The Power of Choice

BN™ II System

Answers for life.

SIEMENS

The intelligent system for advanced protein quantitation

The gold standard in plasma protein analysis

More than 50 years experience in plasma proteins has resulted in four generations of dedicated nephelometric systems, each bringing new advances to laboratories.

Our continuous focus on new and valuable assays has resulted in innovations such as the first direct, fully automated CDT method – an economical test to identify chronic alcohol abuse. Advances in laboratory automation and post-analytic information technology, such as the Protis® software, further highlight our commitment to provide meaningful new solutions for your plasma protein testing needs and beyond.

Protein quantitation has many applications across a range of disease states. The technology employed must meet increasingly higher standards driven by the need to determine proteins accurately in wide concentration ranges and across various body fluids.

Uncompromising performance for your laboratory

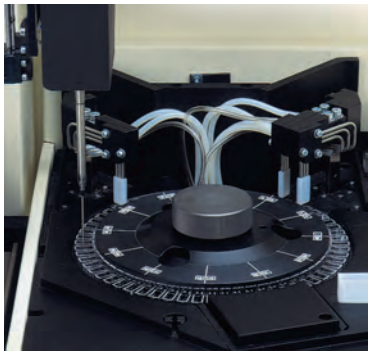
The BN II raises automation and flexibility of use to a higher level, meeting your need to run a wide variety of clinical assays. BN II is capable of quantitating more than 60 assay protocols from an extensive range of reagents and test kits, available from Siemens Healthcare Diagnostics. The BN II is the most powerful nephelometer at the cutting edge of development: not only does it deliver reliable results, it also increases productivity enormously and is highly cost-effective.

The BN II is a fully automated protein analyzer with a number of major technological improvements contributing to a more efficient determination of proteins. Increased workflow efficiency is achieved by:

- the use of real primary tubes, so less hands-on time is required to prepare samples
- bidirectional host interface, reducing the time needed to enter job lists and validate laboratory results
- complete sample processing, requiring less operator intervention in order to obtain final patient results

Saving time

Efficient operational production means savings in time and money for the laboratory. The BN II system meets this demand by offering:



Faster availability of results combined with less hands-on time

Samples can be placed on the BN II in a wide variety of standard tubes. The labor-intensive and less secure procedure of transferring samples into instrument-specific wells is eliminated.

Much less time to load samples

The greater loading capacity of the BN II system is 100 sample tubes at any time with up to 35 reagents immediately available.

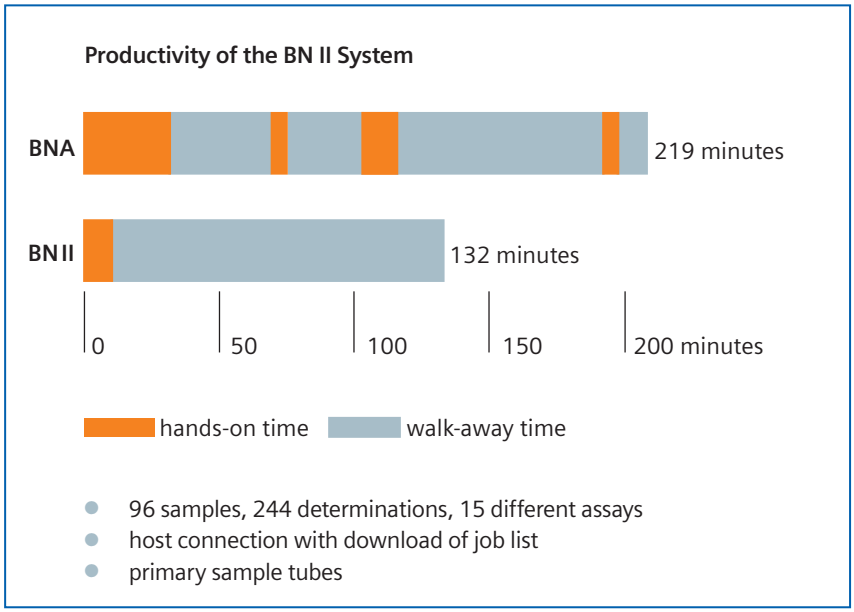
The operator is free to do other work

Job lists can be received from the Laboratory Information System (LIS) via the bidirectional host interface. Just load samples, reagents and dilution wells on the BN II and all measurements will be performed automatically.

No need for the operator to edit or enter job lists manually

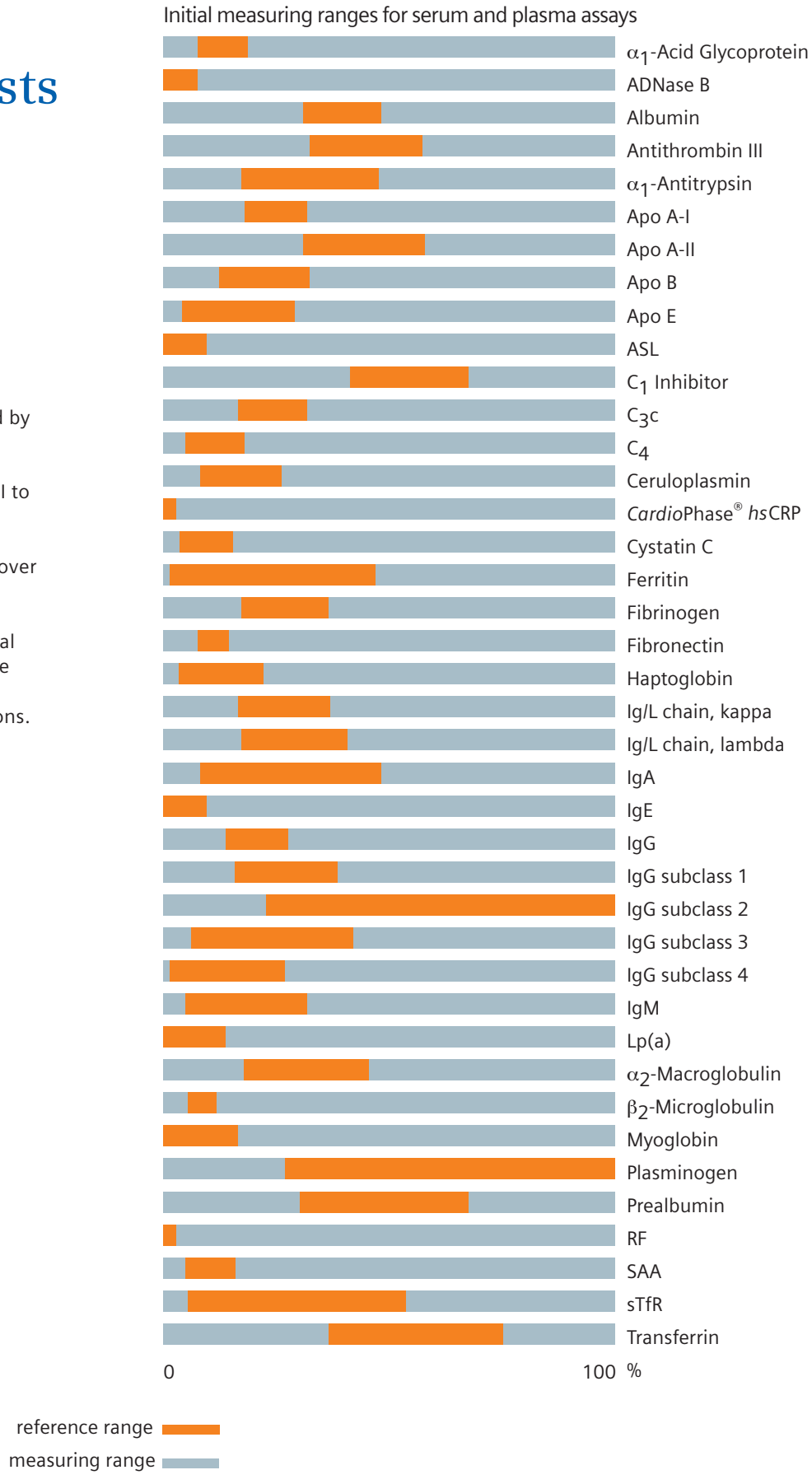
Results measured on the BN II are validated by means of control values. All assay results framed by control values outside the respective confidence intervals are clearly marked in the lab journal.

Less time required to verify and validate laboratory results

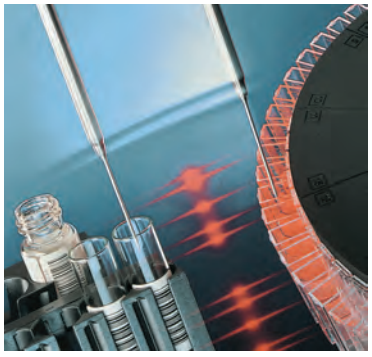


Cutting operational costs

Economical use of reagents is assured by the wide analyte measuring range covered by the initial and any subsequent dilution made by the BN II to obtain a final patient result. Furthermore, the initial measuring ranges (as depicted in the diagram) cover all clinically "normal" ranges plus extended pathological ranges. This means that very few retests (additional "shots" of antisera) are required by the BN II to obtain final patient results, regardless of the analyte concentrations.



BN II – Intelligent solution to automated protein assays



The BN II system is a fully automated true random access analyzer, performing all the processing steps from reading of the barcode labels to evaluation of the patient test results. The BN II also maximizes the reliability of results by virtually eliminating sample and reagent mix-ups, as well as transcription errors. The system also provides reliable results even when analyzing samples with extremely high analyte concentrations. All these features, together with automated assay procedures combined with substantial on-board sample and reagent capacity, make the BN II an ideal walk-away system.

The BN II system delivers automated protein assays with increased reliability and convenience:

Positive sample and reagent identification

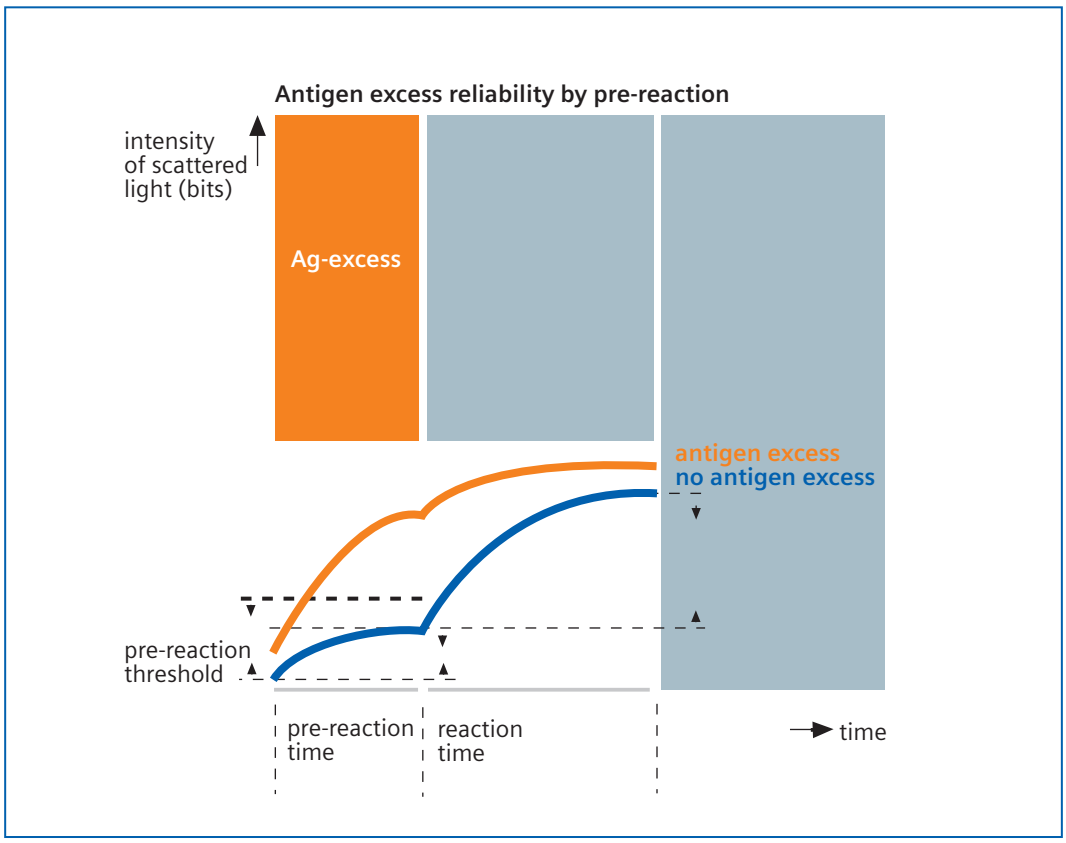
Sample and/or reagent mix-ups are eliminated by the system reading barcoded information from sample tubes and vials of standards, controls and reagents. The BN II scanner can read all common types of barcodes, like codabar, 2 of 5 interleaved, etc.

Place samples and reagents on board in any order

Automatic start of measurements

The BN II starts the measurement process automatically as soon as samples and reagents are placed on board. The flexible bidirectional interface supports this function by allowing download of job lists to the BN II or the automatic "host query" request of job lists from the host computer.

Just load samples and reagents and walk away



Intuitive software informs user of required or missing items

The info screen of the BN II software informs the operator through user-friendly prompts about missing samples and reagents. In addition the amount of reagents needed to perform the existing job list is displayed in the reagent list.

Load as many vials of reagents as the system will need

Multi-lot processing

The BN II system is able to handle up to three different reagent lots during the same processing period. The BN II automatically switches from one reagent lot to another.

Continuous sample processing and reduced turnaround time

Improved antigen excess reliability

Antibody-antigen complexing reactions on the BN systems have been optimized, so that even samples with high analyte concentrations are measured accurately in antibody excess conditions. Samples cannot therefore exceed the maximum of the Heidelberger-Kendall curve. Additionally, antigen excess reliability has been improved on the BN II by introducing automatic pre-reaction protocols for assays requiring maximum sensitivity or covering exceptionally wide dynamic ranges. The pre-reaction protocol uses a small sample quantity mixed with reagents and compares the signal achieved after a short incubation time with a threshold determined during calibration. Samples exceeding the threshold are automatically remeasured in the next higher dilution and checked again.

Reliable operation without operator intervention

BN II – The versatile protein panel covering a wide range of clinical indications

The extensive range of assays makes the BN II a highly productive system, capable of assaying not only serum and plasma but also CSF and urine samples simultaneously. The BN II thus offers capabilities not found with any other analyzer, and its advanced system technology also offers high analytical sensitivity. Siemens Healthcare Diagnostics is committed to ongoing research and development aimed at adding more assays to the BN II.

With precise results

Protein standardization according to IFCC

The objective of the committee on plasma protein standardization of the International Federation of Clinical Chemistry (IFCC) was to achieve one result for one sample worldwide. Siemens Healthcare Diagnostics contribution to the IFCC standardization committee was to define and produce an international reference preparation for 14 plasma proteins. This reference material approved by the IFCC and many other national scientific societies – and now distributed by IRMM and CAP – allows diagnostic companies around the world to calibrate their standards and controls according to the IFCC standardization.

Siemens Healthcare Diagnostics was one of the first companies to standardize according to the IFCC reference material (CRM 470) in parallel to their own reference standards. Assigned values based on IFCC standardization are included in standard and control kits of the relevant analytes. These values are easy to use by reading them into a BN II via the system's barcode wand. In the meantime consensus reference ranges have been accepted by different institutions and will be used worldwide.

The intra- and inter-assay precision of the BN II system has been proven in extensive trials performed in many laboratories throughout the world.

Minimizing interference

The combination of fixed-time kinetic measurement, high sample dilutions and specially developed assay-specific supplementary reagents guarantees minimal interference when analyzing icteric, hemolytic and lipemic samples. For turbid samples a turbidity check can be performed by the BN II prior to assaying in order to detect potential interference. The turbidity check does not require the addition of antiserum and is economical to perform.

Inter-assay precision[1]			
Assay	**Control**	**CV (%)**	**mean (g/L) n=20**
IgG	low	2.4	8.01
	medium	3.4	11.44
	high	3.6	17.06
IgA	low	3.6	1.57
	medium	3.9	2.12
	high	3.1	3.17
IgM	low	2.5	0.81
	medium	4.0	1.15
	high	3.8	1.75
RF	low	4.5	42.88 IU/mL
	high	2.3	170.00 IU/mL

Intra-assay precision			
Assay	**Control**	**CV (%)**	**mean (g/L) n=20**
IgG	low	3.1	8.05
	medium	2.6	11.56
	high	4.0	17.21
IgA	low	2.8	1.58
	medium	2.5	2.16
	high	2.8	3.33
IgM	low	7.9	0.79
	medium	2.2	1.17
	high	2.8	1.77
RF	low	7.2	40.25 IU/mL
	high	3.6	167.10 IU/mL

[1] Dubs RW, Lammers M. Analytical Evaluation of a New Immunonephelometric Analyzer System. Poster presented at the 47th Meeting of the American Association of Clinical Chemistry, Anaheim, July 16 - 20, 1995

Technical specifications

Analyzer:

Measuring principle:	Nephelometry; measurement of the scattered light intensity in a fixed angle of 13 - 24 °
Methods:	More than 60 programmed assay protocols
Sample throughput:	Effective: approx. 130 tests/hour depending on the types of test Nominal: 225 tests/hour
Analysis method:	Fixed-time kinetics, End-point measurement, VLin Integral
Calibration:	Multi-point calibration
Rack transport unit:	Racks for 8 standard or control serum vials, Racks for 7 reagent vials, Racks for 10 sample tubes
Dilution unit:	2 frames for max. 264 dilution cups
Size of sample tubes:	Diameter 12 - 16 mm Height 55 - 100 mm For pediatric samples: conical microtubes with a maximum filling volume of 1.5 mL
Barcode types:	Automatic reading of different barcode types: 2/5 interleaved Codabar Code 39 Code 93 Code 128 UPC EAN
Reagent volume:	40 mL on average
Sample dilution:	1 : 1 to 1 : 40,000
Level detection:	For samples, standards and controls as well as reagents. Also for system liquid containers
Reaction cuvettes:	60 reusable polystyrol cuvettes
Measuring temperature:	37 Ī 1.5°C
Light source:	Infrared high performance LED
Wavelength:	840 Ī 25 nm
Detector:	Silicon photodiode with integrated pre-amplifier

General data:

	Voltage:	100 - 127 V/50 or 60 Hz 187 - 240 V/50 or 60 Hz
Power consumption:Analyzer:	<140 VA (stand-by mode) <400 VA (operating mode)	
Ambient temperature:	18 to 32 °C	
Weight:	Analyzer: Terminal:	150 kg 6.4 kg
Dimensions:	Analyzer: Terminal:	1240 x 630 x 715 mm (w x d x h) 415 x 397 x 85 mm (w x d x h)

The BN II system covers a wide range of clinical indications

Arteriosclerosis risk/myocardial infarction:	Apo A-I, Apo B, Apo A-II, Apo E, Lp(a), Myoglobin, Fibrinogen, *Cardio*Phase *hs*CRP, Homocysteine
Polyclonal and monoclonal gammopathies:	IgA, IgG, IgM, Ig/light chain, type kappa, Ig/light chain, type lambda, IgG subclasses 1 - 4
Nephropathies:	Albumin, α1-Microglobulin, IgG, Transferrin, β2-Microglobulin, α2-Macroglobulin, Total Protein, Ig/light chain, type kappa, Ig/light chain, type lambda, Cystatin C
Inflammatory diseases:	*Cardio*Phase *hs*CRP, α1-Acid Glycoprotein, Haptoglobin, α1-Antitrypsin, Fibrinogen, SAA
Rheumatic diseases:	RF, ASL, *Cardio*Phase hsCRP, ADNase B
Blood-brain barrier dysfunctions:	IgG, IgA, IgM, Albumin, Total protein, β-trace protein[#]
Allergic diseases:	IgE
Malnutrition:	Prealbumin, Albumin, Retinol binding protein, Transferrin, *Cardio*Phase *hs*CRP
Coagulation disorders:	Fibrinogen, AT III, Plasminogen
Anemia:	Haptoglobin, Hemopexin, Transferrin, Ferritin, sTfR
Complement consumption:	C3C, C4, C1 Inhibitor
Others:	Ceruloplasmin, Carbohydrate-deficient Transferrin, Fibronectin
Software support:	Protis – result interpretation and workflow-management software

[#] research use only

Siemens Healthcare Diagnostics, the leading clinical diagnostics company, is committed to providing clinicians with the vital information they need for the accurate diagnosis, treatment and monitoring of patients. Our comprehensive portfolio of performance-driven systems, unmatched menu offering and IT solutions, in conjunction with highly responsive service, is designed to streamline workflow, enhance operational efficiency and support improved patient care.

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