GB

INTENDED 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, nitrite, pH-value, protein, specific gravity and urobilinogen in human urine. The CombiScreen® urine test strips are only for professional use.

SUMMARY AND EXPLANATION

Urine 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 CombiScreen® urine test strips include a test pad which indicates the level of ascorbic acid in the urine. The CombiScreen® PLUS urine test strips include ascorbic acid protection for the blood and the glucose test pad.

This package insert describes all types of CombiScreen® urine test strips listed in the order information. All CombiScreen® urine test strips may be read visually, and the system urine test strips may additionally be evaluated instrumentally. Refer to the carton and label for specific parameter combination on the product you are using.

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.

Bilirubin: A red azo compound is obtained in the presence of acid by coupling of bilirubin with a diazonium salt. The presence of bilirubin 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 punctual colorations on the test pad, whereas hemoglobin and myoglobin are reported by a homogeneous green coloration.

Glucose: The test is based on the glucose 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 colored complex (Legal's test).

Leucocytes: The test is based on the esterase activity of granulocytes. This enzyme cleaves 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 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 of the reagent from blue green to greenish yellow depending on the 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.

REAGENTS

Ascorbic acid: 2,6-dichlorophenolindophenol 0.7 %
Bilirubin: diazonium salt 3.1 %
Blood: tetramethylbenzidine-dihydrochloride 2.0 %, isopropylbenzol-hydroperoxide 21.0 %
Glucose: glucose oxidase 2.1 %; peroxidase 0.9 %; o-tolidine-hydrochloride 5.0 %
Ketones: sodium nitroprusside 2.0 %
Leucocytes: carboxylic acid ester 0.4 %; diazonium salt 0.2 %
Nitrite: tetrahydrobenzo[h]quinolin-3-ol 1.5 %; sulfanilic 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

For In Vitro Diagnostic Use.

For safe handling of urine test strips and for avoiding contact with potentially infectious substances, please follow the general working instructions for laboratories. Do not touch the test pads! Avoid ingestion and contact with eyes and mucous membranes. Keep away from children. Disposal of used test strips should be in accordance with local regulations. The material safety data sheet is available for download from our homepage http://www.analyticon-diagnostics.com.

In case any serious incident 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.

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 urine 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.

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

- 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 the 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.
- 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 daylight (or under daylight lamps), but not under direct sunlight. 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.
- Automated evaluation: For application, please read carefully the detailed instructions for use of the instrument. Precise agreement between visual and automated evaluation is not always possible due to the different spectral sensitivities of the human eye and the optical system of the instrument.

MATERIALS PROVIDED

Package with CombiScreen® urine test strips.

MATERIALS REQUIRED BUT NOT PROVIDED

For the automated evaluation: Analyticon urine analyzer for the CombiScreen® system urine test strips.

QUALITY CONTROL

Performance of urine test strips should be checked with appropriate quality control materials (e.g. REF 93010: CombiScreen® Dip Check; REF 93015: CombiScreen® Drop Check), 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. It is necessary to compare the resulting color development with the label, as some control materials may show atypical color development.

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

- 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 history.
- Not all effects of medicaments, drugs or their metabolic products on the urine test strip are known. In case of doubt, it is recommended to repeat the test after discontinuation of the medication. However, a current medication should only be stopped after respective instruction of the doctor.
- Detergents, cleaning 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 coloration 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.

Bilirubin: 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 atypical coloration. Regarding the metabolites of drugs, refer to urobilinogen.

Blood: Erythrocyte results of the urine test strip and the sediment may vary as lysed 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.
Classic Line: High concentrations of ascorbic acid (vitamin C) can cause false negative results.
PLUS Line: The influence of ascorbic acid has been largely eliminated. From a level at approx. 25 Ery/µl and above, even at high concentrations of ascorbic acid normally no negative results are observed.

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.
Classic Line: High concentrations of ascorbic acid (vitamin C) can cause false negative results.
PLUS Line: The influence of ascorbic acid has been largely eliminated. From a glucose level at approx. 100 mg/dL (5.5 mmol/L) and above, even at high concentrations of ascorbic acid normally no negative results are observed.

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

Leucocytes: 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. nitrofurantoin) 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 vaginal secretion.

Nitrite: Negative results do not exclude significant bacteriuria, since not all infectious species are capable of nitrite production (lack of nitrate reductase). In addition, high diuresis can reduce the retention time of the urine 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, beetroot). 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.

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 CombiScreen® 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
Ascorbic acid: 10–15 mg/dL, **Bilirubin:** >0.6 mg/dL (10 µmol/L), **Blood:** >2 Ery/µL Classic / PLUS, **Glucose:** >40 mg/dL (2.2 mmol/L) Classic; >20 mg/dL (1.1 mmol/L) PLUS, **Ketones:** >5.4 mg/dL (0.5 mmol/L), **Leucocytes:** 15–20 Leu/µL, **Nitrite:** 0.05–0.1 mg/dL (11–22 µmol/L), **Protein:** >15 mg/dL, **Urobilinogen:** 1–2 mg/dL (16.9–33.8 µmol/L).

Test Performance (extended concordance)
Ascorbic acid: n.a., **Bilirubin:** 98.7–99.6 %, **Blood:** 99.6–100 %, **Glucose:** 99.6–100 %, **Ketones:** 100 %, **Leucocytes:** 96.9–98.2 %, **Nitrite:** 100 %, **pH:** 99.6–100 %, **Protein:** 98.2–99.6 %, **SG:** 88.9–96.6 %, **Urobilinogen:** 89.5–100 %.

Automated evaluation (Urilyzer® 100 Pro and 500 Pro)
Sensitivity
Ascorbic acid: 2.5–7 mg/dL, **Bilirubin:** 0.9–1.2 mg/dL (15.4–20.5 µmol/L), **Blood:** 3–7 Ery/µL, **Glucose:** 40–50 mg/dl (2.2–2.8 mmol/L) Classic, 28–32 mg/dl (1.6–1.8 mmol/L) PLUS, **Ketones:** >2.5 mg/dL (0.3 mmol/L), **Leucocytes:** 15–20 Leu/µL, **Nitrite:** >0.14 mg/dL (30.4 µmol/L), **Protein:** 20–25 mg/dL, **Urobilinogen:** 1.5–1.8 mg/dL (25.4–30.2 µmol/L).

Test Performance (extended concordance)
Ascorbic acid: 99.9–100 %, **Bilirubin:** 94.7–100 %, **Blood:** 89.3–100 %, **Glucose:** 98.8–100 %, **Ketones:** 97.8–100 %, **Leucocytes:** 93.1–100 %, **Nitrite:** 99.7–100 %, **pH:** 95.4–100 %, **Protein**: 87.4–100 %, **SG:** 55.7–99.7 %, **Urobilinogen:** 91.3–99,8 %.

n.a.: not applicable

Table 1: Expected values and measuring ranges of the different urine test strip parameters:

Parameter	Expected Values	Unit	Measuring Range
Ascorbic acid	n.a.	Arbitrary	neg., +, ++
		[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/µL]	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. – trace	Arbitrary	neg., (+) [trace], +, ++, +++
		[mg/dL]	neg., 10 [trace], 25, 100, 300
		[mmol/L]	neg., 1.0 [trace], 2.5, 10, 30
Leucocytes	neg.	Arbitrary	neg., +, ++, +++
		[Leu/µL]	0, ~25, ~75, ~500
Nitrite	neg.	Arbitrary	neg., pos.
pH	pH 5–8		5, 6, 6.5, 7, 7.5*, 8, 9
Protein	neg. – trace	Arbitrary	neg., (+) [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
Urobilinogen	norm.	Arbitrary	norm., +, ++, +++, ++++
		[mg/dL]	norm., 2, 4, 8, 12
		[µmol/L]	norm., 35, 70, 140, 200

n.a.: not applicable; *For automated evaluation only; **Visual evaluation only

SYMBOLS

IVD	In vitro diagnostics product		Only single use
CE	The product complies with European legislation	LOT	Batch identification number
	Follow the instructions for use!	REF	Item number
	Use by		Manufacturer
	Permitted storage temperature range		date of manufacture
	Distributor		

Analyticon Biotechnologies GmbH
Am Muehlenberg 10
35104 Lichtenfels
Germany
www.analyticon-diagnostics.com

CombiScreen® PLUS Urine Test Strips

CombiScreen® Urine Test Strips

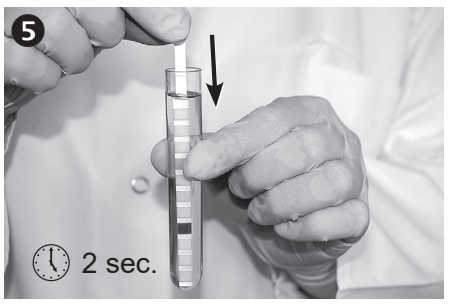
GB DE SE DK FI NO TR ES FR IT PT NL PL CZ GR RU

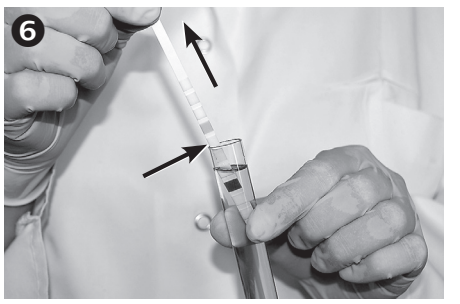
Name	Art.-No.	Cont	Glucose	Ascorbic Acid	Ketones	Protein	pH-Value	Blood	Nitrite	Leucocytes	Spec. Gravity	Bilirubin	Urobilinogen
			Parameter										
CombiScreen® Plus – with ascorbic acid protection													
Glu Plus	94501	50	■										
Nitrit Plus	94506	50							■				
3 Plus	94508 / 94108	50 / 100	■			■	■						
5+Leuko Plus	94517 / 94117	50 / 100	■			■		■	■	■			■
5+N Plus	94535 / 94135	50 / 100	■	■		■	■	■	■				
9 Plus	94115	100	■	■	■	■	■	■	■			■	■
9+Leuko Plus	94250 / 94200	50 / 100	■	■	■	■	■	■	■	■		■	■
10SL Plus	94120	100	■		■	■	■	■	■	■	■	■	■
5SYS Plus[1)]	94109	100	■			■		■	■	■			
7SYS Plus[1)]	94110 / 94110A	100 / 150	■		■	■	■	■	■	■			
11SYS Plus[2)]	94100 / 94150 / 94150BC[3)]	100 / 150 / 150	■	■	■	■	■	■	■	■	■	■	■
CombiScreen® classic line – without ascorbic acid protection													
GP	93104	100	■			■							
3	93108A	150	■			■	■						
GAK	93107 / 93107A	100 / 150	■	■	■								
GPK	93105	100	■		■	■							
10SL	93120 / 93120A / 93120B	100 / 150 / 50	■		■	■	■	■	■	■	■	■	■
11SYS[2)]	93100 / 93150 / 93050	100 / 150 / 50	■	■	■	■	■	■	■	■	■	■	■

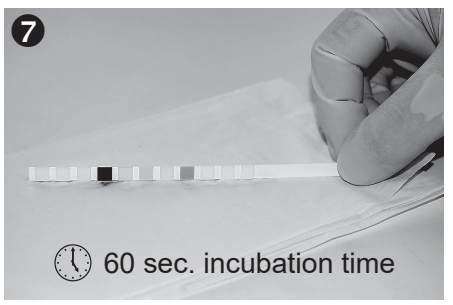
[1)] System test strips to be used with Urilyzer® 100 Pro instruments
[2)] System test strips to be used with CombiScan® and Urilyzer® 100/500 Pro instruments
[3)] System test strips with barcode on the label

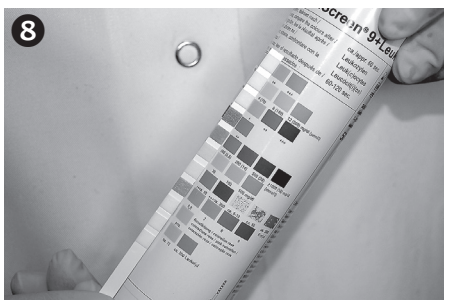
IVD CE

Text passages with grey background were changed in the latest revision of this package insert. / Grau hinterlegte Textpassagen wurden in der letzten Überarbeitung dieser Gebrauchsanweisung geändert. / Grämarkerade delar av texten har ändrats sedan packsedelns senaste revision. / Tekstpassager med grå baggrund er ændret i den seneste version af denne indlægsseddel. / Pakkausselosteessa harmaalla taustalla olevia tekstejä on muutettu viimeksi tehdyssä tarkistuksessa. / Tekstpassasjer med grå bakgrunn ble endret i den seneste revisjonen av dette pakningsvedlegget. / Bu paketin en son revizyonunda gri arka planlı metin pasajları değiştirilmiştir. / Los pasajes de texto con fondo gris se cambiaron en la última revisión de este prospecto. / Les passages de texte sur fond gris ont été modifiés dans la dernière révision de ce mode d'emploi. / I passaggi di testo con sfondo grigio sono stati modificati nell'ultima revisione di questo foglietto illustrativo. / As passagens de texto com fundo cinza foram alteradas na última revisão deste folheto informativo. / Tekstgedeelten met een grijze achtergrond zijn aangepast tijdens de laatste revisie van deze bijsluiter. / Fragmenty tekstu na szarym tle zostały zmienione w najnowszej wersji tej ulotki dołączonej do opakowania. / Části textu se šedým pozadím se změnily při poslední revizi této příbalové informace. / Τα αποσπάσματα κειμένου με γκρίζο φόντο τροποποιήθηκαν στην τελευταία αναθεώρηση του παρόντος ένθετου συσκευασίας. / Текст выделенный серым цветом был изменён в последней версии этой инструкции по применению.









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. Louis: The CV Mosby Company, 1996.

PBA9342_16L_21_001_06.02_20221017