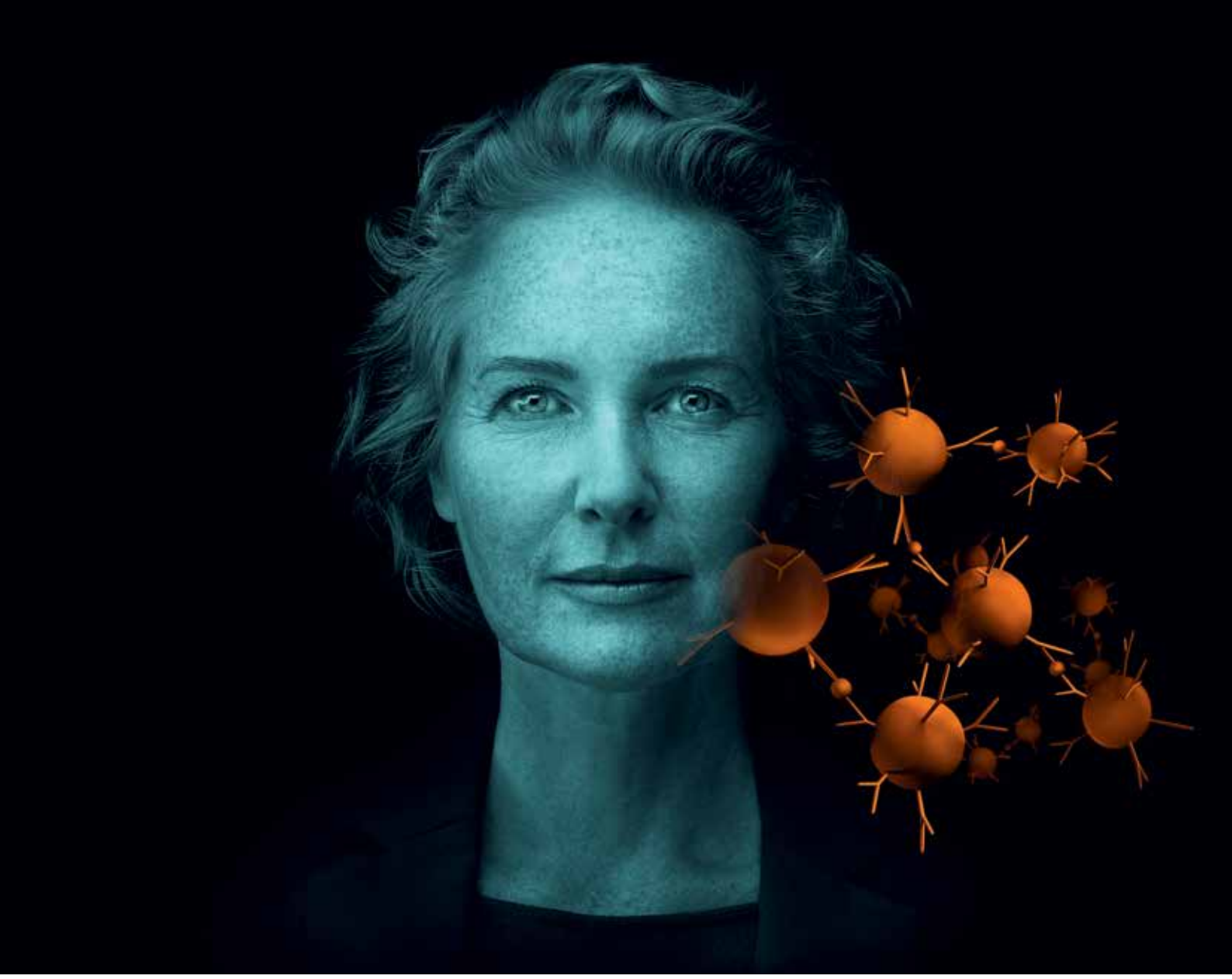

Add consistency to your results

N Latex FLC kappa and
N Latex FLC lambda assays

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Monoclonal disorders: a wide spectrum of diseases

Monoclonal diseases range from asymptomatic, premalignant monoclonal gammopathy of undetermined significance (MGUS) to life-threatening manifestations such as light chain AL amyloidosis or fast-progressing multiple myeloma that require highly aggressive therapy. In monoclonal diseases, an increase in either free light chain (FLC) kappa or FLC lambda might be observed, resulting in an abnormally low or high FLC kappa/lambda ratio.

Clinical application of FLC testing

FLC kappa and lambda measurements are 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

Serum determination of FLC provides significantly improved sensitivity and specificity for the diagnosis of monoclonal gammopathies compared to determination of total light chains in serum or urine. Consequently, serum FLC testing is recommended in several national and international guidelines for diagnosis, assessment of prognosis, and therapy monitoring for monoclonal gammopathies.[1-3] Another important advantage of serum FLC is that it eliminates the need for cumbersome, error-prone 24-hour urine collection.[4]

Analytical requirements for FLC assays

FLC assays have rigorous requirements for analytical performance.

Specificity
FLC assays must be highly selective for the free form of light chains, using only those antibodies that are highly specific for free light chain kappa or lambda. Specificity is critically important to prevent misdiagnosis of malignant disorders in non-affected individuals.

Reliability
Reliable results with no false-low measurements caused by antigen excess are essential for FLC assays. Physicians must be able to trust FLC results, and highly reliable results reduce the need for costly reruns.[5]

Sensitivity
FLC assays must be highly sensitive and precise to allow for appropriate clinical management of patients.

Consistency
Patients with multiple myeloma and other monoclonal gammopathies require regular, long-term monitoring. To identify regression or progression of the disease in an early stage, and to adapt therapy accordingly, results must be consistent across different reagent lots.

Expand precision medicine with N Latex FLC assays

Siemens Healthineers N Latex FLC kappa and N Latex FLC lambda assays are highly sensitive reagents for the quantitative determination of free light chains in human serum and plasma. These assays were developed for use on BN™ II, BN ProSpec,® and Atellica® NEPH 630 systems[6,7] and are also available as an application for use on the Atellica CH 930 Analyzer. Our FLC assays deliver the specificity, reliability, sensitivity, and lot-to-lot consistency required for screening, diagnosis, and monitoring of patients with monoclonal disorders.

Unique monoclonal antibodies

Conventional FLC assays based on polyclonal antibodies are affected by significant limitations in analytical performance.[5,8–10] These issues might include:

- Variability and inconsistency in results obtained from different reagent lots
- False-low results caused by excessive antigen levels
- Gross overestimation in certain samples with FLC polymerization

Siemens Healthineers FLC kappa and lambda assays are based on unique monoclonal antibodies against free and not bound light chains, coupled to polystyrene beads. The combination of the latex-based assay with highly specific monoclonal antibodies and the assay-specific supplementary reagent has demonstrated high-performance characteristics and reliability.[7]

Narrow reference range

The N Latex FLC assays exhibit narrow reference ranges within those of another conventional FLC method, demonstrating the high specificity of these monoclonal assays:

Assay	Reference Range	Percentile
N Latex FLC kappa	6.7–22.4 mg/L	(2.5th–97.5th)
N Latex FLC lambda	8.3–27.0 mg/L	(2.5th–97.5th)
N Latex FLC ratio	0.31–1.56	(minimum–maximum)

Wide measuring range

Our N Latex FLC assays feature a wide measuring range. The initial measuring range covers the complete reference range.

Measuring Range	N Latex FLC kappa	N Latex FLC lambda
Initial	3.5–110 mg/L	1.9–60 mg/L
Total	0.174 to ≥9000	0.47 to ≥6000 mg/L

Variety of sample types

N Latex FLC assays accommodate serum, urine, CSF, heparin plasma, and EDTA plasma samples.*

**Availability of applications for certain samples may not be available in all countries.*

Highly sensitive, precise performance

Siemens Healthineers N Latex FLC assays are confirmed to be highly precise and sensitive compared to the immunofixation method currently regarded as the reference method for detection of monoclonal components.

N Latex assay precision

Repeatability	Within-lab CV
≤4.0%	≤6.3%

Analytical/functional sensitivity

N Latex FLC kappa	N Latex FLC lambda
0.174 mg/L	0.47 mg/L

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 (94.4%)

†FREELITE assays are manufactured by The Binding Site Group, Ltd.

Improved diagnostic accuracy clinicians can trust

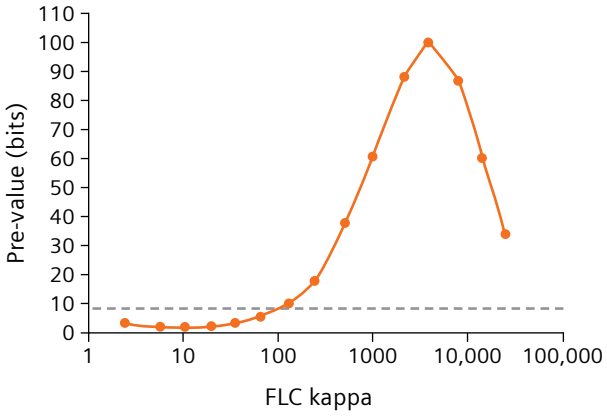
Antigen-excess security is crucial in delivering reliable FLC test results. Extremely high FLC concentrations can cause dissolution of immunoprecipitates, which produces misleading, false-low test results. Such false-low results compromise clinicians' confidence in test results and require expensive and time-consuming reruns.

Siemens Healthineers N Latex FLC assays use built-in pre-reaction protocols for detection of antigen excess. These protocols allow that, even with very high FLC concentrations, less false-low test results are generated. This antigen-excess security delivers results clinicians can trust and reduce the need for costly reruns.

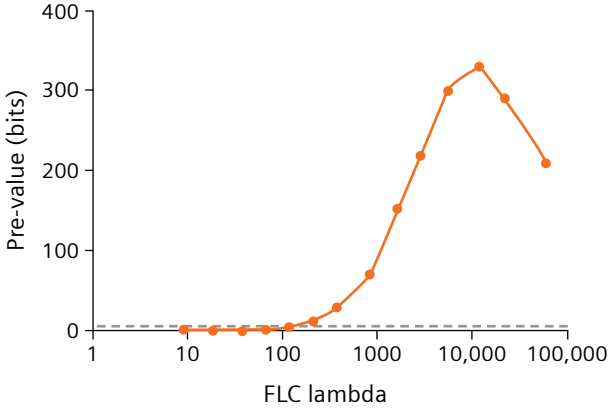
Even the highest FLC kappa and lambda concentrations observed in the clinical trials were correctly determined by the N Latex FLC assays:[6]

FLC Concentration	N Latex FLC kappa	N Latex FLC lambda
Highest tested	23,000 mg/L	57,000 mg/L

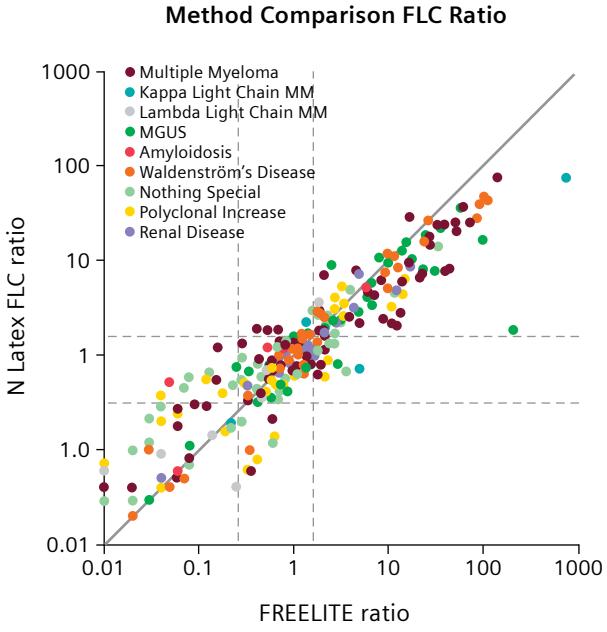
FLC kappa 23,000 mg/L



FLC lambda 57,000 mg/L

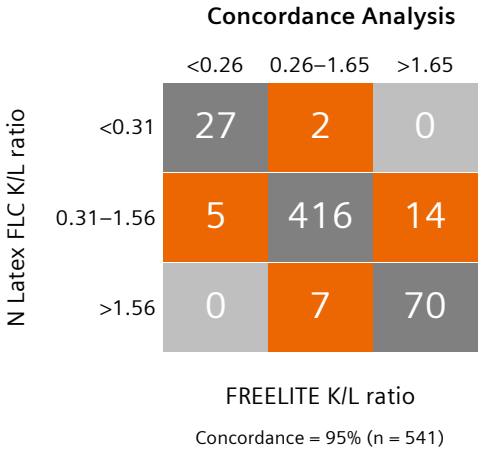


Pre-reaction cutoff = antigen excess detection threshold.



Results comparable to conventional polyclonal assays

In testing a total of 541 consecutive patients with (n = 164) and without (n = 366) monoclonal gammopathy (11 patients were not classified), the concordance between the Siemens Healthineers N Latex FLC and FREELITE assays based on classification of results as abnormal low, normal, and abnormal high was 91% for FLC kappa, 85% for FLC lambda, and 95% for FLC ratio.[6]



Overall, the majority of patient results obtained with both methods provided the same classification and showed good correlation. However, for individual patients, differences between the two methods can occur. The amount of difference between the methods is patient-specific due to individual differences in the monoclonal component. As FLC assays are not standardized, parallel testing is recommended during a transition period when switching to the N Latex FLC assays.

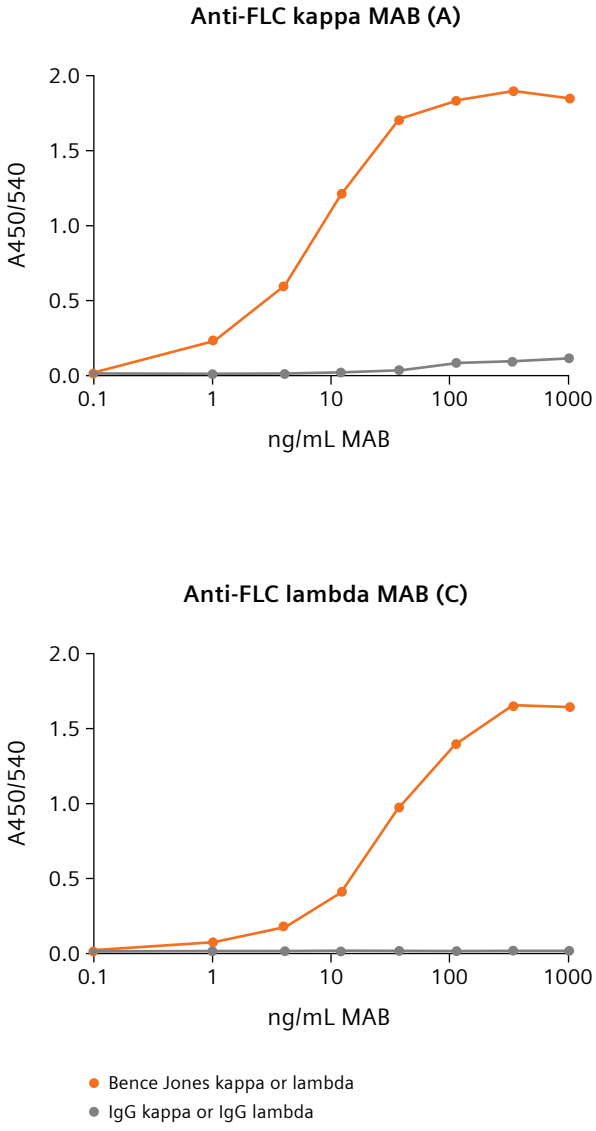
Specific, selective monoclonal antibodies

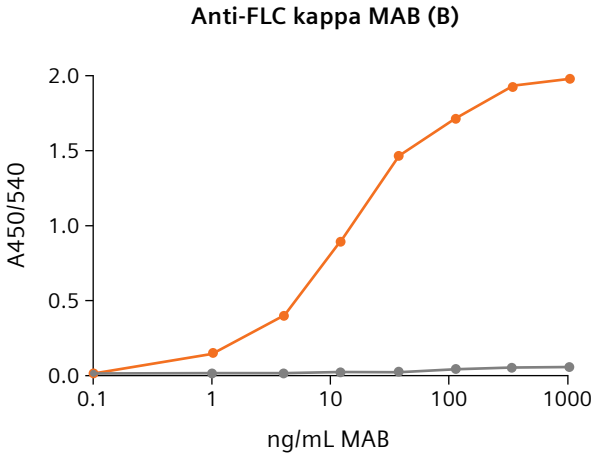
High analytical specificity

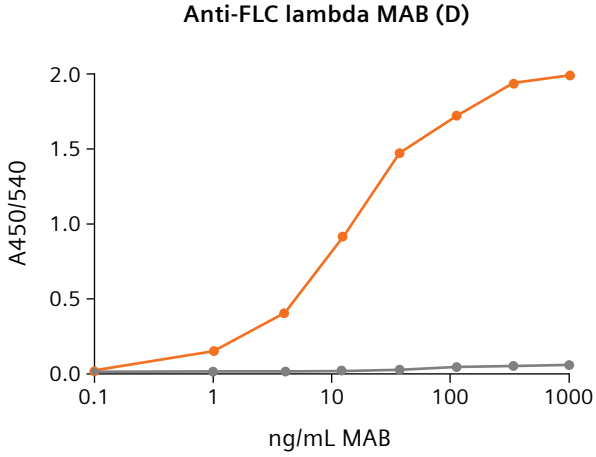
The Siemens Healthineers N Latex FLC kappa and lambda Assays each incorporate two monoclonal antibodies that are highly selective for the free form of the kappa and lambda light chain, respectively.

Graphs A and B show the reactivity of the anti-kappa antibodies with FLC kappa (orange graph) and IgG kappa (gray graph). Graphs C and D show the reactivity of the anti-lambda antibodies with FLC lambda (orange) and IgG lambda (gray).

The very low reactivity with complete immunoglobulin demonstrates the high specificity of the monoclonal antibodies selected for the FLC kappa and lambda assays.[6]







(Graphs A, B, C, and D from te Velthuis H. Clin Chem Lab Med. 2011)

High clinical specificity

The following table shows the FLC kappa/lambda concordance ratios for different patient polulations observed with the N Latex FLC and FREELITE assays.[6]

Patient Population	Clinical Specificity	
	N Latex FLC ratio	FREELITE ratio
Patients submitted for screening without renal disease or polyclonal stimulation	99.4% (164/165)	97.6% (161/165)
Patients with renal disease	98.6% (143/145)	96.6% (140/145)
Patients with polyclonal stimulation	98.2% (55/56)	98.2% (55/56)
All patients screened (n = 366)	98.9% (362/366)	97.3% (356/366)

Consistent results across reagent lots

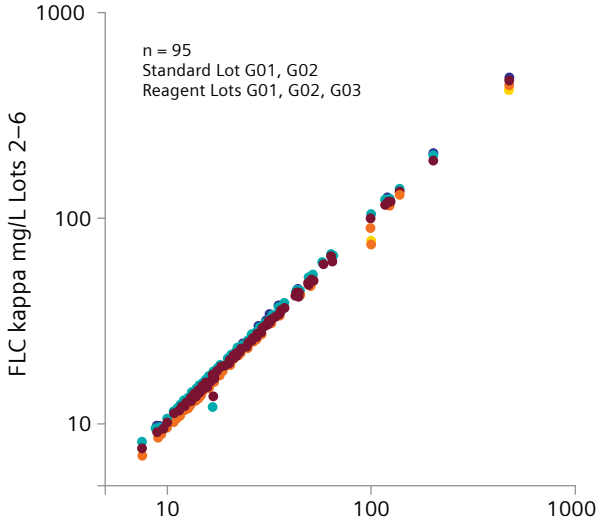
Patients with premalignant and overt malignant disease must be monitored over the long term to evaluate the course of disease and decide on the appropriate therapy. Highly consistent test results across different batches or lots of reagents are crucial for reliable patient monitoring and evaluation.

The monoclonal antibodies used in Siemens Healthineers N Latex FLC assays provide highly stable, consistent reagent lots. The graphs show the results obtained from tests run with three reagent and two calibrator lots (six combinations in total).

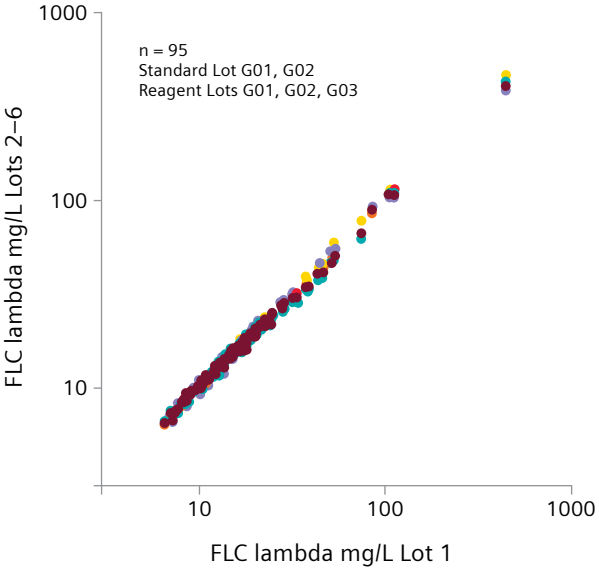
Differences were less than 7.5%, with a correlation coefficient greater than 0.99, demonstrating excellent lot-to-lot consistency for N Latex FLC kappa and lambda assays.

Results generated by our FLC assays remain consistent during patient monitoring due to use of monoclonal antibodies. This allows early detection of changes in disease activity and subsequent adjustments to therapy, and ultimately contributes to improved patient management and outcomes.

Lot-to-lot Comparison: FLC kappa



Lot-to-lot Comparison: FLC lambda



Innovative packaging for efficient, cost-effective processing

All Siemens Healthineers N Latex FLC assay components are packaged individually. Thus they can be ordered separately and used interchangeably and lot-independently.

This allows you to order only the components you need, rather than having to order an entire new kit of components. All components can be completely consumed, minimizing waste and reducing cost.

Also, our N Latex FLC assays require only 6 positions on the analyzer, compared to 10 positions for the FREELITE assays.

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

Single-source service and support for assays and analyzers

Our N Latex FLC assays are designed to run on Siemens Healthineers BN II, BN ProSpec, Atellica NEPH 630 dedicated plasma protein analyzers and the Atellica CH 930 Analyzer.‡ Now you can obtain service and support for FLC assays and analyzers from a single, trusted source.

Add consistency to FLC test results

Siemens Healthineers N Latex FLC assays deliver the consistent results that clinicians demand for patient screening and long-term monitoring. By allowing earlier detection of disease remission or regression and subsequent adjustments to therapy, they allow improved patient management and support improved patient outcomes.

‡Applications for EDTA plasma and serum only on Atellica CH 930 Analyzer.

To learn more about N Latex FLC kappa and lambda assays, contact your Siemens Healthineers representative.

At Siemens Healthineers, our purpose is to enable healthcare providers to increase value by empowering them on their journey toward expanding precision medicine, transforming care delivery, and improving patient experience, all made possible by digitalizing healthcare.

An estimated 5 million patients globally benefit every day from our innovative technologies and services in the areas of diagnostic and therapeutic imaging, laboratory diagnostics, and molecular medicine, as well as digital health and enterprise services.

We are a leading medical technology company with over 120 years of experience and 18,000 patents globally. Through the dedication of more than 50,000 colleagues in 75 countries, we will continue to innovate and shape the future of healthcare.

Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

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