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AZIENDA CERTIFICATA
UNI EN ISO 9001:2008
UNI EN ISO 13485:2012
CERTIFIED COMPANY

CREATININE

Kinetic modified Jaffè method

IVD CE In conformity with Directive 98/79 CE

000271 Rev. 7 of 25/02/14

REF		
	ASR01150	**2x100 + 2x100 ml + STD**
	ASR01150/2	**1x100 + 1x100 ml + STD**
	ASKIT1002	**3x36 + 6x18 ml**

• Principle

Creatinine reacts with picric acid in alkaline conditions to form a yellow-orange colour complex.
The rate of colour formation is proportional to the creatinine concentration in the sample.

• Sample

Serum, heparinized plasma and 24 hours urine.
Urine must be diluted 1:100 with saline solution 0.9%.
Do not use hemolyzed samples.
Creatinine in serum or plasma is stable for 1 day at 2 – 8°C.
Freeze the sample for longer periods.

• Expected value

SERUM	Men	0.7 – 1.2 mg/dl (62 – 106 µmol/l)
	Women	0.6 – 1.1 mg/dl (53 – 97 µmol/l)
URINE		1 – 1.5 g/24h (8.8 – 13.3 mmol/l)
Clarence Creatinine	Men	98 – 160 ml/min
	Women	95 – 150 ml/min

Consider the above mentioned values as a reference.
It is strongly recommended that each laboratory establishes its own normal range according to its geographic area.

• Kit composition and possible danger classification

REAGENT (A)	
Picric Acid	29 mmol/l
REAGENT (B)	
Buffer	100 mmol/l
Sodium Hydroxide	600 mmol/l
STANDARD (C)	
Creatinine	2 mg/dl (0.177 mmol/l)

The Reagent (B), according to current regulation, is classified as dangerous: Xi – Irritant.
R36/38 – Irritating to eyes and skin

• Package: collection and storage

The reagents are stable until the expiration date indicated on the label if stored at 15-25°C and protected from light. Do not use over expiry date.
Once opened reagents are stable for 2 months at 15-25°C if contamination is avoided.
Keep bottles closed when not in use, **especially the Reagent (B).**

• Reagent preparation and stability

Mix the Reagents (A) and (B) into equal parts. Stabilize the working solution 15 minutes before use. Use the necessary quantities depending on the number of analyzes to be carried.
The working solution is stable for 7 days at room temperature.

• Precautions and warning

Whenever agents infettantis, chemical reagents, reagents of human/animal origin, blood or other biological liquids are manipulated, it is advisable to follow the most common recommendations and take all the necessary hygienic precautions as the monouse gloves.

• Waste disposal

Please consult local regulations for a correct waste disposal.

• Operative method

Wavelength:	492nm (490-500)
Cuvette:	1 cm
Temperature:	+37°C
Zero operation:	Against distilled water
Assay type:	Increasing Kinetic
Sample/Reagent ratio:	1/10

Pipetting in tubes:	**A. SAMPLE**	***STANDARD***
Monoreagent	1000 µl	1000 µl
Sample	100 µl	
Standard		100 µl

Mix, incubate at 37°C for 30 seconds, and read the absorbance of the sample (Ax1) and standard (As1). After exactly one minute from the first reading, read the absorbance of the sample (Ax2) and standard (As2).
Volumes can be proportionally modified.
This methodology describes the manual procedure to use the kit.

• Calculation

Serum/plasma:
Creatinine mg/dl = (Ax2 - Ax1) / (As2 - As1) x Standard Value

Urine 24h: Creatinine mg/24h =
= (Ax2 - Ax1)/(As2 - As1) x Std Value x 100 (dilution) x diuresis (in dl)

Clearance creatinine (ml/min)=$\frac{\text{creatinine urine (mg/dl)x[diuresis (ml)/1440]}}{\text{Creatinine serum (mg/dl)}}$

• Performance

A. METHOD PERFORMANCE
LINEARITY: the method is linear up to 30 mg/dl. For higher values, dilute the sample 1:2 and multiply the result by 2.
SENSITIVITY: 0.1 mg/dl

B. INTRA-ASSAY PRECISION:

	Mean	DS	C.V.(%)
Level 1	1.22	0.012	1.01
Level 2	3.76	0.017	0.46

C. INTER-ASSAY PRECISION:

	Mean	DS	C.V.(%)
Level 1	1.25	0.011	0.85
Level 2	3.81	0.021	0.54

D. CORRELATION BETWEEN METHODS
This method compared with a correspondent one from the competition, has given the following results:
Y = 0.9294x + 0.16 r = 0.9998

E. INTERFERENCE
Ascorbic acid up to 100 mg/dl does not interfere.
Bilirubin does not interfere up to 5 mg/dl.
A hemoglobin concentration greater than 100 mg/dl increases the reading.
Glucose up to 500 mg/dl does not interfere.

• Quality Control

It is recommended to execute the quality control at every kit utilization to verify that values are within the reference range indicated by the methodology. For this purpose the use of test serum REF. ASR02011 (Normal level) and REF. ASR02021 (Pathologic level) is suggested.

• Bibliography

1. Jaffè M., Z. Physiol. Chem., 10:391 (1886).
2. Kaplan LA, Pesce AJ, Clinical Chemistry, Mosby Ed. 1989
3. Young, D.S., et al. Clin. Chem. 21:1D (1975).

M.S.D.N: 0313713151-C.T.T.N.H.H
CÔNG TY TNHH HỆ THỐNG CHẨN ĐOÁN XUÂN HOÀI
H.HỌC MÔN-T.P HỒ CHÍ MINH

GIÁM ĐỐC
KS. Võ Xuân Hiền

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REF

ASR01150	**2x100 + 2x100 ml + STD**
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ASKIT1002	**3x36 + 6x18 ml**

		ELLIPSE rev.0 of 28/06/10	LIASYS rev.0 of 28/06/10
Description:		CREATININE	CREATININE
Unit:		mg/dl	mg/dl
Decimals:		2	2
LIS Code:		CRE	CRE
Unit Factor:		1.0	1.0
Slope:		1.00	1.00
Intercept:		0.00	0.00
Reaction Type:		Fixed Time	Fixed Time
Direction:		Up	Up
E.P Limit:			
Depl.Limit:		2.0000	1.8000
First Limit:		1.0000	1.0000
Linear Factor:		1.00	1.00
Fit:			
RBL Replicates:		x 1	X 1
RBL Max CV%:		10	10
RBL Min (abs):		0.2000	0.2000
Max (abs):		0.5000	0.5000
Lin. Lim. Low:		0.00	0.00
High:		30.00	30.00
Rerun when over:		*	*
Calculation Model:		Standard	Standard
Factor:			
Sample Blank:			
Reference Range		*	*
Parameters			
Predilut	Times (sec):		
	Dil./Reag Code:		
	Lot Number:		
	Ratio/Vol (ul):	1/1	1/1
C. + R.1	Times (sec):		
	Dil./Reag Code:	CRE	CRE
	Lot Number:		
	Ratio/Vol (ul):	200	300
	Rinse (ul):	0	0
	Sample (ul):	20	30
Reag 2	Times (sec):		
	Dil./Reag Code:		
	Lot Number:		
	Ratio/Vol (ul):		
	Rinse (ul):		
	Sample (ul):		
Reag 3	Times (sec):		
	Dil./Reag Code:		
	Lot Number:		
	Ratio/Vol (ul):		
	Rinse (ul):		
	Sample (ul):		
Wash			
Incubation		18	26
Read		65 Kinetic	72 Kinetic
Filter 1 (nm):		492	492
Filter 2 (nm):		(none)	(none)
Bichr. Factor:		1.00	1.00
RBL Stability (days):		1	1
Calibration Stab. (days):		7	7
Dinamic Controls (min.):		*	*

* user-defined

• **Performance ELLIPSE**

METHOD PERFORMANCE

Linearity: 30,04 mg/dl

Sensitivity: 0,1 mg/dl = 0.0044A

STABILITY ON BOARD:

Stable two weeks if reagent is kept refrigerated and capped (after working session)

INTRA-ASSAY PRECISION: n=40

	Media	DS	CV
Normal control	1,24	0,02	1,31
Abnormal control	3,88	0,05	1,35

INTER-ASSAY PRECISION: n=40

	Media	DS	CV
Normal control	1,24	0,03	2,46
Abnormal control	3,88	0,07	1,93

CORRELATION BETWEEN METHODS

This method compared with a correspondent one from the competition, has given the following results:

N = 140 r = 0,99 y = 1,0219x - 0,1196

• **Performance LIASYS**

METHOD PERFORMANCE

Linearity: 30,08 mg/dl

Sensitivity: 0,1 mg/dl = 0.0040A

STABILITY ON BOARD:

Stable two weeks if kept capped overnight

INTRA-ASSAY PRECISION: n=40

	Media	DS	CV
Normal control	1,19	0,02	1,60
Abnormal control	3,71	0,03	0,93

INTER-ASSAY PRECISION: n=40

	Media	DS	CV
Normal control	1,19	0,03	2,70
Abnormal control	3,71	0,09	2,46

CORRELATION BETWEEN METHODS

This method compared with a correspondent one from the competition, has given the following results:

N = 140 r = 0,99 y = 1,0118x - 0,0956