

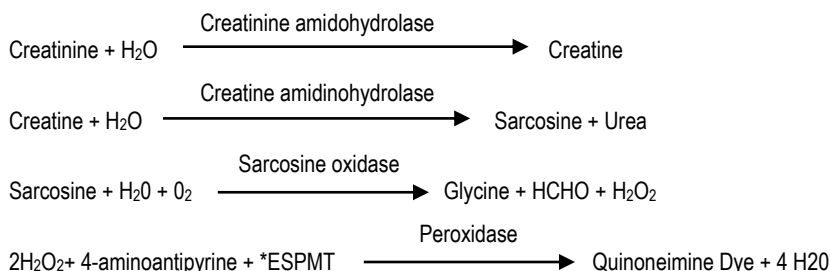
Intended Use

For the quantitative enzymatic determination of creatinine in serum and urine on the Yumizen C560. **Rx Only.**

Principle

Creatinine is a catabolic product of creatine, which is used in skeletal muscle contraction. The daily production of creatine, and subsequently creatinine, depends on muscle mass, which fluctuates very little. Creatinine is excreted entirely by the kidneys and therefore is directly proportional to renal excretory function. Thus with normal renal excretory function, the serum creatinine level should remain constant and normal. Only renal disorders, such as glomerulonephritis, pyelonephritis, acute tubular necrosis, and urinary obstruction, will cause an abnormal elevation in creatinine.¹

The current method employs a two reagent system which eliminates interference by endogenous creatine and ascorbic acid.



*ESPMT: N-ethyl-N-sulfopropyl-m-toluidine

Reagents

Creatinine Enzyme Buffer Reagent (R1): Good Buffer (pH 7.4) 25 mmol/L, Creatine amidinohydrolase > 25 KU/L, Sarcosine oxidase > 7 KU/L, Ascorbate oxidase > 4 KU/L, ESPMT 140 mg/L

Creatinine Enzyme Color Reagent (R2): Good Buffer (pH 7.3) 100 mmol/L, Creatinine amidohydrolase > 250 KU/L, Peroxidase > 5 KU/L, 4-aminoantipyrene 600 mg/L, ESPMT

Reagent Preparation

Reagents are provided as ready to use liquids.

Reagent Storage and Stability

Reagents are stable until expiration dates found on their labels when stored at 2-8°C. Manufacturer studies have shown reagent is stable for 30 days once placed in the refrigerated reagent carousel (2-10°C), however reagent stability may vary based on individual laboratory conditions.

Precautions and Hazards

Hazards:

R1 and R2:

Hazard Classifications: Not a hazardous substance or mixture.

Pictogram: Not required.

Signal Word: Not required.

Hazard Statements: Not a hazardous substance or mixture.

Precautionary Statements: Not a hazardous substance or mixture.

Refer to the Safety Data Sheet for this product (SDS-C7548) available by calling 1-734-487-8300.

Specimen Collection and Storage

1. Serum: Remove specimen from clot promptly to prevent hemolysis.
2. Do not use fluoride or ammonium heparinate to collect sample.²

Sample Stability: Creatinine values have a reported stability of one day at 2-8°C, and several months when frozen (-20°C) and protected from evaporation and contamination. Store urine at 2 -8°C.²

Interferences

No interference was observed by ascorbic acid up to 200 mg/dL, hemoglobin up to 500 mg/dL, bilirubin-conjugate up to 32 mg/dL, and bilirubin-free up to 40 mg/dL. An extensive list of drugs or other agents interfering with creatinine methodologies has been reported by Young et al³.

Materials Provided

1. Creatinine R1 Reagent
2. Creatinine R2 Reagent

Pointe Creatinine (Enzymatic) Reagent Set

Materials Required but not Provided

1. Yumizen C560
2. Yumizen C560 Operation Manual
3. Pointe Chemistry Control, catalog number C7592-100
4. Pointe Chemistry Calibrator, catalog number C7506-50

Calibration

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

Two (2) levels of control material with known Creatinine levels determined by this method, should be analyzed each day of testing.

Expected Values⁴

Normal Range: Male (serum): 0.9 - 1.5 mg/dL
Male (urine): 1000 - 2000 mg/24hrs.
Female (serum): 0.7 - 1.4 mg/dL
Female (urine): 600 - 1500 mg/24hrs.

This range should serve only as a guideline. It is recommended that each laboratory establish its own range of expected values, since differences exist between instruments, laboratories and local populations.

Performance⁵

1. Assay Range: 0.01-30.00 mg/dL. Samples exceeding this value should be diluted 2-fold with deionized water, the assay repeated and results multiplied by 2.
2. Correlation: A study was performed between the Yumizen C560 and a similar analyzer using this method, resulting in the following:

Method	Creatinine
N	80
Mean Creatinine (mg/dL)	3.945
Range (mg/dL)	0.49-22.73
Standard Deviation	5.725
Regression Analysis	$y = 1.046x + 0.036$
Correlation Coefficient	0.9994

3. Precision: Precision studies were performed following a modification of the guidelines contained in the NCCLS document EP5-T2.

Sample	Within Day			Total		
	LOW	MID	HIGH	LOW	MID	HIGH
N	20	20	20	40	40	40
Mean	1.262	4.141	24.984	1.286	4.212	25.161
Standard Deviation	0.011	0.019	0.064	0.021	0.055	0.359
Coefficient of Variation (%)	0.9%	0.5%	0.3%	1.6%	1.3%	1.4%

4. Sensitivity: 2SD limit of detection (95% Conf) = 0.01 mg/dL

Data obtained on Hitachi 717

5. Urine specimens (n = 37) were assayed by this method and by another commercial method. Statistical analysis revealed a correlation coefficient (r) of 0.9854, with a regression equation of $y = 1.0545x + 0.3607$.

References

1. Pagana, KD and TJ Pagana, Mosby's Diagnostic and Laboratory Test Reference, 2nd Ed., Mosby, St. Louis, 1995, p.270.
2. Tietz, Norbert W, Clinical Guide to Laboratory Tests, 3rd Edition, WB Saunders, Philadelphia, 1995, pp 186-188.
3. Young DS et al. Clin Chem 21:286 D, 1975 (Special Issue)
4. Larsen K. Clin Chim Acta 41:209, 1972
5. Manufacturer's Laboratory Data

CHEMISTRY PARAMETERS

Chem:	CREAT-enz	No.:	213	Sample Type:	Serum
Chemistry:	Creatinine (Enzymatic)			Print Name:	CREAT-enz
Reaction Type:	End Point			Reaction Direction:	Positive
Pri Wave:	546			Sec Wave:	660
Unit:	mg/dL			Decimal:	0.01
Blank Time:	47 49			Reaction Time:	80 82
	Sample Vol.	Aspirated	Diluent	Reagent Vol.	Diluent
Standard:	2.0 ul	-- ul	-- ul	R1:	120 ul -- ul
Decreased:	-- ul	-- ul	-- ul	R2:	40 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)	0.01	30	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 Creatinine (Enzymatic) 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	*	*	CREAT-enz	0	mg/dL
Chemistry Calibrator	*	*	*	CREAT-enz	*	mg/dL
Calibration Setup						
Chem:	CREAT-enz					
Calibration Settings						
Math Model:	Two-Point Linear					
Factor:		Replicates:	2			
Acceptance Limits						
Cal Time:	336	Hour				
Slope Diff:	---	SD:	---			
Sensitivity :	---	Repeatability:	---			
Deter Coeff:	---					
Auto Calib.						
<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-C7548-216



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** Lot and batch code **REF** Catalog number
 Manufacturer Temperature limitation Consult instructions for use
IVD In vitro diagnostic medical device **Rx Only:** Prescription Use Only