PreciControl Anemia

cobas®

REF **04415299** 190 **for 6 x 2.0 mL**
REF **04415299** 922 (QCS)

English

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

Summary
Elecsys PreciControl Anemia contains lyophilized control serum based on human serum matrix in three concentration ranges. The controls are used for monitoring the accuracy and precision of the Elecsys Ferritin, Folate, and Vitamin B_{12} immunoassays.

Reagents - working solutions
- PC A1: 2 bottles, each for 2.0 mL of control serum
- PC A2: 2 bottles, each for 2.0 mL of control serum
- PC A3: 2 bottles, each for 2.0 mL of control serum

Substance in human serum matrix	PC A1	PC A2	PC A3	Unit
Ferritin (human, liver)	approx. 30	approx. 400	approx. 800	ng/mL (µg/L)
Folate	approx. 7	approx. 18	approx. 32	nmol/L
	approx. 3	approx. 8	approx. 14	ng/mL (µg/L)
Vitamin B_{12}	approx. 258	approx. 517	approx. 1107	pmol/L
	approx. 350	approx. 700	approx. 1500	pg/mL (ng/L)

The exact lot-specific 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.
If the target values and control ranges are updated at a later time, this information is conveyed either via the reagent barcodes or control barcodes (or provided electronically) and on 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 on the value sheet included in the control kit (or provided electronically), continue to be valid.
Results must be within the corresponding specified ranges. All test steps must be checked when increasing or decreasing trends or suddenly occurring deviations beyond the range limits are seen.
Traceability information is given in the package inserts of the respective Elecsys assay.
Each laboratory should establish corrective measures to be taken if values fall outside the 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.
All human material should be considered potentially infectious.
All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV.
The testing methods applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.
However, as no testing method can rule out the potential risk of infection with absolute certainty, the material should be treated just as carefully as a patient specimen. In the event of exposure the directives of the responsible health authorities should be followed.[1,2]
Avoid the formation of foam with all reagents and sample types (specimens, calibrators, and controls).

Handling
Dissolve carefully the contents of one bottle by adding exactly 2.0 mL of distilled or deionized water and allow to stand closed for 30 minutes to reconstitute. Mix carefully, avoiding the formation of foam.
Transfer aliquots of the reconstituted controls into empty 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 the reconstituted control serum:

at 20-25 °C	up to 8 hours
on the analyzers at 20-25 °C	up to 5 hours
at 2-8 °C	3 days
at -20 °C	1 month (freeze only once)
after thawing	use only once

Materials provided
- Elecsys PreciControl Anemia, 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, ControlSet Vials, 2 x 56 empty snap-cap bottles
- Elecsys 2010, MODULAR ANALYTICS E170 or **cobas e** immunoassay analyzers and assay reagents. See appropriate test package insert and operator's manual for additionally required materials.
- Distilled or deionized water

Assay
For use on the analyzers, treat the reconstituted control serum in the system-compatible labeled bottles for analysis in the same way as the patient samples. Read the data encoded in the barcoded bottle labels and barcodes into the analyzer.
Ensure the controls are at ambient temperature (20-25 °C) before measurement.
Run controls daily in parallel with patient samples, once per reagent kit, and whenever 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. Council Directive (2000/54/EC). Official Journal of the European Communities No. L262 from Oct. 17, 2000.

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

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