Overview

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

Special Instructions
- [Link: Urine Preservatives-Collection and Transportation for 24-Hour Urine Specimens]

Method Name
Immunoturbidity

NY State Available
Yes

Specimen

Specimen Type
Urine

Specimen Required

Container/Tube: Plastic, 5-mL aliquot tube (T465)

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:
1. 24-Hour volume is required.
2. See Urine Preservatives-Collection and Transportation for 24-Hour Urine Specimens in Special Instructions for multiple collections.

Urine Preservative Collection Options

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

<table>
<thead>
<tr>
<th>Preservative Option</th>
<th>Available Status</th>
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<tbody>
<tr>
<td>Ambient</td>
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<tr>
<td>Refrigerate</td>
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Clinical and 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. to 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 >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. We have established normal values in our laboratory and 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 our data. Thus, microalbuminuria has been defined at 30 to 300 mg/24 hours.

The literature has defined the albumin/creatinine ratio (mg/g) <17 as normal for males and <25 for females(2) and is consistent with our normal data. A ratio of albumin to creatinine of > or =300 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 toluene, thymol, or boric acid. Specimens in which nitric acid, hydrochloric acid, sodium carbonate, or acetic acid has been added are 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 nonexercised state.

Clinical Reference


**Performance**

**Method Description**
Albumin is measured by immunoturbidimetry utilizing antibody to human albumin in an automated immunoprecipitin analysis system. (Package insert: Tina-Quant Albumin reagents kit for urinary albumin, Roche Diagnostics, Indianapolis, IN, March 2007)

**PDF Report**
No

**Day(s) and Time(s) Test Performed**
Monday through Sunday; Continuously

**Analytic Time**
1 day

**Maximum Laboratory Time**
Same day/1 day

**Specimen Retention Time**
7 days

**Performing Laboratory Location**
Rochester

**Fees and 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 Regional Manager. 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 U.S. Food and Drug Administration.

**CPT Code Information**
82043

**LOINC® Information**

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