

CLIAwaived™ Microalbumin 2-1 Combo Strip (CLIA-2M)

Microalbumin Creatinine

For in Vitro Diagnostic Use

INTENDED USE

Microalbumin 2-1 combo Strip is designed to give semi-quantitative results for Microalbumin and Creatinine in random urine and also determine the albumin to creatinine ratio in random urine.

For Professional Use Only

SUMMARY AND EXPLANATION OF THE TEST

Microalbumin 2-1 combo Strip is a plastic strip to which two test pads are affixed testing for Microalbumin and Creatinine.

Microalbuminuria, an abnormal elevation of the urinary albumin excretion rate, is many times one of the first signs of renal diseases and renal damage that can lead to renal failure¹. Patients with the highest risk of renal disease where Microalbumin may be present is hypertension and diabetes^{3,4}.

Creatinine measurement is used in the diagnosis and treatment of renal diseases. It can also be used to monitor renal dialysis, and as a calculation basis for measuring other urine analytes. Daily Creatinine excretion related to muscle mass is usually constant⁵. Having the ability to get an Albumin/Creatinine ratio allows for the use of single-void or random testing.

The 2-1 combo strip tests are stored in a bottle along with a drying agent. Tests are ready to use and results are obtained by direct comparison of the test areas to color blocks printed on the bottle label.

TEST PRINCIPLE

Microalbumin: At a constant pH, albumin binds sulfonephthalein dye to develop of any blue color. The resulting color ranges from pale green to aqua blue.

Creatinine: In this assay, creatinine reacts with a creatinine indicator in an alkaline condition to form a purplish-brown color complex. The concentration of creatinine is directly proportional to the color intensity of the test pad.

REAGENTS (Based on dried weight at time of impregnation)

Microalbumin: 1.9% w/w sulfonephthalein color; 94.2% w/w buffer; 3.9% w/w nonreactive ingredients.

Creatinine: 2.5% w/w copper sulfate; 4.5% w/w benzidine; 56.4% buffer; 36.6% w/w non reactive ingredients.

WARNINGS AND PRECAUTIONS

The 2-1 combo strips are for *in vitro* diagnostic use. Do not touch test areas.

STORAGE AND SHELF-LIFE

Store at room temperature between 15°-30°C (59°-86°F) and out of direct sunlight. Do not use after expiration date.

RECOMMENDED HANDLING PROCEDURES

All unused strips must remain in the original bottle. Transfer to any container may cause reagent strips to deteriorate and become nonreactive. Do not remove desiccant from bottle. Do not open container until ready to use. Opened bottles should be used within 3 months after first opening.

Protection against moisture, light and heat is essential to guard against altered reagent reactivity. The reagent strips should be discarded if discoloration or darkening of reagent areas may indicate deterioration.

Please consult local authorities for proper disposal of used product.

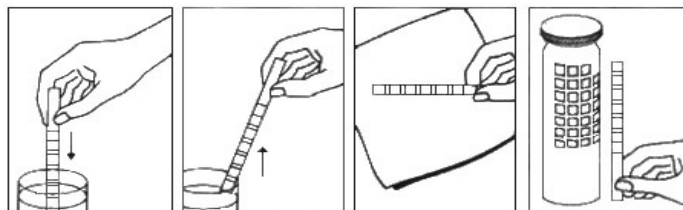
SPECIMEN COLLECTION AND PREPARATION

Collect urine in a clean container and test as soon as possible. Do not centrifuge. The use of urine preservatives is not recommended. If testing cannot be performed within one hour after voiding, refrigerate the specimen immediately. Allow refrigerated specimen to return to room temperature before testing.

TEST PROCEDURE

1. Remove from the bottle only enough strips for immediate use and replace cap tightly.

2. Completely immerse reagent areas of the strip in fresh, well-mixed urine. Remove the strip immediately to avoid dissolving out the reagent areas.
3. While removing, touch the side of the strip against the rim of the urine container to remove excess urine. Blot the lengthwise edge of the strip on an absorbent paper towel to further remove excess urine and avoid running over (contamination from adjacent reagent pads.)
4. Compare each reagent area to its corresponding color blocks on the color chart and read at the times specified. Proper read time is critical for optimal results.
5. Obtain results by direct color chart comparison.



Note: All reagent areas may be read between 1-2 minutes for screening positive urine from negative urine. Changes in color after 3 minutes are of no diagnostic value.

RESULTS

Results are obtained by direct comparison of the color blocks printed on the bottle label. The color blocks represent nominal values; actual values will vary around the nominal values.

As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single test result or method.

CALCULATIONS:

Determine Albumin/Creatinine Ratio as follows:

Albumin/Creatinine Ratio=Albumin Reading (mg/L)/Creatinine Reading (g/L)

Example: Albumin read at 10 mg/L

Creatinine read at 1000mg/L= 1g/L

The ratio of Albumin/Creatinine is 10/1, Result < 30 mg/g (Normal)

TABLE OF RESULTS

Test	Abbr.	Displayed Results	
		Conventional Units	S.I. Units
Micro albumin	Alb	0 mg/L 10mg/L ± 30mg/L + 80 mg/L++ 150mg/L+++	10mg/L ± 30mg/L + 80 mg/L++ 150mg/L+++
Creatinine	Cre	100 mg/L± 500mg/L + 1000mg/L ++ 2000mg/L +++ 3000mg/L ++++	0.9 mmol/L± 4.4 mmol/L+ 8.8 mmol/L ++ 17.7 mmol/L +++ 26.5 mmol/L++++
Albumin/ Creatinine	Alb/Cre	< 30 mg/g (Normal) 30- 300mg/g (Abnormal) >300 mg/g (High Abnormal)	< 3.4 mg/mmol (Normal) 3.4-33.9 mg/mmol (Abnormal) >33.9 mg/mmol (High Abnormal)

QUALITY CONTROL

For best results, performance of reagent strips should be confirmed by testing known negative and positive specimens or controls whenever a new bottle is first opened. Each laboratory should establish its own goals for adequate standards of performance, and should question handling and testing procedures if these standards are not met.

Recommend that users follow federal, state, and local guidelines for the quality control.

LIMITATIONS OF PROCEDURE

1. Visual test does not apply to instrument.
2. Comparison to the color chart is dependent on the interpretation of the individual. It is therefore, recommended that all laboratory personnel interpreting the results of these strips be tested for color blindness

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- The presence of hemoglobin (≥ 5 mg/dL or visibly bloody urine), bilirubin (≥ 15 mg/dl or visibly dark brown color urine) may cause error results with the albumin and creatinine tests. Vitamin C over 100mg/dl does not affect the results of microalbumin and creatinine.
- Substances that cause abnormal urine color, such as drug containing azo dyes (e.g., Pyridium, AZO Gantanol), nitrofurantoin (Macrochantin, Furadantin) and riboflavin may affect the readability of the reagent areas on urinalysis reagent strips.
- Acute illnesses that present with fever are known to cause an increase in urinary albumin excretion, such as urinary tract infection or bleeding into the urinary tract. It is recommended that testing of individuals be performed when there is no longer a condition.

EXPECTED VALUES

Microalbumin: Normal Albumin levels in random urine are under 20 mg/L⁹. Microalbuminuria is indicated by results in the range between 20mg/L-200mg/L. Values above 200mg/L indicate clinical albuminuria. The detection of albuminuria at levels at or above 30mg/L will help clinicians to better diagnose diabetes in its early stages.

Creatinine: Creatinine is usually present in random urine in levels between 10-300mg/dL.(0.9 to 26.5 mmol/L)

Microalbumin/Creatinine ratio: Albumin is normally present in urine at concentrations of less than 30 mg albumin/g creatinine. Microalbuminuria is indicated at a ratio result of 30-300mg albumin/g creatinine (Abnormal) and clinical albuminuria at a ratio result of >300mg/g (High Abnormal)⁶.

SPECIFIC PERFORMANCE CHARACTERISTICS

The performance characteristics of Micro-Albumin 2-1 combo Strip have been determined both in the laboratory and in clinical tests. Parameters of importance to the user are sensitivity, specificity, accuracy, and precision. Generally, Micro-Albumin 2-1 combo Strip have been developed to be specific for the constituent to be measured with the exception of interferences listed above. (See LIMITATIONS OF PROCEDURE)

For visually read strips, accuracy is a function of the manner in which the color blocks on the bottle label are determined and the discrimination of the human eye in reading the test. Precision is difficult to assess in a test of this type because of the variability of the human eye. It is for this reason that users are encouraged to develop their own standards of performance.

Accuracy:

Total 86 Random urine specimens were collected from outpatients. These samples were assayed Albumin, Creatinine by Bayer Clinitek Microalbumin and Micro Albumin 2-1 Combo Strip. In order to cover assay range, some of urine specimens were spiked with known concentration albumin and creatinine. Sensitivity is defined as the percentage of positive results obtained by Micro-Albumin 2-1 combo Strip to those obtained by the comparative methods, while specificity refers to the percentage of negative results.

Percent agreement with Bayer Clinitek Microalbumin in micro albumin test: 91.9%.

Positive Agreement: 96.5%

Negative Agreement: 98.3%

Creatinine

Micro Albumin 2-1 combo Strip detects urinary creatinine in concentration as low as 100 mg/L.

Percent agreement with Bayer Clinitek Microalbumin in creatinine tests: 86%

Precision:

Twenty five replicates of urine specimens at known concentrations were assayed at different levels. The following percents of replicate readings were obtained.












Percents agreement of replicate reading in Micro Albumin: 96.8%

Percents agreement of replicate reading in Creatinine: 92%

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LEGEND

SYMBOL	DEFINITION
	The manufacturer catalogue number
	Consult Instructions for Use
	Manufacturer symbol – before company name and address
	The “CE” marking
	Authorized EU Representative and the Symbol
	Contains SUFFICIENT FOR <n> TESTS
	Protect from light and moisture
	Lot Number for Specified Product
	Defines Expiration Date
	Caution, Consult Accompanying Documents
	Storage Temperature

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