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CombiScreen® mALB / CREA

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

Description	Product code	Content	Albumin	Creatinine
mALB / CREA	94025	25	■	■

References / Referenzen / Referenser / Referencer / Viitteet / Referanser / Referanslar / Referencias / Références / Riferimenti / Referências / Referenties / Referencje / Reference / βιβλιογραφικές αναφορές / Справочный

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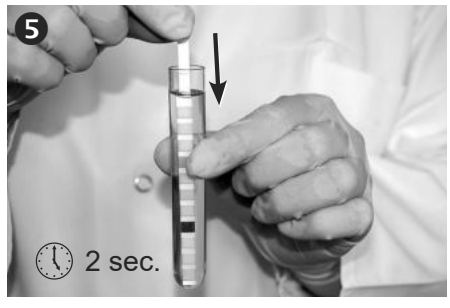
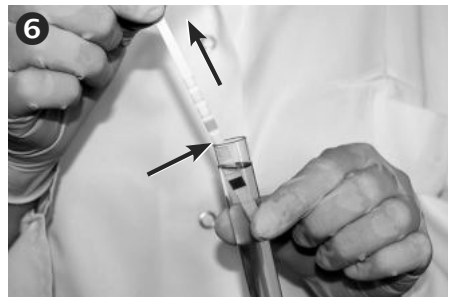
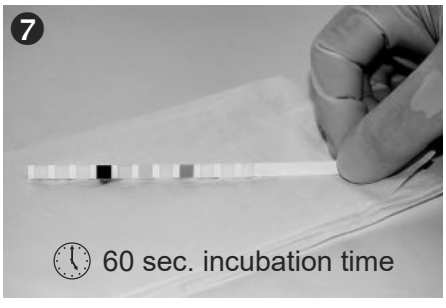
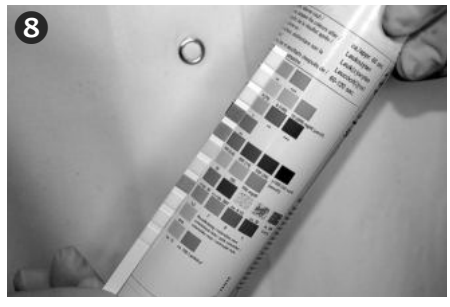
Text passages with grey background were changed in the latest revision of this package insert. / Grau hinterlegte Textpassagen wurden in der letzten Überarbeitung dieser Gebrauchsanweisung geändert. / Grårmarkerade delar av texten har ändrats sedan packsedelns senaste revision. / Tekstpassager med grå 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.









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GB

INTENDED USE

The CombiScreen® urine test strip is an in vitro diagnostic medical device for use as a preliminary screening test for diabetes, liver diseases, haemolytic diseases, urogenital and kidney disorders and metabolic abnormalities by the rapid semi-quantitative determination of ascorbic acid, bilirubin, blood, creatinine, glucose, ketones, leucocytes, microalbumin, nitrite, pH-value, protein, specific gravity and urobilinogen in human urine.
The product is designed for healthcare professionals and can be used for visual analysis.
The CombiScreen® system urine test strips may also be used on semi-automatic urine analyzer.
For further details see the corresponding order information table.

SUMMARY AND EXPLANATION

Microalbuminuria is a symptom of beginning nephropathy and can be a signal for cardio-vascular diseases[1, 2].
The albumin concentration in the urine varies depending on the voided urine volume[3].
Creatinine excretion into the urine is usually constant.
Using the albumin to creatinine ratio it is possible to correct the volume effect and to use spontaneous voided instead of 24-hour urine for the diagnosis of microalbuminuria[4].

TEST PRINCIPLE

Albumin: The test is based on the "protein error" principle of an tetrabromophenol sulfone phthalein derivative as indicator[5].
Under acidic conditions, binding of the dye to albumin leads to a color change from light to dark turquoise.
Creatinine: The test is based on the peroxidase-like activity of a copper-creatinine-complex.
This complex catalyzes the color reaction from light-green to dark blue-green[6].

REAGENTS

Albumin test pad: Tetrabromophenol sulfone phthalein derivative 1,6%
Creatinin test pad: Copper sulfate 1,5 %; Cumolhydroperoxide 4 %; Tetramethylbenzidine 1,7 %

WARNINGS 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 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 2–25 °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.
Open vial stability: 3 months.

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.
Collection of 24-hour urine is not required[7].
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 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 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.
Assess the albumin/creatinine ratio using Table 1.
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® mALB / CREA test strips.

MATERIALS REQUIRED BUT NOT PROVIDED

For the automated evaluation: Analyticon urine analyzer for the CombiScreen® mALB / CREA 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

After identification of the albumin and creatinine concentration the albumin/creatinine ratio can be assessed as "normal", "abnormal" or "high abnormal" according to the interpretation table on the tube label.
X: Sample is too diluted.
Repeat the test with a new sample.

The ratio can also be given in milligram albumin per gram creatinine (mg/g) or as milligram albumin per millimol creatinine (mg/mmol).

Table 1: Interpretation table for the albumin/ creatinine ratio

Albumin	Creatinine				
	A (10 mg/dL) (0.9 mmol/L)	B (50 mg/dL) (4.4 mmol/L)	C (100 mg/dL) (8.8 mmol/L)	D (200 mg/dL) (17.7 mmol/L)	E (300 mg/dL) (26.5 mmol/L)
1 (10 mg/L)	X	Normal	Normal	Normal	Normal
2 (30 mg/L)	High Abnormal	Abnormal	Normal	Normal	Normal
3 (80 mg/L)	High Abnormal	Abnormal	Abnormal	Abnormal	Normal
4 (150 mg/L)	High Abnormal	High Abnormal	Abnormal	Abnormal	Abnormal
5 (500 mg/L)	High Abnormal	High Abnormal	High Abnormal	Abnormal	Abnormal

Example for result interpretation

If a urine sample contains 10 mg/L albumin and 100 mg/dL creatinine, the albumin/creatinine ratio is classified as normal.
A test result of 150 mg/L albumin und 200 mg/dL creatinine is classified as abnormal (microalbuminuria).

Table 2: Expected values of the albumin/creatinine ratio:

Classification	Conv. unit (mg/g)	SI unit (mg/mmol)	Indication for:
Normal	≤ 30	≤ 3.4	
Abnormal	31–299	3.5–33.8	Microalbuminuria
High abnormal	≥ 300	≥ 33.9	Macroalbuminuria, Proteinuria

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 pad.
Various colored urine contents, especially high concentrations of riboflavin , bilirubin or urobilinogen, 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.

PERFORMANCE CHARACTERISTICS

The performance characteristics of the CombiScreen® mALB / CREA urine test strips have been determined on the basis of analytical performance studies.
Standard routine urine samples from doctors' offices were used for performance studies.
These samples were analyzed with CombiScreen® mALB / CREA urine test strip and with an immunological albumin method and an enzymatic creatinine assay[8].
Accuracy of the urine test strips was characterized by its agreement with the comparative methods.
Table 3 shows the results of the performance studies.

Table 3: Performance of the CombiScreen® mALB / CREA urine test strip relative to comparative methods.

Result	Extended concordance	Diagnostic sensitivity	Diagnostic specificity
Visual Albumin/ Creatinine Ratio (ACR) evaluation	100 % (n = 689)	82.3 % (n = 689)	93.4 % (n = 689)
Instrumental Albumin/ Creatinine Ratio (ACR) evaluation	99.7 % (n = 654)	86.1 % (n = 654)	84.0 % (n = 654)

Analytical sensitivity:

Visual evaluation	Albumin: 22–29 mg/L Creatinine: 26–42 mg/dL
Instrumental evaluation (Urilyzer® 100 Pro)	Albumin: 29–50 mg/L Creatinine: 42–50 mg/dL

Precision:

20 parallel determinations with three different lots of CombiScreen® mALB / CREA urine test strips were performed.
Each lot was tested on urine specimen (Within-Run).
For reproducibility data (Day-to-Day), single detections were performed on 20 days with three lots of CombiScreen® mALB / CREA urine test strips.
The precision was calculated from the number of matched readings on the same specimen.

Visual evaluation	Within-Run	Day-to-Day
150 mg/L Albumin	98%	98%
50 mg/dL Creatinine	100%	100%

Instrumental evaluation	Within-Run	Day-to-Day
150 mg/L Albumin	97%	97%
50 mg/dL Creatinine	93%	93%

Analytical specificity/Interferences

The following substances do not affect the test system up to the specified concentration:
Glucose 1500 mg/dL; Bilirubin 4 mg/dL; Ascorbic acid 80 mg/dL; Urobilinogen 12 mg/dL; Sodium nitrite 1 mg/dL; Leukocytes 500 Leu/µl; Hemoglobin 0.87 mg/dL; Lithium acetoacetate 300 mg/dL; Acetylsalicylic acid 60 mg/dL; Caffeine 60 mg/dL; Riboflavin 10 mg/dL; Creatine 10 mg/dL; Formaldehyde 0.1%; Fructose 100 mg/dL; Galactose 80 mg/dL; Uric acid 50 mg/dL; Urea 400 mg/dL; Lactose 10 mg/dL; Human IgG 5 mg/dL; Myoglobin 0.26 mg/dL.
Strongly alkaline samples can produce false-positive results on the albumin test panel.

Measuring range:

The color changes of the test pads correspond to the following concentrations:
Albumin: 10, 30, 80, 150, 500 mg/L.
Creatinine: 10 (0.9), 50 (4.4), 100 (8.8), 200 (17.7), 300 mg/dL (26.5 mmol/L).

SYMBOLS

IVD	In vitro diagnostics medical device	②	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		