

## Overview

### Useful For

Diagnosing multiple sclerosis, especially helpful in patients with equivocal clinical or radiological findings

### Profile Information

Test ID	Reporting Name	Available Separately	Always Performed
KCSFP	Kappa Free Light Chain, CSF	Yes, (KCSF)	Yes
XSRM	Additional sample for reflex OLIGS	No	Yes

### Reflex Tests

Test ID	Reporting Name	Available Separately	Always Performed
OLIGS	Serum Bands	Yes, (Order OLIG, submit CSF and Serum)	No
OLIGC	CSF Bands	Yes, (Order OLIG, submit CSF and Serum)	No

### Testing Algorithm

Kappa free light chain will be performed by nephelometry on all samples. When kappa free light chain results are 0.0600 mg/dL or more, the oligoclonal banding tests will be performed at an additional charge. If the time of testing exceeds the specimen stability for oligoclonal banding tests only kappa free light chain will be performed. Kappa free light chain will only be performed up to specimen stability.

### Method Name

KCSFP: Nephelometry

OLIGC, OLIGS: Isoelectric Focusing (IEF) with IgG Immunoblot Detection

### NY State Available

Yes

## Specimen

### Specimen Type

CSF

Serum

### Specimen Required

**Both serum and spinal fluid are required. Spinal fluid must be obtained within 1 week of serum collection.**

**Specimen Type:** Spinal fluid

**Container/Tube:** Sterile vial

**Specimen Volume:** 1mL

**Collection Instructions:**Label specimen as spinal fluid.

**Specimen Type:** Serum

**Container/Tube:**

**Preferred:** Serum gel

**Acceptable:** Red top

**Specimen Volume:** 1 mL

**Collection Instructions:**

1. Centrifuge and aliquot serum within 2 hours of collection.
2. Label specimen as serum.

### Forms

If not ordering electronically, complete, print, and send a [Neurology Specialty Testing Client Test Request](#) (T732) with the specimen.

### Specimen Minimum Volume

Serum, Spinal fluid: 0.5 mL

### Reject Due To

Gross hemolysis	Reject
Gross lipemia	OK
Gross icterus	OK

### Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
CSF	Frozen (preferred)	14 days	
	Refrigerated	72 hours	
	Ambient	24 hours	
Serum	Frozen (preferred)	14 days	
	Ambient	14 days	
	Refrigerated	14 days	

## Clinical and Interpretive

### Clinical Information

Multiple sclerosis (MS) is a chronic inflammatory demyelinating disease characterized by visual, motor, and sensory disturbances. The diagnosis of MS is dependent on clinical, radiological, and laboratory findings. The detection of increased intrathecal immunoglobulin (Ig) synthesis is the basis for current diagnostic laboratory tests for MS. These tests include the kappa free light chains in cerebrospinal fluid (CSF) and CSF oligoclonal band detection.

### Reference Values

#### KAPPA FREE LIGHT CHAIN

Medical decision point: 0.1000 mg/dL

#### OLIGOCLONAL BANDS:

<2 bands

### Interpretation

When result is 0.1000 mg/dL or more, the kappa free light chain concentration measured in cerebrospinal fluid (CSF) is at or greater than the threshold associated with demyelinating disease. This is a positive result. These findings, however, are not specific for multiple sclerosis (MS) because CSF-specific immunoglobulin synthesis may also be detected in patients with other neurologic diseases (infectious, inflammatory, cerebrovascular, autoimmune, and paraneoplastic). Clinical correlation is recommended. Automatic reflexing to oligoclonal bands will occur.

When result is less than 0.0600 mg/dL, the kappa free light chain concentration measured in CSF is lower than the threshold associated with demyelinating disease. This is a negative result. Testing for oligoclonal banding is not performed. Clinical correlation is recommended.

When result is 0.0600 to 0.0999 mg/dL, the kappa free light chain concentration measured in CSF is slightly elevated but not above the medical decision point of 0.1000 mg/dL associated with demyelinating disease. This is a borderline result. Reflexing to oligoclonal bands will be automatically performed and clinical correlation is recommended.

When the oligoclonal band assay detects 2 or more unique IgG bands in the CSF, the result is positive.

CSF is used in the diagnosis of MS by identifying increased intrathecal IgG synthesis qualitatively (oligoclonal bands). The presence of 2 or more unique CSF oligoclonal bands was reintroduced as one of the diagnostic criteria for MS in the 2017 revised McDonald criteria. These findings, however, are not specific for MS as CSF-specific IgG synthesis may also be found in patients with other neurologic diseases including infectious, inflammatory, cerebrovascular, and paraneoplastic disorders. Clinical correlation is recommended.

### Cautions

Increased intrathecal Ig synthesis may occur in other inflammatory central nervous system diseases, and therefore, these assays are not specific for multiple sclerosis.

### Supportive Data

In a cohort of 1307 patients analyzed in 2018, where 159 had demyelinating disease, the Mayo Clinic oligoclonal banding test had a clinical sensitivity of 74% and clinical specificity of 89%, ROC AUC of 0.813, when 2 or more unique cerebrospinal fluid (CSF) bands are used as a cutoff for positive. This, kappa free light chain test, when considered positive at a concentration greater than or equal to 0.1000 mg/dL as a medical decision point, has a sensitivity of 70% with a specificity of 87%. The differences between the 2 tests are not statistically significant and

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the 2 tests show comparable performance with shorter turn-around-time for results, and an objective quantitative result.

The MSP3 panel combines the ease of use and interpretation of the quantitative measurement of kappa free light chains in CSF and allies it to the traditional interpretation of oligoclonal bands for optimized efficiency in laboratory testing for demyelinating diseases and improved test utilization.

### Clinical Reference

1. Andersson M, Alvarez-Cermeno J, Bernardi G, et al: Cerebrospinal fluid in the diagnosis of multiple sclerosis: a consensus report. *J Neurol Neurosurg Psychiatry*. 1994 Aug;57(8):897-902
2. Tourtellotte WW, Walsh MJ, Baumhefner RW, Staugaitis SM, Shapshak P: The current status of multiple sclerosis intra-blood-brain-barrier IgG synthesis. *Ann NY Acad Sci*. 1984;436:52-67
3. Thompson AJ, Banwell BL, Barkhof F, et al: Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. *Lancet Neurol*. 2018 Feb;17(2):162-173
4. Gurtner KM, Shosha E, Bryant SC, et al: CSF free light chain identification of demyelinating disease: comparison with oligoclonal banding and other CSF indexes. *Clin Chem Lab Med*. 2018;56:1071-1080
5. Saadeh R, Pittock S, Bryant S, et al: CSF Kappa Free Light Chains as a Potential Quantitative Alternative to Oligoclonal Bands in Multiple Sclerosis. In: American Academy of Neurology Annual Meeting. 2019 Philadelphia, PA

### Performance

#### Method Description

Kappa Free Light Chain:

Kappa free light chain is measured by nephelometric method in which 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.

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. An antigen-antibody complex is formed in the final measurement.

The result is calculated by subtracting the 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; Version 2.3, 2008; Addendum to the Instruction Manual 2.3, 08/2017)

Oligoclonal Banding:

The oligoclonal banding (OCB) assay requires paired cerebrospinal fluid (CSF) and serum samples. Unconcentrated CSF and diluted serum are electrophoresed by isoelectric focusing. The separated IgG bands are visualized by an IgG immunoblot, and oligoclonal bands that are present in the CSF and not in the serum are reported. The assay uses reagents from Helena Laboratories. (Keir G, Luxton RW, Thompson EJ: Isoelectric focusing of cerebrospinal fluid immunoglobulin G: an annotated update. *Ann Clin Biochem*. 1990 September;27[5]:436-443; Hortin GL: Amino acids, peptides, and proteins. In: Burtis CA, Burns DE, Sawyer BG, eds. *Tietz Fundamentals of Clinical Chemistry and Molecular Diagnostics*. 7th ed.. Elsevier; 2015;chap 18)

**PDF Report**

No

**Day(s) Performed**

Monday through Friday

**Report Available**

3 to 5 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

83916 x2 (if appropriate)

**LOINC® Information**

Test ID	Test Order Name	Order LOINC Value
MSP3	Multiple Sclerosis Profile	55121-8

Result ID	Test Result Name	Result LOINC Value
KCSFP	Kappa Free Light Chain, CSF	48774-4
XSRM	Additional sample for Reflex OLIGS	No LOINC Needed