

GB

INTENDED USE

The CombiScreen® urine test strip is an in vitro diagnostic medical device for the qualitative detection of albuminuria by the colorimetric method. The test strip is used for diabetes, liver diseases, hemolytic diseases, uremia and kidney disorders and metabolic abnormalities by the naked eye. The test strip is also used for the detection of glucose, blood, creatine, creatinine, ketones, leucocytes, microalbumin, nitrite, pH-value, protein, specific gravity and osmolality.

The product is designed for healthcare professionals and can be used for visual analysis.

The CombiScreen® urine test strips may also be used on semi-automatic urine analyzers.

For further details see the corresponding order information.

SUMMARY AND EXPLANATION

Microalbuminuria is a symptom of beginning nephropathy and can be used for cardiac-vascular diseases.¹

The albumin concentration in the urine varies depending on the time of day.

Creatinine excretion in the urine is usually constant.

Using the albumin to creatinine ratio it is possible to compare the urine effect and to use spontaneously or voread instead of 24-hour urine for the detection of microalbuminuria.²

TEST PRINCIPLE

Albumin. The test is based on the protein "protein" principle of an enzyme-linked sulfone-phthalimide derivative indicator.

Under acidic conditions, binding of the dye to albumin leads to a color change from light green to dark blue-green.

This color change allows the color reaction from light green to dark blue-green.³

REAGENTS

Albumin test: Tetra bromophenol sulfone phthalimide derivative 1.6%.

Creatinine test: Copper sulfate 1.5 %, Cynohydroxy peroxide 4 %, Tetramethylbenzidine 1.7 %.

WARNINGS AND PRECAUTIONS

For In Vitro Diagnostic Use.

For safety reasons, the urine test strip and for avoiding cross-contamination, please follow the general working instructions for laboratories.

Do not touch the test pads!

Avoid contact and contact with eyes and mucous membranes.

Keep away from children.

Discarded test strips should be disposed of according to local regulations.

The material safety data sheet is available for download from our website www.analyticon-diagnostics.com.

In case any serious incident has occurred in relation to the device, please report it to the manufacturer and to the competent authority of the market in which the users or the patients established themselves.

INDICATIONS OF DETERIORATION

No test discoloration of test strips.

Excessive foam, bubbles, light, heat 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: 15–25 °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.

After expiry: stability: 3 months.

SPICEMEN COLLECTION AND PREPARATION

Test strips of fresh, well-washed and non-centrifuged urine is recommended.

Protect the samples from light.

Keep urine test strips preferable and shall be tested within 2 hours.

If immediate testing is not applicable, store at 2–4 °C.

Allow the sample to reach room temperature (15–25 °C) and then centrifuge.

Collection tubes must be clean, dry and free from detergents, biocides or disinfectants.

No add preservatives.

TESTING

Each urine test strip is intended for one use only.

Do not reuse.

Do not mix different urine test strips.

Do not add preservatives.

Do not add water.

Do not add alcohol.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

Do not add iodine.

Do not add chlorine.

Do not add bleach.

Do not add peroxide.

