

Calcium P FS*

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

Order information

| Cat. No. | Kit size | Number of tests |
|------------------|----------------|---|
| 1 1181 99 10 972 | R1 3 x 15.8 mL | BX-3010 3 x 125 tests BX-4000 3 x 82 tests |
| | R2 3 x 6.5 mL | BX-3010 3 x 125 tests BX-4000 3 x 82 tests |

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 gammopathy 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.

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.

| | Cat. No. | Kit size |
|----------|------------------|-----------|
| TruCal U | 5 9100 99 10 063 | 20 x 3 mL |
| | 5 9100 99 10 064 | 6 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 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) | |
| Limit of detection** | 0.1 mg/dL (0.025 mmol/L) calcium |
| On-board stability | 6 weeks |
| Calibration stability | 6 weeks |

| Interfering substance | Interferences < 10% | Analyte concentration |
|-------------------------|---------------------|--------------------------|
| Ascorbate | up to 30 mg/dL | 8.18 mg/dL (2.04 mmol/L) |
| Hemoglobin | up to 700 mg/dL | 8.13 mg/dL (2.03 mmol/L) |
| Bilirubin, conjugated | up to 60 mg/dL | 8.14 mg/dL (2.03 mmol/L) |
| Bilirubin, unconjugated | up to 60 mg/dL | 8.16 mg/dL (2.04 mmol/L) |
| Lipemia (triglycerides) | up to 2000 mg/dL | 9.10 mg/dL (2.27 mmol/L) |
| Lipemia (triglycerides) | up to 2000 mg/dL | 11.0 mg/dL (2.75 mmol/L) |

For further information on interfering substances refer to Young DS [4].

| Precision (Serum/plasma) BX-3010 | | | |
|----------------------------------|----------|----------|----------|
| Within run (n=20) | Sample 1 | Sample 2 | Sample 3 |
| Mean [mg/dL] | 6.28 | 9.04 | 12.7 |
| Mean [mmol/L] | 1.57 | 2.25 | 3.16 |
| Coefficient of variation [%] | 2.12 | 1.10 | 1.48 |
| Between run (n=20) | Sample 1 | Sample 2 | Sample 3 |
| Mean [mg/dL] | 6.07 | 9.16 | 12.1 |
| Mean [mmol/L] | 1.51 | 2.28 | 3.03 |
| Coefficient of variation [%] | 2.20 | 2.59 | 1.80 |

| 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 |

** lowest measurable concentration which can be distinguished from zero mean + 3 SD (n=20) of an analyte free specimen

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

1. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001. p. 20-1 and p. 50-1
2. Endres DB, Rude RK. Mineral and bone metabolism. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1395-1406.
3. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 231-241.
4. 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.
5. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.



Manufacturer

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

| Chemistry Parameters 1 | | | | Sysmex BX-3010 Chemistry Analyzer Analytical Parameters | | |
|---|--------------------------|---------------------|--------------|---|-------------------|--------------------|
| Method No. | * | Method Name | Ca | Reagent Name | Reagent (µL) | Water (µL) |
| Print Name | Calcium | MethodColor | | R1 | Ca 100 | |
| Sample Type | Serum | | | R2 | Ca 25 | |
| Unit | mg/dL | | | Diluent | Disable | |
| Assay Type | End | | | Sample Ppt. Wash | Disable | |
| Measuring points | | Start | End | Stirring Speed R1 | Slow | R2 Slow |
| | 1 | 22 | 23 | | | |
| | 2 | 45 | 46 | | | |
| Wave Length | Prim. 660 | Sec. 800 | | Normal Range | | |
| | | | | No. | Normal Range Name | Min Max |
| | | | | 1 | Male-G1 | * * |
| | | | | 2 | Male-G2 | * * |
| | | | | 3 | Male-G3 | * * |
| | | | | 4 | Female-G1 | * * |
| Normal | Sample Volume (µL) | Diluted Sample (µL) | Diluent (µL) | Technical Range | (Conc) | 0.1 - 20 |
| <input type="checkbox"/> Diluent | Low 0.0 < 1.5 < High 0.0 | | | (mAbs/10) | * | * |
| <input type="checkbox"/> Rerun (High/Prozone) | | | | Previous Result Comparison (%) | * | * % |
| <input type="checkbox"/> Diluent | 0.0 < 1.5 < 0.0 | | | Abnormal Range | (Conc) * | * |
| <input type="checkbox"/> Rerun (Low) | | | | Panic Range | (Conc) * | * |
| <input type="checkbox"/> Diluent | 0.0 < 1.5 < 0.0 | | | Decimal Point | 2 | Profile SI Disable |

*Entered by user

| Chemistry Parameters 2 | | | | Sysmex BX-3010 Chemistry Analyzer Analytical Parameters | | |
|--|---|-------------|---------------|---|---|------------------------------------|
| Method No. | * | Method Name | Ca | Sample | Serum | |
| Limit Checks | <input checked="" type="checkbox"/> Duplicate Limit | 60 | mAbs/10 | Blank measurement | Blank measurement: | Disable reagent blank and C1 blank |
| | <input checked="" type="checkbox"/> Sensitivity Limit | 2500 | mAbs/10 | | Measurement of Reagent Blank during Run: | None |
| | <input checked="" type="checkbox"/> Linearity Limit | | % | | Reagent blank measurement at calibration: | Reagent blank (No sample) |
| | | | (mAbs/10)/min | | The number of measurement: | Duplicate |
| <input type="checkbox"/> Prozone Limit | | Higher | % | <input checked="" type="checkbox"/> Reagent blank limit checks: | Duplicate Limit | 60 mAbs/10 |
| | SL1-S | | SL1-F | | Instrument Factor | a 1.00 b 0.00 |
| | SL2-S | | SL2-F | | | |
| | Sensitivity | | mAbs/10 | | | |
| <input checked="" type="checkbox"/> Absorbance Limit | Abs. in reaction | Decrease | | | | |
| | Limit | 25000 | mAbs/10 | | | |

Calibration Registration

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No.

Method Name

Sample Type

Replication

Check Interval

Test without calibration

Calibration Type

Reagent Lot

Calibrator Name

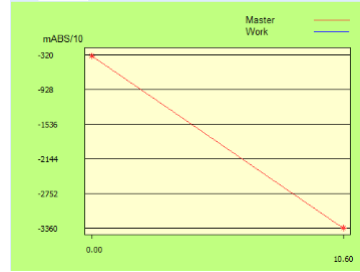
| | Conc. | WORK | MASTER | Calibr. Lot No. | <input type="checkbox"/> All |
|----|-------|-----------------|-----------------|-----------------|------------------------------|
| C1 | 0 | Automatic entry | Automatic entry | * | |
| C2 | * | Automatic entry | Automatic entry | * | |
| C3 | * | | | | |
| C4 | * | | | | |
| C5 | * | | | | |
| C6 | * | | | | |
| C7 | * | | | | |

K C1 Blank
 Reagent Blank for C1

Reagent Lot No.

(R1)
(R2)

Last



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank mAbs/10 Last

Calibration Curve Conc.

Absorbance mAbs/10

*Entered by user

| Chemistry Parameters | | Sysmex BX-4000 Chemistry Analyzer Analytical Parameters | | | | | | | | | | | | | | | | | | | | | | | |
|---|--|--|--|----------------------------------|---|-----|-------------------|-----|-----|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|-----------|---|---|
| Method | * <input type="text"/> | Name | <input type="text" value="Ca"/> | | | | | | | | | | | | | | | | | | | | | | |
| Print Name | <input type="text" value="Calcium"/> | R1 | <input type="text" value="Ca"/> | <input type="text" value="160"/> | <input type="text"/> | | | | | | | | | | | | | | | | | | | | |
| Sample | <input type="text" value="Serum"/> | R2 | <input checked="" type="checkbox"/> Enable | <input type="text" value="Ca"/> | <input type="text" value="40"/> | | | | | | | | | | | | | | | | | | | | |
| Unit | <input type="text" value="mg/dL"/> | | | | | | | | | | | | | | | | | | | | | | | | |
| Assay Type | <input type="text" value="End"/> | Diluent | <input type="checkbox"/> Enable | <input type="text"/> | <input type="text"/> | | | | | | | | | | | | | | | | | | | | |
| Measuring points | | Start | End | Decimal Points | <input type="text" value="2"/> | | | | | | | | | | | | | | | | | | | | |
| | 1 | <input type="text" value="33"/> | - | <input type="text" value="34"/> | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Enable | 2 | <input type="text" value="67"/> | - | <input type="text" value="68"/> | | | | | | | | | | | | | | | | | | | | | |
| Wave Length | Prim. <input type="text" value="660"/> | Sec | <input type="checkbox"/> Disable | <input type="text" value="800"/> | | | | | | | | | | | | | | | | | | | | | |
| <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>No.</th> <th>Normal Range Name</th> <th>Min</th> <th>Max</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Male-G1</td> <td>*</td> <td>*</td> </tr> <tr> <td>2</td> <td>Male-G2</td> <td>*</td> <td>*</td> </tr> <tr> <td>3</td> <td>Male-G3</td> <td>*</td> <td>*</td> </tr> <tr> <td>4</td> <td>Female-G1</td> <td>*</td> <td>*</td> </tr> </tbody> </table> | | | | | | No. | Normal Range Name | Min | Max | 1 | Male-G1 | * | * | 2 | Male-G2 | * | * | 3 | Male-G3 | * | * | 4 | Female-G1 | * | * |
| No. | Normal Range Name | Min | Max | | | | | | | | | | | | | | | | | | | | | | |
| 1 | Male-G1 | * | * | | | | | | | | | | | | | | | | | | | | | | |
| 2 | Male-G2 | * | * | | | | | | | | | | | | | | | | | | | | | | |
| 3 | Male-G3 | * | * | | | | | | | | | | | | | | | | | | | | | | |
| 4 | Female-G1 | * | * | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Normal Dilution | <input type="text" value="2.0"/> | Sampling | Sample (μL) | Diluent (μL) | Technical Range (Conc) <input type="text" value="0.1"/> - <input type="text" value="20"/> | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Rerun (High/Prozone) | <input type="text"/> | | | | (mAbs/10) <input type="text"/> - <input type="text"/> | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Dilution | <input type="text" value="2.0"/> | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Rerun (Low) | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Dilution | <input type="text" value="2.0"/> | | | | | | | | | | | | | | | | | | | | | | | | |
| | | SPT Wash | <input type="checkbox"/> Enable | Reagent Name | <input type="text"/> | | | | | | | | | | | | | | | | | | | | |
| | | Stirring Speed | R1 | <input type="text" value="Low"/> | R2 <input type="text" value="Low"/> | | | | | | | | | | | | | | | | | | | | |

*Entered by user

| Chemistry Parameters | | Sysmex BX-4000 Chemistry Analyzer Analytical Parameters | | | |
|--|-----------------------------------|--|------------------------------------|---------------|------------------------------------|
| Method No. | * <input type="text"/> | Name | <input type="text" value="Ca"/> | Sample | <input type="text" value="Serum"/> |
| Limit Checks | | | | | |
| <input checked="" type="checkbox"/> Duplicate Limit | <input type="text" value="60"/> | | | mAbs/10 | |
| <input checked="" type="checkbox"/> Sensitivity Limit | <input type="text" value="2500"/> | | | mAbs/10 | |
| <input checked="" type="checkbox"/> Linearity Limit | <input type="text"/> | % | <input type="text"/> | (mAbs/10)/min | |
| <input type="checkbox"/> Prozone Limit | <input type="text"/> | % | <input type="text" value="Upper"/> | | |
| | SL1-S | <input type="text"/> | - | SL1-F | <input type="text"/> |
| | SL2-S | <input type="text"/> | - | SL2-F | <input type="text"/> |
| | Sensitivity | <input type="text"/> | | mAbs/10 | |
| <input checked="" type="checkbox"/> Absorbance Limit | | | | | |
| | Reaction | <input type="text" value="Decrease"/> | | | |
| | Limit | <input type="text" value="25000"/> | | mAbs/10 | |
| Blank measurement | | | | | |
| Blank measurement: <input type="text" value="Disable reagent blank and S1 blank"/> | | | | | |
| Measurement of Reagent Blank during Run: <input type="text" value="None"/> | | | | | |
| Reagent blank measurement at calibration: <input type="text" value="Reagent blank (No sample)"/> | | | | | |
| The number of measurement: <input type="text" value="Duplicate"/> | | | | | |
| Reagent blank limit checks: | | | | | |
| <input checked="" type="checkbox"/> Duplicate Limit | <input type="text" value="60"/> | | | mAbs/10 | |
| Instrument Factor | | | | | |
| | a | <input type="text" value="1.00"/> | | b | <input type="text" value="0.00"/> |

| Registration Calibration | | Sysmex BX-4000 Chemistry Analyzer Analytical Parameters | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|-------|--|-----------------|-------------|------------------------------|------------------------------|----|---|-----------------|-----------------|--|--|----|---|-----------------|-----------------|--|--|----|---|--|--|--|--|----|---|--|--|--|--|----|---|--|--|--|--|----|---|--|--|--|--|----|---|--|--|--|--|--|
| <p>Method <input type="text" value="*"/> Name <input type="text" value="Ca"/></p> <p>Sample <input type="text" value="Serum"/></p> <p>Sampling <input type="text" value="Duplicate"/></p> <p>Check Interval <input type="text" value="42"/> days</p> <p>Auto <input type="text" value="Change Lot"/> <input type="text" value="Full Calibration"/></p> <p>Auto Interval <input type="text"/> hours</p> <p>Type <input type="text" value="Linear"/> Lot <input type="text" value="New"/></p> <p>Material Name <input type="text" value="TruCal U"/></p> <table border="1" style="width:100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width:5%;"></th> <th style="width:15%;">Conc.</th> <th style="width:15%;">WORK</th> <th style="width:15%;">MASTER</th> <th style="width:15%;">Lot No. (S)</th> <th style="width:10%;"><input type="checkbox"/> All</th> </tr> </thead> <tbody> <tr><td>S1</td><td>0</td><td>Automatic entry</td><td>Automatic entry</td><td></td><td></td></tr> <tr><td>S2</td><td>*</td><td>Automatic entry</td><td>Automatic entry</td><td></td><td></td></tr> <tr><td>S3</td><td>*</td><td></td><td></td><td></td><td></td></tr> <tr><td>S4</td><td>*</td><td></td><td></td><td></td><td></td></tr> <tr><td>S5</td><td>*</td><td></td><td></td><td></td><td></td></tr> <tr><td>S6</td><td>*</td><td></td><td></td><td></td><td></td></tr> <tr><td>S7</td><td>*</td><td></td><td></td><td></td><td></td></tr> </tbody> </table> <p>K <input type="text" value="Automatic entry"/> <input type="checkbox"/> S1 Blank <input type="checkbox"/> Reagent Blank for S1</p> | | Conc. | WORK | MASTER | Lot No. (S) | <input type="checkbox"/> All | S1 | 0 | Automatic entry | Automatic entry | | | S2 | * | Automatic entry | Automatic entry | | | S3 | * | | | | | S4 | * | | | | | S5 | * | | | | | S6 | * | | | | | S7 | * | | | | | <p>R Lot No. R1 <input type="text" value="*"/></p> <p>R2 <input type="text" value="*"/></p> <p style="text-align: right;">Last <input type="text"/></p> <div style="text-align: center; margin: 10px 0;"> </div> <p style="text-align: center;">The calibration curve is lot dependent</p> <p>Reagent blank <input type="text"/> mAbs/10 Last <input type="text"/></p> <p>Blank <input type="text" value="Automatic entry"/> mAbs/10 Last <input type="text"/></p> <p>Type <input type="text"/> Conc. <input type="text"/></p> <p>Absorbance <input type="text"/> mAbs/10 <input type="button" value="Recalculation"/></p> |
| | Conc. | WORK | MASTER | Lot No. (S) | <input type="checkbox"/> All | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| S1 | 0 | Automatic entry | Automatic entry | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| S2 | * | Automatic entry | Automatic entry | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| S3 | * | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| S4 | * | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| S5 | * | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| S6 | * | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| S7 | * | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

*Entered by user