CREATININE

En

REF T2162 5880 Tests
REF T2163 2262 Tests

FOR USE WITH
ARCHITECT

Diagnostic reagent for determination of Creatinine concentration.
Liquid. Dual Reagents *(Ratio: R1/R2: 4/1)*. Store at +15/+25°C. For in Vitro Diagnostic Use (IVD). Do not freeze.
T2162/T2163 Ref Number Products are Produced Specifically for Architect Chemistry Analyzer Series.

Changes made in the instructions for use are marked as grey.

INTENDED USE

Test for quantitative determination of creatinine in human serum and urine.

TEST SUMMARY AND PROCEDURE [1, 2, 3, 4, 5, 6]

Creatinine measurements are used in the diagnosis and treatment of certain kidney diseases, in monitoring renal dialysis, and as a calculation method for the measurement of other urinary analytes.

A modified version of the kinetic Jaffe reaction is used in the creatinine method. This method has been reported to be less sensitive to interference caused by non-creatinine, Jaffe-positive compounds than conventional methods. Creatinine is generally considered the most useful endogenous substance in the evaluation of renal function.

Creatinine reacts with picric acid in alkaline environment to form a color complex. Developing of this red color can be followed by photometrically at 500-520 nm. The association on surfactant and sodium tetraborate keeps interferences at minimum.

TEST PARAMETERS

Method	: Colorimetric, Kinetic, "mod."Jaffe, Increasing Reaction
Wavelength	: 505 nm (500 nm - 520 nm)
Temperature	: 37°C
Sample	: Serum, Urine
Linearity	: 0.20 mg/dL - 20 mg/dL

REAGENT COMPONENTS

Reagent 1:

Carbonate Buffer	: ≤ 120 mmol/L
Sodium Hydroxide	: ≤ 360 mmol/L

Reagent 2:

Picric Acid	: ≤ 7.8 mmol/L

REAGENT PREPARATION

Reagents are ready for use.

REAGENT STABILITY AND STORAGE [7]

Reagents are stable at +15/+25°C till the expiration date stated on the label which is only for closed vials.

Once opened vials are stable for 30 days at +2/+8°C in optimum conditions. On board stability is strongly related to auto analyzers' cooling specification and carry-over values.

Reagent stability and storage data have been verified by using Clinical and Laboratory Standards Institute (CLSI) EP25-A protocol.

SAMPLE

Creatinine in serum and urine are collected according to the standard procedure.

Stability in serum:
7 days at 15/25°C
7 days at 2/8°C
3 months at (-15) - (-25) °C

Stability in urine (without preservative):
2 days at 15/25°C
6 days at 2/8°C
6 months at (-15) - (-25) °C

Stability in urine (with preservative):
3 days at 15/25°C
8 days at 2/8°C
3 weeks at (-15) - (-25) °C

Unit Conversion:

Serum:
mg/dL x 88.4 = µmol/L

Urine:
mg/dL x 0.0884= mmol/L

REFERENCE INTERVAL (NORMAL VALUES) [8]

Serum samples:
Men : 0.70 - 1.2 mg/dL
Women : 0.60 - 1.1 mg/dL

Children

0-<15m	0.42-1.05 mg/dL
15d-<1y	0.45-0.70 mg/dL
1-<4y	0.50-0.74 mg/dL
4-<7y	0.65-0.80 mg/dL
7-<12y	0.70-0.88 mg/dL
12-<15y	0.70-0.93 mg/dL
15-<17y	0.72-1.05 mg/dL

24h urine:
Men : 1040-2350 mg/24 h
Women : 740-1570 mg/24 h

It is recommended that each laboratory establish its own normal range.

Reference interval has been verified by using Clinical and Laboratory Standards Institute (CLSI) EP28-A3c protocol.

QUALITY CONTROL AND CALIBRATION

Commercially available control material with established values determined by this method may be used. We recommend:

Arcon N (Level I Control) Lyophilized
Ref.No: A3910

Arcon P (Level II Control) Lyophilized
Ref.No: A3920

The assay requires the use of a Creatinine Standard Level I-II Calibrator. We recommend:

Creatinine Standard Level I-Calibrator
Ref.No: A235S

Creatinine Standard Level II-Calibrator
Ref.No: A236S

Calibration Stability: It strongly depends on the application characteristics of in-use auto analyser and capacity of cooling. Calibration stability is 20 days.

Serum traceability is provided by NIST SRM 967 material and urine traceability is provided by NIST SRM 914 material.

Each laboratory should establish its own internal quality control scheme and procedures for corrective and preventive action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if quality control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Limit of Detection (LoD): The limit of detection is 0.15 mg/dL.

Limit of Quantitation (LoQ) [LoQ values are based on Coefficient of Variation Percentage (CV) %≤ 20]:[9] 0.2 mg/dL.

LoD and LoQ values have been verified by using CLSI EP17-A protocol.

High Linearity: The method is linear up to 20 mg/dL.

For values above high linearity, dilute sample with 0.9% saline, repeat the test and multiply the result by the dilution factor.

Linearity may considerably vary depending on the instrument used.

Precision Studies:[10]

Repeatability (Within Run)

Mean Concentration	SD*	CV%	n
0,86 mg/dL	0,03	3,13	40
4,94 mg/dL	0,05	1,06	40

Reproducibility (Day-to-Day Run)

Mean Concentration	SD	CV%	n
0,73 mg/dL	0,01	1,52	84
5,47 mg/dL	0,16	2,87	84

*SD: Standard Deviation
*CV: Variation Coefficient

±10% CV% deviations between devices can be observed

Precision Studies data have been verified by using CLSI EP05-A3 protocol.

Method Comparison:[11, 12]
Correlation with a comparative method is: r= 0.9999
According to Passing-Bablok equation:
Slope: 1.032
Intercept: -0.039

Interference:[2, 3, 4, 13]

No significant interference was observed for hemoglobin, conjugated bilirubin, lipemia, glucose up to the interferent concentration given in the table.

Interfering Substance and Concentration	Creatinine Target (mg/dL)	N	Observed Recovery %
Hemoglobin 1080 mg/dL	1.06	3	91
Bilirubin 3.67 mg/dL	1.38	3	91
Lipemia 2179 mg/dL	0.89	3	98
Glucose 530 mg/dL	2.51	3	107

The acceptable interference limit is set 10% below the highest interference concentration within ± 10% recovery of the target.
Interferences may affect the results due to medication or endogenous substances.

These performance characteristics have been obtained by using an analyzer. Results may vary if a different instrument or a manual procedure is used.

WARNINGS AND PRECAUTIONS

IVD: For in Vitro Diagnostic use only.
Do not use expired reagents.
Reagents with two different lot numbers should not be interchanged.
For professional use.
Follow Good Laboratory Practice (GLP) guidelines.
Contains sodium azide.

CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

Danger

EUH032 :Releases a very toxic gas if contacts with acid.
H317 :May cause allergic skin reaction.

Precaution

P280 :Use protective gloves / clothes / glasses / mask.
P264 :Wash your hands properly after using.

P272 :Contaminated work clothes should not be allowed to be used outside of the workplace.

Intervention

P302+P352 :Wash with plenty of water and soap if it contacts with skin.

P333+P313 :Seek medical help if it irritates your skin or develops rash.

P362+P364 :Remove contaminated clothes and wash properly before using.

Disposal

P501 :Dispose the vials and contents according to the local regulations.

REFERENCES

1. Burtis CA, Ashwood ER. Tietz Fundamentals of Clinical Chemistry, 5th ed. Philadelphia: W.B. Saunders, 2001:23-25, 419-420.
2. Tietz, N.W., Fundamentals of Clinical Chemistry, p. 940, W.B. Saunders Co., Philadelphia, 1987.
3. Tietz NW. Clinical Guide to Laboratory Test. 2nd ed. Philadelphia, PA: WB Saunders Company; 1995,52.
4. Tietz NW. Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia, PA: WB Saunders Company; 1995:88-91.
5. Tietz NW, ed. Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia: WB Saunders 1995:919.
6. Tietz Fundamentals of Clinical Chemistry. 5th ed. Burtis CA, Ashwood ER, eds. Philadelphia, PA: WB Saunders Company; 2001:605.
7. Clinical and Laboratory Standards Institute (CLSI). Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline. CLSI Document EP25-A. Wayne, PA: CLSI; 2009.
8. Clinical and Laboratory Standards Institute (CLSI). Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition. CLSI Document EP28-A3c. Wayne, PA: CLSI; 2010.
9. Clinical and Laboratory Standards Institute (CLSI). Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline.CLSI Document EP17-A. Wayne, PA: CLSI; Vol. 24 No. 34.
10. Clinical and Laboratory Standards Institute (CLSI). Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014
11. Passing-Bablok W et al. A General Regression Procedure for Method Transformation. J Clin Chem Clin Biochem 1988;26.783-79.
12. Clinical and Laboratory Standards Institute (CLSI). Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition; Approved Guideline.CLSI Document EP09-A2. Wayne, PA: CLSI; Vol. 22 No. 19.
13. Clinical and Laboratory Standards Institute (CLSI). Interference Testing in Clinical Chemistry; Approved Guideline.CLSI Document EP07. Wayne, PA: CLSI; 3rd Edition.CHERIAN G., SOLDIN ST. Clin. Chem. 27/5:748-752 (1981)
14. Tietz Textbook of Clinical Chemistry, Second Edition, Burtis- Ashwood (1994).

15. Clinical and Laboratory Standards Institute (formerly NCCLS). Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - Second Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2004. NCCLS Document EP05-A2.
16. HU Bergmeyer - Methods of enzymatic analysis, (1987).
17. Young DS. Effects of Drugs on Clinical Laboratory Tests. 3rd ed. Washington: AACC Press; 1990.
18. Jaffe MZ. Ueber den Niederschlag, welchen Pikrinsaure in normalem Harn erzeugt and ueber eine Reaction des Kreatinins. Zeitschrift Fuer Physiologische Chemie,1886;10:391-400 (Ger).
19. Hare, R.S., Endogenous Creatinine in Serum and Urine.
20. HENRY J.B., Clinical Diagnosis and Management; 17th edition, Saunder Publisher (1984)
21. Tietz NW. Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia, PA: WB Saunders Company; 1995:186-189.

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SYMBOLS

IVD	In Vitro Diagnostic Medical Device
LOT	Lot Number
R1	Reagent 1
R2	Reagent 2
GTIN	Global Trade Item Number
REF	Reference Number
GLP	Good Laboratory Practice
FOR USE WITH	Identifies Products to Be Used Together
PRODUCT OF TURKEY	Product of Turkey
	Manufacturer
	Expiration Date
	Temperature Limits
	Consult Instructions for Use
	Caution
	Number of Tests