

## Overview

### Useful For

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

### Method Name

Immunoturbidity/Enzymatic Colorimetric Assay

### NY State Available

No

## Specimen

### Specimen Type

Urine

### Ordering Guidance

The preferred specimen for urinary albumin measurement is a 24-hour collection. Order ALB24 / Albumin, 24 Hour, Urine.

### Specimen Required

**Supplies:** Sarstedt 5 mL Aliquot Tube (T914)

**Specimen Volume:** 5 mL

**Collection Instructions:**

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

### Specimen Minimum Volume

1 mL

### Reject Due To

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

### 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

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

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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, Hordin GL, et al: Current Issues in Measurement and Reporting of Urinary Albumin Excretion. *Clinical Chemistry.* 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**

Anti-albumin antibodies react with the antigen in the sample to form antigen/antibody complexes that, following agglutination, are measured turbidimetrically.(Package insert: ALBT2, Tina-quant Albumin Gen.2. Roche Diagnostics; V12.0, 05/2019)

Creatinine is measured by the enzymatic method, which is based on the determination of sarcosine from creatinine with the aid of creatininase, creatinase, and sarcosine oxidase. The liberated hydrogen peroxide is measured via a modified Trinder reaction using a colorimetric indicator. Optimization of the buffer system and the colorimetric indicator enables the creatinine concentration to be quantified both precisely and specifically.(Package insert: Creatinine plus ver 2. Roche Diagnostics; 12/2018)

#### **PDF Report**

No

#### **Day(s) Performed**

Monday through Saturday

**Report Available**

1 to 3 days

**Specimen Retention Time**

7 days

**Performing Laboratory Location**

Mayo Clinic Jacksonville Clinical Lab

**Fees & Codes****Fees**

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact [Customer Service](#).

**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

82570

**LOINC® Information**

Test ID	Test Order Name	Order LOINC® Value
RALB	Albumin, Random, U	9318-7

Result ID	Test Result Name	Result LOINC® Value
CRE2	Creatinine	2161-8
A_CR	Albumin/Creatinine Ratio	9318-7
RALB1	Albumin, Random, U	89999-7