Overview

Useful For
Monitoring patients whose urine demonstrates large M-spikes
Confirming the quantitation of specimens that show M-spikes by electrophoresis
Detecting urine monoclonal proteins and identification of specimens that need urine protein electrophoresis

Profile Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>KTLCU</td>
<td>Kappa Total Light Chain, U</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>LTLCU</td>
<td>Lambda Total Light Chain, U</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>KLTRU</td>
<td>Kappa/Lambda TLC Ratio, U</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Special Instructions
- Urine Preservatives-Collection and Transportation for 24-Hour Urine Specimens

Method Name
KTLCU, LTLCU: Nephelometry

NY State Available
Yes

Specimen

Specimen Type
Urine

Specimen Required
If serum is being submitted on the same patient for FLCP / Immunoglobulin Free Light Chains, Serum; order that test under a different order.

Submit only 1 of the following specimens:

Specimen Type: Random urine

Supplies: Urine Tubes, 10 mL (T068)

Container/Tube: Plastic, 10-mL urine tube

Specimen Volume: 1 mL
Collection Instructions: Collect a random urine specimen.

Specimen Type: 24-Hour urine

Supplies: Urine Tubes, 10 mL (T068)

Container/Tube: Plastic, 10-mL urine tube

Specimen Volume: 1 mL

Collection Instructions: Collect urine for 24 hours.

Additional Information: 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>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambient</td>
<td>Yes &lt;72 hours</td>
</tr>
<tr>
<td>Refrigerate</td>
<td>Preferred</td>
</tr>
<tr>
<td>Frozen</td>
<td>Yes</td>
</tr>
<tr>
<td>50% Acetic Acid</td>
<td>No</td>
</tr>
<tr>
<td>Boric Acid</td>
<td>No</td>
</tr>
<tr>
<td>Diazolidinyl Urea</td>
<td>No</td>
</tr>
<tr>
<td>6M Hydrochloric Acid</td>
<td>No</td>
</tr>
<tr>
<td>6M Nitric Acid</td>
<td>No</td>
</tr>
<tr>
<td>Sodium Carbonate</td>
<td>No</td>
</tr>
<tr>
<td>Thymol</td>
<td>No</td>
</tr>
<tr>
<td>Toluene</td>
<td>No</td>
</tr>
</tbody>
</table>

Specimen Minimum Volume

0.5 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>Frozen</td>
<td>20 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ambient</td>
<td>72 hours</td>
<td></td>
</tr>
</tbody>
</table>
Clinical and Interpretive

Clinical Information
Immunoglobulin light chains are usually cleared from blood through the renal glomeruli and reabsorbed in the proximal tubules so that urine light-chain concentrations are very low or undetectable. The production of large amounts of monoclonal light chains, however, can overwhelm this reabsorption mechanism. The detection of monoclonal light chains in the urine (Bence Jones proteinuria) has been used as a diagnostic marker for multiple myeloma since the report by Dr. H. Bence Jones in 1847.

Current laboratory procedures employ protein electrophoresis and immunofixation for the identification and characterization of urine monoclonal light chains, and the monoclonal light chains may be present in large enough amounts to also be quantitated as an M-spike on protein electrophoresis. The electrophoretic M-spike is the recommended method of monitoring monoclonal gammopathies such as multiple myeloma. Monitoring the urine M-spike is especially useful in patients with light-chain multiple myeloma in whom the serum M-spike is very small or absent, but the urine M-spike is large.

Just as quantitative serum immunoglobulins by immunonephelometry are a complement to M-spike quantitation by serum electrophoresis, this quantitative urine light-chain assay may be used to complement urine M-spike quantitation by electrophoresis.

Reference Values
KAPPA TOTAL LIGHT CHAIN
<0.9 mg/dL

LAMBDA TOTAL LIGHT CHAIN
<0.7 mg/dL

KAPPA/LAMBDA RATIO
0.7-6.2

Interpretation
A kappa/lambda (K/L) ratio greater than 6.2 suggests the presence of monoclonal kappa light chains.

A K/L ratio less than 0.7 suggests the presence of monoclonal lambda light chains.

In 24-hour specimens, a greater than 90% increase in concentration suggests progression or relapse; a greater than 90% decrease suggests treatment response.

Increased kappa and/or lambda light chains may be seen in benign (polyclonal) and neoplastic (monoclonal) disorders.

Cautions
Unlike the electrophoretic M-spike, this immunoassay quantitates both polyclonal and monoclonal light chains and is therefore not sensitive for detecting small monoclonal abnormalities. A normal kappa/lambda (K/L) ratio does not rule
out a monoclonal protein, and an abnormal ratio does not identify a monoclonal protein. Urine protein electrophoresis and immunofixation are more sensitive and specific.

The quantitation of urine kappa light chain by immunonephelometry yields results that are approximately 2 times the values from the electrophoresis M-spike. Sequential results should be compared to previous results obtained by the same methodology.

Supportive Data

In a study of 168 urine samples with a monoclonal light chain detected by immunofixation electrophoresis (IFE), there were 20 samples with a normal kappa/lambda (K/L) ratio. These samples had either no M-spike (n=13) or M-spikes <0.5 mg/dL. Conversely, among the 148 cases with an abnormal K/L ratio, there were 12 samples with no M-spike indicating that there is no clear M-spike value at which the K/L ratio identifies monoclonal light chains. In patients with an M-spike, the relationship between the kappa and lambda light-chain quantitation and the size of the M-spike had good correlation (kappa, r^2=0.94; lambda, r^2=0.71) and the regression lines had slopes of 2.4 of kappa and 1.1 for lambda.

Interestingly, there was a single case in which the K/L ratio was 24 and the free light-chain K/L ratio was 58, but the IFE showed polyclonal light chains. The patient was post-transplant for a kappa light-chain multiple myeloma and presumably had multiple forms of a monoclonal kappa light chain that migrated in a smear and was a false-negative by IFE.

Clinical Reference


Performance

Method Description

In this Siemens Nephelometer II method, the light scattered onto the antigen-antibody complexes is measured. The intensity of the measured scattered light is proportional to the amount of antigen-antibody complexes in the sample under certain conditions. If the antibody volume is kept constant, the signal behaves proportionally to the antigen volume.

A reference curve is generated by a standard with a known antigen content on which the scattered light signals of the samples can be evaluated and calculated as an antigen concentration. Antigen-antibody complexes are formed when a sample containing antigen and the corresponding antiserum are put into a cuvette. A light beam is generated with an LED, which is transmitted through the cuvette. The light is scattered onto the immuno-complexes that are present. Antigen and antibody are mixed in the initial measurement, but no complex is formed yet. An antigen-antibody complex is formed in the final measurement.

The result is calculated by subtracting value of the final measurement from the initial measurement. The distribution of intensity of the scattered light depends on the ratio of the particle size of the antigen-antibody complexes to the radiated wavelength. (Instruction manual: Siemens Nephelometer II, Version 3, Siemens, Inc., Newark, DE, 2008)
PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Saturday; Continuously until 3 p.m.

Analytic Time
Same day/1 day

Maximum Laboratory Time
3 days

Specimen Retention Time
14 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
83883 x 2

LOINC® Information

<table>
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<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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</thead>
<tbody>
<tr>
<td>TLCU</td>
<td>Immunoglobulin Total Light Chains,U</td>
<td>In Process</td>
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</table>

<table>
<thead>
<tr>
<th>Result ID</th>
<th>Test Result Name</th>
<th>Result LOINC Value</th>
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<tbody>
<tr>
<td>KLTRU</td>
<td>Kappa/Lambda TLC Ratio, U</td>
<td>33559-6</td>
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<tr>
<td>KTLCU</td>
<td>Kappa Total Light Chain, U</td>
<td>27365-6</td>
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<tr>
<td>LTLCU</td>
<td>Lambda Total Light Chain, U</td>
<td>27394-6</td>
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