

# Built on proven nephelometric experience. Designed for the future.

## BN II System

➤ [siemens-healthineers.us/bn-ii-system](https://siemens-healthineers.us/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, Siemens Healthineers offers comprehensive and flexible solutions for plasma protein testing. Our dedicated nephelometric solutions offer the largest menu\* of plasma protein assays† in the marketplace on a platform that is scalable to your throughput needs. Intuitive analytical software captures results in a regulatory-compliant manner that can be viewed either directly on the system or via dedicated connection to a Laboratory Information Systems (LIS). Combining the specificity and sensitivity of nephelometry on a flexible platform with an industry-leading assay menu, Siemens Healthineers offers a complete solution for confident clinical decision-making in plasma protein analyses.

With the ever-evolving demands on plasma protein testing, the pressure to adopt automated workflows with high-volume capabilities continues to grow. Siemens Healthineers has expanded the capabilities of the BN™ II System to accommodate automated, high-throughput plasma protein testing needs. Connectivity options to our Aptio® Automation and FlexLab™ systems can be combined with data and process management software solutions, allowing streamlined workflows, long walkaway times, and easy integration into your existing lab configuration – our most comprehensive version yet available!

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



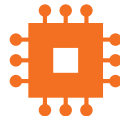
**Enhance clinical capabilities** with an expansive and innovative assay menu.

- Features the industry's largest nephelometric menu of more than 54 plasma protein assay protocols.†
- Consolidates specialty and routine parameters on a single system to support comprehensive disease-state management and reducing send-outs.
- Broad sample options enable testing of serum, urine, plasma, and Cerebrospinal Fluid (CSF).



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

- Capacity for up to 100 samples.
- 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 "on-the-fly" loading of samples and reagents to improve workflow flexibility.



**Operate confidently** with intuitive, compliant software solutions.

- 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.†



**Test with high precision** using specificity and sensitivity of nephelometry.

- Proven nephelometric technology to produce highly precise and reproducible measurements.
- Sophisticated antigen-excess pre-reaction protocol facilitates more accurate results.
- System detects specimen and reagent levels prior to processing to ensure accuracy of results.
- Serial dilution technology supports reliable results across a broad range of analyte concentrations.
- A wider measuring range reduces the potential for repeat testing.



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

- An excellent service track record, with an average of 2–3 service visits per year.
- Extensive and comprehensive 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.

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*"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)

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# Test with higher efficiency and less hands-on time

The ever-evolving demands on sample testing emphasize the need for flexible, streamlined analytical solutions; high throughput capacity and extended walk-away 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 sample and reagent loading extends uninterrupted testing to reduce downtime.



Simultaneous loading and unloading of up to 100 samples reduces hands-on time.



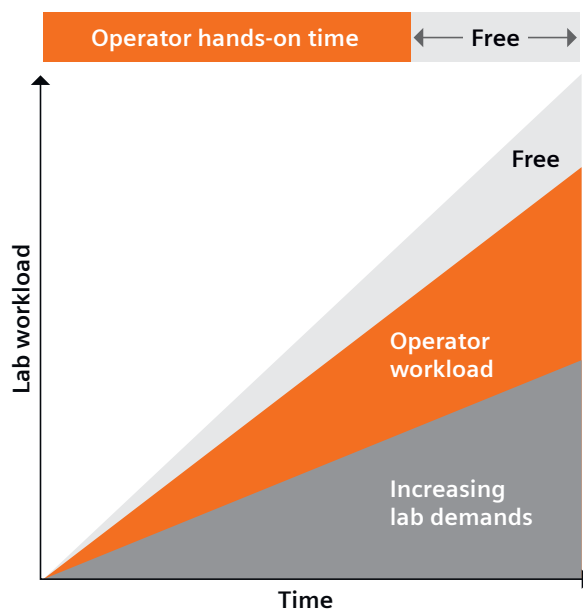
Quick sample release improves availability to facilitate additional sample testing.



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

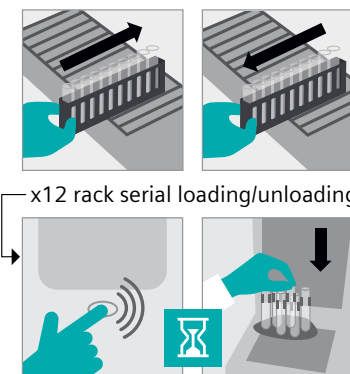
## Workflow study shows BN II System saves 36% hands-on time

In a recent workflow study<sup>1</sup> 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.<sup>1</sup> 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. Total operator hands-on activities were timed to determine the efficiency of the systems.



Sample loading and unloading on the BN II System are straightforward and flexible. 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.

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

Operate confidently with an intuitive user interface and upgraded system software.



## GDPR compliance

The 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.



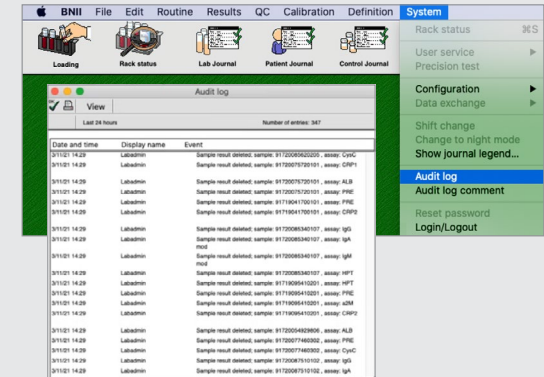
## Audit trail

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.

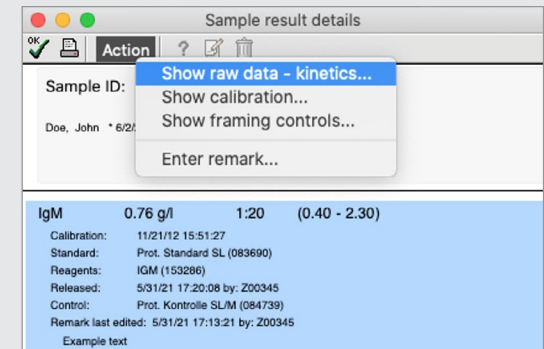


## Traceability

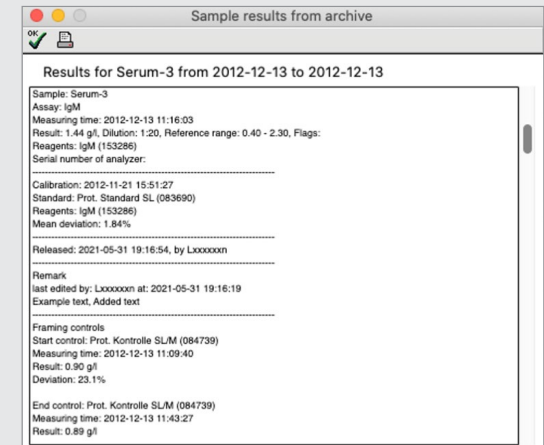
A new traceability feature allows you to trace a variety of information related to individual results, including the standards, calibration curves, framing controls, the operator performing the test, and more. This makes it easier to find specific lot numbers for sample results, either in the system 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

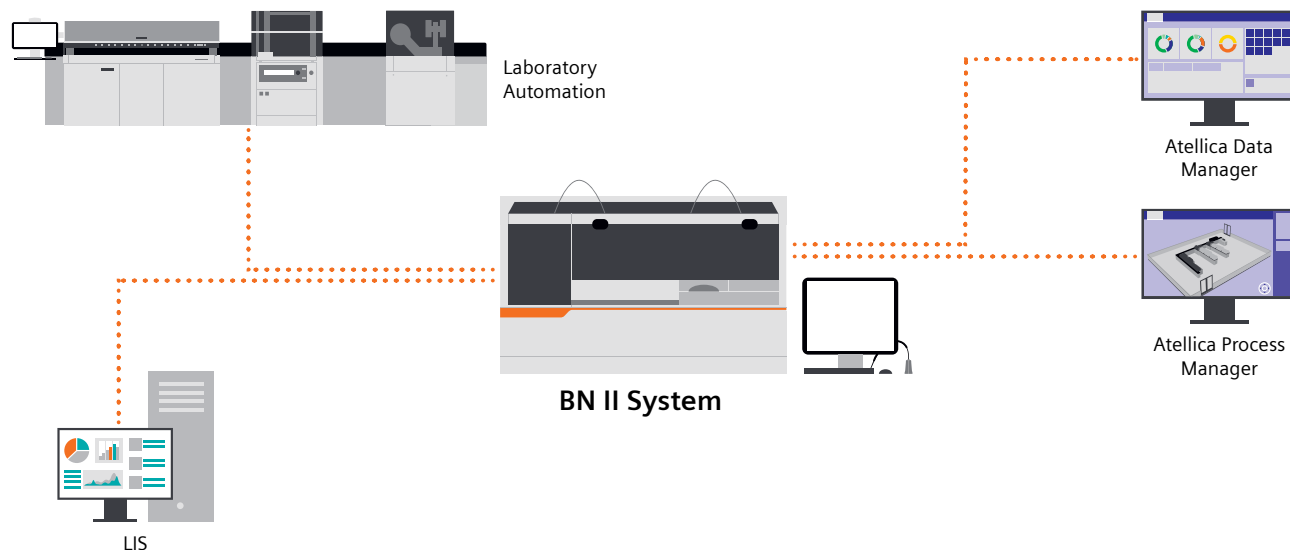


Traceability data automatic backup in archive

# Enhance laboratory effectiveness with a complete, integrated plasma protein solution

The BN II Nephelometer system is designed to thrive in data-driven, high-workload laboratories by interfacing with:

- Bidirectional LIS connection
- Laboratory automation
- 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 a myriad of 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, sensitivity, and repeatability for plasma protein testing.<sup>1-4</sup> It is recommended by International Myeloma Working Group (IMWG) and European Society for Medical

Oncology (ESMO) guidelines for measuring high-sensitivity plasma protein assays. This high measurement 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. Additionally, nephelometry provides wide measurement ranges through automated serial dilutions, eliminating the need for manual redilutions with pipettes.

## 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).

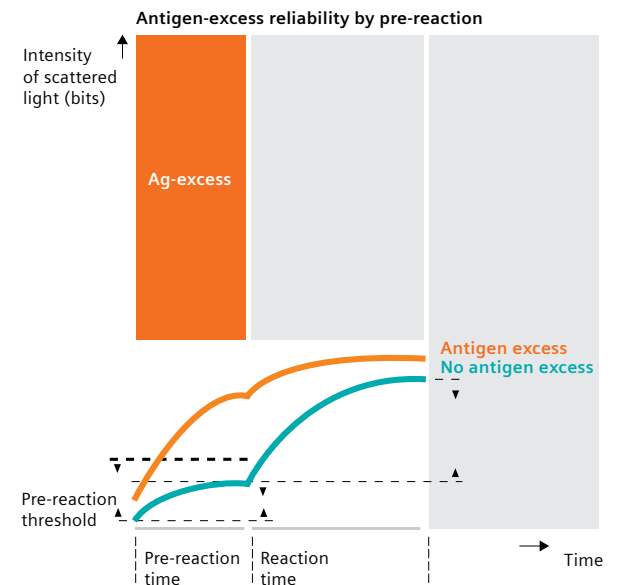
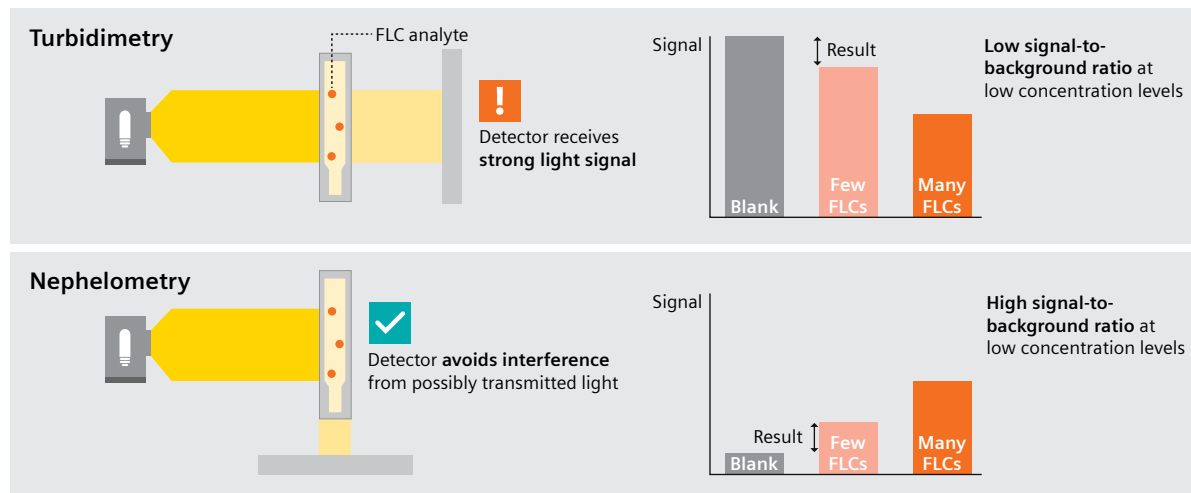


Figure 1. Antigen-excess reliability by pre-reaction.

1. Liu, et al. Comparison of five urinary albumin measurements. *J Clin Lab Anal.* 2011;25.
2. Garcia-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.

# Choose from a broad menu for confident clinical decisions

The BN II Nephelometer assay menu offers more than 54 assay protocols, including cardiac risk assessment, kidney disease, neurological disorders, nutritional assessment, and iron and anemia assessment, supported by innovative assays.

## Polyclonal and Monoclonal Gammopathies/Immune System

β2-Microglobulin  
FLC kappa  
FLC lambda  
Homocysteine  
Ig/Light Chain, type kappa  
Ig/Light Chain, type lambda  
IgA  
IgG  
IgG subclasses 1-4  
IgM

## Inflammation

α1-Acid Glycoprotein  
Ceruloplasmin  
CRP  
Fibrinogen  
Haptoglobin

## Nutritional Assessment

Albumin  
CRP  
Ferritin  
Prealbumin  
RBP (Retinol-binding Protein)  
Transferrin

## Autoimmune/ Rheumatoid Diseases

ADNase B  
ASL  
C3c  
C4  
CRP  
RF

## Cardiovascular Risk/ Acute Cardiac Care

Apo A-I  
Apo B  
Fibrinogen  
High Sensitivity CRP (CardioPhase® hsCRP)  
Lp(a)  
Myoglobin

## Liver Disease/Alcohol Abuse

α1-Antitrypsin  
CDT (Carbohydrate-deficient Transferrin)  
Ceruloplasmin  
CRP  
Transferrin  
(for %CDT calculation)

## Allergic Diseases

IgE

## Neurological Diseases

Albumin CSF  
IgA CSF  
IgG CSF  
IgM CSF

## Coagulation Disorders

AT-III  
Fibrinogen  
Plasminogen

## Anemia/Iron Metabolism

Ferritin  
Haptoglobin  
Hemopexin  
sTfR (Soluble Transferrin  
Receptor)  
Transferrin

## Complement Activity

C1 Esterase Inhibitor  
C3c  
C4

## Kidney Disease

α1-Microglobulin urine  
β2-Microglobulin urine  
Albumin urine  
Cystatin C  
Transferrin urine

## Other Specialty Analytes

α1-Antitrypsin  
α2-Macroglobulin serum

## For Research Use Only (RUO)\*

Apo A-II  
Apo E  
β-trace protein  
Serum Amyloid A (SAA)  
anti-TNF-α (adalimumab, infliximab,  
etanercept)

\* Not for use in diagnostic procedures.  
\*\* All assays listed above are also available on  
existing BN Prospec Systems



Download an overview of the BN II System's full menu at  
[siemens-healthineers.us/bn-ii-system](https://www.siemens-healthineers.us/bn-ii-system)

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Siemens Healthineers also provides a range of services and solutions to enhance healthcare providers' ability to provide high-quality, efficient care. In fiscal 2022, which ended on September 30, 2022, Siemens Healthineers, which has approximately 69,500 employees worldwide, generated revenue of around €21.7 billion and adjusted EBIT of almost €3.7 billion.

Further information is available at [www.siemens-healthineers.com](http://www.siemens-healthineers.com).

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