

Overview

Useful For

Assessing the potential for early onset of nephropathy in diabetic patients using random urine specimens

Method Name

[Only orderable as part of a profile. For more information see:](#)

-ALBR / Albumin, Random, Urine

-RALB / Albumin, Random, Urine.

Immunturbidity

NY State Available

Yes

Specimen

Specimen Type

Urine

Specimen Required

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Supplies: Aliquot Tube, 5 mL (T465)

Specimen Volume: 5 mL

Collection Instructions:

1. Collect a random urine specimen.
2. No preservative.

Reject Due To

All specimens will be evaluated at Mayo Clinic Laboratories for test suitability.

Specimen Minimum Volume

1 mL

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Urine	Refrigerated (preferred)	7 days	
	Ambient	7 days	
	Frozen	7 days	

Clinical & Interpretive

Clinical Information

Diabetic nephropathy is a complication of diabetes and is characterized by proteinuria (normal urinary albumin excretion is <30 mg/day; overt proteinuria is >300 mg/day). Before overt proteinuria develops, albumin excretion increases in those diabetic patients who are destined to develop diabetic nephropathy. Therapeutic maneuvers (eg, aggressive blood pressure maintenance, particularly with angiotensin-converting enzyme inhibitors; aggressive blood sugar control; and possibly decreased protein intake) can significantly delay, or possibly prevent, development of nephropathy. Thus, there is a need to identify small, but abnormal, increases in the excretion of urinary albumin (in the range of 30-300 mg/day, ie, microalbuminuria).

The National Kidney Foundation guidelines for the management of patients with diabetes and microalbuminuria recommend that all type 1 diabetic patients older than 12 years and all type 2 diabetic patients younger than 70 years have their urine tested for microalbuminuria yearly when they are under stable glucose control.(1)

The preferred specimen is a 24-hour collection, but a random collection is acceptable. Studies have shown that correcting albumin for creatinine excretion rates has similar discriminatory value with respect to diabetic renal involvement. The albumin:creatinine ratio from a random urine specimen is also considered a valid screening tool.(2) Several studies have addressed whether the specimen needs to be a fasting urine, an exercised urine, or an overnight urine specimen. These studies have shown that the first-morning urine specimen is less sensitive, but more specific. Studies also have shown that microalbuminuria is a marker of generalized vascular disease and is associated with stroke and heart disease.

Reference Values

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Males: <17 mg/g creatinine

Females: <25 mg/g creatinine

Interpretation

In random urine specimens, normal urinary albumin excretion is below 17 mg/g creatinine for males and below 25 mg/g creatinine for females.(3)

Microalbuminuria is defined as an albumin:creatinine ratio of 17 to 299 for males and 25 to 299 for females.

A ratio of albumin:creatinine of 300 or higher is indicative of overt proteinuria.

Due to biologic variability, positive results should be confirmed by a second, first-morning random or 24-hour timed urine specimen. If there is discrepancy, a third specimen is recommended. When 2 out of 3 results are in the microalbuminuria range, this is evidence for incipient nephropathy and warrants increased efforts at glucose control, blood pressure control, and institution of therapy with an angiotensin-converting-enzyme (ACE) inhibitor (if the patient can tolerate it).

Cautions

Urine collected during menses may contain excess albumin due to blood contamination. Collection during this time should be avoided.

Heavy exercise may increase albumin excretion and should be avoided during collection. Normal values apply to a non-exercised state.

Bilirubin at 20 mg/dL reduces creatinine by 15% to 20%.

Clinical Reference

1. Bennett PH, Haffner S, Kasiske BL, et al: Screening and management of microalbuminuria in patients with diabetes mellitus: recommendations to the Scientific Advisory Board of the National Kidney Foundation from an ad hoc committee of the Council on Diabetes Mellitus of the National Kidney Foundation. *Am J Kidney Dis.* 1995 Jan;25:107-112. doi: 10.1016/0272-6386(95)90636-3
2. Krolewski AS, Laffel LM, Krolewski M, Quinn M, Warram JH: Glycosylated hemoglobin and the risk of microalbuminuria in patients with insulin-dependent diabetes mellitus. *N Engl J Med.* 1995 May 11;332:1251-1255. doi: 10.1056/NEJM199505113321902
3. Zelmanovitz T, Gross JL, Oliveira JR, Paggi A, Tatsch M, Azevedo MJ: The receiver operating characteristics curve in the evaluation of a random urine specimen as a screening test for diabetic nephropathy. *Diabetes Care.* 1997 April;20:516-519. doi: 10.2337/diacare.20.4.516
4. Miller GW, Bruns DE, Hortin GL, et al: Current issues in measurement and reporting of urinary albumin excretion. *Clin Chem* 2009 Jan;55(1):24-38. doi: 10.1373/clinchem.2008.106567
5. Lamb EJ, Jones GRD: Kidney functions tests. In: Rifai N, Horvath AR, Wittwer CT, eds. *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics.* 6th ed. Elsevier; 2018:480-488
6. Sacks DB: Diabetes mellitus. In: Rifai N, Horvath AR, Wittwer CT, eds. *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics.* 6th ed. In: Elsevier; 2018:1197-1199

Performance

Method Description

Albumin is measured by immunoturbidimetry utilizing antibody to human albumin in an automated immunoprecipitation analysis system.(Package insert: ALBT2: Tina-Quant Albumin Gen 2. Roche Diagnostics V13.0 01/2020)

PDF Report

No

Specimen Retention Time

7 days

Performing Laboratory Location

Rochester

Fees & Codes

Test Classification

This test has been modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

82043