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
Yes

Specimen

Specimen Type
Urine

Specimen Required
Supplies: Aliquot Tube, 5 mL (T465)

Specimen Volume: 5 mL

Collection Instructions:
1. Collect a random urine specimen.
2. No preservative.

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

Specimen Minimum Volume
1 mL

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

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urine</td>
<td>Refrigerated (preferred)</td>
<td>7 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ambient</td>
<td>7 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
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<td></td>
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Clinical and Interpretive
Test Definition: RALB
Albumin, Random, U

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 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.

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

Clinical Reference
Test Definition: RALB
Albumin, Random, U


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, September 2018)

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: Roche Diagnostics, Indianapolis IN, December 2018)

PDF Report
No

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

Analytic Time
1 day

Maximum Laboratory Time
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

82570

LOINC® Information

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<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tr>
<td>RALB</td>
<td>Albumin, Random, U</td>
<td>9318-7</td>
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<table>
<thead>
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<tr>
<td>CRE2</td>
<td>Creatinine</td>
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<td>Albumin/Creatinine Ratio</td>
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