QUANTON BIOLIFE SCIENCES
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Potassium Test Kit
Colorimetric

QBL/PDS/K_001

Quantitative determination of Potassium in human Serum / Plasma / other body fluids. Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	Pack Size
POTMONO 25	25 X 1 ml
POTMONO 50	50 X 1 ml
POT 25	1 X 25 ml
POT 50	1 X 50 ml
POT 100	1 X 100 ml
POT 1000	1 X 1000 ml
POT 5000	1 X 5000 ml
POT 10000	1 X 10000 ml

CLINICAL SIGNIFICANCE
Potassium are the major cations of extracellular and intra cellular fluids respectively. Potassium influences the acid base balance and osmotic pressure including water retention. Increased potassium levels are found in renal failure, dehydration, shock and adrenal insufficiency. Decreased levels are found in malnutrition, gastro-intestinal fluid loss, and hyperactivity of the adrenal cortex Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

METHOD
Colorimetric

PRINCIPLE
Potassium reacts with Sodium tetra phenyl boron in a specially prepared buffer to form a colloidal suspension. The amount of the turbidity produced is directly proportional to the concentration of potassium in the sample.

Sodium Tetra phenyl Boron + K^+ ⟶ White turbidity

REAGENT
Reagent l : Potassium Reagent
Potassium standard : 5 mEq/l

REAGENT PREPARATION
The reagents are provided in a ready to use format.

REAGENT STORAGE AND STABILITY
Reagent is stable till expiry when stored at RT

Store protected from light.

WARNING AND PRECAUTIONS
- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.

WASTE MANAGEMENT
Please refer to local legal requirements.

MATERIALS REQUIRED BUT NOT PROVIDED
- NaCl solution 9 g/L
- General laboratory equipment

SAMPLE COLLECTION AND PRESERVATION
Serum or heparin plasma
Separate at the latest 1h after blood collection from cellular contents.
7 days at 2 – 8°C
1 day at –20°C
Stability in serum (separated from cellular contents, hemolysis free) without adding a glycolytic inhibitor
8 h at 25°C
7 days at 2 – 8°C
Only freeze once! Discard contaminated specimens

ASSAY PROCEDURE
Operating Instructions
- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, standard and samples to room temperature 18 – 28 ºC, prior to analysis.

AUTOMATED PARAMETERS	
Wavelength	630 nm
Reaction Type	End Point
Cuvette	1 cm light path
Reaction Temperature	RT
Reaction Type	Increasing
Measurement	Against Reagent Blank
Sample Volume	20µl
Reagent Volume	1000µl
Incubation	05 minutes
Blank Absorbance Limit	< 0.080
Low Normal at 37°C	3.5 mEq/l
High Normal at 37°C	5.5 mEq/l
Linearity at 37°C	7 mEq/l

MANUAL ASSAY PROCEDURE
Pipette into Test Tubes

	BLANK	STD	SAMPLE
Sample	-	-	20µl
Standard	-	20µl	-
Reagent	1000µl	1000µl	1000µl

Mix & Incubate for 05 min. at R.T. Measure absorbance of Sample (AT) and Standard (AS) against Reagent Blank at 630 nm.

SAMPLE DILUTIONS
- This method is linear up to a concentration of 7 mEq/l.
- Dilute samples above this concentration 1:1 with 0.9% saline. Repeat assay. Multiply the result by 2.

CALCULATION
Total Potassium (mEq/l) = AT/AS x Conc. of Standard.

CALIBRATORS AND CONTROLS
For the calibration of automated photometric systems the commercially available suitable multi-calibrator is recommended.

The assigned values of this Potassium Standard have been made traceable to the reference method gas chromatography – isotope dilution mass spectrometry (GC-IDMS).

It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.
Each laboratory should establish corrective action in case of deviations in control recovery

PERFORMANCE CHARACTERISTICS
WITHIN RUN

Sample	Mean Concentration	SD	CV %
Randox 2	3.78	0.12	3.20%
Randox 3	5.66	0.15	2.60%

RUN TO RUN

Sample	Mean Concentration	SD	CV %
Randox 2	3.70	0.12	3.26%
Randox 3	5.70	3.26	1.89%

LINEARITY

The method is linear up to a concentration of 7 mEq/l. dilute samples above this concentration 1:1 with 0.9% saline solution and repeat assay. Multiply the result by 2.

Limit of detection: The limit of detection for Potassium is 0.9 mEq/l..

METHOD COMPARISON

A comparison of Potassium with a commercially available assay (x) using 20 samples gave following results: $R^2 = 0.9800$

REFERENCE VALUES

Serum/Plasma	3.5 - 5.5 mEq/l

The reference values are to be considered as indicative only. Every laboratory should establish its own normal range.

LIMITATION OF THE PROCEDURE

- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

INTERFERENCE

- Hemoglobin: No interference found upto 400 mg/dL.
- Bilirubin: No interference found upto 20mg /dL.
- Lipemia: No interference found upto 400 mg/dL.
  These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

BIBLIOGRAPHY

IMaruna, R.F.L., (1958) Clin. Chem. Acta. 2 : 581 Trinder, P., (1951) Analyst 76 : 596 Terri, A.E., et. al. (1958) J. Clin. Path. 29 : 86 Sunderman, F.W., et. al. (1959) Am. J. Clin. Path. 29 : 95 Schales, O., Schales, S.S., (1941) J. Biol. Chem. 140 : 879 Schoenfeld, R.G., Lewellen, C.J., (1964) Clin. Chem. 10 : 553

GLOSSARY OF SYMBOL

	Consult Instruction for Use
	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight

Paramcare Life Sciences Private Limited, G/F-12/13, Evershine-2,
Survey No. 307/3/1, Balitha N.H No 48, Vapi, Valsad, Gujarat, 396191.

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