Potassium Prec

CYPRESS DIAGNOSTICS

CE

IVD

NaTPB. Colorimetric.
Precipitation
Liquid

Store at 2 - 8 °C

Configuration

REF	HB015
VOL	2 x 50 mL
Reagent 1	1 x 50 mL
Reagent 2	1 x 50 mL
Reagent 3	1 x 50 mL
Standard	1 x 3 mL
Instrument	Universal

Intended use

Quantitative determination of potassium in human serum or heparinized plasma.
For *in vitro* diagnostic use only. For professional use only.

Clinical significance

Potassium is the principal cation of the intra-cellular fluid. It is also an important constituent of the extra-cellular fluid due to its influence on muscle activity. Its intra-cellular function parallels that of its extra-cellular 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.
Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

Principle

The amount of potassium is determined, after precipitation of the proteins, by using sodium tetraphenylboron in an alkaline medium to produce a colloidal suspension. The turbidity produced is proportional to potassium concentration.

Reagent composition

Reagent 1	NaTBP Sodium tetraphenylboron (0,2 mol/L)
Reagent 2	NaOH Sodium hydroxide (2,0 mol/L)
Reagent 3	PREC Trichloroacetic acid (0,3 mol/L)
Standard	Potassium sol (see value on label)

Precautions

- Reagent 2: Danger. H314: Causes severe skin burns and eye damage.
- Reagent 3, Standard: Danger. H314: Causes severe skin burns and eye damage. H335: May cause respiratory irritation. H411: Toxic to aquatic life with long lasting effects.
- P280: Wear eye protection, face protection, protective clothing, protective gloves. P501: Dispose of contents in an appropriate container observing applicable local regulations.
- All body fluid samples should be considered potentially infectious materials and the appropriate precautions should be taken. Wear personal protective equipment such as gloves, safety glasses, lab coats or aprons when working with possible biohazard contaminants.
- Use Good Laboratory Practices (GLP) when handling this product.
- Please refer to the MSDS, available on our website, for further information.

Preparation

Working reagent: Shake R2 (NaOH) before use. Mix proportionally 1:1 Reagent 1 and Reagent 2. After mixing, allow to stand for 30 minutes prior to use. Before each use, the working reagent must be shaken. The working reagent is stable for 7 days at 15-25 °C and 30 days at 2-8 °C.

Storage, stability and disposal

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2 - 8 °C. Handle standard very carefully to prevent contamination.
Do not freeze or expose to elevated temperatures.
Do not use the product if deterioration or contamination is suspected or beyond the expiration date or open container stability period. Dispose unused or deteriorated product and waste in compliance with local regulations.

Additional material required but not provided

- Spectrophotometer or colorimeter measuring at 578 nm
- Matched cuvettes 1,0 cm light path
- General laboratory equipment [Note 3,4]

Samples

Non hemolytic serum or heparin plasma.

Procedure

Make sure the reagents and samples are at room temperature.
1. Wavelength 578 nm; Temperature 37 °C/15-25 °C; Cuvette (1 cm light path).
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette:

PRECIPITATION STEP: [Note 5]	
For Sample	50 µL Sample + 500 µL Reagent 3
Mix carefully. Centrifuge at high speed (± 5000 rpm) for 5-10 minutes. Separate the clear supernatant in a new test tube.	
TEST STEP: pipette into a cuvette:	
For Blank	1,0 mL Working reagent (R1 + R2)
For Standard	100 µL Standard + 1,0 mL Working reagent (R1 + R2)
For Sample	100 µL Supernatant + 1,0 mL Working reagent (R1 + R2)
To produce a homogeneous turbidity, the standard or the clear supernatant must be added to the surface of the working reagent in the cuvette. Mix each cuvette carefully before proceeding to the next sample. Mix and allow to stand for 5 min. Read the absorbance (A) of the standard and samples against working reagent blank between 5 and 30 minutes.	

Calculation

$$\text{Potassium (mEq/L)} = \frac{A_{Sample} - A_{Blank}}{A_{Standard} - A_{Blank}} \; x \; stand.conc. \left(\frac{mEq}{L}\right)$$

Conversion Factor:
mmol/L = 1 x mEq/L
mg/dL = 3,909 x mmol/L

Quality control

Control sera are recommended to monitor the performance of assay procedures. Use Biochemistry Normal and Pathological Controls Specific (HBC01-S, HBC02-S).Prepare and measure these controls the same as samples.
If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

Reference values 1

Serum	3,6 - 5,5 mEq/L (3,6 - 5,5 mmol/L)
Plasma	4,0 - 4,8 mEq/L (4,0 - 4,8 mmol/L)

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

Performance characteristics

Measuring range: from 2,0 mEq/L (detection limit) to 10,0 mEq/L (linearity limit). If the obtained results are greater than 10,0 mEq/L, dilute the sample 1:2 with saline solution, repeat the determination, and multiply the result by factor 2.

Precision:

	intra-assay (n=20)		inter-assay (n=20)	
Mean (mEq/L)	4,64	7,60	4,61	7,63
SD	0,10	0,10	0,11	0,15
CV (%)	2,05	1,32	2,45	1,94

Sensitivity: 1 mEq/L = 0,537 AU

Accuracy: Results obtained using CYPRESS DIAGNOSTICS reagents did not show systematic differences when compared with other commercial reagents.
The results of the performance characteristics depend on the analyzer used.

Interferences

The following substances do not interfere with potassium determination at the indicated concentrations: bilirubin 40 mg/dL, hemoglobin 450 mg/dL, triglycerides 2500 mg/dL and ascorbate 20 mg/dL.

Notes

1. For best use of this kit on a Cypress Diagnostics analyzer, we kindly advise to follow the application sheets of the respective analyzer. Please log in to our website (www.diagnostics.be) as a registered user to download the latest application sheets, which are located under the section of the corresponding analyzer. Compatible Cypress analyzers: CYANSmart, CYANStart, CYANVision.
2. Calibration with the aqueous standard may cause a systematic error in automatic procedures. In this case, it is recommended to use a serum based Biochemistry calibrator Specific (HBC03-S).
3. As red blood cells contain about 25 times the amount of potassium, they have to be separated from the serum within 1 hour after blood collection. Otherwise, falsely elevated potassium concentrations will be found.
4. Traces of detergents produce turbidity which leads to falsely elevated potassium concentrations. They have to be avoided. Therefore, disposable plastic tubes are recommended for the determination. If nevertheless reusable materiel is used, it has to be rinsed carefully with distilled water.

Cypress Diagnostics: Nijverheidsstraat 8 • 2235 Hulshout • Belgium
www.diagnostics.be • Tel: ++ 32 15 67 67 68 • e-mail: cypress@diagnostics.be

5. Samples, Biochemistry Controls Specific (HBC01-S, HBC02-S) and Biochemistry Calibrator Specific(HBC03-S) must be precipitated. Standard must NOT be precipitated.

Bibliography

1. Hillmann G and Beyer GZ. Klin Chem. Klin. Biochem. 5, 93 (1967)
2. Tietz NW. Fundamentals of Clinical Chemistry WB, Saunders Co., Phila, PA, 2nd Ed., p. 876 (1976)

Notice: Any serious incident that has occurred in relation to the device shall be reported to Cypress Diagnostics and the competent authority of the Member State in which the user and/or patient is established.

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Cypress Diagnostics: Nijverheidsstraat 8 • 2235 Hulshout • Belgium
www.diagnostics.be • Tel: ++ 32 15 67 67 68 • e-mail: cypress@diagnostics.be