



04486935001V4.0

C.f.a.s. Lipids 5 mL

USA standardized

REF 04373391 190

→ 5 x 5 mL Calibrator

cobas®

English

Intended use

C.f.a.s. (Calibrator for automated systems) Lipids 5 mL is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the enclosed value sheet.

Summary

C.f.a.s. Lipids 5 mL is a lyophilized calibrator based on human serum.

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 serum with chemical additives and material of biological origin as specified.

The origin of the biological additives is as follows:

Analyte	Origin
HDL-cholesterol	human serum

Non-reactive components:

Preservatives and stabilizers

The concentrations of the calibrator components are lot-specific. The exact calibrator values are given in the enclosed value sheet.

Calibrator value

The calibrator value was determined using the method mentioned in the enclosed value sheet. Determination was performed under strictly standardized conditions on Roche analyzers using Roche system reagents.

The calibrator value was obtained via multiple determinations on multiple analyzer systems. The calibrator value specified is the mean of all values obtained.

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.

For USA: For prescription use only.

CAUTION. WARNING: The bottles contain sodium azide (< 1 %). Avoid contact with skin and mucous membranes. Flush affected areas with copious amounts of water. Get immediate medical attention for eyes or if ingested. Sodium azide may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up. Clean exposed metal surfaces with 10 % sodium hydroxide.

Contact phone: all countries: +49-621-7590, USA: 1-800-428-2336

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 5.0 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.

Storage and stability

Store at 2-8 °C.

Criterion for the stability data stated by Roche:

Recovery within ± 10 % of initial value.

Stability of the lyophilized calibrator at 2-8 °C:

Up to the stated expiration date.

Stability of the components in the reconstituted calibrator:

at 15-25 °C	8 hours
at 2-8 °C	5 days
at (-15)-(-25) °C	4 weeks (when frozen once)

Store calibrator tightly capped when not in use.

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

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

Assay

Use C.f.a.s. Lipids 5 mL as specified in the relevant Method Sheet for the system reagents.

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.

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
GTIN	Global Trade Item Number

FOR US CUSTOMERS ONLY: LIMITED WARRANTY

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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