GENESIS

Instructions For Use

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

EC REP	Authorized Representative		Expiration date
IVD	For in-vitro diagnostic use		CAUTION, consult instructions for use
REF	Catalogue number		
LOT	Lot number		Manufactured by
	Consult instructions for use		Temperature Limit

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

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

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

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

GENESIS LAB FOR DIAGNOSTIC REAGENTS
1st industrial area, Obour City, Cairo, Egypt
(+202) 44891632 Fax : (+202) 44891632
www.genesis-egy.com
info@genesis-egy.com

IFU-POT-05
Rev. (2) 17/09/2023

ISO 13485:2016 Medical Devices

CE

EC REP CMC Medical device, C/ Horacio Lengo n18 C.P 29006, Málaga-Spain