CREATININE E. P.

(JAFFE'S) - COLORIMETRIC END-POINT

LIQUI STAT

BIO LAB DIAGNOSTICS

ISO 9001:2015
ISO 13485:2016
CE

CLINICAL SIGNIFICANCE

Increased levels are associated with substantially impaired renal function.

PRINCIPLE

In an alkaline medium, creatinine reacts with picrate to produce an **ORANGE YELLOW** colour. The coloration is proportional to the creatinine concentration.

REAGENTS COMPOSITION

1. Picric acid	**2 × 80 mL**
Picric acid	9.6 mMol/L
2. Sodium Hydroxide	**50 mL**
Sodium Hydroxide	750 mMol/L
3. Standard	**15 mL**
Creatinine	2 mGs/dL

STORAGE AND STABILITY

18 months at 18-25°C away from light.
Standard to be stored at 2-8°C.

SAMPLE

Non-haemolysed serum or plasma (Heparin or EDTA)
No prior patient preparation is needed. (All samples should be handled as potential infective agents as no laboratory methods make conclusive findings for its safety. Therefore, adequate protective laboratory measures should be taken while handling such materials).

URINE SAMPLE

If Urine to be tested use fresh sample.
Dilute urine 1 to 25 or 1 to 50 in distilled water. Perform test with the dilution as per the serum. Multiply result by dilution factor (25 or 50)

WARNING

This reagent system is for ***invitro*** use only. This reagent system contains preservatives and components that have not established for safety if contacted on broken skin or eye or taken orally. In case of such incidents wash off with plenty of water, or consult a physician.

MANUAL PROCEDURE

STEP 1. PROTEIN PRECIPITATION

Pipette into a Centrifuge tube

Serum or Plasma	**1 mL**
Picric Acid Reagent No. 1	**3 mL**

Mix well. Keep in a boiling water bath for one minute. Cool immediately and separate clear supernatant by centrifuge or filteration.

NOTE : Reagent and sample volumes can be altered proportionately.

STEP 2. COLOURING

	Blank mL	Standard mL	Test mL
Pipette into 3 test tubes			
Distilled water	0.5	-	-
Picric Acid Reagent No. 1	1.5	1.5	
Sodium Hydroxide Reagent No. 2	0.5	0.5	0.5
Standard Reagent No. 3	-	0.5	-
Supernatant from Step 1	-	-	2.0

Mix well. Keep at room temperature for 15 mins. Read optical density (OD) at 500-540 nM or **GREEN** filter against blank. ***Final colour is stable up to 30 minutes.***

RESULTS

Creatinine in mGs/dL

$$= \frac{\Delta \text{ OD Test}}{\Delta \text{ OD Standard}} \times 2$$

EXPECTED VALUES

Serum :	0.68 to 1.48 mGs/dL (60 to 130 µMol/L)
Urine :	1 to 2 Gms/24 hrs (9 to 18 mMol/24 hrs)

As with all diagnostic methods, the final diagnosis should not be made on the result of a single test as well as laboratory diagnosis must be confirmed with clinical manifestations.

LIMITATIONS

Alkaline picrate is sensitive to various metalic elements. ***invitro*** addition of metalic compounds or contaminations make false results.
This assay is linear up to 9 mGs/dL Creatinine.
For values higher than 9 mGs/dL (800 µMol/L), repeat the test diluting the serum with distilled water. Multiply results by the dilution factor (i.e. 2 for a dilution of 1:1).

QUALITY CONTROL

To ensure adequate quality control, each kit should be tested against a standard control sera. It should be realised that the use of quality control material checks both instrument and reagent function together. Factors which might affect the performance of this test include proper instrument function, temperature control, cleanliness of glasswares and accuracy of pipetting and timings.
It is appropriate to establish each laboratory's accuracy constant and interpret values accordingly. Similarly, laboratory findings should be established by clinical manifestations.

BIBLIOGRAPHY

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