

Introducing IgD, C1q, C3PA, and C5 Alliance Applications

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Introduction

Siemens Healthineers is pleased to announce the availability of four new Alliance Applications for use on the Atellica® NEPH 630, BN™ II and BN ProSpec® Systems. Extending our already comprehensive portfolio in immunoglobulin and complement testing, we are adding IgD, C1q, C3PA (C3 Proactivator, Factor B), and C5 Assays.

The four assays are used for the quantitative determination of the respective proteins in serum.

Table 1. **Product Ordering Information**

Product Name	Product Description	Siemens Material Number (SMN)
N Latex IgD Kit	100 tests incl. calibrator and controls	10873729
N Latex C1q Kit	100 tests incl. calibrator and controls	10873731
N C3PA Kit	100 tests incl. calibrator and controls	10873732
N C5 Kit	100 tests incl. calibrator and controls	10873730

Availability

All four products will be available from August 2021 onwards.

Key Features

The four methods are Alliance Applications manufactured by Trimerio Diagnostics, SL (Spain), exclusively designed for use on Siemens Healthineers nephelometric systems. Key features include:

- Reagent, supplement buffer, calibrators, and controls (2 levels) are ready-to-use in BN vials including barcodes for automatic recognition by the analyzer.
- No additional manual steps necessary prior to use.
- One source for reagents, service, and support.
- Addition of four new methods to the comprehensive nephelometric assay offering of Siemens Healthineers.

Clinical Application Overview

IgD in human serum:

High serum IgD concentrations are often found in patients with IgD monoclonal gammopathies. The so-called hyperimmunoglobulinemia D Syndrome (HIDS), or hyper IgD Syndrome, a disease characterized by episodes of periodic fever, is another entity in which IgD concentration is raised. An elevation can also be found in chronic infections (such as leprosy, tuberculosis, salmonellosis, infectious hepatitis, and malaria), in recurrent infections by staphylococci, in autoimmune diseases (such as rheumatoid arthritis or systemic lupus), in immunodeficiencies (such as AIDS), IgD-Multiple Myeloma and allergic disorders.

C1q in human serum:

C1q component of the complement system. Together with the components C1r and C1s, it constitutes the C1 complex. C1q recognizes and binds to Fc fragments of IgG and IgM immunoglobulins bound to antigen thus activating the classical complement pathway cascade. The conformational changes produced by immunoglobulin binding enzymatically activates C1r and C1s which then continue the complement cascade. In addition to activation of the complement classical pathway, another function of C1q is the elimination of immune complexes and apoptotic cells from the body. C1q congenital deficiency is extremely rare. Sometimes acquired deficiency is due to the presence of anti-C1q auto-antibodies. Its deficiency has a significant effect on the host defense mechanisms and in the elimination of immune complexes. Reduced levels of C1q are often found in acquired angioedema, due to the hyperactivation of the classical pathway of complement.

C3 Proactivator in human serum:

The complement system C3 Proactivator (C3PA), also known as Factor B (FB), Properdin Factor B (PFB) or Glycine-rich Beta Glycoprotein (GBG), is one of the proteins in the complement cascade alternative pathway (Complement Factors). Factor B deficiency is rare, but if present, it compromises the activation of the alternative pathway of complement that is essential in the defense against bacterial infections (particularly *Neisseria*). Reduced levels of Factor B normally indicate activation of the complement alternative pathway which can occur in certain kinds of kidney diseases, skin diseases, rheumatoid arthritis sickle cell anemia, as well as gram-negative bacteremia and other infections.

C5 in human serum:

C5 component of the complement system is a protein composed of two polypeptide chains (alpha and beta). Cleavage of C5 results in separation into C5a and C5b. C5a is a powerful anaphylatoxin, and a chemotactic factor that produces an inflammatory response. C5b binds sequentially to C6, C7, C8 and C9 to form the complement membrane attack complex (MAC), responsible for the lysis of invader cells by forming pores in their membrane. Deficiency of C5 is associated with increased susceptibility to recurrent severe bacterial infections, autoimmune diseases (e.g., Systemic Lupus [SLE], Rheumatoid Arthritis). Low levels of C5 and normal levels of C3 and C4 are consistent with C5 deficiency, while if reduced levels of C3 and C4 are also found, complement consumption is indicated.

Product Information Overview

Table 2. Product Information Overview

Item	Description
Technology	Nephelometry
Sample Type	Human serum
Sample Volume	IgD: 3 + 12 μ L (incl. pre-reaction) C1q: 20 μ L C3PA: 15 μ L C5: 60 μ L
Time to First Result	IgD: 3 + 10 min. (incl. pre-reaction) C1q: 12 min. C3PA: 18 min. C5: 18 min.
Calibration	Automatic dilution of calibrator (5 point-calibration)
Calibration Interval	Four (4) weeks, or as long as controls are within confidence range
Reagent Onboard Stability	Up to 4 weeks
(Minimum) and Initial Measuring Range	IgD: (0.3) 1.2 – 20mg/dL (~9 – 140IU/mL) C1q: (0.6) 3.0 – 50mg/dL (~12 – 200IU/mL) C3PA: (3.7) 3.7 – 60mg/dL (~12 – 180IU/mL) C5: (0.8) 3.0 – 50mg/dL (~25 – 400IU/mL)
Traceability	IgD: NIBSC 67/037 C1q: NIBSC W1032 C3PA: NIBSC W1032 C5: NIBSC W1032

Performance Characteristics

For all performance characteristic information, refer to the following published Instructions For Use (IFU):

- IFU “N Latex IgD Kit”, REF TD-42650.
- IFU “N Latex C1q Kit”, REF TD-42550.
- IFU “N C3PA Kit”, REF TD-42720.
- IFU “N C5 Kit”, REF TD-42570.

IFU are available at <https://doclib.siemens-healthineers.com/>.

information is provided by TRIMERO Diagnostics, SL (www.3diag.com).

Additional Information

Application notes for installation on Atellica NEPH 630, BN II or BN ProSpec Systems are available. The assay protocol must be set up by a Siemens Healthineers application specialist or technician according to application instructions.

Quality Control

Each laboratory should select appropriate commercially available controls and evaluate control recovery based on their established internal laboratory quality control (QC) procedure.

Two controls (low and high) are included in each kit.

Target values and ranges have been established for the controls stated in Table 3. Please refer to the vial labels and the respective certificates for lot-specific values.

Table 3. Test Controls for Use on Atellica NEPH 630 and BN Systems

Product Name	Siemens Material Number (SMN)	Target Mean Value (Example)
IgD Control Low	Included in IgD kit	9mg/dL
IgD Control High	Included in IgD kit	16mg/dL
C1q Control Low	Included in C1q kit	10mg/dL
C1q Control High	Included in C1q kit	16mg/dL
C3PA Control Low	Included in C3PA kit	16mg/dL
C3PA Control High	Included in C3PA kit	36mg/dL
C5 Control Low	Included in C5 kit	10mg/dL
C5 Control High	Included in C5 kit	21mg/dL

Regulatory Information

Product and system availability are subject to local regulatory requirements and, therefore, vary by country. If you have any questions or need additional information, please contact your local technical support provider or distributor.

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Additional Assistance

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