

## Overview

### Useful For

Evaluating diabetic patients to assess the potential for early onset of nephropathy

### Special Instructions

- [Urine Preservatives-Collection and Transportation for 24-Hour Urine Specimens](#)

### Method Name

Immunturbidity

### NY State Available

No

## Specimen

### Specimen Type

Urine

### Necessary Information

**24-Hour volume (in milliliters) is required.**

### Specimen Required

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

**Container/Tube:** Plastic urine tube

**Specimen Volume:** 4 mL

#### Collection Instructions:

1. Collect urine for 24 hours.
2. Refrigerate specimen within 4 hours of completion of 24-hour collection.
3. Mix well before taking 4-mL aliquot.

**Additional Information:** See [Urine Preservatives-Collection and Transportation for 24-Hour Urine Specimens](#) for multiple collections.

### Forms

If not ordering electronically, complete, print, and send a [Renal Diagnostics Test Request](#) (T830) with the specimen.

### Urine Preservative Collection Options

**Note:** The addition of preservative or application of temperature controls **must occur within 4 hours of completion** of the collection.

Ambient	OK
Refrigerate	Preferred

Frozen	OK
50% Acetic Acid	No
Boric Acid	OK
Diazolidinyl Urea	No
6M Hydrochloric Acid	No
6M Nitric Acid	No
Sodium Carbonate	No
Thymol	OK
Toluene	No

**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**

Albumin excretion increases in patients with diabetes who are destined to develop diabetic nephropathy. More importantly, at this phase of increased albumin excretion before overt proteinuria develops, therapeutic maneuvers can be expected to significantly delay, or possibly prevent, development of nephropathy. These maneuvers include aggressive blood pressure maintenance (particularly with angiotensin-converting enzyme inhibitors), aggressive blood sugar control, and possibly decreased protein intake. Thus, there is a need for addressing small amounts of urinary albumin excretion (in the range of 30-300 mg/day, ie, microalbuminuria).

The National Kidney Foundation convened an expert panel to recommend guidelines for the management of patients with diabetes and microalbuminuria. These guidelines recommend that all type 1 diabetic patients older than 12 years and all type 2 diabetic patients younger than 70 years should 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 10-hour overnight collection (9 p.m.-7 a.m.) or a random collection are acceptable. Recent studies have shown that correcting albumin for creatinine excretion rates has similar discriminatory value with respect to diabetic renal involvement, and it is now suggested that an albumin/creatinine ratio from a random urine specimen is a valid screening tool.(2)

Several studies have addressed the question of whether this needs to be a fasting urine, an exercised urine, or an overnight urine specimen. From these studies, it is clear that the first-morning urine specimen is less sensitive, but more specific. A positive result should be confirmed by a first-morning random or 24-hour timed urine specimen.

Studies have also shown that microalbuminuria is a marker of generalized vascular disease and is associated with stroke and heart disease.

**Reference Values**

24-Hour excretion: <30 mg/24 hours

Excretion rate: <20 mcg/min

**Interpretation**

An albumin excretion rate of more than 30 mg/24 hours is considered to be microalbuminuric. By definition, the upper end of microalbuminuria is thought to be 300 mg/24 hours. Although this level has not been rigorously defined, it is felt that at this level it is more difficult to change the course of diabetic nephropathy. Laboratory normal values agree with the 30 mg/24 hour level. A normal excretion rate of 20 mcg/minute has also been established in the literature and is consistent with the laboratory data. Thus, microalbuminuria has been defined at 30 to 300 mg/24 hours.

The literature has defined the albumin/creatinine ratio (mg/g) below 17 as normal for males and below 25 for females(2) and is consistent with the laboratory's normal data. A ratio of albumin to creatinine of 300 or more indicates overt albuminuria. Thus, microalbuminuria has been defined as an albumin/creatinine ratio of 17 to 299 for males and 25 to 299 for females.

Due to biologic variability, any patient who has an albumin/creatinine ratio or urinary albumin excretion rate in the positive microalbuminuria range should have this confirmed with a second specimen. If there is discrepancy, a third specimen is recommended. If 2 of 3 results are in the positive microalbuminuria range, this is evidence for incipient nephropathy and warrants increased efforts at glucose control, aggressive blood pressure control, and institution of therapy with an angiotensin-converting enzyme inhibitor (if the patient can tolerate it).

**Cautions**

Urine may be collected and transported ambient, refrigerated, frozen, or preserved in thymol, boric acid, or sodium carbonate.

Urine collected in or that has had nitric, hydrochloric, or acetic acid added is unacceptable because of precipitation of albumin by these acids.

Urine collected during menses may contain excess albumin and 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.

**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;25:107-112

- Zelmanovitz T, Gross JL, Oliveira JR, et al: The receiver operating characteristics curve in the evaluation of a random urine specimen as a screening test for diabetic nephropathy. *Diabetes Care*. 1997;20:516-519
- Krolewski AS, Laffel LM, Krolewski M, et al: Glycosylated hemoglobin and the risk of microalbuminuria in patients with insulin-dependent diabetes mellitus. *N Engl J Med*. 1995;332:1251-1255
- Miller GW, Bruns DE, Hortin GL, et al: Current Issues in Measurement and Reporting of Urinary Albumin Excretion. *Clin Chem*. 2009;55(1):24-38
- 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
- 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)

### PDF Report

No

### Day(s) Performed

Monday through Saturday

### Report Available

Same day/1 to 3 days

### Specimen Retention Time

7 days

### Performing Laboratory Location

Jacksonville

## 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

**LOINC® Information**

Test ID	Test Order Name	Order LOINC® Value
ALB24	Albumin, 24 Hr, U	1755-8

Result ID	Test Result Name	Result LOINC® Value
VL41	Urine Volume	3167-4
TM43	Collection Duration	13362-9
RATE2	Albumin Excretion Rate	58448-2
AL24H	Albumin, 24 Hr, U	1755-8