06361137001V1.0

Preciset Lp(a) Gen.2

cobas®

REF **05852641** 190 → 5 x 1 mL Calibrator

English

System information

For use on Roche/Hitachi MODULAR and **cobas c** analyzers the calibrator codes are 962 - 966. For use on COBAS INTEGRA analyzers the system ID is 07 7546 0.

Intended use

Preciset Lp(a) Gen.2 is intended for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheets.

Summary

Preciset Lp(a) Gen.2 consists of 5 lyophilized calibrators based on a stabilized and lyophilized pool of human plasma. The concentrations of the calibrator components have been adjusted to ensure optimal calibration of the appropriate Roche methods on clinical chemistry analyzers.

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:

Stabilizers

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

The values are also encoded in the enclosed calibrator barcode sheets for Roche/Hitachi MODULAR and COBAS INTEGRA analyzers.

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

Calibrator values

The calibrator values were determined using the method stated in the electronically available or enclosed value sheets. Determinations were performed under strictly standardized conditions on Roche analyzers using Roche system reagents.

Traceability information is given in the relevant Method Sheets for the system reagents.

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]

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 gently mixing for at least 30 minutes on a mechanical mixer. Avoid the formation of foam.

The enclosed barcoded labels are intended exclusively for Roche/Hitachi MODULAR automated analyzers and **cobas c** systems to identify the calibrator. Attach the barcoded labels to the tubes carrying the sample cups containing the calibrator material.

Storage and stability

Store at 2-8 °C.

Criterion for the stability data stated by Roche:
Recovery within ± 10 % of initial value.

Stabilty:

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 calibrator occurs without microbial contamination, e.g. by pouring out.

Store calibrators tightly capped when not in use.

Do not freeze.

Materials provided

- Preciset Lp(a) Gen.2 (bottles 1-5)
- Barcoded labels

Materials required (but not provided)

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

Assay

Use Preciset Lp(a) Gen.2 as specified in the relevant Method Sheet for the system reagents.

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.

Symbols

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

CONTENT	Contents of kit
CALIBRATOR	Calibrator
→	Volume after reconstitution or mixing

CE

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Roche