Audit Diagnostics

CE

POTASSIUM-LQ

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Piruvate Kinase

Quantitative determination of Potassium
IVD
Store at 2-8ºC

INTENDED USE
For the quantitative *in vitro* determination of Potassium in human serum.

PRINCIPLE OF THE METHOD
Potassium is determined spectrophotometrically through a kinetic coupling assay system using potassium dependent pyruvate kinase[2-3]. Pyruvate generated is converted to lactate accompanying conversion of NADH analog to NAD analog. The corresponding decrease of optical density at 380 nm is proportional to the potassium concentration in the serum.

CLINICAL SIGNIFICANCE
Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels. In healthy individuals, an extracellular fluid level of potassium is regulated to maintain at 3,5 – 5,1 mmol/L[1]. Small deviations from normal levels can have severe health consequences. Monitoring serum potassium concentration is important in both routine checks and emergency rooms.

REAGENTS

R 1	LDH NADH analog Substrate Azide Stabilizers	< 50 KU/L < 10 mmol/L 0,05 %
R2	Pyruvate Kinase Azide Stabilizers	< 50 KU/L 0,05 %
CAL L & H	Potassium aqueous primary standard	

PREPARATION
All the reagents are ready to use.

CALIBRATION
This assay should be calibrated using the enclosed L and H standards. Potassium concentration in sample is determined from the calibration curve using the included L & H potassium standards.

STORAGE AND STABILITY
All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC, protected from light and contaminations prevented during their use.
Do not freeze. Do not use reagents over the expiration date.

ADDITIONAL EQUIPMENT
- Spectrophotometer or colorimeter measuring at 380-405 nm.
- Thermostatic bath at 37ºC (± 0,1ºC)
- Matched cuvettes 1,0 cm light path.
- General laboratory equipment (Note 1).

SAMPLES
This assay is formulated for use with non-hemolysed serum. No special handling or pretreatment is needed.

Serum samples should be collected such that testing is performed as soon as possible and within 5 days after the specimen collection.

PROCEDURE
1. Assay conditions:
   Wavelength: .....380-405 nm
   Cuvette:..... 1 cm light path
   Constant temperature:.....37ºC
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette(Note 1):

	Blank	Calibrator L & H	Sample
R1 (µL)	800	800	800
Distilled water	20	--	--
Calibrator (µL)	--	20	--
Sample (µL)	--	--	20

4. Mix and incubate for 5 minutes at 37ºC
5. Add:

	Blank	Calibrator L & H	Sample
R2 (µL)	200	200	200

6. Mix carefully and read the absorbance after 60 s (A_1) and 240 s (A_2).
7. Calculate: $\Delta A = A_2 - A_1$.

CALCULATIONS
$$\frac{(A2-A1)\text{Sample} - (A2-A1)\text{Blank}}{(A2-A1)\text{Calibrator} - (A2-A1)\text{Blank}}$$
Interpolate the ΔA obtained into the calibration curve.

QUALITY CONTROL
Control Sera are recommended to monitor the performance of assay procedures: CONTROL H Normal and Pathologic.

If control values are found outside the defined range, check the instrument, reagent and calibration for problems.
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES
3,5 – 5,1 mmol/L (13,7 – 19,9 mg/dL)

These values are for orientation purpose; each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS
Measuring range: From *detection limit* of 2,0 mmol/L to *linearity limit* of 8,0 mmol/L.
Precision:

	Intra-assay (n=20)		Inter-assay (n=20)	
Mean (mmol/L)	4,62	6,96	4,62	6,96
SD	0,052	0,084	0,081	0,122
CV (%)	1,12	1,20	1,77	1,77

Sensitivity: 1 mmol/L= 0,10129667 (A)
Accuracy: Results obtained using Audit Diagnistics reagents (y) did not show systematic differences when compared with other commercial reagent (x).
The results obtained using 56 samples spanning the range 2,5 to 7,8 were the following:
Correlation coefficient $(r)^2$: 0,9805.
Regression equation: y= 1,0703x – 0,3042
The results of the performance characteristics depend on the analyzer used.

INTERFERENCES
The assay is not interfered by the following substances at indicated concentrations: Na^+ 150 mmol/L, NH_4^+ 0,5 mmol/L, Ca^{2+} 7,5 mmol/L, P_i 2 mmol/L, ascorbic acid 10 mmol/L, Zn^{2+} 0,5 mmol/L, Fe^{3+} 0,5 mmol/L, Cu^{2+} 0,5 mmol/L, triglycerides 1000 mg/dL, hemoglobin 500 mg/dL, conjugated bilirubin 20 mg/dL.

NOTES
1. In order to avoid contamination it is recommended to use disposable material.
2. Use clean disposable pipette tips for its dispensation.
3. **Audit Diagnostics has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.**

BIBLIOGRAPHY

1. Wu, A.H.B., ed. Tietz clinical guide to laboratory tests, 4th edition, p. 880. W.B. Saunders Company, St. Louis (2006).
2. Bergmeyer, H.U., Gawehn, K., and Grassl, M. (1974) in *Methods of Enzymatic Analysis*. Second Edition, Volume I, 509-510, Academic Press, Inc., New York.
3. M.N. Berry,R. D. Mazzachi, M. Pejakovlc,and M. J. Peake Enzymatic Determination of Potassium in Serum. *CLIN. CHEM.* 35/5, 817-820 (1989).

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