Website : www.erbamannheim.com

LIQUIXX
CREATININE (CRE)

CE IVD

Jaffe's Method, Initial Rate

INTENDED USE
Diagnostic reagent for quantitative *in vitro* determination of Creatinine in human serum, plasma and urine by Jaffé method.

CLINICAL SIGNIFICANCE
Creatinine is a waste product formed in muscle from the high energy storage compound, creatine phosphate. The amount of creatinine produced is fairly constant (unlike Urea) and is primarily a function of muscle mass. It is not greatly affected by diet, age, sex or exercise. Creatinine is removed from plasma by glomerular filteration and then excreated in urine without any appreciable resorption by the tubules.
Creatinine is used to assess renal function, however, serum creatinine levels do not start to rise until renal function has decreased by at least 50%.

METHODOLOGY
Modified Jaffe's reaction.

PRINCIPLE
Creatinine reacts with alkaline picrate to produce an orange-yellow colour (the Jaffe's reaction). Specificity of the assay has been improved by the introduction of an initial rate method. However , Cephalosporin antibiotics are still major interferants.
The absorbance of the orange-yellow colour formed is directly proportional to creatinine concentration and is measured photometrically at 500-520 nm.

REAGENT COMPOSITION
REAGENT 1: Picric Acid Reagent

Picric acid	25.8 mmol/L

REAGENT 2: Sodium Hydroxide Reagent

Sodium Hydroxide	95 mmol/L

Creatinine Standard

Creatinine Standard	2 mg/dl (0.166 mmol/L)

REAGENT PREPARATION
Reagent (R1 & R2) are ready to use. Mix equal volume of Reagent (R1 & R2) to prepare working reagent.

STORAGE AND STABILITY
Unopened Reagents 1, 2 and standard are stable till the expiry date stated on the label.

***Keep the Standard vial plugged after use, in order to avoid deterioration.**

The Working Reagent is stable for 21 days at 2-8°C. The absorbance of the reagent blank should be approximately < 0.3 at 505 nm when read against distilled water.

SPECIMEN COLLECTION AND HANDLING
Use serum, plasma (heparin, EDTA) or urine.
It is recommended to follow NCCLS procedures (or similar standardized conditions).

Stability

in serum / plasma:	7 days	at 4–25°C
	at least 3 months	at -20°C
in urine:	2 days	at 20–25°C
	6 days	at 4–8°C
	6 months	at -20°C

For the determination in urine use 24 hours specimen. It is important to exactly measure the volume of collected urine. Dilute urine samples in 1+19 ratio with distilled water and multiply results by 20.
Discard contaminated specimens.

ASSAY PARAMETERS

Mode	Fixed Time
Wavelength (nm)	505
Sample Volume (µl)	50/100
Reagent Volume (µl)	500/1000
Lag Time (Sec.)	20
Kinetic Interval (Sec.)	60
No. of readings	1
Reaction Temperature (°C)	37
Reaction Direction	Increasing
Normal Low (mg/dl)	0.6
Normal High (mg/dl)	1.4
Linearity Low (mg/dl)	0
Linearity High (mg/dl)	25
Absorbance Limit (Max.)	0.3
Blank with	DI Water
Standard Concentration (mg/dl	2
Units	mg/dl

Programme parameters for specific clinical analysers are available on request.

ASSAY PROCEDURE

Pipette	Standard	Test
Working Reagent	1000 µl	1000 µl
Standard	100 µl	-
Test	-	100 µl

Mix well and read initial absorbance (A_1) 20 seconds after mixing and final absorbance (A_2) 80 seconds after mixing.

COMPARISON
A comparison between LIQUIXX CREATININE (y) and a commercially available test (x) using 40 samples gave following results:
r = 0.997
y = 0.998 x + 2.564 µmol/l

Manufactured by : **TRANSASIA BIO-MEDICALS LTD.,** Nalagarh Road, Village Malpur, Baddi, Dist. Solan, (HP) - 173205.
In Technical Collaboration with : ERBA diagnostics Mannheim GmbH **Mallaustr., 69-73, D - 68219, Mannheim / Germany**

CALCULATION

Calculate the results as follows:

$$\Delta A = A_2 - A_1$$

$$\text{Creatinine (mg/dl)} = \frac{\Delta A \text{ of Test}}{\Delta A \text{ of Standard}} \times \text{Concentration of Standard (mg/dl)}$$

LINEARITY

This assay is linear upto 25 mg/dl. For higher values it is recommended to dilute the samples with normal saline and repeat the assay. Multiply the results by dilution factor.

NOTES

1. The reagent and sample volumes may be altered propotionally to accommodate various analyzer requirements.
2. The temperature of the kinetic assay must be maintained costant as the rate of colour development is strongly temperature sensitive.
3. Gross haemolysis causes falsely elevated results.
4. **Bilirubin, acetone, ascorbic acid, pyruvic acid, barbiturates, and protein interferes with Jaffe's reaction. For more comprehensive review of factors affecting creatinine assays refer to the publications of Young et al.**

QUALITY CONTROL

For quality control ERBA NORM and ERBA PATH are recommended.

EXPECTED VALUES

Male	0.7 – 1.4 mg/dl
Female	0.6 – 1.2 mg/dl
Urine	0.06 – 0.2 mg/dl

It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

INTERFERENCES

Following substances do not interfere:
bilirubin up to 15 mg/dl, hemoglobin up to 10 g/l, triglycerides up to 1000 mg/dl.

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ISO 9001, ISO 13485
QUALITY SYSTEM CERTIFIED

PERFORMANCE DATA

Precision :

Within run

	LEVEL I	LEVEL II
Number of samples (n)	20	20
Mean (mg/dl)	1.7	4.84
S. D.	0.06	0.08
C. V. %	3.53	1.65

Between run

Number of samples (n)	20	20
Mean (mg/dl)	1	4.71
S. D.	0.023	0.14
C. V. %	2.3	2.97

WARNING AND PRECAUTIONS

For *in vitro* diagnostic use. To be handled by entitled and professionaly educated person.
The reagent R2 contains irritating 1.0% sodium hydroxide.

WASTE DISPOSAL

All tested samples should be treated as potentially infectious and with an eventual rest of reagents should be disposed in accordance with the internal regulations for dangerous waste, in compliance with local and national regulations relating to the safe handling of dangerous materials.
Paper packing and others should be handed over for recycling or discarded as sorted waste (paper, glass, plastic).

REFERENCES

1. Bowers, L..D. (1980) Clin Chem. 26; 551.
2. Bartel, H. (1972) Clin. Chem. Acta 37, 193.
3. Slot, C. (1965) Scand. J. Clin Lab. Invest 17, 381.
4. Young D.S. (1975) Clin. Chem. 21; 266D.

PACK PRESENTATION

Product Code	Pack size	Reagent-1 Picric Acid Reagent	Reagent-2 Sodium hydroxide Reagent	Creatinine Standard
120246	4 x 60ml	2 x 60ml	2 x 60ml	1 x 5ml

SYMBOLS:

The following symbols are used in the labelling of ERBA Mannheim kits:

REF Catalogue No

CE CE Mark - Device comply with the Directive 98/79/EC

LOT Batch Code

IVD In Vitro Diagnostics

Expiry Date (Last day of the month)

Consult Instruction for Use

Manufactured by

Storage temperature

CRE Product Name

CONT Content