CREATININE "Mod. Jaffe"

Diagnostic reagent for determination of Creatinine concentration.

Liquid. Dual Reagents. Store at 15°C - 25°C
For in Vitro Diagnostic Use. Do not freeze

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
A2160	4X100 ml	T2160	4091 Tests	R2161	962 Tests	L2160	3000 Tests
A2161	4x50 ml	T2161	2841 Tests	BY2160	11136 Tests	L2161	1600 Tests
A2162	4x25 ml	S2160	2338 Tests	BY2161	6264 Tests	M2160	848 Tests
DM2160	960 Tests	S2161	1559 Tests	K2160	7000 Tests	M2161	1061 Tests
N2160	800 Tests	R2160	2885 Tests	K2161	5000 Tests		

INTENDED USE

Test for quantitative determination of creatinin in human serum, plasma and urine.

TEST PRINCIPLE

Creatinine reacts with picric acid in alkaline environment to form a color complex. Developing of this red color may be followed by photometrically at 500-520 nm. The association on surfactant and sodium tetraborate keeps interferences at minimum.

TEST PARAMETERS

Method : Colorimetric, Kinetic, "mod."Jaffe, Increasing Reaction
Wavelength : Hg 510 nm (500 nm - 520 nm)
Temperature : 37°C
Sample : Serum, heparinized Plasma, Urine
Linearity : 0.20 mg/dL - 20 mg/dL

REAGENT COMPOSITION

Reagent 1: (R1)
Carbonate Buffer ≤ 120 mmol/L
Sodium Hydroxide ≤ 360 mmol/L
Reagent 2: (R2)
Picric Acid ≤ 7.8 mmol/L

REAGENT PREPARATION

Mix 1 unit of reagent 1 and 1 unit of reagent 2.
Working reagents are stable up to 30 days at 15-25°C, well capped and away from light sources. Stability of unmixed reagents: up to expiration date on labels at 15-25°C; Stability since first opening of vials of unmixed reagents: ≥ 60 days at 15-25°C.
For manual working procedures; if working reagent will be used; shake the Reagent 2 vial gently before pouring its contents into the Reagent 1 bottle. It is advisable to wash the Reagent 2 vial with a small volume of the prepared mixture in order to completely rinse the vial and avoid any losses.

REAGENT STABILITY AND STORAGE

Store at 2-8ºC.
Reagents are stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during their use.
Once opened vials are stable minimum 30 days at 2-8 C at optimum conditions. On board stability is strongly related to auto analysers cooling specification and carry-over values.

SAMPLE

Serum, plasma, Urine. Creatinine is stable 24 hours at 2-8°C. Freeze samples for prolonged storage.
Dilute urine sample 1:100 with deionized water. It could be convenient a slight acidification of urine with HCl.

TEST PROCEDURE

Sample Start
There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

Substrate Start
There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

$$\frac{\Delta A \text{ Sample}}{\Delta A \text{ Standard}} \times \text{Concentration of Standard} =$$

mg/dL (µmol/L) Creatinine in sample. For urine multiply result by 20.

Unit Conversion
mg/dL x 88.4 = µmol/L

REFERENCE INTERVALS (NORMAL VALUES) (Based on rules CLSI C28-P Document)*

Serum / Plasma:
Serum/plasma samples:
Men : 0.7 - 1.2 mg/dl (62 - 105 µmol/l)
Women: 0.6 - 1.1 mg/dl (53 - 97 µmol/l)

24h urine:
Men : 1000-2000 mg/24h (8.85-17.70 mmol/24h)
Women: 800-1800 mg/24h (7.08-15.93 mmol/24h)

*It is recommended that each laboratory establish its own normal range.

QUALITY CONTROL AND CALIBRATION

All control sera with Creatinine values determined by this method can be used. We recommend:

Assayed Control Serum Normal
A3910 ARCON N
Assayed Control Serum Abnormal
A3920 ARCON P

This assay requires the use of a Creatinine Standard or a Creatinine Calibrator. We recommend:

A2160S Creatinine Standard (Conc. 2 mg/dl)
A39050 Calibrator (ARCAL AUTO)

Any commercially available Standard or Calibrator suitable for this method may be used.

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 1 day in general.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low Linearity: 0.20 mg/dL
High Linearity: The method is linear up to 20 mg/dL.
If the value is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10.

Precision Studies (Based on CLSI EP5 Doc.):

Repeatability (within run)(intra-assay)

mean (mg/dl)	SD (mg/dl)	CV%	n
1.25	0.03	2,60	10
3.87	0.07	1.90	10

Reproducibility (run to run)(inter-assay):

mean (mg/dL)	SD (mg/dL)	CV%	n
1.31	0.04	2.90	20
3.80	0.14	3.80	20

Sensitivity (LOD) (Based on CLSI EP17 document): The limit of detection is 0.2 mg/dl.

Trueness: A comparison between Archem and a commercially available product gave the following results:
Cretinine Archem = x
Creatinine competitor = y
n = 104
y = 0.982x - 0.081 mg/dl r^2 = 0.94

Interferance: No interference was observed by the presence of:
Hemoglobin ≤ 200 mg/dL
Bilirubin ≤ 7 mg/dL
Lipids ≤ 600 mg/dL

These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human&animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should capped and kept at 2-8°C. Caps of the reagents bottles can not be used between two different kind of reagent and between R1 & R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general “Good Laboratory Practice” (GLP) guidelines.

R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
S28 : After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.
S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CLSI : Clinical and Laboratory Standards Institute
CV% : Coefficient of Variation Percentage
EP : Evaluation Protocols
GLP : Good Laboratory Practice
IU : International Unit
mA : miliabsorbance
mL : mililiter
NCCLS : National Committee for Clinical Laboratory Standards
QC : Quality Control

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4. Young DS. *Effects of Drugs on Clinical Laboratory Tests.* 3rd ed. Washington: AACC Press; 1990.
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SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
R2	Reagent 2
CONC	Concentration
INGRED	Reagent Ingredients
SN	Serial Number
REF	Reference Number (Catalog No)
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk

CE

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