Binding Site

Clinical Product Catalog

2020

Protein diagnostics.
Smart solutions.

Binding Site

Binding Site is a Special Protein company committed to the research, development, manufacture, and distribution of innovative immunodiagnostic assays for the global laboratory market. With extensive expertise in antibody specificity technology, Binding Site gives clinicians and laboratory staff the tools to significantly improve diagnosis and management of patients across a range of cancers and immune system disorders.

Binding Site is commited to improving patient lives worldwide through education, collaboration, and innovation. With more than 90% of our products sold overseas Binding Site is a truly international organization. Our global coverage ensures we are able to meet your needs worldwide through our network of subsidiary offices and distributor partnerships.

You can expect the same dedicated Binding Site service and quality wherever you are in the world as we deliver customized service that meets your specific needs and expectations.

Innovative Immunodiagnostic Assays from Binding Site

Freelite® is a well-established serum assay set used for the diagnosis and monitoring of Multiple Myeloma, a cancer of cells in the bone marrow. Freelite® comprises two immunodiagnostic assays for accurate and rapid quantification of free κ (kappa) and free λ (lambda) immunoglobulin light chain concentrations. These assays can be performed on a number of automated platforms giving a sensitivity, accessibility, and consistency never before achievable. Freelite® has enabled significant improvements in both laboratory and clinical practice for the detection and monitoring of Multiple Myeloma.

Freelite® provides complementary insights into Multiple Myeloma and AL Amyloidosis management.

Binding Site is a market leader in the development of products for the investigation of immune status including immunodeficiency diseases. Our current range of specialized products includes assays for:

- Quantifying immunoglobulins & subclasses
- Measuring complement proteins
- CSF Assays

Optimized Instrumentation and Assays

Optilite® has been developed exclusively for Binding Site special protein assays, bringing harmony to assay and analyzer alike. This dedicated system, along with Binding Site's exceptional support, ensures optimal assay performance, and system throughput.

Quality Assurance

Our manufacturing site has quality systems approved to both ISO9001 and ISO13485:2016 certification. These, together with strict adherence to rigorous internal quality control procedures, ensure customers can be confident in the quality of Binding Site products.

Assays for in vitro diagnostic use have been FDA cleared for the USA, Health Canada Registered for Canada and CE marked for Europe. Performance of our assays is regularly monitored by participation in a number of independent national and international quality assurance schemes.

New Assays

Optilite®

New assays have recently been added to the menu on Binding Site's Optilite Optimized Protein System:

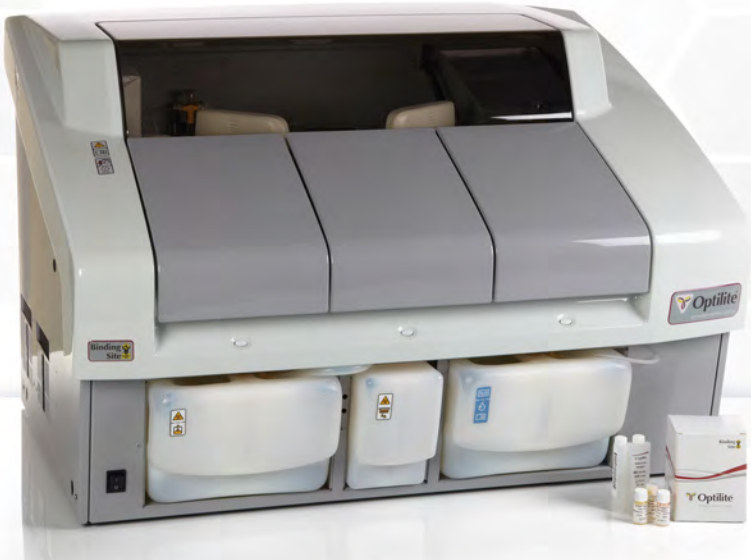
CSF assays for:

- IgG
- IgM
- IgA
- Albumin

All these new assays are fully automated, easy to use, and provide quantitative results.

These additions enhance the range of assays already available on Optilite which includes Freelite® serum free light chain assays, immunoglobulins, IgG and IgA subclasses, complement, albumin, haptoglobin, prealbumin, cystatin C, and β2 microglobulin.

Optilite is ideal for Binding Site's special protein assays and has been designed to bring together instrument, reagents, and exceptional support as a package from a special protein-focused supplier.



See pages 4-6 for more information on Optilite.

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Optilite®

Optilite is the latest innovation in special protein testing, fully optimized to create simplicity from complex analytical processes. It is the culmination of over 25 years of cutting edge research from Binding Site, the global leader in special protein diagnostics.

Optilite combines extensive features to bring you a new level of efficiency, workflow optimization, and confidence in results.

Key features include:

- Automatic re-dilution
- Continuous loading and unloading of samples, reagents, and cuvettes
- Optimized with one of three methods of antigen excess protection
- Optimized assay protocols with wide measuring ranges and large dilution steps

Enhance your efficiency

Time savings and reduced costs

- ☑ Boost your productivity with consistently reliable performance
- ☑ Minimize your reagent usage through optimized assay protocols
- ☑ Maximize your test throughput with continuous loading / unloading

Optimize your workflow

Lean operations

- ☑ Prioritize effectively with flexible, unrestricted access to samples, reagents, and cuvettes
- ☑ Minimize sample preparation time by loading any combination of sample tubes and fluid types
- ☑ Eliminate manual sample dilutions since Optilite re-dilutes to end result

Trust your results

Special protein expertise

- ☑ Optimized with one of three methods of antigen excess detection providing unparalleled protection
- ☑ Simplify data security through automatic lot number recognition and full traceability
- ☑ Access our dedicated technical and clinical special protein experts for all your support needs

Optilite Analyzer and Accessories

DESCRIPTION	PACK	CODE
Optilite Optimized Protein System	1	IE700
TENCELL™ Cuvettes	10800	IK702
Washing Solution (20mL)	4	IK703
Washing Solution (100mL)	6	IK704
Tubing Maintenance Solution	6	IK705
Optilite Special Wash 1(5mL)	6	IK707
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Optilite Cal QC Rack	3	IK712
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Optilite Sample Rack (9 position)	6	IK714
Optilite Sample Rack (9 position) - Blue	3	IK716
Tube Support Plate	6	IK719
0.5mL Sample Cups	1000	989220
Tray 2 PC	2	OTRAY2

Optilite Physical Specification

Dimensions	Width 37 in Depth 27.6 in Height 24.4 in	Weight	242 lbs

Optilite Assays

Units in parentheses apply to both range and sensitivity.

DESCRIPTION	PACK	CODE
Monoclonal Gammopathies		
Freelite® Kappa kit Range 0.60-63500, sensitivity 0.6 (mg/L)	100 test	LK016.OPT.A
Freelite® Lambda kit Range 1.30-139000, sensitivity 1.3 (mg/L)	100 test	LK018.OPT.A
Freelite® Mx™ Kappa kit (Urine) Range 0.33-63500, sensitivity 0.33 (mg/L)	100 test	LK016.M.OPT.A
Freelite® Mx Lambda kit (Urine) Range 0.74-139000, sensitivity 0.74 (mg/L)	100 test	LK018.M.OPT.A
Immunoglobulins		
IgG kit Range 0.165-150, sensitivity 0.165 (g/L)	100 test	NK004.OPT.A
IgA kit Range 0.02-70, sensitivity 0.02 (g/L)	100 test	NK010.OPT.A
IgM kit Range 0.10-150, sensitivity 0.10 (g/L)	100 test	NK012.OPT.A
IgD kit Range 13-16800, sensitivity 13 (mg/L)	100 test	LK013.OPT.A
Subclasses		
IgG1 kit Range 150-144000, sensitivity 150 (mg/L)	100 test	NK006.OPT.A
IgG2 kit Range 20-22000, sensitivity 20 (mg/L)	100 test	NK007.OPT.A
IgG3 kit Range 5.5-2200, sensitivity 5.5 (mg/L)	100 test	LK008.OPT.A
IgG4 kit Range 4.3-64800, sensitivity 4.3 (mg/L)	100 test	LK009.OPT.A
IgA1 kit Range 35-6000, sensitivity 35 (mg/L)	50 test	NK087.OPT.A
IgA2 kit Range 5-1250, sensitivity 5 (mg/L)	50 test	LK088.OPT.A

DESCRIPTION	PACK	CODE
Complement		
C1 inactivator kit Range 0.08-0.88, sensitivity 0.08 (g/L)	50 test	NK019.OPT.A
C3c kit Range 0.025-6, sensitivity 0.025 (g/L)	100 test	NK023.OPT.A
C4 kit Range 0.0064-1.8, sensitivity 0.0064 (g/L)	100 test	NK025.OPT.A
CH50 Reagent Range 12.5-100, sensitivity 12.5 (U/mL)	100 test	NK095.OPT.A
CH50 controls 4x low control, 4x high control, 4x elevated control	4 sets	NQ095.OPT.A
CH50 calibrators	3 vials	NC095.OPT.A
Renal Function		
Albumin kit Range 3.1-77, sensitivity 3.1 (g/L)	100 test	NK032.OPT.A
Low Level Albumin kit Range 11-66500, sensitivity CSF/Urine 11, Serum 2200 (mg/L)	100 test	NK032.L.OPT.A
Beta-2-Microglobulin kit Range 0.3-40, sensitivity 0.3 (mg/L)	100 test	LK043.OPT.A
Beta-2-Microglobulin Urine kit Range 0.03-200, sensitivity 0.03 (mg/L)	100 test	LK043.L.OPT.A
Ceruloplasmin kit Range 0.04-1.64, sensitivity 0.04 (g/L)	50 test	NK045.OPT.A
Cystatin C kit Range 0.4-12, sensitivity 0.4 (mg/L)	100 test	LK048.OPT.A
Specific Proteins		
Alpha-1-Acid Glycoprotein kit Range 0.19-6, sensitivity 0.19 (g/L)	100 test	NK063.OPT.A
Alpha-1-Antitrypsin kit Range 0.35-5, sensitivity 0.35 (g/L)	100 test	NK034.OPT.A
Alpha-2-Macroglobulin kit Range 0.2-6.4, sensitivity 0.2 (g/L)	100 test	NK039.OPT.A
Anti-streptolysin O kit Range 5-1600, sensitivity 5 (IU/mL)	100 test	LK189.OPT.A
C-Reactive Protein Range 5-1425, sensitivity 5 (mg/L)	100 test	NK044.OPT.A
C-reactive Protein Calibrators	2 vials	NC044.OPT.A
C-reactive Protein Controls 2x low control, 2x high control	2 sets	NQ044.OPT.A

DESCRIPTION	PACK	CODE
High Sensitivity C-Reactive Protein Range 0.5-10 mg, sensitivity 0.5 (mg/L)	100 test	LK044.L.OPT.A
Haptoglobin kit Range 0.026-8, sensitivity 0.026 (g/L)	100 test	NK058.OPT.A
Prealbumin kit Range 0.006-0.8, sensitivity 0.006 (g/L)	100 test	NK066.OPT.A
Rheumatoid Factor kit Range 7-1000 IU/mL, sensitivity 7 (IU/mL)	100 test	LK151.OPT.A
Transferin Range 0.14-22.4, sensitivity 0.14 (g/L)	100 test	NK070.OPT.A

DESCRIPTION	PACK	CODE
Central Nervous System Disorders		
Low Level Albumin CSF Range 11-333 mg/L, sensitivity 11 (mg/L)	100 test	NK032.L.OPT.A
IgG CSF Kit Range 7.5-1350 mg/L, sensitivity 7.5 (mg/L)	60 test	NK004.L.OPT.A
IgA CSF Kit Range 0.91-20 mg/L, sensitivity 1.65 (mg/L)	60 test	LK010.L.OPT.A
IgM CSF Kit Range 0.11-40 mg/L, sensitivity 0.11 (mg/L)	60 test	LK012.L.OPT.A

Optilite assays in development

- Apolipoprotein A-1
- Apolipoprotein B
- IgE

The ranges quoted are achieved using the assay specific automatic re-dilution protocols.

SPAPLUS®
Special Protein Analyzer

All SPAPLUS assays have broad, clinically relevant measuring ranges designed to meet the needs of the clinical laboratory. Units in parentheses apply to both range and sensitivity.

DESCRIPTION	PACK	CODE
Freelite® Kappa kit Range 0.4-1800, sensitivity 0.4 (mg/L)	100 test	LK016.S
Freelite® Lambda kit Range 0.45-1650, sensitivity 0.45 (mg/L)	100 test	LK018.S
IgG kit Range 0.165-140, sensitivity 0.165 (g/L)	100 test	NK004.S
IgA kit Range 0.02-70, sensitivity 0.02 (g/L)	100 test	NK010.S
IgM kit Range 0.1-150, sensitivity 0.1 (g/L)	100 test	NK012.S
IgD kit Range 7-16800, sensitivity 7 (mg/L)	100 test	LK013.S
IgG1 kit Range 0.15-144, sensitivity 0.15 (g/L)	100 test	NK006.S.A
IgG2 kit Range 0.02-22, sensitivity 0.02 (g/L)	100 test	NK007.S.A
IgG3 kit Range 0.0055-4, sensitivity 0.0055 (g/L)	100 test	LK008.S.A
IgG4 kit Range 0.003-3.4, sensitivity 0.003 (g/L)	100 test	LK009.S.A
IgA1 kit Range 30-6000, sensitivity 30 (mg/L)	50 test	NK087.S
IgA2 kit Range 5-1250, sensitivity 5 (mg/L)	50 test	LK088.S
C1 inactivator kit Range 0.06-0.8, sensitivity 0.06 (g/L)	50 test	NK019.S.A
C3c kit Range 0.025-6.0, sensitivity 0.025 (g/L)	100 test	NK023.S
C4 kit Range 0.0064-1.8, sensitivity 0.0064 (g/L)	100 test	NK025.S
CH50 reagent Range 12-190, sensitivity 12 (U/mL)	100 test	NK095.S
CH50 Controls 4 x low control, 4 x high control, 4 x elevated control	1 set	NQ095.S
CH50 Calibrators	1 set	NC095.S

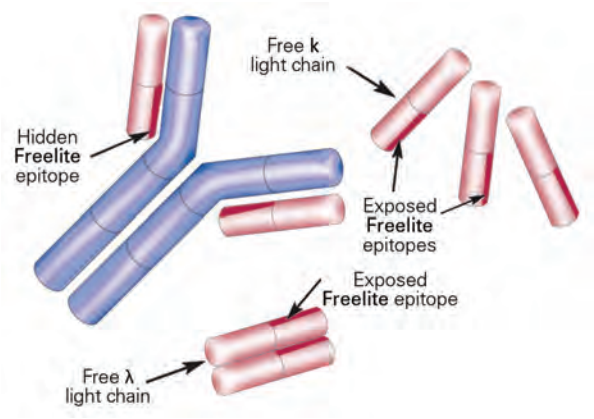
DESCRIPTION	PACK	CODE
Albumin kit Range 0.1-154, sensitivity 0.1 (g/L)	100 test	NK032.S
α1-Acid Glycoprotein kit Range 0.19-6.0, sensitivity 0.19 (g/L)	100 test	NK063.S
α1-Antitrypsin kit Range 0.35-5.0, sensitivity 0.35 (g/L)	100 test	NK034.S
α2-Macroglobulin kit Range 0.2-6.4, sensitivity 0.2 (g/L)	100 test	NK039.S
Anti-Streptolysin-O kit Range 5-1600, sensitivity 5 (IU/mL)	100 test	LK189.S
β2 Microglobulin kit Range 0.3-40, sensitivity serum 0.3 (mg/L)	100 test	LK043.S
β2-Microglobulin Urine kit Range 0.03-20, sensitivity 0.03 (mg/L)	100 test	LK043.U.S
Ceruloplasmin kit Range 0.03-1.64, sensitivity 0.03 (g/L)	50 test	NK045.S
Cystatin C kit Range 0.4-14.7, sensitivity 0.4 (mg/L)	100 test	LK048.S
C-Reactive Protein Range 0.2-400, sensitivity 0.2 (mg/L)	100 test	LK044.S.A
Haptoglobin kit Range 0.026-8, sensitivity 0.026 (g/L)	100 test	NK058.S
Lipoprotein (a) kit Range 7-180, sensitivity 7 (mg/dL)	100 test	LK098.S
Microalbumin kit Range 11-17200, sensitivity 10.193 (mg/L)	100 test	NK032.U.S
Prealbumin kit Range 0.006-0.8, sensitivity 0.006 (g/L)	100 test	NK066.S
Rheumatoid Factor kit Range 7-1040, sensitivity 7(IU/mL)	100 test	LK151.S.A
Transferrin kit Range 0.14-22.4, sensitivity 0.14 (g/L)	100 test	NK070.S
Albumin CSF kit Range 17-810000, sensitivity CSF 17, Serum 5100 (mg/L)	60 test	NK032.L.S
IgG CSF kit Range 4.2-1350, sensitivity 4.2 (mg/L)	60 test	NK004.L.S
IgA CSF kit Range 0.15-48, sensitivity 0.15 (mg/L)	60 test	LK010.L.S
IgM CSF kit Range 0.3-70, sensitivity 0.3 (mg/L)	60 test	LK012.L.S

The ranges quoted are achieved from the assay-specific instrument protocols and may include an offline dilution.

Freelite®
Free Light Chain Assays

Freelite® rapidly quantifies free light chains (FLCs) to aid in the diagnosis and monitoring of specific monoclonal gammopathies.

Affinity purified polyclonal antibodies, reacting specifically with κ and λ FLCs, are pre-coated onto latex particles. These latex reagents are used to produce nephelometric and turbidimetric kits that are specific for FLCs.



The International Myeloma Working Group (IMWG) guidelines recommend the use of Freelite® by name:

> \\ The serum FLC assay (FREELITE®, The Binding Site Ltd., Birmingham, UK) is based on a commercial reagent set of polyclonal antibodies and is performed by immunonephelometry and it can be performed on a number of automated laboratory instruments.[1] //

Freelite® is recommended for use in Multiple Myeloma and AL amyloidosis by the following:

- International Myeloma Working Group[1,2,3,4]
- UK Myeloma Forum[5,6,7]
- Nordic Myeloma Study Group[6]
- British Committee for Standards in Haematology[7]
- The National Comprehensive Cancer Network[8]
- European Society of Medical Oncology[9]
- Consensus guidelines for the conduct and reporting of clinical trials in systemic light-chain (AL) amyloidosis[10]
- International Kidney and Monoclonal Gammopathy Research Group[11]
- Chinese Multiple Myeloma Diagnosis and Treatment Guidelines – version 2013[12]
- Associação Brasileira de Hematologia e Hemoterapia e Terapia Celular Project guidelines: Associação Médica Brasileira – 2012[13]

Serum Reference Ranges

The most extensive serum FLC normal range study was conducted at Mayo Clinic, USA using Binding Site Freelite® assays for the BN™II[14]. In this study serum samples from 282 normal subjects aged from 21 to 90 years were assayed for κ FLC and λ FLC.

Normal Adult Serum	Mean Concn.	Median Concn.	95 %ile Range
κ FLC	8.36 (mg/L)	7.30 (mg/L)	3.30-19.40 (mg/L)
λ FLC	13.43 (mg/L)	12.40 (mg/L)	5.71-26.30 (mg/L)
	Mean	Median	Total range
κ/λ FLC ratio	0.63	0.60	0.26-1.65

Freelite® + SPE + IFE = Guideline-compliant Testing

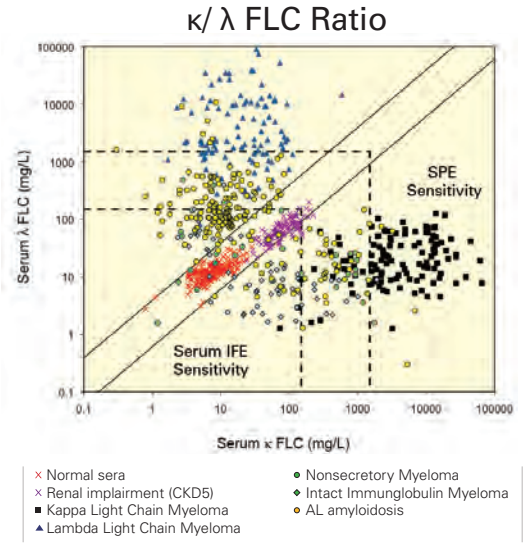


Figure of serum κ FLC and λ FLC concentrations in a selection of clinical conditions. Diagonal lines separate monoclonal from polyclonal FLC production.

The figure above shows the same normal range data (x) used to generate the reference ranges. The κ FLC and λ FLC results for each person were plotted on a logarithmic scale. This form of data presentation includes the κ/λ FLC ratio and is a useful way of visualizing results from patients with different types of Multiple Myeloma or AL amyloidosis. It also shows the number of samples that would be misclassified as negative using Serum Protein Electrophoresis (SPE) and serum Immunofixation Electrophoresis (IFE), but are detected with Freelite® assays.

The high diagnostic sensitivity of the κ/λ FLC ratio identifies additional plasma cell dyscrasias that would otherwise be negative by conventional electrophoretic techniques. In patients with renal impairment, the loss of the preferential filtration of κ FLCs means that the serum κ/λ FLC ratio can increase. As shown on the graph, some patients with chronic kidney disease (x) display slightly elevated κ/λ FLC ratios.

Freelite®
Recommended for use at Diagnosis

Issues with Traditional Assays

- There is a lack of sensitivity of SPE and IFE in FLC detection
- The historic recommendation has been to test a 24 hour urine sample for FLC (Bence Jones Protein) by urine protein electrophoresis (UPEP). However, there are difficulties with collection (patient compliance), transport, storage, processing, and assay sensitivity

In the initial laboratory investigation a strategy of performing SPE and serum κ and λ Freelite® analysis will allow identification of all significant monoclonal proteins.

In all studies, the addition of Freelite® assays to SPE for first line investigation increased the detection of Multiple Myeloma and other plasma cell disorders.[13,14,15,16,17,18,20]

Accuracy of Different Diagnostic Approaches for Monoclonal Testing

Retrospective studies show the optimal pick up rate for all paraproteins can be achieved using simply SPE or CZE (capillary zone electrophoresis) and Freelite®.[15,19-24]

Diagnostic Sensitivity

% of Paraproteins Detected

Protocols	*Multiple Myeloma[15]	**AL amyloidosis[21]	Light Chain Multiple Myeloma[20,24]	Nonsecretory Multiple Myeloma[22]
SPE alone	88	53	57	0
Freelite® alone	97	98	100	68***
SPE, **Freelite®** +/- IFE	>99	98	100	68***

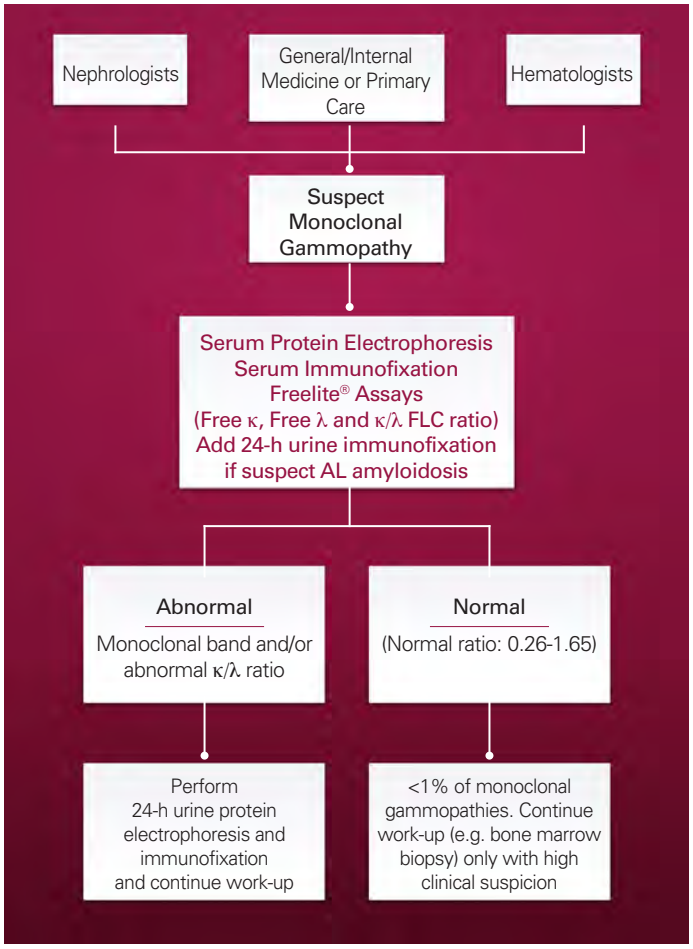
* Myeloma is inclusive of samples from patients identified with Intact Immunoglobulin Multiple Myeloma (IIMM), Light Chain Multiple Myeloma (LCMM) and Nonsecretory Multiple Myeloma (NSMM).

**According to the IMWG guidelines in AL amyloidosis a 24 hour urinalysis is still recommended.[1]

*** A further 4/28 patients with suppression of one or both FLC were identified in addition to this 68% equalling 82%.22

> "...the use of serum PEL plus FLC provides a simple and efficient initial diagnostic screen for the high-tumor-burden monoclonal gammopathies... Urine studies and serum IFE can be ordered more selectively.[13]"

Suggested Laboratory Diagnostic Pathway



SPE + IFE + Freelite® = Guideline Compliant Testing

Request Freelite®, SPE, and IFE in the initial diagnostic workup for patients suspected of having Multiple Myeloma.

Freelite®
Recommended when Monitoring

Monitor more patients accurately and easily

The International Myeloma Working Group recommends Freelite® for the quantitative monitoring of patients with oligosecretory plasma cell disorders, including patients with AL amyloidosis, oligosecretory myeloma, and in nearly two-thirds of patients previously classified as having Nonsecretory Multiple Myeloma.[1] Additionally, the International Myeloma Working Group recommends monitoring Intact Immunoglobulin Multiple Myeloma patients periodically to identify light chain escape.

Use Freelite® to quantitatively monitor patients with specific monoclonal gammopathies

- FLC have a short serum half-life (2-6 hours) which shows response to treatment faster than intact immunoglobulin measurements (half-life 20 days) [19,25,26,27]
- Freelite® is a more reliable and sensitive test than urine analysis[1]
- Improve patient outcome with early detection of light chain escape[1,28,29]

The Freelite® test gives three measurements used to assess patients with a monoclonal gammopathy.

Ratio | κ/λ FLC (measures clonality)
iFLC | involved free light chains (monoclonal FLC production)
uFLC | uninvolved free light chains (polyclonal FLC production)

Advantages of Testing with Freelite®

Freelite®	Urine Protein Electrophoresis
Serum samples	Urine samples
Easy sample collection	Very difficult to collect 24 hour urine samples (patient compliance)
Easy to store/archive samples	Difficult to store large samples
Freelite® is automation friendly	Labor intensive process
Minimal sample processing required	Concentrating of urine required
Fast result turnaround[16]	Slow result turnaround
Fully quantitative assay	Densitometry quantification
Recommended in IMWG guidelines[1]	Only recommended on suspicion of AL amyloidosis[1]

Freelite® Free Light Chain Assays

ANALYZER	DESCRIPTION	PACK	CODE
Binding Site Optilite®	**Freelite® Kappa kit** Range 0.6-63500 (mg/L), sensitivity 0.6 (mg/L)	100 test	LK016.OPT.A
	Freelite® Lambda kit Range 1.3-139000 (mg/L), sensitivity 1.3 (mg/L)	100 test	LK018.OPT.A
	Freelite® Mx Kappa kit (Urine) Range 0.33-63500 (mg/L), sensitivity 0.33 (mg/L)	100 test	LK016.M.OPT.A
	Freelite® Mx Lambda kit (Urine) Range 0.74-139000 (mg/L), sensitivity 0.74 (mg/L)	100 test	LK018.M.OPT.A
Binding Site SPAPLUS®	**Freelite® Kappa kit** Range 0.4-1800 (mg/L), sensitivity 0.4 (mg/L)	100 test	LK016.S
	Freelite® Lambda kit Range 0.45-1650 (mg/L), sensitivity 0.45 (mg/L)	100 test	LK018.S
Roche cobas™ c Systems	**Freelite® Kappa kit** Range 0.8-562 (mg/L), sensitivity 0.8 (mg/L)	100 test	LK016.CB
	Freelite® Lambda kit Range 0.7-748 (mg/L), sensitivity 0.7 (mg/L)	100 test	LK018.CB
Siemens BN™ II	**Freelite® Kappa kit** Range 0.3-15200 (mg/L), sensitivity 0.3 (mg/L)	2x50 test	LK016.T
	Freelite® Lambda kit Range 0.25-12800(mg/L), sensitivity 0.25 (mg/L)	2x50 test	LK018.T

An extended range is possible for some of the kits using manual pre-dilution where validated.

Request FREELITE® by Binding Site to help monitor patients through treatment

Improve your accuracy in detecting specific monoclonal gammopathies

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Immunodeficiency

What are immunodeficiencies?

An immunodeficiency can occur when part of the immune system is defective, most commonly leading to an increased susceptibility to infection.

Primary immunodeficiencies (PIDs) are a series of over 300 disorders caused by genetic alterations that affect cells of the immune system.

Some PIDs become apparent in childhood while others may not develop until adulthood. PIDs are often chronic but can be treated once diagnosed.[1]

Only 30% of patients that receive a diagnosis of primary immunodeficiency are under the age of 15 years[2]

The most common PIDs are those with defects in antibody production.[3]

Potential Warning Signs:

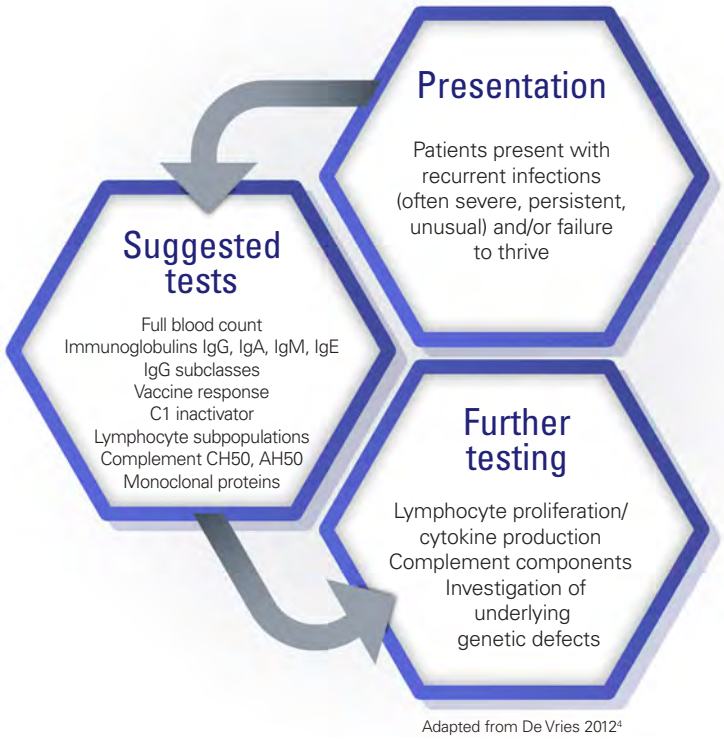
- Severe, Persistent, Unusual, or Recurrent infections (SPUR)
- Infections requiring prolonged or intravenous antibiotic therapy
- Unexplained failure of an infant to thrive
- A family history of known immunodeficiency or recurrent infections

Early diagnosis

- Improves health, quality of life, and lifespan
- Allows cost effective treatment
- Reduces healthcare expenditure

Healthcare costs can be reduced by over 50% after a patient is diagnosed with PID[5]

Diagnostic algorithm for suspected antibody deficiency



Adapted from De Vries 2012[4]

Diagnosis requires the use of information from a variety of laboratory tests.

Secondary immunodeficiencies may arise when the immune system has been compromised by external factors such as malnutrition, treatment with immunosuppressive drugs or chronic infections e.g. HIV.

Impairment can often be reversed with management of the initial condition.[6]

Reference

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IgG Subclasses

Comprehensive Menu of Assays

With extensive expertise in antibody specificity technology and commitment to disease state management and clinical guidelines, Binding Site gives clinicians and laboratory staff the tools to significantly improve diagnosis and management of patients with immune system disorders. Binding Site offers a comprehensive menu of assays for protein analysis.

For more information on Immunodeficiency Disorders (INC586) and Testing Protocols, please email us at **info@bindingsite.com**.

Proper diagnosis requires the use of information from a variety of laboratory test methods.

Specificity

For the reliable measurement of subclass concentrations Binding Site assays utilize highly specific, affinity purified, polyclonal antisera raised in sheep using patented technology.

Sensitivity

Binding Site IgG Subclass assays are optimized for use in the investigation of antibody deficiencies. Latex-enhanced reagents are provided for the measurement of IgG3 and IgG4 enabling accurate quantitation of deficient subclass levels as well as levels at the lower end of pediatric normal ranges.

Standardization

Calibration of an assay against an internationally recognized reference preparation will ensure that sample results remain accurate and consistent. In 1997 Carr-Smith et al. assigned IgG subclass values to the international serum protein reference material CRM470 which is the most commonly used reference material for commercial IgG assays. All Binding Site IgG subclass assays were subsequently calibrated against CRM470, with conversion factors available for customers wishing to compare results with those obtained in assays calibrated against the much earlier reference material WHO67/97 which is no longer available.

A new international reference material, ERM®-DA470k/IFCC(DA470k; Institute for Reference Materials and Management), has been produced. Binding Site assays have been shown to give accurate results when evaluated against this material.

Optilite Optimized Protein System

DESCRIPTION	PACK	CODE
IgG Optilite kit Range 0.165-150, sensitivity 0.165 (g/L)	100 test	NK004.OPT.A
IgG1 Optilite kit Range 150-144000, sensitivity 150 (mg/L)	100 test	NK006.OPT.A
IgG2 Optilite kit Range 0.02-22, sensitivity 0.02 (g/L)	100 test	NK007.OPT.A
IgG3 Optilite kit Range 5.5-2200, sensitivity 5.5 (mg/L)	100 test	LK008.OPT.A
IgG4 Optilite kit Range 4.3-64800, sensitivity 4.3 (mg/L)	100 test	LK009.OPT.A

SPAPLUS Special Protein Analyzer

DESCRIPTION	PACK	CODE
IgG SPAPLUS kit Range 0.165-140, sensitivity 0.165 (g/L)	100 test	NK004.S.A
IgG1 SPAPLUS kit Range 0.15-144, sensitivity 0.15 (g/L)	100 test	NK006.S.A
IgG2 SPAPLUS kit Range 0.02-22, sensitivity 0.02 (g/L)	100 test	NK007.S.A
IgG3 SPAPLUS kit Range 0.0055-4, sensitivity 0.0055 (g/L)	100 test	LK008.S.A
IgG4 SPAPLUS kit Range 0.003-3.4, sensitivity 0.003 (g/L)	100 test	LK009.S.A

Siemens BNII

DESCRIPTION	PACK	CODE
BNII Latex Combi kit (Latex IgG3 & IgG4,non-latex IgG1 & IgG2)	2x48 test	LK001.TB
IgG1 BNII kit Range 2625-84000, sensitivity 131 (mg/L)	2x40 test	NK006.TB
IgG2 BNII kit Range 613-19600, sensitivity 153 (mg/L)	4x40 test	NK007.TB
IgG3 BNII kit Range 55-875, sensitivity 2.7 (mg/L)	4x48 test	LK008.TB
IgG4 BNII kit Range 38-613, sensitivity 1.9 (g/mL)	4x48 test	LK009.TB

It is necessary to open specific channels on the analyzer and this may require the assistance of a Siemens engineer. Please inquire for further information.

DESCRIPTION	PACK	CODE
BNII COMBI kit (Non-latex IgG1, IgG2, IgG3 & IgG4)	4x40 test	NK001.T
IgG1 BNII kit Range 1310-42000, sensitivity 66 (mg/L)	2x40 test	NK006.T
IgG2 BNII kit Range 313-10000, sensitivity 78 (mg/L)	4x40 test	NK007.T
IgG3 BNII kit Range 175-5600, sensitivity 44 (mg/L)	4x48 test	NK008.T
IgG4 BNII kit Range 120-3840, sensitivity 30 (mg/L)	4x48 test	NK009.T

These non-latex kits are intended for use with BN™II pre-programmed parameters. The parameters are provided in the product insert and should be checked against the version of software on the analyzer.

Small Volume Testing

For laboratories with small numbers of patient samples or if only a small volume of sample is available (e.g. pediatric samples) IgG subclasses may be measured using radial immunodiffusion (RID, page 17).

IgA Subclasses

IgA subclass concentrations can assist in the investigation of immunodeficiency, autoimmune, and infectious diseases.

Alterations of the IgA1/IgA2 ratio have been related to specific diseases and to anaphylactic transfusion reactions. IgA2 accounts for only 15% of total IgA therefore a deficiency of IgA2 may not be detected if only total serum IgA concentrations are measured. Grossly elevated levels of either subclass may occur in patients with IgA myeloma.

Latex enhanced reagents are provided for most assays enabling the quantitation of low levels of specific antibody. Each kit contains controls, calibrators, and full instructions for running the assay.

| Units in parentheses apply to both range and sensitivity. |

Binding Site Optilite

DESCRIPTION	PACK	CODE
IgA Optilite kit Range 0.02-70 sensitivity 0.02 (g/L)	100 test	NK010.OPT.A
IgA1 Optilite kit Range 35-6000, sensitivity 35 (mg/L)	50 test	NK087.OPT.A
IgA2 Optilite kit Range 50-1250, sensitivity 50 (mg/L)	50 test	LK088.OPT.A

Binding Site SPAPLUS

DESCRIPTION	PACK	CODE
IgA SPAPLUS kit Range 20-28000, sensitivity 20 (mg/L)	100 test	NK010.S
IgA1 SPAPLUS kit Range 30-6000, sensitivity 30 (mg/L)	50 test	NK087.S
IgA2 SPAPLUS kit Range 5-1250, sensitivity 5 (mg/L)	50 test	LK088.S

Siemens BNII

DESCRIPTION	PACK	CODE
IgA1 BNII kit Range 375-6000, sensitivity 94 (mg/L)	40 test	NK087.1T
IgA2 BNII kit Range 63-1000, sensitivity 3 (mg/L)	40 test	LK088.1T
IgA subclass BNII COMBI kit (Latex IgA2, non-latex IgA1)	2x40 test	LK003.T

A new protocol must be selected in order to run these assays.

Radial Immunodiffusion

DESCRIPTION	PACK	CODE
IgA subclass COMBI -NL RID kit 2 plates IgA1 range 640-6400 mg/L 2 plates IgA2 range 50-500 mg/L	4 plate kit	RK015

The ranges quoted are achieved from the assay-specific instrument protocols.

Nephelometry

Latex Enhanced Assays

The latex enhanced nephelometric assays are provided by Binding Site for easy implementation onto existing systems. The use of particle enhancement technology increases aggregation of immune complexes generating a high level of sensitivity. These kits contain a complete package including the latex enhanced reagent, buffer, calibrators, and controls.

DESCRIPTION	PACK	CODE
IgD BNII kit Range 6.5-4150 mg/L, sensitivity 1.3 mg/L	2x50 test	LK013.T
β2 Microglobulin BNII kit for serum and urine Range 0.7-22.5 mg/L, Sensitivity 0.14 mg/L (serum), 0.04 mg/L (urine)	3x50 test	LK043.T

SPE and Immunofixation

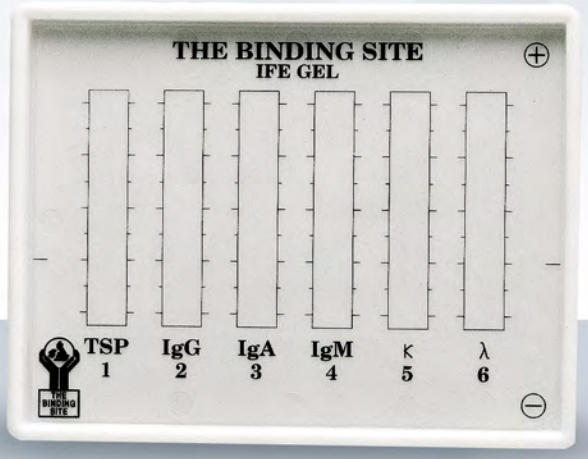
Serum Protein Electrophoresis (SPE) is particularly suitable for the initial screening of serum for monoclonal immunoglobulins and free light chains (Bence Jones proteins), aiding in the diagnosis of monoclonal gammopathies.

Immunofixation (IFE) is used to identify immunoglobulins and free light chains. Quantitation of free light chains can be performed by automated methods using Freelite® (page 10).

SPE kits contain 10 gels and reagents (sufficient for 100 tests). IFE kits contain 10 gels and reagents (sufficient for 10 samples).

Gels measure 102 x 77 mm and can be used with most popular manufacturers of electrophoresis tanks.

DESCRIPTION	PACK	CODE
Kappa (Free) IFE antisera	1.4 mL	PX016
Lambda (Free) IFE antisera	1.4 mL	PX018
IgD IFE antisera	1.4 mL	PX013
Serum Protein Electrophoresis (SPE) kit	100 test	XK003
Immunofixation (IFE) kit	10 test	XK001



Radial Immunodiffusion

The Digital RID Reader is designed to simplify and speed-up the process of reading precipitin radial immunodiffusion rings.

Radial Immunodiffusion is a well-established technique based on the complex formed between antigen and antibody, producing a visible precipitin ring in the gel. The concentration of specific proteins can be determined efficiently and accurately by measuring the precipitin ring diameter using our RID reader.

The Binding Site provides a solution to determine the precipitin ring diameter using the RID Reader or a jeweller's eye piece. Using a range of quantitative calibration methods, the RID Reader provides a diameter reading tailored for each assay kit.

With advanced software, the RID Reader is more efficient and user friendly, meeting all your laboratory needs.

The use of this software allows:

- Accuracy in reading
- Efficiency in measurement
- Confidence in results

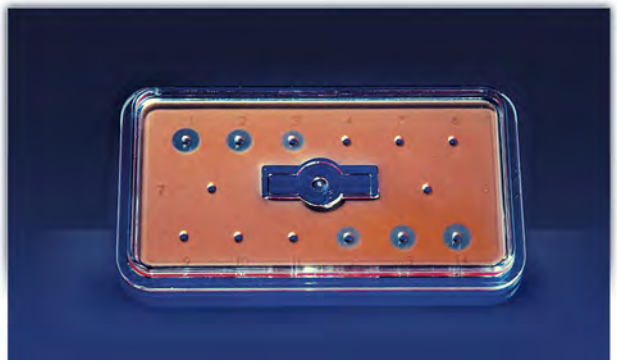
Accurate in reading and efficient in measurement

User-friendly software to enhance your experience

Advanced technology to bring you defining rings

Human Coagulation Proteins

DESCRIPTION	PACK	CODE
Antithrombin III - NL RID kit	3 plate kit	RN040.3
Fibrinogen - NL RID kit	3 plate kit	RN056.3
Plasminogen - NL RID kit	3 plate kit	RN065.3
NANORID™ Protein C RID kit	3 plate kit	GT118.3



Total Hemolytic Complement plate after hemolysis.

Human Complement Functional Assays

Functional assays are effective as screening tools to detect complement deficiencies and aid in the monitoring of total complement activity. Assays are based on the hemolysis of red blood cells following activation of the complement system.

DESCRIPTION	PACK	CODE
Total Hemolytic Complement kit	3 plate kit	RC001.3
	2 plate kit	RC001.2
	1 plate kit	RC001.1
Functional C1 Inactivator kit	3 plate kit	RC002.3
Functional C1 Inactivator COMBI kit Two plates of Functional C1 Inactivator One plate of C1 Inactivator	3 plate kit	RK019

Human Immunoglobulins

DESCRIPTION	PACK	CODE
IgG - NL RID kit	3 plate kit	RN004.3
IgG1 Subclass - SD RID kit	3 plate kit	RN106.3
IgG2 Subclass - SD RID kit	3 plate kit	RN107.3
IgG3 Subclass - SD RID kit	3 plate kit	RN108.3
IgG4 Subclass - SD RID kit	3 plate kit	RN109.3
IgG Subclass COMBI - SD RID kit One plate each of IgG1, IgG2, IgG3 and IgG4	4 plate kit	RK021
IgA - NL RID kit	3 plate kit	RN010.3
IgA Subclass COMBI kit - NL RID kit Two plates each of IgA1 and IgA2	4 plate kit	RK015
IgM - NL RID kit	3 plate kit	RN012.3
IgG, IgA, IgM COMBI - NL RID kit One plate each of IgG, IgA, and IgM	3 plate kit	RK002
IgD - NL RID kit	3 plate kit	RN013.3

Human Complement Proteins

DESCRIPTION	PACK	CODE
C1 Inactivator - NL RID kit	3 plate kit	RN019.3
C1q - NL RID kit	3 plate kit	RN020.3
C3 - NL RID kit	3 plate kit	RN023.3
C4 - NL RID kit	3 plate kit	RN025.3
C5 - NL RID kit	3 plate kit	RN027.3

Human Proteins

DESCRIPTION	PACK	CODE
Albumin - NL RID kit	3 plate kit	RN032.3
α1 - Antitrypsin - NL RID kit	3 plate kit	RN034.3
NANORID™ β2 - Microglobulin - EL RID kit	3 plate kit	GT043.3
NANORID™ CRP - EL RID kit	3 plate kit	GT044.3
Haptoglobin - NL RID kit	3 plate kit	RN058.3
Transferrin - NL RID kit	3 plate kit	RN070.3

IMMPROVE™ Quality Assurance Schemes

IMMPROVE™ Quality Assurance (QA) Schemes allow laboratories to monitor the standard of their own results over time and compare them to other methods available. Participants in the schemes are located in more than 15 countries worldwide. Laboratories may join a scheme at any time during the year. Each laboratory is allocated a reference number on registration and all reports are generated against the relevant number in order to preserve confidentiality.

In all Binding Site IMMPROVE QA Schemes the participating laboratory is asked to run the sample provided on their routine assays and report the results obtained. Following analysis of the results a report is sent to each participating laboratory. The number of samples issued per 12 months is indicated in the table.

Registration is for one year at the end of which there is the opportunity to re-register for a further year on an annual basis.

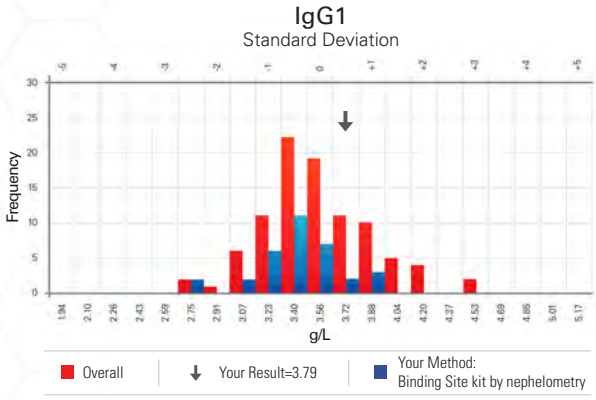
To register or re-register, please contact your local Binding Site representative for more information.

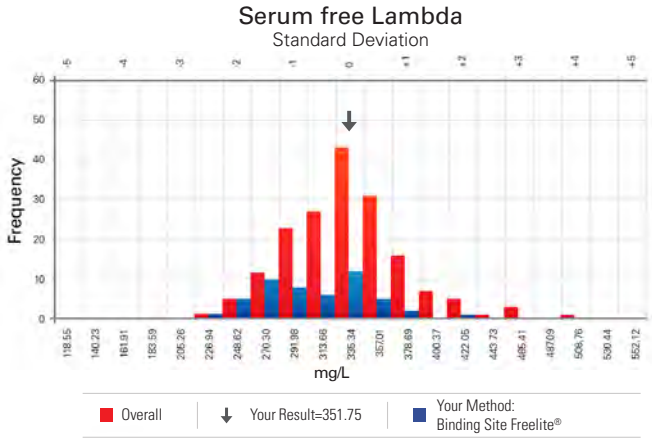
Subclass QA Scheme

This scheme is for the analysis of any or all of the following tests: IgG, IgA, IgM, IgG1, IgG2, IgG3, IgG4, IgA1 and IgA2. Results can be returned via the IMMPROVE website with password protected secure access. The report members receive provides a full statistical analysis of results with cumulative, performance related scoring. More than 170 laboratories worldwide participate.

Serum Paraprotein QA Scheme

Serum sample analysis for IgG, IgA, IgM, β2 Microglobulin, free kappa, free lambda, and the kappa/lambda (κ/λ) ratio plus screening and typing techniques. Results can be returned via the IMMPROVE website with password protected secure access. The report members receive includes a full statistical analysis of results to enable the participating laboratory to assess their performance, together with images of electrophoresis gels and interpretative comments. Over 300 laboratories participate.





Urine Paraprotein QA Scheme

Urine sample analysis for free kappa, free lambda, and the kappa/lambda (κ/λ) ratio, together with results for screening and typing. Results can be returned via the IMMPROVE website with password protected secure access. The report members receive includes a full statistical analysis of results to enable the participating laboratory to assess their performance, together with images of electrophoresis gels. Approximately 110 laboratories participate.

DESCRIPTION	PACK	CODE
IMMPROVE™ Subclass Q.A. Scheme registration	6 issues	QA001
IMMPROVE™ Serum Paraproteins Q.A. Scheme registration	4 issues	QA003
IMMPROVE™ Urine Paraproteins Q.A. Scheme registration	2 issues	QA006

Notes

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