

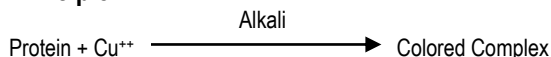
Intended Use

For the quantitative determination of total protein concentration in serum using the Yumizen C560 analyzer. **Rx Only.**

Method History

The color reaction of protein molecules with cupric ions, known as the Biuret color reaction, has been known since 1878. Since the Riegler¹ publications of 1914, several attempts have been made to stabilize the cupric ions in the alkaline reagent. Kingsley,^{2,3} modified the procedure in 1939 and 1942 to include the use of sodium potassium tartrate as a complexing agent. This procedure was later modified by Weichselbaum⁴ and Gornall.⁵ The present method is based on these modifications.

Principle



Protein in serum forms a violet colored complex when reacted with cupric ions in an alkaline solution. The intensity of the violet color is proportional to the amount of protein present when compared to a solution with known protein concentration.

Reagent Content

Sodium Hydroxide 600mM, Copper Sulfate 12mM, Sodium Potassium Tartrate 32mM, Potassium Iodide 30mM, Non-reactive ingredients.

Precautions and Hazards

1. This reagent is for *in vitro* diagnostic use only.
2. Avoid ingestion. DO NOT PIPETTE BY MOUTH. In case of ingestion drink large amounts of water and seek medical attention quickly.
3. Avoid contact with skin and eyes. The reagent contains sodium hydroxide which is corrosive. In case of contact with skin, flush with water. For eyes, seek medical attention.

Hazards:

Hazard Classifications: Skin Corrosion/Irritation (Category 1), Serious eye damage/eye irritation (Category 1)

Hazard Statements: H314: Causes severe skin burns and eye damage, H318 : Causes serious eye irritation

Precautionary Statements: **Prevention:** P260: Do not breathe dust/fume/gas/mist/vapors/spray. P264: Wash skin thoroughly after handling. P280: Wear protective gloves/protective clothing/eye protection/face protection. **Response:** P310: Immediately call a POISON CENTER or doctor/physician. P363: Wash contaminated clothing before reuse. P301+P330+P331 : If SWALLOWED : Rinse mouth. Do NOT induce vomiting. P303+P361+P353 : IF ON SKIN (or hair) : Remove/Take off immediately all contaminated clothing. Rinse SKIN with water/shower. P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. **Storage:** P404 : Store in a closed container. **Disposal:** P501 : Dispose of contents into sewer system after diluting with large volumes of water, if in accordance with local regulations. **Refer to the Safety Data Sheet for this product (SDS-T7528) available by calling 1-734-487-8300.**



Signal Word: Danger

Reagent Preparation

Reagent comes in a ready to use form.

Reagent Storage and Stability

Store reagent at room temperature (15-30°C). The reagent is stable until the expiration date appearing on the label when stored as directed. Manufacturer studies have shown reagent is stable for 30 days once placed in the refrigerated reagent carousel (2-10°C).

Reagent Deterioration

The reagent should be a clear, pale blue solution. Turbidity or the presence of a black precipitate indicates reagent deterioration and should not be used.

Specimen Collection and Storage

1. Unhemolyzed serum is the specimen of choice.
2. Gross hemolysis will cause elevated results because of the released hemoglobin as well as the increase in background color.
3. Lipemic sera cause elevated results. A serum Blank should be performed.
4. Samples with bromosulphophthalein (BSP) will result in falsely elevated results.⁸
5. Protein in serum is stable for one week at room temperature (18-25°C) and for at least one month refrigerated (2-8°C) when guarded against evaporation.⁶

Interferences

Young, et al.⁷ has reviewed a number of drugs and substances that may affect protein concentrations.

Materials Provided

Total Protein reagent

Pointe Total Protein (Biuret) Reagent Set

Materials Required but not Provided

1. Yumizen C560 Analyzer
2. Yumizen C560 operation manual
3. Chemistry Calibrator, catalog number C7506-50
4. Chemistry control, catalog number C7592-100

Calibration

Use an NIST-traceable serum calibrator. The procedure should be calibrated according to the instrument manufacturer's calibration instructions. If control results are found to be out of range, the test may need to be re-calibrated. Under typical operating conditions manufacturer calibration stability studies have shown the calibration curve will be stable for at least 14 days.

Quality Control

1. Use control sera with known total protein concentrations to monitor the integrity of the reaction.
2. Quality control requirements should be performed in conformance with local, state, and/or Federal regulations or accreditation requirements.

Limitations

1. Samples with values above 15.0 g/dl should be diluted 1:1 with 0.9% saline, re-run and result multiplied by two.
2. The Biuret procedure is not sensitive at low ranges (<1 g/dl). Do not use for urine or spinal fluid.

Expected Values⁸

6.2 – 8.5 g/dl

1. The effect of posture, when blood is drawn, varies with the individual but recumbent values are usually lower than ambulatory. Differences may be as much as 1.2 g/dl.
2. It is strongly recommended that each laboratory establish its own range.

Performance

1. Assay Range: 1.0 – 15.0 g/dL
2. Correlation: A study was performed between the Yumizen C560 and a similar analyzer using this method, resulting in the following:

Method	Total Protein
N	84
Mean Total Protein (g/dL)	7.11
Range (g/dL)	3.7-9.6
Standard Deviation	1.36
Regression Analysis	$y = 0.937x + 0.11$
Correlation Coefficient	0.9969

3. Precision: Precision studies were performed using the Yumizen C560 analyzer following a modification of the guidelines which are contained in NCCLS document EP5-T2.⁹

Sample	Within Day			Total		
	LOW	MID	HIGH	LOW	MID	HIGH
N	20	20	20	40	40	40
Mean	3.40	6.99	11.51	3.40	6.95	11.64
Standard Deviation	0.00	0.03	0.03	0.12	0.12	0.23
Coefficient of Variation (%)	0.0%	0.4%	0.3%	3.5%	1.7%	2.0%

4. Sensitivity: 2SD limit of detection (95% Conf) = 0.0 g/dL

References

1. Riegler, E., Anal. Chem. 53:242 (1914).
2. Kingsley, G.R., J. Biol. Chem. 131:197 (1939).
3. Kingsley, G.R., J. Lab. Clin. Med. 27:840 (1942).
4. Weichselbaum, T., Amer. J. Clin. Path. 16:40 (1946).
5. Gornall, A., et al, J. Biol. Chem. 177:752 (1949).
6. Henry, R.J., et al, Clinical Chemistry: Principles and Technics, Harper & Row, New York, p.415 (1974).
7. Young, D.S., et al, Clin. Chem. 21:1D (1975).
8. Tietz, N.W., Fundamentals of Clinical Chemistry Philadelphia, W.B. Saunders, pp. 299, (1976).
9. NCCLS document "Evaluation of Precision Performance of Clinical Chemistry Devices", 2nd Ed. (1992).

CHEMISTRY PARAMETERS

Chem:	TP	No.:	229	Sample Type:	Serum
Chemistry:	Total Protein			Print Name:	TP
Reaction Type:	End Point			Reaction Direction:	Positive
Pri Wave:	546			Sec Wave:	660
Unit:	g/dL			Decimal:	0.1
Blank Time:	10 12			Reaction Time:	33 35
	Sample Vol.	Aspirated	Diluent	Reagent Vol.	Diluent
Standard:	2.7 ul	-- ul	-- ul	R1: 120 ul	-- ul
Decreased:	-- ul	-- ul	-- ul	R2: -- ul	-- ul
Increased:	-- ul	-- ul	-- ul	R3: -- ul	-- ul
	<input type="checkbox"/> Sample Blank	<input checked="" type="checkbox"/> Auto Rerun		R4: -- ul	-- ul
<u>Slope/Offset Adjustment</u>					
	Slope: 1	Offset: 0			

Linearity Range (Standard)	1	15	Linearity Limit:
Linearity Range (Decreased)	---	---	Substrate Depletion:
Linearity Range (Increased)	---	---	Mixed Blank Abs:
R1 Blank Abs:	---	---	Uncapping Time
Blank Response:	---	---	Reagent Alarm Limit:
Twin Chemistry:			<input type="checkbox"/> Enzyme Linear Extension
<input type="checkbox"/> Prozone Check		<input type="radio"/> Rate Check	<input type="radio"/> Antigen Addition
Q1:	Q2:	Q3:	Q4:
PC:	ABS:		

Pointe Total Protein (Biuret) Reagent Set

CALIBRATION PARAMETERS

Calibrator Definition						
Calibrator:	*	Lot No.:	*			
Exp Date:	*					
Carousel		Pos				
Sample Carousel 1	*					
Sample Carousel 2						
Sample Carousel 3						
Reagent/Calibration						
<u>Calibrator</u>	<u>Pos</u>	<u>Lot No</u>	<u>Exp Date</u>	<u>Chem</u>	<u>Conc</u>	<u>Unit</u>
Water	W	*	*	TP	0	g/dL
Chemistry Calibrator	*	*	*	TP	*	g/dL
Calibration Setup						
Chem:	TP					
<u>Calibration Settings</u>						
Math Model:	Two-Point Linear					
Factor:	Replicates:		2			
<u>Acceptance Limits</u>						
Cal Time:	336	Hour				
Slope Diff:	---	SD:	---			
Sensitivity :	---	Repeatability:	---			
Deter Coeff:	---					
<u>Auto Calib.</u>						
<input type="checkbox"/> Bottle Changed	<input type="checkbox"/> Lot Changed	<input type="checkbox"/> Cal Time				

It is recommended that two levels of control material be assayed daily.

* Indicates user defined parameter.

REF 14-T7528-480



Manufactured by
HORIBA Instruments Incorporated-Pointe Brand
5449 Research Drive Canton, MI 48188



Certified to Perform Reagents

The Pointe reagents are certified to be manufactured according to specified parameters. Any Pointe reagent product not meeting specifications through its listed expiration date will be remedied immediately without charge.

Manufactured by HORIBA Instruments Incorporated – Pointe Brand
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Symbol Key



Use by (YYYY-MM-DD)



Lot and batch code



Catalog number



Manufacturer



Temperature limitation



Consult instructions for use



In vitro diagnostic medical device **Rx Only:** Prescription Use Only