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 catalyzes the dephosphorylation of phosphoenolpyruvate 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®920 carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.

Warnings and Precautions
1. The potassium test is very susceptible to potassium contamination. The sole use of ultrapure glassware 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.
4. In very rare cases, samples of patients with gammopathy might give falsified results.
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.

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.

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Kit size</th>
</tr>
</thead>
<tbody>
<tr>
<td>TruCal E 1 9310 99 10 079</td>
<td>4 x 3 mL</td>
</tr>
<tr>
<td>TruLab N 5 9000 99 10 062</td>
<td>20 x 5 mL</td>
</tr>
<tr>
<td>TruLab P 5 9050 99 10 062</td>
<td>20 x 5 mL</td>
</tr>
</tbody>
</table>

Performance Characteristics in serum

<table>
<thead>
<tr>
<th>Interfering Substance</th>
<th>Interferences ≤ 5.4 %</th>
<th>Potassium concentration ≤ 6 mmol/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ascorbate</td>
<td>up to 60 mg/dL</td>
<td>3.24 mmol/L</td>
</tr>
<tr>
<td>Bilirubin, conjugated</td>
<td>up to 40 mg/dL</td>
<td>3.26 mmol/L</td>
</tr>
<tr>
<td>Bilirubin, unconjugated</td>
<td>up to 60 mg/dL</td>
<td>3.26 mmol/L</td>
</tr>
<tr>
<td>Lipemia (Triglyceride)</td>
<td>up to 1000 mg/dL</td>
<td>3.09 mmol/L</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>up to 500 mg/dL</td>
<td>2.89 mmol/L</td>
</tr>
<tr>
<td>Hemolysis interferes because Potassium is released by erythrocytes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium</td>
<td>135 – 180 mmol/L</td>
<td>3.35 mmol/L</td>
</tr>
<tr>
<td>Ammonia</td>
<td>up to 250 µmol/L</td>
<td>4.61 mmol/L</td>
</tr>
<tr>
<td>Calcium</td>
<td>1.8 – 10.0 mmol/L</td>
<td>3.01 mmol/L</td>
</tr>
<tr>
<td>Magnesium</td>
<td>up to 3.0 mmol/L</td>
<td>4.94 mmol/L</td>
</tr>
<tr>
<td>Manganese</td>
<td>up to 200 mmol/L</td>
<td>3.03 mmol/L</td>
</tr>
<tr>
<td>Phosphorus</td>
<td>up to 200 mmol/L</td>
<td>5.16 mmol/L</td>
</tr>
<tr>
<td>Zinc</td>
<td>up to 500 µmol/L</td>
<td>3.08 mmol/L</td>
</tr>
<tr>
<td>Iron</td>
<td>up to 1000 µmol/L</td>
<td>4.97 mmol/L</td>
</tr>
<tr>
<td>Copper</td>
<td>up to 500 µmol/L</td>
<td>5.14 mmol/L</td>
</tr>
</tbody>
</table>

For further information on interfering substances refer to Young DS [3].

Precision
**Within run (n=20)**

<table>
<thead>
<tr>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [mmol/L]</td>
<td>4.40</td>
<td>4.83</td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>1.03</td>
<td>1.08</td>
</tr>
</tbody>
</table>

**Between run (n=20)**

<table>
<thead>
<tr>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [mmol/L]</td>
<td>3.26</td>
<td>4.33</td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>1.99</td>
<td>3.73</td>
</tr>
</tbody>
</table>

Method comparison (n=108)

<table>
<thead>
<tr>
<th>Test x</th>
<th>Flame Atomic Emission Spectrometry (FAES) EFOX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test y</td>
<td>DiaSys Potassium FS (respons®920)</td>
</tr>
<tr>
<td>Slope</td>
<td>0.962</td>
</tr>
<tr>
<td>Intercept</td>
<td>0.116 mmol/L</td>
</tr>
<tr>
<td>Coefficient of correlation</td>
<td>0.991</td>
</tr>
</tbody>
</table>

Conversion factor
Kalium [mmol/L] = Kalium [mEq/L]
Kalium [mmol/L] = Kalium [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


Manufacturer

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany
## Potassium FS

**Application for serum and plasma**

### Test Details

<table>
<thead>
<tr>
<th>Test</th>
<th>Sample Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kenz</td>
<td>Serum</td>
</tr>
</tbody>
</table>

### Test Volumes

<table>
<thead>
<tr>
<th>Volume</th>
<th>Dilution Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>16.00 µL</td>
</tr>
<tr>
<td>Increase</td>
<td>20.00 µL</td>
</tr>
<tr>
<td>Decrease</td>
<td>5.00 µL</td>
</tr>
</tbody>
</table>

### Reference Ranges

**Category:** Male

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>Upper Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.50</td>
<td>5.10</td>
</tr>
</tbody>
</table>

### Assay Type

- **Assay Type:** RATE-A
- **Curve Type:** Cubic Spline
- **Reagent R1:** Kenz R1
- **Reagent R2:** Kenz R2

### Sample Types

- **Serum**
- **Urine**
- **CSF**
- **Plasma**
- **Whole Blood**
- **Other**

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**Consumables/Calibrators:**

- **Sample Replicates:** 1
- **Standard Replicates:** 3
- **TruCal E Level 1:**
- **TruCal E Level 2:**
- **TruCal E Level 3:**
- **TruCal E Level 4:**

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**Reaction Direction:** Decreasing

**Prozone Limit %:** 0

**Linearity Limit %:** 0

**Technical Minimum:** 0.0000

**Technical Maximum:** 0.0000

**Y = aX + b**

- **a:** 1.0000
- **b:** 0.0000

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### Reagent Volumes and Stirrer Speed

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

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### Technical Minimum

- **Linearity Limit %:** 0
- **Prozone Limit %:** 0
- **Delta Abs./Min.:** 0.0000

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### Reference Range

- **Lower Limit:** 3.50
- **Upper Limit:** 5.10

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### Sample Types

- **Serum**
- **Urine**
- **CSF**
- **Plasma**
- **Whole Blood**
- **Other**