Test Definition: FLCP

Immunoglobulin Free Light Chains, S

Overview

Useful For

Monitoring serum from patients with monoclonal light chain diseases without a M-spike on protein electrophoresis

Profile Information

Test ID	Reporting Name	Available Separately	Always Performed
KFLC	Kappa Free Light Chain, S	No	Yes
LFLC	Lambda Free Light Chain, S	No	Yes
KLR	Kappa/Lambda FLC Ratio	No	Yes

Testing Algorithm

The following algorithms are available in Special Instructions:

-Laboratory Approach to the Diagnosis of Amyloidosis

-Laboratory Screening Tests for Suspected Multiple Myeloma

Special Instructions

- Laboratory Approach to the Diagnosis of Amyloidosis
- Laboratory Screening Tests for Suspected Multiple Myeloma

Method Name

Nephelometry

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Specimen Volume: 1 mL

Forms

If not ordering electronically, complete, print, and send a General Request (T239) with the specimen.

Specimen Minimum Volume

0.5 mL

Reject Due To

Gross hemolysis	OK
Gross lipemia	Reject
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	28 days	
	Frozen	28 days	
	Ambient	72 hours	

Clinical and Interpretive

Clinical Information

The monoclonal gammopathies are characterized by a clonal expansion of plasma cells that secrete a monoclonal immunoglobulin (Ig). The monoclonal Ig secreted by these cells serves as a marker of the clonal proliferation and the quantitation of monoclonal protein can be used to monitor the disease course.

The monoclonal gammopathies include multiple myeloma (MM), light chain multiple myeloma (LCMM), Waldenstrom macroglobulinemia (WM), nonsecretory myeloma (NSMM), smoldering multiple myeloma (SMM), monoclonal gammopathy of undetermined significance (MGUS), primary systemic amyloidosis (AL), and light chain deposition disease (LCDD).

Monoclonal proteins are typically detected by serum protein electrophoresis (SPEP) and immunofixation (IF). However, the monoclonal light chain diseases (LCMM, AL, LCDD) and NSMM often do not have serum monoclonal proteins in high enough concentration to be detected and quantitated by SPEP.

A sensitive nephelometric assay specific for kappa free light chain (FLC) and lambda free light chain (FLC) that doesn't recognize light chains bound to Ig heavy chains has recently been described. This automated, nephelometric assay is reported to be more sensitive than IF for detection of monoclonal FLC. In some patients with NSMM, AL, or LCDD, the FLC assay provides a positive identification of a monoclonal serum light chain when the serum IF is negative. In addition, the quantitation of FLC has been correlated with disease activity in patients with NSMM and AL.

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Reference Values

KAPPA-FREE LIGHT CHAIN

0.33-1.94 mg/dL

LAMBDA-FREE LIGHT CHAIN

0.57-2.63 mg/dL

KAPPA/LAMBDA FLC RATIO

0.26-1.65

Interpretation

The specificity of this assay for detection of monoclonal light chains relies on the ratio of free kappa and lambda (K/L) light chains. Once an abnormal free light chain (FLC) K/L ratio has been demonstrated and a diagnosis has been made, the quantitation of the monoclonal light chain is useful for monitoring disease activity.

Changes in FLC quantitation reflect changes in the size of the monoclonal plasma cell population. Our experience to date is limited, but changes of more than 25% or trending of multiple specimens are needed to conclude biological significance.

Cautions

Elevated kappa and lambda (K/L) free light chain (FLC) may occur due to polyclonal hypergammaglobulinemia or impaired renal clearance. A specific increase in FLC (eg, FLC K:L ratio) must be demonstrated for diagnostic purposes.

Moderate-to-marked lipemia may interfere with the ability to perform testing.

Supportive Data

Studies at Mayo Clinic have shown that in some patients with urine monoclonal light chains and negative serum immunofixation (IF), the free light chain (FLC) assay can identify monoclonal FLC in the serum. These studies support the increased sensitivity of the nephelometric FLC assay. In a series of patients with primary systemic amyloid treated by stem cell transplantation, the quantitation and monitoring of FLC predicted organ response (eg, disease course).

Clinical Reference

Drayson M, Tang LX, Drew R, et al: Serum free light chain measurements for identifying and monitoring patients with nonsecretory multiple myeloma. Blood 2001;97(9):2900-2902

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 a light-emitting diode (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, Siemens, Inc, Newark, DE, Version 3, 2008)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Friday; Continuously until 3 p.m.

Analytic Time

Same day/1 day

Maximum Laboratory Time

2 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 cleared, approved or is exempt by the U.S. Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

83883 x 2

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
FLCP	Immunoglobulin Free Light Chains, S	81632-2

Result ID	Test Result Name	Result LOINC Value
KFLC	Kappa Free Light Chain, S	80515-0
KLR	Kappa/Lambda FLC Ratio	80517-6

Result ID	Test Result Name	Result LOINC Value
LFLC	Lambda Free Light Chain, S	80516-8