

PreciControl Lung Cancer

cobas®

REF 07360070 190

→ 4 x 3.0 mL

English

Intended use

PreciControl Lung Cancer is used for quality control of the Elecsys SCC, ProGRP, CYFRA 21-1 and NSE immunoassays on the Elecsys and cobas e immunoassay analyzers.

Summary

PreciControl Lung Cancer is a lyophilized control based on human serum in two concentration ranges. The controls are used for monitoring the accuracy and precision of the specified Elecsys immunoassays.

Reagents - working solutions

- PC LC 1: 2 bottles, each for 3.0 mL of control serum
- PC LC 2: 2 bottles, each for 3.0 mL of control serum

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 specified 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.

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.

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 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}

The controls may not be used after the expiration date.

Avoid foam formation in all reagents and sample types (specimens, calibrators and controls).

Handling

Carefully dissolve the contents of one bottle by adding exactly 3.0 mL of distilled or deionized water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding foam formation.

Transfer the reconstituted controls into the empty labeled snap-cap bottles supplied or into additional snap-cap bottles (ControlSet Vials). Attach the supplied labels to these additional bottles. Aliquots intended for storage at -20 °C should be frozen immediately.

Perform **only one** control procedure per aliquot.

Please note: Both the vial labels, and the additional labels (if available) contain 2 different barcodes. The barcode between the yellow markers is for cobas 8000 systems only. If using a cobas 8000 system, please turn

the vial cap 180° into the correct position so the barcode can be read by the system. Place the vial on the instrument as usual.

PreciControl Lung Cancer also contains SCC antigen. SCC reactive determinants are shed naturally in skin particles, saliva and other body fluids and can easily be distributed in dust or aerosols, e.g. as a result of sneezing. Contamination of the samples, the CalSet Vials or the Elecsys consumables with SCC may cause falsely elevated SCC results. Gloves should be used throughout the test procedure when handling reagents, samples, CalSet Vials etc. A face mask is also recommended.

Storage and stability

Store at 2-8 °C.

The lyophilized control serum is stable up to the stated expiration date.

Stability of the reconstituted controls:	
either at -20 °C	28 days (freeze only once)
or at 2-8 °C	7 days
or at 20-25 °C	7 hours

Store controls **upright** in order to prevent the control solution from adhering to the snap-cap.

Materials provided

- PreciControl LC, 2 barcode cards, control barcode sheet, 2 x 2 labeled empty snap-cap bottles, 2 x 6 bottle labels

Materials required (but not provided)

- REF 03142949122, ControlSet Vials, 2 x 56 empty snap-cap bottles
- MODULAR ANALYTICS E170 or cobas e immunoassay analyzers and assay reagents
- Distilled or deionized water

See the assay Method Sheet and the operator's manual for additionally required materials.

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 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

- Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.
- 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 the Method Sheets of all necessary components (if available in your country).

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.



SCC antigens and ProGRP antigen used in the Roche PreciControl Lung Cancer are licensed by Fujirebio Diagnostics, Inc.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard:

CONTENT
SYSTEM

Contents of kit

Analyzers/Instruments on which reagents can be used

PreciControl Lung Cancer

cobas[®]

REAGENT

Reagent

CALIBRATOR

Calibrator



Volume after reconstitution or mixing

GTIN

Global Trade Item Number

COBAS, COBAS E, ELECSYS and PRECICONTROL are trademarks of Roche.

All other product names and trademarks are the property of their respective owners.

Additions, deletions or changes are indicated by a change bar in the margin.

© 2016, Roche Diagnostics



Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com

