



### PACKAGING

Ref.: 101-0552	Cont.: 2 x 50 mL
Ref.: 101-0687	Cont.: 2 x 100 mL

Store at 2 - 8° C

# **CLINICAL SIGNIFICANCE**

Potassium (K+) is the major positive ion within cells and is particularly important for maintaining the electric charge on the cell membrane. This charge allows nerves and muscles to communicate and is necessary for transporting nutrients into cells and waste products out of the cell. The concentration of potassium inside cells is about 30 times that in the blood and other fluids outside of cells. Potassium levels are mainly controlled by the steroid hormone aldosterone. Aldosterone is secreted from the adrenal gland when levels of potassium increase. Aldosterone, in turn, causes the body to rid itself of the excess potassium. Metabolic acidosis (for example, caused by uncontrolled diabetes) or alkalosis (for example, caused by excess vomiting) can affect blood potassium. In normal people, taking potassium supplements or potassium-containing drugs is of no consequences, because the kidneys efficiently dispose of excess potassium.

# **PRINCIPLE OF THE METHOD**

Potassium ions in a protein-free alkaline medium react with sodium tetraphenylboron to produce a finely dispersed turbid suspension of potassium tetraphenyylboron. The turbidity produced is proportional to the potassium concentration and read photometrically.

# REAGENTS

<b>R1</b> TPB-Na	Sodium tetraphenylboron (TPB-Na)	0.2 mol/L	
R2 NaOH	Sodium hydroxide	2.0 mol/L	
R3 PREC	Trichloroacetic acid (TCA)	0.3 mol/L	
K-p CAL	Potassium aqueous primary standard 5.0 mmol/L		

# **Optional (not included in the kit)**

Contro-N	Ref.: 101-0252	4 x 5 mL	Lyophilized human	
Colluo-IN	Ref.: 101-0083	20 x 5 mL	control serum	
Contro-P	Ref.: 101-0253	4 x 5 mL	Lyophilized human	
	Ref.: 101-0084	20 x 5 mL	control serum	

# **PRECAUTIONS**

R2 (NaOH), R3 (TCA), WR: C; R35 Causes severe burns.

CAL: Xi; R 36/38 Irritating to eyes and skin.

S24/25 Avoid contact with skin and eyes. S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S37/39: Wear suitable gloves and eye/face protection. S45: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

# PREPARATION

#### Working reagent (WR):

Mix equal volumes of R1 TPB-Na and R2 NaOH (Shake before to use). Don't use before 30 min. after its mixing .The working reagent must be shaked before each use.

The working reagent is stable for 7 days at 15 - 25° C and 30 days at 2 - 8° C.

# STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2 - 8° C, protected from light and contaminations prevented during their use.

# Do not use reagents over the expiration date.

# ADDITIONAL EOUIPMENT

- Spectrophotometer or colorimeter measuring at 578 nm.
- Matched cuvettes 1.0 cm light path.
  General laboratory equipment (Note 1, 2, 3).

# SAMPLES

- Non-haemolytic serum or heparin plasma

### PROCEDURE

Notes: CHRONOLAB SYSTEMS has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

K-p CAL: Proceed carefully with this product because due its nature it can get contamined easily.

As red blood cells contain about 25 times the amount of potassium, they have to be separated from the serum within one hour after blood collection. Otherwise, falsely elevated potassium concentrations will be found.

Traces of detergents produce turbidity which leads to falsely elevated potassium concentrations. They therefore have to be avoided.

Calibration with the aqueous standard may cause a systematic error in automatic procedures. In these cases, it is recommended to use a serum Calibrator.

The R2 (NaOH) and the working reagent must be shaked before their use.

1.	Assay conditions:
	Wavelength:
	Cuvette: 1 cm. light path
	Temperature

2. Adjust the instrument to zero with distilled water.

3. Pipette into a cuvette:

Sample (µL)	50
R3 (µL)	500

4 Mix carefully.

5. Centrifuge at high speed for 5-10 min.

Separate the clear supernatant and pipette on another cuvettte: 6

	Standard	Sample
Working reagent (mL)	1.0	1.0
Standard (µL)	100	
Supernatant (µL)		100

7. To produce an homogeneous turbidity, the standard or the clear supernatant must to be added to the center of the surface of the working reagent in the cuvette. Mix each cuvette carefully before proceding to the next sample.

Read the absorbance (A) of standard and samples against working reagent blank after 5 min. Color is stable up to 30 minutes.

# **CALCULATIONS**

 $\frac{A \text{ sample}}{2} \times 5.00 \text{ (Standard conc.)} = \text{mmol/L potassium in the sample}$ A STD

**Conversion factor:** mmol/L = mEq/L.

P	ICC054e	
۷	2014/2	





### **QUALITY CONTROL**

Control sera are recommended to monitor the performance of assay procedures.

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems.

Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

# **REFERENCE VALUES<sup>1</sup>**

Serum:	3.60 - 5.50 mmol/L
Plasma:	4.00 - 4.80  mmol/L

These values are for orientation purpose; each laboratory should establish its own reference range.

# **PERFORMANCE CHARACTERISTICS**

**Measuring range:** From detection limit of 2 mmol/L to linearity limit of 20 mmol/L.

If the results obtained were greater than linearity limit, dilute the sample 1/2 with NaCl (9 g/L) and multiply the result by 2.

#### **Precision:**

	Intra-assay (n=20)				-assay =20)
Mean (mmol/L)	4.15	6.70		4.15	6.70
SD	0.11	0.176		0.152	0.19
CV (%)	2.58	2.54		4.11	2.23

Sensitivity: 1 mmol/L = 0.537 A.

Accuracy: Results obtained using CHRONOLAB reagents did not show systematic differences when compared with other commercial reagents.

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

# **INTERFERENCES**

A list of drugs and other interfering substances with potassium determination has been reported by Young et.  $a1^{5,6}$ .

# BIBLIOGRAPHY

- 1. Hillmann, G., Beyer, G., Z. Klin. Chem. Klin. Biochem. 5, 93 (1967)
- 2. Henry, R.J., Clin. Chem., Harper & Row, New York, Sec. Edit. 646 (1974)
- 3. Tietz, N.W., Fundamentals of Clinical Chemistry, Saunders, Philadelphia, Sec. Edit., 876 (1976)
- 4. ISO 15223 Medical devices Symbols to be used with medical device labels, labelling and information to be supplied.
- 5. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
- 6. Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.