Binding Site

International Clinical Product Listing 2022

The Specialist Protein Company

Not for use in the USA and China.

Binding Site

Binding Site is a Specialist Protein company committed to the research, development, manufacture and distribution of innovative immunodiagnostic assays and the instrumentation needed to run them, 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.

With more than 90% of our products sold overseas Binding Site is a truly international organisation. 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. We deliver a bespoke solution that meets your specific needs and expectations.

Assays for *in vitro* use have been CE marked for Europe, FDA cleared for the USA and registered by the regulatory authorities in many individual countries.

Binding Site is committed to working in a responsible way, meeting our own high standards to ensure we continue to grow as a sustainable organisation. Our systems and processes respect, benefit and protect all our employees, customers, the communities and environments in which we work. Our head office (Birmingham, UK) is designed to reduce energy and water consumption, has provisions for rainwater harvesting and meets strict carbon emission restrictions.

www.bindingsite.com

Unique assays

The Freelite® assay has allowed significant improvements in both laboratory and clinical practice for the detection and follow-up of monoclonal gammopathies. Freelite has over 3000 publications, is mentioned by name in international guidelines and it was FDA cleared in 2001 to aid in diagnosis and monitoring of multiple myeloma. The Optilite® Freelite assay offers the state of the art in free light chain testing.

Hevylite® is a unique immunoassay panel designed for identification and quantification of immunoglobulin heavy + light chain isotypes.

Freelite and Hevylite together provide a monitoring solution for the management of multiple myeloma patients.

Immune status

Binding Site is a market leader in the development of products for the investigation of immune status including Primary Immunodeficiency Diseases (PID). Our current range of specialised products includes assays for measuring specific antibody response to vaccination, quantifying immunoglobulins and subclasses and measuring complement proteins.

Dedicated support

We pride ourselves in providing unrivalled after sales support built on 3 key areas: product installation & evaluation, technical & functional product training and front line product guidance & support.

Index

Optilite®

Optimised and proven special protein analysis

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Optimised and proven special protein analysis

Optilite delivers innovation in special protein testing, fully optimised to create simplicity from complex analytical processes. It is the culmination of over 25 years of cutting edge research from Binding Site - the global leaders in special proteins.

Optilite combines an extensive range of smart working features to bring you a new level of efficiency, workflow optimisation and confidence in results.

Developed in response to your evolving needs, Optilite is the natural successor to the SPAPLUS® protein analyser. Integrating powerful technology and intelligent software, it is the perfect solution for the modern protein laboratory.

Enhance your efficiency

Save time and reduce your costs with this easy-to-use, intelligent system

- Boost your productivity with consistently reliable performance
- Minimise your reagent usage through optimised assay protocols
- Maximise your test throughput with continuous loading / unloading
- Save space in your laboratory with this compact, self-contained design

Increase your confidence

Be sure that you will always provide the best possible special protein service

- Trust your results with three methods of antigen excess detection providing unparalleled protection
- Simplify data security through automatic lot number recognition and full traceability
- Enhance your reputation by using the latest special protein system available
- Feel valued with dedicated technical and scientific support from special protein experts

Optimise your workflow

Streamline your workload for smart resource management and optimal productivity

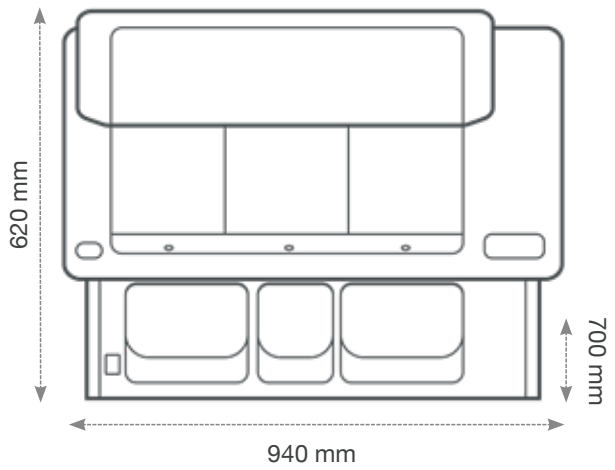
- Prioritise effectively with flexible, unrestricted access to samples, reagents and cuvettes
- Minimise sample preparation time by loading any combination of sample tubes and fluid types
- Simplify sample ordering and result analysis with automatic bar coded identification and full LIS connectivity
- Eliminate manual sample dilution with Optilite built-in automatic dilution to end result

Optilite analyser and accessories

DESCRIPTION	PACK	CODE
Optilite Optimised 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	6	IK707
Optilite Diluent 1	6	IK709
Optilite Diluent 2	6	IK710
Optilite Diluent 3	3	IK711
Optilite Cal QC Rack	3	IK712
Optilite Sample Rack (7 position)	6	IK713
Optilite Sample Rack (9 position)	6	IK714
Optilite Sample Rack (9 position) - Blue	3	IK716
0.5mL Sample Cups	1000	989220

Optilite physical specification

Dimensions:	Width	940mm
	Depth	700mm
	Height	620mm
	Weight	110kg



Optilite assays

DESCRIPTION	PACK	CODE
Monoclonal Gammopathies		
Freelite Kappa Latex kit Range 0.60-127000, sensitivity 0.6 (mg/L)	100 test	LK016.OPT
Freelite Lambda Latex kit Range 1.30-139000, sensitivity 1.3 (mg/L)	100 test	LK018.OPT
Hevylite IgG Kappa kit Range 0.115-120, sensitivity 0.115 (g/L)	50 test	NK621.OPT
Hevylite IgG Lambda kit Range 0.075-105, sensitivity 0.075 (g/L)	50 test	NK622.OPT
Hevylite IgA Kappa kit Range 0.018-112, sensitivity 0.018 (g/L)	50 test	NK623.OPT
Hevylite IgA Lambda kit Range 0.016-104, sensitivity 0.016 (g/L)	50 test	NK624.OPT
Hevylite IgM Kappa Latex kit Range 0.02-150, sensitivity 0.02 (g/L)	50 test	NK625.OPT
Hevylite IgM Lambda Latex kit Range 0.018-135, sensitivity 0.018 (g/L)	50 test	NK626.OPT
Immunoglobulins		
IgG kit Range 0.165-140, sensitivity 0.165 (g/L)	100 test	NK004.OPT
IgA kit Range 0.02-70, sensitivity 0.02 (g/L)	100 test	NK010.OPT
IgM kit Range 0.10-150, sensitivity 0.10 (g/L)	100 test	NK012.OPT
IgD Latex kit Range 0.013-16.8, sensitivity 0.013 (g/L)	100 test	LK013.OPT
IgE Reagent Range 10-5000, sensitivity 10 (IU/mL)	100 test	LK014.OPT
Subclasses		
IgG1 kit Range 0.15-144, sensitivity 0.15 (g/L)	100 test	NK006.OPT
IgG2 kit Range 0.02-28, sensitivity 0.02 (g/L)	100 test	NK007.OPT
IgG3 Latex kit Range 0.0055-8.8, sensitivity 0.0055 (g/L)	100 test	LK008.OPT
IgG4 Latex kit Range 0.0043-64.8, sensitivity 0.0043 (g/L)	100 test	LK009.OPT
IgA1 kit Range 0.035-6, sensitivity 0.035 (g/L)	50 test	NK087.OPT
IgA2 Latex kit Range 0.005-1.25, sensitivity 0.005 (g/L)	50 test	LK088.OPT

The ranges quoted are achieved using the assay specific automatic re-dilution protocols. Units in brackets apply to both range and sensitivity.

The assays detailed here are CE marked. We also offer FDA cleared assays. Please contact your local representative for information on FDA cleared assays.

Please see page 8 for more Optilite Assays.

Optilite®

Optilite assays continued

DESCRIPTION	PACK	CODE
Complement		
C1 inactivator kit Range 0.08-0.88, sensitivity 0.08 (g/L)	50 test	NK019.OPT
C3c kit Range 0.025-6, sensitivity 0.025 (g/L)	100 test	NK023.OPT
C4 kit Range 0.0064-1.8, sensitivity 0.0064 (g/L)	100 test	NK025.OPT
CH50 Reagent Range 12.5 - 100, sensitivity 12.5 (U/mL)	100 test	NK095.OPT
Renal function		
Albumin kit Range 3.1-77, sensitivity 3.1 (g/L)	100 test	NK032.OPT
α1-Microglobulin Urine kit Range 5-1000, sensitivity 5 (mg/L)	100 test	NK036.U.OPT
α1-Macroglobulin Urine Kit Range 2.7- 85, sensitivity 2.7 (mg/L)	100 test	NK039.U.OPT
β2-Microglobulin Latex kit Range 0.3-40, sensitivity 0.3 (mg/L)	100 test	LK043.OPT
β2-Microglobulin Urine Latex kit Range 0.03-200, sensitivity 0.03 (mg/L)	100 test	LK043.L.OPT
Cystatin C Latex kit Range 0.4-12, sensitivity 0.4 (mg/L)	100 test	LK048.OPT
Low Level Albumin kit* Range 11-66500, sensitivity CSF/Urine 11, Serum 2200 (mg/L)	100 test	NK032.L.OPT
Low Level IgG kit* Range 7.5-27000, sensitivity CSF/Urine 7.5, Serum 1500 (mg/L)	60 test	NK004.LL.OPT
Transferrin Urine kit Range 2-600, sensitivity 2 (mg/L)	100 test	NK070.U.OPT
Central nervous system disorders		
Freelite Mx™ Kappa Latex kit* Range 0.33-127000 Sensitivity 0.33 (mg/L)	100 test	LK016.M.OPT
Freelite Mx™ Lambda Latex kit* Range 0.74-139000 Sensitivity 0.74 (mg/L)	100 test	LK018.M.OPT
IgA CSF kit* Range 0.91-8000, sensitivity CSF 0.91, Serum 330 (mg/L)	60 test	LK010.L.OPT
IgM CSF kit* Range 0.11-3200, sensitivity CSF 0.11, Serum 60 (mg/L)	60 test	LK012.L.OPT
Low Level Albumin kit* Range 11-66500, sensitivity CSF/Urine 11, Serum 2200 (mg/L)	100 test	NK032.L.OPT
Low Level IgG kit* Range 7.5-27000, sensitivity CSF/Urine 7.5, Serum 1500 (mg/L)	60 test	NK004.LL.OPT

The ranges quoted are achieved using the assay specific automatic re-dilution protocols. Units in brackets apply to both range and sensitivity.

* Measuring range is dependent on sample type. See product insert for further information.

Please contact your local representative for details of other assays in development.

DESCRIPTION	PACK	CODE
Specific proteins		
α1-Acid Glycoprotein kit Range 0.19-6, sensitivity 0.19 (g/L)	100 test	NK063.OPT
α1-Antitrypsin kit Range 0.35-5, sensitivity 0.35 (g/L)	100 test	NK034.OPT
α2-Macroglobulin kit Range 0.2-6.4, sensitivity 0.2 (g/L)	100 test	NK039.OPT
Anti-streptolysin O Latex kit Range 5-1600, sensitivity 5 (IU/mL)	100 test	LK189.OPT
Apolipoprotein A1 Reagent Range 0.048-5.5, sensitivity 0.048 (g/L)	100 test	NK085.OPT
Apolipoprotein B Reagent Range 0.065-5.5, sensitivity 0.065 (g/L)	100 test	NK086.OPT
Caeruloplasmin kit Range 0.04-1.64, sensitivity 0.04 (g/L)	50 test	NK045.OPT
C-Reactive Protein Reagent Range 5-1425, sensitivity 5 (mg/L)	100 test	NK044.OPT
Haptoglobin kit Range 0.026-8, sensitivity 0.026 (g/L)	100 test	NK058.OPT
High Sensitivity C-Reactive Protein kit Range 0.5-10, sensitivity 0.5 (mg/L)	100 test	LK044.L.OPT
Lipoprotein (a) Reagent Range 3.38-440, sensitivity 3.38 (nmol/L)	100 test	LK098.OPT
Prealbumin kit Range 0.006-0.8, sensitivity 0.006 (g/L)	100 test	NK066.OPT
Rheumatoid Factor kit Range 7-6500, sensitivity 7 (IU/mL)	100 test	LK151.OPT
Tetanus toxoid kit Range 1.667-50, sensitivity 1.667 (IU/mL)	200 test	LK110.OPT
Total Protein Reagent Range 0.5-300, sensitivity 0.5 (g/L)	100 test	NK061.OPT
Transferrin kit Range 0.14-22.4, sensitivity 0.14 (g/L)	100 test	NK070.OPT
Optilite calibrators		
Apolipoprotein A1 Calibrator	1 pack	NC085.OPT
Apolipoprotein B Calibrator	1 pack	NC086.OPT
CH50 Calibrator	1 pack	NC095.OPT
C-Reactive Protein Calibrator	1 pack	NC044.OPT
IgE Calibrator	1 pack	NC014.OPT
Lipoprotein (a) Calibrator	1 pack	NC098.OPT
Total Protein Calibrator	1 pack	NC061.OPT
Optilite controls		
Apolipoprotein A1 Controls x2 L, x2 H	1 pack	NQ085.OPT
Apolipoprotein B Controls x2 L, x2 H	1 pack	NQ086.OPT
CH50 Controls x4 L, x4 H, x4 Elevated	1 pack	NQ095.OPT
C-Reactive Protein Controls x2 L, x2 H	1 pack	NQ044.OPT
IgE Controls x2L, x2H,	1 pack	NQ014.OPT
Lipoprotein (a) Controls x2 L, x2 H	1 pack	NQ098.OPT
Total Protein Controls x2 L, x2 H	1 pack	NQ061.OPT

Freelite®

Free light chain assays &

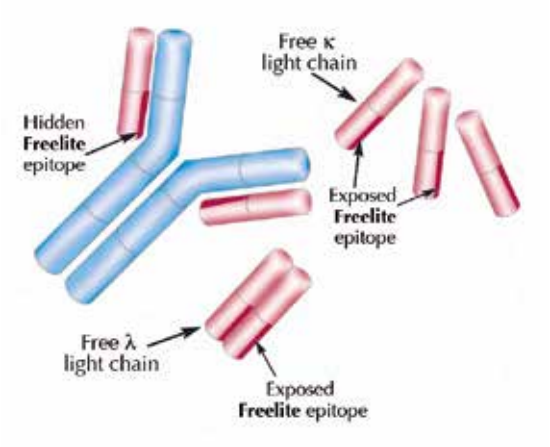
Hevylite®

Heavy + light chain isotype assays

Learn more about Freelite & Hevylite
for myeloma patient management

Freelite®

Free light chain assays



The **Freelite** assay is composed of two sensitive and specific polyclonal immunodiagnostic tests to measure κ & λ free light chains (FLCs) in serum.

Affinity purified polyclonal antibodies, reacting specifically with κ or 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 κ/λ FLC ratio is a sensitive marker of light chain clonality.

International Myeloma Working Group (IMWG) recommend Freelite for use:[1,2,3]

- At diagnosis - to confirm disease state
- When monitoring - to measure response to treatment

Key terminology

TERM	DEFINITION	EXAMPLE IN A λ LCMM PATIENT
iFLC	Involved free light chains (measures monoclonal FLC production)	λ
uFLC	Uninvolved free light chains (measures polyclonal FLC production)	κ
FLC Ratio	κ/λ sFLC (indicates clonality)	κ/λ
dFLC	iFLC – uFLC	λ–κ

Reference ranges

NORMAL ADULT SERUM	95 PERCENTILE RANGE
κ FLC	3.30 - 19.40 mg/L
λ FLC	5.71 - 26.30 mg/L
	100 PERCENTILE RANGE
κ/λ FLC ratio	0.26 - 1.65

Freelite serum free light chain assays

Ranges quoted are for initial recommended sample dilution. An extended range is possible for all kits using automatic instrument dilutions and manual pre-dilutions where validated. Units in brackets apply to both range and sensitivity.

ANALYSER	DESCRIPTION	PACK	CODE
Binding Site Optilite®	Freelite Kappa Latex kit Range 2.9-127, sensitivity 0.6 (mg/L)	100 test	LK016.OPT
	Freelite Lambda Latex kit Range 5.2-139, sensitivity 1.3 (mg/L)	100 test	LK018.OPT
Roche cobas c™ Systems c501/c502	Freelite Kappa Latex kit Range 3.7-56.2 , sensitivity 0.8 (mg/L)	100 test	LK016.CB
	Freelite Lambda Latex kit Range 5.6-74.8, sensitivity 0.7 (mg/L)	100 test	LK018.CB
Siemens BN™ II	Freelite Kappa Latex kit Range 5.9-190, sensitivity 0.3 (mg/L)	2x50 test	LK016.T
	Freelite Lambda Latex kit Range 5-160, sensitivity 0.25 (mg/L)	2x50 test	LK018.T
Siemens BN ProSpec™	Freelite Kappa Latex kit Range 5.9-190, sensitivity 0.3 (mg/L)	2x50 test	LK016.P
	Freelite Lambda Latex kit Range 5-160, sensitivity 0.25 (mg/L)	2x50 test	LK018.P

Please see page 36 for information on Freelite in CSF testing.

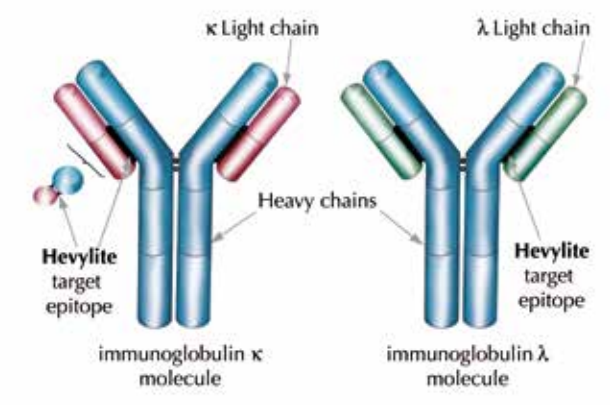
1. Dispenzieri A, et al. International Myeloma Working Group guidelines for serum-free light chain analysis in multiple myeloma and related disorders. Leukemia 2009; 23:215-224

2. Rajkumar SV, et al. International Myeloma Working Group updated criteria for the diagnosis of multiple myeloma. Lancet Oncology 2014; 15:e538-e548

3. Kumar S, et al. International Myeloma Working Group consensus criteria for response and minimal residual disease assessment in multiple myeloma. Lancet Oncology 2016; 17:e328-346

Hevylite®

Heavy + light chain isotype assays



The Hevylite assay works by targeting epitopes between the heavy chain and light chain constant regions.

Hevylite assays identify and quantify individual heavy + light chain isotypes, i.e. IgGκ, IgGλ, IgAκ, IgAλ, IgMκ and IgMλ. These molecules are measured in pairs e.g. IgGκ/IgGλ to produce ratios in the same way as the κ/λ serum FLC ratio.

Use Hevylite:

- At diagnosis - to baseline for monitoring
- When monitoring - intact immunoglobulin multiple myeloma patients

Key terminology

TERM	DEFINITION	EXAMPLE IN AN IgGK PATIENT
iHLC	Involved heavy + light chain isotype (measures monoclonal production)	IgGκ
uHLC	Uninvolved heavy + light chain isotype (measures polyclonal production)	IgGλ
HLC Ratio	Indicates clonality	IgGκ/IgGκ
dHLC	iHLC – uHLC	IgGκ-IgGλ
HLC pair suppression	uHLC below reference interval + ratio abnormal	Low IgGλ

Reference ranges

NORMAL ADULT SERUM	95 PERCENTILE RANGE FOR OPTILITE®
IgG Kappa IgG Lambda IgGκ/IgGλ Ratio	4.03 - 9.78 g/L 1.97 - 5.71 g/L 0.98 - 2.75
IgA Kappa IgA Lambda IgAκ/IgAλ Ratio	0.588 - 2.984 g/L 0.432 - 2.035 g/L 0.911 - 2.416
IgM Kappa IgM Lambda IgMκ/IgMλ Ratio	0.19 - 1.63 g/L 0.12 - 1.01 g/L 1.18 - 2.74

Hevylite heavy + light chain isotype assays

Ranges quoted are for initial recommended sample dilution. An extended range is possible for all kits using automatic instrument dilutions and manual pre-dilutions where validated. Units in brackets apply to both range and sensitivity.

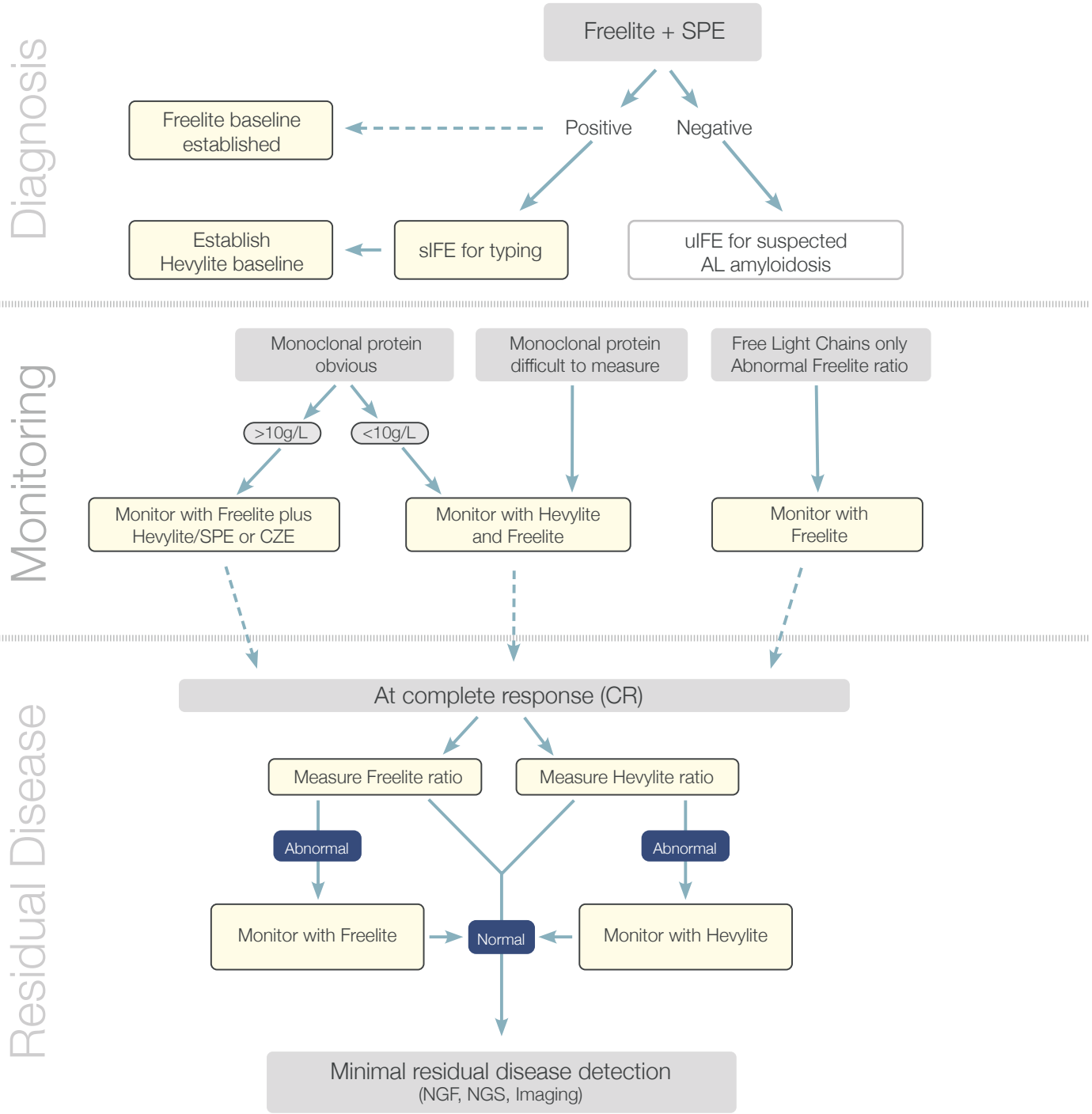
ANALYSER	DESCRIPTION	PACK	CODE
Binding Site Optilite®	Hevylite IgG Kappa kit Range 2.3-30, sensitivity 0.115 (g/L)	50 test	NK621.OPT
	Hevylite IgG Lambda kit Range 1.5-17.5, sensitivity 0.075 (g/L)	50 test	NK622.OPT
	Hevylite IgA Kappa kit Range 0.18-11.2, sensitivity 0.018 (g/L)	50 test	NK623.OPT
	Hevylite IgA Lambda kit Range 0.16-10.4, sensitivity 0.016 (g/L)	50 test	NK624.OPT
	Hevylite IgM Kappa Latex kit Range 0.2-5, sensitivity 0.02 (g/L)	50 test	NK625.OPT
	Hevylite IgM Lambda Latex kit Range 0.18-4.5, sensitivity 0.018 (g/L)	50 test	NK626.OPT

Freelite® & Hevylite®

Free light chain assays Heavy + light chain isotype assays

Freelite and Hevylite in the management of monoclonal gammopathies

(in conjunction with other laboratory tests and clinical findings)



SPE = Serum Protein Electrophoresis
sIFE = serum Immunofixation Electrophoresis
uIFE = urine Immunofixation Electrophoresis
NGS = Next Generation Sequencing
NGF = Next Generation Flow Cytometry
CZE = Capillary Zone Electrophoresis

LCMM = Light Chain Multiple Myeloma
MGUS = Monoclonal Gammopathy of Undetermined Significance
NICE = National Institute for Clinical Excellence
HLC = Heavy Light Chain
FLC = Free Light Chain
sFLC = serum Free Light Chain
UPE = Urine Protein Electrophoresis

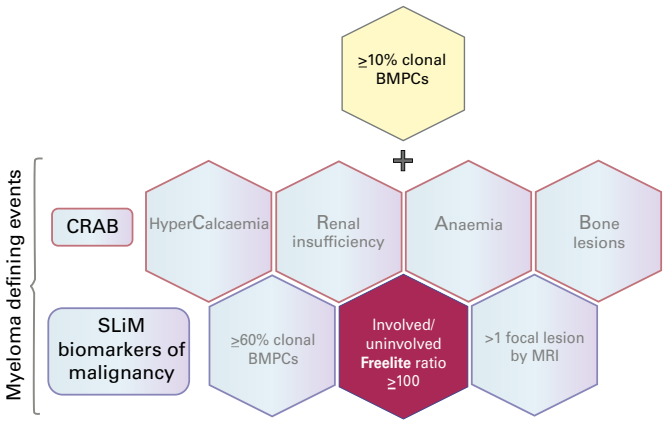
Freelite for diagnosis

Diagnostic criteria

The IMWG guidelines recommend Freelite for the diagnosis of monoclonal gammopathies in conjunction with other laboratory tests and clinical findings.[1] The Freelite assays quantitatively measure free light chains and improve diagnostic sensitivity when used in combination with serum electrophoresis.[2]

IMWG criteria for diagnosis of multiple myeloma

A diagnosis of MM requires the presence of at least one myeloma defining event PLUS ≥10% clonal bone marrow plasma cells (BMPCs) or biopsy-proven bony or extramedullary plasmacytoma: [3]



An involved/uninvolved sFLC ratio ≥100 is now a recognised biomarker of malignancy (based on Freelite assay, when iFLC is ≥100mg/L). [3]

Benefits of testing serum with Freelite

- Avoid potential missed diagnoses when a urine sample is not available[4]
- A serum only algorithm of SPE + Freelite has greater sensitivity for detection of myeloma than SPE + serum IFE + urine IFE[2]
- Earlier diagnosis may reduce disease-related complications such as renal damage[5]
- More LCMM patients have measurable disease by sFLC levels than urine protein electrophoresis at diagnosis and during disease monitoring[6]

National Institute for Health and Care Excellence (NICE, UK) guidelines now recommend SPE and sFLC assessment to screen for monoclonal protein in patients with suspected myeloma.

MGUS risk stratification

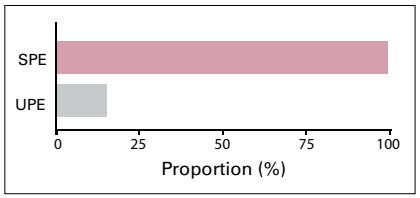
Monoclonal gammopathy of undetermined significance (MGUS) is a pre-malignant, asymptomatic disorder estimated to affect 3% of the population aged ≥50 years.[7] Patients with MGUS progress to myeloma or a related malignancy at around 1% per year.[8]

IMWG guidelines for MGUS risk stratification are based on three independent risk factors:[9]

1. Abnormal κ/λ sFLC ratio
2. Serum monoclonal protein ≥15 g/L
3. IgA or IgM type

A fourth risk factor, Heavy Light Chain (HLC) pair suppression (Hevylite, page 24) is also an independent risk factor for MGUS progression.[10]

> *…urine testing was only done in a fraction of the people being tested. This could have resulted in potential missed diagnosis if the serum free light chain test was not performed as an alternative*[4]



UK National Pathology Benchmarking Review[5]

1. Dispenzieri A, et al. International Myeloma Working Group guidelines for serum-free light chain analysis in multiple myeloma and related disorders. Leukemia 2009; 23:215-224
2. Katzmann JA, et al. Screening panels for detection of monoclonal gammopathies. Clin Chem 2009; 55:1517-22
3. Rajkumar SV, et al. International Myeloma Working Group updated criteria for the diagnosis of multiple myeloma. Lancet Oncology 2014; 15:e538-e548
4. Myeloma: diagnosis and management. NICE Guidelines NG35, 2016
5. Holding S, et al. Use of serum free light chain analysis and urine protein electrophoresis for detection of monoclonal gammopathies. Clin Chem Lab Med 2011; 49:83-8
6. Dejoie T, et al. Serum free light chains, not urine specimens, should be used to evaluate response in light-chain multiple myeloma. Blood 2016; 128:2941-2948
7. Kyle RA, et al. Long-term follow-up of monoclonal gammopathy of undetermined significance. N Engl J Med 2018; 378:241-249
8. Kyle RA, et al. A long-term study of prognosis in monoclonal gammopathy of undetermined significance. N Engl J Med 2002; 346:564-569
9. Kyle RA, et al. Monoclonal gammopathy of undetermined significance (MGUS) and smoldering (asymptomatic) multiple myeloma: IMWG consensus perspectives risk factors for progression and guidelines for monitoring and management. Leukemia 2010; 24:1121-1127
10. Katzmann J, et al. Suppression of uninvolved immunoglobulins defined by heavy/light chain pair suppression is a risk factor for progression of MGUS. Leukemia 2013; 27:208-212

Freelite® & Hevylite®

Free light chain assays Heavy + light chain isotype assays

Freelite for diagnosis

AL amyloidosis

Primary systemic or light chain Amyloidosis (AL) is characterised by accumulation of monoclonal FLCs or their fragments as insoluble amyloid fibrils, leading to functional and structural organ damage.

Freelite allows detection of up to 98% of AL amyloidosis cases and can quantitatively monitor most AL amyloidosis patients[1]. Evaluation of sFLCs at baseline provides important information in AL amyloidosis, and is recommended in IMWG guidelines.[1]

Haematological response criteria for AL amyloidosis are based on FLC measurements, with significantly different outcomes for the different response categories.[2]

RESPONSE CATEGORY	DEFINITION
Complete response	Normalisation of sFLC levels and ratio, negative serum and urine immunofixation
Very good partial response	A reduction in the dFLC to <40mg/L
Partial response	A >50% reduction in the dFLC
No response	Less than a partial response

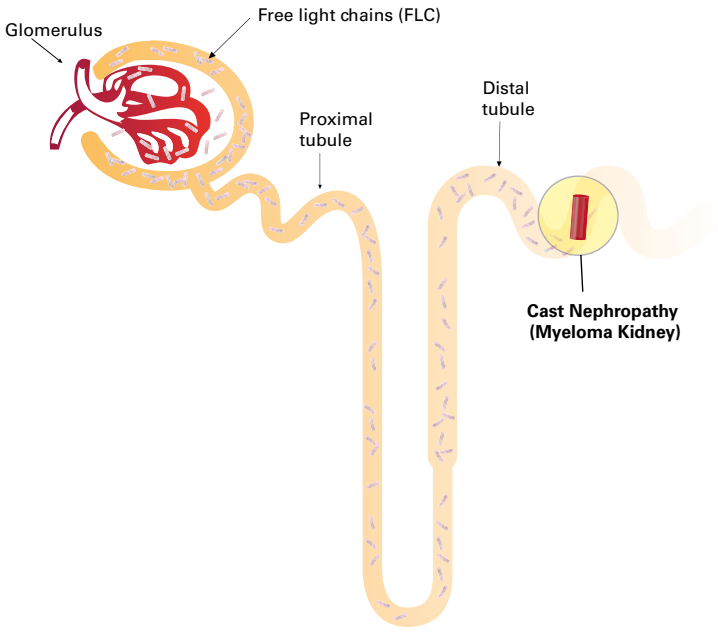
Studies have shown that AL amyloidosis is the most common form of cardiac amyloidosis[3] and that early diagnosis and prompt treatment is associated with improved survival.[4]

> *Routine use of the immunoglobulin FLC assay in patients with unexplained heart failure may be a relatively efficient, economical and non-invasive means to screen patients with AL amyloidosis.*[4]

Myeloma in patients with acute kidney injury (AKI)

Up to 45% of newly diagnosed myeloma patients may have renal insufficiency.[5]

AKI has many causes including the presence of nephrotoxic free light chains. Irreversible kidney damage may be prevented by early detection of nephrotoxic monoclonal FLCs, and prompt myeloma treatment. The International Kidney and Monoclonal Gammopathy Research Group recommend sFLC analysis in the investigation of new, unexplained AKI.[6]



1. Dispenzieri A, et al. International Myeloma Working Group guidelines for serum-free light chain analysis in multiple myeloma and related disorders. Leukemia 2009; 23:215-224
2. Comenzo RL, et al. Consensus guidelines for the conduct and reporting of clinical trials in systemic light-chain (AL) amyloidosis. Leukemia 2012; 26: 2317-2325
3. Gertz MA, et al. Pathophysiology and treatment of cardiac amyloidosis. Nat. Rev. Cardiol 2015; 12:91-102
4. Grogan M, et al. Light-chain cardiac amyloidosis: strategies to promote early diagnosis and cardiac response. Heart 2017; 103:1065-1072
5. Dimopoulos MA, et al. Significant improvement in the survival of patients with multiple myeloma presenting with severe renal impairment after the introduction of novel agents. Ann Oncol 2014; 25:195-200
6. Hutchison CA, et al. The pathogenesis and diagnosis of acute kidney injury in multiple myeloma. Nat Rev Nephrol 2011; 8:43-51

Freelite for monitoring

Freelite enhances multiple myeloma monitoring

Measurement of involved dFLC aids monitoring in AL amyloidosis and multiple myeloma patients. Guidelines recommend dFLC measurement instead of the κ/λ FLC ratio, determined using Freelite, as it provides a better assessment of response to therapy.[1]

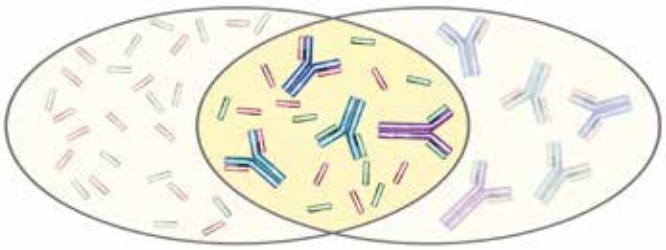
> *For serial measurements, either the involved FLC or the difference between the involved and uninvolved (dFLC) should be used.*[1]

Use Freelite as a highly sensitive monitoring tool for:

- Rapid evaluation of response to therapy & early relapse[2]
- Detection of stringent complete response[3]
- Identification of light chain escape[1]

Freelite & Hevylite for monitoring

Freelite and Hevylite measure independent biomarkers in multiple myeloma:



Freelite
measures free light chains (mg/L)

Hevylite
measures intact immunoglobulins (g/L)

Use together
in conjunction with other tests for optimal management of myeloma patient care

Key guidelines

YEAR	GUIDELINES
2016	International Myeloma Working Group consensus criteria for response and minimal residual disease assessment in multiple myeloma. Kumar S, *et al. Lancet Oncol* 2016; 17:e328-46
2016	National Institute for Health and Care Excellence (NICE). Myeloma: diagnosis and management. NICE Guidelines NG35 2016
2016	National Comprehensive Cancer Network (NCCN). Clinical practice Guidelines in Oncology - Multiple Myeloma Kumar SK, *et al. J Natl Compr Canc Netw* 2017; 15:230-69
2014	International Myeloma Working Group updated criteria for the diagnosis of multiple myeloma. Rajkumar SV, *et al*. *Lancet Oncology* 2014; 15:e538-e548
2014	International Myeloma Working Group recommendations for global myeloma care. Ludwig H, *et al*. *Leukemia* 2014; 28:981-992
2012	New criteria for response to treatment in immunoglobulin light chain amyloidosis based on free light chain measurement and cardiac biomarkers: impact on survival outcomes. Palladini, *et al*. *J Clin Onc* 2012; 30:4541-4549
2011	Consensus recommendations for the uniform reporting of clinical trials: report of the International Myeloma Workshop Consensus Panel 1. Rajkumar SV, *et al*. *Blood* 2011; 117:4691-4695
2010	Monoclonal gammopathy of undetermined significance (MGUS) and smoldering (asymptomatic) multiple myeloma: IMWG consensus perspectives risk factors for progression and guidelines for monitoring and management. Kyle RA, *et al*. *Leukemia* 2010; 24:1121-1127
2009	International Myeloma Working Group guidelines for serum-free light chain analysis in multiple myeloma and related disorders. Dispenzieri A, *et al*. *Leukemia* 2009; 23:215-224
2006	International uniform response criteria for multiple myeloma. Durie BGM, *et al*. *Leukemia* 2006; 20:1467-1473

1. Dispenzieri A, et al. International Myeloma Working Group guidelines for serum-free light chain analysis in multiple myeloma and related disorders. Leukemia 2009; 23:215-224
2. Fuchida SI, et al. Serial measurement of free light chain detects poor response to therapy early in three patients with multiple myeloma who have measurable M-proteins. Int J Hematol 2012; 96:664-668
3. Kumar S, et al. Lancet Oncol 2016; 17:e328-46

FLC = free light chain
sFLC = serum free light chain
IMWG = International Myeloma Working Group
AKI = acute kidney injury
dFLC = involved free light chain - uninvolved free light chain
iFLC = involved free light chain
SPE = serum protein electrophoresis
IFE = immunofixation electrophoresis

Hevylite®

Heavy + light chain isotype assays

Hevylite for monitoring

Hevylite is fully quantitative

Hevylite can be used when traditional electrophoresis methods (SPE/IFE) are inaccurate or insensitive. Quantitative numerical values by Hevylite make it easier to monitor multiple myeloma patients.

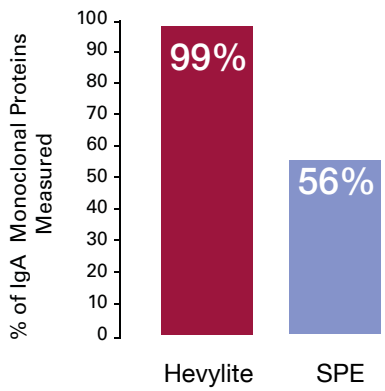
IgA monoclonal proteins that co-migrate into the β-region on SPE can be difficult to measure – this happens in about 44% of samples - but Hevylite accurately quantifies them.[1-6]

COMPARISON OF INFORMATION	HEVY-LITE	SPE	IFE
Quantification of monoclonal protein	✓	✓	✗
Typing of monoclonal protein	✓*	✗	✓
Avoids subjective interpretation	✓	✗	✗
Accurate measurements below 10g/L	✓	✗	✗
Quantification of uninvolved HLC (unique immunosuppression data)	✓	✗	✗

* Run 6 Hevylite assays for typing

Hevylite overcomes the difficulty in measuring IgA monoclonal protein

- Improve result accuracy when IgA is difficult to quantify
- Quantitative analysis for better monitoring
- Save time by using one assay to monitor instead of using both IFE plus Total IgA



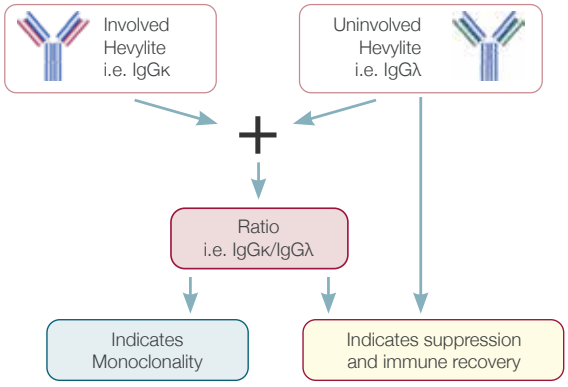
In combined studies of more than 430 patients, only 56% of IgA monoclonal proteins were measurable by SPE but 99% were measurable with Hevylite[1-6]

Measuring therapy response using Hevylite is clinically relevant [7]

- A study of over 500 myeloma patients compared the response categories assigned to patients following therapy (e.g. complete response), as measured either by Hevylite or IMWG methods (SPE, IFE)
- In a high number of patients, results from Hevylite indicated better therapy response - this was supported by improved outcomes
- Overall this study indicates that Hevylite adds clinical value to current methods when assessing patient response to therapy

Measure immune recovery with a simple serum test

Analysis using Hevylite provides a unique measure of immuno-suppression and immune recovery in multiple myeloma; this is not available from traditional techniques. Normal uninvolved heavy light chain levels post therapy are associated with improved outcomes.[7,8]



1. Boyle E, et al. IgA kappa/IgA lambda heavy/light chain assessment in the management of patients with IgA myeloma. Cancer 2014; 120:3952-3957
2. Elssner-Freund J, et al. IgA subtypes: A supplement to M-protein quantification by electrophoretic methods in monitoring patients with multiple myeloma. Hematology Reports 2015; 7:F102a
3. Ludwig H, et al. Immunoglobulin heavy/light chain ratios improve paraprotein detection and monitoring, identify residual disease and correlate with survival in multiple myeloma patients. Leukemia 2013, 27:213-219
4. Amolak B, et al Assessment of IgA heavy/light chain immunoassays utility in multiple myeloma patients. Biochimica Clinica 2013; 37:W233a
5. Bengoufa D, et al Usefulness of a hevylite immunoassay in serum for the diagnosis and the follow up of IgA monoclonal gammopathy. Hematology Reports 2010; 2:G68a
6. Steele PS, et al Evaluation of novel nephelometric assays for the quantification of serum immunoglobulins in monoclonal gammopathies. Hematology Reports 2010; 2:F60a
7. Michallet M, et al. Heavy+light chain monitoring correlates with clinical outcome in multiple myeloma patients. Leukemia 2018; 32:376-382
8. Harutyunyan NM, et al. Levels of uninvolved immunoglobulins predict clinical status and progression-free survival for multiple myeloma patients. Br J Haematol 2016; 174:81-87

Specialist Immunology Assays

Learn more about our comprehensive assay range

Assessment of Immune Status

Measurement of the proteins of the innate and the adaptive immune systems is an important step in the evaluation of immune competence such as in the diagnosis of immunodeficiency and the investigation of immune-mediated disease states which may result from dysregulation of the normal immune response.

> ***Immunodeficiency:*** *A state in which the immune system's ability to fight infectious disease is compromised or entirely absent*

Comprehensive menu of assays

With extensive expertise in antibody specificity technology and commitment to disease state management, Binding Site gives clinicians and laboratory staff the tools to significantly improve diagnosis and management of patients with immune system disorders. The comprehensive test menu is aligned to the clinical guidelines, including assays for immunoglobulins, subclasses, vaccine response and complement screening.

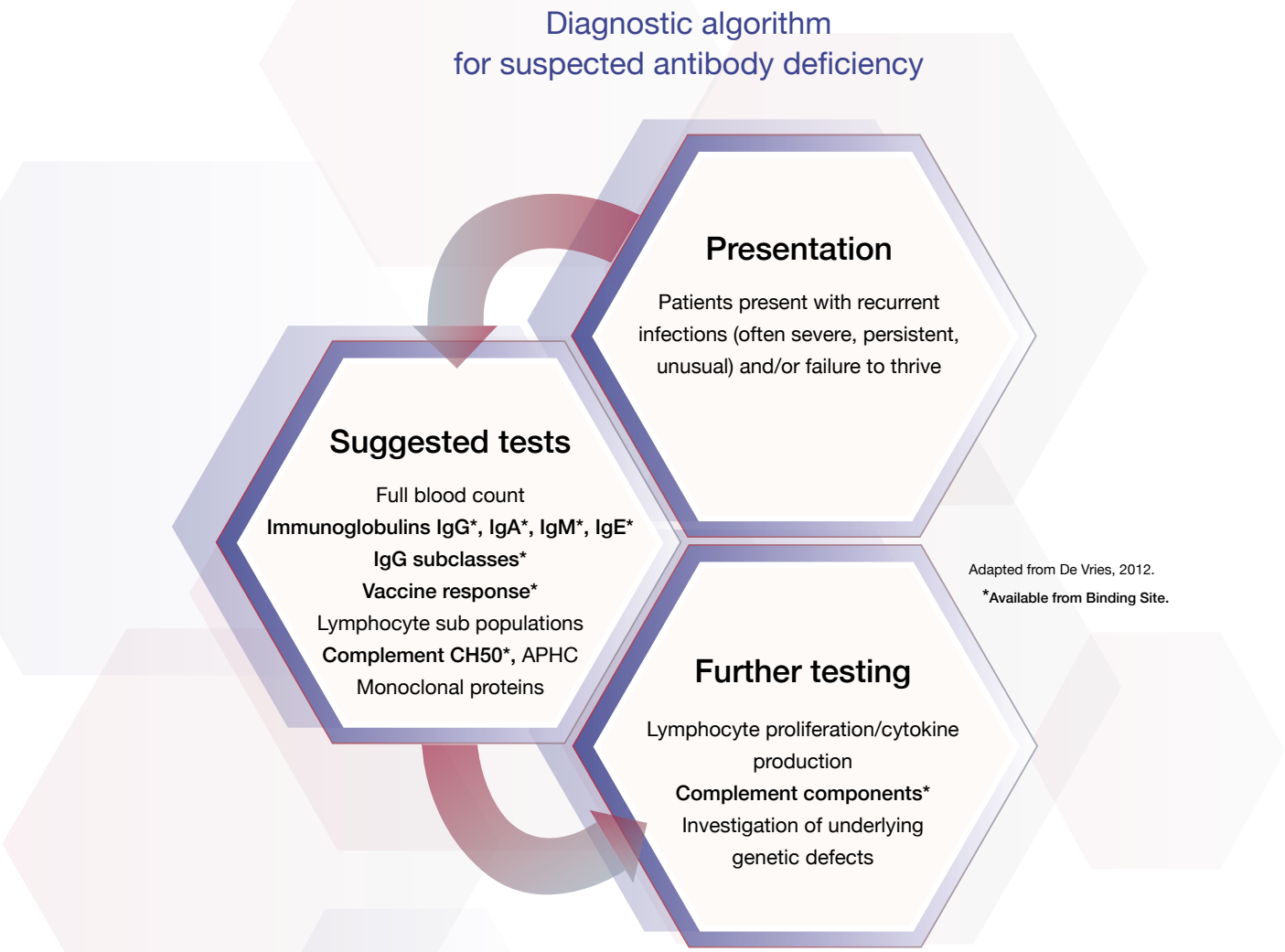


Fig. 1 Diagnosis of immunodeficiency requires the use of information from a variety of laboratory tests alongside clinical presentation. Guidelines for diagnosis are available from the European Society for Immunodeficiency (ESID)[1] and the American Academy of Allergy, Asthma and Immunology.[2]

Primary & Secondary Immunodeficiency

Primary Immunodeficiency (PID)

Primary immunodeficiencies are a series of over 350 disorders caused by genetic alterations that affect cells of the immune system. Some PIDs become apparent in childhood whilst others may not develop until adulthood. PIDs are often chronic but can be treated once diagnosed.[1] PIDs are classified into major groups according to the predominant immune mechanism that is defective. The most common PIDs are those with defects in antibody production.[3]

> *Just over 30% of patients that receive a diagnosis of primary immunodeficiency are under the age of 15 years.*[3]

Potential warning signs of Primary Immunodeficiency:

- 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

> *Patients with predominantly antibody deficiency, the most common type of PID, can experience a median delay of 7.5 years before diagnosis.*[4]

Prognosis of Primary Immunodeficiency:

Long-term prognosis of PID is variable depending on the specific type of immunodeficiency.[5] It can also depend on a number of common factors, many of which are related to time between first onset of symptoms and final diagnosis. These include:

- Age of the patient at diagnosis
- Age of the patient when they receive definitive treatment
- Presence of infections and non-infectious complications
- Other co-morbidities

> *Immunodeficient patients may require expensive or lifelong treatments – these complex care needs can be a significant burden on the healthcare system.*[6]

Benefits of early diagnosis of Immunodeficiency:

- Improved patient health, quality of life and overall lifespan
- Allows cost effective treatment
- Reduces healthcare expenditure

> *Healthcare costs can be reduced by over 50% after a patient is diagnosed with PID.*[7]

Secondary Immunodeficiency (SID)

Secondary immunodeficiencies (SID) may arise when the immune system has been compromised by external factors such as malnutrition, treatment with immunosuppressive drugs or chronic infections. Impairment can often be reversed with management of the initial condition [8], however administration of immunoglobulins and antibiotics may also be useful in some cases to prevent serious and potentially fatal infections.

Specific antibody function is reduced in several types of secondary immunodeficiency including [9]:

- disease-related secondary antibody deficiency (e.g. in haematological malignancies such as Chronic Lymphocytic Leukaemia (CLL) and Multiple Myeloma (MM))
- iatrogenic secondary antibody deficiency as a side effect of specific therapies, including B cell targeting drugs and other immunosuppressive treatments
- solid organ transplantation, particularly heart, lung and kidney transplants

References:

1. De Vries E. Patient-centred screening for primary immunodeficiency, a multistage diagnostic protocol designed for non-immunologists: 2011 update. Clin Exp Immunol 2012; 167:108-119
2. Bonilla FA, et al. Practice parameter for the diagnosis and management of primary immunodeficiency. J Allergy Clin Immunol 2915; 136:1186-1205
3. Bousfiha AA, et al. Primary Immunodeficiency Diseases Worldwide: More Common than Generally Thought. J Clin Immunol 2012; 33:1-7
4. Slade C et al. Delayed diagnosis and complications of predominantly antibody deficiencies in a cohort of Australian adults. Front. Immunol. 2018. Vol 9. 694
5. Raje, N and Dinakar, C. Overview of Immunodeficiency Disorders. Immunol Allergy Clin North Am. 2015 Nov; 35(4): 599–623.
6. Available online at: https://www.immunology.org/policy-and-public-affairs/briefings-and-position-statements/immunodeficiency
7. Modell V, et al. Global study of primary immunodeficiency diseases (PI)-diagnosis, treatment, and economic impact: an updated report from the Jeffrey Modell Foundation. Immunol Res 2011; 51:61-70
8. Chinen J, et al. Secondary immunodeficiencies, including HIV infection. J Allergy Clin Immunol 2010; 125:S195-203
9. Patel S.Y. et al. The Expanding Field of Secondary Antibody Deficiency: Causes, Diagnosis, and Management. Front. Immunol. 2019. Vol 10. 33

Immunoglobulins (Ig)

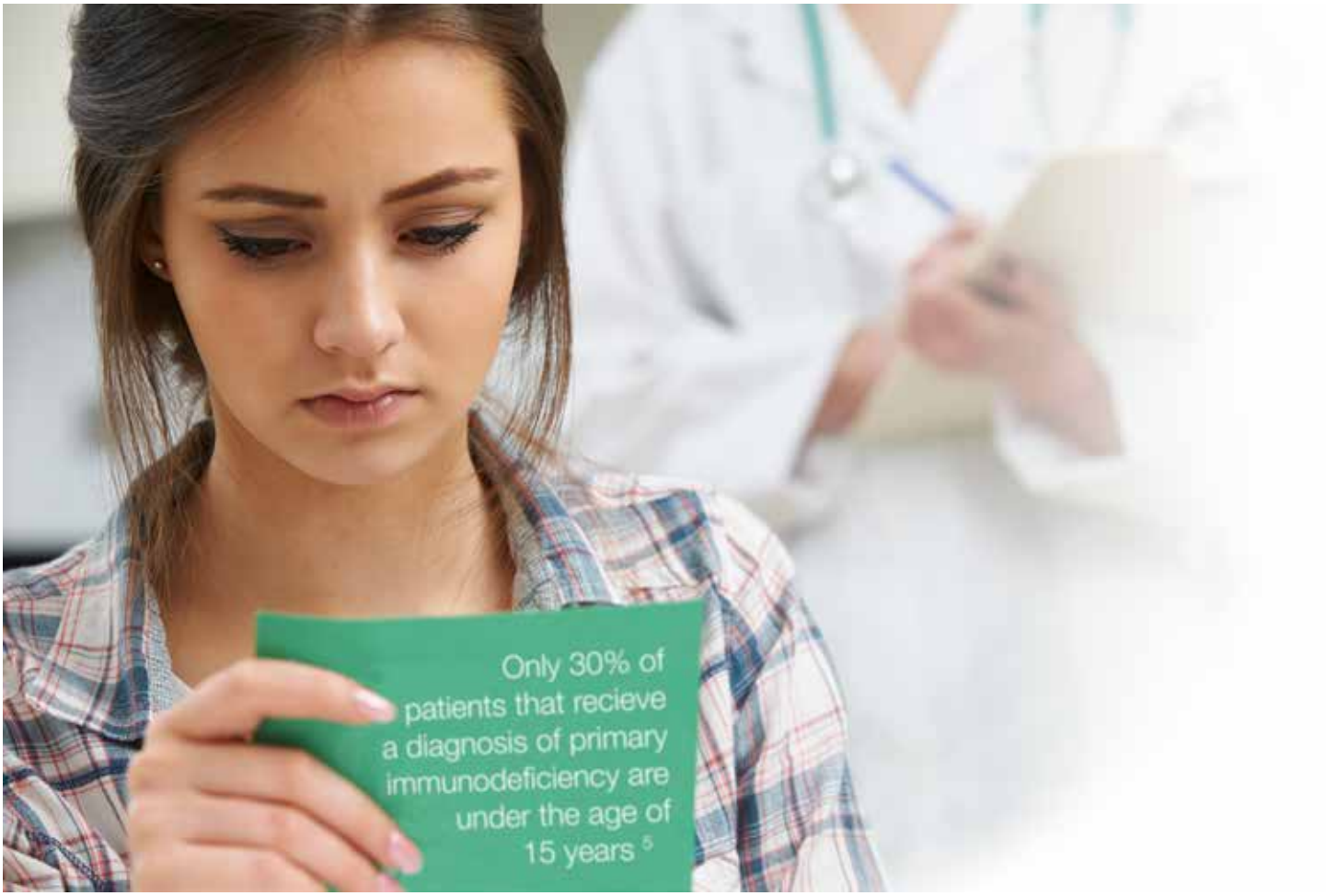
IgG, A and M

The quantification of serum immunoglobulins is a vital first-line test in the investigation of primary immunodeficiency. These diagnostic assays test for the presence of agammaglobulinemia and hypogammaglobulinemia.[1,2] The results are often the basis for further investigative testing such as IgG Subclass testing and antibody function. Over half of individuals diagnosed with primary immunodeficiencies have defects in immunoglobulin levels.[3]

IgE

Measurement of total IgE can be useful to aid in the diagnosis of various diseases.

Elevated IgE levels can be found in allergic disorders, atopy, Hyper IgE Syndromes (HIES), immune deficiencies, liver diseases, malignancies, parasitic infections, graft-versus host disease, severe burns and some viral infections.[4]



References:

1. de Vries, Clin Exp Immunol 2012;167:108-119
2. Bonilla FA, et al. Practice parameter for the diagnosis and management of primary immunodeficiency. J Allergy Clin Immunol 2015; 136:1186-1205
3. Mahlaoui N, et al. The European Society for Immunodeficiencies (ESID) Registry: recent advancements in the epidemiology of Primary Immunodeficiencies and how does that translate in clinical care. Rare Diseases and Orphan Drugs 2014; 1:25-27
4. Marshall, W.J, Lapsley, M, Day, A. & Aylin, R.M. (2014) Clinical Biochemistry Metabolic and Clinical Aspects. Elsevier

IgG Subclasses

The measurement of IgG subclasses can aid in the diagnosis of many immunodeficiency disorders including IgG subclass deficiency, IgA with IgG subclass deficiency, common variable immunodeficiency and specific antibody deficiency.

Patients with recurrent infections may still present with normal or elevated IgG levels making diagnosis of immune deficiency difficult. In these circumstances IgG subclass measurements may be a useful tool for diagnosis of primary immunodeficiency alongside other tests. There is often a delayed diagnosis of these patients resulting in a reduction of quality of life.

Standardisation

Calibration of an assay against an internationally recognised 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.

Binding Site Optilite®

DESCRIPTION	PACK	CODE
IgG1 Optilite kit Range 0.15-144, sensitivity 0.15 (g/L)	100 test	NK006.OPT
IgG2 Optilite kit Range 0.02-28, sensitivity 0.02 (g/L)	100 test	NK007.OPT
IgG3 Optilite kit Range 0.0055-8.8, sensitivity 0.0055 (g/L)	100 test	LK008.OPT
IgG4 Optilite kit Range 0.0043-64.8, sensitivity 0.0043 (g/L)	100 test	LK009.OPT

Roche cobas™ 6000

DESCRIPTION	PACK	CODE
IgG1 kit Range 0.33-60, sensitivity 0.33 (g/L)	100 test	NK006.CB
IgG2 kit Range 0.12-20 , sensitivity 0.12 (g/L)	100 test	NK007.CB
IgG3 kit Range 0.014-4.375, sensitivity 0.014 (g/L)	100 test	LK008.CB
IgG4 kit Range 0.018-2.7, sensitivity 0.018 (g/L)	100 test	LK009.CB

The user is required to set up a user-defined reagent (UDR) for each assay.

Units in brackets apply to both range and sensitivity.

See page 6 for more information on Optilite.

IgG Subclasses

Siemens BN™ II

DESCRIPTION	PACK	CODE
IgG1 kit Range 0.131-336, sensitivity 0.131 (g/L)	4x40 test	NK006.TB
IgG2 kit Range 0.153-98, sensitivity 0.153 (g/L)	4x40 test	NK007.TB
IgG3 Latex kit Range 0.003-3.5, sensitivity 0.003 (g/L)	4x48 test	LK008.TB
IgG4 Latex kit Range 0.0019-2.452, sensitivity 0.0019 (g/L)	4x48 test	LK009.TB

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

Siemens BN ProSpec™

DESCRIPTION	PACK	CODE
COMBI kit (Latex IgG3 & IgG4, non-latex IgG1 & IgG2)	2x44 test 2x40 test	LK001.P
IgG1 kit Range 0.131-336, sensitivity 0.131 (g/L)	4x40 test	NK006.P
IgG2 kit Range 0.153-98, sensitivity 0.153 (g/L)	4x40 test	NK007.P
IgG3 Latex kit Range 0.003-3.5, sensitivity 0.003 (g/L)	4x48 test	LK008.P
IgG4 Latex kit Range 0.0019-2.452, sensitivity 0.0019 (g/L)	4x48 test	LK009.P

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

IgA Subclasses

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

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 brackets apply to both range and sensitivity.

Binding Site Optilite®

DESCRIPTION	PACK	CODE
IgA1 Optilite kit Range 0.035-6, sensitivity 0.035 (g/L)	50 test	NK087.OPT
IgA2 Latex Optilite kit Range 0.005-1.25, sensitivity 0.005 (g/L)	50 test	LK088.OPT

Siemens BN™ II

DESCRIPTION	PACK	CODE
IgA1 kit Range 0.09375-30, sensitivity 0.09375 (g/L)	40 test	NK087.1T
IgA2 Latex kit Range 0.00315-4, sensitivity 0.00315 (g/L)	40 test	LK088.1T
IgA subclass COMBI kit (Latex IgA2, non-latex IgA1)	2x40 test	LK003.T

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

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

Complement

The complement system is a complex part of the immune system comprising of numerous proteins which act as a cascade. These assays are efficient as screening tools to detect complement deficiencies.

Complement is involved in initiating an inflammatory response and destroying certain bacteria and viruses. Where complement deficiency is suspected it maybe necessary to test for the specific components of the complement system.

Complement testing is recommended in the diagnosis and monitoring of many conditions.

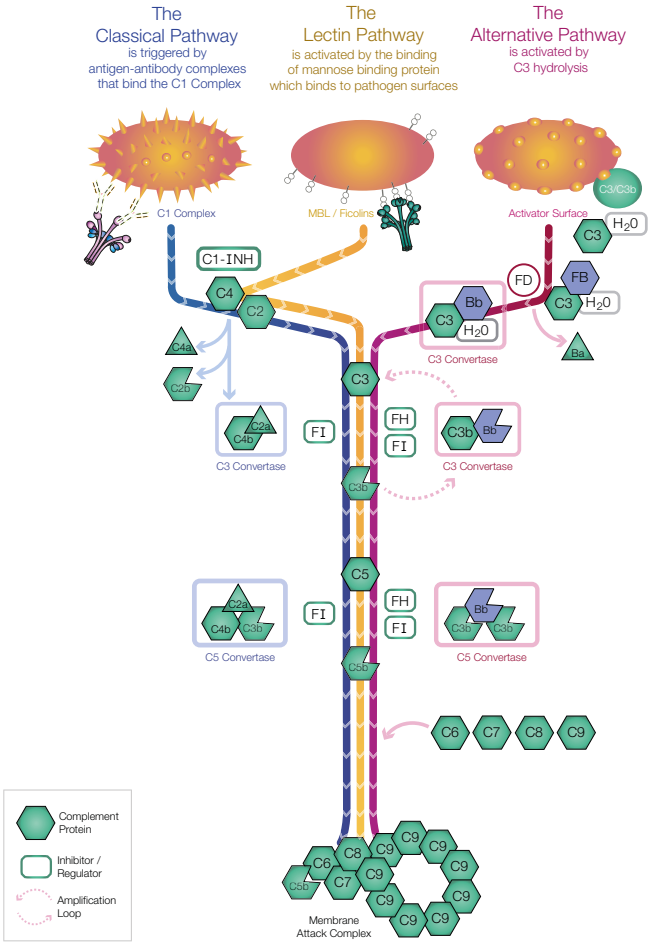
Binding Site Optilite®

DESCRIPTION	PACK	CODE
C1 Inactivator Kit Range 0.08-0.88, sensitivity 0.08 (g/L)	50 test	NK019.OPT
C3c Kit Range 0.025-6, sensitivity 0.025 (g/L)	100 test	NK023.OPT
C4 Kit Range 0.0064-1.8, sensitivity 0.0064 (g/L)	100 test	NK025.OPT
CH50 Reagent Range12.5-100, sensitivity 12.5 (U/mL)	100 test	NK095.OPT
CH50 Calibrator	1 pack	NC095.OPT
CH50 Controls x4 L, x4 H, x4 Elevated	1 pack	NQ095.OPT

See page 6 for more information on Optilite

Complement testing is recommended in the diagnosis and monitoring of many conditions

The complement system consists of three different pathways which are triggered by different mechanisms. The pathway is regulated by protein cascades involving more than 30 proteins. The complement system is an integral part of the immune system.



VaccZyme®

Vaccine Response Assays

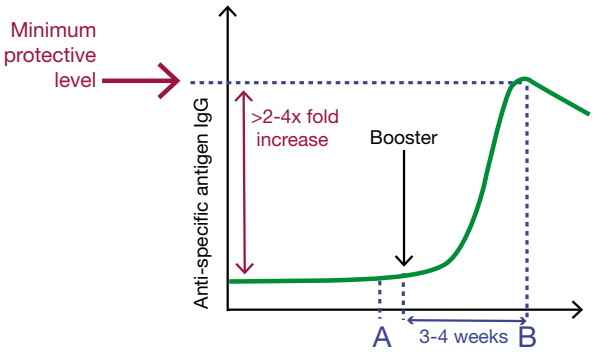
Specific antibody measurement

VaccZyme is a unique panel of enzyme-linked immunosorbent assays (ELISAs) for assessing the immune system's ability to produce functionally active specific antibodies against protein, peptide-conjugated & pure polysaccharide antigens.

Quantitative results and easy interpretation aid in the diagnosis and monitoring of patients with immunodeficiency and immune system disorders.[1,2]

Using vaccines to assess immune response

A serum sample is taken prior to vaccination, followed by a second sample a number of weeks post-vaccination or booster. The samples are then assayed and specific antibody concentrations are measured. Clinicians can either assess the ratio of the post-vaccination concentration relative to the pre-vaccination concentration or assess whether the post-vaccination concentration is greater than a defined minimum protective level. This will determine whether the response to vaccination has been adequate or deficient.



Vaccines are widely used to measure the ability of the immune system to produce functionally active specific antibodies and it is important to investigate the response to protein antigens and pure polysaccharide antigens as the immune response of an individual can vary depending on the nature of the antigen initiating the response.[3] Failure to produce the appropriate response may result in recurrent and/or persistent infection.

Vaccine response in immunodeficiency

Diagnostic vaccination to measure specific antibody levels is a key tool in the diagnosis and monitoring of primary and secondary immunodeficiency, particularly when other immunological markers are normal.[1-4]

Specific antibody measurement in plasma screening

The accurate measurement of specific antibodies is also important during the screening of donors for the manufacture of therapeutic immunoglobulin and hyperimmune products.

Protein Antigens (T-cell dependent response)

DESCRIPTION	PACK	CODE
VaccZyme Tetanus toxoid IgG kit Range 0.01-7 IU/mL	96 test	MK010
VaccZyme Diphtheria toxoid IgG kit Range 0.004-3 IU/mL	96 test	MK014

Peptide-Conjugated Antigens (T-cell dependent response)

DESCRIPTION	PACK	CODE
VaccZyme *Haemophilus influenzae* type b IgG kit Range 0.11-9 mg/L	96 test	MK016

Polysaccharide Antigens (T-cell independent response)

DESCRIPTION	PACK	CODE
VaccZyme PCP IgG kit Range 3.3-270 mg/L	96 test	MK012
VaccZyme Salmonella typhi Vi IgG kit Range 7.4-600 U/mL	96 test	MK091

Research use only assays

DESCRIPTION	PACK	CODE
VaccZyme PCP IgG2 kit Range 1.1-90 mg/L	96 test	MK013

PCP = Pneumococcal Capsular Polysaccharide. These kits utilise PneumovaxTM vaccine. Conjugated vaccines are also available.

1. Orange J.S. et al. Use and interpretation of diagnostic vaccination in primary immunodeficiency: A working group report of the Basic and Clinical Immunology Interest Section of the American Academy of Allergy, Asthma & Immunology. J Allergy Clin Immunol. 2012;130(3 Suppl):S1-24.
2. Jolles S, et al. When to initiate immunoglobulin replacement therapy (GRT) in antibody deficiency: a practical approach. Clin Exp Immunol 2017; 188:333-341
3. De Vries E. Using vaccines to diagnose antibody deficiencies. European Paediatrics 20018; 372:489-502
4. Bonilla, F.A. et al. Practice parameter for the diagnosis and management of primary immunodeficiency. Ann Allergy Asthma Immunol 2005;94:S1-63.

Assays for Central Nervous System Disorders

Central Nervous System Disorders

Cerebrospinal fluid (CSF) is a clear, colourless fluid located between the meninges, the protective membranes surrounding the brain and spinal cord.

Its main function is to protect the brain and spinal cord from trauma, as well as supplying nutrients and removing waste products to support cerebral metabolism.

Central nervous system disorders are a group of disorders affecting the central nervous system (CNS).

Local (intrathecal) synthesis of immunoglobulins within the CSF occurs in a wide variety of CNS disorders, but is most commonly associated with CNS infections (e.g. viral encephalitis, cerebral malaria) or autoimmune disorders such as multiple sclerosis (MS).[1]

CSF assay panel on Optilite

- Free light chains
  - **Freelite Mx™** Kappa
  - **Freelite Mx™** Lambda
- Albumin
  - Low Level Albumin
- Immunoglobulins
  - Low Level IgG
  - IgA CSF
  - IgM CSF

Our assays have published utility for use in certain CNS disorders[2], for example, like oligoclonal band analysis (the current gold standard for CSF analysis in diagnosing MS). Freelite Mx™ can be used to characterise intrathecal synthesis of immunoglobulins.

Our Low Level Albumin and immunoglobulin assays can be used to assess blood-brain barrier function, which is useful in the diagnosis of a variety of diseases of the CNS.[3, 4]

Contact us to learn more:
www.bindingsite.com/contact

1. Fischer et al. Clinical Chemistry (2004) 50:10;1809-1813
2. Presslauer S et al. J Neurol 2008; 255:1508-1514
3. Reiber H, Peter JB. Cerebrospinal fluid analysis: disease-related data patterns and evaluation programs. J Neurol Sci 2001;184:101-122
4. Regeniter A et al. A modern approach to CSF analysis: pathophysiology, clinical application,
proof of concept and laboratory reporting. Clin Neurol Neurosurg. 2009 May;111(4):313-318

Your integrated solution for CSF analysis

CSF analysis on Optilite

Optilite offers an integrated solution for the analysis of CSF samples. The comprehensive assay menu plus the enhanced analytical features of Optilite combine to streamline measurement of CSF samples into your special protein workflow.

CSF assay panel

Consolidate all your CSF assays onto one special protein analyser; the Optilite.

DESCRIPTION	PACK	CODE
Freelite Mx™ Kappa Latex kit* Range 0.33-127000, sensitivity 0.33 (mg/L)	100 test	LK016.M.OPT
Freelite Mx™ Lambda Latex kit* Range 0.74-139000, sensitivity 0.74 (mg/L)	100 test	LK018.M.OPT
Low Level Albumin kit* Range 11-66500, sensitivity CSF/Urine 11, Serum 2200 (mg/L)	100 test	NK032.L.OPT
Low Level IgG kit* Range 7.5-27000, sensitivity CSF/Urine 7.5, Serum 1500 (mg/L)	60 test	NK004.LL.OPT
IgA CSF kit* Range 0.91-8000, sensitivity CSF 0.91, Serum 330 (mg/L)	60 test	LK010.L.OPT
IgM CSF kit* Range 0.11-3200, sensitivity CSF 0.11, Serum 60 (mg/L)	60 test	LK012.L.OPT

* Measuring range is dependent on sample type. See product insert for further information. Optilite kits are also for use with serum.

IMMPROVE™

Quality Assurance Schemes

IMMPROVE™ Quality Assurance

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 30 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 includes a full 12 month issue for your registered scheme.

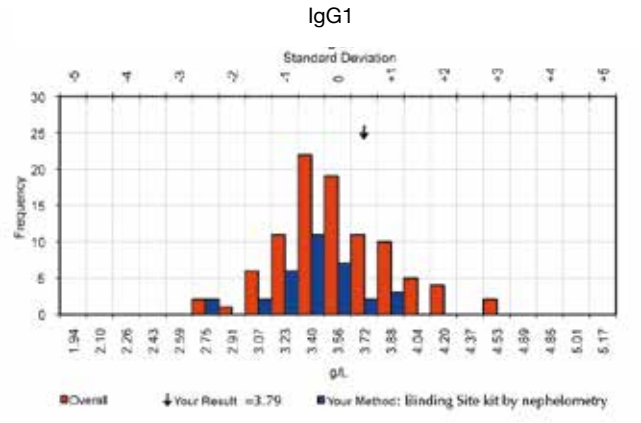
At the end of year 1 there is the opportunity to re-register for a further year and on an annual basis.

To register or re-register please contact your local Binding Site representative.

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, IgA2, Tetanus toxoid IgG, Diphtheria toxoid IgG, PCP IgG and Haemophilus influenzae type b IgG. 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 150 laboratories worldwide participate.

IgG1

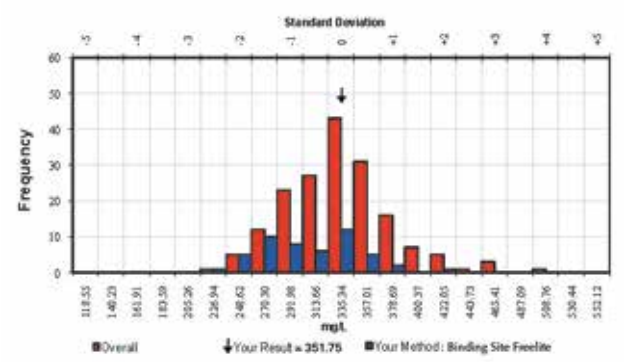


Serum Paraprotein QA Scheme

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.

A pilot scheme for Hevylite IgGκ, IgGλ, IgAκ, IgAλ, IgMκ, IgMλ assays is also available. For further details of this scheme please contact your local Binding Site representative.

Serum free lambda



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. Around 110 laboratories participate.

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

Comprehensive Support

Customer support & Scientific education

Customer Support

Becoming part of your laboratory

Our team of technical experts is dedicated to supporting our customers and pride themselves in providing an exemplary customer experience. We offer unrivalled after sales support, built on three key areas:

Product installation and evaluation

Swift and efficient integration of products into your laboratory with minimal disruption to routine work flow, ensuring optimal product performance and confidence in your results from day one.

Technical and functional product training

Comprehensive product training, providing clear instruction and advice to ensure full competency in product use. All training is customised to your specific requirements, giving you complete flexibility to train within your own laboratory or at our dedicated Binding Site training facilities.

Available training packages include:

End user training
Refresher training
Advanced product training
Product upgrade training
Special Events and Seminars for your laboratory

Front line product guidance and support

Ongoing support and guidance is available from the first use of your new product and beyond. Our dedicated team is ready and available to answer any specific questions you have and perform problem determination to resolve any issues encountered in a prompt and complete manner. We offer unparalleled, friendly field service and application support and no query is closed until full customer satisfaction is achieved.

We encourage constant feedback from our customers throughout their use of our products to help us maintain and improve on the service we offer. It is our mission to ensure our products meet and exceed your expectations, giving you the tools to provide the highest quality of patient care and management.

From product installation through to front line guidance and support, our friendly and knowledgeable Customer Support Team is here to help you get the very best out of our market leading products.

Scientific Liaison

Educational support

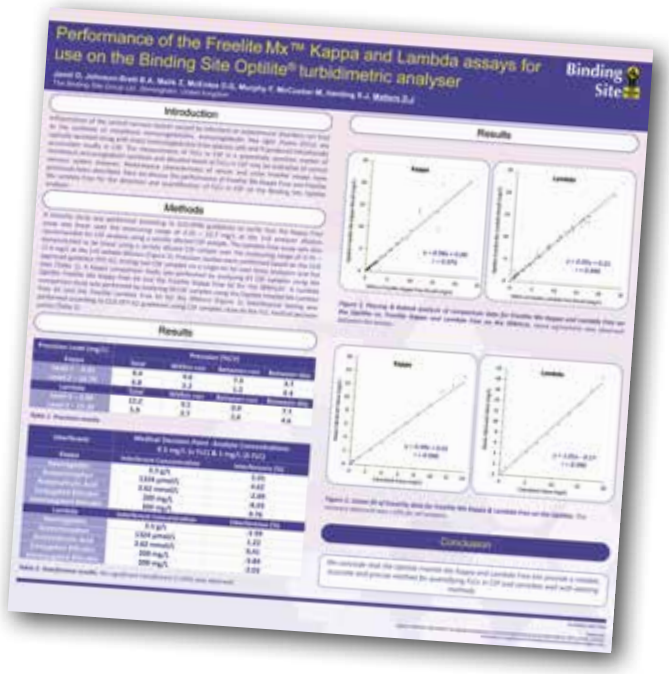
We are proud of our origins - we grew out of the Medical School at Birmingham University and retain strong ties to the institution.

We continually strive to expand our knowledge and understand the challenges facing patients and medical professionals in our industry. Working closely with key opinion leaders we share and develop ideas, delivering new, innovative solutions to our customers.

Our Medical Science Liaisons are available to provide you with educational support:

Educational seminars

We can provide educational seminars at your hospital, laboratory or conference.


Performance of the Freelite Mx™ Kappa and Lambda assays for use on the Binding Site Optilite® turbidimetric analyser

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We can help you initiate and evaluate clinical studies using Binding Site products and can assist in the publication of conference abstracts, posters and journal manuscripts.

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Binding Site is committed to improving patient lives worldwide through education, collaboration and innovation

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