



Instructions For Use

GENESIS

Potassium (Turbidimetric Tetraphenylborate (TPB) Method)

Cat no.	size
1305 101	2*25
1305 102	4*25

INTENDED USE

Potassium reagent is intended for the in-vitro quantitative diagnostic estimation of potassium in human serum or Plasma on manual systems.

DIAGNOSTIC CHARACTERISTICS

Sodium and Potassium are the major cations of extracellular and intracellular fluids respectively. Sodium maintains the normal distribution of water and the osmotic pressure in the various fluid compartments. Potassium influences the acid base balance and osmotic pressure including water retention. Increased sodium levels are found in severe dehydration and excessive treatment with sodium salts. Decreased levels are found in severe polyuria, metabolic acidosis Diarrhea and renal insufficiency Increased potassium levels are found in renal failure, dehydration, shock and adrenal insufficiency. Decreased levels are found in malnutrition, gastrointestinal fluid loss, and hyperactivity of the adrenal cortex.

ASSAY PRINCIPLE

Sodium-Tetraphenylborate Method

At an alkaline pH Potassium ions and TPB form a turbid emulsion, the increase of which can be measured quantitatively in a photometer at 578 nm. The increase of the absorbance (A) is directly proportional to the concentration of Potassium in the sample.

COMPOSITION

Reagent (R)	NaOH	0.50 mol/L
	TPB-Na	240 mmol/L
Standard (S)	Potassium standard	5.00 mmol/L

PRECAUTIONS AND WARNING

Do not ingest or inhale. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries, seek medical advice immediately.

REAGENT PREPARATION

Reagent and standard are supplied ready-to-use and

STORAGE AND STABILITY

Reagent and standard are stable till the expiration date stated on the vial label when stored at 2 - 8 °C. Once opened, the reagent and standard are stable for 3 months at the specified temperature.

SPECIMEN COLLECTION AND STABILITY

Non hemolized serum or heparinized plasma

Potassium is stable 5 days in specimen at 2 - 8 °C

PROCEDURE

1. Bring the reagent to room temperature

2. Assay parameters

Wavelength	630 nm
Optical path	1 cm
Assay type	colorimetric end-point
Direction	Increase

Symbols in Product Labeling			
	Authorized Representative		Expiration date
	For in-vitro diagnostic use		CAUTION, consult instructions for use
	Catalogue number		Manufactured by
	Lot number		Temperature Limit
	Consult instructions for use		

3. Adjust the instrument against blank

Pipette into clean test tubes:

	Blank	Standard	Sample
Reagent	1.0 ml	1.0 ml	1.0 ml
Standard (µL)		20 µL	
Sample (µL)			20 µL

Mix well and let stand 5 minutes at room temperature, and then read absorbance of sample and standard against reagent blank.

CALCULATION

$$\frac{A_{\text{Sample}}}{A_{\text{Standard}}} \times 5 = \text{Serum Potassium Concentration}$$

REFERENCE VALUES

Serum 3.6-5.5 mmol/L

Plasma 4.0-4.8 mmol/L

QUALITY CONTROL

It is recommended to use the Control Serum level I and II to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control

METROLOGICAL CHARACTERISTICS

From detection limit of 2 mmol/L to linearity limit of 20 mmol/L. Analytical sensitivity: 1 mmol/L

Linearity limit: 20.0 mmol/L

For higher values dilute sample 1/2 with physiological saline and repeat measurement.

-Repeatability (within run):

	Level 1	Level 2
n	20	20
Mean (mg/dL)	4.1	7.4
SD	0.21	0.3
CV%	5	4

-Reproducibility (run to run):

	Level 1	Level 2
n	20	20
Mean (mg/dL)	4.1	7.4
SD	0.4	0.5
CV%	10	6

INTERFERENCES

Hemolysis: Hemolized sera produce elevated results

Icterus: No significant interference up to a bilirubin level of 40 mg/dL.

Lipemic Turbid or lipemic samples produce falsely elevated results.

Nitrogen urea nitrogen above 80 mg/dL will produce elevated results.

Sera containing high levels of ammonia should be avoided

BIBLIOGRAPHY

- Hillman, G.; Beyer, G.: Z. Klin. Biochem. 5 (1967), 93.
- Hoeflmayr, J.: Praxis und Helferlin 8 (1979)
- Tietz, N.W.: Fundamentals of Clin. Chem. (1976), 876

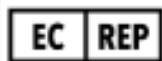
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