# TRUEchemie Creatinine Test Kit (SR - Modified JAFFE)









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### INTENDED USE

The TRUEchemie Creatinine Test Kit (SR - Modified JAFFE) is used for the quantitative determination of Creatinine in serum or plasma or urine

### INTRODUCTION

Creatinine is the catabolic product of creatine phosphate, which is used by the skeletal muscle. The daily production depends on muscular mass and it is excreted out of the body entirely by the kidneys. Elevated levels are found in renal dysfunction, reduced renal blood flow (shock, dehydration, congestive heart failure) and diabetes acromegaly. Decreased levels are found in muscular dystrophy

### PRINCIPLE

Picric acid in an alkaline medium reacts with Creatinine to form an orange coloured complex with the alkaline picrate. Intensity of the colour formed during the kinetic fixed time is directly proportional to the amount of Creatinine present in the sample

Creatinine + Picric acid

Alkaline Medium

Creatinine - Picrate Complex

PA	CK	SI	ZE

Kit size	2 x 50 ml		
Cat no.	ADX121		
Kit contents			
1) Creatinine (SR) Reagent	2 x 50 ml		
2) Creatinine Standard (2 mg/dL)	1 x 5 ml		

### REAGENTS COMPOSITION

REAGENT PREPARATION

### 1) Creatinine (SR) Reagent

Picric acid > 5.0 mmol/l Sodium hydroxide > 150 mmol/L Activators and stabilizers

2) Creatinine Standard

2 mg/dL

# Ready to use reagents.

### WARNINGS AND PRECAUTIONS

- 1. For in vitro diagnostic use.
- 2. Specimens should be considered infectious and handled appropriately
- 3. Avoid ingestion. DO NOT PIPETTE BY MOUTH.
- 4. The disposal of the residues has to be done as per local legal regulations

### CALIBRATION

The procedures are calibrated with the standard solution which is included with each series of tests. Its absorbance is used to calculate the results.

## **REAGENT STORAGE & STABILITY**

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8 °C and contaminations are prevented during their use. Do not use reagents over the expiration date

# SPECIMEN COLLECTION AND STORAGE

Serum/ Plasma Urine (dilute 1: 100 with distilled water before assay)

Creatinine in serum/plasma is stable for 2 days when stored at 2-8°C

## MATERIALS REQUIRED BUT NOT PROVIDED

- 1. Pipettes to accurately measure required volumes
- 2. Test tubes/rack
- 3. Timer
- 4. 37°C heating block or water bath
- 5. Photometer capable of accurately measuring absorbance at 520 nm.

## TEST PROCEDURE

Wavelength 520 nm (500 - 520 nm)

Temperature

Prewarm the reagent to reaction temperature.

	Blank(µL)	Standard (µL)	Sample (µL)
Distilled water	1000		
Creatinine (SR) Reagent		1000	1000
Creatinine Standard	-	100	
Sample			100

## Reading and Calculations:

Blank the Photometer with Distilled water.

Mix well and read absorbance of sample and test against distilled water at 520 nm as

Initial absorbance  $A_0$  – Exactly after 30 sec. Final absorbance  $A_1$  – Exactly after 90 sec. after  $A_0$ Determine ΔA for Standard (S) and Test (T)

 $\Delta AS = AS_1 - AS_0$  $\Delta AT = AT_1 - AT_0$ 

Serum/plasma Creatinine (mg/dl) =  $\frac{\Delta AT}{\Delta AS}$  x 2

# **QUALITY CONTROL**

Quality Controls are recommended to monitor the performance of automated assay procedures. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

# **EXPECTED VALUE**

Serum / Plasma Males

0.6 – 1.5 mg/dL 0.6 – 1.4 mg/dL Females Urine in 24 hours collection 1.1 - 3.0 am

Females : 1.0 – 1.5 gm It is strongly recommended that each laboratory establish its own normal range.

### PERFORMANCE CHARACTERISTICS

Sensitivity: 0.05 mg/dL

Linearity: Up to 20 mg/dL under the described assay conditions. If the concentration is greater than linearity (20 mg/dL), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor. The linearity limit depends on the sample / reagent ratio, as well as the

### PRECISION:

Intra-assay precision within run (n=10)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Control Level - 1	2.5	0.1	3.3
Control Level - 2	5.4	0.1	2.2

Inter-assay precision run to run (n=12)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Control Level - 1	2.4	0.1	4.6
Control Level - 2	5.6	0.2	2.8

The reagent was tested for 12 days, using two different Creatinine concentrations. The coefficient of variation was <5%.

### **AUTOMATED PROCEDURE**

Appropriate program sheet is available for different analyzers upon request

### METHOD COMPARISON

Results obtained using TRUEchemie Creatinine reagent (y) did not show systematic differences when compared with another commercial reagent (x) with similar characteristics. The results obtained is below: The correlation coefficient  $(r^2)$  was 0.998 and the regression equation is y=1.006x+0.140. The results of the performance characteristics depend on the analyzer used.

## INTERFERENCES

- Lipemia (intralipid < 4 g/L) does not interfere
- Bilirubin (< 5 mg/dl) does not interfere. Hemoglobin (< 4 g/L), does not interfere
- Other drugs and substances may interfere

### WASTE MANAGEMENT

Please refer to local regulation requirements

### SYSTEM PARAMETERS

Fixed Time / Initial Rate / Two point Kinetic Mode Std. conc. Wave length 520 nm Units mg/dL Flow cell temp 37°C Blank Distilled Water Reagent volume 1000 µL Sample volume 100 uL Delay (Lag) time 30 Sec Fixed read time 90 Sec Low normal 0.6 High normal 1.5 0.05 Sensitivity Linearity 20 Reaction Slope Increasing

## REFERENCES

- 1. Browers, L.D., (1980), Clin.Chem ,26:551
- 2. Text book of Clinical Chemistry,3rd edition, Edited by N.W.Tietz P 1271 1280 3. W.B.Saunders Co., Philadelphia. PA. 1986.
- Bartels, H. et al,(1971),Clin.Chem.Acta,32:81.
- 5, ISO 15223-1:2021 Medical devices Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

# Index of Symbols



Consult instructions for use



In vitro diagnostic medical



REF Catalogue number





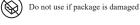
Caution





Date of manufacture







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