POTASSIUM- Single Reagent

Diagnostic reagent for the in-vitro quantitative determination of potassium in human serum and plasma on manual systems.

REF: BS.1/PO02.025.0050	50 test	REF: BS.1/ PO02.050.0100	100 test
REF: BS.1/PO04.020.0080	80 test	REF: BS.1/PO04.025.0100	100 test
		REF: BS.1/ PO02.100.0200	200 test

CLINICAL SIGNIFICANCE

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.

METHOD PRINCIPLE

Turbidmetric Tetraphenylborate (TPB) without Deproteinization.
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 is directly proportional to the concentration of Potassium in the sample.

REAGENT COMPOSITION

R1: Standard	5.0 mmol/L
R2: Reagent NaOH TPB-Na	 0.50 mmol/L 240 mmol/L

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- 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.
- Respect country requirement for waste disposal.
  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.

For further information, refer to the **Lab.Vie**. potassium reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

Lab.Vie. potassium reagents are supplied ready-to-use. All reagents are stable until expiration date stated on label when stored at 2-8°C. The remaining stability after opening the bottles is 1 month at 18 - 25°C.

Deterioration
The **Lab.Vie**. potassium reagent is normally clear, do not use reagent if it is turbid.

SPECIMEN COLLECTION AND PRESERVATION

Serum is recommended. Potassium in serum is stable for at least 2 weeks at 2 - 8°C. Specimens for serum potassium analysis should be free from hemolysis since the high concentration of potassium released from red cells significantly increase the serum levels and this invalidates the test results. Blood specimens should also be separated from the red cells shortly after collection to prevent any leakage of potassium from the intracellular into the extracellular fluid.
Plasma from anticoagulants not containing potassium is also suitable (potassium free heparin).

SYSTEM PARAMETERS

Wavelength	578 nm
Optical path	1 cm
Assay type	End-point
Direction	Increase
Sample Reagent Ratio e.g.: Reagent volume Sample volume	1:50 1 ml 20 µl
Temperature	25 - 37°C
Incubation time	3 min at 37°C, 5 min at 25°C
Zero adjustment	Reagent blank
Sensitivity	0.14 mmol/L
Linearity	8 mmol/L

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes, automatic pipet
- Centrifuge and spectrophotometer

ASSAY PROCEDURE

	Blank	Standard	Specimen
Reagent	1.0 ml	1.0 ml	1.0 ml
Standard		20 µl	
Specimen			20 µl

Mix, incubate for 3 min at 37°C, 5 min at 25°C. Measure absorbance of specimen and standard against reagent blank. The color is stable for at least 30 minutes.

CALCULATION

potassium concentration (mmol/L) = $\frac{\text{Abs. specimen x 5}}{\text{Abs. standard}}$

QUALITY CONTROL

To ensure adequate quality control, it is recommended that normal and abnormal commercial control serum of known concentrations included in each run. If control values are found outside the defined range, check the instrument calibration, and reagent for problems. If control still out of range please contact **Lab.Vie**. technical support.

PERFORMANCE CHARACTERISTICS

Precision	Within run (Repeatability)		Run to run (Reproducibility)	
	Normal level	High level	Normal level	High level
n	20	20	20	20
Mean mmol/l	4.64	7.60	4.61	7.63
SD.	0.095	0.10	0.113	0.148
CV. %	2.05	1.32	2.45	1.94

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

Accuracy (Methods Comparison)
Result obtained from **Lab.Vie**. potassium reagent compared with commercial reagent of the same methodology performed on 20 human sera give a correlation of 0.997.

Sensitivity
When run as recommended, the minimum detection limit of the assay is 0.14 mmol/L.

Linearity
The reaction is linear up to concentration of 8 mmol/L. Specimens showing higher concentration should be diluted 1+1 using physiological saline and repeat the assay (result×2).

INTERFERING SUBSTANCES

Bilirubin
Bilirubin above 40 mg/dl and Urea Nitrogen above 80 mg/dl will produce elevated results.

Haemoglobin
Hemolyzed sera produce elevated results.

Drugs
Young in 1990 has published a comprehensive list of drugs and substances, which may interfere with this assay.

EXPECTED VALUES

Serum 3.6 - 5.5 mmol/L
Plasma 4.0 – 4.8 mmol/L

DYNAMIC RANGE

2 - 7 mmol/L.

REFERENCES

1. Hillman, G.; Beyer, G.: Z. Klin. Biochem. 5 (1967), 93
2. Henry, R.F. et. al., Clinical Chemistry Principles and Techniques, 2nd Ed., Harper and Row, Hagerstown, M.D.,(1974)
3. Tietz, N.W.: Fundamentals of Clin. Chem. (1976), 876

SYMBOLS IN PRODUCT LABELLING

IVD	For in-vitro diagnostic use		Number of <n> test in the pack
LOT	Batch Code/Lot number		Caution
REF	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		