



30-3073/R2

AEROSET®

c8000 $^{\mathrm{TM}}$

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.

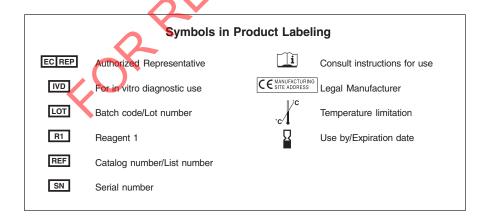
Customer Support

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







ABBOTT Max-Planck-Ring 2 65205 Wiesbaden Germany +49-6122-580



NAME

TOTAL PROTEIN

INTENDED USE

The 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 erythematosis, 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 e

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.

<u>Plasma</u>: 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. 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

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

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



SPECIFIC PERFORMANCE CHARACTERISTICS

AEROSET

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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 C	oncentration	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	Withir	n Run	Betwe	en Run	Betwe	en Day	To	tal
		(g/dL)	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 Analy compared with the Boehringer Mannheim Total Protein assay (biuret reaction methodology) on the Hitachi 717 Analyzer. Seruri 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	Withir	n Run	Betwe	en Run	Betwe	en Day	To	otal
		(g/dL)	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
	REFER		
	K .		

AEROSET SYSTEM ASSAY PARAMETERS

AEROSET

Total Protein Serum/Plasma—Conventional Units

Assay Nam	e	Assa	av #			Lir	ne
TP		14	.y "			_ine	
Quantitativ	e Ranges	3					
Min Text	Min	Panic-L	L-Refere	ence-H	Panic-H	Max	Max Text
*	0.0*	0.0	6.4	8.3	0.0	0.0*	*
		0.8**	L-Linear R	ange-H	18.4		
Reference	Ranges*						
	Age		Male		Fe	emale	
	0 Year		0.0 - 0.0	0	0.0	0.0 - 0.0	
	0 Year		0.0 - 0.0	0	0.0 - 0.0		
	0 Year		0.0 - 0.0	0	0.0	0.0 - 0.0	
	U Teal		0.0 - 0.0	0	0.0	0.0 - 0.0	
Qualitative	Ranges	N/A			-		

	Assay Configuration: Base Page										
Reaction Mode END UP		Wavelength-Pr 572 / 66		Read Time- 14 – 16		AbsMaxVar 0.0					
Sample Blank	c Test	Blank Read	Time	Abs Wi	ndow	Abs Limits					
(_)	0 - 0		0 –	0.0 - 0.0						
	S.Vol	DS.Vol	D.Vol	W.Vol							
Standard	4.0	0.0	0	0		Rgt Name/Pos					
Dil 1	4.0	0.0	0	0	Diluent	*					
Dil 2	4.0	0.0	0	0	Type#***	0					
	Rgt N	lame/Pos	R.Vol	W.Vol	Type#***						
Reagent 1	TP00	061 –*	200	0	0						
Reaction Ch	eck	Read Time-	-A/B	Ran	ge	Minimum					
	_	1 – 1 / 1 –	· 1	0.0 -	0.0	0.0					
Factor/Interc	ept	Decimal F	Places	Units							
1.0 / 0.0		1		g/dL							

	Assa	y Config	guration: C	alibratio	n Page					
	Mode			Interval (H)						
Linear	ſ					552				
Blank	/Calib Replicates	Extra	apolation%	Span	Spa	n Abs Range				
3/3		0		BLK –	νV	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				
			0			FAC Limit (%)*** 10				

	Assay	Configura	ation: SmartWash Page
Rgt Probe			
•	Reagent	Wash	Vol
	_	_	_
Cuvette			
	Assay Name	Wash	Vol
	_	_	_
Sample Pro	be		
•	Wash		
	_		

Total Protein Serum/Plasma—SI Units

		Assay C	onfiguratio	n: Outli	ne Page		
Assay Nam	е	Assa 14		Line B-Line			
Quantitative	Ranges						
Min Text *	Min 0.0*	Panic-L 0.0	L-Refere 64	nce-H 83	Panic-H 0.0	Max 0.0*	Max Text
		8**	L-Linear Ra	nge-H	184		
Reference F	Ranges*						
	Age		Male		Fe	emale	
	0 Year 0 Year 0 Year		0.0 - 0.0 0.0 - 0.0 0.0 - 0.0 0.0 - 0.0		0.0	0 - 0.0 0 - 0.0 0 - 0.0 0 - 0.0	
Qualitative	Ranges	N/A			1		

		Assay Conf	iguration	ı: Base Paç	je	
Reaction Mode		Wavelength-Pri		Read Time-		AbsMaxVar
END UP		572 / 660		14 – 16	0 – 0	0.0
Sample Blank T	est	Blank Read T	ime	Abs Wi	ndow	Abs Limits
(.)	0-0		0 –	0	0.0 - 0.0
	S.Vol	DS.Vol	D.Vol	W.Vol		
Standard	4.0	0.0	0	0		Rgt Name/Pos
Dil 1	4.0	0.0	0	0	Diluent	*
Dil 2	4.0	0.0	0	0	Type#***	0
	Rgt N	lame/Pos	R.Vol	W.Vol	Type#***	_
Reagent 1	TP00	0061 –*	200	0	0	
Reaction Chec	k	Read Time-	A/B	Ran	ge	Minimum
	-	1 – 1 / 1 –	1	0.0 -	0.0	0.0
Factor/Intercep	ot	Decimal P	laces	Units		
1.0 / 0.0		0		g/L		
l						

	Assa	y Config	guration: C	alibratio	n Page	
Calib	Mode					Interval (H)
Linear						552
Blank	/Calib Replicates	Extr	apolation%	Spar	n Spa	an 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 (Configura	ation: SmartWash Page
Rgt Probe			
•	Reagent	Wash	Vol
	_	_	_
Cuvette			
	Assay Name	Wash	Vol
	_	_	_
Sample Pro	be		
•	Wash		
	_		

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

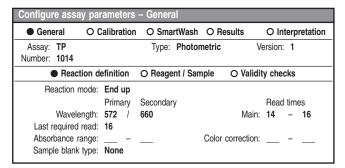
- User defined or instrument defined.
- ** The linear low value (L-Linear Range) is LOQ rounded up to the number of decimal places defined in the decimal places parameter field.

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

ARCHITECT c8000 SYSTEM ASSAY PARAMETERS

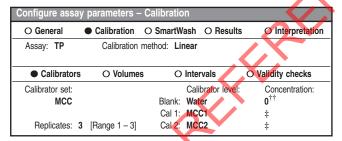
c8000

Total Protein Serum/Plasma—Conventional and SI Units



O Rea	ction def	inition 🗶 🛭	Reagent / Sa	mple (O Validity checks	
					R1	
Reagent: T	P000		R	eagent volu	ıme: 200	
Diluent: S	aline			Water volu	ıme:	
Diluent dispense	mode: 1	Гуре 0		ispense m	ode: Type 0	
Dilution name	Sample	Diluted sample	Diluent	Water	Dilution factor	Default dilution
STANDARD:	4.0			=	1:1.00	•
:				=	:	0
:				=	:	0

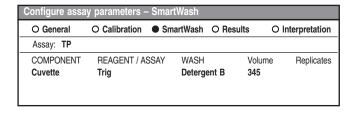
O Reaction definition	O Reagent / Sample	Validity checks
Reaction check: None		
Maxir	num absorbance variation:	



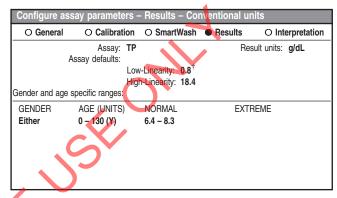
ı							
I	O Calibrators	Volumes	O Interval	s	O Validity	checks	
I	Calibrator: MCC	Calibrator level	Sample	Diluted sample	Diluent	Water	
I		slank: Water	4.0				
I		Cal 1: MCC1 Cal 2: MCC2	4.0 4.0	_	_		
ı	(Jai Z. WICCZ	4.0				

	O Calibrators	O Volumes	Interv	/als	O Validity checks
	Calib	ration intervals:			
ı		Full interval:	552 (hour	rs)	
ı	C	Calibration type:			
		Adjust type:	None		
	O Calibrators	O Volumes	O Interv	vals	 Validity checks

O Calibrators	O Volumes	01	nte	rvals	Validity checks
Blank	absorbance range:		-	Water	
Spar	absorbance range:	Blank		water	
	Expected cal factor:				
Expected ca	factor tolerance %:	0			



Total Protein Serum/Plasma—Conventional Units



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

Total Protein Serum/Plasma—SI Units

Assay: TP Assay defaults: Low-Linearity: 8 [†]	Resu	It units: g/L
,		
High-Linearity: 184		
Gender and age specific ranges:		
GENDER AGE (UNITS) NORMAL	EXTRE	ME
Either 0 – 130 (Y) 64 – 83		

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

- † 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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