## Contact us

www.bindingsite.com

to find your local office or representative
in over 80 countries

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Not for use in the USA and China.

The information presented in this catalogue is effective
October 2019 and supersedes all previous publications.

DELIVERY INFORMATION WITHIN THE UNITED KINGDOM:

DELIVERY
Orders received between 12.00pm Mon – 12.00pm Tues = ship Weds
Orders received between 12.00pm Tues – 12.00pm Thurs = ship Thurs
Orders received between 12.00pm Thurs -16.30pm Thurs = ship Mon
Orders received between 16.30pm Thurs -12.00pm Mon = ship Tues

CHARGES
All deliveries attract a £20.00 carriage charge.

October 2019
EBK056

The Specialist Protein Company

Not for use in the USA and China.

Binding Site
Protein diagnostics.
Smart solutions.

# International Clinical Product Listing


2019 / 2020

# Protein diagnostics. Smart solutions.

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.

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


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 as we deliver a bespoke service that meets your specific needs and expectations.

Binding Site believes that quality matters. We adhere to International regulations and hold ISO13485:2016 and ISO9001:2015 certification.

Assays for *in vitro* use have been FDA cleared for the USA, CE marked for Europe 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.

THE QUEEN'S AWARDS FOR ENTERPRISE: INTERNATIONAL TRADE 2016

bsi. ISO 13485:2016 Medical Devices Quality Management FM73489 ISO 9001:2015 Quality Management FMS52528

www.bindingsite.com

Binding Site THE BINDING SITE

## Our optimised systems family

Optilite® - our optimised protein system's custom design and powerful technology delivers the ideal solution for your special protein laboratory.

SPAPLUS® - our Specialist Protein Analyser is now available reconditioned with the same great support it has always had.

Both systems have been developed exclusively for Binding Site specialist protein assays, bringing harmony to assay and analyser alike.

DataSite; Binding Site's data management system, bringing a new level of simplicity, efficiency & confidence.

## Unique assays

The **Freelite®** assay has allowed significant improvements in both laboratory and clinical practice for the detection and follow-up of B cell malignancies. **Freelite** has over 3000 publications and is mentioned by name in international guidelines, it was FDA cleared in 2001 for both 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, front line product guidance & support.

## Scientific support

Binding Site is known for it's unique educational support. Our Medical Science Liaisons are available to provide you with educational support, seminars, clinical studies, scientific publication reprints and our educational website:
www.wikilite.com

## Research

We also make available a range of antigens and antibodies which are for research use only. For further information on these products, please visit
www.immunologicals.com

Learn more via our website

Binding Site — Protein diagnostics. Smart solutions.

# Index

## Systems



## Assays



## Support



Optilite®

OPTIMISED PROTEIN SYSTEM

# Optimised and proven special protein analysis


Learn more via our website

Optilite®
OPTIMISED PROTEIN SYSTEM

# Optimised and proven special protein analysis


Optilite is the latest 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 existing protein analysers. 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

## Optimise your work flow

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 dilutions since Optilite re-dilutes to end result

## 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


Work smarter, not harder

Learn more

## 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 brings simplicity to complex processes

## Optilite assays

| DESCRIPTION | PACK | CODE |
|---|---|---|
| **Monoclonal Gammopathies** | | |
| Freelite Kappa Latex kit<br>Range 0.60-127000, sensitivity 0.6 (mg/L) | 100 test | LK016.OPT |
| Freelite Lambda Latex kit<br>Range 1.30-139000, sensitivity 1.3 (mg/L) | 100 test | LK018.OPT |
| Hevylite IgG Kappa kit<br>Range 0.115-120, sensitivity 0.115 (g/L) | 50 test | NK621.OPT |
| Hevylite IgG Lambda kit<br>Range 0.075-105, sensitivity 0.075 (g/L) | 50 test | NK622.OPT |
| Hevylite IgA Kappa kit<br>Range 0.018-112, sensitivity 0.018 (g/L) | 50 test | NK623.OPT |
| Hevylite IgA Lambda kit<br>Range 0.016-104, sensitivity 0.016 (g/L) | 50 test | NK624.OPT |
| Hevylite IgM Kappa Latex kit<br>Range 0.02-150, sensitivity 0.02 (g/L) | 50 test | NK625.OPT |
| Hevylite IgM Lambda Latex kit<br>Range 0.018-135, sensitivity 0.018 (g/L) | 50 test | NK626.OPT |
| **Immunoglobulins** | | |
| IgG kit<br>Range 0.165-140, sensitivity 0.165 (g/L) | 100 test | NK004.OPT |
| IgA kit<br>Range 0.02-70, sensitivity 0.02 (g/L) | 100 test | NK010.OPT |
| IgM kit<br>Range 0.10-150, sensitivity 0.10 (g/L) | 100 test | NK012.OPT |
| IgD Latex kit<br>Range 0.013-16.8, sensitivity 0.013 (g/L) | 100 test | LK013.OPT |
| IgE Reagent<br>Range 10-5000, sensitivity 10 (IU/mL) | 100 test | LK014.OPT |
| **Subclasses** | | |
| IgG1 kit<br>Range 0.15-144, sensitivity 0.15 (g/L) | 100 test | NK006.OPT |
| IgG2 kit<br>Range 0.02-28, sensitivity 0.02 (g/L) | 100 test | NK007.OPT |
| IgG3 Latex kit<br>Range 0.0055-8.8, sensitivity 0.0055 (g/L) | 100 test | LK008.OPT |
| IgG4 Latex kit<br>Range 0.0043-64.8, sensitivity 0.0043 (g/L) | 100 test | LK009.OPT |
| IgA1 kit<br>Range 0.035-6, sensitivity 0.035 (g/L) | 50 test | NK087.OPT |
| IgA2 Latex kit<br>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 request sheet MKG884 from your representative.

Please see page 4 for more Optilite Assays.

Optilite®
OPTIMISED PROTEIN SYSTEM

## Optilite assays continued

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

| DESCRIPTION | PACK | CODE |
|---|---|---|
| **Specific proteins** | | |
| α1-Acid Glycoprotein kit<br>Range 0.19-6, sensitivity 0.19 (g/L) | 100 test | NK063.OPT |
| α1-Antitrypsin kit<br>Range 0.35-5, sensitivity 0.35 (g/L) | 100 test | NK034.OPT |
| α2-Macroglobulin kit<br>Range 0.2-6.4, sensitivity 0.2 (g/L) | 100 test | NK039.OPT |
| Anti-streptolysin O Latex kit<br>Range 5-1600, sensitivity 5 (IU/mL) | 100 test | LK189.OPT |
| Apolipoprotein A1 Reagent<br>Range 0.048-5.5, sensitivity 0.048 (g/L) | 100 test | NK085.OPT |
| Apolipoprotein B Reagent<br>Range 0.065-5.5, sensitivity 0.065 (g/L) | 100 test | NK086.OPT |
| Caeruloplasmin kit<br>Range 0.04-1.64, sensitivity 0.04 (g/L) | 50 test | NK045.OPT |
| C-Reactive Protein Reagent<br>Range 5-1425, sensitivity 5 (mg/L) | 100 test | NK044.OPT |
| Haptoglobin kit<br>Range 0.026-8, sensitivity 0.026 (g/L) | 100 test | NK058.OPT |
| High Sensitivity C-Reactive Protein kit<br>Range 0.5-10, sensitivity 0.5 (mg/L) | 100 test | LK044.L.OPT |
| Lipoprotein (a) Reagent<br>Range 3.38-440, sensitivity 3.38 (nmol/L) | 100 test | LK098.OPT |
| Prealbumin kit<br>Range 0.006-0.8, sensitivity 0.006 (g/L) | 100 test | NK066.OPT |
| Rheumatoid Factor kit<br>Range 7-6500, sensitivity 7 (IU/mL) | 100 test | LK151.OPT |
| Tetanus toxoid kit<br>Range 1.667-50, sensitivity 1.667 (IU/mL) | 200 test | LK110.OPT |
| Total Protein Reagent<br>Range 0.5-300, sensitivity 0.5 (g/L) | 100 test | NK061.OPT |
| Transferrin kit<br>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 |

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.



DataSite®

Binding Site's
data management system

Bringing a new level of simplicity, efficiency and confidence.

# DataSite®

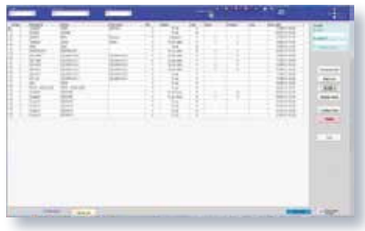
## What is DataSite?

DataSite is Binding Site's data management system. It has been optimised to run in conjunction with Binding Site instruments. Benefits include full QC and validation modules to increase the efficiency and productivity of your laboratory.

DataSite is focused on improving your laboratories' technical efficiency through advanced features and effective workflow management.

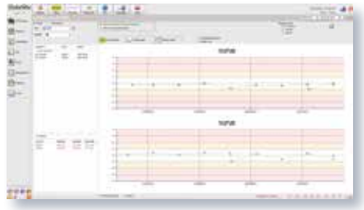
### Automating the laboratory to enhance your workflow

- Automatic validation by exception
- Reduce user error
- Reflex testing in line with your laboratory protocol



### Simple and efficient result handling

- Perform technical validation before results are reported
- Clear colour alerts indicating results which require further attention*
- View final & intermediate results together



### Helps achieve your laboratory's regulatory and quality compliance

- All user actions are fully traceable on the system
- All reagent, QC, user ID and previous result information traceable to each patient result
- Assay Validation Module to assist you with a number of validation procedures

### Easy to generate meaningful reports saving you time

- Generate reports for results of a specific test or a specific lot number of reagent or QC
- All information required for each test on one screen

### Manage your laboratory time and costs more effectively

- Interface future analysers with reduced connection costs
- Reducing analyser hands on time
- Test count management

### Effective QC management ensures your results are accurate

- Full Westgard rules
- Levey Jennings charts for monitoring QC performance
- Clear colour alerts verify result accuracy

### Full maintenance management - consistent, reliable results

- Track all analyser maintenance status on one screen
- Make comments to record observations about the analyser condition
- Trace when and by whom the maintenance was performed

### Accreditation

- Supports EN ISO 15189 & EN ISO 22870 compliance
- Integration with BIO-RAD UNITY program

**DataSite®** is the solution to the high demands of your laboratory bringing a new level of simplicity, efficiency and confidence.

*Based on user-defined criteria.



SPA PLUS®

Specialist Protein Analyser

Reconditioned

# Specialist Protein Analyser*

The SPAPLUS is ideal for Binding Site's specialist protein assays and has been designed to bring together instrument, reagents and exceptional support.

## Add flexibility to your laboratory

The SPAPLUS is a compact, turbidimetric platform for specialist protein testing. The fully automated SPAPLUS system enables laboratories to maintain the quality of results and high throughput required for specialised protein assays. It can be placed alongside the laboratory's main-line analysers or in other areas of the laboratory.

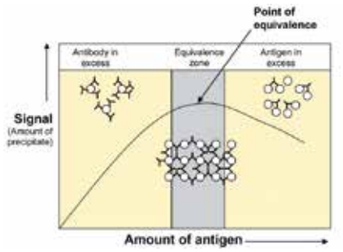
The SPAPLUS offers an expanding menu of diagnostic tests related to disease state management and clinical practice guidelines. Pre-programmed protocols developed and manufactured by Binding Site provide highly sensitive and reproducible results that match or have greater sensitivity than nephelometry.

The SPAPLUS analyser has been specifically designed to use **Freelite** (see page 17). This will provide you with a proven automated solution to aid in the diagnosis and monitoring of monoclonal gammopathy alongside electrophoretic methods.

The modular design with intuitive Windows™ based software makes the SPAPLUS very easy to use. It is engineered to a high standard demonstrating excellent reliability with minimal daily, weekly and monthly maintenance procedures.

## Confidence in results

- Automatic antigen excess check
- Minimal carry over through contact free sample/reagent air mixing
- Intuitive software and robust hardware
- Optimised to run **Freelite**




## Easy to operate

- Ready-to-use bar coded reagents
- Fully integrated bi-directional RS232 interface capability
- Direct loading calibrators and controls
- Simple loading & unloading of reagents and samples


## Exceptional customer support

- Supported by a highly skilled technical and engineering team
- Dedicated professionals with knowledge and practical expertise
- Delivering customer satisfaction

## Increase productivity

- First result in 15 minutes, subsequent results every 15 or 30 seconds depending on the assay
- Up to 240 tests per hour**
- On-board reagent cooling/monitoring
- Wide measuring range minimises re-runs ensuring optimal reagent usage and throughput

## Reliable

- Mean time between failure - up to 258 days
- Quick start up and shut down
- Very short downtime ensuring continuity of laboratory service

* Only available as a reconditioned system. Please ask your local Binding Site representative for information.

** CH50

## SPAPLUS physical specification

Dimensions: Width 800mm
Depth 640mm
Height 520mm

Weight: 96kg


## SPAPLUS analyser and accessories

| DESCRIPTION | PACK | CODE |
|---|---|---|
| SPAPLUS Specialist Protein Analyser | 1 | IE610 |
| SPAPLUS Sample Diluent | 6x60mL | SN080.S |
| SPAPLUS Sample Diluent 2 | 3x200 test | SN114.S |
| SPAPLUS Weekly Wash Protocol & Bottles | 6 | IK050.S |
| SPAPLUS Halogen Lamp | 1 | SP2057 |
| SPAPLUS Reaction Cuvettes | 60 | 23-07-0055 |
| SPAPLUS Alkaline Washing Solution | 500mL | SP2208 |
| SPAPLUS Acid Washing Solution | 500mL | SP2209 |
| SPAPLUS Sample Cups | 1000 | TBS043 |
| SPAPLUS Universal Tube Elevators | 30 | IK520 |
| SPAPLUS Calibrator Rack Direct Load | 1 | IK530 |
| SPAPLUS Control Rack Direct Load 1 | 1 | IK540.1 |
| SPAPLUS Control Rack Direct Load 2 | 1 | IK540.2 |
| SPAPLUS Data Extractor | 1 | IK550 |

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

*For these assays a validated extended measuring range is achievable by re-running with a manual pre-dilution. Please see package insert for assay-specific manual dilution protocols.

## SPAPLUS assays

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

| DESCRIPTION | PACK | CODE |
|---|---|---|
| **Monoclonal Gammopathies** | | |
| Freelite Kappa Latex kit* Range 0.4-1800, sensitivity 0.4 (mg/L) | 100 test | LK016.S |
| Freelite Lambda Latex kit* Range 0.45-1650, sensitivity 0.45 (mg/L) | 100 test | LK018.S |
| **Immunoglobulins** | | |
| IgG kit Range 0.165-140, sensitivity 0.165 (g/L) | 100 test | NK004.S |
| IgA kit* Range 0.02-28, sensitivity 0.02 (g/L) | 100 test | NK010.S |
| IgM kit* Range 0.1-15, sensitivity 0.1 (g/L) | 100 test | NK012.S |
| IgD Latex kit* Range 7-210, sensitivity 7 (mg/L) | 100 test | LK013.S |
| IgE kit Range 30-1500, sensitivity 30 (IU/mL) | 100 test | LK014.S |
| **Subclasses** | | |
| IgG1 kit Range 0.15-144, sensitivity 0.15 (g/L) | 100 test | NK006.S |
| IgG2 kit Range 0.02-28, sensitivity 0.02 (g/L) | 100 test | NK007.S |
| IgG3 Latex kit Range 0.0055-4, sensitivity 0.0055 (g/L) | 100 test | LK008.S |
| IgG4 Latex kit Range 0.003-3.4, sensitivity 0.003 (g/L) | 100 test | LK009.S |
| IgA1 kit Range 0.03-6, sensitivity 0.03 (g/L) | 50 test | NK087.S |
| IgA2 Latex kit Range 0.005-1.25, sensitivity 0.005 (g/L) | 50 test | LK088.S |
| **Complement** | | |
| C1 inactivator kit Range 0.06-0.8, sensitivity 0.06 (g/L) | 50 test | NK019.S |
| C2 Kit Range 4-90, sensitivity 4 (mg/L) | 100 test | LK022.S |
| C3c kit Range 0.025-6, 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 12-95, sensitivity 12 (U/mL) | 100 test | NK095.S |
| CH50 Controls for SPAPLUS 4 x low control, 4 x high control, 4 x elevated control | 1 set | NQ095.S |
| CH50 Calibrators for SPAPLUS | 1 set | NC095.S |

For more assays please see page 10.

SPA PLUS®

# Specialist Protein Analyser

## SPAPLUS assays - continued

| DESCRIPTION | PACK | CODE |
|---|---|---|
| **Renal function** | | |
| Albumin kit<br>Range 0.1-154, sensitivity 0.1 (g/L) | 100 test | NK032.S |
| β2-Microglobulin Latex kit*<br>Range 0.3-40 mg/L,<br>Sensitivity serum 0.3 mg/L,<br>Sensitivity urine 0.03 mg/L | 100 test | LK043.S |
| β2-Microglobulin Urine Latex kit*<br>Range 0.03-20, sensitivity 0.03 (mg/L) | 100 test | LK043.U.S |
| Cystatin C Latex kit<br>Range 0.4-14.7, sensitivity 0.4 (mg/L) | 100 test | LK048.S |
| **Specific proteins** | | |
| α1-Acid Glycoprotein kit<br>Range 0.19-6, sensitivity 0.19 (g/L) | 100 test | NK063.S |
| α1-Antitrypsin kit<br>Range 0.35-5, sensitivity 0.35 (g/L) | 100 test | NK034.S |
| α2-Macroglobulin kit<br>Range 0.2-6.4, sensitivity 0.2 (g/L) | 100 test | NK039.S |
| Anti-Streptolysin O kit<br>Range 5-1600, sensitivity 5 (IU/mL) | 100 test | LK189.S |
| Caeruloplasmin kit<br>Range 0.03-1.64, sensitivity 0.03 (g/L) | 50 test | NK045.S |
| C-Reactive Protein kit<br>Range 5 - 2500, sensitivity 5 (mg/L) | 100 test | NK044.S |
| Ferritin kit<br>Range 7-868, sensitivity 7 (ng/mL) | 100 test | LK055.S |
| Full Range C-Reactive Protein kit<br>Range 0.2-400, sensitivity 0.2 (mg/L) | 100 test | LK044.S |
| Haptoglobin kit<br>Range 0.026-8, sensitivity 0.026 (g/L) | 100 test | NK058.S |
| High Sensitivity C-Reactive Protein kit<br>Range 0.5-10, sensitivity 0.5 (mg/L) | 100 test | LK044.L.S |
| Lipoprotein (a) kit<br>Range 7-180, sensitivity 7 (mg/dL) | 100 test | LK098.S |
| Microalbumin kit*<br>Range 11-3440, sensitivity 11 (mg/L) | 100 test | NK032.U.S |
| Prealbumin kit<br>Range 0.006-0.8, sensitivity 0.006 (g/L) | 100 test | NK066.S |
| Rheumatoid Factor kit<br>Range 7-1040, sensitivity 7 (IU/mL) | 100 test | LK151.S |
| Tetanus toxoid Latex kit<br>Range 1.56-50, sensitivity 1.56 (IU/mL) | 1000 test | LK710.S |
| Transferrin kit<br>Range 0.14-22.4, sensitivity 0.14 (g/L) | 100 test | NK070.S |

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

*For these assays a validated extended measuring range is achievable by re-running with a manual pre-dilution. Please see package insert for assay-specific manual dilution protocols.

| DESCRIPTION | PACK | CODE |
|---|---|---|
| **Central nervous system disorders** | | |
| Freelite Kappa Latex CSF kit*<br>Range 0.1-18, sensitivity 0.1 (mg/L) | 100 test | LK016.L.S |
| Freelite Lambda Latex CSF kit*<br>Range 0.1-16.5, sensitivity 0.1 (mg/L) | 100 test | LK018.L.S |
| Albumin CSF kit<br>Range 17-2700, sensitivity CSF 17 (mg/L)<br>Sensitivity Serum 5100 (mg/L) | 60 test | NK032.L.S |
| IgG CSF kit<br>Range 4.2-1350, sensitivity 4.2 (mg/L) | 60 test | NK004.L.S |
| IgA Latex CSF kit<br>Range 0.15-48, sensitivity 0.15 (mg/L) | 60 test | LK010.L.S |
| IgM Latex CSF kit<br>Range 0.3-70, sensitivity 0.3 (mg/L) | 60 test | LK012.L.S |

NB. **Freelite** CSF kits are also for use with serum and urine.


## SPAPLUS reconditioned

SPAPLUS Specialist protein analyser has proven to be a reliable and user friendly system since its launch in 2006. Over 500 systems have been placed around the world.

A reconditioned SPAPLUS enables you to provide special protein testing on a dedicated, reliable and robust analyser.

## Exceptional technical support and service

Binding Site assists you with every step of the implementation process, from validation to training and beyond.

## Reliable automation

Ensuring you provide an optimal service to your clinicians and patients.



MININEPH® PLUS

# Assays and accessories

MININEPH® PLUS

# Assays and accessories

## MININEPH assays

These include high and low controls plus a magnetic swipe card containing the lot-specific calibration curve and assay parameters.

| DESCRIPTION | PACK | CODE |
|---|---|---|
| IgG kit<br>Range 0.9-113.6 g/L | 50 test | ZK004.R |
| IgG1 kit<br>Range 655-115000 mg/L | 10 test | ZK006.R |
| IgG2 kit<br>Range 365-48125 mg/L | 10 test | ZK007.R |
| IgG3 Latex kit<br>Range 6.9-6050 mg/L | 2x5 test | ZK008.L.R |
| IgG4 Latex kit<br>Range 2.2-4235 mg/L | 2x5 test | ZK009.L.R |
| IgA kit<br>Range 0.17-27 g/L | 50 test | ZK010.R |
| C1 Inactivator kit<br>Range 0.075-9.9 g/L | 25 test | ZK019.R* |
| C3 kit<br>Range 0.125-8.88 g/L | 50 test | ZK023.R |
| C4 kit<br>Range 0.035-2.464 g/L | 50 test | ZK025.R |
| α1-Antitrypsin kit<br>Range 0.35-5.0 g/L | 25 test | ZK034.R |
| Anti-Streptolysin-O Latex kit<br>Range 7.5-10560 IU/mL | 2x25 test | ZK189.L.R |
| β2-Microglobulin Latex kit<br>Range 0.075-132 mg/L | 2x10 test | ZK043.L.R |
| C-Reactive Protein Latex kit<br>Range 0.44-1232 mg/L | 2x25 test | ZK044.L.R |
| Caeruloplasmin kit<br>Range 0.14-1.64 g/L | 25 test | ZK045.R |
| Haptoglobin kit<br>Range 0.11-42.79 g/L | 25 test | ZK058.R |
| Microalbumin kit<br>Range 15-2585 mg/L | 25 test | ZK032.U.R |
| Prealbumin kit<br>Range 0.03-10.23 g/L | 25 test | ZK066.R |
| Rheumatoid Factor Latex kit<br>Range 8.6-5000 IU/mL | 2x25 test | ZK151.L.R |
| Transferrin kit<br>Range 0.18-70.4 g/L | 25 test | ZK070.R |

*For research use only.

## Accessories

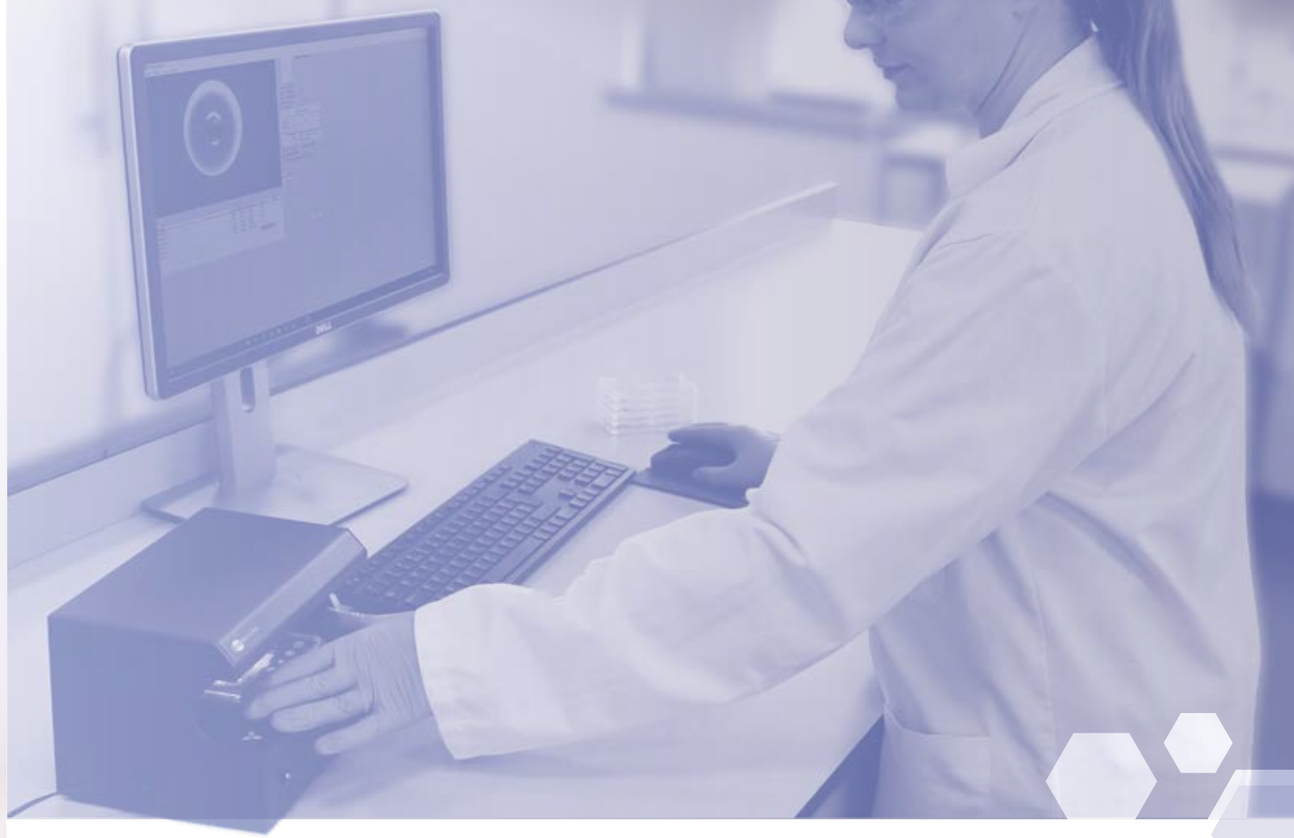
| DESCRIPTION | PACK | CODE |
|---|---|---|
| MININEPHPLUS Accessory Pack<br>200 x Cuvettes, 200x Stirring bars,<br>2x60 mL Sample Diluent | 1 | ZK500.R |
| MININEPHPLUS On-Board Buffer 1 | 1x45 mL<br>4x45 mL | SN107.1<br>SN107.4 |
| MININEPHPLUS Sample Diluent Pack | 4x60 mL | ZK502.R |
| MININEPHPLUS Printer (optional) | 1 | AP1310DPKIT63 |
| MININEPHPLUS Thermal Printer Paper | 20 | AO5856TPR1 |
| Hand Held Bar code Reader (optional) | 1 | AD500.2 |




RID READER™
ACCURATE MEASUREMENT OF RADIAL IMMUNODIFFUSION

& Radial Immunodiffusion assays

Bringing simplicity to a proven science.



RID READER™
ACCURATE MEASUREMENT OF RADIAL IMMUNODIFFUSION

## The Digital RID Reader is designed to simplify & standardise 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 jewellers' eye piece. Using a range of quantitative calibration methods, the RID Reader provides a diameter reading tailored for each assay kit.

### Accurate and Efficient

- Accurate measurement of precipitin rings with enlarged imagery.
- Minimise error and save time associated with manual calculations.
- Reduces cost with RID Reference Table by maximising well use.
- Choose from 3 methods of curve calibration to suit your needs.
- Pre-enter data to generate calibration curve and final sample concentration accordingly.
- Storage capabilities useful for training traceability and quality control.

### RID Reader Technical Specification

Camera Specifications
CCR Video System

Light Source
LED Array

Operating temperature
5 - 40$^0$

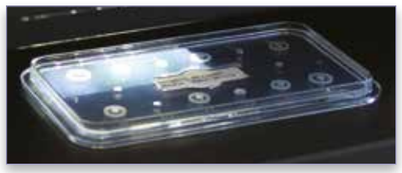
Dimensions
Width 220mm
Height 140mm
Depth 160mm

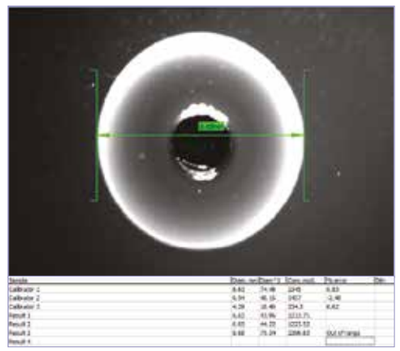
Instrument weight
1.14kg

Power Requirements
100/200v 50/60Hz, 0.6A
12V DC, 0.8A

Computer Requirements
USB port,
Windows 7
Windows 10

| DESCRIPTION | PACK | CODE |
|---|---|---|
| Digital RID Plate Reader (RIDRead software included) | 1 | AD400 |
| Replacement Bulb | 1 | AD001.1 |
| Jeweller's Eye-Piece | 1 | AD040 |
| LED Array Lamp | 1 | AD400.1 |





# Radial Immunodiffusion Assays

Radial Immunodiffusion (RID) is based on the complexing of antigen and antibody to produce a visible precipitin ring.

NANORID™ kits use a novel patented technology to enable accurate quantitation of very low concentrations of protein in biological materials. NANORID™ kits are ideal where increased sensitivity is required as latex enhanced antibodies are used.

BINDARID™ kits use conventional antibody antigen binding RID technology. This is the common method used for the Binding Site RID products.

Unless otherwise stated all assays are BINDARID™.

The procedures for three different methods are included in the instructions:

1. RID Reference Table (Mancini)
2. Complete Diffusion (Mancini)
3. Incomplete Diffusion (Fahey and McKelvey)

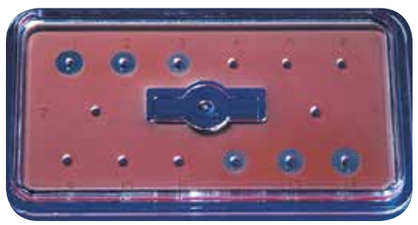
### Human Complement Functional Assays

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 haemolysis of red blood cells following activation of the complement system.

| DESCRIPTION | PACK | CODE |
|---|---|---|
| Total Haemolytic Complement kit<br>Maximum 12 weeks from manufacturing to expiry | 3 plate kit<br>2 plate kit<br>1 plate kit | RC001.3<br>RC001.2<br>RC001.1 |
| Alternative Pathway Haemolytic Complement kit<br>Maximum 6 weeks from manufacturing to expiry | 3 plate kit<br>1 plate kit | RC003.3*<br>RC003.1* |
| Functional C1 Inactivator kit<br>Maximum 12 months from manufacturing to expiry | 3 plate kit | RC002.3 |
| Functional C1 Inactivator COMBI kit<br>Two plates of Functional C1 Inactivator, One plate of C1 Inactivator. Maximum 12 months from manufacturing to expiry | 3 plate kit | RK019 |

### Human Coagulation Proteins

| DESCRIPTION | PACK | CODE |
|---|---|---|
| Antithrombin III - NL RID kit<br>Range 50-500 mg/L | 3 plate kit | RN040.3 |
| Fibrinogen - NL RID kit<br>Range 450-4500 mg/L | 3 plate kit | RN056.3 |
| Plasminogen - NL RID kit<br>Range 20-200 mg/L | 3 plate kit | RN065.3 |
| NANORID™ Protein C RID kit<br>Range 0.5-5.0 mg/L | 3 plate kit | GT118.3 |



### RID kit contents

- RID Plates - 14 pre-cut wells per plate. Gel sectioning blades allow fewer than 14 wells to be used.
- Calibrators - Each kit contains either a single high calibrator or a 3 calibrator set.
- Controls - Control material is include in the majority of kits.
- Sample Diluent - Used to dilute samples, controls and calibrators where necessary; eliminates the possibility of viscosity differences causing inaccurate or incorrect results.
- Instruction Leaflet and Results Table - Full instructions are included together with a RID Reference Table containing protein concentration values for specific ring diameters.

### Human Complement Proteins

| DESCRIPTION | PACK | CODE |
|---|---|---|
| C1 Inactivator - NL RID kit<br>Range 45-450 mg/L | 3 plate kit | RN019.3 |
| C1q - NL RID kit<br>Range 23-230 mg/L** | 3 plate kit | RN020.3 |
| C2 - NL RID kit<br>Range 7.2-36 mg/L | 3 plate kit | RN022.3 |
| C3 - NL RID kit<br>Range 155-1550 mg/L | 3 plate kit | RN023.3 |
| C4 - NL RID kit<br>Range 58-580 mg/L | 3 plate kit | RN025.3 |
| C4 - Binding Protein - NL RID kit<br>Range 50-500 mg/L | 3 plate kit | RN026.3* |
| C5 - NL RID kit<br>Range 20-200 mg/L | 3 plate kit | RN027.3 |
| C6 - NL RID kit<br>Range 12-120 mg/L | 3 plate kit | RN102.3* |
| C7 - NL RID kit<br>Range 22-110 mg/L | 3 plate kit | RN103.3* |
| C8 - NL RID kit<br>Range 20-200 mg/L | 3 plate kit | RN089.3* |
| C9 - NL RID kit<br>Range 50-500 mg/L | 3 plate kit | RN028.3* |
| Factor B - NL RID kit<br>Range 45-450 mg/L | 3 plate kit | RN029.3 |
| Factor H (β 1H) - NL RID kit<br>Range 70-700 mg/L | 3 plate kit | RN030.3* |
| Factor I - NL RID kit<br>Range 7-70 mg/L | 1 plate kit | RN031.1* |

* For research use only.
** Diluted sample applied - assay range may be extended using neat sample.
See page 9 for the CH50 SPAPLUS assay and page 4 for the CH50 Optilite assay.

# Radial Immunodiffusion Assays

## Human Proteins

| DESCRIPTION | PACK | CODE |
|---|---|---|
| Albumin - NL RID kit<br>Range 5000-50000 mg/L** | 3 plate kit | RN032.3 |
| Albumin - ML RID kit<br>Range 16-160 mg/L | 3 plate kit | RL032.3* |
| α1-Antitrypsin - NL RID kit<br>Range 280-2800 mg/L | 3 plate kit | RN034.3 |
| NANORID™ β2-Microglobulin - EL RID kit<br>Range 1-10 mg/L | 3 plate kit | GT043.3 |
| Haptoglobin - NL RID kit<br>Range 190-1900 mg/L | 3 plate kit | RN058.3 |
| NANORID™ Lysozyme - NL RID kit<br>Range 1.05-10.5 mg/L | 3 plate kit | GT073.3 |
| Transferrin - NL RID kit<br>Range 440-4400 mg/L | 3 plate kit | RN070.3 |

* For research use only.
** Diluted sample applied - assay range may be extended using neat sample.
Manufacturing date to expiry ranges from 13 to 26 months, unless otherwise stated.

## Human Immunoglobulins

| DESCRIPTION | PACK | CODE |
|---|---|---|
| IgG - NL RID kit<br>Range 2250-22500 mg/L | 3 plate kit | RN004.3 |
| IgG - ML RID kit<br>Range 18-180 mg/L | 3 plate kit | RL004.3* |
| IgG1 Subclass - SD RID kit<br>Range 1400-14000 mg/L** | 3 plate kit | RN106.3 |
| IgG2 Subclass - SD RID kit<br>Range 800-8000 mg/L** | 3 plate kit | RN107.3 |
| IgG3 Subclass - SD RID kit<br>Range 120-1200 mg/L | 3 plate kit | RN108.3 |
| IgG4 Subclass - SD RID kit<br>Range 50-500 mg/L | 3 plate kit | RN109.3 |
| IgG Subclass COMBI - SD RID kit<br>One plate each of IgG1, IgG2, IgG3 and IgG4 | 4 plate kit | RK021 |
| IgA - NL RID kit<br>Range 545-5450 mg/L | 3 plate kit | RN010.3 |
| IgA - ML RID kit<br>Range 8.5-85 mg/L | 3 plate kit | RL010.3* |
| NANORID™ IgA - UL RID kit<br>Range 0.43-4.3 mg/L | 3 plate kit | GL010.3* |
| IgA Subclass COMBI kit - NL RID kit<br>Two plates each of IgA1 and IgA2<br>IgA1 Range 640-6400 mg/L**<br>IgA2 Range 50-500 mg/L** | 4 plate kit | RK015 |
| Secretory IgA - NL RID kit<br>Range 45-450 mg/L | 3 plate kit | RN148.3* |
| IgM - NL RID kit<br>Range 265-2650 mg/L | 3 plate kit | RN012.3 |
| IgG, IgA, IgM COMBI - NL RID kit<br>One plate each of IgG, IgA and IgM | 3 plate kit | RK002 |
| IgD - NL RID kit<br>Range 8.5-85 mg/L | 3 plate kit | RN013.3 |



# Freelite® &

Free light chain assays

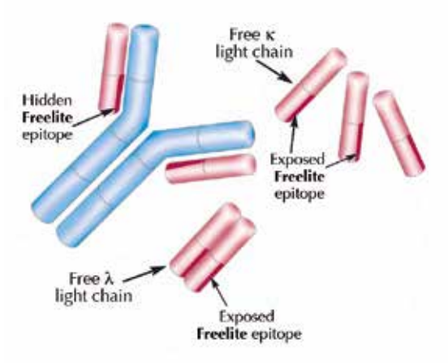
# Hevylite®

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 |
| κ/λ FLC ratio | 100 percentile range |
| | 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<br>Range 2.9-127, sensitivity 0.6 (mg/L) | 100 test | LK016.OPT |
| | Freelite Lambda Latex kit<br>Range 5.2-139, sensitivity 1.3 (mg/L) | 100 test | LK018.OPT |
| Binding Site SPAPLUS® | Freelite Kappa Latex kit<br>Range 4.0-180, sensitivity 0.4 (mg/L) | 100 test | LK016.S |
| | Freelite Lambda Latex kit<br>Range 4.5-165, sensitivity 0.45 (mg/L) | 100 test | LK018.S |
| Beckman IMMAGE™ | Freelite Kappa Latex kit<br>Range 6-180, sensitivity 3 (mg/L) | 2x50 test | LK016.IM |
| | Freelite Lambda Latex kit<br>Range 4.8-162, sensitivity 2.4 (mg/L) | 2x50 test | LK018.IM |
| Roche cobas™ c Systems c501/c502 | Freelite Kappa Latex kit<br>Range 3.7-56.2 , sensitivity 0.8 (mg/L) | 100 test | LK016.CB |
| | Freelite Lambda Latex kit<br>Range 5.6-74.8, sensitivity 0.7 (mg/L) | 100 test | LK018.CB |
| Siemens BN™II | Freelite Kappa Latex kit<br>Range 5.9-190, sensitivity 0.3 (mg/L) | 2x50 test | LK016.T |
| | Freelite Lambda Latex kit<br>Range 5-160, sensitivity 0.25 (mg/L) | 2x50 test | LK018.T |
| Siemens BN ProSpec™ | Freelite Kappa Latex kit<br>Range 5.9-190, sensitivity 0.3 (mg/L) | 2x50 test | LK016.P |
| | Freelite Lambda Latex kit<br>Range 5-160, sensitivity 0.25 (mg/L) | 2x50 test | LK018.P |

Please see page 34 for information on Freelite in CSF testing.

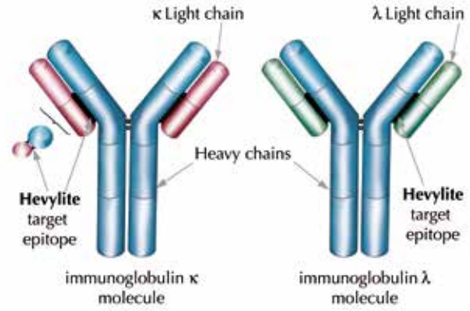
Find the guidelines


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 IgGκ 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/IgGλ |
| 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<br>IgG Lambda<br>IgGκ/IgGλ Ratio | 4.03 - 9.78 g/L<br>1.97 - 5.71 g/L<br>0.98 - 2.75 |
| IgA Kappa<br>IgA Lambda<br>IgAκ/IgAλ Ratio | 0.588 - 2.984 g/L<br>0.432 - 2.035 g/L<br>0.911 - 2.416 |
| IgM Kappa<br>IgM Lambda<br>IgMκ/IgMλ Ratio | 0.19 - 1.63 g/L<br>0.12 - 1.01 g/L<br>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.

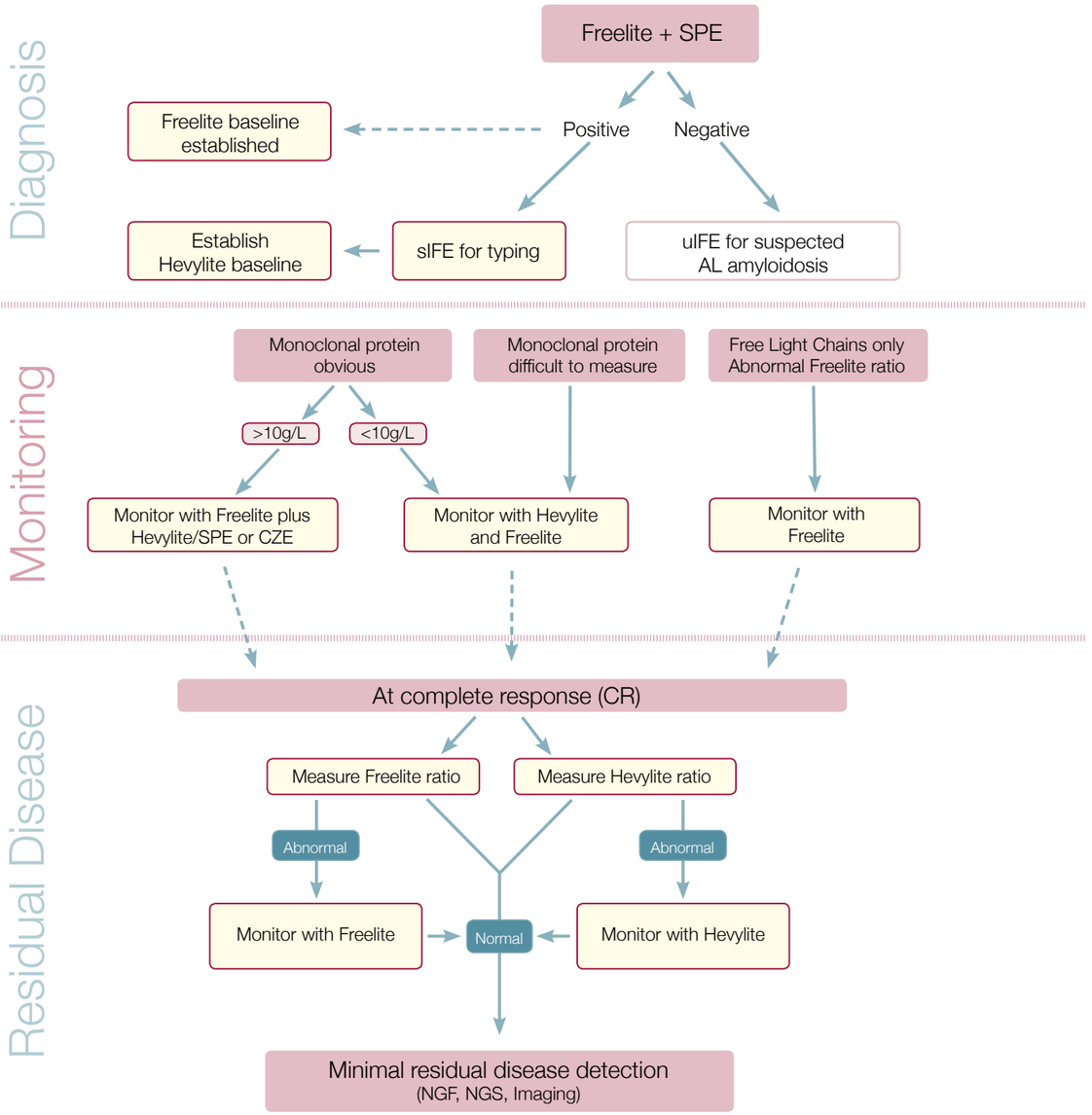
| ANALYSER | DESCRIPTION | PACK | CODE |
|---|---|---|---|
| Binding Site Optilite® | Hevylite IgG Kappa kit<br>Range 2.3-30, sensitivity 0.115 (g/L) | 50 test | NK621.OPT |
| | Hevylite IgG Lambda kit<br>Range 1.5-17.5, sensitivity 0.075 (g/L) | 50 test | NK622.OPT |
| | Hevylite IgA Kappa kit<br>Range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



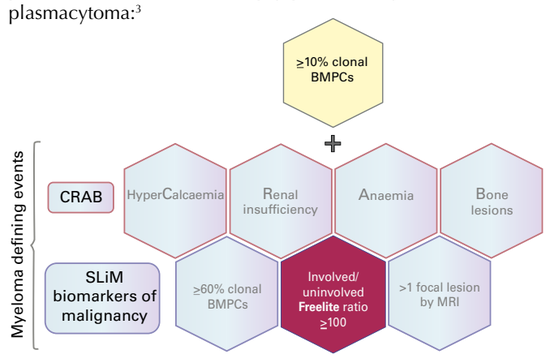
## Freelite for diagnosis

### 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]



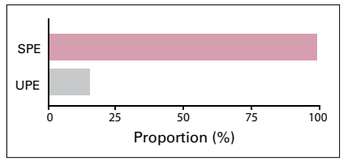

An involved/uninvolved sFLC ratio ≥100 is now a recognised biomarker of malignancy (based on Freelite assay, when iFLC is ≥100mg/L). [3]

### 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.

> *…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]

### 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]


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]

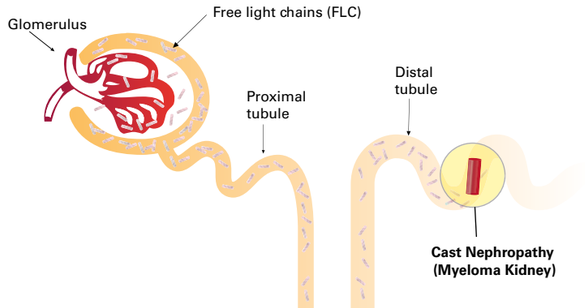

Learn more

Dowload the Amyloidosis postcard for more information.

### 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]

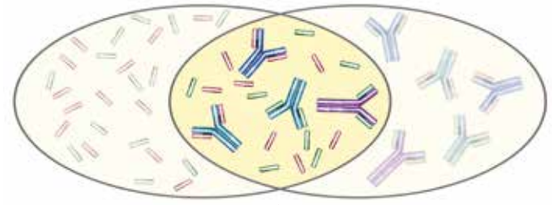
> *For serial measurements, either the involved FLC or the difference between the involved and uninvolved (dFLC) should be used.*[1]

### 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**

Learn more

Watch our animated learning activity to understand more about the recent utilities of the **Freelite** and **Hevylite** assays along the myeloma patient pathway, from MGUS to monitoring.


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


## Key guidelines

| Year | Guidelines |
|---|---|
| 2016 | International Myeloma Working Group consensus criteria for response and minimal residual disease assessment in multiple myeloma.<br>Kumar S, *et al. Lancet Oncol* 2016; 17:e328-46 |
| 2016 | National Institute for Health and Care Excellence (NICE). Myeloma: diagnosis and management.<br>NICE Guidelines NG35 2016 |
| 2016 | National Comprehensive Cancer Network (NCCN). Clinical practice Guidelines in Oncology - Multiple Myeloma<br>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.<br>Rajkumar SV, *et al*. *Lancet Oncology* 2014; 15:e538-e548 |
| 2014 | International Myeloma Working Group recommendations for global myeloma care.<br>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.<br>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.<br>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.<br>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.<br>Dispenzieri A, *et al*. *Leukemia* 2009; 23:215-224 |
| 2006 | International uniform response criteria for multiple myeloma.<br>Durie BGM, *et al*. *Leukemia* 2006; 20:1467-1473 |

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.

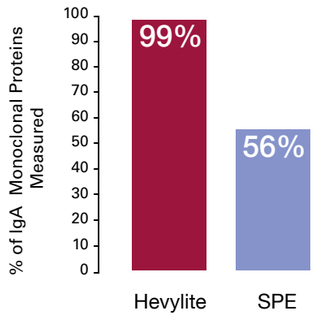
IgA monoclonal proteins that co-migrate into the β–region on SPE can be difficult to measure – this happens in about 44% of samples - but **Hevylite** accurately quantifies them.[1-6]

| Comparison of information | Hevylite | 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



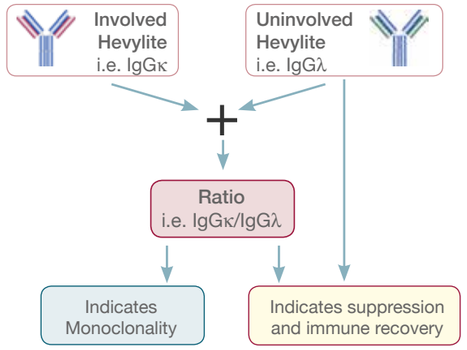

In combined studies of more than 430 patients, only 56% of IgA monoclonal proteins were measurable by SPE but 99% were measurable with **Hevylite**[1-6]

### 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.

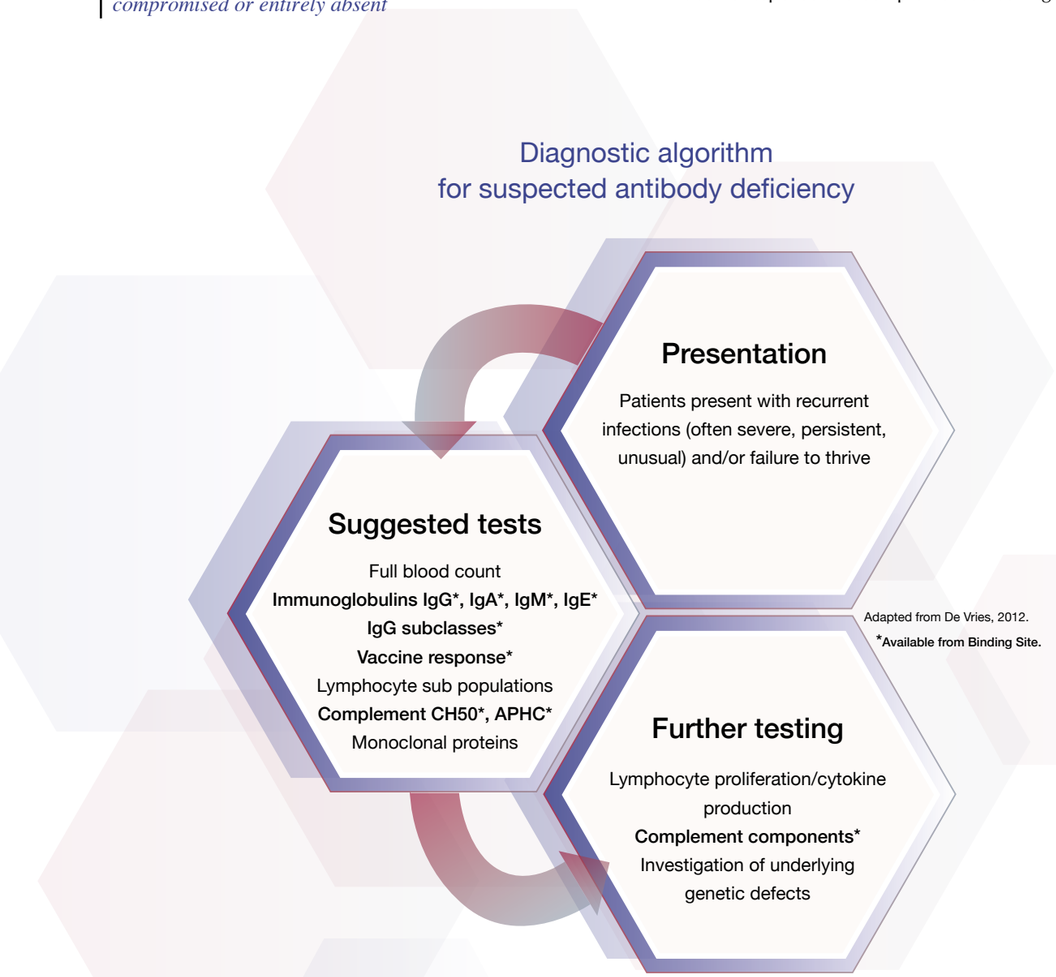



Fig. 1 Diagnosis of immunodeficiency requires the use of information from a variety of laboratory tests alongside clinical presentation. Guidelines for diagnosis are available from the European Society for Immunodeficiency (ESID)[1] and the American Academy of Allergy, Asthma and Immunology.[2]



# 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)

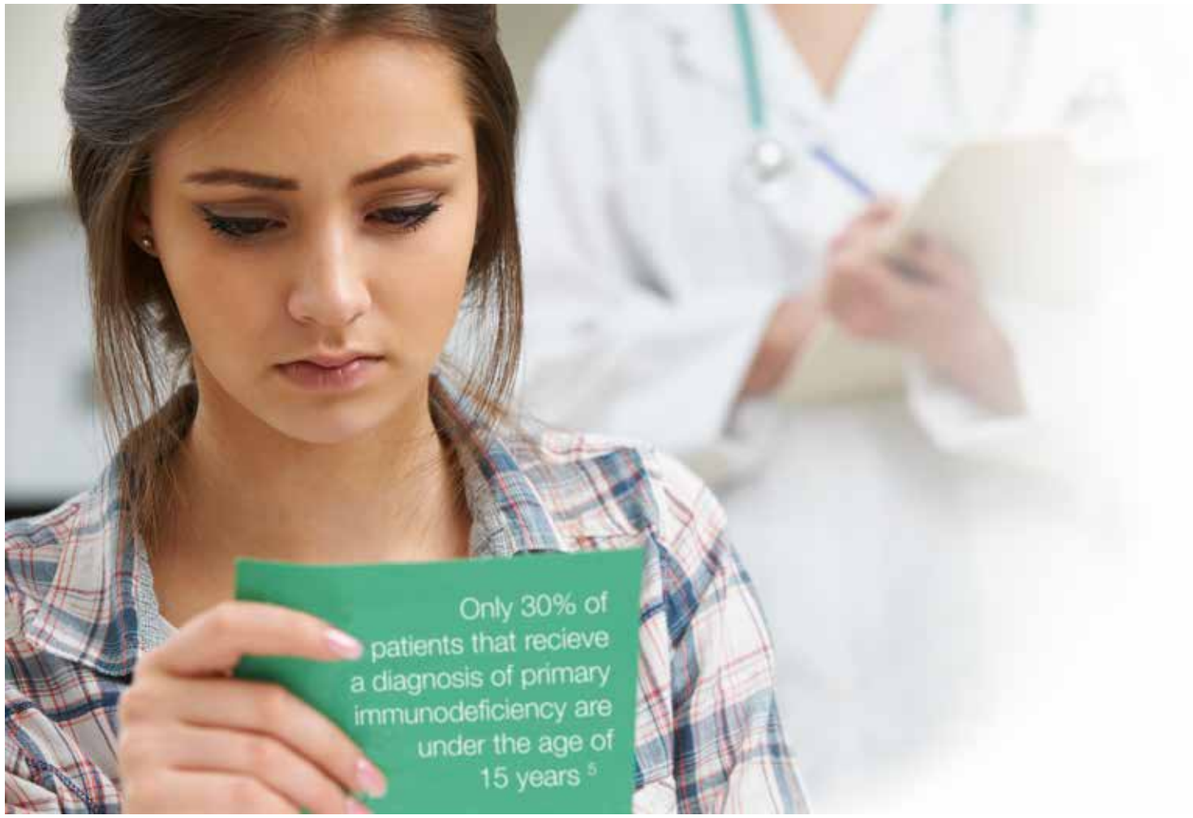
## IgG, A and M

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
5. Bousfi ha AA, *et al.*Primary Immunodefi ciency Diseases Worldwide: More Common than Generally Thought. *J Clin Immunol* 2012; 33:1-7




# IgG Subclasses

## Specificity

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

## Sensitivity

Binding Site IgG Subclass assays are optimised 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 paediatric normal ranges.

## 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<br>Range 0.15-144, sensitivity 0.15 (g/L) | 100 test | NK006.OPT |
| IgG2 Optilite kit<br>Range 0.02-28, sensitivity 0.02 (g/L) | 100 test | NK007.OPT |
| IgG3 Optilite kit<br>Range 0.0055-8.8, sensitivity 0.0055 (g/L) | 100 test | LK008.OPT |
| IgG4 Optilite kit<br>Range 0.0043-64.8, sensitivity 0.0043 (g/L) | 100 test | LK009.OPT |

## Binding Site SPAPLUS®

| DESCRIPTION | PACK | CODE |
|---|---|---|
| IgG1 SPAPLUS kit<br>Range 0.15-144, sensitivity 0.15 (g/L) | 100 test | NK006.S |
| IgG2 SPAPLUS kit<br>Range 0.02-28, sensitivity 0.02 (g/L) | 100 test | NK007.S |
| IgG3 Latex SPAPLUS kit<br>Range 0.0055-4, sensitivity 0.0055 (g/L) | 100 test | LK008.S |
| IgG4 Latex SPAPLUS kit<br>Range 0.003-3.4, sensitivity 0.003 (g/L) | 100 test | LK009.S |

## Roche cobas™ 6000

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

## Beckman IMMAGE™

| DESCRIPTION | PACK | CODE |
|---|---|---|
| IgG1 kit<br>Range 0.15-40, sensitivity 0.15 (g/L) | 58 test | NK006.IM |
| IgG2 kit<br>Range 0.0972-26.25, sensitivity 0.0972 (g/L) | 58 test | NK007.IM |
| IgG3 Latex kit<br>Range 0.01-2, sensitivity 0.01 (g/L) | 58 test | LK008.IM |
| IgG4 Latex kit<br>Range 0.0073-1.5, sensitivity 0.0073 (g/L) | 58 test | LK009.IM |

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 2 for more information on Optilite and page 8 for more information on SPAPLUS.

# IgG Subclasses

## Siemens BN™II

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

## Small Volume Testing

For laboratories with small numbers of patient samples or if only a small volume of sample is available (e.g. paediatric samples) IgG subclasses may be measured using radial immunodiffusion (RID, page 14).

The ranges quoted are achieved from the assay-specific instrument protocols. Maximum manufacturing date to expiry is 12 months.
*Diluted sample applied - assay range may be extended using neat sample.

# 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<br>Range 0.035-6, sensitivity 0.035 (g/L) | 50 test | NK087.OPT |
| IgA2 Latex Optilite kit<br>Range 0.005-1.25, sensitivity 0.005 (g/L) | 50 test | LK088.OPT |

## Binding Site SPAPLUS®

| DESCRIPTION | PACK | CODE |
|---|---|---|
| IgA1 SPAPLUS kit<br>Range 0.03-6, sensitivity 0.03 (g/L) | 50 test | NK087.S |
| IgA2 Latex SPAPLUS kit<br>Range 0.005-1.25, sensitivity 0.005 (g/L) | 50 test | LK088.S |

## Siemens BN™II

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

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

## Beckman IMMAGE®

| DESCRIPTION | PACK | CODE |
|---|---|---|
| IgA1 Latex kit<br>Range 0.0355-6, sensitivity 0.0355 (g/L) | 40 test | LK087.IM |
| IgA2 Latex kit<br>Range 0.005-1.25, sensitivity 0.005 (g/L) | 40 test | LK088.IM |

## Radial Immunodiffusion

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



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

## Binding Site SPAPLUS®

| DESCRIPTION | PACK | CODE |
|---|---|---|
| C1 Inactivator Kit<br>Range 0.06-0.8, sensitivity 0.06 (g/L) | 50 test | NK019.S |
| C2 Kit<br>Range 4-90, sensitivity 4 (mg/L) | 100 test | LK022.S |
| C3c Kit<br>Range 0.025-6, sensitivity 0.025 (g/L) | 100 test | NK023.S |
| C4 Kit<br>Range 0.0064-1.8, sensitivity 0.0064 (g/L) | 100 test | NK025.S |
| CH50 Reagent***<br>Range 12-95, sensitivity 12 (U/mL) | 100 test | NK095.S |
| CH50 Calibrator | 1 pack | NC095.S |
| CH50 Controls<br>x4 L, x4 H, x4 Elevated | 1 pack | NQ095.S |

See page 2 for more information on Optilite, page 8 for more information on SPAPLUS & page 14 for more information on the RID Reader.

* For research use only.
** Diluted sample applied - assay range may be extended using neat sample.
*** For these assays a validated extended measuring range is achievable by re-running with a manual pre-dilution. Please see package insert for assay-specific manual dilution protocols.

## Binding Site RID Reader

### Human Complement Protein Assays

Complement protein assays are useful for identifying immune deficiencies.

| DESCRIPTION | PACK | CODE |
|---|---|---|
| C1 Inactivator - NL RID kit<br>Range 45-450 mg/L | 3 plate kit | RN019.3 |
| C1q - NL RID kit<br>Range 23-230 mg/L** | 3 plate kit | RN020.3 |
| C2 - NL RID kit<br>Range 7.2-36 mg/L | 3 plate kit | RN022.3 |
| C3 - NL RID kit<br>Range 155-1550 mg/L | 3 plate kit | RN023.3 |
| C4 - NL RID kit<br>Range 58-580 mg/L | 3 plate kit | RN025.3 |
| C4 - Binding Protein - NL RID kit<br>Range 50-500 mg/L | 3 plate kit | RN026.3* |
| C5 - NL RID kit<br>Range 20-200 mg/L | 3 plate kit | RN027.3 |
| C6 - NL RID kit<br>Range 12-120 mg/L | 3 plate kit | RN102.3* |
| C7 - NL RID kit<br>Range 22-110 mg/L | 3 plate kit | RN103.3* |
| C8 - NL RID kit<br>Range 20-200 mg/L | 3 plate kit | RN089.3* |
| C9 - NL RID kit<br>Range 50-500 mg/L | 3 plate kit | RN028.3* |
| Factor B - NL RID kit<br>Range 45-450 mg/L | 3 plate kit | RN029.3 |
| Factor H (β 1H) - NL RID kit<br>Range 70-700 mg/L | 3 plate kit | RN030.3* |
| Factor I - NL RID kit<br>Range 7-70 mg/L | 1 plate kit | RN031.1* |

## 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 haemolysis of red blood cells following activation of the complement system.

| DESCRIPTION | PACK | CODE |
|---|---|---|
| Total Haemolytic Complement kit<br>Maximum 12 weeks from manufacturing to expiry | 3 plate kit<br>2 plate kit<br>1 plate kit | RC001.3<br>RC001.2<br>RC001.1 |
| Alternative Pathway Haemolytic Complement kit<br>Maximum 6 weeks from manufacturing to expiry | 3 plate kit<br>1 plate kit | RC003.3*<br>RC003.1* |
| Functional C1 Inactivator kit<br>Maximum 12 months from manufacturing to expiry | 3 plate kit | RC002.3 |
| Functional C1 Inactivator COMBI kit<br>Two plates of Functional C1 Inactivator, One plate of C1 Inactivator. Maximum 12 months from manufacturing to expiry | 3 plate kit | RK019 |

# VaccZyme™

Vaccine Response Assays

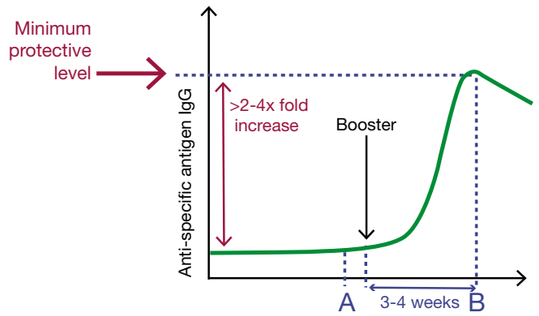
## Specific antibody measurement

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.



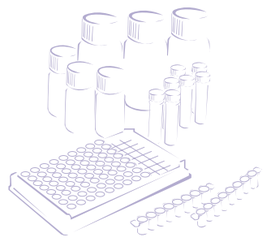

Vaccines are widely used to measure the ability of the immune system to produce functionally active specific antibodies and it is important to investigate the response to protein antigens and pure polysaccharide antigens as the immune response of an individual can vary depending on the nature of the 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.



## Vaccine response assays

### Protein Antigens (T-cell dependent response)

| DESCRIPTION | PACK | CODE |
|---|---|---|
| VaccZyme Tetanus toxoid IgG kit<br>Range 0.01-7 IU/mL | 96 test | MK010 |
| VaccZyme Diphtheria toxoid IgG kit<br>Range 0.004-3 IU/mL | 96 test | MK014 |
| VaccZyme VZVgp Low Level IgG kit<br>Range 10-810 mIU/mL | 96 test | MK092 |

### Peptide-Conjugated Antigens (T-cell dependent response)

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

### Polysaccharide Antigens (T-cell independent response)

| DESCRIPTION | PACK | CODE |
|---|---|---|
| VaccZyme PCP IgG kit<br>Range 3.3-270 mg/L | 96 test | MK012 |
| VaccZyme PCP IgA kit<br>Range 0-270 U/mL | 96 test | MK120 |
| VaccZyme PCP IgM kit<br>Range 0-270 U/mL | 96 test | MK121 |
| VaccZyme *Salmonella typhi Vi* IgG kit<br>Range 7.4-600 U/mL | 96 test | MK091 |

### Plasma Screening Assay (high measuring ranges)

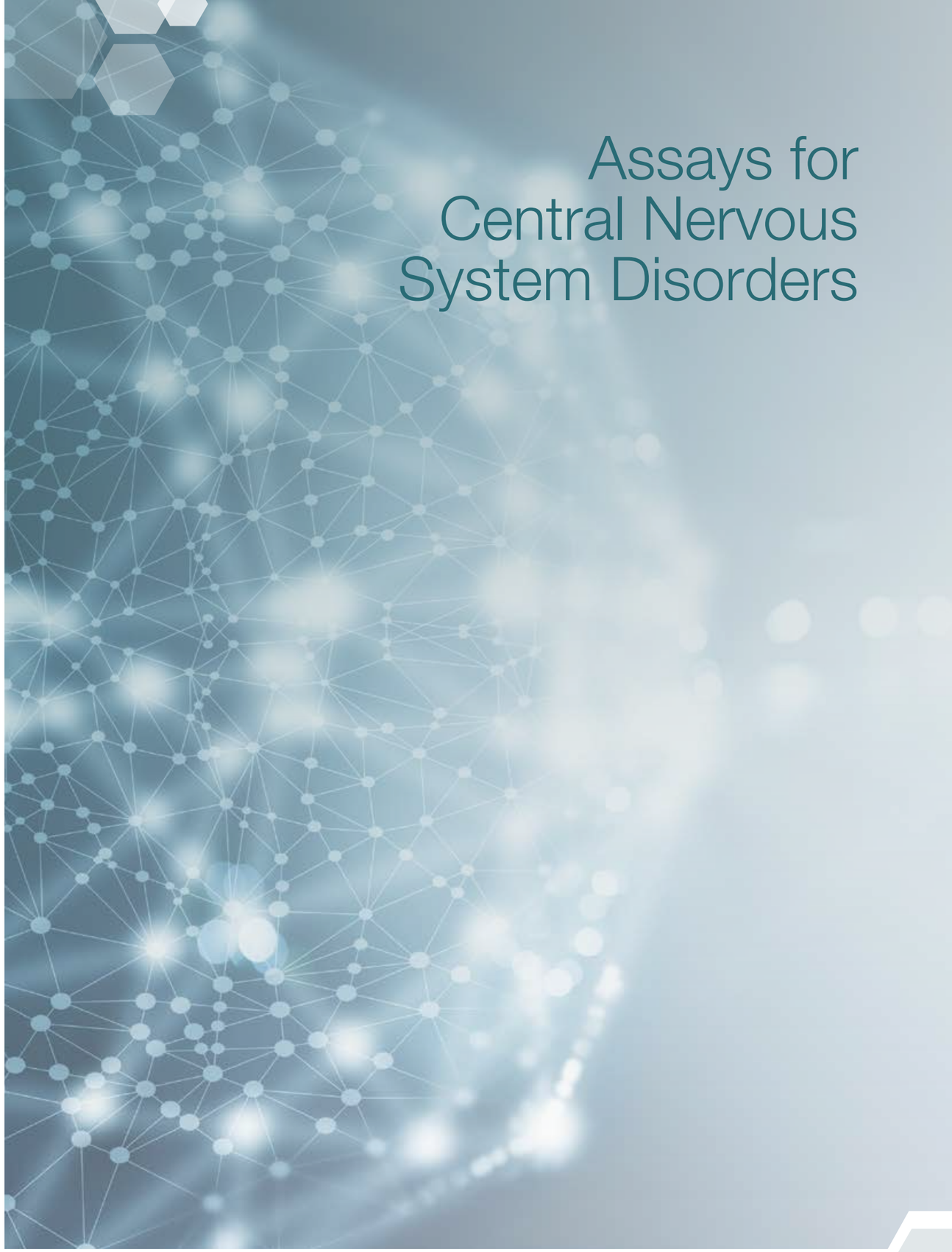
| DESCRIPTION | PACK | CODE |
|---|---|---|
| VaccZyme Tetanus toxoid IgG kit<br>Range 0.25-60 IU/mL (1:200 dilution)<br>Range 1.23-300 IU/mL (1:1000 dilution) | 10x96 test | MK010.4 |

## Research use only assays

| DESCRIPTION | PACK | CODE |
|---|---|---|
| VaccZyme Tetanus toxoid IgG1 kit<br>Range 0.67-54 mg/L | 96 test | MK011 |
| VaccZyme PCP IgG2 kit<br>Range 1.1-90 mg/L | 96 test | MK013 |

PCP = Pneumococcal Capsular Polysaccharide. These kits utilise Pneumovax™ 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, **Freelite Mx™** can be used to support a diagnosis of MS in conjunction with tests such as oligoclonal band analysis (the current gold standard for CSF analysis in diagnosing MS).

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. Learn more about Optilite on page 2.

### CSF assay panel

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

| DESCRIPTION | PACK | CODE |
|---|---|---|
| Freelite Mx™ Kappa Latex kit*<br>Range 0.33-127000<br>Sensitivity 0.33 (mg/L) | 100 test | LK016.M.OPT |
| Freelite Mx™ Lambda Latex kit*<br>Range 0.74-139000<br>Sensitivity 0.74 (mg/L) | 100 test | LK018.M.OPT |
| Low Level Albumin kit*<br>Range 11-66500, sensitivity CSF/Urine 11, Serum 2200 (mg/L) | 100 test | NK032.L.OPT |
| Low Level IgG kit*<br>Range 7.5-27000, sensitivity CSF/Urine 7.5, Serum 1500 (mg/L) | 60 test | NK004.LL.OPT |
| IgA CSF kit*<br>Range 0.91-8000, sensitivity CSF 0.91, Serum 330 (mg/L) | 60 test | LK010.L.OPT |
| IgM CSF kit*<br>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. We also offer a SPAPLUS CSF assay panel - see page 10.

## DataSite for comprehensive CSF reporting

DataSite, our data management system, facilitates the interpretation of your CSF results using pre-programmed quotient and index calculations. Learn more about DataSite on page 6.

| | QUOTIENT CALCULATION | INDEX CALCULATION |
|---|---|---|
| κ FLC | $Q_{\kappa\ FLC} = \kappa\ FLC_{CSF} / \kappa\ FLC_{serum}$ | κ FLC index = $Q_{\kappa\ FLC} / Q_{Alb}$ |
| λ FLC | $Q_{\lambda\ FLC} = \lambda\ FLC_{CSF} / \lambda\ FLC_{serum}$ | λ FLC index = $Q_{\lambda\ FLC} / Q_{Alb}$ |
| Albumin | $Q_{Alb} = Albumin_{CSF} / Albumin_{serum}$ | - |
| IgG | $Q_{IgG} = IgG_{CSF} / IgG_{serum}$ | IgG index = $Q_{IgG} / Q_{Alb}$ |
| IgA | $Q_{IgA} = IgA_{CSF} / IgA_{serum}$ | IgA index = $Q_{IgA} / Q_{Alb}$ |
| IgM | $Q_{IgM} = IgM_{CSF} / IgM_{serum}$ | IgM index = $Q_{IgM} / Q_{Alb}$ |

Custom laboratory-specific calculations can also be defined and provide flexibility to allow you to create your own CSF algorithms.



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.

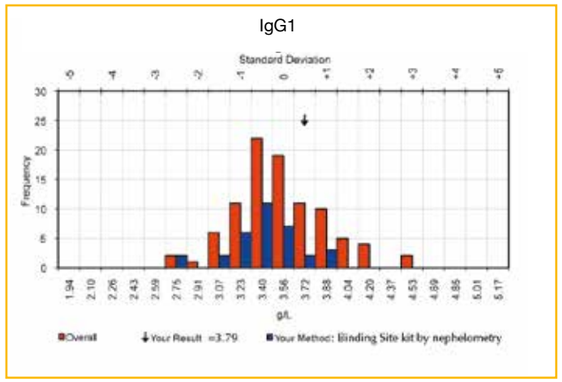
In all Binding Site IMMPROVE QA Schemes the participating laboratory is asked to run the sample provided on their routine assays and report the results obtained. Following analysis of the results a report is sent to each participating laboratory. The number of samples issued per 12 months is indicated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

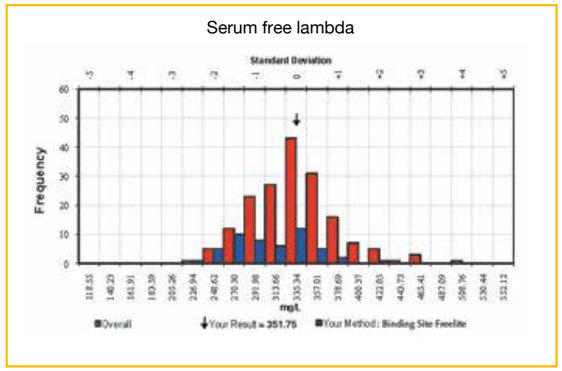
This scheme is for the analysis of any or all of the following tests: IgG, IgA, IgM, IgG1, IgG2, IgG3, IgG4, IgA1, IgA2, Tetanus toxoid IgG, Diphtheria toxoid IgG, PCP IgG and *Haemophilus influenzae* type b IgG. Results can be returned via the IMMPROVE website with password protected secure access. The report members receive provides a full statistical analysis of results with cumulative, performance related scoring. More than 150 laboratories worldwide participate.




## 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.




## Urine Paraprotein QA Scheme

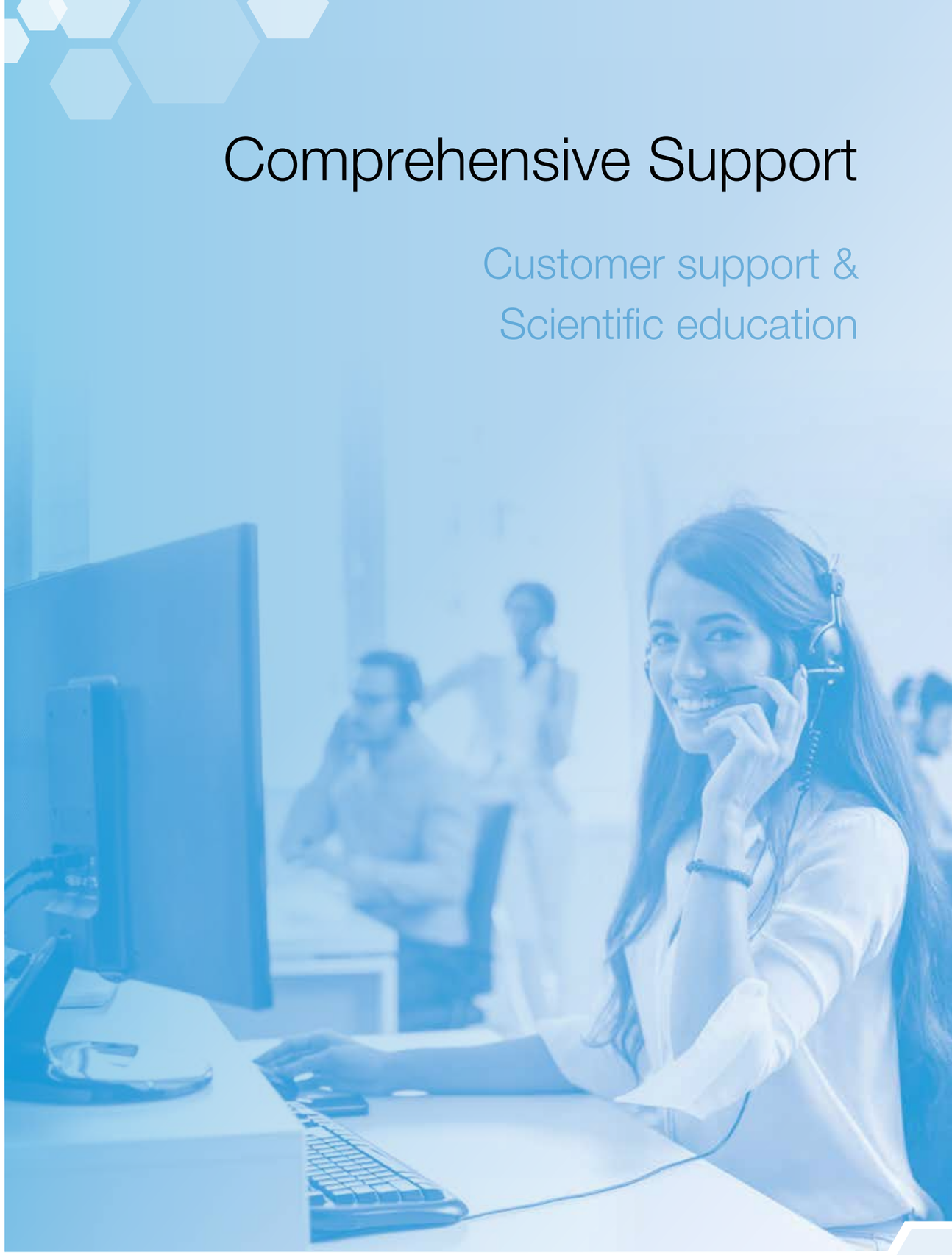
Urine sample analysis for free kappa, free lambda and the kappa/lambda (κ/λ) ratio, together with results for screening and typing. Results can be returned via the IMMPROVE website with password protected secure access. The report members receive includes a full statistical analysis of results to enable 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.

### Clinical Studies

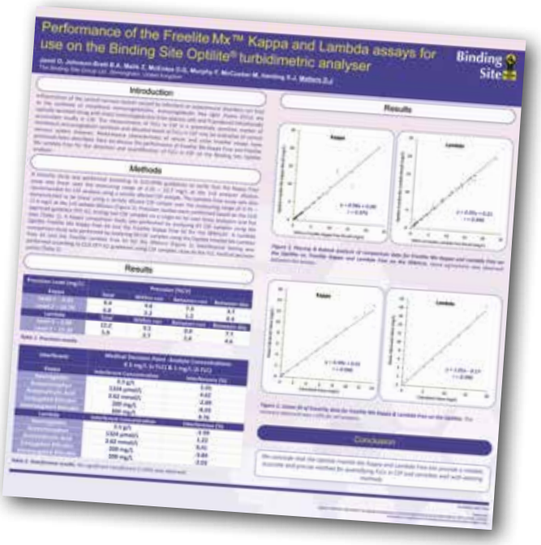
We can help you initiate and evaluate clinical studies using Binding Site products and can assist in the publication of conference abstracts, posters and journal manuscripts.

### Scientific Publication Reprints

A range of these documents are available to order.

### Wikilite.com

The Wikilite.com website is maintained as an up-to-date resource, in which the hundreds of new publications are reviewed and rapidly integrated into a changing and challenging subject.





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

Binding Site | Protein diagnostics. Smart solutions.