Abbott
CLINICAL CHEMISTRY

TOTAL PROTEIN
List No. 7D73-20
30-3073/R2

AEROSET® / *c*8000™

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

EC REP	Authorized Representative		Consult instructions for use
IVD	For in vitro diagnostic use	CE MANUFACTURING SITE ADDRESS	Legal Manufacturer
LOT	Batch code/Lot number	°C	Temperature limitation
R1	Reagent 1		Use by/Expiration date
REF	Catalog number/List number		
SN	Serial number		

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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 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 2[2] 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

Serum[6]

	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

AEROSET / c8000

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 Substances[10]

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.

Precision

The results from precision studies for serum using NCCLS protocol EP5-T2[12] are found below.

Serum

Control	N	Mean (g/dL)	Within Run SD	Within Run %CV	Between Run SD	Between Run %CV	Between Day SD	Between Day %CV	Total SD	Total %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-A[14] are found below.

Control	N	Mean (g/dL)	Within Run SD	Within Run %CV	Between Run SD	Between Run %CV	Between Day SD	Between Day %CV	Total SD	Total %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
	0.0 – 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

	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 Name/Pos	R.Vol	W.Vol	Type#***
Reagent 1	TP00061 – ___*	200	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: 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
	—

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
	0.0 – 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

	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 Name/Pos	R.Vol	W.Vol	Type#***
Reagent 1	TP00061 – ___*	200	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: 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

c8000

Total Protein Serum/Plasma—Conventional and SI Units

Configure assay parameters – General

● General ○ Calibration ○ SmartWash ○ Results ○ Interpretation

Assay: **TP** Type: **Photometric** Version: **1**
Number: **1014**

● Reaction definition ○ Reagent / Sample ○ Validity checks

Reaction mode: **End up**

	Primary	Secondary	Read times
Wavelength:	**572** /	**660**	Main: **14** – **16**

Last required read: **16**
Absorbance range: ___ – ___ Color correction: ___ – ___
Sample blank type: **None**

○ Reaction definition ● Reagent / Sample ○ Validity checks

				R1		
Reagent:	**TP000**		Reagent volume:	**200**		
Diluent:	**Saline**		Water volume:	___		
Diluent dispense mode:	**Type 0**		Dispense mode:	**Type 0**		

Dilution name	Sample	Diluted sample	Diluent	Water	Dilution factor	Default dilution
STANDARD	: **4.0**	___	___	___ =	**1:1.00**	●
_____	: ___	___	___	___ =		○
_____	: ___	___	___	___ =		○

○ Reaction definition ○ Reagent / Sample ● Validity checks

Reaction check: **None**

Maximum absorbance variation: ___

Configure assay parameters – Calibration

○ General ● Calibration ○ SmartWash ○ Results ○ Interpretation

Assay: **TP** Calibration method: **Linear**

● Calibrators ○ Volumes ○ Intervals ○ Validity checks

Calibrator set: **MCC**

Calibrator level:	Concentration:
Blank: **Water**	**0**††
Cal 1: **MCC1**	‡
Cal 2: **MCC2**	‡

Replicates: **3** [Range 1 – 3]

○ Calibrators ● Volumes ○ Intervals ○ Validity checks

Calibrator: **MCC**

Calibrator level	Sample	Diluted sample	Diluent	Water
Blank: **Water**	**4.0**	___	___	___
Cal 1: **MCC1**	**4.0**	___	___	___
Cal 2: **MCC2**	**4.0**	___	___	___

○ Calibrators ○ Volumes ● Intervals ○ Validity checks

Calibration intervals:
Full interval: **552** (hours)
Calibration type:
Adjust type: **None**

○ Calibrators ○ Volumes ○ Intervals ● 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

○ General ○ Calibration ● SmartWash ○ Results ○ 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

○ General ○ Calibration ○ SmartWash ● Results ○ 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

○ General ○ Calibration ○ SmartWash ● Results ○ 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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TRADEMARKS