Analyticon Biotechnologies AG
D-35104 Lichtenfels
Am Muehlenberg 10 · Germany
www.analyticon-diagnostics.com

Distribuito da / Distributed by: **GIMA S.p.A.**Via Marconi, 1
20060 Gessate (MI) Italy

URINE SCREEN 10

GB DE SE DK FI NO TR ES

 $\begin{picture}(c){c} \hline \end{picture} \begin{picture}(c){c} \hline \end{$

URINE 11

Parametri / Parameter

| Descrizione Description | Codice prodotto Product code | Contenuto Content | Glucosio Glucose | Acido ascorbico Ascorbic Acid | Chetoni Ketones | Proteine Protein | Valori pH pH-Value | Sangue Blood | Nitriti Nitrite | Leucociti Leucocytes | Peso specifico Spec. Gravity | Bilirubina Bilirubin | Urobilinogeno Urobilinogen |
|----------------------------|---------------------------------|----------------------|---------------------|----------------------------------|--------------------|---------------------|-----------------------|-----------------|--------------------|-------------------------|---------------------------------|-------------------------|-------------------------------|
| URINE SCREEN 10 | 24073 / 93120 | 100 | • | | | - | | | | • | - | • | - |
| URINE SCREEN 11 | 24074 / 93100 | 100 | • | | | | | | | | | | |



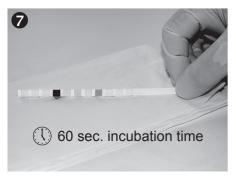














References / Referenzen / Referenser / Referencer / Viitteet / Referanser / Referanslar / Referencias / Références / Riferimenti / Referências / Referenties / Referencje / Reference / βιβλιογραφικές αναφορές / Справочный Referenzbereiche für Kinder und Erwachsene von Heil/

Ehrhardt (Roche) [pH Referenz daraus entnommen]; oder alternativ aus "Textbook of Urinalysis and Body Fluids" von Landy J. McBride: Kaplan L.A., Pesce A.J. Clinical chemistry. 3rd ed. St.

Kaplan L.A., Pesce A.J. Clinical chemistry. 3rd ed. St Louis: The CV Mosby Company, 1996.



INTENDED USE

INTENDEU USE.

For use as a preliminary screening test for diabetes, liver diseases, hemolytic diseases, urogenital and kidney disorders and metabolic abnormalities.

Urine test strips for the rapid semi-quantitative determination of ascorbic acid, bilirubin, blood, glucose, ketones, leucocytes, nitritle, pH-value, protein, specific gravity and urobilinogen in human urine.

The URINE SCREEN urine test strips are only for professional use.

use.

SUMMARY AND EXPLANATION

Unine test strips are semi-quantitative test systems used to measure certain analytes in urine. These measurements are used in the screening for renal, hepatic and metabolic disorders as well as urinary tract infection of bacterial origin. Since ascorbic acid in urine might interfere with the reaction of some parameters, some URINE SCREEN urine test strips include a test pad which indicates the level of ascorbic acid in the urine.

This package insert describes all types of URINE SCREEN urine test strips may be read visually. Refer to the carton and label for specific parameter combination on the product you are using.

TEST PRINCIPLE

TEST PRINCIPLE

Ascorbic acid: The test is based on the discoloration of Tillman's reagent. In the presence of ascorbic acid, the color changes from grey-blue to orange.

Billimbin: A red azo compound is obtained in the presence of acid by coupling of billirubin with a diazonium salt. The presence of billirubin leads to a color of red-orange peach. Blood: The test is based on the pseudo-peroxidative activity of hemoglobin and myoglobin, which catalyze the oxidation of an indicator by an organic hydroperoxide and a chromogen producing a green color. Intact erythrocytes are reported by uncutau clorations on the test pad, whereas hemoglobin and myoglobin are reported by a homogeneous green coloration. Glucose: The test is based on the glucoso oxidase-peroxidase-chromogen reaction. The presence of glucose leads to a color change from yellow via lime green to dark teal.

Ketones: The test is based on the reaction of acetone and acetoacetic acid with sodium nitroprusside in alkaline solution to give a violet clorider compile; (Legal's test).

Leucocytes: The test is based on the seterase activity of granulocytes. This enzyme clasves heterocyclic carboxylates. If the enzyme is released from the cells, it reacts with a diazonium salt producing a violet dye.

Nitrite: The test is based on the principle of the Grisss

Nitrite: The test is based on the principle of the Griess reaction. Any degree of pink-orange coloration should be interpreted as a positive result.

pH: The test paper contains pH indicators, which clearly change color between pH 5 and pH 9 (from orange to green to turquoise). Protein: The test is based on the "protein error" principle of an indicator. The test is especially sensitive in the presence of albumin. Other proteins are indicated with less sensitivity. The presence of proteins leads to a color change from yellowish to mint green.

Specific Gravity: The test is based on a color change reagent from blue green to greenish yellow depending a concentration of ions in the urine.

Urobilinogen: The test is based on the coupling of urobilinogen with a stabilized diazonium salt to a red azo compound. The presence of urobilinogen leads to a color change from light to dark pink.

change from light to dark pink.

REAGENTS

Ascorbic add: 2,6-dichlorophenolindophenol 0.7 %

Bilirubin: diazonium salt 3.1 %

Blood: tetramethybenzidine-dihydrochloride 2.0 %,
isopropybenzol-hydroperoxide 21.0 %

Gluoses: gluoses ordiades 2.1 %, peroxidase 0.9 %;

-o-lolidine-hydrochloride 5.0 %

Ketones: sodium nitroprusside 2.0 %

Leucocytes: carboxylic acid ester 0.4 %; diazonium salt 0.2 %

Nitrite: tetrahydrobenzo(hyduniolin-3-ol 1.5 %; sulfanilic
acid 1.9 %

pth: methyl red 2.0 %; bromothymol blue 10.0 %

acid 1.9 %
pH: methyl red 2.0 %; bromothymol blue 10.0 %
Protein: tetrabromophenol blue 0.2 %
Specific Gravity: bromothymol blue 2.8 %
Urobilinogen: diazonium salt 3.6 %

WARNING AND PRECAUTIONS

WARNING AND PRECAUTIONS
For In Vitro Diagnostic Use.
For side handling of urine test strips and for avoiding contact with potentially infectious substances, please follow fire general working instructions for laboratories. Do not touch the test pads! Avoid ingestion and contact with eyes and mucous membranes. Keep eavy from children. Disposal of used test strips should be in accordance with local regulations. The malerial safety data sheet is available for download from our homepage http://www.analyticon-diagnostics.com. In case any serious includent has occurred in relation to the device, please report to the manufacturer and, if applicable, to the competent authority of the country in which the users and or the patients established themselves.

NIDICATIONS OF INTERIDATION

INDICATIONS OF DETERIORATION
Do not use discolored urine test strips. External influences such as humidity, light and extreme temperatures can cause a discoloration of test pads and may indicate deterioration.

STORAGE AND STABILITY
Store the tubes in a cool and dry place (storage temperature 2-30°C). Keep jurine test strips protected from direct sunlight, humidity and extreme temperatures. The urine test strips can be used until the given expiry date if stored and handled as specified in the package insert.

specified in the package insert.

SPECIMEN COLLECTION AND PREPARATION
Testing of fresh, native, well-mixed and non-centrifuged
urine is recommended. Protect the samples from light. First
morning urine is preferable and shall be tested within 2 hours.
If immediate testing is not applicable, store samples at 2–4 °C.
Allow the sample to reach room temperature (15–25 °C) and
mix them before testing.
Collection tubes must be clean, dry and free from detergents,
biocides or disinfectants. Do not add preservatives.

PROCEDURE

- PROCEDURE

 Use fresh, well-mixed native urine.
 Remove only the number of urine test strips intended to be used for measurement, and immediately close the vial again tightly with the original cap.
 Dip fine urine test strip shortly (approx. 1–2 seconds) into the well-mixed urine. Make sure that all test pads are immersed in the sample.
 Wipe the edge of the strip on the rim of the sample container to remove excess urine.
 Dab the edge of the urine test strip on an absorbent paper towel.

- Dab the edge of the urine test strip on an absorbent paper towel.

 Visual evaluation; To prevent interaction of adjacent test pads, hold the urine test strip in a horizontal position during incubation. Compare the test pads on the urine test strip with the corresponding color chart on the vial 60 seconds (60–120 seconds for leucocytes) after immersion. Color changes that appear more than 2 minutes after immersion should not be evaluated. Visual evaluation should be carried out in diffuse daylight (below daylight lamps, at the window etc.). Any color change that cannot be assigned to the color chart on the vial label, or that is restricted to the rim of the test pads, is without meaning and should not be used for interpretation.

MATERIALS PROVIDED
Package with URINE SCREEN urine test strips.

QUALITY CONTROL

QUALITY CONTROL
Performance of urine test strips should to be checked with
the CombiScreen* Dip Check (REF 93010) and Drop
Check (REF93015), according to the internal guidelines of
the laboratory and the local regulations. It is recommended
to perform control measurements after opening a new vial
of urine test strips or with a new batch of urine test strips.
Each laboratory is obliged to establish its own quality control
standards. If control solutions other than CombiScreen* Dip
Check and Drop Check are used, it is necessary to confirm the
specificity of the color changes on the test pads.

RESULTS AND EXPECTED VALUES
Each laboratory should evaluate the transferability of
the expected values to its own patient population and, if
necessary, determine its own reference ranges.

The color changes of the test pads correspond to the analyte concentrations described in Table 1.

LIMITATIONS OF THE PROCEDURE

IMITATIONS OF THE PROCEDURE

In order to establish a final diagnosis and prescribe an appropriate therapy, the results obtained with urine test strips need to be evaluated in combination with other medical results and the patient's medical insults of the patient's medical insults of the medication. However, a current medication should only be stopped after respective instruction of the doctor. Detergents, denaining agents, disinfectants and preservatives may interfere with the reaction on the test pads. Various colored urine contents, especially high concentrations of hemoglobin (≥ 5 mg/dL) or bilirubin (≥ 2 mg/dL), can lead to atypical obloration on the test pads. The content of the urine is variable (e.g., content of activators or inhibitors and ion concentration in the urine), therefore the reaction conditions are not constant. In rare cases, this may lead to variations in the color of the test pad.

Billirubin: Low or negative results may be caused by large amounts of vitamin C or nitrite and by a prolonged exposure of the sample to direct light. Increased concentrations of urobilinogen may increase the sensitivity of the bilirubin test pad. Various urine contents (e.g. urine indican) can lead to an applical coloration. Regarding the metabolites of drugs, refer to urobilinogen.

Blood: Enthrocyte results of the urine test strip and the sediment may vary as lysed cells cannot be detected by the sediment may vary. Sed cells cannot be detected by the sediment analysis. False positive reactions can be caused by residuals of peroxide containing cleansing agents, by formalin, or activities of microbial oxidase due to infections of the urogenital tract. High concentrations of ascorbic acid (vitamin C) can cause false negative results.

Index regative results.

Glucose: An inhibitory effect is caused by gentisic acid, a pH value of 5 and a high specific gravity. False positive reactions can also be induced by a residue of peroxide containing cleansing agents.

High concentrations of ascorbic acid (vitamin C) can cause false negative results.

index regative results.

Ketones: Phenylketones in higher concentrations produce variable colors. The keton body B-Hydroxybutyric acid is not detected. Phthatien compounds and derivatives of onthreachinone interfere by producing a red coloration in the alkaline range which may mask the coloration caused by ketones.

ketones. Leurocytes: Leucocyte results of the urine test strip and the sediment may vary as lysed cells cannot be detected by the sediment analysis. Strongly colored compounds in the urine (e.g. nitrofurantion) may disturb the color of the reaction. Glucose or oxalic acid in high concentrations, or drugs containing cephalexine, cephalothine or tetracycline can lead to weakened reactions. False positive results may be caused by contamination with valgnal secretion.

by contamination with vaginal secretion.

Nitrite: Negative results do not exclude significant bacteriuria, since not all infectious species are capable of nitrite production (tack or nitrate reductase). In addition, thin diuresis can reduce the retention time of the union in the bladder and can lead to highly diluted urine which prevents the assimilation of detectable concentrations of nitrite. Moreover, a diet with low nitrate content and a high uptake of vitamin C can also cause false negative results. False positive results may occur for stale urines, in which nitrite has been formed by contamination of the specimen, and in urines containing dyes (derivatives of pyridinium, bestroot). Red or blue borders or edges which may appear must not be interpreted as a positive result.

pH: Bacterial contamination and growth in the urine after sample collection may lead to false results. Red borders which may appear next to the nitrite field must not be taken into consideration.

into consideration. Protein: Highly alkaline urine samples (pH > 9), high specific gravity, infusions with polyvinylpyrrolidone (blood substitute), medicaments containing quinine and also disinfectant residues in the urine sampling vessel containing quaternary ammonium groups can lead to false positive results.

Specific Gravity: The color scale has been optimized for urine with pH 6. Highly alkaline (pH > 8) urines lead to slightly lower results, highly acidic (pH < 6) urines may cause slightly higher results. Glucose and urea do not interfere with the test.

Urobilinogen: Higher concentrations of formaldehyde or exposure of the urine to light for a longer period of time may lead to lowered or false negative results. Beetroot or metabolites of drugs which give a color at low ph (phenazopyridine, azo dyes, p-aminobenzoic acid) may cause false positive results.

PERFORMANCE CHARACTERISTICS

The performance characteristics of the URINE SCREEN urine test strips have been determined on the basis of analytical performance studies. The test performance of the urine test strips was characterized by its agreement with commercially available urine test strips. Visual evaluation Sensitivity

Sensitivity
Ascorbic acid: 10–15 mg/dL, Bilirubin: >0.6 mg/dL (10 µmol/L), Blood: 2 Ery/µL, Glucose: >40 mg/dL (2 2 mmol/L), Ketones: >5.4 mg/dL (0.5 mmol/L), Leucocytes: 15–20 Leu/µL, Nitrice 0.05–0.1 mg/dL (1-722 µmol/L), Protein: >15 mg/dL, Urobilinogen: 1–2 mg/dL (16.9–33.8 µmol/L).

able 1: Expected values and measuring ranges of the fferent urine test strip parameters:

| Parameter | Expected Values | Unit | Measuring Range |
|---------------------|--------------------|-----------|----------------------------------------------------|
| Ascorbic | n.a. | Arbitrary | neg., +, ++ |
| acid | | [mg/dL] | neg., 20, 40 |
| | | [g/L] | neg., 0.2, 0.4 |
| Bilirubin | neg. | Arbitrary | neg., +, ++, +++ |
| | | [mg/dL] | neg., 1, 2, 4 |
| | | [µmol/L] | neg., 17, 35, 70 |
| Blood | neg. | Arbitrary | neg., +, ++, +++ |
| | | [Ery/dL] | neg., 5-10, ~50, ~300 |
| Glucose | norm. | Arbitrary | norm., +, ++, +++, ++++, 5+ |
| | | [mg/dL] | norm., 50, 100, 250, 500, 1000 |
| | | [mmol/L] | norm., 2.8, 5.6, 14, 28, 56 |
| Ketones | neg | Arbitrary | neg., (+) [trace], +, ++, +++ |
| | trace | [mg/dL] | neg., 10 [trace], 25, 100, 300 |
| | | [mmol/L] | neg., 1.0 [trace], 2.5, 10, 30 |
| Leuco- | neg. | Arbitrary | neg., +, ++, +++ |
| cytes | | [Leu/µL] | 0, ~25, ~75, ~500 |
| Nitrite | neg. | Arbitrary | neg., pos. |
| pН | pH 5-8 | | 5, 6, 6.5, 7, 8, 9 |
| Protein | neg | Arbitrary | neg., (+) [trace], +, ++, +++ |
| | trace | [mg/dL] | neg., 15 [trace], 30, 100, 500 |
| | | [g/L] | neg., 0.15 [trace], 0.3, 1.0, 5.0 |
| Specific Gravity | 1.015- 1.025 | | 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030 |
| Urobilino- | norm. | Arbitrary | norm., +, ++, +++, ++++ |
| gen | | [mg/dL] | norm., 2, 4, 8, 12 |
| | l | [umol/L] | norm., 35, 70, 140, 200 |

| SYMB | OLS | | |
|------|------------------------------------------------------|-----|-------------------------------|
| IVD | In vitro diagnostics product | 8 | Only single use |
| C€ | The product complies with European legislation | LOT | Batch identificatio number |
| (Ii | Follow the instructions for use! | REF | Item number |
| ₽ | Use by | ш | Manufacturer |
| X | Permitted storage temperature range | M | Date of manufacture |