

Human IgG subclasses from Amsterdam

kits and reagents
including free of charge Quality Survey

'Measurement of total levels of IgG subclasses or assessment of the subclass pattern of specific antibodies is essential in patients with increased susceptibility to bacterial infections when the total IgG level is within or slightly below the normal range. It is also useful for research purposes.'

(second IUIS / WHO report)



A BROAD RANGE OF KITS AND REAGENTS

Based on years of outstanding immunological research, high-quality diagnostic laboratory services and extensive experience in the production of immune reagents, Sanquin Reagents offers a broad range of kits and reagents for the detection and quantitative determination of IgG subclasses.

Sanquin Reagents strives to develop and produce high-quality, reliable reagents to meet the demands of customers in accordance with strict levels of specificity and standardisation.

Specificity

The most important characteristic of any immunological assay is the specificity of the antisera or antibodies used. Sophisticated procedures for immunisation and purification guarantee highly avid antisera with high

specificity, that is ascertained by tests with isolated paraproteins and IgG subclass deficient human sera.

Standardisation

All Sanquin IgG subclass reagents and assays are calibrated against CRM BCR-470. Values for CRM BCR-470 have been assigned using WHO67/97 as calibrator. Results have been presented at the meeting for Biological and Environmental Reference Materials (BERM) in Berlin 2003.

Values assigned to CRM BCR-470

	IgG1	IgG2	IgG3	IgG4
n	143	120	144	119
Mean (g/L)	6.21	3.45	0.390	0.591
Sd	0.32	0.16	0.021	0.021

Copies of the poster are available on request.

INDICATIONS OF A DISTURBED IMMUNE RESPONSE

Deficiencies of IgG subclasses are an indication of a disturbed immune response, although asymptotically decreased IgG subclass levels may occur as well. Several disease states are associated with decreased or increased levels of IgG subclasses.

Subclass determination

Since a decreased level of one IgG subclass may be accompanied by increased levels of one or more of the other subclasses, the total IgG level may well be normal. Consequently, the determination of IgG subclass levels is important, even when the total IgG level is within or only slightly below the reference range of healthy individuals.

Clinical consequences

Deficiencies and complete deficiency/absence of individual IgG subclasses may have several consequences:

IgG1: IgG1 deficiencies often result in a decreased level of total IgG (hypogammaglobulinemia). A deficiency of this quantitatively most important subclass is often associated with recurrent infections and might occur in combination with (individual) deficiencies of other subclasses, e.g. IgG3. In an evaluation of IgG1 concentrations in adults (n=1175) with suspected IgG subclass abnormalities, decreased IgG1 levels were

observed in 28% of the individuals. IgG1 subclass deficiencies have been reported in patients with chronic fatigue syndrome, whereas all other immunoglobulin isotypes were normal.

IgG2: In about half of all IgG subclass deficiencies in children the IgG2 concentrations are decreased. An isolated IgG2 deficiency is associated with decreased responses to infections with encapsulated bacteria and after immunisation with polysaccharide antigens. These patients show recurrent respiratory tract infections with pneumococci and/or Haemophilus influenzae type B. Low concentrations of IgG2 often occur in association with a deficiency in IgG4 and IgA.

IgG3: Along with IgG1, the IgG3 subclass is most frequently present in the antibody response to protein antigens. IgG3 deficiency has been associated with a history of recurrent infections, leading to chronic lung disease. Decreased IgG3 levels are frequently associated with IgG1 deficiency.

IgG4: An IgG4 deficiency is frequently associated with recurrent respiratory tract infections, often in combination with other immunoglobulin deficiencies, in particular IgG2.

'The possibility of an IgG subclass deficiency should be considered in all children with recurrent infections and chronic obstructive bronchitis.'

FREE OF CHARGE QUALITY SURVEY

Certification

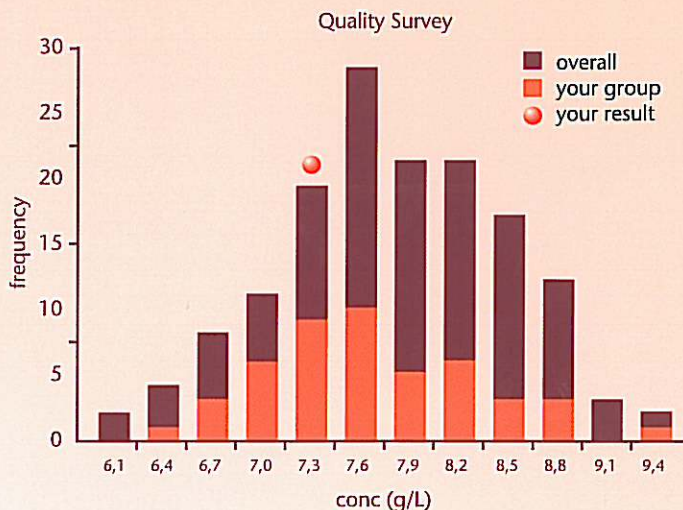
Sanquin Reagents is ISO 9001:2000 and ISO 13485 certified and all IgG subclass kits are CE marked. As a service to its customers, Sanquin Reagents provides a Quality Survey for in-house assessment of human IgG subclass assays. Laboratories in any part of the world may participate. Participation in the Quality Survey of Sanquin Reagents is free of charge even if kits are used from other manufacturers.

Procedure

Twice yearly, 3 encoded samples are distributed among the participating laboratories. Levels of IgG1, IgG2, IgG3, IgG4 and total IgG are determined by the respective laboratories and all results are evaluated centrally. This procedure is suitable to detect any systematic errors in the assays performed by the participating laboratories.

Realtime interactive website

For the input of data, processing and reports of results, Sanquin uses CueSee, a real-time interactive website tool, developed to assess the performance (accuracy and precision) of in vitro diagnostic (IVD) products.



This figure shows an example of some representative data from this Quality Survey. The participating laboratories quantify the four IgG subclasses and total IgG in the three samples, by means of ELISA, nephelometry, turbidimetry or other techniques with kits or reagents supplied by Sanquin Reagents or by other manufacturers. The example given in the figure shows the results of IgG1 determination obtained by one of the participating laboratories, using a specific technique and reagents. These results are compared with those from other participating laboratories using the same technique and reagents, as well as with the overall results, obtained by all techniques used. The data are presented in the format of histograms. By regularly participating in these Quality Surveys, laboratories will be able to check the consistency of their tests.



PRODUCT RANGE

- PeliClass™ kits for nephelometry:
 - PeliClass™ Array® kit
for 50 nephelometric tests, product code M1682
 - PeliClass™ IMAGE® / IMAGE® 800 kit
for 50 nephelometric tests, product code M1775
- PeliRIDe™ kit for Radial Immunodiffusion, product code M1557
- PeliClass™ ELISA kit, product code M1551
- antisera for agglutination
- monoclonal antibodies

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Sanquin Blood Supply Foundation

Sanquin is a not-for-profit organisation that provides blood supplies and transfusion medicine, in a manner that meets the most stringent quality, safety and efficiency requirements. The foundation provides products and services, carries out research and provides education.

In case of a proven deficiency of one or several IgG subclasses, suppletion therapy with immunoglobulines may be considered. For this therapy, intravenous and subcutaneous immunoglobulines are appropriate preparations. Sanquin produces immunoglobulines from the plasma of voluntary and unpaid blood donors. Sanquin's Diagnostics Division functions as reference laboratory for Dutch hospitals and has an extensive experience in a.o. the measurement of IgG subclass deficiencies.



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