Potassium FS*

Diagnostic reagent for quantitative in vitro determination of potassium in serum or plasma on photometric systems

Order Information

Cat. No.
1 5221 99 10 021 R1 5 x 20 mL + R2 1 x 25 mL

Summary [1-2]

Potassium (K^+) is the major cation in the intracellular space (ICS) and is essential for many body functions, mainly the neuromuscular excitability. The potassium gradient between ICS and extracellular space (ECS) is built up by a Na^+/K^+ pump and contributes considerably to the electrical potential difference at the cell membrane. K^+ balance is regulated by the kidneys under hormonal control of the renin-angiotensin-aldosteron system.
Potassium levels in serum are mainly affected by acute and chronic renal failure, severe diarrhea and vomiting, some medication (e. g. ACE inhibitors, angiotensin receptor blockers, diuretics), disorders of acid balance and massive cell lysis or hemolysis after injury, surgery or burns. Furthermore, potassium values are used for monitoring cardiovascular insufficiency, changes in blood pH or diuretic therapies.

Method

Enzymatic photometric test

Principle

Pyruvate kinase is activated by K^+ ions in the sample and subsequently catalyzes the dephosphorylation of phosphoenolpyruvate to pyruvate. In a second step pyruvate is transformed to lactate under consumption of a NADH analogue. The signal decrease measured at 340 nm is proportional to the amount of potassium in the sample.

Reagents

Components and Concentrations

R1:	Buffer	pH 8.25	40 mmol/L
	NADH analogue		0.4 mmol/L
	Phosphoenolpyruvate	(PEP)	2.5 mmol/L
	ADP		2.5 mmol/L
	Lactate dehydrogenase	(LDH)	> 5 kU/L
R2:	Buffer	pH 7.0	200 mmol/L
	Pyruvate kinase	(PK)	> 0.5 kU/L

Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 - 8 °C, protected from light and contamination is avoided. Do not freeze the reagents!

Warnings and Precautions

1. The potassium test is very susceptible to potassium contamination. The sole use of ultrapure glass ware and disposable materials is strongly recommended.
2. Reagents contain biological material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [8].
4. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
5. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use.

Materials required but not provided

General laboratory equipment

Specimen

Serum or lithium heparin plasma

Stability [3]:	1 week	at	20 – 25 °C
	1 week	at	4 – 8 °C
	1 year	at	–20 °C

Separate from cellular contents within 1 hour after blood collection. Do not use hemolytic samples. [4]

Discard contaminated specimens. Freeze only once!

Assay Procedure

Application sheets for automated systems are available on request.

Wavelength	340 nm
Optical path	1 cm
Temperature	37 °C
Measurement	Against reagent blank

	Blank	Sample or calibrator
Sample or calibrator	-	100 µL
Dist. Water	100 µL	-
Reagent 1	1000 µL	1000 µL
Mix, incubate for 5 min. at 37°C		
Reagent 2	250 µL	250 µL
Mix, incubate at 37 °C, read absorbance A1 after 2 min and start stopwatch. Read absorbance A2 after 1, 2 and 3 min at 37 °C and calculate ΔA/min.		

Calculation

The concentration of potassium in unknown samples is derived from a calibration curve using an appropriate mathematical model such as cubic spline. The calibration curve is obtained with the levels 1 - 4 of the electrolyte calibrator TruCal E.

Conversion factor

Potassium [mmol/L] = Potassium [mEq/L]
Potassium [mmol/L] x 3.91 = Potassium [mg/dL]

* fluid stable

Calibrators and Controls

For calibration, DiaSys TruCal E calibrator is recommended. The assigned values of TruCal E have been made traceable to the NIST Standard Reference Material® SRM 956. For internal quality control DiaSys TruLab N and P controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal E	1 9310 99 10 079	4 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL

Performance Characteristics

Measuring range

The test has been developed to determine potassium concentrations within a measuring range from 2 to 8 mmol/L.

Specificity/Interferences

Interfering Substance	Interferences ≤ 4.5%	Potassium concentration
Ascorbate	up to 60 mg/dL	3.24 mmol/L
	up to 60 mg/dL	4.90 mmol/L
Bilirubin, conjugated	up to 40 mg/dL	3.26 mmol/L
	up to 50 mg/dL	5.30 mmol/L
Bilirubin, unconjugated	up to 60 mg/dL	3.26 mmol/L
	up to 60 mg/dL	5.27 mmol/L
Lipemia (Triglyceride)	up to 1000 mg/dL	3.09 mmol/L
	up to 800 mg/dL	4.84 mmol/L
Hemoglobin	up to 500 mg/dL	2.89 mmol/L
	up to 500 mg/dL	5.02 mmol/L
Hemolysis interferes because potassium is released by erythrocytes.		
Sodium	135 - 180 mmol/L	3.35 mmol/L
	106 - 206 mmol/L	5.34 mmol/L
Ammonia	up to 250 µmol/L	4.61 mmol/L
Calcium	1.8 - 10.0 mmol/L	3.01 mmol/L
	2.2 - 10.0 mmol/L	5.02 mmol/L
Magnesium	up to 3.0 mmol/L	4.94 mmol/L
Manganese	up to 200 nmol/L	3.03 mmol/L
	up to 200 nmol/L	5.16 mmol/L
Phosphate	up to 7.0 mmol/L	3.22 mmol/L
	up to 7.0 mmol/L	5.22 mmol/L
Zinc	up to 500 µmol/L	3.08 mmol/L
	up to 500 µmol/L	4.97 mmol/L
Iron	up to 1000 µmol/L	3.11 mmol/L
	up to 1000 µmol/L	5.14 mmol/L
Copper	up to 500 µmol/L	3.33 mmol/L
	up to 500 µmol/L	5.28 mmol/L
For further information on interfering substances refer to Young DS [5].		

Limit of Detection

The lower limit of detection is 0.4 mmol/L.

Precision

Intra-assay n = 20	Mean [mmol/L]	SD [mmol/L]	CV [%]
Sample 1	4.40	0.05	1.03
Sample 2	4.83	0.05	1.08
Sample 3	7.05	0.08	1.17

Inter-assay n = 20	Mean [mmol/L]	SD [mmol/L]	CV [%]
Sample 1	3.26	0.07	1.99
Sample 2	4.33	0.16	3.73
Sample 3	7.06	0.16	2.20

Method Comparison

A comparison of DiaSys Potassium FS (y) to the reference method Flame Atomic Emission Spectrometry (FAES, x) using 108 samples gave following results:
y = 0.962 x + 0.118 mmol/L; r = 0.991.

Reference Range

In Plasma

Adults [2]	3.6 – 4.8 mmol/L
Children [6]	
0 – 7 days	3.2 – 5.5 mmol/L
8 – 31 days	3.4 – 6.0 mmol/L
1 – 6 month(s)	3.5 – 5.6 mmol/L
6 months – 1 year	3.5 – 6.1 mmol/L
> 1 year	3.3 – 4.6 mmol/L

In Serum [7]

Adults	3.5 – 5.1 mmol/L
Children	
Newborn	3.7 – 5.9 mmol/L
Infant	4.1 – 5.3 mmol/L
Child	3.4 – 4.7 mmol/L

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Külpmann WR, Stumvoll HK, Lehmann P. Electrolytes – Clinical and Laboratory Aspects. 1st ed. Wien: Springer-Verlag; 1996. p. 32–41.
2. Thomas L ed. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft, 1998: p. 306–313.
3. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 40-1.
4. Einer G, Zawta B. Präanalytikfibel. 2. Auflage. Heidelberg: Johann Ambrosius Barth Leipzig; 1991; p. 219–220, 238
5. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th. ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press, 2000.
6. Soldin SJ, Brugnara C, Wong EC. Pediatric Reference Intervals. 6th ed. Washington DC: AACC Press, 2007: p. 162-3.
7. Tietz textbook of clinical chemistry and molecular diagnostics. 4th ed. St. Louis: Elsevier Saunders; 2006. p. 2291.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanism, detection and prevention. Clin Chem Lab Med 2007; 45(9): 1240–1243.

Manufacturer

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