

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

Intended Use

Spectrum-Diagnostics 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 inhale. 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 °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 Serum is the preferred specimen .
 Do not use lipemic or turbid samples.

SYMBOLS IN PRODUCT LABELLING

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

System Parameters

Wavelength	578 nm
Optical path	1 cm
Assay type	Colorimetric end-point
Direction	Increase
Sample: Reagent Ratio	1:50
Temperature	25-37 °C
Equilibration Time	30 seconds
Zero adjustment	Against reagent blank
Reagent blank	Low 0.0 AU High 1.5 AU
Sensitivity	1.5 mmol/L
Linearity	10 mmol/L

Procedure

	Reagent Blank	Standard	Sample
Reagent R	1mL	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 blank.

Calculation

$$\text{Serum Potassium Conc. (mmol/L)} = \frac{A_{\text{Sample}}}{A_{\text{Standard}}} \times 5$$

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 Diagnostics Potassium reagent and a commercial reagent of the same methodology was performed on 20 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.

Icterus

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 should be avoided.

Expected Values

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

Note:

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 Helferlin 8 (1979)
3. Tietz, N.W.: Fundamentals of Clin. Chem. (1976), 876

ORDERING INFORMATION

CATALOG NO.	QUANTITY
298 001	2 x 25 ml 50 Test
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298 003	2 x 100 ml 200 Test
298 004	4 x 100 ml 400 Test



Egyptian Company for Biotechnology (S.A.E)

Obour city industrial area. block 20008 piece 19 A. Cairo. Egypt.

Tel: +202 4489 2248 - Fax: +202 4489 2247

www.spectrum-diagnostics.com

E-mail: info@spectrum-diagnostics.com



MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany



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