respons®910

Potassium FS*

Diagnostic reagent for quantitative in vitro determination of potassium in serum or plasma on DiaSys respons®910

Order Information

Cat. No. 1 5221 99 10 921
4 twin containers for 100 tests each

Method

Enzymatic photometric test

Principle

Pyruvate kinase is activated by K^+ ions in the sample and subsequently catalizes the dephosphorylation of phosphoenol-pyruvate to pyruvate. In a second step pyruvate is transformed to Lactate under consumption of a NADH analogue. The rate of 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 analogon		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. DiaSys respons containers provide protection from light. 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. The bottles are placed directly into the reagent rotor.

Specimen

Serum or lithium heparin plasma

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

Separate from cellular components within one hour after blood collection. Do not use hemolytic samples! [2]

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

For calibration, the 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 2 – 8 mmol/L potassium	
Limit of detection**	0.4 mmol/L potassium
On-board stability	4 weeks
Calibration stability	7 days

Interfering Substance	**Interferences ≤ 4.5%**	**Potassium concentration**
Ascorbate	up to 60 mg/dL	3.25 mmol/L
	up to 60 mg/dL	4.85 mmol/L
Bilirubin, conjugated	up to 35 mg/dL	3.28 mmol/L
	up to 60 mg/dL	5.04 mmol/L
Bilirubin, unconjugated	up to 60 mg/dL	3.23 mmol/L
	up to 60 mg/dL	5.08 mmol/L
Lipemia (Triglyceride)	up to 1000 mg/dL	3.04 mmol/L
	up to 1000 mg/dL	4.99 mmol/L
Hemoglobin	up to 500 mg/dL	3.14 mmol/L
	up to 500 mg/dL	5.34 mmol/L
Hemolysis interferes because Potassium is released by erythrocytes.		
Sodium	130 – 170 mmol/L	3.24 mmol/L
	106 – 206 mmol/L	5.23 mmol/L
Ammonium	up to 300 µmol/L	4.50 mmol/L
Calcium	1.8 – 10.0 mmol/L	3.07 mmol/L
	2.2 – 10.0 mmol/L	5.04 mmol/L
Magnesium	up to 2.8 mmol/L	5.25 mmol/L
Manganese	up to 200 nmol/L	2.88 mmol/L
	up to 200 nmol/L	4.88 mmol/L
Phosphate	0.9 – 7.0 mmol/L	2.87 mmol/L
	1.2 – 7.0 mmol/L	4.72 mmol/L
Zinc	up to 500 µmol/L	2.92 mmol/L
	up to 500 µmol/L	4.88 mmol/L
Iron	up to 1000 µmol/L	3.40 mmol/L
	up to 1000 µmol/L	5.38 mmol/L
Copper	up to 500 µmol/L	3.65 mmol/L
	up to 500 µmol/L	5.58 mmol/L
For further information on interfering substances refer to Young DS [3].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mmol/L]	3.30	4.69	7.34
Coefficient of variation [%]	1.90	1.44	1.98
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mmol/L]	3.28	4.61	7.34
Coefficient of variation [%]	3.58	2.47	2.26

Method comparison (n=121)	
Test x	Flame Atomic Emission Spectrometry (FAES) EFOX
Test y	DiaSys Potassium FS (respons®910)
Slope	0.977
Intercept	0.117 mmol/L
Coefficient of correlation	0.987

** according to NCCLS document EP17-A, vol. 24, no. 34

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Conversion factor

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

Reference Range

In Plasma

Adults [4]	3.6 – 4.8 mmol/L
Children [5]	
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 [6]

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. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 40-1.
2. Einer G, Zawta B. Präanalytikfibel. 2. Auflage. Heidelberg: Johann Ambrosius Barth Leipzig; 1991; p. 219-220, 238.
3. 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.
4. Thomas L ed. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft, 1998: p. 306 - 313.
5. Soldin SJ, Brugnara C, Wong EC. Pediatric Reference Intervals. 6th ed. Washington DC: AACC Press, 2007: p. 162-3.
6. Tietz textbook of clinical chemistry and molecular diagnostics. 4th ed. St. Louis: Elsevier Saunders; 2006. p. 2291.
7. Külpmann WR, Stumvoll HK, Lehmann P. Electrolytes – Clinical and Laboratory Aspects. 1st ed. Wien: Springer-Verlag; 1996. p. 32-41.
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Manufacturer

IVD CE

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respons®910

Potassium FS

Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	K
Shortcut:	
Reagent barcode reference:	058
Host reference:	058

Technic	
Type:	Linear kinetic
First reagent:[µL]	160
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	40
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	340
Secondary wavelength:[nm]	700
Polychromatic factor:	1.0000
1 st reading time [min:sec]	06:36
Last reading time [min:sec]	07:48
Reaction way:	Decreasing
Linear Kinetics Substrate depletion: Absorbance limit	0.4000
Linearity: Maximum deviation [%]	100.0000
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	System water
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	2.0000
Concentration technical limits-Upper	8.0000
SERUM	
Normal volume [µL]	16.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	
Above normal dilution (factor)	
URINE	
Normal volume [µL]	16.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	
Above normal dilution (factor)	
PLASMA	
Normal volume [µL]	16.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	
Above normal dilution (factor)	
CSF	
Normal volume [µL]	16.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	
Above normal dilution (factor)	
Whole blood	
Normal volume [µL]	16.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	
Above normal dilution (factor)	

Results	
Decimals	2
Units	mmol/L
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	
SERUM	>=3.50 <=5.10
URINE	
PLASMA	>=3.60 <=4.80
CSF	
Whole blood	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details	
Calibrator list	**Concentration**
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
	Max delta abs.
Cal. 1	0.100
Cal. 2	0.100
Cal. 3	0.100
Cal. 4	0.100
Cal. 5	
Cal. 6	
Drift limit [%]	0.80

Calculations	
Model	Cubic Spline
Degree	

* Enter calibrator value