SBio POTASSIUM KIT

(Colorimetric Method)

(For invitro diagnostic use only)

REF	90690050
Σ	50 Tests

CE

30°C / 15°C Store at R.T.	Manufacturer	IVD *In vitro* Diagnostic Medical Device	L1 Potassium Reagent	Colorimetric Colorimetric Method
Use by (Last day of stated month)	Consult Instructions for use	LOT Batch Number	S Na^+ / K^+ Standard (150/5 mmol/l)	
Date of Manufacture	REF Catalogue Number	Σ Contains sufficient for <n> tests	This way up	EC REP Authorised Representative in the European Community

INTENDED USE

Potassium Kit is used for the determination of potassium in serum.

PRINCIPLE OF THE TEST

Potassium reacts with sodium tetraphenyl 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.

Tetraphenyl Boron + K^+ ⟶ White Turbidity

CLINICAL SIGNIFICANCE

Potassium works with sodium to maintain the body's water balance. The kidneys regulate the level of potassium in the body. Potassium deficiency is not common but may result from excessive losses due to severe diarrhea, poor diabetic control, low-calorie diets (less than 800 calories per day), chronic alcoholism, hard exercise, or some diuretics and laxatives.

PRESENTATION	50 Tests
L1 : Potassium Reagent	150 ml
S : Na^+ / K^+ Standard (150/5 mmol/l)	5 ml

COMPOSITION

Potassium: Sodium Tetraphenyl Boron ≥ 35 mmol; Preservatives.

STORAGE / STABILITY

Contents are stable at R.T. till the expiry date mentioned on the labels.

SAMPLE REQUIRED

Serum, free from hemolysis is required. Serum should be separated from the clot immediately / as soon as possible.

REAGENT PREPARATION

Reagents are ready to use.

SAMPLE WASTE AND DISPOSAL

Do not reuse the reagent containers, bottles, caps or plugs due to the risks of contamination and the potential to compromise reagent performance.

This product requires the handling of human specimen. It is recommended that all human sourced material are considered potentially hazardous and are handled in accordance with the OSHA standard on blood borne pathogens.

Appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

Handle specimen, solid and liquid waste and test components in accordance with local regulations and NCCLS guidelines M29, or other published biohazard safety guidelines.

PROCEDURE

Wavelength / filter : 630 nm (Hg 623) / Red

Temperature : R.T.

Light path : 1 cm.

MATERIAL REQUIRED BUT NOT PROVIDED

General laboratory instrumentation like Spectrophotometer/Analyzer, Thermostatic Cuvette holder, Cuvettes, Micropipettes, Test tubes, Waterbath, Stopwatch/Timer.

Pipette into clean dry test tubes labelled as Blank (B), Standard (S) and Test (T):

Addition Sequence	B (ml)	S (ml)	T (ml)
Potassium Reagent (L1)	1.0	1.0	1.0
Deionized Water	0.02	--	--
Na^+ / K^+ Standard (S)	--	0.02	--
Sample	--	--	0.02

Mix well and incubate at R.T. for 5 mins. Measure the absorbance of the Blank (Abs.B), Standard (Abs.S), and Test Sample (Abs.T) against blank within 15 mins.

CALCULATIONS

$$\text{Potassium in mmol/l} = \frac{\text{Abs. T}}{\text{Abs. S}} \times 5$$

QUALITY CONTROL

The following process is recommended for QC during the assay of Potassium. *Define and establish acceptable range for your laboratory.

1. Two levels of control (Normal and Abnormal) are to be run on a daily basis.
2. If QC results fall outside acceptance criteria, recalibration may be necessary.
3. Review QC results and run acceptance criteria following a change of reagent lot.

SPECIFIC PERFORMANCE CHARACTERISTICS

Linearity:

The Potassium assay is linear upto 8 mmol/l. If values exceed this limit, dilute the sample with deionised water (free from K^+ ions) and repeat the assay. Calculate the value using the proper dilution factor.

Limit of detection:

The limit of detection for Potassium is 0.1 mmol/l

Interferences:

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

Precision:

Precision studies were performed with two controls using NCCLS protocol EP5-A. The results of the precision studies are shown below:

Sample	Within-run		Between-run		Total	
	Mean	CV%	Mean	CV%	Mean	CV%
Control 1	3.40	2.66	3.49	2.91	6.89	5.57
Control 2	6.12	2.11	6.13	2.76	12.25	4.87

Method comparison:

Comparative studies were done to compare our reagent with another commercial Potassium Assay. No significant differences were observed. Details of the comparative studies are available on request.

REFERENCE RANGE

Potassium : 3.5 - 5.5 mmol/l

It is recommended that each laboratory establish its own normal range representing its patient population.

NOTES

Separate serum from the clot as soon as possible as potassium may leach from the RBC's which have a very high potassium level. Turbid or icteric samples may produce falsely elevated results. Do not use deteriorated or leaking reagents.

REFERENCES

(1) Maruna, R.F.L., (1958) Clin. Chem. Acta. 2: 581.

(2) Trinder, P., (1 951) Analyst 76: 596.

(3) Terri, A.E., et. al. (1958) J. Clin. Path. 29: 86.

(4) Sunderman, F.W., et. al. (1959) Am. J. Clin. Path. 29: 95.

(5) Schales, O., Schales, S.S., (1941) J. Biol. Chem. 140: 879.

(6) Schoenfeld. R.G., Lewellen, C.J., (1964) Clin. Chem. 10: 553.

Mfd. for:

Singapore SB Biosciences PTE Ltd.

11 Yishun Street 51, # 04-23, The Criterion, Singapore 767971.

EC REP

CMC Medical Devices & Drugs S.L.,
C/ Horacio Lengo No. 18, CP 29006, Malaga, Spain.

POT1(SBio)/0420/VER-02