AGD

CliniPak

CREATININE

(Jaffe Method)

Code	Pack Size
AGDSP - CRA200	R1 : 5 X 20 mL R2 : 5 X 20 mL
AGDSPCRA180	R1-5 x 18mL R2-5 x 18mL
AGDSPCRA360	R1-10 x 18mL R2-10 x 18mL
AGDSPCRA230	R1-5 x 23mL R2-5 x 23mL

INTENDED USE

This reagent kit is intended for in vitro quantitative determination of Creatinine in serum, plasma or urine.

CLINICAL SIGNIFICANCE

Creatinine is released during metabolism of creatine phosphate, and is excreted by the kidneys. Creatinine concentration in blood and in urine is a primary indicator for renal function.

Increased levels: are observed in kidney failure.

Decreased levels: are observed in juvenile diabetes melitus, pregnancy and muscular dystrophy.

PRINCIPLE

Creatinine in an alkaline solution reacts with picrate to form a colored creatinine picrate complex.The rate of development ofcolour is proportional to concentration of creatinine and is measured at 505nm (480 – 520nm).

Creatinine + Picrate → Creatinine- Picrate Complex

PROCEDURE

Reagent 1 + Sample + (150 µL) (60 Sec) Incubation + (30µL)

Reagent 2 ⟶ Measurement (150 µL) 90 sec (505nm)

REAGENT COMPOSITION

REAGENT 1

Sodium Hydroxide	500 mmol/L

REAGENT 2

Sodium Picrate	32 mmol/L

REAGENT STORAGE AND STABILITY

Creatinine is a two-reagent system ready to use.

The reagent is stable till the expiry date stated on the reagent bottle label when stored at 2-8ºC and protected from light.

SAMPLE

Collect sample using standard sampling tube. Fasting sample are preferred. Serum or plasma can be used. Creatinine determination in urine containing thymol as preservative is usually carried out on a 12- or 24-hour urine sample.

BASIC PARAMETER

SHORT NAME	CREAT
NAME	Creatinine
METHOD	JAFFE
ASSAY	Fixed Time
MAIN WAVE	505nm
SUB WAVE	0
DECIMAL	2
UNIT	mg/dL
R1 VOLUME	150µL
INCUBATION	60 secs
R2 VOLUME	150µL
INCUBATION	60 secs
SAMPLE VOLUME	30µL
REACTION TIME (DELAY)	30 secs
CHECK TIME (READ)	60 secs
LINEAR RANGE	0-25
ABSORBANCE RANGE	0-2.5
LINEARITY LIMIT	30
SUBSTRATE SHORTAGE	> 1.3
DILUTION RATIO	6
SAMPLE VOLUME	50
CALIBRATION TYPE	SINGLE SPOT LINEARITY

*Enter calibrator value as per the lot of calibrator and method

LINEARITY

Reagent is linear up to 25 mg/dL.
Dilute the sample appropriately and re-assay if creatinine concentration exceeds 25 mg/dL. Multiply result with dilution factor.

PRECISION

Reproducibility of within run, determined using quality control sera as shown below.

Quality control material	Mean mg/dL	SD mg/dL	% CV
Low Control serum	1.42	0.013	0.089
High Control serum	3.57	0.025	0.67

n=15

REFERENCE NORMAL VALUE

Serum/Plasma
Males : 0.6 -1.3 mg/dL
Females : 0.5 - 0.9 mg/dL

Creatinine Clearance rate

Males : 97-137 mL/min/1.73m^2 Females : 88 -128 mL/min/1.73m^2

QUALITY CONTROL

To ensure adequate quality control,it is recommended that the laboratory should use a normal and abnormal commercial reference control serum.The quality control material is used to check the function of reagents and the machine together.

LIMITATIONS & PRECAUTIONS

- Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
- Storage condition as mentioned on the kit to be adhered.
- Before the assay bring all the reagents to the room temperature.
- Avoid contamination of the reagent during assay process.
- Use clean glassware free from dust and debris.
- Reagent to sample ratio as mentioned above must be strictly adhered, as any changes it affects the factor and result.
- In case reagent comes in contact with eyes,immediately rinse with plenty of water and seek medical advice.

REFERENCES

- mod.acc.to Bartels, H,et.al.(1971).Clin. Chem. Acta 32:81.
- Schirmeister. J.et.al. (1964). Dtsch. Med. Wschr. 89:1018

AGD Biomedical Pvt. Ltd.
Site 2 : Plot No. W-29 E, TTC Industrial Area,MIDC,Thane Belapur Road, Rabale, Navi Mumbai,Thane, Maharashtra,(India)- 400701.
E : indiasales@agdbio.com
W : www.agdbio.com

ISO 13485:2016 ISO 9001:2015

EU REP

Obelis s. a.
Bd General Wahis
53 1030 Brussels Belgium
Phone : +32 2 732 59 54