one hour from collection, refrigerate the sample immediately. Before performing the test, bring the sample to room temperature and homogenize without centrifugation.

PROCEDURE

This procedure SHOULD BE FOLLOWED EXACTLY to achieve reliable test results. Unused strips should be kept in their original container. Do not touch test area of the strip. The work area should be clean, free from detergents and other contaminants.

- 1- Confirm that the product is within the expiration date and that its temperature as well as the temperature of the samples is over 20°C.
- 2- Remove one strip from the container and replace cap immediately.
- 3- Inspect the strip and confirm it is in good condition (See INSTABILITY OR DETERIORATION OF REAGENTS).
- 4- Dip the test strip completely in fresh urine sample no more than 1 second. Excessive urine on the strip may cause erroneous results. Remove the excessive urine against the rim of the container, without touching the reagent areas. Excessive urine may be removed by blotting the lengthwise edge on absorbent paper.
- 5- All reactive areas, with the exception of leukocytes, should be read within 60 to 90 seconds to discriminate between positives and negatives. Leukocytes should be read between 90 and 120 seconds.
- 6- Carefully compare the results with the color chart on the container, keeping the strip horizontally and under a good light source. Proper reading time is critical for optimal results. Color changes observed only at the edges of the reactive areas, or after 2 minutes of reaction, have not diagnostic significance.

INTERPRETATION OF THE RESULTS

The results are obtained by direct comparison with the color chart printed in the container label.

QUALITY CONTROL METHOD

The obtained results with the test strips can be confirmed with positive or negative control samples.

PROCEDURE LIMITATIONS

This method has been developed for screening. Both positive and negative but uncertain results and those that do not correspond with the patient's clinical condition must be verified by confirmatory methods.

The effects of drugs and other metabolites on individual tests are not known for all the cases. It is recommended that in case of doubt the test should be repeated after withdrawal of the medication.

An adequate washing procedure of the material used for sampling is highly recommended since, for instance, hypochlorite residues may affect the sensitivity of some tests.

Urobilinogen: the complete absence of urobilinogen cannot be demonstrated by this method. Normal urines usually yield light pink colors. Concentrations of formalin above 0.2% can give false negative results. Nitrite concentrations > 2.5 mg/dl turn the reaction negative.

Glucose: when there is an increase of the urine pH, the reactivity may decrease. It can also vary with temperature. Ascorbic acid concentrations ≥ 25 mg/dl give false negative results and ketones > 40 mg/dl reduce the sensitivity of the reaction. Urines that contain levodopa or dipirona, may yield false negative results.

Ketones: false positive results may appear with pigmented urines or those containing large quantities of levodopa metabolites.

Bilirubin: since bilirubin is photosensitive, its exposure to light may yield false negative results. False positive results may be obtained in the presence of diagnostic or therapeutic dyes in the test urine.

Proteins: alkaline urines (pH 9) may yield false positive results. In turbid urines the interpretation of results is difficult.

Nitrite: any uniform pink coloration must be considered positive. However, pink dots or pink coloration on the corners should not be interpreted as positive. The nitrite test only detects nitrite reducing bacteria. Thus, a negative result does not completely discard urine contamination. The test turns negative with ascorbic acid concentrations ≥ 50 mg/dl. False positive results may be obtained when drugs with dyes excreted through urine are administered.

pH: bacterial growth in urine increases pH, by ammonia release from urea. Urine coloration may interfere with the determination.

Blood: occasionally, false negative results are observed in presence of bacteriuria. Ascorbic acid or proteins may reduce the sensitivity of the blood test. Strong oxidants, such as hypochlorite, may yield false positive results. In some cases, women urine during the menstrual period may produce false positive results.

Specific gravity: in the presence of moderate quantities of proteins (100-700 mg/dl) high specific gravity readings may be

obtained. Bacteriuria increases ammonia, which regulates pH medium and prevents the specific gravity pad from showing the color corresponding to the real specific gravity. Therefore, falsely decreased specific gravities are determined.

Leukocytes: formaldehyde may yield false positives. Proteins decrease test sensitivity in concentrations > 500 mg/dl.

Ascorbic acid: false positive values may be obtained with additional reducing agents.

EXPECTED VALUES

Urobilinogen: in this test, the normal range of urobilinogen is 0.1 to 1.0 mg/dl. If results exceed a 2.0 mg/dl concentration, the patient and/or urine sample should be further evaluated.

Glucose: normally, glucose is not detected in urine, although a small amount is excreted by the normal kidney. This test detects approximately 100 mg/dl. This concentration may be considered as abnormal if found consistently.

Ketones: with this reagent, ketonic bodies should not be detected in normal urines. Ketonic bodies may appear in urine if vomit, diarrhea, digestive disorders, pregnancy or intense physical exercise are present.

Bilirubin: bilirubin is not detectable in urine of healthy individuals, even with the most sensitive methods. An increase in its levels indicates disease and is the earliest sign of cellular disease and/or bile obstruction. The appearance of bilirubin traces is enough evidence to justify a subsequent test.

Proteins: normal urine samples usually contain some proteins (0-4 mg/dl). Therefore, only highly persistent levels of urine proteins indicate kidney or urinary tract disease. Protein results in traces or higher quantities indicate significant proteinuria, and thus further clinical testing is required. Pathologic proteinuria usually yields results above 30 mg/dl and is persistent.

Nitrite: any pink coloration degree after 30 seconds indicates clinically significant bacteriuria, usually due to kidney, ureters, bladder or urethra infections.

pH: normal urine is slightly acid with a pH of 6, that can range from 5 to 8. It is an important indicator of kidney, gastrointestinal, respiratory and metabolic factors.

Blood: the appearance of hemoglobin in urine indicates kidney or urinary tract disease. The test is highly sensitive to hemoglobin and intact erythrocytes, thus complementing the microscopic examination.

Specific gravity: adults random urines have a specific gravity ranging from 1.003 to 1.040. Twenty four hour urines from normal adults, with balanced diets and normal fluid intake, have a specific gravity of 1.016-1.022. This test detects values between 1.000 and 1.030.

Leukocytes: normally no leukocytes are detectable in urine. Individually observed trace results may have questionable clinical significance. If positive results are observed, a subsequent study of the patient should be performed. Occasionally, in women urine, it is possible to find leukocytes due to vaginal contamination.

Ascorbic acid: the presence of high concentration of ascorbic acid in the urine of individuals, who routinely ingest doses of vitamin C, may interfere with glucose, blood, bilirubin and nitrite tests. If ascorbic acid is detected, the test should be repeated at least 24 hours after the last dose of vitamin C.

PERFORMANCE

a) Correlation study: the product performance is based on clinical assays and laboratory studies. Studies performed in two medical institutions with 125 and 113 patients respectively, comparing Wiener lab. **Urine Strip** with a similar product, showed the following correlation results:

	Concordance of results	
	Negative	Positive
Hemoglobin	98%	93%
Bilirubin	95%	95%
Urobilinogen	96%	100%
Ketones	93%	100%
Glucose	100%	98%
Proteins	98%	93%
Nitrite	100%	100%
Leukocytes	96%	95%

Correlation of results was observed both for pH and for specific gravity. Correlations not reaching 100% may be due to the operator's different interpretation in regards to the difference between the images of the negative and the traces results. The ability to distinguish a slight color change, as positive or negative, is influenced by the operator's perception, the light and the presence or absence of inhibitors, usually present in urine, such as ascorbic acid, pH changes and specific gravity.

b) Sensitivity:

Urobilinogen: 0.1 mg/dl, thus, a light pink coloration may be observed even in normal urines.

Glucose: 100 mg/dl, specific for glucose.

Ketones: 5 mg/dl acetoacetate.

Bilirubin: 0.5 mg/dl.

Proteins: 15-30 mg/dl proteins in urine. More sensitivity for albumin than for γ -globulins, Bence Jones proteins and mucoproteins is observed.

Nitrite: 0.05-0.15 mg/dl in urines with ascorbic acid concentration below 25 mg/dl.

pH: a color change is produced between pH 5 and 9. Changes can be read per unit.

Blood: 0.015 mg/dl hemoglobin or 5-10 intact erythrocytes/ul.

Specific gravity: this test detects urine specific gravity of 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030.

Leukocytes: 10-25 leukocytes/ul in urines with protein concentrations \leq 500 mg/dl.

Ascorbic acid: 5 mg/dl.

WIENER LAB. PROVIDES

Tubes containing 100 test strips for the following determinations:

- **Urine Strip 10:** urobilinogen, glucose, ketones, bilirubin, proteins, nitrite, pH, blood, specific gravity and leukocytes.

- **Urine Strip 10 AA:** urobilinogen, glucose, ketones, bilirubin, proteins, nitrite, pH, blood, specific gravity and leukocytes (with compensation area for automatic strip reader).
- **Urine Strip 11:** urobilinogen, glucose, ketones, bilirubin, proteins, nitrite, pH, blood, specific gravity, leukocytes and ascorbic acid.
- **Urine Strip 11 AA:** urobilinogen, glucose, ketones, bilirubin, proteins, nitrite, pH, blood, specific gravity, leukocytes and ascorbic acid (with compensation area for automatic strip reader).

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- Graff, L. - A Handbook of Routine Urinalysis. Philadelphia, J. B. Lippincott Co., 1983.
- Jurgeris, E. - Spot Test Analysis N.Y. John Wiley & Sons, 1985.
- Kark, R. et al. - A primer of urinalysis, 2nd ed. N.Y., Harper and Row; 1963.

SYMBOLS

The following symbols are used in packaging for Wiener lab. diagnostic reagents kits.



This product fulfills the requirements of the European Directive 98/79 EC for "in vitro" diagnostic medical devices

	Authorized representative in the European Community
	"In vitro" diagnostic medical device
	Contains sufficient for <n> tests
	Use by
	Temperature limitation (store at)
	Do not freeze
	Biological risks
	Volume after reconstitution
	Contents
	Batch code
	Manufactured by:
	Harmful
	Corrosive / Caustic
	Irritant
	Consult instructions for use
	Calibrator
	Control
	Positive Control
	Negative Control
	Catalog number

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