

PACKAGING

Ref.: 101-0763	Cont.: 3 x 20 / 3 x 9 mL
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Store at 2 - 8° C

CLINICAL SIGNIFICANCE

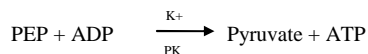
Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterised by low or high blood potassium levels.

INTENDED USE

For the quantitative *in vitro* determination of Potassium in serum and plasma.

PRINCIPLE OF THE METHOD⁽¹⁾

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



REAGENTS

R 1	Tris buffer, pH 8.2	250 mmol/L
Buffer / Enzyme-	Cryptand	12 mmol/L
Substrate	PEP	≥ 3.3 mmol/L
	ADP	≥ 3.15 mmol/L
	I-oxoglutarate	≥ 1.2 mmol/L
	NADH	≥ 0.35 mmol/L
	GLDH	≥ 11 mmol/L
	PK	≥ 1.2 mmol/L
R2 Enzyme/ Diluent	LDH	≥ 65 U/mL

Optional (not included in the kit)

Contro-N	Ref.: 101-0252	4 x 5 mL	Lyophilized human control serum
	Ref.: 101-0083	20 x 5 mL	
Contro-P	Ref.: 101-0253	4 x 5 mL	Lyophilized human control serum
	Ref.: 101-0084	20 x 5 mL	

PREPARATION

R1. Buffer/Enzyme-Substrate
Dissolve the contents of 1 vial of Enzyme-Substrate R1b in a portion of Buffer R1a; then transfer the entire contents to Buffer R1a, rinsing vial R1b several times.

R2. Enzyme /Diluent
Dissolve 1 vial Enzyme R2b in a portion of Diluent R2a; then transfer the entire contents to Diluent R2a, rinsing vial R2b several times.

STORAGE AND STABILITY

R1 is stable for 7 days at 2 - 8° C.
R2 is stable for 2 weeks at 2 - 8° C.
Do not use reagents over the expiration date.

ADDITIONAL EQUIPMENT

- Spectrophotometer or colorimeter measuring at 340 nm.
- Matched cuvettes 1.0 cm light path.
- General laboratory equipment ^(Note 1).

SAMPLES

Serum, plasma treated with lithium heparinate.

PROCEDURE

Notes: CHRONOLAB SYSTEMS has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

In order to avoid contamination it is recommended to use disposable material.

- Assay conditions:
Wavelength: 340nm
Cuvette: 1 cm light path
Constant temperature 37° C / 15 - 25° C
- Adjust the instrument to zero with distilled water.
- Pipette into a cuvette:

	Standard	Sample
R1	720 µL	720 µL
R2	290 µL	290 µL
Standard	20 µL	----
Sample	----	20 µL

- Mix and read the absorbance after 120 s (A₁) and 240 s (A₂).
- Calculate: ΔA= A₂ - A₁.

CALCULATIONS

$$\frac{(\Delta A)_{\text{Sample}}}{(\Delta A)_{\text{Calibrator}}} \times \text{Calibrator conc} = \text{mmol/L potassium in the sample}$$

QUALITY CONTROL

Control Sera are recommended to monitor the performance of assay procedures.

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⁽²⁾

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

Linearity: The method is linear to potassium concentrations of 11.2 mmol/L

Sensitivity: The minimum detectable concentration of potassium with an acceptable level of precision was determined as 2.46 mmol/L.

Precision:

	Intra-assay (n=20)			Inter-assay (n=20)		
Mean (mmol/L)	3.37	4.37	6.40	3.17	4.05	6.04
SD	0.09	0.14	0.12	0.09	0.07	0.09
CV (%)	2.67	3.23	1.95	2.95	1.67	1.53

Accuracy: Results obtained using CHRONOLAB reagents (y) did not show systematic differences when compared with other commercial reagent (x).

The results obtained using 77 samples spanning the range 2.51 to 9.99 were the following:

Correlation coefficient (r): 0.99.

Regression equation: y= 0.99x - 0.07

The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

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

Intralipid®	750 mg/dL
Bilirubin	25 mg/dL
Triglyceride	1000 mg/dL
Haemoglobin	250 mg/dL

BIBLIOGRAPHY

1. Berry, M. N. et al., (1989) Clin. Chem. **35**,817.
2. Tietz, N. W. (1986) Textbook of Clinical Chemistry, p. 1841. W.B. Saunders Company, Philadelphia.