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Alinity c Total Protein2

INTENDED USE

- The Total Protein2 assay is used for the quantitation of total protein in human serum or plasma on the Alinity c system.
- The Total Protein2 assay is to be used as an aid in the diagnosis and treatment of a variety of diseases involving the liver, kidney, or bone marrow as well as other metabolic or nutritional disorders.

SUMMARY AND EXPLANATION OF THE TEST

- Total protein is divided into two fractions: albumin (A) and globulins (G). While albumin accounts for 70% of the colloid-osmotic pressure and transports small molecules in blood, globulins majorly comprise of immune defense, enzymes, specific transport proteins, hormones, and others.*1* The A/G ratio has commonly been used as an index of the distribution between the albumin and globulin fractions.
- Measurements of total protein are used in the diagnosis and treatment of a variety of diseases involving liver, kidney, lymph nodes, spleen, or bone marrow. High protein levels 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. Low protein levels 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).
- High or low total protein may lead one to suspect pathologic variation of individual proteins and may indicate additional testing including serum protein electrophoresis, hematocrit, electrolytes, testing for specific proteins and other organ or disease specific markers.*2*

PRINCIPLES OF THE PROCEDURE

- The Total Protein2 assay is an automated clinical chemistry assay.
- Polypeptides containing at least two peptide bonds react with the biuret reagent. In an alkaline solution, the cupric ion forms a coordination complex with protein-nitrogen with very little difference between albumin and globulin on a protein-nitrogen basis.

Methodology: Biuret

- For additional information on system and assay technology, refer to the Alinity ci-series Operations Manual, Section 3.

REAGENTS

Kit Contents

Total Protein2 Reagent Kit 04T81

NOTE: Some kit sizes may not be available. Please contact your local distributor.

Volumes (mL) listed in the following table indicate the volume per cartridge.

REF	**04T8120**	**04T8130**
Tests per cartridge	200	780
Number of cartridges per kit	4	4
Tests per kit	800	3120
R1	20.7 mL	67.5 mL
R1- Active ingredient: copper (II) sulfate pentahydrate (6.600 g/L).		

Warnings and Precautions

- For *In Vitro* Diagnostic Use

Safety Precautions

- **CAUTION:** This product requires the handling of human specimens. It is recommended that all human-sourced materials and all consumables contaminated with potentially infectious materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate regional, national, and institutional biosafety practices should be used for materials that contain, are suspected of containing, or are contaminated with infectious agents.*3, 4, 5, 6*
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The following warnings and precautions apply to:	
DANGER	Contains sodium hydroxide and copper (II) sulfate pentahydrate.

H314	Causes severe skin burns and eye damage.
H401*	Toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.
H290	May be corrosive to metals.
Prevention	
P260	Do not breathe mist / vapors / spray.
P264	Wash hands thoroughly after handling.
P280	Wear protective gloves / protective clothing / eye protection.
P234	Keep only in original container.
P273	Avoid release to the environment.
Response	
P301+P330+P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water / shower.
P310	Immediately call a POISON CENTER or doctor / physician.
P390	Absorb spillage to prevent material damage.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

* Not applicable where regulation EC 1272/2008 (CLP) has been implemented.
Follow local chemical disposal regulations based on your location along with recommendations and content in the Safety Data Sheet to determine the safe disposal of this product.
For the most current hazard information, see the product Safety Data Sheet.
Safety Data Sheets are available at www.corelaboratory.abbott or contact your local representative.
For a detailed discussion of safety precautions during system operation, refer to the Alinity ci-series Operations Manual, Section 8.

Reagent Handling

- Upon receipt, place reagent cartridges in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- If a reagent cartridge is dropped, place in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- Reagents are susceptible to the formation of foam and bubbles. Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may adversely affect results.
  For a detailed discussion of reagent handling precautions during system operation, refer to the

Alinity ci-series Operations Manual, Section 7.

Reagent Storage

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	15 to 30°C	Until expiration date	Store in upright position.
Onboard	System Temperature	30 days	
Opened	15 to 30°C	Until expiration date	Store in upright position. Do not reuse original reagent caps or replacement caps due to the risk of contamination and the potential to compromise reagent performance.

- Reagents may be stored on or off the system. If removed from the system, store reagents with new replacement caps in an upright position at 15 to 30°C. For reagents stored off the system, it is recommended that they be stored in their original trays or boxes to ensure they remain upright.
  For information on unloading reagents, refer to the Alinity ci-series Operations Manual, Section 5.

Indications of Reagent Deterioration

- Deterioration of the reagents may be indicated when a calibration error occurs or a control value is out of the specified range. Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary.
  For troubleshooting information, refer to the Alinity ci-series Operations Manual, Section 10.

INSTRUMENT PROCEDURE

- The Total Protein2 assay file must be installed on the Alinity c system prior to performing the assay.
  For detailed information on assay file installation and viewing and editing assay parameters, refer to the Alinity ci-series Operations Manual, Section 2.
  For information on printing assay parameters, refer to the Alinity ci-series Operations Manual, Section 5.
  For a detailed description of system procedures, refer to the Alinity ci-series Operations Manual.

Alternate Result Units

- Edit assay parameter "Result Units" to select an alternate unit.
  Conversion formula:
  (Concentration in Default result unit) x (Conversion factor) =
  (Concentration in Alternate result unit)

Default Result Unit	Conversion Factor	Alternate Result Unit
g/dL	10	g/L

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

- The specimen types listed below were verified for use with this assay.
  Other specimen types and collection tube types have not been verified with this assay.

Specimen Types	Collection Tubes
Serum	Serum Serum separator
Plasma	Dipotassium EDTA Lithium heparin Lithium heparin separator Sodium heparin

- Due to the presence of fibrinogen protein, the values obtained for a plasma sample are generally higher than for serum.[7] Therefore, values obtained using both tube types cannot be used interchangeably. Refer to the EXPECTED VALUES section of this package insert for additional information.
- Liquid anticoagulants may have a dilution effect resulting in lower concentration values for individual specimens.
- The instrument does not provide the capability to verify specimen types. It is the responsibility of the operator to verify that the correct specimen types are used in the assay.

Specimen Conditions

- Do not use:
  - heat-inactivated specimens
  - pooled specimens
  - grossly hemolyzed specimens
  - specimens with obvious microbial contamination
  - specimens with fungal growth
- For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.
- To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.

Preparation for Analysis

- Follow the tube manufacturer's processing instructions for collection tubes. Gravity separation is not sufficient for specimen preparation.
- Specimens should be free of bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.
- To ensure consistency in results, recentrifuge specimens prior to testing if
    - they contain fibrin, red blood cells, or other particulate matter.
    - NOTE: If fibrin, red blood cells, or other particulate matter are observed, mix by low speed vortex or by inverting 10 times prior to recentrifugation.
- Prepare frozen specimens as follows:
    - Frozen specimens must be completely thawed before mixing.
    - Mix thawed specimens thoroughly by low speed vortex or by inverting 10 times.
    - Visually inspect the specimens. If layering or stratification is observed, mix until specimens are visibly homogeneous.
    - If specimens are not mixed thoroughly, inconsistent results may be obtained.
    - Recentrifuge specimens.
- Recentrifugation of Specimens
    - Transfer specimens to a centrifuge tube and centrifuge.
    - Transfer clarified specimen to a sample cup or secondary tube for testing. For centrifuged specimens with a lipid layer, transfer only the clarified specimen and not the lipemic material.

Specimen Storage

Specimen Type	Temperature	Maximum Storage Time
Serum/Plasma	Room temperature (20 to 25°C)	7 days[8]
	2 to 8°C	7 days[8]
	-20°C	3 months[9]
- Avoid multiple freeze/thaw cycles.[9]
- It is the responsibility of the individual laboratory to determine specific specimen stability criteria for their laboratory per their laboratory workflow.
- For additional information on sample handling and processing, refer to CLSI GP44-A4.[10] The storage information provided here is based on references or data maintained by the manufacturer.
- Each laboratory may establish a range around -20°C from either the freezer

manufacturer's specifications or your laboratory standard operating procedure(s) for specimen storage.

- Stored specimens must be inspected for particulates. If present, mix with a low speed vortex or by inversion and centrifuge the specimen to remove particulates prior to testing..

PROCEDURE

Materials Provided

- 04T81 Total Protein2 Reagent Kit

Materials Required but not Provided

- Total Protein2 assay file
- 04V6201 Consolidated Chemistry Calibrator
- Controls containing total protein
  For information on materials required for operation of the instrument, refer to the Alinity ci-series Operations Manual, Section 1.
  For information on materials required for maintenance procedures, refer to the Alinity ci-series Operations Manual, Section 9.

Assay Procedure

- For a detailed description of how to run an assay, refer to the Alinity ci-series Operations Manual, Section 5.
- If using primary or aliquot tubes, refer to the Alinity ci-series Operations Manual, Section 4 to ensure sufficient specimen is present.
- Minimum sample cup volume is calculated by the system and printed on the Order List report. To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.
  Minimum sample volume requirements:
- Sample volume for single test: 3.2 µL.
  NOTE: This amount does not include the dead volume plus the additional over-aspiration volume. For total sample volume requirements, refer to the Alinity ci-series Operations Manual, Section 4.
- Refer to the Consolidated Chemistry Calibrator package insert 04V6201 and/or commercially available control material package insert for preparation and usage.
- For general operating procedures, refer to the Alinity ci-series Operations Manual, Section 5.
- For optimal performance, it is important to perform routine maintenance as described in the Alinity ci-series Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

Sample Dilution Procedures

- Sample dilutions have not been evaluated for the Total Protein2 assay. Samples with a total protein value exceeding 17.2 g/dL (172 g/L) are flagged with the code "> 17.2 g/dL"
("> 172 g/L"). The standard dilution factor for the Total Protein2 assay is 1:2.57.
For details on configuring automated dilutions, refer to the Alinity ci-series Operations Manual, Section 2.

Calibration

- For instructions on performing a calibration, refer to the Alinity ci-series Operations Manual, Section 5.
Calibration is stable for approximately 30 days (720 hours), but is required with each change in reagent lot. Verify calibration with at least 2 levels of controls according to the established quality control requirements for your laboratory. If control results fall outside acceptable ranges, recalibration may be necessary.
This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

Quality Control Procedures

- At least 2 levels of controls (low and high) are to be run every 24 hours.
- If quality control results do not meet the acceptance criteria defined by your laboratory, sample results may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary. For troubleshooting information, refer to the Alinity ci-series Operations Manual, Section 10.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.
- Controls should be used according to the guidelines and recommendations of the control manufacturer. Concentration ranges provided in the control package insert should be used only for guidance.
- For any control material in use, the laboratory should ensure that the matrix of the control material is suitable for use in the assay per the assay package insert.

RESULTS

Calculation

- The Total Protein2 assay utilizes the Linear data reduction method to generate a calibration and results.

Flags

- Some results may contain information in the Flags field. For a description of the flags

that may appear in this field, refer to the Alinity ci-series Operations Manual, Section 5.

Reportable Interval

- Based on representative data for the limit of quantitation (LoQ) and the limit of detection (LoD), the ranges over which results can be reported are provided below according to the definitions from CLSI EP34, 1st ed.[12]
-

	g/dL	g/L
Analytical Measuring Interval (AMI)[a]	0.2 - 17.2	2 - 172
Reportable Interval[b]	0.2 - 17.2	2 - 172

[a] AMI: The AMI extends from the LoQ to the upper limit of quantitation (ULoQ). This is determined by the range of values in g/dL (g/L) that demonstrated acceptable performance for linearity, imprecision, and bias.

[b]The reportable interval extends from the LoD to the upper limit of the AMI.
NOTE: The default Low Linearity value of the assay file corresponds to the lower limit of the analytical measuring interval.

LIMITATIONS OF THE PROCEDURE

- Results should be used in conjunction with other data; e.g., symptoms, results of other tests, and clinical impressions.
- Substances that demonstrated interference with the Total Protein2 assay are listed in the SPECIFIC PERFORMANCE CHARACTERISTICS, Analytical Specificity, Interference section of this package insert.
- Potential interference has not been evaluated for substances other than those described in the SPECIFIC PERFORMANCE CHARACTERISTICS, Analytical Specificity, Interference section of this package insert.
- In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.[13]
- The Total Protein2 assay is susceptible to positive interference effects from dextran in the therapeutic concentration range.[14]

EXPECTED VALUES

Refer to **LABADM1.8- Reference Ranges, Critical Values, and Units of Measure** policy

Plasma values are generally 0.3 to 0.5 g/dL (3 to 5 g/L) higher than serum values due to the presence of fibrinogen. This difference has been shown to vary among specific populations.

SPECIFIC PERFORMANCE CHARACTERISTICS

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

The Alinity c system and the ARCHITECT c System utilize the same reagents and sample/reagent ratios.

Unless otherwise specified, all studies were performed on the Alinity c system.

Precision

Within-Laboratory Precision

A study was performed based on guidance from CLSI EP05-A3.16 Testing was conducted using 3 lots of the Total Protein2 reagent, 3 lots of the Consolidated Chemistry Calibrator, 1 lot of commercially available controls, and 1 instrument. Two controls and 3 human serum panels were tested in duplicate, twice per day on 20 days on 3 reagent lot/calibrator lot/instrument combinations, where a unique reagent lot and a unique calibrator lot is paired with 1 instrument. The performance from a representative combination is shown in the following table.

Sample	n	Mean (g/dL)	Within-Run (Repeatability)		Within-Laboratory[a]	
			SD	%CV	SD (Range[b])	%CV (Range[b])
Control Level 1	82	6.5	0.05	0.7	0.08 (0.06 - 0.08)	1.2 (1.0 - 1.2)
Control Level 2	82	4.1	0.04	0.9	0.06 (0.05 - 0.06)	1.4 (1.3 - 1.4)
Panel A	82	0.8	0.00	0.0	0.00 (0.00 - 0.03)	0.0 (0.0 - 3.6)
Panel B	82	9.0	0.04	0.5	0.07 (0.07 - 0.09)	0.8 (0.8 - 1.1)
Panel C	82	16.7	0.18	1.1	0.18 (0.18 - 0.22)	1.1 (1.1 - 1.4)

[a] Includes within-run, between-run, and between-day variability.

[b] Minimum and maximum SD or %CV across all reagent lot and instrument combinations.

Sample	n	Mean (g/L)	Within-Run (Repeatability)		Within-Laboratory[a]	
			SD	%CV	SD (Range[b])	%CV (Range[b])
Control Level 1	82	65	0.5	0.7	0.8 (0.6 - 0.8)	1.2 (1.0 - 1.2)
Control Level 2	82	41	0.4	0.9	0.6 (0.5 - 0.6)	1.4 (1.3 - 1.4)
Panel A	82	8	0.0	0.0	0.0 (0.0 - 0.3)	0.0 (0.0 - 3.6)

Panel B	82	90	0.4	0.5	0.7 (0.7 - 0.9)	0.8 (0.8 - 1.1)
Panel C	82	167	1.8	1.1	1.8 (1.8 - 2.2)	1.1 (1.1 - 1.4)

[a] Includes within-run, between-run, and between-day variability.

[b] Minimum and maximum SD or %CV across all reagent lot and instrument combinations.

Accuracy

A study was performed to estimate the bias of the Total Protein2 assay relative to standard reference material (NIST SRM 927e). Testing was conducted using 1 lot of the Total Protein2 reagent, 1 lot of the Consolidated Chemistry Calibrator, and 1 instrument. The bias was -1.6%.

Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2.*17* Testing was conducted using 3 lots of the Total Protein2 reagent kit on each of 2 instruments over a minimum of 3 days. The maximum observed limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ) values are summarized below.

	g/dL	**g/L**
LoB[a]	0.0	0
LoD[b]	0.2	2
LoQ[c]	0.2	2

[a]The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.

[b]The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 60 replicates of low-analyte level samples.

[c] The LoQ is defined as the lowest concentration at which a maximum allowable precision of

20 %CV was met and was determined from n ≥ 60 replicates of low-analyte level samples.

Linearity

A study was performed based on guidance from CLSI EP06-A.*18*

This assay is linear across the analytical measuring interval of 0.2 to 17.2 g/dL (2 to 172 g/L).

Analytical Specificity

Interference

This study was performed on the ARCHITECT c System.

Potentially Interfering Endogenous Substances

A study was performed based on guidance from CLSI EP07-A2.*19* Each substance was tested at 2 levels of the analyte (approximately 6 g/dL and 8 g/dL). No significant interference (interference within ± 10%) was observed at the following concentrations.

Potentially Interfering Substance	Interferent Level	
	Default Units	Alternate Units
Bilirubin - conjugated	30 mg/dL	355.8 µmol/L
Bilirubin - unconjugated	30 mg/dL	513.0 µmol/L
Hemoglobin	150 mg/dL	1.50 g/L
Paraprotein (IgM lambda)[a]	0.3 g/dL	3.00 g/L
Triglycerides	3000 mg/dL	33.9 mmol/L

Interference beyond ± 10% [based on 95% confidence interval (CI)] was observed at the concentrations shown below for the following substances.

Potentially Interfering Substance	Interferent Level		Analyte Level		% Interference (95% CI)
	Default Units	Alternate Units	Default Units	Alternate Units	
Hemoglobin	300 mg/dL	3.00 g/L	6 g/dL	60 g/L	12% (12%, 13%)
Paraprotein (IgM lambda)[a]	1 g/dL	10.0 g/L	6 g/dL	60 g/L	37% (37%, 38%)
Paraprotein (IgM lambda)[a]	1 g/dL	10.0 g/L	8 g/dL	80 g/L	34% (33%, 34%)

[a] Interference was evaluated against expected total protein result which included the added paraprotein.

Potentially Interfering Exogenous Substances

A study was performed based on guidance from CLSI EP07-A2.*19* Each substance was tested at 2 levels of the analyte (approximately 6 g/dL and 8 g/dL). No significant interference (interference within ± 10%) was observed at the following concentrations.

Potentially Interfering Substance	Interferent Level	
	Default Units	Alternate Units
Acetaminophen	250 mg/L	1655 µmol/L
Acetylcysteine	1663 mg/L	10 194 µmol/L
Acetylsalicylic acid	1000 mg/L	5550 µmol/L
Amino acids	117 µmol Cys/L	N/A
Ammonium hydroxide	107 µmol Nitrogen/L	N/A
Ampicillin-Na	1000 mg/L	2692.6 µmol/L
Ascorbic acid	300 mg/L	1704 µmol/L
Azlocillin	5 g/L	10.8 mmol/L
Calcium dobesilate	200 mg/L	478.0 µmol/L
Carbenicillin	300 mg/dL	7929 µmol/L
Cefotaxime	31 mg/dL	682.0 µmol/L
Cefoxitin	2500 mg/L	5850 µmol/L
Chloramphenicol	500 mg/L	1545 µmol/L
Cyclosporine	5 mg/L	4.16 µmol/L
Desacetylcefotaxime	6 mg/dL	145.1 µmol/L
Dextran	2 g/L	50.0 µmol/L
Doxorubicin	70 mg/L	128.9 µmol/L
Doxycycline	50 mg/L	112.5 µmol/L
Ibuprofen	500 mg/L	2425 µmol/L
Levodopa	20 mg/L	101.4 µmol/L
Methyldopa	20 mg/L	94.6 µmol/L
Metronidazole	200 mg/L	1168 µmol/L
Penicillin G	500 mg/L	1497 µmol/L
Phenobarbital	10 mg/dL	431.0 µmol/L
Phenylbutazone	400 mg/L	1296 µmol/L
Primidone	4 mg/dL	183.2 µmol/L
Rifampicin	60 mg/L	73.2 µmol/L
Sodium heparin	10 U/mL	N/A
Sulfasalazine	30 mg/dL	753.0 µmol/L
Theophylline (1,3-dimethylxanthine)	100 mg/L	555.0 µmol/L
Valproic Acid	50 mg/dL	3465 µmol/L

N/A = Not applicable Interference beyond ± 10% [based on 95% confidence interval (CI)] was observed at the concentrations shown below for the following substances.

Potentially Interfering Substance	Interferent Level		Analyte Level		% Interference (95% CI)
	Default Units	Alternate Units	Default Units	Alternate Units	
Azlocillin	6 g/L	13.0 mmol/L	6 g/dL	60 g/L	11% (10%, 12%)
Dextran	7.5 g/L	187.5 µmol/L	6 g/dL	60 g/L	30% (29%, 30%)
Dextran	7.5 g/L	187.5 µmol/L	8 g/dL	80 g/L	25% (24%, 25%)
Doxorubicin	105 mg/L	193.4 µmol/L	6 g/dL	60 g/L	15% (14%, 15%)
Doxorubicin	105 mg/L	193.4 µmol/L	8 g/dL	80 g/L	11% (11%, 12%)

Interferences from medication or endogenous substances may affect results.*20*

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Key to Symbols

For interpretation of the symbols found in this SOP, refer to the PolicyStat procedure: "Abbott Alinity Key to Symbols SOP".

Attachments

TProtein2_PkgIns

Approval Signatures

Step Description	Approver	Date
Chemistry Lab Director	Adina Badea: Director of Toxicology	06/2025
	Kimberly Paiva: Mgr Satellite Laboratories	06/2025

Applicability

Newport Hospital, Rhode Island Hospital/Hasbro Children's, The Miriam Hospital