

PROTIS IT Clinical Decision Support Software

Digitalizing result interpretation in protein testing

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A software solution that offers assistance where lab testing ends

Physicians require a fast, complete overview of individual patients' results to quickly and confidently diagnose their conditions.

Results for one patient often come from different sources and are documented in separate reports. As the complexity of tests continues to increase, correct interpretation of results becomes more challenging.¹ Also, much of the new clinical data generated by lab tests can require a high level of interpretative skills and knowledge of specific algorithms and clinical pathways. Studies have indicated that about 5% of medical errors are related to misinterpretation of laboratory results.

Interaction between physicians, biologists, and the laboratory can be required in interpreting patient results, particularly when results from multiple sources must be integrated, analyzed, and considered. Responding to such requests requires the time of lab personnel and, increasingly, the expertise of specialists.

PROTIS® clinical decision support software (PROTIS IT Solution) enables consolidated result reporting and clinical decision support.

- Integrates results from different platforms into one report.
- Presents data in an easy-to-follow graphical format.
- Provides a fast, consolidated overview of results for a single patient and for different indications.

Consolidate result reporting

The PROTIS clinical decision support software* automatically consolidates test results based primarily on plasma protein determinations and obtained from a variety of Siemens Healthineers platforms into one, easy-to-understand report for an individual patient.

Confidently interpret results

PROTIS Assessment Kits employ standardized rules established by experts to assist with result interpretation and improve the quality of physicians' diagnoses. They support a wide range of clinical indications and help laboratories and physicians to diagnose and treat patients more effectively.

*Product availability varies by country.

Expand high-quality decision support to physicians without adding resources

PROTIS IT Solution helps laboratories and physicians to diagnose and treat patients more effectively. PROTIS Assessment Kits support a wide range of clinical indications:



CSF testing

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



Multiple sclerosis

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.



Kidney disease

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



Nutritional assessment

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

Customizable, value-added reporting

- All results at a glance in a single-page report.
- Provides all recommendations for patient management, if appropriate.
- Provides easy-to-follow graphical results (e.g., Reiber diagrams).
- Assessments are designed to be activated and used individually.

Focuses on relevant determinations

Inappropriate or unnecessary testing contributes significantly to the escalating cost of healthcare. PROTIS Assessment Kits help physicians order the correct tests by requiring that specific assay panels be ordered for each assessment.

This requirement encourages more-targeted ordering of tests and helps reduce inappropriate and unnecessary testing. In addition, the patient reports generated by each assessment module suggest further testing when necessary to help physicians make more-efficient and effective diagnoses.

Builds expertise and competency

PROTIS Assessment Kits help clinicians and laboratory personnel build expertise in interpreting patient results. The software modules provide all the relevant information required for accurate results interpretation, and they use standardized rules established by experts to automatically evaluate and interpret results.

By comparing testing results with the interpretations generated by the assessment modules, clinicians can recognize patterns of results and associate them with appropriate interpretations and diagnoses.

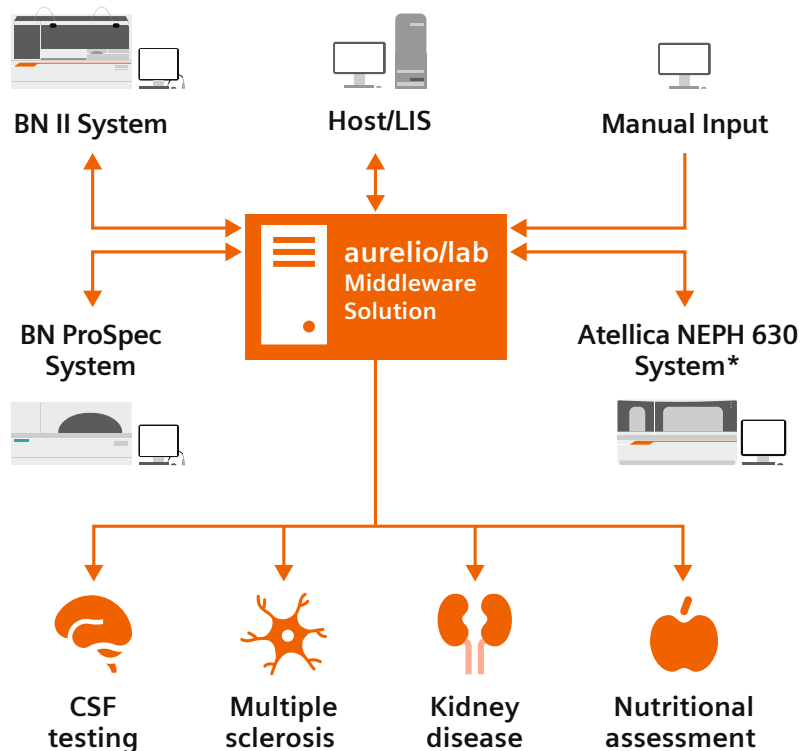
Digitalizing healthcare by enabling consolidated data and analysis

The PROTIS IT Solution is based on aurelio/lab and various clinical assessment kits. aurelio/lab is powerful, flexible laboratory middleware that includes extensive connectivity, data management, and workflow support features for making lab processes more efficient. It is designed to work seamlessly with PROTIS Assessment Kits: dedicated modules that provide automated, expert interpretation of individual patient results for a variety of parameters.

When used with the PROTIS Assessment Kits, the aurelio/lab management system produces patient assessment reports that include consolidated test results presented in both tabular and graphic formats supplemented with guidance on interpreting the results.

To even better meet the needs of today's labs, the latest software version offers improved usability and a simplified interface, a complete audit trail, database and backup encryption options, and the latest cybersecurity measures.

aurelio/lab middleware is instrument-independent and can manage results produced by a wide range of diagnostic analyzers from Siemens Healthineers and other sources.



**Product availability varies by country.*



Benefit from extensive connectivity, data management, and workflow support features for efficient lab processes

Simple, convenient data management

- Single interface between multiple platforms and LIS (laboratory information system)
- Patient data and sample administration
- Centralized, long-term storage of patient history data
- Flexible release management of patient sample results
- Reports can be printed or exported as PDF or JPG files
- Audit trail, database and backup encryption options for a high level of data privacy and security

Economical testing and result interpretation

- Reduces manual work and staff labor costs through automatic generation of result interpretation suggestions and standardized reporting
- Automatically calculates assessment-specific algorithms (e.g., GFR[†] estimation for kidney function assessment)
- Helps reduce requests from physicians for assistance with result interpretation

Easy-to-use software and user interface

- Intuitive graphical user interface
- Runs on MICROSOFT WINDOWS 10 operating system
- Online data transfer between connected platforms and LIS
- Allows manual data input
- Flexible configuration options of assessment kits
- Software available in multiple languages

Improved workflow

- Automated job list management between connected platforms and LIS
- Connects to the following Siemens Healthineers platforms: Atellica® NEPH 630, BN ProSpec® and BN™ II Systems
- ASTM protocol enables additional connections
- Direct communication with Atellica NEPH 630 and BN Systems to import assay results, automatically order additional tests, and retest samples

[†]GFR: glomerular filtration rate

Intuitively assess inflammatory processes in the central nervous system through sophisticated algorithms

The PROTIS Cerebrospinal Fluid (CSF) Assessment Kit is based on the concept developed and published by Professor Hansotto Reiber. His CSF/serum quotient graphs are considered to be the gold standard for CSF analysis. Reiber diagrams visualize in an integrated way both the function of the CSF-blood barrier and the presence of intrathecal immunoglobulin synthesis. They have been established to evaluate intrathecal synthesis of immunoglobulins, IgG, IgA, and IgM. Plotting the immunoglobulin CSF/serum quotient in relation to the albumin CSF/serum quotient into a logarithmic diagram provides an easy-to-read graphical presentation of protein data. Recently, a Reiber diagram using kappa free light chains in CSF has been developed to assess multiple sclerosis (see page 8).

Diagnostic assessment support

- Evaluation of results using CSF/serum quotient diagrams
- Assessment of intrathecal immunoglobulin (Ig) synthesis and CSF-blood barrier function
- Result interpretation based on cell count/cell typing, protein results, and specific antibody indices
- Serological identification of infectious pathogens
- Identification of CSF leakage

Core CSF assessment report

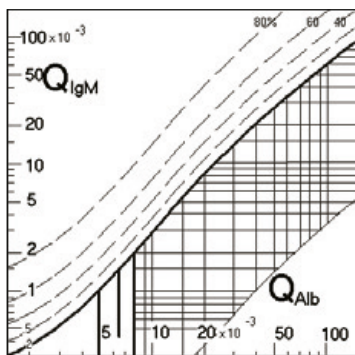
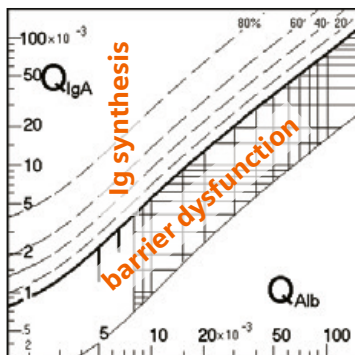
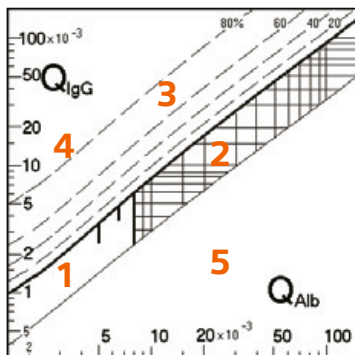
- IgG and albumin CSF/serum ratios
- CSF sample information: place of puncture, optical appearance, hemoglobin
- Patient record including date of birth for calculation of age-dependent algorithms and diagrams
- Graphical result presentation in Reiber diagrams
- Result interpretation suggestions

Extended panel for further CSF analysis

- IgA and IgM CSF/serum ratios
- Cell count and cell differentiation, including a predefined list of cell types
- Determination of intrathecal microorganism-specific immune response: viruses (e.g., measles, rubella, VZV, HSV I/II, EBV, CMV, HIV); bacteria (e.g., *Borrelia burgdorferi*, *Treponema pallidum*, *Chlamydia*); protozoa (e.g., *Toxoplasma gondii*), and species-specific ratio of IgG, IgA, or IgM in CSF and serum
- Oligoclonal bands using a predefined interpretation pattern
- Other biochemical markers such as glucose, lactate, β -trace protein, and other proteins determined in CSF
- Microbiological culture and PCR—predefined list of organisms for culture and PCR results

PROTIS **CSF Assessment**

Graphical result presentation
in Reiber diagrams²



1. Normal finding
2. Pure blood-CSF-barrier dysfunction
3. Intrathecal Ig synthesis with reduced CSF turnover
4. Intrathecal Ig synthesis without change in CSF turnover
5. Implausible result

CSF Assessment Report

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Patient Information

Patient ID: 20000001
 Name: Patient, Sample CSF Age: 57 Y Date of birth: 7/1/1963 Sex: M

Samples

CSF: 2000000607 Received date/time: 7/10/2020 Date of Puncture:
 Serum: 2000000601

Diagnostic Question

Place of Puncture	Visual Inspection	Hemoglobin	Volume (ml)
LP CP VP	clear	0	

Cells

Proteins

	CSF	Serum	Q (CSF/Serum)	local Synthesis (IF)
Total Protein				
Albumin	280 mg/l	44 g/l	6.4	9 %
IgG	60 mg/l	11.7 g/l	5.1	53 %
IgA	22 mg/l	3.4 g/l	6.5	0 %
IgM	1.1 mg/l	1.4 g/l	0.8	0 %

Oligoclonal IgG

Additional Parameter

CSF	Serum	Q (CSF/Serum)
		(Synthesis in CNS: AI ≥ 1.5)

Antibody Indices

Interpretation

<input type="checkbox"/> Normal CSF (Based on Cells, Oligoclonal IgG, AI)	<input type="checkbox"/> Normal CSF proteins (Based on Albumin, IgG, IgA, IgM)
<input type="checkbox"/> Blood-CSF barrier dysfunction	<input type="checkbox"/> Increased cell count
<input checked="" type="checkbox"/> Inflammatory proc. in CNS	<input type="checkbox"/> Spec. Ab synthesis in CNS

Comment

Print date:
 7/10/2020 2:04 PM

Signature

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Patient, Sample CSF
 20000001

1/1

Hyperbolic Reiber diagram for visualization of biomarkers used in assessment of multiple sclerosis

Diagnosis of multiple sclerosis (MS) can be challenging, and there is no single lab test that definitively rules in or rules out MS. Based on the 2017 McDonald criteria, MS is diagnosed based on evidence of central nervous system (CNS) damage that is disseminating in space or appearing in multiple regions of the nervous system, and evidence of damage that is disseminating in time or occurring at different points in time.

The presence of oligoclonal bands (OCB) can be regarded as sufficient to fulfill the criteria for dissemination (neurological damage) in time. OCBs are also indicative of CNS inflammation and are an independent predictor of relapse in individuals with clinically isolated syndrome (CIS). However, detection of OCBs is a laborious method in the routine laboratory that requires skilled, experienced staff.

Intrathecal produced kappa free light chains (kFLC) have recently been identified as a novel, promising biomarker with characteristics comparable to oligoclonal bands. They have been established as a suitable screening test to detect an intrathecal humoral immune response and could also reduce the number of manual OCB tests. In addition, quantification of kFLC in CSF can be fully automated, and multiple studies were performed using the Siemens Healthineers N Latex FLC kappa assay on nephelometric platforms.

The most common method to determine the intrathecal kFLC fraction is to calculate the CSF/serum kFLC quotient with reference to the albumin CSF/serum quotient (QkFLC/QAlbumin): the so-called KFLC index. Recently, Prof. Reiber developed a theoretically and empirically founded hyperbolic function similar to his traditional hyperbolic function for the immunoglobulins A, G, and M used in the PROTIS CSF assessment kit.³ This kFLC Reiber diagram has been validated for patient populations with MS as well as CIS,^{4,5} offering an easy and reliable method to determine intrathecal kFLC synthesis.

Diagnostic assessment support

- Assessment of intrathecal protein synthesis
- Display of results using kFLC (CSF/serum) quotient diagram
- Optional display of immunoglobulin results, including Reiber diagrams for IgG, IgA, and IgM
- Serological identification of infectious pathogens

Core CSF assessment

- kFLC and albumin CSF/serum ratios
- CSF sample information: place of puncture, optical appearance, hemoglobin
- Graphical result presentation in Reiber diagram

Extended panel for further assessment (optional parameters)

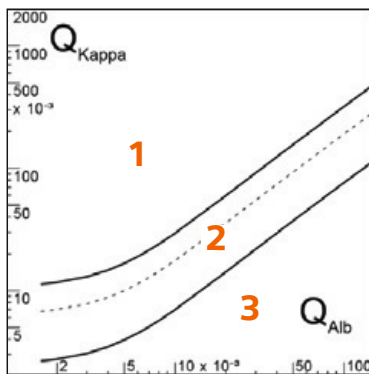
- Oligoclonal bands using a predefined interpretation pattern
- IgG, IgA, and IgM CSF/serum ratios and Reiber diagrams
- Cell count and differentiation, including a predefined list of cell types
- Determination of intrathecal microorganisms based on the CSF assessment kit (see page 6) with species-specific ratios of IgG, IgA, or IgM in CSF and serum
- Other biochemical markers such as glucose or lactate and other proteins determined in CSF
- Neurofilament light chains in serum and CSF

Please note that the MS assessment kit will not provide suggestions for clinical result interpretation comparable to the CSF assessment. Clinical interpretation decisions regarding patient care and treatment are the clinician's responsibility and must be entered manually for each patient.



PROTIS MS Assessment

"Reiber's κFLC diagram shows a great diagnostic performance to detect an intrathecal κFLC production in patients with MS."⁴



1. Intrathecal κFLC synthesis
2. Normal situation
3. Implausible result

MS Assessment

Account

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Patient Information		Patient ID	200013				
Name	Patient 03, Sample	Age	51 Y	Date of birth	9/8/1971	Sex	F
Samples		Received date/time	Date of Puncture				
CSF	2200001207						
Serum	2200001201						

Place of Puncture			Visual Inspection	Hemoglobin	Volume (ml)
LP	CP	VP	clear	0	

Cells

Cell Count	4 /μl	Erythrocytes Count	1 /μl
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Proteins

	CSF	Serum	Q (CSF/Serum) x 10 ⁻³	local Synthesis (IF)
Total Protein				
Albumin	183.3 mg/l	47 g/l	3.9	
Free Ig/L-chain, type kappa	0.97 mg/l	10.7 mg/l	90.7	84 %
IgG	36.1 mg/l	8.7 g/l	4.1	38 %

	CSF	Serum	Q (CSF/Serum)
Neurofilament light chain protein		1.2 pg/ml	

Oligoclonal IgG

Additional Parameter

	CSF	Serum	Q (CSF/Serum)
Lactate	0.12 mmol/l		

Antibody Indices

(Synthesis in CNS: AI ≥ 1.5)

Comment

Print date:
10/5/2022 4:20 PM

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Patient 03, Sample
200013

1/1

Intelligently assess differential diagnoses of kidney disease

The PROTIS Kidney Assessment Kit assists with early detection and diagnosis of renal diseases. It provides estimation of glomerular filtration rate (GFR) using cystatin C and/or creatinine-based formulas. It also aids in differential diagnosis of proteinuria and hematuria.

Differential diagnosis support

- Glomerular filtration rate
- Glomerular nephropathy
- Tubular nephropathy
- Mixed type nephropathy
- Differential diagnosis of hematuria

Automated basic and sensitive workflows

- Exclusion/differential diagnosis of nephropathy, including:
 - GFR assessment
 - Proteinuria differentiation
 - Hematuria differentiation
- Determination of appropriate sample dilution for marker proteins based on total protein content of urine sample

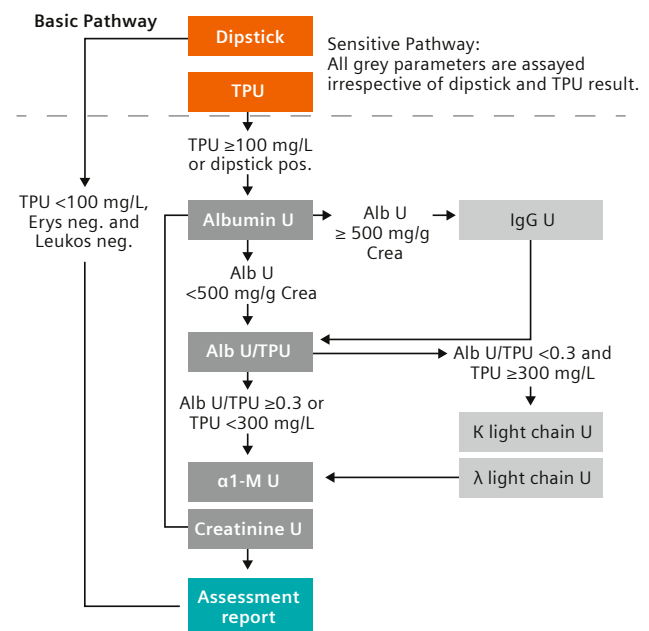
GFR assessment

- Cystatin C in serum
 - Calculation of cystatin C-based GFR, including the latest recommended formulas, e.g., KDIGO⁶ or CAPA⁷ equations
 - Combined creatinine/cystatin C-based equations according to (KDIGO)
- Creatinine clearance
- Serum creatinine
 - MDRD formula
 - MDRD/IDMS formula
 - Cockcroft-Gault formula
 - Schwartz formula

Differentiation of proteinuria using urine samples:

- Dipstick analysis
- Total protein (TPU)
- Albumin (Alb U)
- Creatinine (Crea)
- α 1-Microglobulin (α 1-M U)
- α 2-Macroglobulin
- IgG (IgG U)
- Ig light chains/kappa and lambda
- Microscopic erythrocytes evaluation

Workflows in Kidney Assessment



Example of an automated workflow for measurement of additional parameters based on previous results without manual support.



PROTIS Kidney Assessment

Kidney Assessment Report

Account

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Patient Information

Name **Kidney Patient, Sample** Patient ID **20000014** Sex **F**
Height (cm) Age **60 Y** Date of birth **7/7/1960**
Weight (kg) Race

Samples

Urine 2000001902 Volume (ml)
Serum 2000001901 Volume (ml)

Parameter	Result	Reference	Unit	Concentration
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Serum Assays

Cystatin C	3.8	0.62 - 1.11	mg/l	
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Glomerular Filtration Rate

GFR Cystatin C	12	>=90	ml/min	
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Urine Assays

Creatinine				50 mg/dl
Total Protein	744.0	<100	mg/g Crea	0.372 g/l
Albumin	460.0	<20	mg/g Crea	230 mg/l
Immunoglobulin G	31.6	<10	mg/g Crea	15.8 mg/l
a1-Microglobulin	70.8	<14	mg/g Crea	35.4 mg/l
a2-Macroglobulin	4.2	<10	mg/g Crea	2.1 mg/l

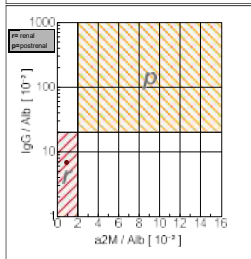
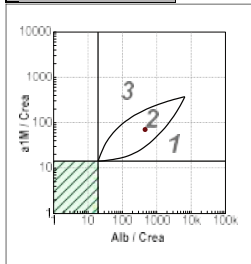
Ratios

IgG/Albumin	6.9 %	a1-Microglobulin/Albumin	15.4 %
a2-Macroglobulin/Albumin	0.9 %	Albumin/Total Protein	61.8 %

Dipstick Results

	Cell Counts
Erythrocytes a.	++
Leukocytes a.	0
Protein a.	++
Glucose a.	0

In majority of cases:
1 prim. glomerulopathy
2 sec. glomerulopathy
3 tubulo-interstitial nephropathy



Interpretation

GFR estimation indicates a drastic decrease in glomerular filtration, which is classified as renal failure. (Based on the Cystatin C formula)

Glomerular proteinuria is present. This is classified as significant (presence of macroalbuminuria). Additional, significant tubular proteinuria exists.

This constellation is compatible with glomerulopathy with restricted tubulo-interstitial reabsorption. The presence of renal hematuria is highly likely; additional erythrocytes from postrenal sources cannot be ruled out.

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Kidney Patient,
Sample
20000014

1/1

All reports come in a standardized format but are adaptable to meet your needs, e.g., adding your clients, assay mix, or logo.

Combined result interpretation from multiple sources:

- Dipstick
- Nephelometer
- Clinical chemistry
- Local IT system

Illustration of glomerulopathy/nephropathy/hematuria status

Detailed clinical interpretation

Reduce patient management costs through holistic nutritional status checks

Protein calorie malnutrition is common in hospitalized patients but often remains undiagnosed. At-risk patients are often among the most severely ill, and failure to recognize malnourished patients can affect patients' health, increase the length of stay, and add to hospital-associated costs.

The PROTIS Nutritional Assessment Kit aids in identifying a patient's risk category, provides recommendations for further patient management, and suggests appropriate monitoring of the nutrition status.

Consolidated malnutrition risk assessment

- Evaluation of nutritional status based on prealbumin, albumin, and weight-based data
- Integration of anamnestic data (e.g., body mass index [BMI], weight loss)
- Alert feature for underlying conditions that might affect the concentration of nutritional protein markers, such as inflammation, liver disease, or hemoconcentration/hemodilution
- Combined results from multiple analyzers
- Recommendations for further patient monitoring
- Alerts if nutritional supplementation may be indicated

- At-a-glance evaluation of the most relevant nutritional markers
- Calculation of Nutritional Risk Index (NRI)⁸ and Prognostic Inflammatory and Nutritional Index (PINI)⁹

Nutritional protein markers

- Core assays for nutritional assessment:
 - Prealbumin/Transthyretin
 - Albumin
- Extended protein panel for further characterization:
 - Inflammation
 - CRP
 - α1-acid glycoprotein
 - Liver disease
 - Prothrombin time (PT)
 - Hemoconcentration or hemodilution
 - Hematocrit

Nutritional indices

$$\text{NRI} = 1.52 \times \text{albumin (g/L)} + 41.7 \times (\text{actual/usual weight})$$

$$\text{PINI} = \frac{\text{CRP (mg/L)} \times \alpha 1\text{-acid glycoprotein (mg/L)}}{\text{albumin (g/L)} \times \text{prealbumin (mg/L)}}$$

Classification of nutritional status

Parameter	Levels of Malnutrition			
	None	Mild	Moderate	Severe
Prealbumin (g/L)	>0.2	0.11–0.2	0.05–0.11	<0.05
Albumin (g/L)	>35	30–35	20–30	<20 (<25 for age ≥70 years)
NRI	>97.5%	90–97.5%	83.5–90%	<83.5%
Weight loss in last 3 months	<2%	2–5%	5–10%	>10%
BMI	—	—	—	<17.0 (≤20.0 for age ≥70 years)

Nutritional Parameters			Scoring (example data)			
	Result	Unit	Normal	Mild	Moderate	Severe
Weight loss	3.2	%		●		
BMI	25.4	—	●			
Prealbumin	0.095	g/L			●	
Albumin	31.5	g/L		●		
Nutritional Risk Index	88.2	%			●	



PROTIS Nutritional Assessment

Nutritional Assessment Report

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Account

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Patient Information

Name
Patient ID
Date of birth

Patient Nutrition,
Sample
40041
5/4/1957

Samples

Serum 2000000301

Height 161 cm
Current weight 48.0 kg
Usual weight 57.0 kg
Current weight as % of usual weight 84.2 %

Nutritional Marker	Result	Reference	Unit	Scoring			
				normal	mild	moderate	severe
Weight change	-15.8	(-2 - 2)	%				X
BMI	18.5	(20 - 25)		X			
Albumin	28.0	(35 - 52)	g/l			X	
Prealbumin/Transthyretin	12	()	mg/l				X
Nutritional Risk Index	77.6	(>=97.5)	%				X
CRP	7.8	(<3)	mg/l				
a1-Acid Glycoprotein (Orosomucoid)	0.7	(0.5 - 1.2)	g/l				
Transferrin	2.3	(2 - 3.6)	g/l				
PIN Index	16.25	(<=1)					
Retinol binding protein	1.1	()	mg/l				

Interpretation

Signs of severe malnutrition.

Nutrition:

Enteral nutrition is strongly indicated. If enteral nutrition is impossible or insufficient, contact nutrition specialist for advise and consider parenteral nutrition.

Follow-up:

Check weight twice per week, check prealbumin/transthyretin once per week, check albumin once every 3 weeks.

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Patient Nutrition,
Sample
40041

1/1

Detailed sample result table with nutritional assessment scoring

Timely, holistic nutritional assessment helps improve patient outcomes and can yield significant cost savings. The cost savings were generally found to be associated with reduced complications, reduced mortality, and reduced length of hospital stay.¹⁰

Notes

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.

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