Creatinine Kit

CliniQuant - FSR

Jaffe's Method, Initial Rate

Meril Diagnostics

IVD For *in vitro* diagnostic use
Read this pack insert thoroughly before use

REF	Pack Size	R1 Picric Acid Reagent	R2 Alkaline Reagent	R3 Creatinine Standard
CREFSR-03	4 x 25ml	2 x 25ml	2 x 25ml	1 x 5ml
CREFSR-04	6 x 50ml	3 x 50ml	3 x 50ml	1 x 5ml
CREFSR-05	2 x 250ml	1 x 250ml	1 x 250ml	2 x 5ml
CREFSR-06	2 x 500ml	1 x 500ml	1 x 500ml	2 x 5ml

INTENDED USE

This reagent is intended for quantitative determination of creatinine concentration in human serum or plasma and urine.

CLINICAL SIGNIFICANCE

Creatinine is a waste product formed from creatine phosphate, a high energy storage compound. It is removed from plasma by glomerular filtration and then excreted in urine. Creatinine is a useful indicator of renal function.

Elevated levels of creatinine are associated with abnormal renal function as it relates to glomerular filtration.

Serum creatinine levels are used in combination with Urea/BUN to differentiate between pre-renal and renal causes of azotemia (condition of increased BUN level).

PRINCIPLE OF THE METHOD

Creatinine reacts with picric acid in alkaline environment to form an orange-red color complex. Developing of this orange-red color may be followed photometrically at 500-520 nm.

$$\text{Creatinine} + \text{Picrate} \xrightarrow{\text{alkaline medium}} \text{orange-red complex}$$

KIT COMPONENTS

Composition :

R1- Picric Acid Reagent : Picric Acid 11 mmol/l

R2 – Alkaline Reagent : Alkaline solution 394 mmol/l

R3 - Creatinine Standard : 2 mg/dl

MATERIALS REQUIRED BUT NOT PROVIDED

Laboratory instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi automated, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/ rack, heating bath, controls, saline.

REAGENT PREPARATION, STORAGE & STABILITY

Reagent 1 and Reagent 2 are ready to use. Keep away from direct light sources.

Stability: up to expiration date on labels at 2-8 °C.

Upon opening of kit, store Reagents R1 and R2 at 15-30 °C and standard at 2-8 °C.

REAGENT DETERIORATION

Keep the Standard vial plugged after use, in order to avoid deterioration.

WARNINGS AND PRECAUTIONS

1. Reagent contains strong alkali. Do not mouth pipette. It is recommended to handle carefully by entitled and professionally educated person, avoiding contact with skin and ingestion.
2. Picric acid may cause allergic reactions.
3. Specimens should be considered infectious and handled appropriately.
4. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN

Serum (preferred) plasma (heparinate). Avoid severely hemolysed specimen collection. Samples are stable for 7 days at 2-8 °C & 3 months when frozen.

Dilute urine sample 1:100 with deionised water and multiply results by 100.

Programme Parameter for MERILYZER CliniQuant

Reading Mode	Kinetic
Standard Conc.	2.0 (mg/dl)
Filter – 1 (nm)	505
Temperature	37 °C
Volume (µl)	500
Delay Time (Sec)	60
Read Time (Sec)	60
Reaction Direction	Increase
Reference Low	0.6
Reference High	1.4
Linearity Limit	30

CE
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TEST PROCEDURE

Dispense	Standard	Sample
Reagent 1	500 µl	500 µl
Reagent 2	500 µl	500 µl
Standard	100 µl	-
Sample	-	100 µl
Mix, incubate for 60 seconds at 37°C, then record absorbance as A_1. After exactly 60 seconds, record again absorbance as A_2.		

RESULT CALCULATION

Serum/plasma:

creatinine mg/dl = A_2-A_1(sample)/A_2-A_1(standard) x Concentration of Standard

Random urine sample:

creatinine mg/dl = A_2-A_1(sample)/A_2-A_1(standard) x Concentration of Standard x 100

24 hours urine sample (creatinine mg/24h):

A_2-A_1(sample)/A_2-A_1(standard) x Concentration of Standard x 100 x Urine volume

SI conversion factor: 1 mg/dl x 88.4 = 1 µmol/l

EXPECTED VALUES

Men: 0.6 – 1.4 mg/dl OR 53 – 124 µmol/l

Women: 0.6 – 1.2 mg/dl OR 53 – 106 µmol/l

24h urine:

Men: 1000 – 2000 mg/24h OR 8.84 - 17.68 µmol/24h

Women: 800 – 1800 mg/24h OR 7.07 - 15.91 µmol/24h

It is recommended that each laboratory verifies this range or derives reference interval for the population it serves.

QUALITY CONTROL AND CALIBRATION

It is suggested to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result.

Using the recommended Calibrator (BioCal) or the Standard included, calibrate the assay:

a. When using a new reagent or lot

b. When QC values are out of range

PERFORMANCE CHARACTERISTICS

1. Linearity

The linearity is up to 30 mg/dl or 2652 µmol/l.

2. Sensitivity/ Limit of detection (LOD)

The limit of detection is 0.1 mg/dl.

The limit of quantification is 0.3 mg/dl.

3. Interferences

Gross hemolysis causes falsely elevated results.

4. Precision

Intra-assay precision/ Within run precision

	Mean	SD	CV
n = 20	mg/dl	mg/dl	%
sample 1	1.49	0.01	0.56
sample 2	3.88	0.02	0.52

Inter-assay precision/ Run to run precision

	Mean	SD	CV
n = 20	mg/dl	mg/dl	%
sample 1	1.44	0.05	3.54
sample 2	3.89	0.14	3.67

5. Methods Comparison

Comparison was done between reference Creatinine Reagent and CliniQuant - FSR Creatinine Reagent (test)

N = 36 $y = 1.032x - 0.076$

$r^2 = 0.991$

LIMITATIONS

Samples with values above 30 mg/dl should be diluted with 0.9% saline, re-run and multiply results by dilution factor.

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for correct waste disposal.

REFERENCES

1. Burtis, C.A., Ashwood, E.R., editors. Tietz Textbook of Clinical Chemistry. 2nd ed. Philadelphia, W.B. Saunders Company, 1994, p. 1532 - 1537.

2. Data on file: Meril Diagnostics.

IFU/CREFSR03/01

17-12-2018

Symbols used on Meril Diagnostics labels:

REF	Catalogue No.		Attention See Instruction for Use
LOT	Batch No.	IVD	*In vitro* Diagnostics
	Expiry Date		Consult Instruction for Use
	Manufacturer		Storage Temperature
	Keep Dry		Keep Away from Sunlight
	Manufacturing Date		Do not use if package is damaged
EC REP	Authorized European Representative in the European Community		