

# PreciControl Lp(a) Gen.2

REF 05852650190

05852650500

→ 2 x 1 mL Level Low

→ 2 x 1 mL Level High

## English

### System information

For use on **cobas c** and COBAS INTEGRA analyzer systems, refer to the corresponding method sheet of the assay for the identification on the systems.

### Intended use

PreciControl Lp(a) Gen.2 is intended for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.

### Summary

PreciControl Lp(a) Gen.2 consists of 2 lyophilized controls based on a human plasma matrix.

The adjusted concentrations of the control components are in the low concentration range for Level Low and the elevated concentration range for Level High.

Some methods specified in the relevant value sheet may not be available in all countries.

### Reagents – working solutions

#### Reactive components in the lyophilizate:

Human plasma with chemical additives and material of biological origin as specified.

#### Non-reactive components:

##### Stabilizer

The concentrations of the control components are lot-specific. The exact target values are given in the electronically available or enclosed value sheets.

The values are also encoded in the enclosed control barcode sheets for COBAS INTEGRA analyzers.

For the **cobas c** analyzers the values are encoded in electronic files sent via the **cobas** link to the analyzers.

### Target values and ranges

The target values were determined using the method stated in the electronically available or enclosed value sheets. Determinations for Roche methods were performed under strictly standardized conditions on Roche analyzers using Roche system reagents. The target value is the mean of all values obtained. The corresponding control range is calculated as the target value  $\pm 3$  standard deviations (the standard deviation being the value obtained from several target value determinations). Results should be within the defined ranges. Each laboratory should establish corrective measures to be taken if values fall outside the range.

The traceability of the target value is given in the respective Method Sheets for the system reagents to be used in combination with the recommended calibrator.

### Precautions and warnings

For in vitro diagnostic use for laboratory professionals. Exercise the normal precautions required for handling all laboratory reagents.

#### Infectious or microbial waste:

Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

#### Environmental hazards:

Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:



Danger

H360D

May damage the unborn child.

H411 Toxic to aquatic life with long lasting effects.

### Prevention:

P201 Obtain special instructions before use.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.

### Response:

P308 + P313 IF exposed or concerned: Get medical advice/attention.

P391 Collect spillage.

### Disposal:

P501 Dispose of contents/container to an approved waste disposal plant.

### Hazardous components:

- kanamycin sulphate

Product safety labeling follows EU GHS guidance.

Contact phone: all countries: +49-621-7590

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 use assays that have been approved or cleared by the FDA or that are in compliance with the legal rules of the European Union (IVDR 2017/746/EU, IVDD 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.<sup>1,2</sup>

### Handling

Carefully open one bottle avoiding the loss of lyophilizate, and pipette in exactly 1.0 mL of distilled/deionized water. Carefully close the bottle and dissolve the contents completely by occasional gentle swirling within 30 minutes. Avoid the formation of foam.

The enclosed barcoded labels are intended exclusively for **cobas c** systems to identify the control. Attach the barcoded labels to the tubes carrying the sample cups containing the control material.

### Storage and stability

Store at 2-8 °C.

Criterion for the stability data stated by Roche:

Recovery within  $\pm 10\%$  of initial value.

#### Stability:

unopened: up to the stated expiration date at 2-8 °C

after opening/reconstitution: 14 days at 2-8 °C, provided that the dispensing of the control occurs without microbial contamination, e.g. by pouring out.

Store control tightly capped when not in use.

### Materials provided

- PreciControl Lp(a) Gen.2 (Level Low and Level High)
- Barcoded labels

### Materials required (but not provided)

- Roche system reagents and clinical chemistry analyzers
- General laboratory equipment

# PreciControl Lp(a) Gen.2

## Assay

Dispense the required volume into a sample cup and analyze in the same way as patient samples.

The controls should be run daily in parallel with patient samples and after every calibration. Control intervals must be adapted to individual laboratory's 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.

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.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

## Symbols

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

	Contents of kit
	Volume for reconstitution
	Global Trade Item Number
	Bottle lot

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

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