QUADRAPED™

CREATININE KIT

(Mod. Jaffe's Kinetic Method)

(For veterinary invitro diagnostic use only)

INTENDED USE

QUADRAPED™ Creatinine kit is used for the determination of Creatinine in serum.

SUMMARY

Creatinine is the catabolic product of creatinine 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) 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 fixed time is directly proportional to the amount of creatinine present in the sample.

Creatinine + Alkaline Picrate ⟶ Orange Coloured Complex

EXPECTED VALUES

Species	Creatinine (mg/dl)
Dog	0.5 - 1.7
Cat	0.9 - 2.2
Cow	0.5 - 2.2
Horse	0.4 - 2.2
Pig	1.0 - 2.7
Sheep	1.2 - 1.9
Goat	1.0 - 1.8
Rabbit	0.5 - 2.5
Buffalo	0.5 - 1.5

It is recommended that each laboratory establish its own range as reference ranges may vary between laboratories.

PRESENTATION

REF	1126080235
Pack Size	2 x 35 ml
L1 Picric Acid Reagent	35 ml
L2 Buffer Reagent	35 ml
S Creatinine Standard (2 mg/dl)	5 ml

COMPOSITION

Picric Acid 10mM; NaOH 150mM; Non Reactive Stabilizers and Preservatives.

STORAGE / STABILITY

Contents are stable at 23-29°C till the expiry mentioned on the labels.

REAGENT PREPARATION

Reagents are ready to use. Do not pipette with mouth.

Working reagent: For larger assay series a working reagent may be prepared by mixing equal volumes of Picric Acid Reagent and Buffer Reagent. The Working reagent is stable at R.T. (25 - 30° C) for at least one week.

SAMPLE MATERIAL

Serum. Creatinine is reported to be stable in the serum for 3 days at 2-8°C.

SAMPLE WASTE AND DISPOSAL

Do not reuse the reagent containers, bottles, caps or plugs due to the risks of contamination and the potential to compromise reagent performance.
Appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.
Handle specimens, solid and liquid waste and test components in accordance with local regulations and NCCLS guidelines M29, or other published biohazard safety guidelines.

MATERIALS REQUIRED BUT NOT PROVIDED

Photometer analyzer with standard thermostatic cuvette holder, micropipette and appropriate laboratory equipment.

PROCEDURE

Wavelength / filter : 520 nm (Hg 492 nm) / Green
Temperature : 30° C / 37° C
Light path : 1 cm

Pipette into clean dry test tubes labelled as Standard (S) or Test (T):

Addition Sequence	(S) / (T) 30° C / 37° C
Picric Acid Reagent (L1)	0.5 ml
Buffer Reagent (L2)	0.5 ml
Bring reagents to the assay temperature and add	
Creatinine Standard (S) / Sample	0.1 ml

Mix well and read the initial absorbance A_1 for the Standard and Test after exactly 30 secs. Read another absorbance A_2 of the Standard and Test exactly 60 secs. later. Calculate the change in absorbance ΔA for both the Standard and Test.

For Standard $\Delta AS = A_2S - A_1S$
For Test $\Delta AT = A_2T - A_1T$

CALCULATIONS

$$\text{Creatinine in mg/dl} = \frac{\Delta AT}{\Delta AS} \times 2.0$$

QUALITY CONTROL

The following process is recommended for QC during the assay of Creatinine. *Define and establish acceptable range for your laboratory.

1. Two levels of control (Normal and Abnormal) are to be run on a daily basis.
2. If QC results fall outside acceptance criteria, recalibration may be necessary.
3. Review QC results and run acceptance criteria following a change of reagent lot.

SPECIFIC PERFORMANCE CHARACTERISTICS

LOD: 0.1 mg/dl
LOQ: 0.06 mg/dl
Lower Limit:0.1 mg/dl
Higher Limit: 20 mg/dl
If values exceed this limit, dilute the sample with distilled water and repeat the assay. Calculate the value using the proper dilution factor.

Interferences:

Sample when spike with interferent such as upto 15 mg/dl Bilirubin, 1000 mg/dl intralipid and 10 g/L Haemoglobin does not affect the ability of the kit to determine the creatinine concentration.

Precision:

Within run

Within run	n	Mean	SD	% CV
Sample 1	10	1.49	0.02	1.10
Sample 2	10	3.91	0.05	1.31
Sample 3	10	1.00	0.07	7.66

Between run

Between run	n	Mean	SD	% CV
Sample 1	10	1.49	0.02	1.13
Sample 2	10	3.92	0.04	1.10
Sample 3	10	1.04	0.04	4.40

Method comparison:

Comparative studies were done to compare our reagent with another commercial Creatinine Assay. No significant differences were observed. Details of the comparative studies are available on request.

NOTE

In vitro diagnostic reagent for laboratory and professional use only Not for medicinal use. The reagent contain sodium azide 0.1% as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water. Only clean and dry glassware must be used. The determination is not specific and may be affected by the presence of large quantities of reducing substances. As the test is temperature sensitive it is essential to maintain the indicated reaction timings and temperatures meticulously during the test procedure.
Standard is Traceable to Standard Reference Material (SRM) 909b.
.Do not use turbid, deteriorated or leaking reagents.

REFERENCES

1. Bowers, L.D. (1980) Clin. Chem. 26:551.
2. Bowers, L.D. et al. (1980) Clin. Chem. 26: 655.
3. Duncan and Prasse's Veterinary Laboratory Medicine: Clinical Pathology, Kenneth S. Latimer, ISBN Jane Wardrop, 6th Edition - 2010.
4. Clinical Biochemistry of Domestic Animals, Sixth Edition, 2008 by Kaneko J.J., Harvey J.W. & Bruss M.L.
5. Data on file: Coral Clinical Systems.

System Parameters			
Reaction	: Fixed Time Kinetic	**Interval**	: 60 Sec.
Wavelength	: 520 nm	**Sample Vol.**	: 0.10 ml
Zero Setting	: Distilled Water	**Reagent Vol.**	: 1.00 ml
Incub. Temp.	: 30° C / 37° C	**Standard**	: 2 mg/dl
Incub. Time	: —	**Factor**	: —
Delay Time	: 30 Sec.	**React. Slope**	: Increasing
Read Time	: 60 Sec.	**Linearity**	: 20 mg/dl
No. of read.	: 2	**Units**	: mg/dl

SYMBOL KEYS

29°C / 23°C Store at 23-29°C	Manufacturer	IVD *In vitro* Diagnostic Medical Device	L1 Picric Acid Reagent	Mod. Jaffe's Kinetic — Mod. Jaffe's Kinetic Method
Use by (Last day of stated month)	Consult Instructions for use	LOT Batch Number	L2 Buffer Reagent	H315
Date of Manufacture	REF Catalogue Number	This way up	S Creatinine Standard (2 mg/dl)	

Manufactured by:
Coral Clinical Systems
A Division of Tulip Diagnostics (P) Ltd.
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REGD. OFFICE : GITANJALI, TULIP BLOCK, DR. ANTONIO DO REGO BAGH, ALTO SANTACRUZ, BAMBOLIM COMPLEX P.O., GOA-403 202, INDIA.

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