Calcium AS FS*

Diagnostic reagent for quantitative in vitro determination of calcium in serum, plasma or urine on photometric systems

Order Information
Cat. No. Kit size
1 1130 99 10 021 R 5 x 25 mL + 1 x 3 mL Standard
1 1130 99 10 026 R 6 x 100 mL
1 1130 99 10 023 R 1 x 1000 mL
1 1130 99 10 704 R 8 x 50 mL
1 1100 99 10 030 6 x 3 mL Standard

Summary [1,2]
Calcium plays an essential role in many cell functions: intracellularly in muscle contraction and glycogen metabolism, extracellularly in bone mineralization, in blood coagulation and in transmission of nerve impulses. Calcium is present in plasma in three forms: free, bound to proteins or complexed with anions as phosphate, citrate and bicarbonate. Decreased total calcium levels can be associated with diseases of the bone apparatus (especially osteoporosis), kidney diseases (especially under dialysis), defective intestinal absorption and hypoparathyroidism. Increased total calcium can be measured in hyperparathyroidism, malignant diseases with metastases and sarcoidosis. Calcium measurements also help in monitoring of calcium supplementation mainly in the prevention of osteoporosis.

Method
Photometric test using arsenazo III

Principle
Calcium with arsenazo III at neutral pH yields a blue colored complex, whose intensity is proportional to the calcium concentration. Interference by magnesium is eliminated by addition of 8-hydroxyquinoline-5-sulfonic acid.

Reagents
Components and Concentrations
Reagent:
Phosphate buffer pH 7.5 50 mmol/L
8-Hydroxyquinoline-5-sulfonic acid 5 mmol/L
Arsenazo III 120 µmol/L
Standard: 10 mg/dL (2.5 mmol/L)

Storage Instructions and Reagent Stability
Reagent and standard are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C and contamination is avoided.

Warnings and Precautions
1. As calcium is an ubiquitous ion, essential precaution must be taken against accidental contamination. Only use disposable materials.
2. Traces of chelating agent, such as EDTA can prevent the formation of the colored complex.
3. The reagent contains sodium azide (0.95 g/L) as preservative.

Calculation
With standard or calibrator
Calcium [mg/dL] = \frac{A \text{ Sample}}{A \text{ Std} / \text{Cal}} \times \text{Conc. Std / Cal [mg/dL]}

Conversion factor
Calcium [mg/dL] x 0.2495 = Calcium [mmol/L]
Calcium/U [mg/24 h] x 0.025 = Calcium/U [mmol/24 h]
Calibrators and Controls

For calibration of automated photometric systems the DiaSys TruCal U calibrator is recommended. This method has been standardized against the reference method Atomic Absorption Spectrometry (AAS). For internal quality control DiaSys TruLab N and P or TruLab Urine controls should be assayed. Each laboratory should establish corrective actions in case of deviations in control recovery.

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Kit size</th>
</tr>
</thead>
<tbody>
<tr>
<td>TruCal U</td>
<td>5 9100 99 10 063 20 x 3 mL</td>
</tr>
<tr>
<td></td>
<td>5 9100 99 10 064 6 x 3 mL</td>
</tr>
<tr>
<td>TruLab N</td>
<td>5 9000 99 10 062 20 x 5 mL</td>
</tr>
<tr>
<td></td>
<td>5 9000 99 10 061 6 x 5 mL</td>
</tr>
<tr>
<td>TruLab P</td>
<td>5 9050 99 10 062 20 x 5 mL</td>
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<td>5 9050 99 10 061 6 x 5 mL</td>
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<tr>
<td>TruLab Urine Level 1</td>
<td>5 9170 99 10 062 20 x 5 mL</td>
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<td></td>
<td>5 9170 99 10 061 6 x 5 mL</td>
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<tr>
<td>TruLab Urine Level 2</td>
<td>5 9180 99 10 062 20 x 5 mL</td>
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<tr>
<td></td>
<td>5 9180 99 10 061 6 x 5 mL</td>
</tr>
</tbody>
</table>

Performance Characteristics

Measuring range
The test has been developed to determine calcium concentrations within a measuring range from 0.04 – 20 mg/dL (0.01 – 5 mmol/L). When values exceed this range, samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

Specificity/Interferences
No interference was observed by ascorbic acid up to 30 mg/dL, bilirubin up to 40 mg/dL, hemoglobin up to 500 mg/dL, lipemia up to 2000 mg/dL, triglycerides and magnesium up to 15 mg/dL. Strontium salts in medicine may lead to strongly increased calcium values. For further information on interfering substances refer to Young DS [6].

Sensitivity/Limit of Detection
The lower limit of detection is 0.04 mg/dL (0.01 mmol/L).

Precision (at 20 – 25°C)

<table>
<thead>
<tr>
<th>Intra-assay precision</th>
<th>Mean [mg/dL]</th>
<th>SD [mg/dL]</th>
<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>8.79</td>
<td>0.09</td>
<td>1.04</td>
</tr>
<tr>
<td>Sample 2</td>
<td>12.5</td>
<td>0.15</td>
<td>1.20</td>
</tr>
<tr>
<td>Sample 3</td>
<td>14.0</td>
<td>0.24</td>
<td>1.73</td>
</tr>
</tbody>
</table>

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<tr>
<th>Inter-assay precision</th>
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<th>SD [mg/dL]</th>
<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>8.82</td>
<td>0.18</td>
<td>2.01</td>
</tr>
<tr>
<td>Sample 2</td>
<td>12.3</td>
<td>0.11</td>
<td>0.90</td>
</tr>
<tr>
<td>Sample 3</td>
<td>13.7</td>
<td>0.26</td>
<td>1.92</td>
</tr>
</tbody>
</table>

Method Comparison
A comparison of DiaSys Calcium FS (y) with a commercially available test (x) using 70 samples gave following results:
y = 1.02 x - 0.20; r = 0.999

Reference Range

Serum/Plasma [2]:
8.6 – 10.3 mg/dL (2.15 – 2.57 mmol/L)

Urine [1]:
Women < 250 mg/24 h (6.24 mmol/24 h)
Men < 300 mg/24 h (7.49 mmol/24 h)

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