URIACTION 10
Instructions for use

Ref.: 122

Intended use . System of reagent strips for semi-quantitative determination of bilirubin, ketones, density, glucose, leukocytes, nitrite, pH, proteins, blood and urobilinogen, in urine.

[For in vitro diagnostic use only.]

Sample

When handling samples and urine strips usual safety care shall be applied.

1. The sample should be collected in clean disposable bottle and leak proof.

2. The sample should be free of fecal contamination, vaginal secretion, smegma, pubic hair, powders, oils, lotions and other foreign materials. Urine from diapers should not be recovered.

3. A urine sample should be promptly delivered to the laboratory and the test should be completed within 1-2 hours of collection. It is generally accepted that changes begin to occur in the composition and deterioration of formed elements after two hours at ambient temperature. Bilirubin, urobilinogen and ketone may be reduced. Bacterial growth reduces glucose, increases the nitrite and causes changes in pH.

4. As urine test accuracy is dependent on the quality of sample, all care should be taken so that the urine sample is properly collected, stored and transported.

5. The chosen sample for chemical analysis is the first in the morning (8-hours concentrated) not centrifuged maintained between 15 and 25 ºC. Alternatively, a sample obtained from random collection can be used.

6. When the urine could not be analyzed within two hours, the sample may be cooled, but it should be at room temperature before starting the analysis. However, refrigeration is not intended to protect all the constituents such as bilirubin and urobilinogen and can induce the precipitation of amorphous phosphate and urates.

7. It is not recommended to add preservatives to the sample.

Procedure and interpretation of results

1. Before opening the bottle containing the urine strips, be sure that its temperature is in equilibrium with the ambient temperature. Exposure of urine strips to direct sunlight, chemical vapors and ambient humidity can affect the reaction areas and produce incorrect results.

2. Remove only the amount of urine strips required for testing and immediately close the container with the original cover.

3. Do not touch the reactive areas of the urine strips.

4. Dip the urine strip into the urine for approximately 2 seconds so that all areas are almost simultaneously submerged.

5. Remove excess urine by sliding the side of urine strip by the edge of bottle which contains the urine or in tissue paper.

6. Keep the urine strips horizontally during the time of testing in order to avoid any interference along with the reaction areas.

7. To perform the reading of the test, after 30 to 120 seconds (leukocytes after 60 to 120 s), under appropiate light source, bring the test strip beside the color chart present on the label and compare the colors.

8. Stains present only at the edge of tests or that become visible after 2 minutes from the beginning of test have no meaning and shall not be interpreted.

Clinical applications, principle of the test, expected values and interferences

Glucose . Measurement of urinary glucose is used for diagnosis of carbohydrate metabolism disorders including Diabetes mellitus and hyperglycemia. The test is based on the reaction of glucose oxidase: peroxidase: chromogen. The color of reaction area varies from green to brown. Small quantities of glucose are normally excreted in urine[3]. Test interpretation can be carried out after 10-seconds reaction for qualitative results and 30-seconds reaction for semi-quantitative results. The test is highly specific for glucose. No other substance excreted in urine is able to produce positive results. The sensitivity can be reduced in sample density with >1.025 and with ascorbic acid concentrations with ≥10 mg/dL.

Bilirubin . Measurement of conjugated bilirubin in the urine is useful for diagnosis of hepato-biliary tract diseases. The test is based on coupling bilirubin reaction with a diazonium salt in acidic medium by forming a pink color. Atypical results (staining of the respective reagent area different from those shown on the label) may indicate that other pigments present in the sample are masking the bilirubin reaction. The presence of bilirubin-derived bile pigments may mask the bilirubin reaction. This phenomenon is characterized by development of color that does not correlate with the colors on the bottle label. Typically bilirubin is not found in the urine. Any positive result indicates a pathological condition requiring further investigation. False positive result can be found in samples containing high concentrations of chlorpromazine or rifampen. High concentration of ascorbic acid may reduce the sensitivity of the test.

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Ketone . Ketones are not normally present in urine. Detectable levels of ketones in the urine may occur under conditions of physiological stress such as fasting, pregnancy and physical activity in excess[4-6]. In starvation diets or in other situations of abnormal metabolism of carbohydrates, ketones can be detected in urine in concentrations too high before seric ketone rising levels[7]. The test is based on reaction of ketones and acetoacetic acid with sodium nitroprusside modifying the color of light pink area (negative test) to dark pink to purple (positive test).

Density . Parameters used to estimate the renal capacity to concentrate or dilute urine. The urine density shall vary depending on the volume of fluid intake and the reduction of renal function. Very dilute urine with density 1.000 may indicate the loss of renal capacity to concentrate urine. The test is based on the apparent pKa change of certain polyelectrolytes in relation to ionic concentration. In the presence of an indicator, background colors vary from blue-green in the urine of low ionic concentration to green and yellow-green in urine of high ion concentration. The urine density can randomly vary from 1.003 to 1.040. 24-hour urine of healthy adults with normal diet (solids and liquids) shall have density between 1.016 and 1.022[8]. Ketoacidosis or protein >100 mg/dL can lead to obtaining high results. Non-ionic urinary components (as glucose) do not alter the results. Add 0.005 to density value measured on samples at pH>7.0.

Blood . Occult blood in the urine can indicate serious kidney or urologic disease. Microhematuria does not promote changes in urine color and is only detected by microscopic examination or chemical tests. The test is based on hemoglobin peroxidase activity which catalyzes the reaction of cumene hydroperoxide, and 3,3 ', 5,5'-tetramethylbenzidine. The color of test area varies from orange to green and dark blue. Any point or green color present in the test area within 60 seconds is significantly by suggesting more detailed urine investigation. The urine sample may be contaminated with blood during menstrual period. A uniform blue color indicates the presence of myoglobin, hemoglobin or red cell hemolysates. Dispersed or compressed blue points indicate the presence of intact erythrocytes. Aiming at facilitating test interpretation, different color scales for hemoglobin and erythrocytes are provided. It has been reported that high urine pH leads to reduction of sensitivity while ascorbic acid in high concentration inhibits color formation. Microbial peroxidase associated with urinary tract infection can produce false positive reaction. The test is slightly more sensitive to free hemoglobin and myoglobin than to intact erythrocytes.

pH . Urinary pH estimates are used to evaluate the acidity or alkalinity which is related to several metabolic or renal diseases and in monitoring patients on specific diets. Persistence of high pH indicates a urinary tract infection. The test is based on dual system information which has a broad scope covering the entire urinary pH range. The colors of reagent area change from orange to yellow and green to blue. The newborns' pH value in urine ranges from of 5-7 and pH expected for other normal samples is 4,5 -8, with an average pH value of 6. If the test procedure is not properly performed and excess urine remains on the urine dipstick, a phenomenon known as "runover" may occur, where acidic buffer of protein reagent area reaches the pH reagent area causing a low pH artificial result. The pH measurement is not affected by variations in urinary buffer concentration.

Proteins . The test is based on the "protein error" of indicator. At constant pH, development of any green color is due to the presence of protein. Coloration ranging from yellow to yellow-green for negative result and from green to green blue for positive result. 1-14 mg/dL of protein may be excreted by a healthy person[9] The test is very sensitive to albumin and less sensitive to hemoglobin, mucoprotein and globulin. A negative result does not exclude the presence of these other proteins. False positive result can be obtained in alkaline urine or with high buffering capacity. Urine contamination with quaternary ammonium compounds or antiseptics containing chlorhexidine produces false positive results. False negative result can be obtained in samples with high density.

Urobilinogen . Urobilinogen determination (bile pigment, hemoglobin degradation product) in urine is used for diagnosis of liver diseases and increasing hemoglobin catabolism as a result of hemolytic diseases. The test is based on the modified Ehrlich reaction between p-dimethylaminobenzaldehyde and urobilinogen acid in strongly acidic medium that produces pink color. The urobilinogen is one resulting from heme synthesis and is typically present in urine. The expected range for normal urine is 0.2 to 1.0 mg/dL (3.5 to 17 μmol/L). A score of 2.0 mg/dL (35 μmol/L) may have clinical significance suggesting more detailed investigation of the patient sample. A negative result at any time means the absence of urobilinogen in the specimen. The test suffers positive interference of known substances by reacting with Ehrlich's reagent, such as p-aminosalicylic acid and sulfonamide. False positive results may be obtained in the presence of formalin. The test does not apply to the porphobilinogen detection.

Nitrite . The nitrite identification is used for diagnosis of bacterial infections in the urinary tract. This test depends on the conversion of nitrate to nitrite by action of gram-negative bacteria in urine. In an acidic environment, the nitrite present in the urine reacts with p-arsanylic to form a diazonium compound. The diazonium compound reacts with an N-(1-Naphthyl) ethylenediamine by producing a pink color. A positive result in cases of infection depends on the time which urine is kept in bladder prior to collection. The test is a positive one in 40% of cases for samples kept in bladder for a short-term interval and in 80% of cases where samples are kept in bladder for 4 hours. The test is specific to nitrite and does not react with any other substance in urine. Any degree of uniform pink to red color is to be interpreted as a positive result suggesting the presence of nitrite. The color intensity is not related to the number of bacteria present in the sample. Points or edges with pink color should not be construed as a positive result. The comparison of reagent area against a white background can help to detect small amounts of nitrite that may not be perceived. Ascorbic acid >30 mg/dL may produce false negative results in samples with concentrations of sodium nitrite <0.05 mg/dL. Test sensitivity is reduced in alkaline samples with high buffering capacity. For more accurate results, the use of antibiotics should be discontinued for at least 3 days before sample collection for testing. A negative result does not exclude the presence of bacteriuris at any time. Negative results can occur in urinary tract infections by organisms that do not contain reductase to convert nitrate to nitrite; when the urine in the bladder is not maintained for sufficient time (4 h) for occurring the conversion of nitrate to nitrite; or absence of dietary nitrate.

Leukocytes . Leukocytes in urine indicate renal inflammatory disease and urinary tract suggesting further investigation. The granulocyte esterase releases heterocyclic carboxylic ester, the lysis product reacts with a diazonium salt forming a violet color. The samples of healthy patients do not contain leukocytes. The presence of traces of leukocyte suggests analysis of a new fresh sample. Repeated presence of traces and positive results are of clinical significance. The test should be read between 60 and 120 seconds aiming to allow full color development. Developed color intensity is proportional to the number of leukocytes in the sample. High density, glucose concentration >500 mg/dL, presence of cephalexin or cephalothin, and high concentration of oxalic acid may produce falsely decreased results. Tetracycline may reduce the reactivity and high levels of the drug may provide false negative result. Protein concentration >500 mg/dL can reduce reaction color intensity. The test does not react with erythrocytes or bacteria commonly present in urine.

Active components

Glucose . 1.5% Glucose oxidase, 0.5% Peroxidase; 10.0% Potassium iodide
Bilirubin . 0.5% Diazonium salt
Ketones . 5.0% Sodium nitroprusside
Density . 2.5% Bromothymol blue
Blood . 4.0% Tetramethylbenzidine (TMB), 6.0% Cumene hydroperoxide
pH . 0.5% Methyl red, 5.0% Bromothymol blue
Protein . 0.3% Blue tetrabromophenol
Urobilinogen . 2.5% p-dimethylaminobenzaldehyde
Nitrite . 1.5% p-arsanylic
Leukocytes . 0.5% Carboxylic ester, 0.4% Diazonium salt

Stability . Store between 2 - 30 ºC. The urine strips stored under specified conditions are stable until the expiration date printed on label. Do not use them after expiration date. **After opening, the remaining urine strips are stable for 3 months kept in original bottle tightly closed and protected from the action of direct sunlight and moisture. The stability may be reduced if stored in an environment with high humidity.**

Notes

1. Do not mix different lots of urine strips in same bottle.

2. The establishment of diagnosis and prescription of appropriate therapy should be performed by considering the results obtained with the test urine strips and the patient's clinical data.

3. The effect of drugs or their metabolites on the test are not known in all cases. In case of doubt, it is recommended to repeat the test after stopping medication. The interruption of medication, if needed, should only occur after indicated by the doctor who is carrying out the treatment.

4. Due to the volatile composition to different urine samples (e.g., activators or inhibitors variable content, fluctuations in the ionic concentration) the reaction conditions are not always the same, so that the intensity and color tone can vary in sporadic cases.

5. For reflectometric reading, read instructions carefully for using the instrument. As a result of different spectral sensitivities of the human eye and the optical system of the instruments, it is not always possible to obtain a perfect correlation between the values obtained by visual readout and results in the instrument.

6. For in vitro diagnostic use only. For trained personnel only; not suitable for own use.

7. Visual reading of the test is under some variability degree due to different interpretations of color given by the operators. This way, well-trained personnel is requested to perform the test.

8. Do not ingest; avoid contact with eyes and mucous membranes; keep out of reach of children.

9. As samples are potentially infectious, we suggest handling them by following the rules established for Biosafety.

10. To discard the reagents and biological materials, we suggest applying for applicable local, state or federal environmental protection.

Quality control . The use of control samples for validating the dry chemical areas performance must be a habit in the clinical laboratory. It is suggested to use a sample control with negative or normal results and a sample with values on the detection limit of each reagent area. The obtained values for controls must follow the limits established for the laboratory. It is recommended the participation in external programs of proficiency for evaluating the performance of chemical determination in urine analysis.

Referências

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Presentation

Product	Reference	Content	
UriAction 10	122-100	Reagent strips	100 un
	122-150	Reagent strips	150 un

For information about other commercial presentations, consult the website www.labtest.com.br or contact SAC.

Consumer information

[Warranty conditions]

Labtest Diagnóstica warrants the performance of this product under the specifications until the expiration date shown in the label since the application procedures and storage conditions, indicated on the label and in this insert, have been followed correctly.

Labtest Diagnóstica S.A.
CNPJ: 16.516.296 / 0001 - 38
Av. Paulo Ferreira da Costa, 600 - Vista Alegre - CEP 33240-152
Lagoa Santa . Minas Gerais Brasil - **www.labtest.com.br**
Consumer Service | e-mail: customerservice@labtest.com.br

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Símbolos utilizados com produtos diagnósticos in vitro

Símbolos usados con productos diagnósticos in vitro . Symbols used with ivd devices

Conteúdo suficiente para < n > testes Contenido suficiente para < n > tests Contains sufficient for < n > tests	**Consultar instruções de uso** Consultar instrucciones de uso Consult instructions for use	**Controle** Control Control	**Tóxico** Tóxico Poison
Data limite de utilização (aaaa-mm-dd ou mm/aaaa) Estable hasta (aaaa-mm-dd o mm/aaaa) Use by (yyyy-mm-dd or mm/yyyy)	**Número do catálogo** Número de catálogo Catalog Number	**Controle negativo** Control negativo Negative control	**Reagente** Reactivo Reagent
Material Calibrador Material Calibrador Calibrator Material	**Adições ou alterações significativas** Cambios o suplementos significativos Significant additions or changes	**Controle positivo** Control positivo Positive control	**Fabricado por** Elaborado por Manufactured by
Material Calibrador Material Calibrador Calibrator Material	**Produto diagnóstico in vitro** Dispositivo de diagnóstico in vitro In vitro diagnostic device	**Controle** Control Control	**Número do lote** Denominación de lote Batch code
Limite de temperatura (conservar a) Temperatura limite (conservar a) Temperature limitation (store at)	**Liofilizado** Liofilizado Lyophilized	**Risco biológico** Riesgo biológico Biological risk	**Período após abertura** Período post-abertura Period after-opening
Representante Autorizado na Comunidade Europeia Representante autorizado en la Comunidad Europea Authorized Representative in the European Community	**Corrosivo** Corrosivo Corrosive	**Marca CE** Marcado CE CE Mark	**Uso veterinário** Uso veterinario Veterinary use
Instalar até Instalar hasta Install before	**Fabricado em** Elaborado en Manufactured on	**Produto de uso único** Producto de un solo uso Single use product	Ref.: 280322