TRUEchemie Creatinine Test Kit (2R - Modified JAFFE)

for the quantitative determination of Creatinine in human serum or plasma or urine

INTENDED USE

The TRUEchemie Creatinine Test Kit (2R - 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. 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 $\xrightarrow{\text{Alkaline Medium}}$ Creatinine - Picrate Complex

PACK SIZE

Kit size	**4 x 50 ml**
Cat no.	**ADX131**
Kit contents	
1) Creatinine Reagent (R1)	2 x 50 ml
2) Creatinine Reagent (R2)	2 x 50 ml
3) Creatinine Standard (2 mg/dL)	1 x 5 ml

REAGENTS COMPOSITION

1) Working Reagent

Picric acid : > 7.0 mmol/L
Sodium hydroxide : > 120 mmol/L
Activators and stabilizers

2) Creatinine standard : 2 mg/dL

REAGENT PREPARATION

Working reagent: Mix Creatinine Reagent (R1) and Creatinine Reagent (R2) at the ratio of 1:1.The prepared working reagent is stable for 1 week, if stored in dark at room temperature.

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 15-30ºC 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 : 37°C
Prewarm the reagent to reaction temperature.

	Blank (µl)	Standard (µl)	Sample (µl)
Distilled Water	1000	-	-
Working Reagent	-	1000	1000
Creatinine Standard	-	50	-
Sample	-	-	50

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 follows:

Initial absorbance A_0 – Exactly after 30 sec.
Final absorbance A1 – Exactly after 90 sec. after A_0
Determine ΔA for Standard (S) and Test (T)

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

Calculations:

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

Urine Creatinine (g/L) = $\frac{\Delta AT}{\Delta AS} \times 2$

Urine Creatinine / 24 hours = Urine Creatinine in g/L x Vol. of Urine in 24 hours collected in litres

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 : 0.9 – 1.5 mg/dL
Females : 0.7 – 1.37 mg/dL
Urine in 24 hours collection
Males : 1.1 – 3.0 gm
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 25 mg/dL under the described assay conditions. If the concentration is greater than linearity (Up to 25 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 analyzers used.

PRECISION:

Intra-assay precision within run (n=10)	**Mean (mg/dL)**	**SD (mg/dL)**	**CV (%)**
Low	2.2	0.1	4.3
High	5.6	0.2	3.0

Inter-assay precision run to run (n=12)	**Mean (mg/dL)**	**SD (mg/dL)**	**CV (%)**
Low	2.5	0.1	4.1
High	5.5	0.1	2.4

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=0.991x+0.109. 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

Mode	:	Fixed Time / Initial Rate / Two point Kinetic
Std. conc.	:	2
Wave length	:	520 nm (490 – 520)
Units	:	mg/dL
Flow cell temp.	:	37°C
Blank	:	Distilled Water
Working reagent volume	:	1000 µl
Sample volume	:	50 µl
Delay (Lag) time	:	30 Sec.
Fixed read time	:	90 Sec.
Low normal	:	0.7
High normal	:	1.5
Sensitivity	:	0.05
Linearity	:	25
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 W.B.Saunders Co., Philadelphia. PA. 1986.
3. Bartels, H. et al,(1971),Clin.Chem.Acta,32 : 81.
4. 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	REF Catalogue number	Caution
IVD *In vitro* diagnostic medical device	LOT Batch code	Non-sterile
15°C 30°C Temperature limit 15-30°C	Do not re-use	Use-by date
Manufacturer	Date of manufacture	Keep dry
Do not use if package is damaged		Keep away from sunlight

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