Creatinine (Cr)
(Jaffe/Colorimetric(1:1) Method)

- **Kit Specifications:**

	Reagent/Quantity	Storage
Cat. No.: **CR0011**	R.1: 3x 50 ml R.2 3x50ml total 300 ml	2-8°C
Cat. No.: **CR0017**	R.1: 3 x 50 ml R.2 3x 50ml total 300 ml	2-8°C

- **Intended Use:**
In Vitro Diagnostic reagent pack for the quantitative determination of Creatinine in human serum/plasma and urine on automated and semi-automated photometric systems.

- **Summary and Explanation:**
The Creatinine is a composition that contain nitrogen but non protein, exist in the blood stream which produce in muscle and remove by urine. The creatinine is a final product of creatine dehydration or dephosphorelation of phosphor creatine. This reaction normally occurred in the all muscles. The all process is an unlike of urea. The serum amount of creatinine is not influenced by other factors which is not related to kidney such as intensity of dehydration and the protein catabolism. The creatinine unlike urea with a firm amount appearance on blood stream which pass through the glomerular filtration rate (GFR) and remove by urine. The amount of creatinine in healthy person should be stable but the extreme fluctuations of it is not related to the volume of consumed fluids and volume of the urine pass. The level of the creatinine is low related to diet, age, gender and exercise. The increase level of creatinine in plasma is an indicator of low filtration in GFR, so there is kidney failure occurred. The creatinine is not a sensitive indicator of kidney disease in early stages but is essential in chronic kidney disease. The direct relation of creatinine concentration plasma and GFR is critical. The analysis of urine creatinine is important when the clearance of creatinine test was performed. So collect 24 hours' urine should be done in precisely way. The clearance creatinine is an appropriate factor for estimating the value of GFR so it is valuable to diagnostic the kidney disease and their function. So, the measurement of creatinine in serum and urine in the same time is essential. In the old person and child, the level of the creatinine is low as they have a low level of muscle. Meanwhile, the amount of creatinine increase in some disease such as glomerulonephritis, acute tubular necrosis and urinary tract obstruction.

Principle of the Method:
The principle of this assay is measurement the level of creatinine in alkaline base, alkaline picrate (picric acid). The complex is make color and measurable on ٤٩٠ to ٥١٥ Nano meter. The intensity of color is related to amount of creatinine in the sample.

$$\text{Creatinine} + \text{Picric acid} \xrightarrow{\text{pH/alkaline}} \text{Creatinine Picrate complex}$$

- **Reagent Preparation and Stability:**
Reagent is ready for use.
Before use, mix reagent by gently inverting each bottle.
Reagent is stable until the expiration date on the label when stored tightly closed at 2-8°C, protected from light and contaminations prevented during their use.
Do not use reagents over the expiration date.
Do not freeze and protect from light. For assay the mixture should mix by with 1 volume of R1 and same volume of R2. R1 is transparent and colorless but R2 is transparent and light yellow. The mixture ready to use, stability at 2-8°C is 10 days and at the room temperature for 5 days. Avoid direct sunlight.

Waste Management:
Refer to local legal requirements for chemical disposal regulations.
Warning: Handle waste as potentially biohazardous material.
Dispose of waste according to accepted laboratory instructions and procedures.

- **Warnings and Precautions:**
For In Vitro Diagnostics Use Only.
For Professional Use Only.
The Sodium hydroxide and picric acid are used in this kit only for In vitro diagnostic.
Carefully read instructions for use.
In case of serious damage to the bottle or cap, resulting in product leakage or contamination, do not use the reagent pack and contact your distributor.
Take all necessary precautions required when handling laboratory reagents.
Do not use components past the expiry date stated on the Bottles.
Do not interchange caps among components as contamination may occur and compromise test results. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.

- **Type of Specimen:**
Use fresh serum/plasma heparinized with EDTA and urine. The stability of creatinine in serum/plasma samples at 4-25°C for 7 days and at-20°C for 3 months. Avoid any contamination, freezing and DE freezing the samples.
The creatinine stability in the urine sample at room temperature is for 2 days. At 2-8°C for 6 days and -20°C for 6 months.
The urine sample should not add any material and diluted 1 to 50 with distilled water. The number should multiply by 51. Avoid any contamination, freezing and DE freezing the samples.

Required but not Supplied:
General chemistry calibrator from TKS or other valid calibrators.
General chemistry control Level 1 & 2 from TKS or other valid controls.
Saline solution 0.9 % NaCl
General laboratory equipments

- **Notes:**
Carefully read instructions for use.
The Sodium hydroxide and picric acid are used in this kit are stimulator and toxic. Avoid any contact with human body otherwise wash with plenty water.
It is recommended to use disposable material. If glassware is used the material should be scrupulously cleaned with hydrochloric acid 1 N and then thoroughly rinsed it with distilled water.
Use clean disposable pipette tips for its dispensation.
Disposable and glassware material used must be free of metals, ions and detergents.

Performance Characteristics:
Performance results can vary with the instrument used.
Data obtained in each individual laboratory may differ from these values.

Maximum determination in this assay is 20 mg/dl
LOD: 0.1 mg/dl
For samples with a higher concentration (20 mg/dl), dilute 1:10 with 0.9 % NaCl and re-assay. Multiply result by 11.
Precision:
Intra Assay-Within run Creatinine

Sample	n	Mean (mg/dl)	SD (mg/dl)	CV (%)
1	20	0.92	0.03	2.76
2	20	3.43	0.07	1.90

Inter Assay-Between run Creatinine

Sample	n	Mean (mg/dl)	SD (mg/dl)	CV (%)
1	20	0.96	0.04	3.97
2	20	3.50	0.09	2.51

- **Accuracy:**
Results obtained using BIOMEDIC reagents (y) did not show systematic differences when compared with other commercial reagents (x).
Correlation coefficient (r): 0.9958
Regression equation: Y = 0.953 (X) + 0.075 mg/dl
The results of the performance characteristics depend on the analyzer used.

- **Interfering Substances:**
the less concentration of below items are not interfering in this assay.

Bilirubin (mixed isomer)	Less than 25% interference up to 200 µmol/l Bilirubin
Lipemia	Less than 10% interference up to 5 g/l Intralipid
Haemolysis	Less than 10% interference up to 5g/l Hemoglobin.

- **Reference Values:**
Serum/plasma

Manufactured by: TOSE'E KIMIA SA'ADAT, No.5, 32nd Alley, Asadabadi St. Yousef abad, Tehran-IRAN
Factory Address: No.18, Niloufar 6, Toska Blvd., Nakhl Blvd., Paytakht Industrial Town, 54 km of Tehran-Semnan Road
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www.tksmed.com - info@tksmed.com

Creatinine men	**0.7-1.4 mg/dl**
Creatinine women	**0.6- 1.3 mg/dl**

Urine

Creatinine men	**800-2000 mg/24h** **20-26mg/Kg/24h**
Creatinine women	**600-1800 mg/24h** **۱۴-۲۲ mg/Kg/24h**

Creatinine Clearance

Creatinine men	**98-156 ml/min/1.73m²**
Creatinine women	**95-160 ml/min/1.73m²**

Each laboratory should establish its own expected values. The creatinine results should always be reviewed with the patient's medical examination and history.

- **Assay Procedure:**

Allow reagents to reach working temperature before using.

A proportional variation of the reaction volumes indicated does not change the result

Assay conditions:

490-510nm	**Wavelengths**
37°C	**Incubation Temperature**
1 cm	**Cuvette**

Adjust the instrument to zero with distilled water.

Control/Sample/Calibrator	**Blank**	
500 µl	500 µl	**R1**
100 µl	-	**Control/Sample/Calibrator**
Gently mix and incubate for 5 minutes. Then added R2.		

500 µl	500 µl	**R2**
Gently mix and incubate for 30 seconds. Measure the first absorbance A1 then after 120 seconds, Measure second absorbance A2 **ΔA= A2 – A1**		

Control/Sample/Calibrator	**Blank**	
1000 µl	1000 µl	**Single Reference**
100 µl	-	**Control/Sample/Calibrator**
Gently mix and incubate for 30 seconds. Measure the first absorbance A1 then after 120 seconds, Measure second absorbance A2 **ΔA= A2 – A1**		

- **Calculations:**

Creatinine (mg/dl) = Abs sample x Cal /STD.Conc. (mg/dl)
Abs STD./Cal

Creatinine (mg/dl) = Abs sample x Cal /STD.Conc. (mg/dl) x 51
Abs STD./Cal

Urine Creatinine (mg/24h) = Urine creatinine (mg/dl) x Urine(ml)
100

Creatinine Clearance (ml/min) = Urine creatinine x Urine(ml/24h)
Serum creatinine x 1440

Conversion units:

Creatinine (mg/dl) x 88.4 = Creatinine (µmol/L)

TOSE'E KIMIA SA'ADAT has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

- **References:**

1-Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998.p.366-74.
2-Clinical Laboratory Tests: Values and Implications, 3rd Ed, 2001.
3-Jaffe MZ. Physio Chem. 10(1889)391.
4-Bastis H. et.al; Clin.Chem Acta.,37(1972)193.
5-Burtis CA, Ashwood ER. Tietz Fund. Of Clin. Chem. 5th ed. 30-54, 419-422 and 975.
6-Hienegard D, Diderstrom G., Clin. Chem. Acta 43, (1973) 305.
7-Voit R. Plasma-Serum-Unterschiede und Lagerungs stabilitat klinisch-chemischer Meβgroβen bei Verwendung von Plasmatrennrohrchen [Dissertation]. Munich: Ludwig-Maximilian-University, 1993.
8-Tietz NW, ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia, Pa: WB Saunders Company 1995:186-188.

Symbols:

The following symbols are used in the labelling of TOSE'E KIMIA SA'ADAT systems:

IVD	In Vitro Diagnostics	Σ	Contains sufficient for <n> tests
LOT	Batch Code		Temperature limit
REF	Catalogue No.		Consult instruction for use
	Expiry Date		Caution
	Date of Manufacture		Keep dry
	Manufactured by		This way up
	Biological Risks		Keep away from sunlight

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BRS
ISO 13485:2016
ISO 9001:2015

IVD

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