SEKURE® CHEMISTRY

EN

ENZYMATIC CREATININE ASSAY

CATALOGUE NUMBER: 265-30 **SIZE**: R1 - 3 x 100 mL
R2 - 1 x 100 mL

Note: Changes are highlighted.

INTENDED USE

For the *in vitro* quantitative measurement of creatinine in serum, plasma and urine.

TEST SUMMARY

This enzymatic method for creatinine utilizes a multi-step approach ending with a photometric end-point reaction. The enzyme creatinine amidohydrolase is used to convert creatinine to creatine.

Creatine is broken down to sarcosine and urea by creatine amidinohydrolase. Further enzyme linked steps with sarcosine oxidase and peroxidase yield a colored chromogen read at 545nm.

Creatinine measurements are used in the diagnosis and treatment of kidney diseases, in the monitoring of dialysis patients, and as an integral part of diagnostic equations to measure renal function.

TEST PRINCIPLE

$$\text{Creatinine} + H_2O \xrightarrow{\text{Creatinine amidohydrolase}} \text{Creatine}$$

$$\text{Creatine} + H_2O \xrightarrow{\text{Creatine amidinohydrolase}} \text{Sarcosine} + \text{Urea}$$

$$\text{Sarcosine} + H_2O + O_2 \xrightarrow{\text{Sarcosine oxidase}} \text{Glycine} + HCHO + H_2O_2$$

$$2H_2O_2 + \text{4-Aminoantipyrine} + \text{ESPMT} \xrightarrow{\text{Peroxidase}} \text{Quinoneimine Dye} + 4\,H_2O$$

ESPMT: N-ethyl-N-sulfopropryl-m-toluidine

REAGENTS

Enzymatic Creatinine Start Reagent (R1): a solution containing buffer (pH 7.5 at 25°C), >12,000 U/L creatine amidinohydrolase (microbial), >4,000 U/L sarcosine oxidase (microbial), >0.24 mmol/L N-ethyl-N-sulfopropryl-m-toluidine, ascorbate oxidase (botanical), stabilizers, surfactants, and preservatives.

Enzymatic Creatinine Reagent (R2): a solution containing buffer (pH 7.5 at 25°C), >135,000 U/L creatinine amidohydrolase (microbial), >1.5 mmol/L 4-aminoantipyrine, >2,000 U/L peroxidase (botanical), stabilizers, surfactants, and 7.7 mmol/L sodium azide.

WARNINGS & PRECAUTIONS FOR USE

IVD

For *in vitro* diagnostic use

℞ ONLY

Enzymatic Creatinine R1



Danger
Contains: Oxidase, sarcosine (CAS No) 9029-22-5; Creatine amidohydrolase (CAS No) 37340-58-2
Hazard statements
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
Precautionary statements
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray.
P284 - [In case of inadequate ventilation] wear respiratory protection.
P304+P341 - If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.
P342+P311 - If experiencing respiratory symptoms: Call a poison center or doctor.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Enzymatic Creatinine R2



Danger
Contains: Creatininase (CAS No) 9025-13-2
Hazard statements
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
Precautionary statements
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray.
P284 - [In case of inadequate ventilation] wear respiratory protection.
P304+P341 - If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.
P342+P311 - If experiencing respiratory symptoms: Call a poison center or doctor.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

REAGENT PREPARATION, STORAGE & STABILITY

Reagents are ready for use.

Supplied reagents stable at 2-8°C until expiry. Once opened, reagents stable at 2-8°C for 8 weeks.

Stability claims are based on real time studies.

REAGENT DETERIORATION

The reagent solutions should be clear. Turbidity would indicate deterioration.

DISPOSAL

Reagents must be disposed of in accordance with all Federal, Provincial, State and local regulations.

SPECIMEN

Fresh, clear, unhemolysed serum, lithium heparin plasma or urine. Urine is to be collected without additives. For manual dilution, dilute urine with 0.9% saline or deionized water and multiply the result by the dilution factor. Pre-dilution of 1 part urine to 4 parts saline is usually required for urine samples.

SAMPLE STORAGE

Specimens may be stored at 2-8°C for seven days and at minus 20°C for longer periods.[1]

ANALYTICAL SPECIFICITY (CLSI EP7)[2]

Cross contamination studies have not been performed on automated instruments. Certain reagent/instrument combinations used in sequence with this assay may interfere with reagent performance and test results. The existence of, or effects of, any potential cross contamination issues are unknown.

Interferences from icterus, lipemia, hemolysis and ascorbic acid were evaluated for this creatinine method on an ADVIA® 1650 analyzer using a significance criterion of >10% variance from control. Interference data was collected in serum and urine. Plasma is expected to be similar.

Concentration of Analyte in Serum		Substance Tested	Concentration of Interferent Where Interference is Insignificant	
Conventional Units	SI Units			
0.79 mg/dL	69.4 µmol/L	Hemoglobin	1000 mg/dL	155.0 µmol/L
0.76 mg/dL	67.2 µmol/L	Ascorbic Acid	3000 µg/dL	170 µmol/L
0.75 mg/dL	66.3 µmol/L	Unconj. Bilirubin	16 mg/dL	273.6 µmol/L
1.08 mg/dL	94.9 µmol/L	Conj. Bilirubin	40 mg/dL	474 µmol/L
0.75 mg/dL	66.3 µmol/L	Intralipid	1000 mg/dL	3000 mg/dL (33.9 mmol/L) Simulated Triglycerides

Concentration of Analyte in Urine		Substance Tested	Concentration of Interferent Where Interference is Insignificant	
Conventional Units	SI Units			
71.7 mg/dL	6338.3 µmol/L	Hemoglobin	1000 mg/dL	155.0 µmol/L
137.4 mg/dL	12148.0 µmol/L	Ascorbic Acid	3000 µg/dL	170 µmol/L
75.7 mg/dL	6691.9 µmol/L	Unconj. Bilirubin	40 mg/dL	684 µmol/L
95.9 mg/dL	8477.6 µmol/L	Conj. Bilirubin	40 mg/dL	474 µmol/L
31.7 mg/dL	2802.3 µmol/L	Intralipid	1000 mg/dL	3000 mg/dL (33.9 mmol/L) Simulated Triglycerides

Samples containing elevated levels of Immunoglobulin M (IgM) or samples from patients with Waldenstrom's Macroglobulinemia may produce unreliable results.

Samples containing the following should not be used: dopamine, dobutamine, catecholamine, phenindione, hydroxocobalamin, and eltrombopag.

The information presented above is based on results from SEKISUI Diagnostics studies and is current at the date of publication.

A summary of the influence of drugs on clinical laboratory tests may be found by consulting Young, D.S.[3]

ANALYTICAL PROCEDURE

MATERIALS PROVIDED

SEKISUI Diagnostics' enzymatic creatinine reagents.

MATERIALS REQUIRED (BUT NOT PROVIDED)

1. Automated analyzer capable of accurately measuring absorbance at appropriate wavelengths as per instrument application.
2. Calibration material.
3. Quality Control materials.

TEST CONDITION

For data presented in this insert, studies using this reagent were performed on an automated analyzer using an endpoint test mode, with a sample to reagent ratio of 1:15:5 and a wavelength reading 545 nm. For assistance with applications on automated analyzers within Canada and the U.S., please contact SEKISUI Diagnostics Technical Services at (800) 565-0265. Outside Canada and the U.S., please contact your local distributor.

CALIBRATION

Calibration material should be used to calibrate the procedure. The frequency of calibration, if necessary, using an automated system is dependent on the system and the parameters used.

QUALITY CONTROL

A normal and abnormal concentration control should be analyzed as required. The results should fall within the quality control range established by the individual laboratory.

CALCULATION

The analyzer automatically calculates the creatinine concentration of each sample.

TEST LIMITATIONS

A sample with a creatinine concentration exceeding the linearity limit should be diluted with 0.9% saline and reassayed incorporating the dilution factor in the calculation of the value.

REFERENCE INTERVALS[1]

Serum/Plasma	Male:	≤1.2 mg/dL (≤104 µmol/L)
	Female:	≤1.0 mg/dL (≤84 µmol/L)
Urine 1st morning:	Male:	40-280 mg/dL (3500-25000 µmol/L)
	Female:	30-230 mg/dL (2600-20000 µmol/L)

These values are suggested guidelines. It is recommended that each laboratory establish the normal range for the area in which it is located.

PERFORMANCE CHARACTERISTICS

Data presented was collected on an Advia 1650 analyzer unless otherwise stated.

RESULTS

Serum, plasma, and urine creatinine concentration are reported as mg/dL (µmol/L).

REPORTABLE RANGE (CLSI EP6)[2]

Serum and Plasma - The linearity of the procedure described is 30.00 mg/dL (2652 µmol/L). The low limit of detection is 0 mg/dL (0 µmol/L) and the limit of quantitation is 0.03 mg/dL (3 µmol/L). This data results in a reportable range of 0.03-30.0 mg/dL (3-2652 µmol/L).

Urine - The linearity of the procedure described is 175.00 mg/dL (15470 µmol/L). The low limit of detection is 0 mg/dL (0 µmol/L) and the limit of quantitation is 0.02 mg/dL (2 µmol/L). This results in a reportable range of 0.02-175.00 mg/dL (2-15470 µmol/L). It is recommended that urine samples be diluted 1 part urine to 4 parts saline prior to assay. Incorporate the dilution calculation into the final result.

PRECISION STUDIES (CLSI EP5)[2]

Total precision was collected on three concentrations of serum controls and three concentrations of urine controls in 40 runs conducted over 20 days.

Enzymatic Creatinine	N	Mean		Standard Deviation		Coefficient of Variation %
		mg/dL	µmol/L	mg/dL	µmol/L	
Serum 1	80	0.68	60.11	0.017	1.500	2.5
Serum 2	80	1.32	115.80	0.032	2.830	2.4
Serum 3	80	6.12	540.12	0.166	14.670	2.7
Urine 1	80	22.01	1945.68	0.323	28.55	1.5
Urine 2	80	44.66	3947.94	0.423	37.390	0.9
Urine 3	80	93.31	8248.60	1.269	112.180	1.4

Within run precision was collected on three concentrations of serum controls and three concentrations of urine controls each run 20 times in a single assay.

Enzymatic Creatinine	N	Mean		Standard Deviation		Coefficient of Variation %
		mg/dL	µmol/L	mg/dL	µmol/L	
Serum 1	20	0.62	54.81	0.004	0.35	0.6
Serum 2	20	1.27	112.27	0.007	0.53	0.5
Serum 3	20	5.85	517.14	0.018	1.59	0.3
Urine 1	20	22.19	1961.60	0.049	4.15	0.2
Urine 2	20	45.12	3988.61	0.083	7.16	0.2
Urine 3	20	88.38	7812.79	0.221	19.54	0.2

ACCURACY (CLSI EP9)[2]

The performance of this method was compared with the performance of a similar method on an Advia 1650. 40 patient serum samples ranging from 0.7-31.2 mg/dL (61.88 - 2758.08 µmol/L) gave a correlation coefficient of 1.0000. Linear regression analysis gave the following equation:

This method = 1.03 (Comparison Method) - 0.13 mg/dL (11.49 µmol/L).

The performance of this method was compared with the performance of a similar method on an Advia 1650. 40 patient urine samples ranging from 13.5-141.7 mg/dL (1193.40 - 12526.28 µmol/L) gave a correlation coefficient of 0.9995. Linear regression analysis gave the following equation:

This method = 1.04 (Comparison Method) + 1.06 mg/dL (93.70 µmol/L).

The performance of this plasma method was compared with the performance of this serum method on an Advia 1650. 33 patient serum samples ranging from 0.61 - 27.04 mg/dL (53.92 - 2390.34 µmol/L) gave a correlation coefficient of 0.9997. Linear regression analysis gave the following equation:

This method (Plasma) = 1.01 (This Method- Serum) - 0.03 mg/dL (2.92 µmol/L)

The information presented above is based on results from SEKISUI Diagnostics studies and is current at the date of publication.

TRADEMARKS

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All other trademarks are the property of their respective owners.

Symbols



Batch Code



Manufacturer



Consult instructions for use



In vitro diagnostic medical device



Use-by Date
YYYY-MM-DD or YYYY-MM



Catalogue number



Temperature limit



Health hazard

℞ONLY

Caution: Federal law restricts this device to sale by or on the order of a physician

REFERENCES

1. Heil, W., Koberstein, R., Zawta, B. Reference Ranges for Adults and Children, Roche Diagnostics, Mannheim, 2002.
2. *CLSI Method Evaluation Protocols,* Clinical and Laboratory Standards Institute, Wayne, PA.
3. Young, D.S., Effects of Drugs on Clinical Laboratory Tests, AACC Press, Washington, Third Edition, 1990.

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