LiquiCHEK™ AGECRT AGAPPE

ENZYMATIC CREATININE

2 x 40 mL, 2 x 60 mL, 4 x 60 mL
11420002, 11420003, 11420004

Intended Use

This reagent is intended for *in vitro* quantitative determination of creatinine in serum, plasma and urine.

· Enzymatic Method
· High Linearity of 200 mg/dL
· Ready to use reagents

Clinical Significance

Creatinine is formed in muscles from phosphocreatinine. It is an important form of energy by being a store of high energy phosphate. Creatinine determinations have one advantage over urea determination that it is not affected by a high protein diet.

Serum creatinine is more specific & sensitive indicator of renal function. Simultaneous estimations of serum urea & creatinine provide better information. Serum urea nitrogen & creatinine ratio is > 15 in prerenal failure & < 10 in renal failure. Decreased levels are found in muscle dystrophy.

Principle

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

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

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

$$2\,H_2O_2 + \text{4-AA *1} + \text{TOOS *2} \xrightarrow{\text{Peroxidase}} \text{Quinone pigment} + 4\,H_2O$$

* 1 : 4- Aminoantipyrine,
* 2 : N-ethyl-N-(2-hydroxy -3-sulfopropyl)-m-toluidine

Creatinine concentration can be obtained by measuring quinone pigment photometrically.

Kit Components

Reagent/ Component	Product code: 11420002	Product code: 11420003	Product code: 11420004	Description
E.Creatinine (S.L) R1	2 x 30 mL	2 x 45 mL	4 x 45 mL	Creatinase - 175000 IU/L SarcosineOxidase1500 IU/L TOOS 1.13 mmoL
E.Creatinine (S.L) R2	2 x 10 mL	1 x 30 mL	2x 30 mL	Creatininase 75000 IU/L Peroxidase 4500 units/L 4-AA 0.75 mmol
Creatinine Standard	1 x 4 mL	1 x 4 mL	1 x 4 mL	Creatinine Std. Conc.2 mg/dL

Risk & safety

Material Safety data sheets (MSDS) will be provided on request.

Reagent Preparation

Reagent 1, Reagent 2 & Standard are ready to use.

Reagent Storage and stability

The sealed reagents are stable up to the expiry date stated on the label, when stored at 2- 8°C and protected from light.

Open Vial Stability

Once opened, the reagent is stable up to 30 days at 2-8°C if contamination is avoided.

On-board Calibration Stability

On-board Calibration stability is 30 days.

Reagent Deterioration

Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the Agappe Qualichek Norm & Path control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using a fresh vial of reagent.

Precaution

To avoid contamination, use clean laboratory wares. Use clean, dry disposable pipette tips for dispensing. Close reagent bottles immediately after use.

Avoid direct exposure of reagent to light. Do not blow into the reagent bottles.

This reagent is only for IVD use and follow the normal precautions required for handling all laboratory reagents

Waste Management

Reagents must be disposed off in accordance with local regulations.

Sample

Fresh Serum/plasma & urine (24 hour).

Interferences

No interference for

Bilirubin up to	20 mg/dL
Ascorbic acid up to	40 mg/dL
Haemoglobin up to	500 mg/dL

Materials Provided

Enzymatic creatinine reagent R1, R2 & Standard.

Materials required but not provided

- Pipettes& Tips
- Test Tubes & racks
- Timer
- Incubator
- Analyzer

Test Parameter

Semi Auto Analyser	
Mode of reaction	End Point
Slope of Reaction	Increasing
Wavelength I	546 nm
Wavelength II	630 nm
Temperature	37°C
Standard concentration	2 mg/dL
Linearity	200 mg/dL
Incubation time	5 +5 min
Blank	Reagent
Sample Volume	10 µL
Reagent 1 Volume	450 µL
Reagent 2 Volum	150 µL
Cuvette	1 cm light path

Application parameters for various instrument are available. Please contact customer support department for specific information.

Unit Conversion

Traditional Unit	SI Unit	Conversion from Traditional to SI
mg/dL	µmol/L	x 88.40

Calibration

Agappe multicalibrator is recommended for Calibration of this assay in fully auto analyzers.

Enzymatic creatinine standard is recommended for calibration of this assay on Semi auto analyzer.

Procedure notes

Laboratory procedure for Semi Auto Analyzer.			
	Blank	Calibrator	Sample/control
E. CRT R1	450 µL	450 µL	450 µL
Standard	-	10 µL	-
Sample / control	-	-	10 µL
Mix & incubate for 5 min at 37°C then add			
E.CRT R2	150 µL	150 µL	150 µL
Mix and incubate for 5 min at 37°C and read absorbance of sample and standard against the reagent blank.			

SYMBOLS USED ON THE LABELS

IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

AGAPPE DIAGNOSTICS LTD.
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Rev.3.151220

CE ISO 9001 : 2015
EN ISO 13485: 2016

Quality control

It is recommended to use Agappe Qualicheck Norm & Path (11601001) to verify the performance of the assay. Each laboratory has to establish its own internal quality control scheme and procedure for corrective action, if control do not recover within the acceptable range.

Reference Range

it is recommended that each laboratory establish its own reference value.

The following value may be used as guide line.

Serum/Plasma :	0 - 14 days	: 0.3 - 0.92 mg/dL
	2 months to 1 year	: 0.2 - 0.4 mg/dL
	2 Year to 5 year	: 0.2 - 0.45 mg/dL
	6 Year to 9 Year	: 0.22 - 0.55 mg/dL
	10 Year to 15 year	: 0.4 - 0.8 mg/dL
	Adult Male	: 0.62 - 1.17 mg/dL
	Adult Female	: 0.5 - 0.95 mg/dL

Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance

1. Linearity

This reagent is linear upto 200 mg/dL.

If the concentration is greater than linearity dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.

2. Comparison

A comparison study has been performed between Agappe reagent and another internationally available reagent yielded a correlation coefficient of r^2= 0.9907 and a regression equation of y =1.0362x

3. Precision

Intra Run

	Control Level 1	Control Level 2
n	20	20
Mean (mg/dL)	1.7	4.8
SD	0.04	0.1
CV(%)	2.13	2.08

Inter Run

	Control Level 1	Control Level 2
n	20	20
Mean (mg/dL)	1.78	4.71
SD	0. 07	0.13
CV(%)	3.8	2.69

Accuracy (mg/dL)		
Control	Expected Value	Measured Value
Control Level 1	1.79 ± 0.36	1.7
Control Level 2	4.96 ± 0.99	5
Qualicheck Norm	1.0 ± 0.26	1
Qualicheck Path	4 ± 0.75	3.8

4. Sensitivity

Lower detection Limit is 0.1 mg/dL

Bibliography

1. Artiss J.D,Mc Enroe,Zak,B.
2. Clin chem,30 (1984) 1389.
3. Burtis, Ashwood, Bruns & Saunders : Tietz Text Book of Clinical Chemistry 4th Edition -2006

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