Urinalysis Reagent Strips (Microalbumin/Creatinine) (Urine) Package Insert
Product Code: CD-MAC25

For in vitro diagnostic use only.
The strips are for use on the Clarity Urocheck 120C Urine Analyzer only.
Rx Only.

INTENDED USE

The Clarity Urinalysis Reagent Strip (Microalbumin/Creatinine) is intended for the semi- quantitative measurement of albumin (ALB) and creatinine (CRE) in urine. For use with the *Clarity Urocheck 120C* Urine Analyzer. Results are used to aid in the diagnosis of kidney function. This test is for professional use and at the point of care. Positive results should be confirmed with a quantitative method.

INFORMATION REGARDING CLIA WAIVER

This test is waived under CLIA '88 regulations. Failure to adhere to the instructions for use will result in the test being considered high complexity and subject to all CLIA requirements. A CLIA Certificate of Waiver is required to perform this test in a waived setting. A Certificate of Waiver can be obtained from the Centers for Medicare & Medicaid Services. Visit www.cms.gov to obtain an application (Form CMS-116).

SUMMARY

Disease or other health problems can cause urine to change before major change is seen in the blood. A urine test is a useful signal of health or disease. It can also play a part in routine health screening. The test can screen for microalbuminuria and helps find patients at risk of early-stage kidney damage. Patients with diabetes or high blood pressure are at highest risk. Also at risk are those with immune disorders or who have been exposed to kidney toxins. Microalbuminuria may also be an early sign of preeclampsia in the pregnant.[1]

PRINCIPLES AND EXPECTED VALUES

Albumin: The reagent pad turns blue if there is albumin in urine at a constant pH. Results may vary from a pale green to an aqua blue. Normal urine albumin levels are less than 20 mg/L.[2] A low level (less than 10 mg/L) will turn the ALB pad white. A result of 20-200 mg/L may signal microalbuminuria. This may suggest early stage kidney disease. Results of >200 mg/L indicate clinical albuminuria. These levels may predict albumin excretion rates of 30-300 mg/24 hrs and >300 mg/24 hrs, respectively.[4] Exercise, acute illness and fever, and urinary tract infections may raise urine albumin for a time.

Creatinine: Creatinine in urine results in a color change from orange through green to blue. A normal urine creatinine level is 10-300 mg/dL.

Albumin-to-Creatinine Ratio: A normal urine albumin to creatinine ratio is less than 30 mg albumin/g creatinine. 30-300 mg/g (abnormal) shows microalbuminuria. Higher than 300 mg/g (high abnormal) shows clinical albuminuria.[5]

REAGENT COMPOSITION

Reagent	Composition	
ALB	bis(3',3"-diiodo-4',4"-dihydroxy-5',5"-dinitrophenyl)	
	-3,4,5,6-tetrabr omosulfo- nephthalein;	0.02mg
	buffer;	0.86mg
	nonreactive ingredients	0.11mg
CRE	copper acetate;	0.05mg
	diisopropylbenzene dihydroperoxide;	0.09mg
	3,3',5,5'-tetramethylbenzidine;	0.03mg
	buffer;	1.70mg
	nonreactive ingredients	0.32mg

MEASUREMENT RANGE

Parameter Name (Abbreviation on Display)	Conventional/ Arbitrary	SI
Albumin (ALB)	10 mg/L 30 mg/L 80 mg/L 150 mg/L	10 mg/L 30 mg/L 80 mg/L 150 mg/L
Creatinine (CRE)	10 mg/dL 50 mg/dL 100 mg/dL 200 mg/dL 300 mg/dL	0.9 mmol/L 4.4 mmol/L 8.8 mmol/L 17.7 mmol/L 26.5 mmol/L

PRECAUTIONS

- For *in vitro* diagnostic use only.
- As with all lab tests, final diagnostic decisions should not be based on a single result or method.
- Do not use after the expiration date.
- Do not reuse the test strips.
- Do not expose the strips to direct sunlight.
- Keep strips in the closed canister until use.
- Protect strips from moisture, light, and heat.
- Do not touch the reagent pads of the strip.
- Throw away any strips that are discolored.
- Handle all urine samples as if they were infectious.
- Discard all used strips according to local laws.
- Follow the directions exactly for best results.
- Use fresh urine samples for best results.
- A result at the maximum measurement range may have a higher actual value. Confirmatory tests may be needed to find the actual value.

STORAGE AND STABILITY

Store in the closed canister at temperatures between 36-86ºF (2-30ºC). Keep out of direct sunlight. The strip is stable through the expiration date on the canister. Do not take out the desiccant. Take out just enough strips to use right away. Put the cap back on as soon as you can. Screw the cap back on tightly. **DO NOT FREEZE.** Do not use past the expiration date.

Note: Once the canister has been opened, the strips left in it are stable for up to 3 months. Strips may be less stable if in a humid place.

SAMPLE COLLECTION AND PREPARATION

Collect urine in a clean and dry container. Test as soon as you can. Do not centrifuge. If you cannot test within an hour post void, refrigerate urine right away. Bring the urine sample to room temperature before you test.

Urine stored at room temperature for a long time may become infected. This can cause pH to shift and low ALB results.

Any single void urine sample can be used to test albumin.[5-7] It is best to test the first morning urine.[8] Testing three urine samples in the span of 3-6 months may improve the predictive value due to day-to-day changes in urine. To measure the excretion rate of albumin, 24 hour or timed collections may also be used. For more detail on screening guidelines, see the American Diabetes Association's statement.[5]

MATERIALS

Materials Provided

- Strips
- Package insert

Materials Required But Not Provided

- Sample collection container
- Timer
- Paper Towel

DIRECTIONS FOR USE

Allow the strip, urine, and/or controls to reach room temperature (59-86ºF) prior to testing.

1. **Read the Strip on the *Clarity Urocheck 120C Urine Analyzer only*.** Press "START" after Power on.
2. Remove the strip from the bottle. Replace the cap tightly.
3. Dip the test pads briefly into the urine for up to 3 seconds. Make sure both pads are wet.
4. Take the strip out right away. Drag the edge of the strip against the rim of the urine container to remove excess urine.
5. Touch the edge of the strip to a paper towel to blot it.
6. Place the strip, with the reagent pads face-up, on the strip holder.
7. Slide the strip onto the strip holder. The strip should touch the end of the strip holder.
8. Press "START" again.
9. The strip holder is pulled into the reader. The reader checks and reads the strip. Results are then displayed and/or printed.
10. Record your results, and discard the strip into a suitable trash container.

***Note**:* Wipe off built up urine on the strip holder with a damp, lint-free cloth as needed to prevent urine build-up.

TABLE OF RESULTS

The following table shows the results that can be seen on a *Clarity Urocheck 120C Urine Analyzer* . Abnormal results are shaded in gray:

Test	Printed/Displayed Results	
	Conventional	S.I. Units
ALB	10 mg/L 80 mg/L 30 mg/L 150 mg/L	10 mg/L 80 mg/L 30 mg/L 150 mg/L
CRE	10 mg/dL 200 mg/dL 50 mg/dL 300 mg/dL 100 mg/dL	0.9 mmol/L 26.5 mmol/L 17.7 mmol/L 8.8 mmol/L 4.4 mmol/L
A:C	<30mg/g (Normal)	<3.4 mg/mmol (Normal)

	30-300 mg/g (Abnormal) >300 mg/g (High Abnormal)	3.4-33.9 mg/mmol (Abnormal) >33.9 mg/mmol (High Abnormal)

QUALITY CONTROL

Each lab should set its own standards and procedures for performance. Test known controls (i.e., Clarity Liquid Urine Controls, Product Code, CD-UCTL30) in case of any of the following events, following local, state, and/or federal requirements:

- A new canister of strips is opened
- A new operator uses the analyzer
- Test results seem wrong
- After performing maintenance or service on the analyzer

If the QC tests do not give expected results, make the following checks:

- Make sure the strips used are not past their expiration date.
- Make sure the controls are not past their expiration date.
- Repeat the test to make sure no errors were made during the test.
- Make sure the strips are fresh from a new canister.

For Support please call Clarity Diagnostics Technical Support at 1-(877)-485-7877 for further assistance.

To run a quality control test:

1. Wet each pad of a new urine strip with the controls.
2. Blot off excess liquid. Place the strip on the strip holder.
3. Press “START”.
4. Compare QC results with the expected values. If the QC results do not match, do not test any patient samples until the problem is fixed. Repeat until the results are correct.
5. QC values are preset by Clarity on the analyzer and cannot be changed.

LIMITATIONS

- Use these strips with a *Clarity Urocheck 120C Urine Analyzer only*. **Do not read visually.**
- These strips may be affected by substances that affect urine color such as drugs containing azo dyes (e.g. Pyridium, Azo Gantrisin, Azo Gantanol), nitrofurantoin (Microdantin, Furadantin), and riboflavin. These can mask the color on the test pad. There may also be color reactions that could be read as false results. Soap, detergent, antiseptic, or skin cleanser in the urine may also affect test results. As with all tests, results must be considered with all clinical data available to the doctor.
- False high results for both the albumin and creatinine tests can be seen with hemoglobin in urine (≥5 mg/dL or blood seen in urine).
- The effects of drugs and their breakdown products on these tests are not known in all cases. If the results are still in question, repeat the test and also use a confirmation test. Both ALB and the A:C results should be taken into account during decision making about clinical diagnosis or the need for confirmation tests.

  The table below shows the lowest levels at which the listed substances were seen to affect ALB and CRE test results.

Test	Level at which interference is seen	Result (Change in color block)
ALB	Sodium bicarbonate ≥1200 mg/dL	False high (+1)
	Hemoglobin ≥10 mg/dL	False high (+1)
	Potassium chloride ≥1500 mg/dL	False high (+1)
	Blood ≥0.05 %	False high (+1)
	Human Immunoglobulin ≥25 mg/dL	False high (+1)
	High pH (pH ≥10)	False high (+1)
	Specific gravity 1.000	False low (-1)
CRE	Sodium bicarbonate ≥1750 mg/dL	False high (+1)
	Hemoglobin ≥10 mg/dL	False high (+1)
	Blood ≥0.05 %	False high (+1)
	Specific gravity ≥1.035	False high (+1)

PRECISION

Reproducibility was tested in within run and between run precision studies at three POL sites. Level 1 (Neg.), Level 2 (Low) and Level 3 (High) controls were used.

Within run: Each control level was tested (n=20) in one day at each POL site.

Between run: Each control was tested once per run, 2 runs per day for 20 days. 3 users from each site took part.

The results show that the Clarity Urocheck 120C had over 99% agreement with target values.

SPECIFIC PERFORMANCE CHARACTERISTICS

Accuracy: Clinical studies were held at 3 POC sites. ~360 urine samples were tested. Samples were tested by the Clarity Urocheck 120C Analyzer with Clarity Urine Microalbumin/Creatinine Reagent Strips and by a reference method. The results agreed >95% of the time.

The results are shown below:

A:C (Reference method)	Anticipated bins (Clarity Urocheck 120C)	% of samples in bin
≤23	<30	97.0%
24-39	<30 or 30-300	100.0%
40-233	30-300	96.4%
234-390	30-300 or >300	100.0%
>391	>300	98.4%
Total	351/360	97.5%

BIBLIOGRAPHY

1. Nisell, H. *et al:* Renal Function in Gravidas with Chronic Hypertension With and Without Superimposed Preeclampsia. *J. Hypertens. Pregnancy 15:* 127-134; 1996.
2. Burtis, C.A. and Ashwood, E.R.: *Tietz Textbook of Clinical Chemistry,* 3rd ed. Philadelphia: Saunders; 1999; pp. 483-484.
3. Mangili, R. *et al.:* Prevalence of Hypertension and Microalbuminuria in Adult Type 1 (Insulin-Dependent) Diabetic patients Without Renal Failure in Italy-Validation of Screening Techniques to Detect Microalbuminuria. *Acta Diabetol. 29:* 156-166; 1992.
4. American Diabetes Association, Clinical Practice Recommendations, Diabetes Care, Vol. 31, Suppl. 1, January 2008.
5. Position Statement: Diabetic Nephropathy. *Diabetes Care 20:* S24-S27; 1997.
6. Nathan, D.M.; Rosenbaum, C.; and Protasowicki, V.D.: Single-void Urine Samples Can be Used to Estimate Quantitative Microalbuminuria. *Diabetes Care 10:* 414-418; 1987.
7. Ginsberg, J.M. *et al.:* Use of single Voided Urine Samples to Estimate Quantitative proteinuria. *N. Wng. J. Med. 309:* 1543-1456; 1983.
8. Cowell, C.T.; Rogers, S.; and Silink, M.: First Morning Urinary Albumin Concentration is a Good Predictor of 34-Hour Urinary Albumin Excretion in Children with Type 1 (Insulin-Dependent) Diabetes. *Diabetologia 29:* 97-99; 1986.

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Printed in China

Number:
Effective date: 201x-xx-xx