Built on proven nephelometric experience. Designed for the future.

BN II System

siemens-healthineers.com/bn-II-system

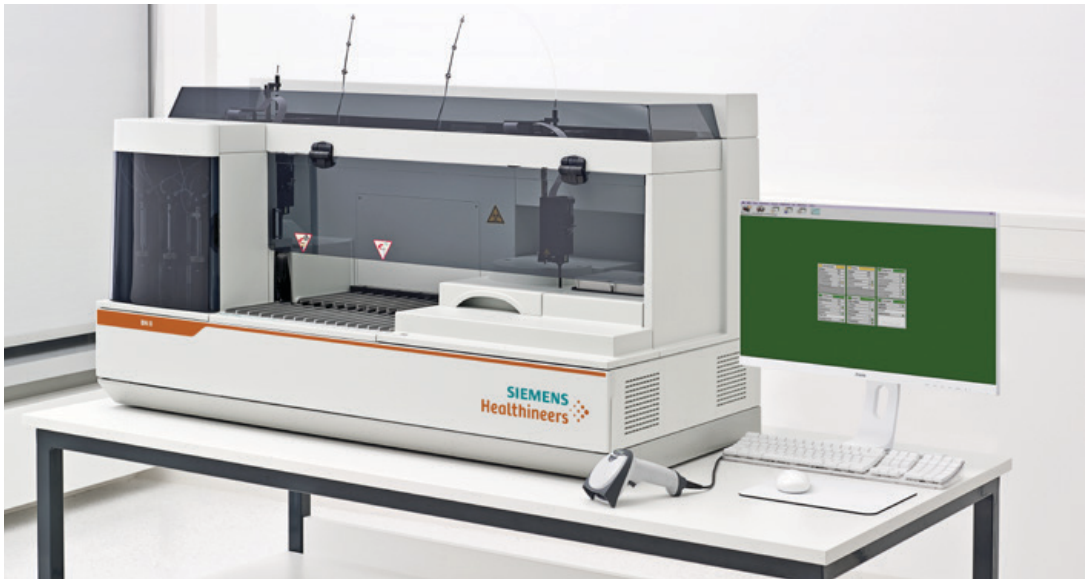
SIEMENS Healthineers

Get ready for the future of high-volume, nephelometric plasma protein testing

As a global market leader with more than 60 years of experience in dedicated plasma protein testing, Siemens Healthineers offers a total solution for your plasma protein testing needs. With the industry's largest menu* of plasma protein assays† and a scalable offering of dedicated plasma protein systems, these assay products deliver results with nephelometric sensitivity and provide a complete picture for confident clinical decision making.

With constantly increasing plasma protein testing demand and the need for streamlined workflows, high-volume plasma protein testing solutions are more important than ever. Recognizing this trend, Siemens Healthineers upgraded the BN™ II System for high-throughput plasma protein testing to become the most comprehensive version yet available. Built on robust hardware and equipped with state-of-the-art software, it is a solution that meets the industry's current and future needs.

The BN II System is a fully automated nephelometer featuring high throughput, reliability, sensitivity, and flexibility combined with the broadest plasma protein assay menu available and optimized for high-volume laboratories. Connectivity options for Aptio® Automation and FlexLab™ systems, intuitive software, and IT data and process management solutions complement its capabilities, allowing streamlined workflows, long walkaway times, and easy integration into your existing lab configuration.



**As of 10/2022.*
†Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

Fully equip your lab for high-demand testing

Enhance clinical support capabilities with a growing and innovative assay menu.

- Features the industry's largest nephelometric menu of more than 70 plasma protein assays.†
- Consolidates specialty and routine parameters on one system, supporting comprehensive disease-state management and reducing send-outs.
- Flexible testing options enable testing on serum, urine, plasma, and CSF.

Streamline lab workflows with high throughput, flexible configuration, and less hands-on time.

- Load up to 100 samples to reduce hands-on time.
- Connects to Aptio Automation to increase walkaway time.
- Quick sample release allows additional testing without delays.
- Provides average effective throughput of approximately 130 tests/hour.
- Continuous loading of samples and reagents at any time supports improved testing workflow and less downtime.

Operate confidently with intuitive, state-of-the-art software.

- State-of-the-art software and user management provide a high level of data privacy.
- Software includes a state-of-the-art, comprehensive audit trail that complies with FDA CFR part 11.
- Comprehensive software traceability features include tracking of assays and consumables.
- Seamlessly integrates into the laboratory's IT ecosystem, with connectivity to Atellica® Data Manager and Atellica Process Manager.†
- Provides optional clinical decision support using the PROTIS® IT Software Solution.

Test with high precision using sensitive, nephelometric technology.

- Proven nephelometric technology offers high precision and reproducibility.
- Sophisticated antigen-excess pre-reaction protocols provide more-accurate results and fewer repeats.
- Wide initial measuring ranges reduce the need for retesting.
- System detects specimen and reagent levels prior to processing to ensure accuracy of results.
- Serial dilution technology supports reliable results and helps to keep the dilution factor low.

Rely on a proven system that is established in the market and built for the future.

- The BN II System has an excellent service track record, with an average of 2–3 service visits per year.
- Siemens Healthineers has extensive, long-term experience and expertise as an instrument service provider. You can be confident in our support for your lab's operations.
- Our continuous launches of innovative tests and advances in laboratory automation demonstrate our commitment to providing meaningful new solutions for your current and future plasma protein testing needs.

"Staff are extremely happy with the transition and now have more time to perform other tasks due to confidence in the BN II System."

Ms. Ashurst
Chief Biomedical Scientist
Immunology Department
Norfolk & Norwich University Hospital (UK)

†Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

Test with higher efficiency and less hands-on time

With increasing testing demand, high throughput and extended walkaway time are critical factors in managing testing needs and streamlining workflows. The BN II System's high-capacity testing and smart design help reduce overall hands-on time and boost efficiency in plasma protein testing.

Flexible, automated sample processing includes applications for serum, plasma, urine, and CSF samples and various tube types.

Continuous loading of samples and consumables supports uninterrupted testing and reduces downtime.

Easy, simultaneous loading and unloading of up to 100 samples reduces hands-on time.

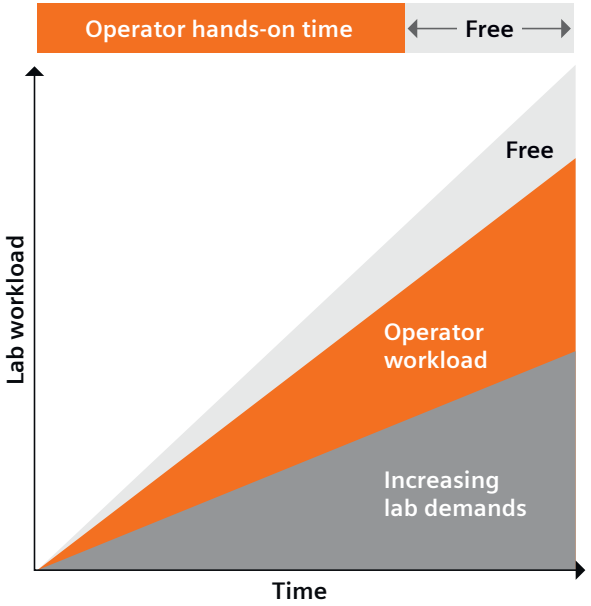
Quick sample release makes the sample available for additional testing and supports improved lab workflows.

Average effective throughput of approximately 130 tests/hour enables efficient testing and fast turnaround times.

Comprehensive results overview supports streamlined reporting.

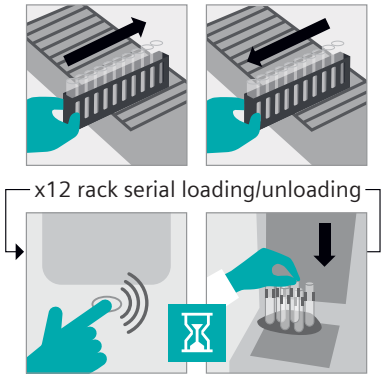
Workflow study shows BN II System saves 36% hands-on time

In a recent workflow study comparing free light chain testing on The Binding Site's OPTILITE system and the BN II System, the BN II System allowed operators over 2 hours of walkaway time and reduced overall operator hands-on time by 36%.



36% time saved in comparison study with OPTILITE system.[1] Workflow comparison was conducted without connecting the BN II System to automation.

The FREELITE assay was tested on the OPTILITE system (both products from The Binding Site), and the N Latex FLC assay was tested on the BN II System (both products from Siemens Healthineers). A total of 40 samples were tested for 2 consecutive days on both instruments, and all operator hands-on activities were timed to determine the efficiency of the systems.



Sample loading and unloading are straightforward and flexible on the BN II System. You can push in all racks in parallel on the loading platform, and the BN II System will automatically push out the racks for unloading when the sampling is completed. There is no need to interact with the software to remove samples or open and close a lid. You can easily see when a sample rack is ready for removal. These improvements provide a more flexible work environment, with less hands-on time and longer walkaway time.

For more information about the OPTILITE system comparison study, contact your Siemens Healthineers sales representative.

1. LD workflow study: BN II System vs. OPTILITE System. Siemens Healthcare Diagnostics Inc. 2020 Oct.

Operate confidently with state-of-the-art software and comprehensive services

Operate confidently with an intuitive user interface and upgraded system software. New features include:

GDPR compliance

The system's user management software complies with data privacy laws and regulations, including the General Data Protection Regulation (GDPR). You can configure user privileges in accordance with these regulations, and private and patient data cannot be viewed or exported by unauthorized persons.

Improved user-management interface

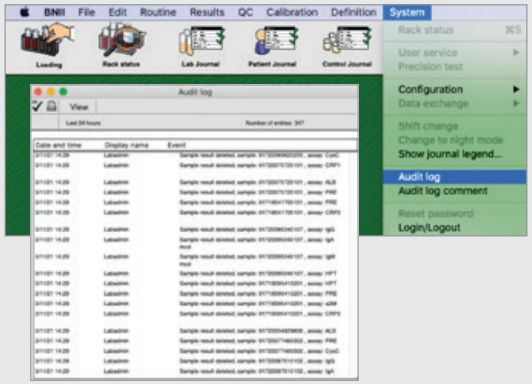
User management has been changed to comply with industry standards. Rather than the previously role-based user management, all users now have individual login accounts with configurable privileges and electronic signature trails (required for audit trail purposes). This improved user management makes the system more secure and helps prevent unauthorized access.

Audit trail

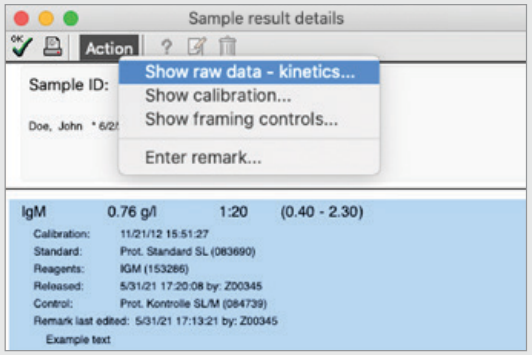
You can now easily track user activity related to generated results in compliance with the FDA CFR 21 part 11 regulation. You can also make comments on user activity if necessary. The log files can be exported and printed.

Traceability

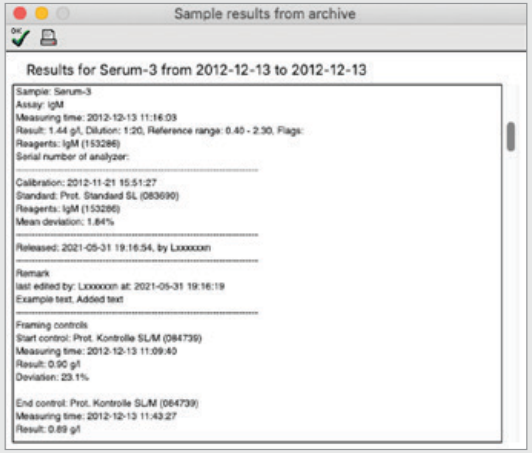
A new traceability feature allows you to trace a variety of information related to individual results, including the standards, calibration curves, framing controls, the operator performing the test, and more. This makes it easier to find specific lot numbers for sample results, either in the system or stored in the archive. The additional data that can now be viewed on a separate screen in the user interface improves overall searchability, the ability to use test result data, and system walkaway time. Results are now automatically stored in the system without the need for manual backup.



Audit log conform FDA CFR 21 part 11 regulation



Traceability dialogue with centralized result data



Traceability data automatic backup in archive

Get the most value from BN II System result data through integrated result interpretation and data management solutions

Digitalize result interpretation with PROTIS clinical decision support software

Operating the BN II System with **PROTIS clinical decision support software** allows consolidation of test results based on plasma protein determinations into one, easy-to-understand report for each patient.

PROTIS software supports a wide range of clinical indications and helps laboratories and physicians diagnose and treat patients more effectively.

CSF Assessment Software

Aids in assessment of blood-CSF barrier dysfunction and detection of intrathecal immunoglobulin synthesis using Reiber diagrams.

Basic assessment based on immunoglobulins and antibody indices in CSF samples (>130 parameters available).

Kidney Assessment Software

Helps evaluate kidney function by estimating the glomerular filtration rate and supports differential diagnosis of proteinuria using a comprehensive menu of kidney-related parameters.

Basic assessment based on urine and serum markers used for kidney disease (>35 parameters available).

Nutrition Assessment Software

Evaluates the patient's nutritional status and, if indicated, provides recommendations for supplementation therapy and patient monitoring.

Basic assessment based on prealbumin/albumin/ RbP/a1-glycoprotein (>25 parameters available).

MS Assessment Software

Provides interpretation of CSF testing in patients with signs of or at risk for multiple sclerosis using a Reiber diagram based on kappa free light chains.

Basic assessment based on kappa free light chains in CSF (>100 parameters available).

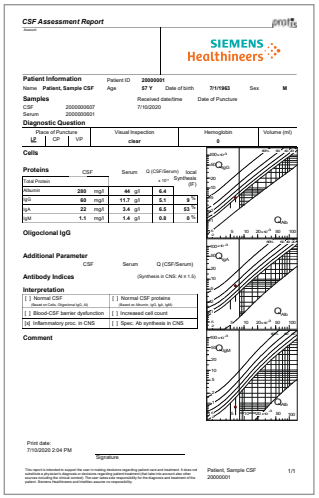
Simplified operations and greater insights through integration with Atellica Diagnostics IT

Our scalable, easy-to-use solutions simplify tasks and maximize the effectiveness of your laboratory and staff. Atellica IT helps enhance visibility, automate processes, and centralize management across instruments, automation, sites, and networks.

- **Atellica Data Manager** enables standardized testing protocols and result management throughout the lab and across lab networks.
- **Atellica Process Manager** provides centralized oversight and control of all systems, while also helping labs to standardize and optimize processes through built-in analytics.

To learn more about the BN II System and how we can help meet your plasma protein testing needs, contact your local Siemens Healthineers representative today.

▲ The BN II System connected to Atellica Data Manager software enables sample tracking and QC monitoring on the instruments in your laboratory.

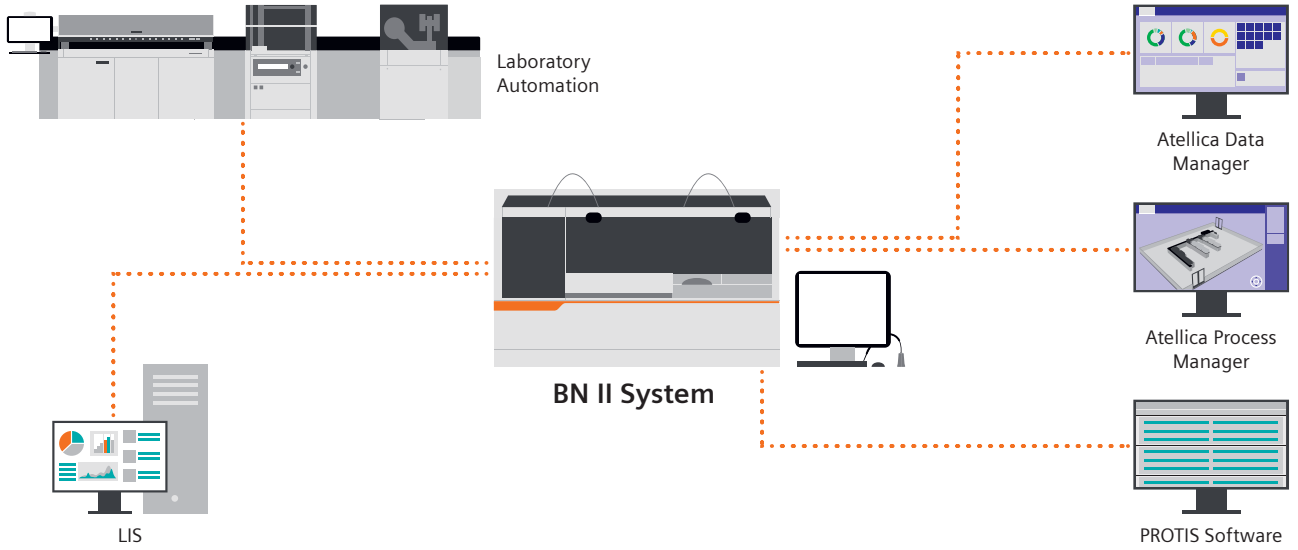


▶ The BN II System connected to PROTIS software enables digitalized interpretation of protein testing results.

Enhance laboratory effectiveness with a complete, integrated plasma protein solution

The BN II System fits in a digital, high-workload laboratory environment with the following offerings:

- Bidirectional LIS connection
- Laboratory automation
- PROTIS software
- Atellica Data Manager software
- Atellica Process Manager software



Improve laboratory workflow even more by connecting to automation

The BN II System is the first dedicated protein analyzer that can be connected to lab automation. It uses an interface module that transfers sample tubes from the track into the BN II System racks and pushes the racks onboard the analyzer. After samples have been diluted, the rack is immediately released and sample tubes are transferred back onto the track.

Even when automatic sample loading is employed, manual loading is still possible. Specialty samples using micro cups or control vials can be placed on the system at any time without interfering with the operation of the interface module.

The BN II System can be connected to Aptio Automation and FlexLab automation solutions.

Automation helps streamline workflow with:

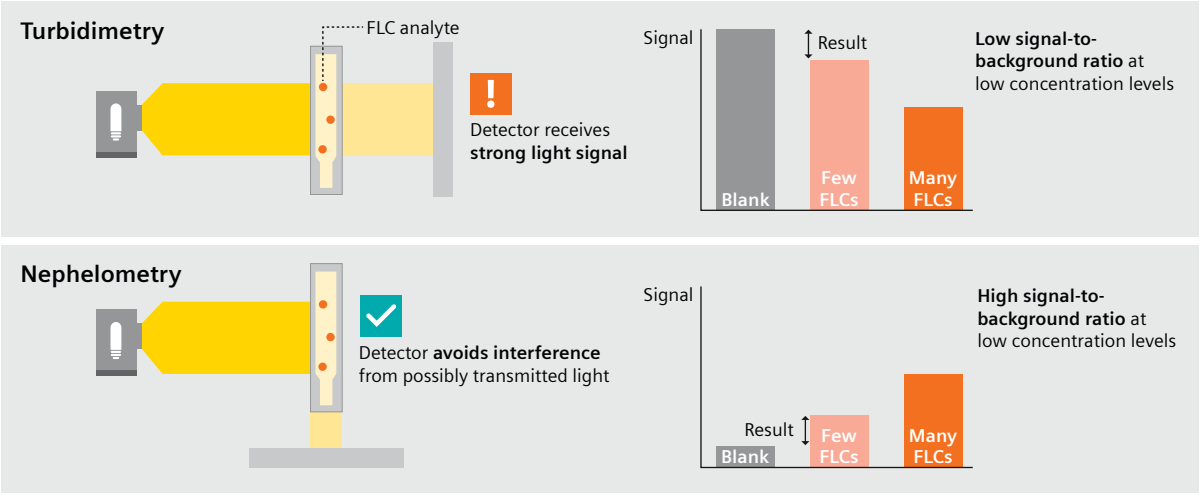
- Reduced manual interaction
- Extended walkaway capability
- Continuous access to reagents and consumables
- Optional manual loading of specialty samples that need more care
- Improved biohazard safety

Advance lab performance through dedicated, high-sensitivity, nephelometric plasma protein testing

Protein quantification has many applications across a range of disease states. Siemens Healthineers offers the industry's largest nephelometric menu of plasma protein assays.

Nephelometry offers analytical advantages over turbidimetry in terms of precision and sensitivity for plasma protein testing.[1-4] It is recommended by IMWG and ESMO guidelines for measuring high-sensitivity plasma protein assays. This additional sensitivity is critical for testing diseases such as multiple myeloma, for which accurate free light chain test results are required to derive a true free light chain kappa-to-lambda ratio. In addition, nephelometry provides wide measurement ranges through automatic dilutions, eliminating the need for manual redilutions.

Upgrading your lab with a BN II System for dedicated plasma protein testing offers workflow and clinical advantages. With its extensive test menu, it helps you expand your testing capabilities and gain broader insights into clinical conditions. Adding the system to your lab makes specialty testing available in-house and reduces the need for costly send-outs, helping to improve time to result and overall patient outcomes.



Accurate, consistent results

The BN II System provides reliable results when analyzing samples with extremely high analytical concentrations. Optimized reaction conditions and assay-specific, automated antigen-excess detection protocols improve reliability of results without operator intervention (Figure 1).

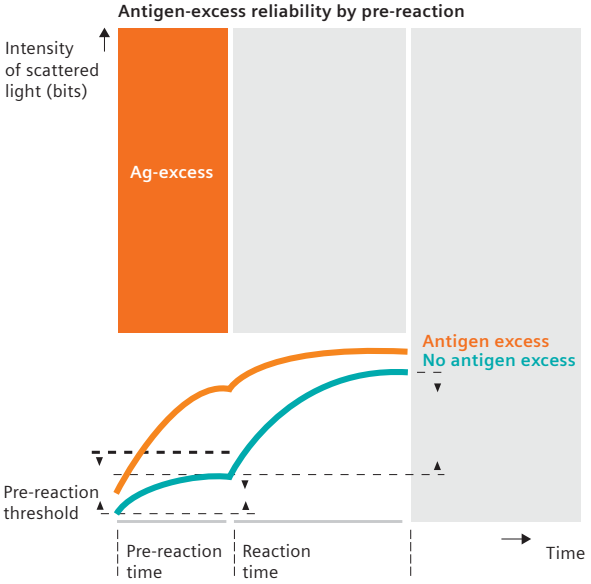


Figure 1. Antigen-excess reliability by pre-reaction.

1. Liu, et al. Comparison of five urinary albumin measurements. J Clin Lab Anal. 2011;25.
2. Carcia-Casal, et al. Performance and comparability of laboratory methods for measuring ferritin concentrations. PLOS One. 2018 May.
3. Manufacturers' instructions for use. FLC kappa detection limits: Siemens Healthineers nephelometry—0.17 mg/L; TBS turbidimetry (FREELITE assay)—0.60 mg/L.
4. Lawler DM. Turbidity, turbidimetry, and nephelometry. In: Chemistry, molecular sciences and chemical engineering. Elsevier; 2016.

Reduce send-outs and get a comprehensive disease-state picture with the broadest plasma protein testing menu

The BN II System's assay menu offers more than 70 assays, including therapeutic drug monitoring, cardiac risk assessment, kidney disease, neurological disorders, nutritional assessment, and iron and anemia assessment, supported by innovative assays.

N Latex FLC kappa and N Latex FLC lambda assays are designed for improved management of patients with monoclonal gammopathies.

N Latex aTNFα assay offers labs an automated, cost-effective, and accessible assay for monitoring therapeutic drug levels of adalimumab, infliximab, and etanercept.

N Latex BTP assay is a fast and accurate screening method for detection of cerebrospinal fluid (leakage) and estimation of residual renal function.

N Latex CDT assay provides a highly specific method for the detection of chronic alcohol abuse.

IgG Subclass 1–4 immunoassays offer a comprehensive solution for IgG determination. This determination is indicated for diagnostic clarification in patients suffering from a broad range of conditions associated with immune and nonimmune abnormalities. The ability to measure all four subclasses provides insight into deficiencies that may be masked in a total IgG measurement or predominant IgG1 levels.

Choose from a broad menu for confident clinical decisions

With the broadest menu available on a reliable, dedicated plasma protein system, the BN II System enables confident clinical decisions.

Polyclonal and Monoclonal Gammopathies/Immune System

ß2-Microglobulin
FLC kappa
FLC lambda
Ig/Light Chain, type kappa
Ig/Light Chain, type lambda
IgA
IgD‡
IgG
IgG subclasses 1-4
IgM

Kidney Disease

α1-Microglobulin urine
α2-Macroglobulin urine
ß2-Microglobulin urine
ß-trace protein
Albumin urine
Cystatin C
FLC kappa urine
FLC lambda urine
Ig/Light Chain, type kappa urine
Ig/Light Chain, type lambda urine
IgG urine
Transferrin urine

Inflammation

α1-Acid Glycoprotein
CRP
Fibrinogen
SAA

Autoimmune/Rheumatoid Diseases

ADNase B
ASL
Calprotectin‡
C3c
C4
CRP
RF
TNFa Inhibitors (adalimumab, infliximab, etanercept)

Cardiovascular Risk/Acute Cardiac Care

Albumin urine
Apo A-I
Apo B
Cystatin C
Fibrinogen
High Sensitivity CRP (*Cardio*Phase® hsCRP)
Homocysteine
Lp(a)
Myoglobin

Chronic Alcohol Abuse

CDT (Carbohydrate-deficient Transferrin) (for %CDT calculation)

Allergic Diseases

IgE

Nutritional Assessment

Albumin
CRP
Ferritin
Prealbumin
RBP (Retinol-binding Protein)

Coagulation Disorders

AT-III
Fibrinogen
Plasminogen

Anemia/Iron Metabolism

Ferritin
Haptoglobin
Hemopexin
sTfR (Soluble Transferrin Receptor)
Transferrin

Complement Activity

C1 Esterase Inhibitor
C1q‡
C3c
C3 Proactivator‡
C4
C5‡

Blood-CSF Barrier Dysfunction

Albumin
Albumin CSF
ß-trace Protein (CSF leakage)
FLC kappa CSF
FLC lambda CSF
IgA
IgA CSF
IgG
IgG CSF
IgM
IgM CSF

Other Specialty Analytes

α1-Antitrypsin
α2-Macroglobulin serum
Apo A-II
Apo E
Ceruloplasmin
Fibronectin

Download an overview of the BN II System's full menu at siemens-healthineers.com/bn-II-system.

‡Alliance application manufactured by third party, distributed by Siemens Healthcare Diagnostics Inc.

Notes

At Siemens Healthineers, we pioneer breakthroughs in healthcare. For everyone. Everywhere. By constantly bringing breakthrough innovations to market, we enable healthcare professionals to deliver high-quality care, leading to the best possible outcome for patients.

Our portfolio, spanning from in-vitro and in-vivo diagnostics to image-guided therapy and innovative cancer care, is crucial for clinical decision-making and treatment pathways. With our strengths in patient twinning, precision therapy, as well as digital, data, and artificial intelligence (AI), we are well positioned to take on the biggest challenges in healthcare. We will continue to build on these strengths to help fight the world's most threatening diseases, improving the quality of outcomes, and enabling access to care.

We are a team of 66,000 highly dedicated employees across more than 70 countries passionately pushing the boundaries of what's possible in healthcare to help improve people's lives around the world.

Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

Siemens Healthineers Headquarters
Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen, Germany
Phone: +49 9131 84-0
siemens-healthineers.com

Published by
Siemens Healthcare Diagnostics Inc.
Laboratory Diagnostics
511 Benedict Avenue
Tarrytown, NY 10591-5005
USA
Phone: +1 914-631-8000

Published by Siemens Healthcare Diagnostics Inc. · Order No. 30-22-DX-1778-76 · 11-2022 ·