

Potassium (Single Reagent)

REF: 298 001 (2 x 25ml) 50 test REF: 298 002 (4 x 25ml) 100 test REF: 298 003 (2 x 100ml) 200 test REF: 298 004 (4 x 100ml) 400 test REF: ZL-298 001 50 test

Intended Use

Spectrum Potassium reagent is intended for the in-vitro quantitative diagnostic estimation of potassium in human serum or plasma on manual systems.

Background

Sodium and Potassium are the major cations of extracellular and intracellular fluids respectively. Sodium maintains the normal distribution of water and the osmotic pressure in the various fluid compartments. Potassium influences the acid base balance and osmotic pressure including water retention. Increased sodium levels are found in severe dehydration and excessive treatment with sodium salts. Decreased levels are found in severe polyurea, metabolic acidosis, diarrhea and renal insufficiency. Increased potassium levels are found in renal failure, dehydration, shock and adrenal insufficiency. Decreased levels are found in malnutrition, gastrointestinal fluid loss and hyperactivity of the adrenal cortex.

Method

Turbidimetric Tetraphenylborate (TPB)

Assay Principle

At an alkaline pH Potassium ions and TPB form a turbid emulsion, the increase of which can be measured quantitatively in a photometer at 578 nm. The increase of the absorbance (A) is directly proportional to the concentration of Potassium in the sample.

Reagent

| Reagent R | NaOH TPB-Na | 0.50 mol/L 240 mmol/L | |
|-----------|----------------|--------------------------|--|
| Standard | Potassium | 5.0 mmol/L | |

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Irritant (Xi): R36/38: Irritating to eyes and skin. 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.

Reagent Storage and Stability

Reagent and standard are ready-to-use and stable till the expiration date stated on the vial label at $2-8\,^{\rm O}$ C. Once opened the reagent and the standard are stable for 3 months at the specified temperature.

Caution: Reagent is a microemulsion. Therefore, a slight apparent precipitation could occur, showing a light white deposit at the bottom of the vial. It is a normal behaviour and it is recommended to resuspend solution before analysis with mild shaking.

Specimen Collection and preservation

Human nonhemolyzed serum is the preferred specimen .Heparin is the only acceptable anticoagulant. No other anticoagulant can be used. Do not use lipemic or turbid samples.

SYMBOLS IN PRODUCT LABELLING

ECREP Authorised Representative

Use by/Expiration Date IVD For in-vitro diagnostic use / CAUTION. Consult instructions LOT Batch Code/Lot number for use REF Manufactured by Catalogue Number Consult instructions for use X (Xi) - Irritant Temperature Limitation

System Parameters

Wavelength 578 nm Optical path 1 cm

Colorimetric end-point Assay type Increase

Direction Sample: Reagent Ratio 1:50 25-37 °C Temperature Equilibration Time 30 seconds

Zero adjustment Against distilled water

Reagent blank Low 0.0 AU High 1.5 AU Sensitivity 1.5 mmol/l Linearity 10 mmol/L

Procedure

| | Standard | Sample | |
|-----------|----------|--------|--|
| Reagent R | 1 mL | 1 mL | |
| Standard | 20 μL | | |
| Sample | | 20 μL | |

Mix and incubate for 3 minutes at 37 °C or 5 minutes at 25 °C. Mix again thoroughly and read absorbance of sample (A_{sample}) and standard ($A_{standard}$) against distilled water.

Calculation

Serum Potassium Conc.(mmol/L) =

Quality Control

Normal and abnormal commercial control serum of known concentrations should be analyzed with each run.

Performance Characteristics

Precision

Within run (Repeatability)

| | Level 1 | Level 2 |
|---------------|---------|---------|
| n | 20 | 20 |
| Mean (mmol/L) | 4.1 | 7.4 |
| SD | 0.21 | 0.3 |
| CV% | 5.12 | 4.05 |

Run to run (Reproducibility)

| | Level 1 | Level 2 |
|---------------|---------|---------|
| n | 20 | 20 |
| Mean (mmol/L) | 4.1 | 7.4 |
| SD | 0.4 | 0.5 |
| CV% | 9.76 | 6.76 |

Methods Comparison

A comparison between Spectrum Potassium reagent and a commercial reagent of the same methodology was performed on 200 human sera. A correlation of 0.978 was obtained.

Sensitivity

When run as recommended, the minimum detection limit of the assay is 1.5 mmol/L.

Linearity

The assay is linear up to 10 mmol/L

Interfering substances

Haemolysis

Hemolyzed sera produce elevated results.

No significant interference up to bilirubin level of 40 mg/dL.

Lipemia

Turbid or lipemic samples produce falsely elevated results.

Nitrogen Urea Nitrogen above 80 mg/dL will produce elevated results. Sera containing high levels of ammonia shoud be avoided.

Expected Values

3.6 - 5.5 mmol/L 4.0 – 4.8 mmol/L Serum Plasma

It is recommended for each laboratory to establish and maintain its own reference values. The given data are only an indication.

Spectrum Diagnostics does not interpret the results of a clinical laboratory procedure; interpretation of the results is considered the responsibility of qualified medical personnel. All indications of clinical significance are supported by literature references.

Waste Disposal

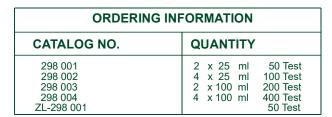
This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal. S56: dispose of this material and its container at hazardous or special waste collection point.

S57: use appropriate container to avoid environmental contamination.

S61: avoid release in environment. refer to special instructions/safety data sheets.

References

- 1. Hillman, G.; Beyer, G.: Z. Klin. Biochem. 5 (1967), 93 2. Hoeflmayr, J.: Praxis und Helferin 8 (1979) 3. Tietz, N.W.: Fundamentals of Clin. Chem. (1976), 876



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