respons®920

Potassium FS*

Diagnostic reagent for quantitative in vitro determination of potassium in serum or plasma on DiaSys respons®920

Order Information

Cat. No. 1 5221 99 10 921
4 twin containers for 100 determinations 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. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
4. In very rare cases, samples of patients with gammopathy might give falsified results [8].
5. 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.
6. 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

DiaSys TruCal E calibrator is recommended for calibration. 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 in serum

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	3.24 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 [3].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mmol/L]	4.40	4.83	7.05
Coefficient of variation [%]	1.03	1.08	1.17
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mmol/L]	3.26	4.33	7.06
Coefficient of variation [%]	1.99	3.73	2.20

Method comparison (n=108)	
Test x	Flame Atomic Emission Spectrometry (FAES) EFOX
Test y	DiaSys Potassium FS (respons®920)
Slope	0.962
Intercept	0.118 mmol/L
Coefficient of correlation	0.991

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

Conversion factor

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

* fluid stable

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.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240–1243.

Manufacturer

IVD CE

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Alte Strasse 9 65558 Holzheim Germany

respons®920

Potassium FS

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	Kenz				Auto Rerun		☐
Report Name	:	Potassium enz				Online Calibration		☐
Unit	:	mmol/L	Decimal Places	:	2	Cuvette Wash		☐
Wavelength-Primary	:	340	Secondary	:	700	Total Reagents	:	2
Assay Type	:	RATE-A	Curve Type	:	Cubic Spline	Reagent R1	:	Kenz R1
M1 Start	:	0	M1 End	:	0	Reagent R2	:	Kenz R2
M2 Start	:	22	M2 End	:	26	**Consumables/Calibrators:**		
Sample Replicates	:	1	Standard Replicates	:	3	TruCal E Level 1		*
Control Replicates	:	1	Control Interval	:	0	TruCal E Level 2		*
Reaction Direction	:	Decreasing	React. Abs. Limit	:	0.0000	TruCal E Level 3		*
Prozone Limit %	:	0	Prozone Check	:	Upper	TruCal E Level 4		*
Linearity Limit %	:	0	Delta Abs./Min.	:	0.0000			
Technical Minimum	:	0.0000	Technical Maximum	:	0.0000			
Y = aX + b a =	:	1.0000	b=	:	0.0000			

* Enter blank value/calibrator value.

Test Details			Test Volumes	Reference Ranges
Test	:	Kenz		
Sample Type	:	Serum		

Sample Volumes

Normal	:	16.00	µL	Dilution Ratio	:	1 X
Increase	:	20.00	µL	Dilution Ratio	:	1 X
Decrease	:	5.00	µL	Dilution Ratio	:	1 X
Standard Volume	:	16.00	µL			

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	160	µL	R1 Stirrer Speed	:	High
RGT-2 Volume	:	40	µL	R2 Stirrer Speed	:	High

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	Kenz		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (mmol/L)	Upper Limit (mmol/L)
Normal	:	3.50	5.10
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other