

# C.f.a.s. IgA/IgM CSF

REF 06533850 190

→ 3 x 1 mL Calibrator

## English

### System information

For use on Roche/Hitachi **cobas c** analyzers the calibrator code is 408.

### Intended use

C.f.a.s. (Calibrator for automated systems) IgA/IgM CSF is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheets.

### Summary

C.f.a.s. IgA/IgM CSF 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.

*Non-reactive components:*

Preservative and stabilizers

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

For the **cobas c** analyzers (except for the **cobas c 111** analyzer) the values are encoded in electronic files sent via the **cobas** link to the analyzers.

### Calibrator values

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

The calibrator values were obtained via single determinations performed in different laboratories in several separate runs. The calibrator value specified is the median 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.

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

H412 Harmful to aquatic life with long lasting effects.

### Prevention:

P273 Avoid release to the environment.

### Disposal:

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

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 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.<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 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.

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	2 days
at (-15)-(-25) °C	2 weeks (when frozen once)

Store calibrator tightly capped when not in use.

## Materials provided

- See "Reagents – working solutions" section
- Barcoded labels

## Materials required (but not provided)

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

## Assay

Use C.f.a.s. IgA/IgM CSF 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

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Significant additions or changes are indicated by a change bar in the margin.

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