

IgG subclass testing on the Optilite[®]

High quality and performance



Optilite IgG Subclass Assays

Measuring IgG subclass concentrations enables clinicians to support the diagnosis of antibody deficiency and other subclass-related disorders. The Optilite® analyser offers a complete solution for IgG subclass testing with unparalleled quality and performance.

Increase your confidence - IgG subclass calibration to reference standard DA470k

IgG subclass concentrations were assigned to DA470k by The Binding Site using an IFCC approved value transfer method from CRM470.¹ IgG has proven stability in DA470k therefore this standard is suitable reference material for IgG subclass standardisation.

Key advantages of DA470k include:

- Full traceability for assurance
- IgG pure protein value has been assigned accurately
- Proven stability between -70°C and 20°C
- Peace of mind with reliable IgG subclass test results
- DA470k is accepted by the International Federation of Clinical Chemistry (IFCC)

Alternative IgG subclass assays are calibrated to the World Health Organisation standard WHO67/97 (Sanquin M1590).

Measuring IgG3 and IgG4 concentrations in WHO 67/97 have shown considerable laboratory to laboratory variability.²⁻⁶



Enhance your efficiency - Optilite has the highest throughput for a mix of IgG subclass samples

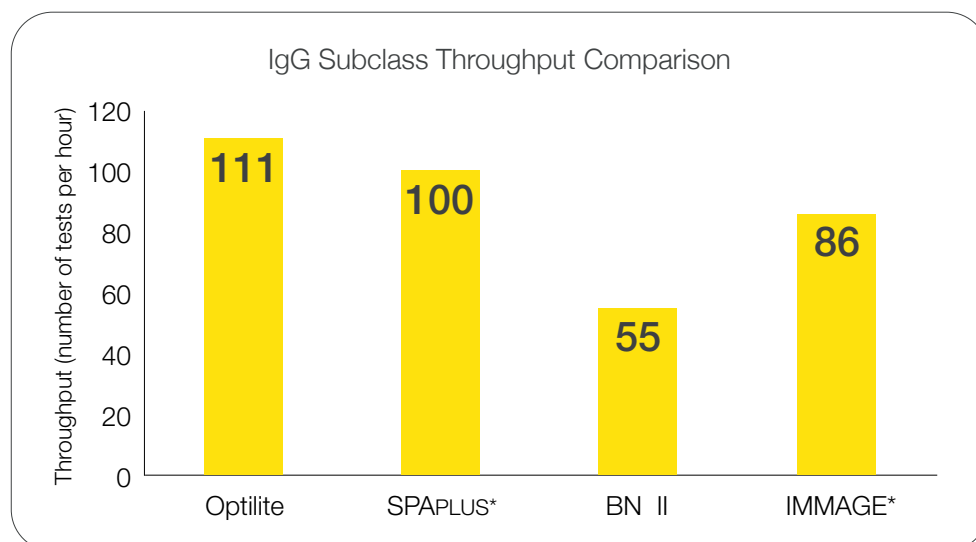
The Optilite system has intelligent scheduling to help streamline your laboratory's workflow and ensure faster test turnaround times. Each assay has been optimised to enhance your productivity:

- Automatic re-dilution to end result ensures no additional manual dilutions are required
- Wide measuring ranges with large dilution steps minimises reagent usage

The efficiency of our IgG subclass assays was compared to alternative reagents/platforms. An identical set of samples were run on Optilite, SPAPLUS®, Siemens BN™II and Beckman IMMAGE™ systems using reagents from the respective instrument manufacturers.

The data demonstrated that Optilite is:

- ~50% faster than BN™II
- ~33% faster than IMMAGE™



*Data for the SPAPLUS and IMMAGE does not include the time required to perform manual dilutions.

30 samples were analysed from healthy individuals and individuals under investigation for immunological disorders. The throughput (number of tests per hour) was calculated using the formula (number of tests/time in minutes between the first and last result) x60.

Product Information

Optilite Assay	IgG1	IgG2	IgG3	IgG4
Product Code	NK006.OPT	NK007.OPT	LK008.OPT	LK009.OPT
Full Measuring Range	150 - 144000 mg/L	20 - 28000 mg/L	5.5 - 8800 mg/L	4.3 - 64800 mg/L
Initial Measuring Range	1500 - 36000 mg/L	200 - 7000 mg/L	55 - 2200 mg/L	54 - 2700 mg/L
Reference Interval	3824 - 9286 mg/L	2418 - 7003 mg/L	218.2 - 1760.6 mg/L	39.2 - 864 mg/L
Automated Antigen Excess Check	N/A*	N/A*	YES (reaction kinetic method)	YES (control addition method)

*Automated antigen excess check is not required due to the inherent antigen excess capacity.

Optilite - Comprehensive assay menu

In addition to IgG subclass assays Optilite has a comprehensive menu for complement, renal function and specific protein analysis. Please visit www.bindingsite.com for further details.

Committed to Quality

Our manufacturing facility conforms to rigorous internal quality control procedures and has quality systems accredited to ISO13485:2016 and MDSAP certification.

We also participate in a number of independent national and international quality assurance schemes ensuring that our high quality assay performance is consistently maintained.

Unrivalled Support

Expert technical and scientific support is available either direct from our headquarters in Birmingham, UK, or from one of our eight global subsidiary offices. Contact details can be found below.

Contact us www.bindingsite.com to find your local office or representative in over 80 countries

Follow us on     

References

1. Williams, D.R. *et al.* Assignment of IgG Subclass Values to the Protein Reference Preparation DA470k. Clin. Chem. Vol. 55, No. S6, PS C-90
2. Klein, F. *et al.* 1985. The quantification of human IgG subclasses in reference preparations. Clin Chim Acta 150: 119-127
3. Schauer U. *et al.* IgG Subclass concentrations in Certified Reference Material 470 and Reference Values for Children and Adults Determined with The Binding Site Reagents. Clin Chem 2003;49:1924-9
4. Wilson C. *et al.* Significant, quantifiable differences exist between IgG subclass standards WHO67/97 and ERM-DA470k and can result in different interpretation of results. Clin Biochem 2013;46:1751-5.
5. Bernasconi L. *et al.* Variable and inaccurate serum IgG4 levels resulting from lack of standardization in IgG subclass assay calibration. Clin Chem Lab Med 2019;10:1515
6. Usami Y. *et al.* Cut-off values of serum IgG4 among three reagents, including a novel IgG4 reagent: a multicenter study. Scientific Reports 11.1 (2021): 1-7

Optilite® is a registered trademark of The Binding Site Group Ltd (Birmingham, UK) in certain countries. BN™II is a trademark of Siemens Healthcare Diagnostics Inc. Other brand or product names may be trademarks of their respective holders.



March 2022
MKG877.1