N Latex FLC kappa and lambda assays

Improving diagnostic accuracy in patients with monoclonal gammopathies

One reference range for simplified result interpretation and confident patient management

Unlocking insight into monoclonal diseases

The International Myeloma Working Group (IMWG) and other international societies recommend serum free light chains (sFLC) testing on nephelometry as an **indicator and differentiator** for the different stages of monoclonal gammopathies.[1-5]

N Latex FLC kappa and lambda assays enable **more reliable management** of patients with paraproteinemias, including evaluation of monoclonal gammopathies of undetermined significance (MGUS).

Broad portfolio of nephelometric assays for consistent results and confident management of monoclonal diseases

Nephelometric assay portfolio for gammopathies

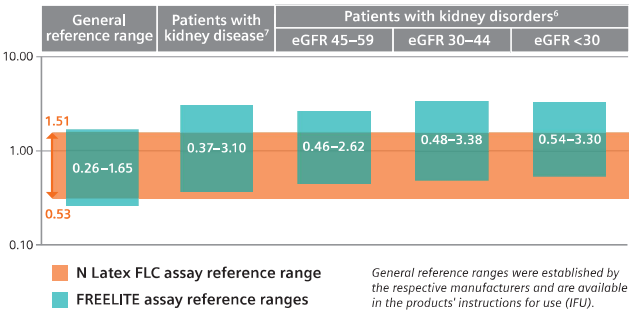
ß2-Microglobulin	IgA	▶ **FLC kappa**
α1-microglobulin	IgG	▶ **FLC lambda**
α2-microglobulin	IgM	Ig/Light Chain, type kappa
IgG subclasses 1–4		Ig/Light Chain, type lambda

Clinical utility

Free light chain assay measurements may be used as an aid in the diagnosis, assessment, and monitoring of monoclonal diseases, including:

- Multiple myeloma
- Waldenström's macroglobulinemia
- AL amyloidosis
- Light chain deposition disease
- Lymphocytic neoplasm

One reference range across all patient populations[6]



General reference ranges were established by the respective manufacturers and are available in the products' instructions for use (IFU).

Healthcare impact

Achieve consistent results

Monoclonal antibodies support **consistency of results** across reagent lots for unbiased monitoring of disease activity.

Simplify interpretation

One **easy-to-interpret reference range** for all patients—including those with impaired renal function—reduces the risk of patient misclassification.

Confidently identify patients

Nephelometry enables precise measurements at both very high and very low concentrations for **accurate FLC ratio determinations.**

SIEMENS Healthineers

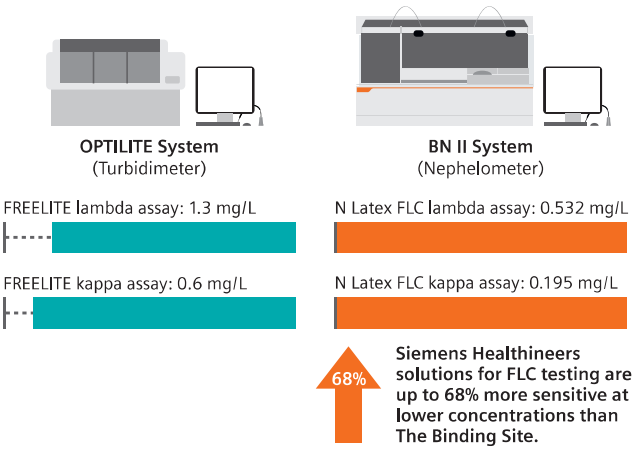
Sensitivity compared to immunofixation†

Assay	IFE κ Positive (60)	IFE λ Positive (59)
N Latex FLC kappa	60 (100%)	–
FREELITE kappa	59 (98.3%)	–
N Latex FLC lambda	–	58 (98.3%)
FREELITE lambda	–	56 (94.9%)

Assay highlights

	N Latex FLC kappa	N Latex FLC lambda
Assay principle	Nephelometric quantification on BN II and BN ProSpec Systems	
Sample types	Serum, heparin/EDTA plasma	
Sample volume	50 µL	50 µL
Initial dilution	1:100	1:20
Analytical measuring range	3.4–110 mg/L	1.9–60 mg/L
Time to first result	12 min.	13 min.

Free light chain measurements (low-end concentration)



Limit of quantitation using the FREELITE assays on a turbidimeter (OPTILITE system from The Binding Site) and N Latex FLC assays on a nephelometer (BN II System from Siemens Healthineers).
Source: Manufacturers' IFU.

Ordering information

Catalog No.	Product	No. of Tests
OPJA	N Latex FLC kappa	3 x 37 tests
OPJB	N Latex FLC lambda	3 x 37 tests
OPJC	N FLC Supplement Reagent	3 x 0.5 mL Supp A 3 x 2 mL Supp B
OPJD	N FLC Standard SL	3 x 1 mL
OPJE	N FLC Control SL1	3 x 1 mL
OPJF	N FLC Control SL2	3 x 1 mL

Visit siemens-healthineers.com/flc to learn more about N Latex FLC assays—the first assays to be FDA cleared for evaluation of MGUS.

References:
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7. Hutchinson CA, et al. Quantitative Assessment of serum and urinary polyclonal free light chains in patients with chronic kidney disease. Clin J Am Soc Nephrol. 2008 Nov;3(6): 1684-90.

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†Data obtained during validation at Jeroen Bosch Hospital, Den Bosch, NL

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