POTASSIUM (K)

Enzymatic

Diagnostic reagent for determination of potassium concentration.

Liquid. Dual Reagents. Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze.

Ref No	Pack
ZA66	4 x 25 mL

INTENDED USE

The test is applied for the in vitro quantitative determination of potassium in serum, plasma and urine.

TEST PRINCIPLE

Potassium is determined enzymatically via potassium dependant pyruvate kinase activity using phosphoenol- pyruvate as substrate. The pyruvate formed reacts with NADH in the presence of LDH to form Lactate and NAD. The corresponding decrease in absorbance at 340nm is proportional to the potassium concentration.

$$PEP + ADP \xrightarrow{K+/(PK)} Pyruvate + ATP + PK + LDH$$

$$Pyruvate + NADH + H^{+} \xrightarrow{LDH} Lactate + NAD^{+}$$

TEST PARAMETERS

Method : Enzymatic Colorimetric
Wavelength : 340 nm
Temperature : 37°C
Sample : Serum, plasma
Linearity : 2 mmol/L - 10 mmol/L.

REAGENT COMPOSITION

Reagent 1. Buffer/Enzymes

Tris buffer	≤ 280 mmol/L PH8.2
Cryptand	≤ 14 mmol/L
PET	≥ 3.3 mmol/L
ADP	≥ 3.15 mmol/L
α-oxoglutarrte	≥ 1.2 mmol/L
NADH	≥ 0.35 mmol/L
GLDH	≥ 11 U/mL
PK	≥ 1.2 U/mL

Reagent 2. Enzyme

LDH	≥ 65 U/mL

Low Standard	3 mmol/L
High Standard	7 mmol/L

REAGENT PREPARATION

Working reagents are stable at 2-8ºC in case of closed vials and avoiding contamination after preparation.

For manual working procedures; if working reagent will be used; shake the Reagent 2 vial gently before pouring its contents into the Reagent 1 bottle. It is advisable to wash the Reagent 2 vial with a small volume of the prepared mixture in order to completely rinse the vial and avoid any losses.

REAGENT STABILITY AND STORAGE

Reagents are stable up to the expiry date when stored at 2-8°C. Once opened the reagent is stable for 4 weeks on-board the analyser at approximately 10°C.

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

SAMPLE

Serum and plasma treated with lithium heparinate are collected by standard procedures.

Potassium in serum is stable for 1 week at 20 - 25°C, 1 week at 2-8ºC and 1 year at -20°C.

Potassium in urine is stable for 45 days at 20 - 25°C, 2 week at 2-8ºC and 1 year at -20°C.

TEST PROCEDURE

Sample Start

There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

Substrate Start
There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

$$\frac{\text{A Sample}}{\text{A Standard}} \text{ x conc. of standard}$$

= Potassium in sample (mg/dL)

Unit Conversion

mmol/L x 3.9682 = mg/dL

REFERENCE INTERVAL (NORMAL VALUES)*

3.5 -5.1 mmol/L (13.9 -19.9 mg/dL)

*It is recommended that each laboratory establish its own reference range.

QUALITY CONTROL AND CALIBRATION

Archem Assayed Multisera, Level 2 and Level 3 are recommended for daily quality control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.
4. Check the quality of the water used for reagents reconstitution.

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 15 days.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

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

PERFORMANCE CHARACTERISTICS

Low linearity: 2 mmol/L

High Linearity: This method is linear up to 10 mmol/L. The minimum detectable concentration of potassium with an acceptable level of precision was determined as 0.8 mmol/L.
Linearity may considerably vary depending on the instrument used.

Precision Studies:

Repeatibility (within run) (Intra-assay)

Mean conc.	SD	CV	n
4.04	0.04	0.93%	20
6.14	0.04	0.59 %	20

Reproducibility (run to run) (Inter-assay)

Mean conc.	SD	CV	n
3.98	0.046	1.16%	20
6.05	0.106	1.76%	20

Sensitivity (LOD): Detection limit of this test is 0.8 mmol/L.

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

Interferance: The following analytes were tested up to the levels indicated and found not to interfere:

Bilirubin	≤ 665 µmol/L
Hemoglobin	≤ 1 g/L,
Triglyceride	≤ 24.2 mmol/L

Methods comparison: This method (Y) was compared with another commercially available method (X). 77 patient samples were analysed with values spanning the range 2.09 mmol/L to 9.87 mmol/L. Linear regression analysis of the data gave the following equation:

Y=0.94 x + 0.20, and a correlation coefficient of r = 1.0

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

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the

reagents bottles cannot be used between two different kind of reagent and between R1 & R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general “Good Laboratory Practice” (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 : After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.
S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CV% : Coefficient of Variation Percentage
GLP : Good Laboratory Practice
IU : International Unit
LDH : Lactate Dehidrogenase
mA : miliabsorbance
mL : mililiter
NAD : Nicotinamid Adenine Dinucleotide
NCCLS : National Committee for Clinical Laboratory Standards
PEP : Phosphoenol pyruvate
QC : Quality Control

REFERENCES

1. Tietz, N. W. (1986) .textbook of clinical Chemistry, p.1841 .W .B.Saundres Company, Philadelphia
2. Young DS. Effects of Drugs on Clinical Laboratory Tests. 3rd ed. Washington: AACC Press; 1990.
3. Eisenman G. Glass Electrodes for Hydrogen and Other Cations, Principles and Practice. New York: Marcel Dekker Inc.; 1967:2.
4. Berry, M. N. et al., (1988) Clin. Chem.35:817
5. 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.
6. Wu, Alan H.B. Tietz Clinical Guide to Laboratory Tests. 4th ed. Saunders Elsevier, St. Louis, MO: 2006, 880-885.

SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
R2	Reagent 2
CONC	Concentration
INGRED	Reagent Ingredients
REF	Reference Number (Catalog No)
SN	Serial Number
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk

CE

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