12147939001V17

# PreciControl Bone

cobas®

REF **11972227** 122 **for 6 x 2.0 mL**
REF **11972227** 922 (QCS)

***English***

**Intended use**
Elecsys PreciControl Bone is used for quality control of specified Elecsys immunoassays on Elecsys and **cobas e** immunoassay analyzers.

**Summary**
Elecsys PreciControl Bone is a lyophilized control serum based on equine serum in 3 concentration ranges. The controls are used for monitoring the accuracy and precision of the Elecsys β-CrossLaps/serum, N-MID Osteocalcin, PTH, PTH (1-84), total P1NP, Vitamin $D_3$ (25-OH) and Vitamin D total immunoassays.

**Reagents - working solutions**
PC BONE1: 2 bottles, each for 2.0 mL of control serum
PC BONE2: 2 bottles, each for 2.0 mL of control serum
PC BONE3: 2 bottles, each for 2.0 mL of control serum

| Substance in an equine serum matrix | PC BONE1 | PC BONE2 | PC BONE3 | Unit |
|---|---|---|---|---|
| β-CTx (synthetic) | approx. 0.315<br>approx. 315 | approx. 0.75<br>approx. 750 | approx. 3.0<br>approx. 3000 | ng/mL<br>pg/mL |
| Osteocalcin (synthetic) | approx. 20 | approx. 100 | approx. 205 | ng/mL<br>(µg/L) |
| Parathyroid hormone (synthetic) | approx. 60<br>approx. 6.4 | approx. 205<br>approx. 22 | approx. 850<br>approx. 90 | pg/mL<br>pmol/L |
| Parathyroid hormone (1-84) (synthetic) | approx. 55<br>approx. 5.8 | approx. 160<br>approx. 17 | approx. 600<br>approx. 64 | pg/mL<br>pmol/L |
| P1NP (human) | approx. 75 | approx. 200 | approx. 400 | ng/mL<br>(µg/L) |
| 25-OH vitamin $D_3$ | approx. 20<br>approx. 50 | approx. 40<br>approx. 100 | approx. 70 *<br>approx. 175 * | ng/mL<br>nmol/L |

* PC BONE3 is not intended for use with the Elecsys Vitamin D total assay and therefore not linked to the test.

The exact target values and ranges are encoded in the barcodes as well as printed on the enclosed (or electronically available) value sheet.

**Target values and ranges**
The target values and ranges were determined and evaluated by Roche. They were obtained using the Elecsys assay reagents and analyzers available at the time of testing.
If the target values and control ranges are updated, this information is conveyed either via the reagent barcodes, or control barcodes (or provided electronically) and in an additional value sheet included in the reagent kit. This value sheet lists all control lots to which the new values apply.
If some of the values remain unchanged, the original values conveyed via the CBC (Control Barcode) and in the value sheet included in the control kit (or provided electronically), remain valid.
Results must be within the specified ranges. In the event that increasing or decreasing trends, or any other suddenly occurring deviations beyond the range limits are observed, all test steps must be checked. When necessary, measurement of the patient sample tested should be repeated.
Traceability information is given in the Method Sheet of the relevant Elecsys assay.
Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

**Precautions and warnings**
For in vitro diagnostic use.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.
Safety data sheet available for professional user on request.
The materials of human origin used for the controls were tested for HIV, HBV and HCV infection. The findings were negative.
However, as no testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a patient specimen. In the event of exposure, the directives of the responsible health authorities should be followed.[1,2]
Avoid foam formation in all reagents and sample types (specimens, calibrators, and controls).

**Handling**
Carefully dissolve the contents of one bottle by adding exactly 2.0 mL of distilled or deionized water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding foam formation.
Transfer aliquots of the reconstituted controls into empty Elecsys snap-cap bottles (ControlSet Vials). Attach the supplied labels to these additional bottles. Aliquots intended for storage at -20 °C should be frozen immediately.

**Storage and stability**
Store at 2-8 °C.
The lyophilized control serum is stable up to the stated expiration date.
Stability of the components in reconstituted/thawed control serum:

| | |
|---|---|
| at 20-25 °C | up to 8 hours |
| at 2-8 °C | 5 days |
| at -20 °C | 1 month (4 freeze/thaw cycles possible) |

**Materials provided**
- Elecsys PreciControl Bone, 3 barcode cards, control barcode sheet, 3 x 2 labeled empty snap-cap bottles, 3 x 6 bottle labels

**Materials required (but not provided)**
- REF 03142949122, Elecsys ControlSet Vials, 2 x 56 empty bottles with snap-caps
- Elecsys 2010, MODULAR ANALYTICS E170 or **cobas e** immunoassay analyzers and assay reagents. See appropriate Method Sheet and operator's manual for additionally required materials.
- Distilled or deionized water

**Assay**
Treat the reconstituted control serum in the system-compatible labeled bottles for analysis in the same way as patient samples. Read the data into the analyzer.
Ensure the controls are at ambient temperature (20-25 °C) prior to measurement.
Run controls daily in parallel with patient samples, once per reagent kit, and whenever a calibration is performed. The control intervals and limits should be adapted to each laboratory's individual requirements.
Follow the applicable government regulations and local guidelines for quality control.

**References**
1. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.
2. Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

For further information, please refer to the appropriate operator's manual for the analyzer concerned, the respective application sheets, the product information, and Method Sheets of all necessary components.



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