Creatinine – Instructions for use (IFU)

Distributed by: ISE S.r.l. CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

R1: 4 x 50 mL – R2: 4 x 20 mL • REF A-R0200000501

R1: 3 x 18,5 mL – R2: 1 x 18,5 mL • REF R3330000018

IVD CE

INTENDED USE
Product for use in the quantitative determination in vitro of the Creatinine concentration in human serum or urine. The results of the test must always be interpreted in conjunction with the clinical context. For professional use only.

CLINICAL SIGNIFICANCE
Creatinine is synthesized in the kidneys, the liver and the pancreas, and is subsequently transported in the blood to other organs such as the muscles and the brain. As the production of endogenous creatinine is proportional to the muscular mass, it varies according to age and sex. The influence of the amount of meat taken in daily in the diet can be considered to be approximately 10%. In general, however, daily fluctuations in the creatinine present in the diet cause only minor variations in the daily excretion levels. High creatinine levels are seen in cases of acute or chronic renal insufficiency and in dehydration.

PRINCIPLE
Jaffé (1) was the first to describe the reaction which takes place between creatinine and an alkaline picrate solution, with formation of a coloured compound. Subsequently the method used for the determination of serum creatinine was modified to improve its specificity. Creatinine reacts with alkaline picrate, forming a coloured compound which is measured at 505 nm. The rate of the colour formation is proportional to the creatinine concentration.

REAGENTS
A-R0200000501 R1: 4 x 50 mL - R2: 4 x 20 mL
Reagent 1: n°4 vials x 50,0 mL ready for use
Reagent 2: n°4 vials x 7,0 mL ready for use
R333000018 - R1: 3 x 18,5 mL - R2: 1 x 18,5 mL
Reagent 1: n°3 vials x 12,6 mL ready for use
Reagent 2: n°1 vials x 4,4 mL ready for use

Concentrations

Reagent 1:			
	Conc.	**U.M.**	
Picric Acid	20,5	mM	 *GHS05
Reagent 2:			
Sodium Hydroxide 5%	1,25	M	 *GHS05

*_ **Warning:** DANGER
Only for R2: *Contains Sodium hydroxide (CAS 1310-73-2)*
H314 – It causes severe skin burns and severe eye damage.
P303+P361+P353 - IN CASE OF CONTACT WITH SKIN (or hair): remove all contaminated clothing immediately. Rinse skin/take a shower.
P305+P351+P338 – IN CASE OF CONTACT WITH EYES: rinse thoroughly for several minutes. Remove any contact lenses if it is easy to do so. Keep rinsing.
P310 – Contact a POISON CENTER/doctor immediately.
P321 - Specific treatment (see on this label).
P501 – Dispose of the product/container in accordance with local / regional / national / international regulations.

Precautions for use
Kit for professional laboratory use, used only by qualified and properly trained technical personnel, under the supervision of a doctor in charge of the laboratory. In addition to any risk statements relating to active components, reagents may contain non-active components such as preservatives and detergents. The total concentration of these components is below the limits set out in EC 1272/2008 Regulation and subsequent amendments and additions. However, it is recommended to handle the reagents according to the rules of good laboratory practice.

Reports of serious incidents
In the event of a serious incident in relation to the use of the device, please inform the manufacturer (via your distributor) and the competent authority of the European Union member state where the incident occurred. For other jurisdictions, reporting must be made in accordance with regulatory requirements. Reporting serious incidents helps provide more information about the safety of the diagnostic medical device.

Storage and stability
Store at 2 - 8°C; protect from direct light. When correctly stored, the reagents are stable up to the expiry date reported on the label.
A slight variation in the composition of the reagents may occur between batches, but this has no effect on the test results.
After opening, the vial R1 and R2 are stable 30 days if recapped immediately and protected from contamination, evaporation, direct light and stored at correct temperature

SAMPLE COLLECTION
Type of sample and storage
Creatinine is stable in the samples (serum or urine) for 24 h if stored at 2 - 8°C. Fluoride or fluoride or thymol can be used as preservative to store the creatinine at room temperature for about 5 days. If frozen at – 10°C, creatinine is stable in the plasma or serum for several months (2). Use non diluted serum, or urine collected in 24 hours diluted 1:100 with distilled water.

Precautions
All human samples must be handled and disposed of as potentially infectious materials.

Procedure
Quality control
Control sera with a known titer of Creatinine are commercially available for quality control, including certificates of analysis showing the values and confidence limits. Normal and pathological control sera are available as "Normal control serum" cod. R0400000006 and "Pathological control serum" code R0400000106. The values obtained must be contained within the acceptability range. In case of incorrect results check the following points:
- Glassware cleaning.
- Wavelength.
- Expiration date of reagents.

Automation
Although this device has been developed and manufactured to be used with manual methods and instrumental systems, it can also be used in combination with other instrumental devices that are able to meet the requirements indicated in the paragraph "Reaction conditions / Technique".
All applications that are not explicitly approved cannot be guaranteed in terms of performance and will therefore have to be evaluated by the user.

Calibration
For calibration use the kit "Multicalibrator" code R0300000006. For ISE srl instruments calibration every 10 days is recommended.

Reaction conditions
Wavelength (primary): 510 nm
Wavelength (secondary): 660 nm
Temperature: 37°C

Technique - Procedure with Regaente B as starter
Bring the reagents to the reaction temperature.

	U.M.	**Calib. Serum**	**Sample**	**Blanck**
Reagent A	µL	1000	1000	1000
Calib.Serum	µL	20	-	-
Sample	µL	-	20	-
Water	µL	-	-	20
Mix gently and incubate at 37°C for 1-5 min. and add				
Reagente B	µL	100	100	100

Mix well and incubate at 37°C. Then read the first extinction value after 30 seconds from the addition of the sample, make the second reading after 60 seconds.
Read the absorbances of the sample and the calibration serum by subtracting the absorbance of the reagent white.
The reaction volumes can be varied proportionately, the calculation remaining unchanged.

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Results
The concentration of Creatinine is obtained through this formula:

$$\frac{\Delta \text{ D. O. Sample}}{\Delta \text{ D.O. Calib.Serum}} \times \text{Conc. Calibr.} = \text{Creatinine mg/dL}$$

$$\frac{\Delta \text{ D. O. Sample}}{\Delta \text{ D.O. Calib. Serum}} \times \text{Conc. Calibr. x 100} = \text{Creatinine urine mg/dL}$$

Mix well and after 3 minutes of waiting take the reading at 37 ° C. Read the absorbances of the sample and the calibration serum by subtracting the absorbance of the reagent white, complete the readings within 5 minutes The reaction volumes can be varied proportionally, the calculation remains unchanged

Results
The concentration of Creatinine is obtained through the following formula:

$$\frac{\Delta \text{ D.O.Campione}}{\Delta \text{ D.O.Siero di Calibrazione}} \text{ x Conc. Siero di Calib. (mg/dL)} = \text{Conc.Creatinina (mg/dL)}$$

Reference range

Serum		
Woman	mg/dL	0,3 – 0,8
Man	mg/dL	0.4 – 1.1
Urine		
Man/Woman	mg/day	1000 – 1700

Each laboratory should establish its own normal values according to the population in which it operates.

Materials included in the kit
Reagent described above.

Necessary materials not included in the kit
Controls and calibrators.

ANALYTICAL CHARACTERISTICS/PERFORMANCE
Linearity
The method is linear up to 7.0 mg/dL. For higher concentrations, dilute the sample with purified water and multiply the result by the dilution factor.

Specificity
This method is more specific than the normal «End Point» methods.

Interference
The following substances showed no interference up to the concentrations reported: Glucose 600 mg/dL, Fructose 200 mg/dL, Acetone 20 mg/dL, Ascorbic Acid 20 mg/dL. Serum and plasma samples contain proteins which react nonspecifically in the Jaffé method. Serum and plasma results can be corrected by 0.3 mg/dL (26.5 µmol/L) to obtain accurate values.

Accuracy-Recovery
Accuracy studies were performed on normal samples to which known amounts of Creatinine had been added. The results indicate an average recovery of 100.2%.

Sensitivity
At λ 505 nm a concentration of about 0.055 mg/dL of Creatinine, in the conditions established for this test.

Precision of the method

Within-run precision					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	mg/dL	0.868	0.062	6.91%	20
High	mg/dL	2.23	0.107	4.78%	20
Between-run precision					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	mg/dL	0.868	0.062	7.15%	30
High	mg/dL	2.23	0.130	5.83%	30

Comparative method
The test was compared with the Teger-Nilsson method (3) which utilizes ionic-exchange resins to obtain the true Creatinine value, and the following results were obtained: y = 0.856x – 0.33 and a correlation coefficient: r = 0.941.

Disposal of reagents
Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

Manufacturer:
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Symbols used in IFU and Packaging	
IVD In vitro diagnostic medical device vitro	Manufacturer
REF Catalogue Number	Instruction for use
LOT Lot Number	Temperature limitation
Expiration date	

Reference

1. Jaffe M. Z Physiol Chem 1886; 10: 391-400.
2. Henry RJ. Clinical Chemistry: Principles and Technics. Harper & Row Publishers, New York 1968; 287-292.
3. Teger-Nilsson AC. Scand J Clin Lab Invest 1961; 13: 326-331.

REVISION	DATE	CHANGE
Rev.A	12/2022	New Issue for IVDR Regulation (UE) 2017/746 compliance