



POTASSIUM LR liquid reagent

REF C4900650/C4900650A 6x50 ml

CE C4900620/C4900620A 6x20 ml
IVD For in vitro medical device

Use

Kit for measurement of potassium in serum or plasma. Turbidimetric method

Summary

Potassium is released by platelets during covering process, so potassium level in serum is lightly higher than plasma. Either lower levels and higher levels are important for clinical determination.

Principle

The tetraphenylboron precipitates with potassium ions giving turbidity proportional to sample concentration of potassium.

Reagents

R1	Tris buffer	30.0 mmol/l
	NA-TPB	134.0 mmol/l
	Boric acid	250 mmol/l

Reagent Preparation

Reagents are liquid and ready to use.

Storage and stability

- Store the kit at 15-25°C.
- After opening, the vial is stable 60 days if recapped immediately and protected from contamination, evaporation, direct light, and stored at the correct temperature.

Precaution in Use

The product is not classified as dangerous (DLg. N. 285 art. 28 l. n. 128/1998). However the reagent should be handled with caution, according to good laboratory practice. Caution: the reagents contain Sodium Azide (0.095%) as preservative. Avoid swallowing and contact with skin, eyes and mucous membranes.

Waste Management

Please refer to the local legal requirements.

Specimen Collection and Preparation

- Serum or plasma without haemolysis

Note

- The kit, according to this method, must be used in manual procedures. About automatic using follow specific applications.
- Avoid direct light, contamination and evaporation.
- The volumes in the procedure can be changed proportionally.
- In case of complaint or quality control request, refer to the lot number on the package or the lot number on the single vials.

Procedure

Wavelength	λ: 578 nm
Working Temperature	37°C
Optical path	1 cm
Reaction	"end point"

-- Monoreagent Procedure "sample starter"

	BLANK	STD	SAMPLE
Working Reagent	1000 µl	1000 µl	1000 µl
Sample	--	--	25 µl
Standard	--	25 µl	--

Reset the instrument with distilled water. Mix to obtain a omogeneous turbidity. Read after five minutes. Mix again before reading

Calculation

OD sample x [STD]
OD STD

The reagent performances are related to 37°C, 1 cm and 578 nm.

Reference Values

Serum	3.6 - 5.5 mmol/l
Plasma	4.0 - 4.8 mmol/l

Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

ANALYTICAL PERFORMANCES

Linearity

Reaction is linear up to a concentration of 10 mmol/l. Samples with values exceeding this value must be diluted with saline solution. Then multiply the result for diluting factor.

"Intra-Assay" precision (within-Run)

Determined on 20 samples for each control (N-H) (Normal- High). Results:

MEAN (mmol/l)	N = 3.96	P = 6.10
S.D.	N = 0.11	P = 0.08
C.V.%	N = 2.75	P = 1.24

"Inter-Assay" precision (between-Run)

Determined on 20 samples for each control (N-H) (Normal- High). Results:

MEAN (mmol/l)	N = 3.96	P = 6.08
S.D.	N = 0.10	P = 0.08
C.V.%	N = 2.56	P = 1.33

Analytical sensitivity

The test sensitivity in terms of detection limit is: 0.05 mmol/l.

Correlation

A study based comparing this method with a similar method on 20 samples has given a correlating factor: **r = 0.97**

Interferences

No interference was observed by the presence of: Bilirubin ≤ 10 mg/dl. For a comprehensive review of interfering substances, refer to the publication by Young.

Quality controls

It's necessary, every time the kit is used, to make the quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

Bibliography

Kaplan, L.A., Pesce, A.J.: "Clinical Chemistry", Young D.S., Effects of Drugs on Clinical Laboratory Tests, AACC Press, Washington, DC 5th ed.2000.

Symbols

CE CE Mark (requirement of 98/79 regulation)

IVD in vitro medical device

LOT Batch Code

Use by

Storage temperature limits
Read instruction for use

Producer