

AEROSET®

c8000™

TOTAL PROTEIN

This package insert contains information to run the Total Protein assay on the AEROSET System and the ARCHITECT® c8000 System.











NOTE: Changes to AEROSET System Information Highlighted
(Supplemental and format changes are not highlighted)


NOTE: This package insert must be read carefully prior to product use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Customer Support


United States: 1-800-527-1869
Canada: 1-800-387-8378 (English speaking customers)
 1-800-465-2675 (French speaking customers)
International: Call your local Abbott representative

Symbols in Product Labeling

	Authorized Representative		Consult instructions for use
	For in vitro diagnostic use		Legal Manufacturer
	Batch code/Lot number		Temperature limitation
	Reagent 1		Use by/Expiration date
	Catalog number/List number		
	Serial number		

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NAMETOTAL PROTEIN

INTENDED USEThe Total Protein assay is used for the quantitation of total protein in human serum or plasma.

SUMMARY AND EXPLANATION OF TEST

Plasma proteins derive primarily from synthesis in the liver, plasma cells, lymph nodes, spleen, and bone marrow. In disease states both the total plasma protein level and the ratio of the individual fractions may be dramatically altered from their normal values. Hypoproteinemia may be caused by such conditions as nephrotic syndrome, extensive bleeding, sprue (deficient protein absorption), severe burns, salt retention syndromes, and Kwashiorkor (acute protein starvation). Hyperproteinemia may be observed in cases of severe dehydration and disease states such as multiple myeloma. Changes in the proportions of the plasma proteins may occur in one or several of the protein fractions and often without alterations in the quantity of the total protein. The A/G ratio has commonly been used as an index of the distribution between the albumin and globulin fractions. This ratio can be significantly altered in such conditions as cirrhosis of the liver, glomerulonephritis, nephrotic syndrome, acute hepatitis, lupus erythematosus, and in some acute and chronic infections.

PRINCIPLES OF PROCEDURE

Polypeptides containing at least two peptide bonds react with biuret reagent. In alkaline solution, cupric ion forms a coordination complex with protein nitrogen with very little difference between albumin and globulin on a protein-nitrogen basis.

REAGENTS**Reagent Kit**

Total Protein, List No. 7D73, is supplied as a liquid, ready-to-use, single reagent kit which contains:

- Reagent 1 (R1) 10 x 84 mL

Estimated tests per kit are 3,622. Calculation based on minimum reagent fill volume per kit.

Reactive Ingredients

Ingredient	Concentration
Sodium Potassium Tartrate	23.4 mmol/L
Sodium Hydroxide	613 mmol/L
Potassium Iodide	6.6 mmol/L
Copper Sulfate	13.2 mmol/L

REAGENT HANDLING AND STORAGE**Reagent Handling**

Remove air bubbles, if present in the reagent cartridge, with a new applicator stick. Alternatively, allow the reagent to sit at the appropriate storage temperature to allow the bubbles to dissipate. To minimize volume depletion, do not use a transfer pipette to remove the bubbles.

CAUTION: Reagent bubbles may interfere with proper detection of reagent level in the cartridge, causing insufficient reagent aspiration which could impact results.

Reagent Storage

The unopened reagents are stable until the expiration date when stored at 15 to 30°C.

Reagent stability is 23 days if the reagent is uncapped and onboard.

WARNINGS AND PRECAUTIONS**Precautions for Users**

1. For in vitro diagnostic use.
2. Do not use components beyond the expiration date.
3. Do not mix materials from different kit lot numbers.
4. Reagent 1 (R1) contains sodium hydroxide and is classified per applicable European Community (EC) Directives as: Irritant (Xi). The following are the appropriate Risk (R) and Safety (S) phrases:



- R38 Irritating to skin.
- R41 Risk of severe damage to eyes.
- S25 Avoid contact with eyes.
- S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice immediately.
- S35 This material and its container must be disposed of in a safe way.
- S37/39 Wear suitable gloves and eye/face protection.
- S46 If swallowed, seek medical advice immediately and show this container or label.

SPECIMEN COLLECTION AND HANDLING

Suitable Specimens

Serum and plasma are acceptable specimens.

Serum: Use serum with or without gel barrier collected by standard venipuncture techniques in glass or plastic tubes. Ensure complete clot formation has taken place prior to centrifugation. Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may exhibit increased clotting time. If the specimen is centrifuged before a complete clot forms, the presence of fibrin may cause erroneous results. Separate from red blood cells as soon after collection as possible.

Plasma: Use plasma without gel barrier (acceptable anticoagulants: lithium heparin, ammonium heparin, and sodium heparin) collected by standard venipuncture techniques in glass or plastic tubes. Ensure centrifugation is adequate to remove platelets. Separate from red blood cells as soon after collection as possible.

For total sample volume requirements, refer to the instrument-specific ASSAY PARAMETERS section of this package insert and *Section 5* of the instrument-specific operations manual.

CAUTION: This product requires the handling of human specimens. It is recommended that all human sourced materials are considered potentially infectious and be handled in accordance with the OSHA Standard on Bloodborne Pathogens.¹ Biosafety Level 2² or other appropriate biosafety practices^{3,4} should be used for materials that contain or are suspected of containing infectious agents.

Specimen Storage

Serum and plasma: Total protein is stable in serum and plasma for 1 week at room temperature, for at least 1 month when refrigerated, and for up to 2 months at -20°C.⁵

An in-house study confirmed total protein is stable in serum for 34 days at 2 to 8°C.

NOTE: Stored specimens must be adequately mixed prior to testing.

PROCEDURE

Materials Provided

Total Protein Reagent Kit, List No. 7D73

Materials Required but not Provided

- AEROSET System or ARCHITECT c8000 System
- Multiconstituent Calibrator, List No. 1E65
 - CAL 1: 3 x 5 mL
 - CAL 2: 3 x 5 mL
- Control Material
- Saline (0.85 to 0.90%), if desired for specimen dilution

Assay Procedure

For a detailed description of how to run an assay, refer to *Section 5* of the instrument-specific operations manual.

Specimen Dilution Procedures

Use saline to dilute samples outside of the linearity of the assay. The AEROSET System and the ARCHITECT c8000 System have Automatic Dilution features; refer to *Section 2* of the instrument-specific operations manual for additional information.

CALIBRATION

Calibration is stable for approximately 23 days (552 hours) and calibration is required with each lot number change. Verify calibration with at least two levels of controls according to the established Quality Control requirements for your laboratory. If control results fall outside acceptable ranges, recalibration may be necessary.

For a detailed description of how to calibrate an assay, refer to *Section 6* of the instrument-specific operations manual.

For information on calibrator standardization, refer to the Multiconstituent Calibrator package insert.

QUALITY CONTROL

The following process is the recommendation of Abbott Laboratories for quality control during the Total Protein procedure. As appropriate, refer to your laboratory Standard Operating Procedure(s) and/or Quality Assurance Plan for additional quality control requirements and potential corrective actions.

- Two levels of controls (normal and abnormal) are to be run every 24 hours.
- If more frequent control monitoring is required, follow the established Quality Control procedures for your laboratory.
- If quality control results do not fall within an acceptable range defined by your laboratory, patient values may be suspect. Follow the established Quality Control procedures for your laboratory.
- If quality control results fall outside acceptance criteria, recalibration may be necessary.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

RESULTS

Refer to the instrument-specific operations manual for information on results calculations.

- **AEROSET System Operations Manual—Appendix A**
- **ARCHITECT System Operations Manual—Appendix C**

LIMITATIONS OF THE PROCEDURE

Refer to the SPECIMEN COLLECTION AND HANDLING and SPECIFIC PERFORMANCE CHARACTERISTICS sections of this package insert.

EXPECTED VALUES

Reference Range

Serum⁶

	Range (g/dL)	Range (g/L)
Premature	3.6 to 6.0	36 to 60
Newborn	4.6 to 7.0	46 to 70
Cord	4.8 to 8.0	48 to 80
1 week	4.4 to 7.6	44 to 76
7 months to 1 year	5.1 to 7.3	51 to 73
1 to 2 years	5.6 to 7.5	56 to 75
≥ 3 years	6.0 to 8.0	60 to 80
Adult, Ambulatory	6.4 to 8.3	64 to 83
Adult, Recumbent	6.0 to 7.8	60 to 78
> 60 years	lower by ~ 0.2	lower by ~ 2

To convert results from g/dL to g/L, multiply g/dL by 10.

Plasma

Plasma values are generally 0.3 to 0.5 g/dL higher than serum values due to the presence of fibrinogen.⁷ This difference has been shown to vary among specific populations.⁸

It is recommended that each laboratory determine its own reference range based upon its particular locale and population characteristics.

SPECIFIC PERFORMANCE CHARACTERISTICS

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Linearity

Total Protein is linear up to 18.4 g/dL (184 g/L). Linearity was verified using NCCLS protocol EP6-P.⁹

Limit of Detection (LOD)

The LOD is the mean concentration of an analyte-free sample + 2 SD, where SD = the pooled, within-run standard deviation of the analyte-free sample. The LOD for Total Protein is 0.07 g/dL (0.7 g/L).

Limit of Quantitation (LOQ)

The LOQ is the analyte concentration at which the CV = 20%. The limit of quantitation for Total Protein is 0.76 g/dL (7.6 g/L).

Interfering Substances¹⁰

Interference studies were conducted on the AEROSET System using NCCLS protocol EP7-P.¹¹ Interference effects were assessed by Dose Response and Paired Difference methods, at the medical decision level of the analyte concentration or activity.

Interfering Substance	Interferent Concentration		N	Target (g/dL)	Observed (% of Target)
Bilirubin	30 mg/dL	(513 µmol/L)	3	6.6	96.2
Bilirubin	60 mg/dL	(1,026 µmol/L)	3	6.6	93.4
Hemoglobin	125 mg/dL	(1.25 g/L)	3	5.2	106.2
Hemoglobin	250 mg/dL	(2.50 g/L)	3	5.2	112.1
Human Triglyceride	750 mg/dL	(8.5 mmol/L)	4	8.9	100.2
Human Triglyceride	1,000 mg/dL	(11.3 mmol/L)	4	8.9	99.5

Bilirubin levels were prepared by the addition of a bilirubin stock to human serum pools. Hemoglobin levels were prepared by addition of hemolysate to human serum pools. Triglyceride levels were prepared by mixing a high triglyceride level human serum pool with a normal triglyceride level human serum pool.

SPECIFIC PERFORMANCE CHARACTERISTICS (Continued)

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Precision

The results from precision studies for serum using NCCLS protocol EP5-T2¹² are found below.

Serum

Control	N	Mean (g/dL)	Within Run		Between Run		Between Day		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Level 1	80	6.5	0.03	0.5	0.04	0.7	0.03	0.4	0.06	0.9
Level 2	80	4.1	0.03	0.6	0.03	0.7	0.04	1.0	0.06	1.4

Method Comparison

Correlation studies were performed using NCCLS protocol EP9-A.¹³ Serum results from the Total Protein assay on the AEROSET System were compared with the Boehringer Mannheim Total Protein assay (biuret reaction methodology) on the Hitachi 717 Analyzer. Serum results observed on the AEROSET System ranged from 2.20 to 11.46 g/dL.

Serum

Y - Intercept	0.167
Correlation Coefficient	0.984
Slope	1.020
Number of Samples	80

SPECIFIC PERFORMANCE CHARACTERISTICS (Continued)

c8000

Precision

The results from precision studies for serum using NCCLS protocol EP5-A¹⁴ are found below.

Control	N	Mean (g/dL)	Within Run		Between Run		Between Day		Total		
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	
Level 1											
Instrument 1	80	6.5	0.02	0.3	0.01	0.1	0.06	0.9	0.06	1.0	
Instrument 2	80	6.5	0.02	0.4	0.02	0.3	0.07	1.1	0.08	1.2	
Instrument 3	80	6.5	0.01	0.2	0.03	0.4	0.09	1.4	0.09	1.4	
Level 2											
Instrument 1	80	4.1	0.01	0.4	0.03	0.6	0.04	1.0	0.05	1.2	
Instrument 2	80	4.1	0.02	0.5	0.02	0.4	0.04	1.0	0.05	1.2	
Instrument 3	80	4.1	0.01	0.4	0.02	0.4	0.08	1.8	0.08	1.9	

Method Comparison

Correlation studies were performed based on NCCLS protocol EP9-A.¹³ Serum results from the Total Protein assay on the ARCHITECT c8000 System were compared with the Total Protein assay on the AEROSET System. Serum results observed on the AEROSET System ranged from 1.94 to 16.77 g/dL.

	Instrument 1	Instrument 2	Instrument 3
Y - Intercept	-0.008	0.000	-0.013
Correlation Coefficient	1.000	1.000	1.000
Slope	0.994	0.989	0.995
Number of Samples	100	100	100

AEROSET SYSTEM ASSAY PARAMETERS

AEROSET

Total Protein Serum/Plasma—Conventional Units

Assay Configuration: Outline Page							
Assay Name	Assay #		Line				
TP	14		B-Line				
Quantitative Ranges							
Min Text	Min	Panic-L	L-Reference-H		Panic-H	Max	Max Text
*	0.0*	0.0	6.4	8.3	0.0	0.0*	*
		0.8**	L-Linear Range-H		18.4		
Reference Ranges*							
Age		Male		Female			
0 Year		0.0 – 0.0		0.0 – 0.0			
0 Year		0.0 – 0.0		0.0 – 0.0			
0 Year		0.0 – 0.0		0.0 – 0.0			
0 Year		0.0 – 0.0		0.0 – 0.0			
Qualitative Ranges							
N/A							

Total Protein Serum/Plasma—SI Units

Assay Configuration: Outline Page							
Assay Name	Assay #		Line				
TP	14		B-Line				
Quantitative Ranges							
Min Text	Min	Panic-L	L-Reference-H		Panic-H	Max	Max Text
*	0.0*	0.0	64	83	0.0	0.0*	*
		8**	L-Linear Range-H		184		
Reference Ranges*							
Age		Male		Female			
0 Year		0.0 – 0.0		0.0 – 0.0			
0 Year		0.0 – 0.0		0.0 – 0.0			
0 Year		0.0 – 0.0		0.0 – 0.0			
0 Year		0.0 – 0.0		0.0 – 0.0			
Qualitative Ranges							
N/A							

Assay Configuration: Base Page							
Reaction Mode	Wavelength-Prim/Sec		Read Time-Main/Flex		AbsMaxVar		
END UP	572 / 660		14 – 16 / 0 – 0		0.0		
Sample Blank Test	Blank Read Time		Abs Window		Abs Limits		
____ (____)	0 – 0		0 – 0		0.0 – 0.0		
Standard	S.Vol	DS.Vol	D.Vol	W.Vol	Rgt Name/Pos		
Dil 1	4.0	0.0	0	0	Diluent ____ _ _ *		
Dil 2	4.0	0.0	0	0	Type#*** 0		
Reagent 1	Rgt Name/Pos	R.Vol	W.Vol	Type#***			
TP00061 – ____ *	200	0	0	0			
Reaction Check	Read Time–A/B		Range		Minimum		
____ _	1 – 1 / 1 – 1		0.0 – 0.0		0.0		
Factor/Intercept	Decimal Places		Units				
1.0 / 0.0	1		g/dL				

Assay Configuration: Base Page							
Reaction Mode	Wavelength-Prim/Sec		Read Time-Main/Flex		AbsMaxVar		
END UP	572 / 660		14 – 16 / 0 – 0		0.0		
Sample Blank Test	Blank Read Time		Abs Window		Abs Limits		
____ (____)	0 – 0		0 – 0		0.0 – 0.0		
Standard	S.Vol	DS.Vol	D.Vol	W.Vol	Rgt Name/Pos		
Dil 1	4.0	0.0	0	0	Diluent ____ _ _ *		
Dil 2	4.0	0.0	0	0	Type#*** 0		
Reagent 1	Rgt Name/Pos	R.Vol	W.Vol	Type#***			
TP00061 – ____ *	200	0	0	0			
Reaction Check	Read Time–A/B		Range		Minimum		
____ _	1 – 1 / 1 – 1		0.0 – 0.0		0.0		
Factor/Intercept	Decimal Places		Units				
1.0 / 0.0	0		g/L				

Assay Configuration: Calibration Page						
Calib Mode	Interval (H)					
Linear	552					
Blank/Calib Replicates	Extrapolation%		Span	Span Abs Range		
3 / 3	0		BLK – 1	0.0 – 0.0		
Sample	S.Vol	DS.Vol	D.Vol	W.Vol	BLK Abs Range	
BLK Water	4.0	0.0	0	0	0.0 – 0.0	
C1 MCC 1	4.0	0.0	0	0	Cal Deviation	
C2 MCC 2	4.0	0.0	0	0	0.0	
					FAC Limit (%)***	
					10	

Assay Configuration: Calibration Page						
Calib Mode	Interval (H)					
Linear	552					
Blank/Calib Replicates	Extrapolation%		Span	Span Abs Range		
3 / 3	0		BLK – 1	0.0 – 0.0		
Sample	S.Vol	DS.Vol	D.Vol	W.Vol	BLK Abs Range	
BLK Water	4.0	0.0	0	0	0.0 – 0.0	
C1 MCC 1	4.0	0.0	0	0	Cal Deviation	
C2 MCC 2	4.0	0.0	0	0	0.0	
					FAC Limit (%)***	
					10	

Assay Configuration: SmartWash Page			
Rgt Probe	Reagent	Wash	Vol
____	____	____	____
Cuvette	Assay Name	Wash	Vol
____	____	____	____
Sample Probe	Wash		
____	____		

Assay Configuration: SmartWash Page			
Rgt Probe	Reagent	Wash	Vol
____	____	____	____
Cuvette	Assay Name	Wash	Vol
____	____	____	____
Sample Probe	Wash		
____	____		

Refer to **Assay Configuration** in *Section 2* of the **AEROSET System Operations Manual** for information regarding assay parameters.

* User defined or instrument defined.

** The linear low value (L-Linear Range) is LOQ rounded up to the number of decimal places defined in the decimal places parameter field.

*** This field is not available with AEROSET Software v1.00ER005 or 1.00ER005.2.

ARCHITECT c8000 SYSTEM ASSAY PARAMETERS

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Total Protein Serum/Plasma—Conventional and SI Units

Configure assay parameters – General			
<input checked="" type="radio"/> General	<input type="radio"/> Calibration	<input type="radio"/> SmartWash	<input type="radio"/> Results
Assay: TP Type: Photometric Version: 1			
Number: 1014			
<input checked="" type="radio"/> Reaction definition	<input type="radio"/> Reagent / Sample	<input type="radio"/> Validity checks	
Reaction mode: End up			
Primary		Secondary	
Wavelength: 572 / 660		Read times Main: 14 - 16	
Last required read: 16			
Absorbance range: ___ - ___		Color correction: ___ - ___	
Sample blank type: None			

Configure assay parameters – Results – Conventional units			
<input type="radio"/> Reaction definition	<input checked="" type="radio"/> Reagent / Sample	<input type="radio"/> Validity checks	
Reagent: TP000 Reagent volume: 200 R1			
Diluent: Saline Water volume: ___			
Diluent dispense mode: Type 0 Dispense mode: Type 0			
Dilution name	Sample	Diluted sample	Dilution factor
STANDARD:	4.0	___	1:1.00
___	___	___	___
___	___	___	___
Default dilution: <input checked="" type="radio"/>			

Configure assay parameters – Calibration			
<input type="radio"/> Reaction definition	<input type="radio"/> Reagent / Sample	<input checked="" type="radio"/> Validity checks	
Reaction check: None			
Maximum absorbance variation: ___			

Configure assay parameters – Calibration			
<input type="radio"/> General	<input checked="" type="radio"/> Calibration	<input type="radio"/> SmartWash	<input type="radio"/> Results
Assay: TP Calibration method: Linear			
<input checked="" type="radio"/> Calibrators	<input type="radio"/> Volumes	<input type="radio"/> Intervals	<input type="radio"/> Validity checks
Calibrator set: MCC	Blank: Water	Calibrator level: 0^{††}	Concentration: ___
Replicates: 3 [Range 1 – 3]	Cal 1: MCC1	Cal 2: MCC2	‡

Configure assay parameters – Calibration			
<input type="radio"/> Calibrators	<input checked="" type="radio"/> Volumes	<input type="radio"/> Intervals	<input type="radio"/> Validity checks
Calibrator: MCC	Calibrator level	Sample	Diluted sample
Blank: Water	4.0	___	___
Cal 1: MCC1	4.0	___	___
Cal 2: MCC2	4.0	___	___

Configure assay parameters – Calibration			
<input type="radio"/> Calibrators	<input type="radio"/> Volumes	<input checked="" type="radio"/> Intervals	<input type="radio"/> Validity checks
Calibration intervals:			
Full interval: 552 (hours)			
Calibration type:			
Adjust type: None			

Configure assay parameters – Calibration			
<input type="radio"/> Calibrators	<input type="radio"/> Volumes	<input type="radio"/> Intervals	<input checked="" type="radio"/> Validity checks
Blank absorbance range: ___ - ___			
Span: Blank - Water			
Span absorbance range: ___ - ___			
Expected cal factor: 0.00			
Expected cal factor tolerance %: 0			

Configure assay parameters – SmartWash				
<input type="radio"/> General	<input type="radio"/> Calibration	<input checked="" type="radio"/> SmartWash	<input type="radio"/> Results	<input type="radio"/> Interpretation
Assay: TP				
COMPONENT	REAGENT / ASSAY	WASH	Volume	Replicates
Cuvette	Trig	Detergent B	345	

Total Protein Serum/Plasma—Conventional Units

Configure assay parameters – Results – Conventional units				
<input type="radio"/> General	<input type="radio"/> Calibration	<input type="radio"/> SmartWash	<input checked="" type="radio"/> Results	<input type="radio"/> Interpretation
Assay: TP Result units: g/dL				
Assay defaults:				
Low-Linearity: 0.8[†]				
High-Linearity: 18.4				
Gender and age specific ranges:				
GENDER	AGE (UNITS)	NORMAL	EXTREME	
Either	0 – 130 (Y)	6.4 – 8.3		

Configure result units – Conventional units	
Assay: TP	Version: 1
Result units: g/dL	Decimal places: 1 [Range 0 – 4]
Correlation factor: 1.000	Intercept: 0.000

Total Protein Serum/Plasma—SI Units

Configure assay parameters – Results – SI units				
<input type="radio"/> General	<input type="radio"/> Calibration	<input type="radio"/> SmartWash	<input checked="" type="radio"/> Results	<input type="radio"/> Interpretation
Assay: TP Result units: g/L				
Assay defaults:				
Low-Linearity: 8[†]				
High-Linearity: 184				
Gender and age specific ranges:				
GENDER	AGE (UNITS)	NORMAL	EXTREME	
Either	0 – 130 (Y)	64 – 83		

Configure result units – SI units	
Assay: TP	Version: 1
Result units: g/L	Decimal places: 0 [Range 0 – 4]
Correlation factor: 1.000	Intercept: 0.000

[†] The linear low value (Low-Linearity) is LOQ rounded up to the number of decimal places defined in the decimal places parameter field.
[‡] Refer to concentration specified on calibrator labeling or value sheet.
^{††} Displays the number of decimal places defined in the decimal places parameter field.

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