N Latex FLC kappa assay

Simplify assessment of multiple sclerosis

Multiple sclerosis (MS) is a leading chronic inflammatory and neurodegenerative disorder of the central nervous system, most commonly affecting young adults – particularly women.[1] Testing for MS has historically been performed by measuring oligoclonal bands (OCBs) using electrophoresis, which requires both expensive specialty equipment and a high level of skill, leading many laboratories to outsource this sophisticated, labor-intensive testing.

With the 2024 update to diagnostic guidelines, labs can now leverage the N Latex FLC kappa assay* as a fast, simple, and more accessible alternative to traditional OCB analysis.

Fast, easy, and cost-effective

No need for electrophoresis or expert interpretation

Ideal for routine clinical use

**N Latex FLC kappa assay is not cleared as an aid in the diagnosis of MS in the U.S.*

SIEMENS Healthineers

Updates to the McDonald Criteria: A significant step forward in MS diagnostics

The 2024 McDonald diagnostic criteria for multiple sclerosis now recognizes kappa free light chains (KFLC) in cerebrospinal fluid as a valid alternative to oligoclonal IgG bands for demonstrating intrathecal immunoglobulin synthesis.

The KFLC index (recommended cut-off value of 6.1) is considered interchangeable with oligoclonal bands and can therefore be used in their place when confirming a diagnosis of multiple sclerosis.[2,3]

> *"The kFLC index is an appropriate paraclinical test for the diagnosis of multiple sclerosis."*
>
> The Lancet Neurology[3]

The updates represent a significant change to diagnostic guidelines and are the first major change to the global diagnostic framework for MS since 2017.

The criteria revision is in response to accumulated clinical evidence and real-world diagnostic challenges, particularly around early diagnosis, biomarker integration, and reducing disparities across clinical settings.

The guideline revisions were developed by the **International Advisory Committee on Clinical Trials in MS (IACCTMS)** and involved 56 experts across 16 countries, spanning neurology, radiology, methodology, epidemiology, and patient advocacy.[4]

Why is kappa FLC recommended in the 2024 McDonald Criteria?

Interchangeable

KFLC index is interchangeable with oligoclonal bands in MS diagnosis.[3]

High concordance

KFLC index and OCB concordance is ~90%, indicating strong agreement between methods.[2,3,5]

Sensitive and specific

Diagnostic sensitivity and specificity of KFLC is equal to OCB on a 95% confidence level.[2]

Proven performance

A systematic review of 32 studies with approximately 3300 CIS/MS patients and 5800 controls showed strong diagnostic performance of the KFLC index.[2,5]

How are KFLC results interpreted?

The N Latex FLC kappa assay provides quantitative results for objective decision-making. Clinicians typically assess KFLC in cerebrospinal fluid using one of two established methods.

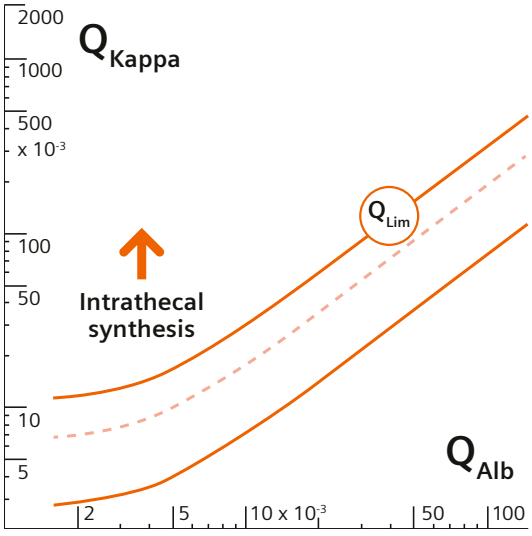
$$\frac{KFLC_{CSF/serum}}{Albumin_{CSF/serum}}$$

Recommended cut-off value: 6.1

KFLC Index

This approach measures KFLC and albumin levels in both CSF and serum to generate a numerical index.

A **recommended cut-off value of 6.1** indicates intrathecal KFLC synthesis – an important marker supporting a diagnosis of multiple sclerosis.

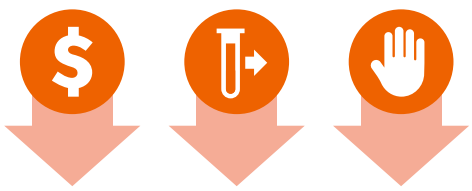


Reiber Diagram

This graphical method plots the KFLC quotient against the albumin quotient.

When the plotted point lies **above the Q-Lim (upper reference line)**, it signals intrathecal immunoglobulin synthesis.

Why N Latex FLC kappa assay?



The N Latex FLC kappa assay offers a fast, simple, and more accessible alternative to traditional OCB analysis. The nephelometric Atellica NEPH 630* and BN II Systems automate MS testing workflows – **reducing costs, send-outs, and hands-on time.**

**Not available for sale in the U.S.*

Streamline your diagnostic testing

Time and cost savings are possible for more than just the diagnosis of MS. Our plasma protein instrument and assay portfolio enables labs to manage neurology testing in-house. Proven nephelometric systems and a broad portfolio of more than 70 assays provide both scalability and versatility in protein testing, empowering even small labs to realize the financial, labor, and workflow benefits of automated, on-site testing.

Assay	Biomarker	Clinical Application
KFLC (CSF)*	Kappa Free Light Chains	Aids in MS diagnosis, assessment of intrathecal immunoglobulin synthesis, and kappa index calculation.
IgG/A/M (CSF)	Immunoglobulins	Supports differential diagnosis and immune response profiling in neurological diseases.
Albumin (CSF)	Albumin	Assesses blood-CSF barrier integrity and enables quotient calculations for CSF analysis.
BTP (CSF containing fluid)*	Beta-Trace Protein	Detects CSF leaks and aids in differentiation of neurological diseases.

**N Latex FLC kappa assay is not cleared as an aid in the diagnosis of MS in the U.S.*

Learn more about the benefits of N Latex FLC kappa assay and our proven nephelometric testing portfolio.

References:

1. Multiple sclerosis (MS) [Internet]. National Institute of Neurological Disorders and Stroke. [cited 2026 Feb 20]. Available from: https://www.ninds.nih.gov/health-information/disorders/multiple-sclerosis-ms.
2. Deisenhammer F, Hegen H, Arrambide G, Banwell BL, Coetzee T, Gnanapavan S, et al. Positive cerebrospinal fluid in the 2024 McDonald criteria for multiple sclerosis. EBioMedicine [Internet]. 2025;120(105905):105905. Available from: http://dx.doi.org/10.1016/j.ebiom.2025.105905.
3. Montalban X, Lebrun-Frénay C, Oh J, Arrambide G, Moccia M, Pia Amato M, et al. Diagnosis of multiple sclerosis: 2024 revisions of the McDonald criteria. Lancet Neurol [Internet]. 2025;24(10):850–65. Available from: http://dx.doi.org/10.1016/S1474-4422(25)00270-4.
4. McDonald Diagnostic Criteria [Internet]. ECTRIMS. 2024 [cited 2026 Feb 20]. Available from: https://ectrims.eu/mcdonald-diagnostic-criteria.
5. Hegen H, Walde J, Berek K, Arrambide G, Gnanapavan S, Kaplan B, et al. Cerebrospinal fluid kappa free light chains for the diagnosis of multiple sclerosis: A systematic review and meta-analysis. Mult Scler [Internet]. 2023;29(2):169–81. Available from: http://dx.doi.org/10.1177/13524585221134213.

Siemens Healthineers Headquarters
Siemens Healthineers AG
Siemensstr. 3
91301 Forchheim, Germany
Phone: +49 9191 18-0
siemens-healthineers.com

Published by
Siemens Healthcare Diagnostics Inc.
Specialty Lab Solutions
511 Benedict Avenue
Tarrytown, NY 10591-5005
USA
Phone: +1 914-631-8000

Published by Siemens Healthcare Diagnostics Inc. · SLS-26-4515-76 · QR700035351 · 03-2026 · ©*Siemens Healthcare Diagnostics Inc., 2026*