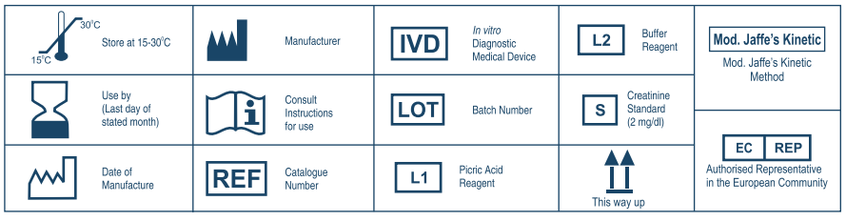
SBio CREATININE KIT

(Mod. Jaffe's Kinetic Method)

(For invitro diagnostic use only)

REF	90452275	90462150
Pack Size	2 x 75 ml	2 x 150 ml

CE



INTENDED USE

Creatinine Kit is used for the determination of Creatinine in serum and urine.

PRINCIPLE OF THE TEST

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

CLINICAL SIGNIFICANCE

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.

PRESENTATION	2 x 75 ml	2 x 150 ml
L1 : Picric Acid Reagent	75 ml	150 ml
L2 : Buffer Reagent	75 ml	150 ml
S : Creatinine Standard (2 mg/dl)	2 x 5 ml	15 ml

COMPOSITION

Picric Acid 10 mM; NaOH 150 mM.

STORAGE / STABILITY

Contents are stable at R.T. (15-30°C) till the expiry mentioned on the labels.

SAMPLE REQUIRED

Serum or Urine.

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 (15 - 30°C) for at least one week.

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.

This product requires the handling of human specimen. It is recommended that all human sourced material are considered potentially hazardous and are handled in accordance with the OSHA standard on blood borne pathogens.

Appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

Handle specimen, solid and liquid waste and test components in accordance with local regulations and NCCLS guidelines M29, or other published biohazard safety guidelines.

PROCEDURE

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

MATERIALS REQUIRED BUT NOT PROVIDED

General laboratory instrumentation like Spectrophotometer/Analyzer, Thermostatic Cuvette holder, Cuvettes, Micropipettes, Test tubes, Waterbath, Stopwatch/Timer.

Pipette into clean dry test tubes labeled 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 / Diluted Urine	0.1 ml

Mix well and read the initial absorbance A_1 for the Standard and Test after exactly 30 seconds. Read another absorbance A_2 of the Standard and Test exactly 60 seconds 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

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

$$\text{Urine Creatinine in g/L} = \frac{\Delta AT}{\Delta AS} \times 1.0$$

Urine Creatinine g/24 Hrs. = Urine Creatinine in g/L x Vol. of urine in 24 Hrs.

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

Linearity:

The procedure is linear upto 20 mg/dl of Creatinine. If values exceed this limit, dilute the sample with distilled water and repeat the assay. Calculate the value using the proper dilution factor.

Limit of detection:

The limit of detection for Creatinine is 0.1 mg/dl.

Interferences:

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Precision:

Precision studies were performed with two controls using NCCLS protocol EP5-A. The results of the precision studies are shown below:

Sample	Within-run		Between-run		Total	
	Mean	CV%	Mean	CV%	Mean	CV%
Control 1	0.93	4.07	0.98	5.69	1.91	9.76
Control 2	3.8	2.80	4.02	2.73	7.82	5.53

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.

REFERENCE RANGE

	Serum	Urine in 24 hrs. collection
Males :	0.6 - 1.2 mg%	1.1 - 3.0 gm
Females :	0.5 - 1.1 mg%	1.0 - 1.8 gm

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

NOTE

Creatinine is stable in serum for 1 day at 2-8°C. Urine of 24 hours collection is preferred. Dilute the specimen 1:50 with distilled / deionised water before the assay. 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. The reagent may be used in several automated analyzers. Instructions are available on request.

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.

Mfd. for:

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EC REP

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