

Cyclosporine Calibrators

Cyclosporine Calibrators

REF 20766305 122

1 x 2.5 mL

5 x 2.0 mL

cobas®

English

System information

For use on COBAS INTEGRA analyzers the system ID is 07 6630 5.

Intended Use

Cyclosporine Calibrators is for use in the calibration of quantitative determination of cyclosporine using the COBAS INTEGRA Cyclosporine reagent on COBAS INTEGRA analyzers.

Summary

Cyclosporine Calibrators are frozen liquid calibrators based on whole blood hemolysate.

The concentrations and activities of the calibrator components have been adjusted to ensure optimal calibration of the COBAS INTEGRA Cyclosporine test on COBAS INTEGRA analyzers.

Reagent – contents and concentrations

Reactive components:

Cyclosporine in human whole blood hemolysate

Non-reactive components:

Preservatives

Calibrator values

The calibrators contain the following concentrations:

Calibrators	0	50	100	200	350	500
Cyclosporine (ng/mL)	0	50.0	100.0	200.0	350.0	500.0
Cyclosporine (nmol/L)	0	41.6	83.3	166.5	291.4	416.3

The cyclosporine stock solution for these calibrators is prepared using standard gravimetric procedure and the concentration of the stock solution is established with high-performance liquid chromatography (HPLC). Aliquots of the stock solution are added to measured amounts of calibrator matrix to yield the desired final concentrations.

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}

For USA: For prescription use only.

Handling

Prior to initial use, calibrators must be completely thawed with no ice crystals remaining. Allow calibrators to thaw at room temperature (18-25 °C) for approximately one hour or at a refrigerated temperature of 2-8 °C overnight. Before use, gently invert the calibrator vials at least ten times to ensure that the contents are thoroughly mixed. Do not vortex.

Storage and stability

Unopened calibrators must be stored frozen at -10 °C or below.

Once the calibrators have been thawed, they must not be refrozen and must be stored at 2-8 °C.

Storage after opening: 8 weeks at 2-8 °C but not beyond the expiration date printed on the label.

Materials provided

- Cyclosporine Calibrators (0 ng/mL), 1 x 2.5 mL
- Cyclosporine Calibrators (50-500 ng/mL), 5 x 2.0 mL

Materials required (but not provided)

- Cyclosporine Calibrator 0 ng/mL, Cat. No. 20766399 122
- COBAS INTEGRA Cyclosporine Sample Pretreatment Reagent, Cat. No. 20766364 122
- COBAS INTEGRA Cyclosporine II, Cat. No. 04340892 190
- General laboratory equipment

Instructions for use

The Cyclosporine Calibrators should be pretreated with the COBAS INTEGRA Cyclosporine Sample Pretreatment Reagent. Refer to the package insert of the COBAS INTEGRA Cyclosporine Sample Pretreatment Reagent for the procedure and the method sheet for the COBAS INTEGRA Cyclosporine test.

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

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