**Calcium P FS***

Diagnostic reagent for quantitative in vitro determination of calcium in serum or plasma on Sysmex BX-Series

**Order information**

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Kit size</th>
<th>Number of tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 1181 99 10 972</td>
<td>R1</td>
<td>3 x 15.8 mL</td>
</tr>
<tr>
<td></td>
<td>R2</td>
<td>3 x 6.5 mL</td>
</tr>
</tbody>
</table>

**Method**

Photometric endpoint determination with Phosphonazo III

**Principle**

At acidic pH calcium forms a purple-blue colored complex with phosphonazo III. In a second step calcium is bound to a chelating agent whereby the specific signal is eliminated. The resulting difference in absorbance is directly proportional to the calcium concentration in the sample. This guarantees a specific measurement of calcium.

**Reagents**

**Components and Concentrations**

- **R1**: Malonic acid buffer pH 5.0 150 mmol/L
- **Phosphonazo III** 150 µmol/L
- **R2**: Malonic acid 150 mmol/L
- Chelating agent < 150 mmol/L

**Storage Instructions and Reagent Stability**

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

**Warnings and Precautions**

1. **Reagent 1**: Warning. H319 Causes serious eye irritation. H412 Harmful to aquatic life with long lasting effects. P273 Avoid release to the environment. P280 Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice/attention. P501 Dispose of contents/container to hazardous or special waste collection point.

2. As calcium is an ubiquitous ion, special precaution must be taken against accidental contamination. Only use disposable materials.

3. Traces of chelating agent, such as EDTA can prevent the formation of the colored complex.

4. In very rare cases, samples of patients with gammadopathy might give falsified results [5].

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, heparin plasma

Do not use EDTA plasma.

**Stability [1]**:

- in Serum/Plasma: 7 days at 20 – 25°C
  3 weeks at 4 – 8°C
  8 months at -20°C

Discard contaminated specimens. Freeze only once.

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**Calibrators and Controls**

For calibration, 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 controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

**Performance Characteristics**

Measuring range up to 20 mg/dL (5.0 mmol/L) calcium (in case of higher concentrations re-measure samples after manual dilution with NaCl (9 g/L) or use rerun function).

<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>TruLab N</td>
<td>5 9000 99 10 062 6 x 3 mL</td>
</tr>
<tr>
<td>TruLab P</td>
<td>5 9050 99 10 062 6 x 5 mL</td>
</tr>
</tbody>
</table>

**Precision (Serum/plasma) BX-3010**

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 mg/dL</td>
<td>6.28</td>
<td>9.04</td>
</tr>
<tr>
<td>Mean mmol/L</td>
<td>1.57</td>
<td>2.25</td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>2.12</td>
<td>1.10</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 mg/dL</td>
<td>6.07</td>
<td>8.16</td>
</tr>
<tr>
<td>Mean mmol/L</td>
<td>1.51</td>
<td>2.28</td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>2.20</td>
<td>2.59</td>
</tr>
</tbody>
</table>

**Method comparison (n=110)**

| Test x | Calcium P FS (BioMajesty 6010C) |
| Test y | Calcium P FS (BX-3010) |
| Slope | 1.03 |
| Intercept | -0.465 mg/dL (0.116 mmol/L) |
| Coefficient of correlation | 0.997 |

**Conversion factor**

Calcium [mg/dL] x 0.2495 = Calcium [mmol/L]

**Reference Range**

Serum/Plasma [2]:

8.6 – 10.3 mg/dL (2.15 – 2.57 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
## Chemistry Parameters 1

<table>
<thead>
<tr>
<th>Method No.</th>
<th>Method Color</th>
<th>Method Name</th>
<th>Reagent Name</th>
<th>Reagent (µL)</th>
<th>Water (µL)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Calcium</td>
<td>Ca</td>
<td>R1</td>
<td>Ca 100</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Serum</td>
<td>Ca</td>
<td>R2</td>
<td>Ca 25</td>
</tr>
</tbody>
</table>

### Sample Type
- Serum

### Unit
- mg/dL

### Assay Type
- End

### Measuring points
- Start: 22 - End: 23
- Start: 45 - End: 46

### Stirring Speed
- R1: Slow
- R2: Slow

### Wave Length
- Prim.: 660
- Sec.: 800

### Normal Range
- Male-G1
- Male-G2
- Male-G3
- Female-G1

### Diluent Sample (µL)
- Low: 0.0
- Normal: 1.5
- High: 0.0

### Diluent (µL)
- Low: 0.0
- Normal: 1.5
- High: 0.0

### Technical Range
- (Conc): 0.1 - 20
- (mAbs/10): 1 - 1

### Decimal Point
- 2

### Profile SI
- Disable

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## Chemistry Parameters 2

### Limit Checks
- Duplicate Limit: 60 mAbs/10
- Sensitivity Limit: 2500 mAbs/10
- Linearity Limit: %
- Prozone Limit: Higher %
- Absorbance Limit: Decrease
- Abs. in reaction: 25000 mAbs/10

### Blank measurement
- Blank measurement: Disable reagent blank and C1 blank
- Measurement of Reagent Blank during Run: None
- The number of measurement: Duplicate
- Reagent blank limit checks: Duplicate Limit 60 mAbs/10

### Instrument Factor
- a: 1.00
- b: 0.00

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### Calibration Registration

<table>
<thead>
<tr>
<th>Method No.</th>
<th>Method Name</th>
<th>Sample Type</th>
<th>Replication</th>
<th>Check Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ca</td>
<td>Serum</td>
<td>Duplicate</td>
<td>42</td>
</tr>
</tbody>
</table>

- **Test without calibration**: Disable
- **Calibration Type**: Linear
- **Reagent Lot**: New
- **Calibrator Name**: TruCal U

### Analytical Parameters

**Reagent Lot No.**
- \( (R_1) \)
- \( (R_2) \)

**Calibration Curve**
- The calibration curve is lot dependent

**Conc.** | **WORK** | **MASTER** | **Calibr. Lot No.** | **All**
---|---|---|---|---
C1 | 0 | Automatic entry | Automatic entry | *
C2 | * | Automatic entry | Automatic entry | *
C3 | * | | |
C4 | | | |
C5 | | | |
C6 | | | |
C7 | | | |
K | | | |

- **C1 Blank**
- **Reagent Blank for C1**

*Entered by user*
# Calcium P FS

## Chemistry Parameters

### Analytical Parameters

<table>
<thead>
<tr>
<th>Method No.</th>
<th>Name</th>
<th>Sample</th>
<th>Serum</th>
</tr>
</thead>
<tbody>
<tr>
<td>*</td>
<td><strong>Ca</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Limit Checks</th>
<th>Blank measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duplicate Limit</td>
<td>Disable reagent blank and S1 blank</td>
</tr>
<tr>
<td>Sensitivity Limit</td>
<td>Measurement of Reagent Blank during Run: None</td>
</tr>
<tr>
<td>Linearity Limit</td>
<td>Reagent blank measurement at calibration: Reagent blank (No sample)</td>
</tr>
<tr>
<td>Prozone Limit</td>
<td>The number of measurement: Duplicate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sensitivity</th>
<th>mAbs/10</th>
</tr>
</thead>
<tbody>
<tr>
<td>SL1-S</td>
<td>SL1-F</td>
</tr>
<tr>
<td>SL2-S</td>
<td>SL2-F</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Absorbance Limit</th>
<th>Reaction Limit</th>
<th>Ink Color</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decrease</td>
<td>25000 mAbs/10</td>
<td>a 1.00</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Wave Length</th>
<th>1</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prim.</td>
<td>660</td>
<td>Sec. 800</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Normal Range Sampling</th>
<th>Normal Range Name</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Male-G1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Male-G2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Male-G3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 Female-G1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dilution</th>
<th>2.0</th>
<th>Diluent</th>
<th>(mAbs/10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1</td>
<td></td>
<td></td>
<td>0.1</td>
</tr>
<tr>
<td>R2</td>
<td></td>
<td></td>
<td>-20</td>
</tr>
</tbody>
</table>

## Method

<table>
<thead>
<tr>
<th>Print Name</th>
<th>Sample</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium</td>
<td>Serum</td>
<td>mg/dL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Assay Type</th>
<th>Measuring points</th>
</tr>
</thead>
<tbody>
<tr>
<td>End</td>
<td>Start</td>
</tr>
<tr>
<td>1</td>
<td>33</td>
</tr>
<tr>
<td>2</td>
<td>67</td>
</tr>
</tbody>
</table>

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**Calcium P FS**

**Method**

- Name: Ca

**Sample**

- Serum

**Sampling**

- Duplicate

**Check Interval**

- 42 days

**Auto Change Lot**

- Full Calibration

**Auto Interval**

- hours

**Type**

- Linear

**Material Name**

- TruCal U

**Conc.**

<table>
<thead>
<tr>
<th>WORK</th>
<th>MASTER</th>
<th>Lot No. (S)</th>
<th>All</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1</td>
<td>0</td>
<td>Automatic</td>
<td>Automatic entry</td>
</tr>
<tr>
<td>S2</td>
<td>*</td>
<td>Automatic</td>
<td>Automatic entry</td>
</tr>
<tr>
<td>S3</td>
<td>*</td>
<td>Automatic</td>
<td>Automatic entry</td>
</tr>
<tr>
<td>S4</td>
<td>*</td>
<td>Automatic</td>
<td>Automatic entry</td>
</tr>
<tr>
<td>S5</td>
<td>*</td>
<td>Automatic</td>
<td>Automatic entry</td>
</tr>
<tr>
<td>S6</td>
<td>*</td>
<td>Automatic</td>
<td>Automatic entry</td>
</tr>
<tr>
<td>S7</td>
<td>*</td>
<td>Automatic</td>
<td>Automatic entry</td>
</tr>
</tbody>
</table>

**K**

- Automatic entry
- S1 Blank
- Reagent Blank for S1

*Entered by user*

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**Sysmex BX-4000 Chemistry Analyzer**

**Analytical Parameters**

- **R Lot No.**
  - R1: 
  - R2: 
- **Last:**

**Reagent blank**

- **mAbs/10**
- **Last:**

**Blank**

- **mAbs/10**
- **Last:**

**Type**

- **Conc.**

**Absorbance**

- **mAbs/10**
- **Recalculation**

The calibration curve is lot dependent.

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**Application BX-4000**

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**June 2016/1**