POTASSIUM (STB)

INTENDED USE
Bioline Potassium reagent is intended for the "In Vitro " quantitative determination of Potassium in Serum based on colorimetric method.

CLINICAL SIGNIFICANCE
Potassium is the principle cation of the intracellular fluid. It is also an important constituent of the extracellular fluid due to its influence on muscle activity. Its intracellular function parallels that of its extracellular function, namely influencing acid-base balance and osmotic pressure, including water retention.

Elevated potassium levels (hyperkalemia) are often associated with renal failure, dehydration shock or adrenal insufficiency. Decreased potassium levels (hypokalemia) are associated with malnutrition, negative nitrogen balance, gastrointestinal fluid losses and hyperactivity of the adrenal cortex.

In previously described colorimetric methods for determination of potassium or sodium, prior deproteinization of serum or plasma specimen was required. Our improved method is the direct spectrophotometric measurement of potassium in blood or plasma.

METHOD AND PRINCIPLE
Potassium reacts with sodium tetraphenol 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.

REAGENT COMPOSITION
1. Potassium Reagent: Sodium Tetraphenyl boron 2.1 mM, preservatives and thickening agents
2. Potassium standard: 5mmol/L

WARNING AND PRECAUTIONS
1. Potassium Reagent Set is for "*in vitro* diagnostic use" only. Sodium Tetraphenyl boron is a corrosive substance. Avoid skincontact or ingestion. DO NOT PIPET BY MOUTH. Flush withwater if contact occurs.

REAGENT PREPARATION
Reagent and standard both are in ready to use form.

REAGENT STORAGE AND STABILITY
Store the potassium reagent at room temperature (15-30°C) . The reagent and standard are stable until expiration date indicated on the package label.

REAGENT DETERIORATION
Do not use if:
1. The reagent is very cloudy.
2. The reagent fails to achieve assigned value on fresh control serum.

SPECIMEN COLLECTION AND STORAGE
1. Serum is recommended.
2. 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.

INTERFERENCES
Turbid or icteric samples produce falsely elevated results. Bilirubin above 40 mg/dL and Urea Nitrogen above 80 mg/dL will produce elevated results. Hemolyzed sera produce elevated results. Sera containing high levels of ammonia should be avoided.

ASSAY PROCEDURE FOR SEMIAUTO ANALYZER.
Wavelength : 630 nm
Temperature : RT

	Blank	Standard	Sample
Reagent	1000 µL	1000 µL	1000 µL
Double Distilled water	50 µL	-	-
Standard	-	50 µL	-
Sample	-	-	50 µL

Mix and read the optical density (OD) of standard and sample against reagent blank after 5 minutes of incubation at RT.

CALCULATIONS
Abs. = Absorbance

$$\frac{\text{Abs. of unknown}}{\text{Abs. of Standard}} \times \text{Concentration of Standard} = \text{Concentration Potassium (mmol/L)}$$

Example:
Abs. of unknown = 0.849 Abs. of Standard = 1.135
Concentration of Standard = 5 mmol/L

$$\frac{0.849}{1.135} \times 5 \text{ mmol/L} = 3.74 \text{ mmol/L}$$

CALIBRATION
The procedures are calibrated with the standard solution which is included with each series of tests. Its absorbance is used to calculate results. It is recommended to establish a linearity curve up to 7 mmol/L with other available commercial standard solutions to verify the performance of the instruments and reagents.
Factor above 6 indicates standard deterioration, in that case discard the standard and use fix factor of 6 for result calculation.

LIMITATIONS
Samples with Potassium values above 7 mmol/L should be diluted 1:1 with distilled water, re-run and resulting value multiplied by two.Care should be exercised not to touch pipette tips with the fingers.

QUALITY CONTROL
Normal and abnormal control sera of known concentrations of Potassium should be analyzed routinely with each group of unknown samples.

EXPECTED VALUES

3.4- 5.3 mmol/L.

It is strongly recommended that each laboratory establish its own normal range.

PERFORMANCE CHARTERISTICS

1.Linearity: 2-7 mmol/l

Sensitivity : Based on instrument resolution abs of A=0.001 the present method has a sensitivity of 0.006 mmol/l

2. Comparison : A comparison study performed between our method and a similar method resulted in the correlation coefficient of 0.99 with a regression equation of Y=1.06X-0.37.

Precision:

	Within Run		Between Run	
Mean(mmol/ll)	S.D.	C.V.(%)	S.D.	C.V.(%)
4.1	0.1	5	0.4	10
7.4	0.3	4	0.5	6

General Test Parameters.

Mode	**End Point**
Wavelength (Filter)	**630(600-650)nm**
Reaction Direction	**Increasing**
Reagent Blank	**Yes**
Sample Vol.	**50 µL**
Reagent Vol.	**1000 µL**
Incubation Time	**5 min at RT**
Reagent Blank Abs.(Max)	**NMT 0.500 Abs**
Calibration Method	**1- Point**
Standard (Conc.)	**5 mmol/L**
Linearity	**7 mmol/L**
Decimal Places	**1**
Temp.	**RT**
Unit	**mmol/L**
Ref. Low	**3.4 mmol/L**
Ref. High	**5.3 mmol/L**

REFERENCES

1. Henry, R.F. et. a1., *Clinical Chemistry Principles andTechniques,* 2nd Ed., Harper and Row, Hagerstown, M.D., (1974).
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3. Terri, A.E. and Sesin, P.G., *And. J. Clin. Perth.,* 29:86(1958).